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SOCIAL & LEGAL PERSPECTIVES ON UNDERUSE OF MEDICATION-ASSISTED TREATMENT FOR OPIOID DEPENDENCE

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Submitted to the faculty of the University Graduate School in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Law, Indiana University July 2016.

ACCEPTANCE

Accepted by the Graduate Faculty, Indiana University, in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

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This dissertation is dedicated to my Committee Chair and close friend, Jody Madeira. Your kindness, optimism, selflessness, work ethic, and creativity inspire me daily. It was fate that led me to register for your Torts class in law school. Thank you for everything from the bottom of my heart.

ADKNOWLEDGEMENTS

There are many individuals who have helped me along this Ph.D. journey. First, I would like to thank my Committee Members: Professors Jody Madeira, Kosali Simon, M. Aaron Sayegh, Yvonne Cripps, and Mark Janis. Your feedback and advice have been invaluable. I feel extraordinarily fortunate to have a dissertation committee composed of intelligent and caring individuals. I would also like to thank two physicians who selflessly work for the good of some of the most vulnerable members of our community, Dr. R. Andrew Chambers and Dr. Camilla Arnaudo. I extend a special thank you to Matthew Capone, who has assisted me with research, editing, and provided moral support on innumerable occasions. I would like to thank my husband, Alexander Christou, my parents, Margaret and Bohdan Andraka, and my siblings, Natalia and Tomek Andraka for their love, support, and reminders to relax. I also thank those anonymous individuals whom I interviewed for my research. Finally, I would like to thank every person who works to end the stigma of drug dependence, who treats individuals suffering from drug dependence with respect, and who provides access to life-saving treatment.

ABSTRACT

SOCIAL & LEGAL PERSPECTIVES ON UNDER-USE OF MEDICATION-ASSISTED TREATMENT FOR OPIOID DEPENDENCE

Medication-assisted treatment (MAT) in combination with counseling is considered the most effective treatment for opioid dependence by the World Health Organization, U.S. Department of Health and Human Services, and American Society of Addiction Medicine. Two MAT medications, buprenorphine and methadone, are considered essential medicines by the World Health Organization. Despite MAT's effectiveness, it is severely underused in U.S. treatment settings, including physicians' offices, hospitals, the Veterans Administration, residential treatment centers, prisons, and drug courts. The dissertation examines social and legal reasons for under-use of MAT in the U.S., including dominance of abstinence-only treatment methods, separation of addiction treatment from mainstream medical treatment, insurance barriers, statutory and regulatory barriers, under-education of physicians in addiction medicine, under-education of mental health counselors in MAT, lack of physician involvement in the criminal justice system, and public understanding of addiction as a spiritual disease rather than a brain disease. The dissertation concludes with suggestions for expanding access to MAT, including government funding incentives and integration of MAT into existing addiction treatment centers and educational programs.

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INTRODUCTION

I. Dissertation Methodology and Organization

This dissertation examines the reasons for underuse of medication-assisted treatment (MAT) from a social and legal perspective. MAT is the most effective treatment for opioid dependence, especially in combination with counseling, yet it is severely underused within the U.S., including in treatment settings and within the criminal justice system. MAT underuse stems from a complex combination of factors: failure to understand addiction as a disease; historical separation of addiction treatment from mainstream medication; statutory and regulatory barriers to MAT access; the hegemonic 12-step movement, which emphasizes spirituality over medication; and lack of education about MAT among physicians and counselors. I argue that governmental policies for increasing MAT are unlikely to influence the addiction treatment field and the criminal justice system unless the policies also address the barriers described above.

This dissertation is partially based on a comprehensive literature review and partially on original research. The literature review includes health-related articles from medical journals, health policy journals, and public health journals, as well as state and federal regulations and statutes. Additionally, I examined literature from the fields of sociology, psychology, communication and social work.

It is also based primarily on original research. I conducted 58 qualitative interviews in person and over the telephone with professionals involved in substance use prevention, treatment or research, including the following professionals: 17 drug and veterans court judges in the state of Indiana (representing 20 drug and veterans courts), 1 judge who oversees a prison-based treatment center, 21 physicians, 8 mental health counselors, 1 state-level criminal justice policy maker, 1 probation officer, 3 CEOs of SUD treatment centers, 3 sociologists who study stigma

and access to SUD treatment, 3 researchers in the field of pharmacological development for mental health treatment, 3 public health researchers in the field of opioid dependence, 3 marketing representatives of MAT manufacturers, and 1 director of a city-wide needle-exchange program. I have also observed two board certified addiction psychiatrists as they treat patients suffering from SUD.

To recruit judges, I emailed adult drug court judges and veterans' court judges listed in the Indiana Problem-Solving Court Directory. Recruited judges included 11 drug court judges, three veterans' courts judges, and three judges who each oversaw a veterans' court and a drug court. Additionally, I interviewed one judge from a prison-based treatment program, the successful completion of which results in reduced sentences. In total, the judges oversaw 20 problem-solving courts and one prison-based treatment program. Each of the veterans' courts required substance abuse treatment for participants. Generally speaking, the veterans' courts operate similarly to drug courts except that they only include veterans and require more extensive treatment for co-occurring health conditions (e.g. post-traumatic stress disorder).

To recruit physicians, I emailed every physician listed in the Indiana University Medical School directory who practiced or conducted research in the field of addiction medicine. I also emailed every psychiatrist practicing in Bloomington, Indiana listed in the psychiatry directory at www.healthgrades.com. To recruit counselors, I emailed every counselor who was listed on the <u>www.psychologytoday.com</u> website as practicing in the field of addiction treatment in the greater Bloomington area. I also emailed counselors listed as addiction treatment practitioners for the largest local mental health/SUD treatment center. Counselors whom I interviewed included psychologists with no bachelor's degrees and graduate degrees, as well as licensed social workers and licensed clinical social workers. In addition to these recruitment methods, I

was contacted by counselors, physicians, SUD treatment facility administrators, the director of the local needle exchange program, researchers, and an MAT pharmaceutical representative after these individuals attended two talks that I gave at Indiana University about underuse of MAT. Other individuals whom I interviewed were either recruited at public health conferences that I had attended, or were individuals whom I knew personally prior to conducting the interview.

I obtained IRB approval for conducting these interviews from Indiana University in 2015, and I received informed consent prior to beginning every interview. All interviews were semistructured and conducted during 2015 and the spring of 2016. Each interview lasted approximately 45 minutes to one hour. Interview questions explored attitudes, beliefs, and practices related to self-help groups, residential treatment, and MAT.¹ The interviews were coded using NVIVO and then analyzed for themes. I used Grounded Theory methodology due to its suitability for studying under-explored research areas and identifying fundamental issues; a research gap exists regarding reasons for underuse of MAT.² Grounded theory methodology involves multiple steps: analyzing data for themes, developing themes into codes, grouping codes into categories, and using categories to develop theory.³

The introduction to this dissertation provides an overview of the current opioid addiction and overdose epidemic, causes of opioid dependence, and different treatment methodologies for opioid dependence, with a focus on MAT. Part I examines bias against MAT: in the context of history and popular culture (Chapter 1) and law (Chapter 2). Part II investigates reasons for underuse of MAT in two contexts: drug courts (Chapter 3) and physician offices (Chapter 4). The dissertation concludes by discussing theories of innovation diffusion (to describe how MAT can disseminate), and provides suggestions for increasing access to MAT in the U.S.

II. The Opioid Addiction and Overdose Epidemic

A. The Opioid Crisis

Opioids are a category of addictive substances that activate an opioid receptor in the brain called the mu receptor. Opioids include opium, morphine, heroin, and synthetic pain killers (such as oxycodone, hydrocodone, and fentanyl). Currently, the U.S. is in the middle of an opioid use epidemic. Approximately 21.5 million Americans had a substance use disorder (SUD) involving illicit drugs or alcohol.⁴ Approximately 1.9 million Americans suffer from an SUD involving opioid pain killers and 586,000 from an SUD involving heroin.⁵ Each day approximately 78 people in the U.S. die of an opioid overdose.⁶ The rate of opioid overdoses has skyrocketed in the last decade, primarily due to the over-prescription of opioid pain killers⁷, which depress the nervous system when used in large quantities or when combined with other central nervous system depressants.⁸

Opioid overdoses are part of a growing national trend of drug overdoses, including those from other addictive substances such as benzodiazepines and alcohol.⁹ The rate of drug overdoses is a public health crisis, with more individuals dying annually from drug overdoses than from car accidents.¹⁰ Overdose deaths from all opioids have quadrupled over the last decade,¹¹ with a 3.4-fold increase in overdose deaths from prescription pain killers and a six-fold increase in overdose deaths from prescription opioid pain killers have become less widely available and more expensive, more individuals have turned to heroin.¹³ Four in five new heroin users began by using prescription opioid pain killers.¹⁴ As a result, the rate of heroin overdose quadrupled between 2000 and 2013. One reason for skyrocketing overdoses of heroin is heroin's addictive potential. It is estimated that approximately 23% of heroin users will develop an opioid dependence.¹⁵

Some states such as Kentucky have been hit especially hard by the opioid epidemic; there, deaths from heroin overdoses increased by 500% from 2011 to 2012.¹⁶ The opioid overdose rate varies significantly between states; states with high poverty rates tend to have higher overdose rates. ¹⁷ Residents of rural areas, non-Hispanic whites, Alaskan Natives/Native Americans, and Medicaid-eligible individuals also have disproportionately high rates of opioid overdose.¹⁸ These demographic groups have the lowest rates of access to medical treatment overall, compounding the problem, and are also particularly likely to live in poverty and have low social mobility.¹⁹

According to the American Society of Addiction Medicine (ASAM), the increasing rate of opioid dependence is driving the increase in overdoses.²⁰ Opioid dependence has many negative (sometimes tragic) consequences for the individuals dependent on opioids, their families, and society,²¹ including productivity loss, increased medical costs (especially from emergency room visits and hospitalization), mental distress, death,²² decreased economic productivity, and drug-related crimes.²³

B. What is Drug Dependence and Where Does It Come From?

While the Diagnostic and Statistical Manual of Mental Disorders now uses the phrase "substance use disorder" (SUD) as a catch-all phrase to cover all spectrums of drug use (from occasional use to physical and psychological dependence), throughout this dissertation I will refer to SUD and dependence separately. I will refer to SUD as a spectrum of disorders²⁴, with dependence being one part of the spectrum. Drug dependence is a disorder (or disease) characterized by the following symptoms: continued use of the substance despite recurrent psychological, social, or physical problems caused by the drug; tolerance of the drug (marked by needing increased amounts of the substance to feel the desired effect); and occurrence of

withdrawal syndromes when the individual stops using the drug.²⁵ In this dissertation, for simplicity I will use the phrase drug dependence or opioid dependence as a synonym of addiction, even some scholars prefer to describe physical dependence separately from addiction, which they characterize as including both physical and psychological dependence.²⁶

Opioid dependence can arise in a number of ways. Opioid dependence may begin as a result of repeated illicit behavior, such as purposely using opioids to "get high." Some individuals suffering from other mental health conditions such as depression, post-traumatic stress disorder, or bi-polar disorder, use opioids illicitly in an attempt to "self-treat" their condition.²⁷ Opioid dependence can also result when patients take opioids that their physicians prescribe for chronic or acute pain; in that case, opioid dependence is an iatrogenic disease, meaning it is caused by the medical profession.²⁸ Opioid dependence is particularly prevalent among chronic pain patients. One study estimates that 5 to 24% of primary care patients taking opioids for chronic pain improperly use opioids.²⁹

Eventually, repeated voluntary use, whether illicit or licit, becomes compulsive and involuntary, and individuals face psychologically and physically painful withdrawal symptoms when they attempts to stop.³⁰ Even if the individual is able to stop using opioids long enough for withdrawal symptoms to cease, psychological and physical cravings will remain for months or years, in part because the brain's dopamine function is impaired³¹. Repeated drug use causes physiological changes to the brain, disrupting "motivation, learning, judgement, insight, and affect regulation."³²

Most individuals who use drugs do not become dependent.³³ For those that do become dependent, heredity is estimated to account for up to 50% of the reason behind dependence, according to studies of twins.³⁴ Humans, like all mammals, possess an opioid receptor in the

brain, suggesting an evolutionary mammalian predisposition to opioid use and susceptibility to opioid dependence.³⁵ In addition, a confluence of other environmental, behavioral, social, and psychological factors impact the likelihood of whether one will become drug dependent.

For example, in one well-known study, isolated rats were repeatedly given cocaine. A significant minority of the rats became addicted to cocaine, choosing to forgo food and water in order to obtain more of the drug.³⁶ However, other rats that were repeatedly given cocaine while living in a "rat park" (a pleasant space with opportunities for socialization, exercise and fun) were significantly less likely to become dependent.³⁷ Of course, it is impossible to ensure that all humans live in the equivalent of a "rat park"; even those living in an ideal environment may still become dependent. Nora Volkow, Director of the National Institute on Drug Abuse, argues that a positive environment can serve as a "protective factor" against drug dependence but does not guarantee that one will never become drug dependent.³⁸

The influence of all these factors are summarized in the Ecological Framework. According to that Framework, susceptibility to addiction may result from complex interaction between four levels of factors: the individual level (e.g. heredity, other MHDs); personal relationships (e.g. sexual abuse, unstable home life); community (e.g. availability of drugs in the neighborhood or schools); and societal (e.g. cultural norms, national distribution of prevention and treatment programs).³⁹ According to the Framework, successful prevention and treatment programs should address all four levels of factors.⁴⁰

The fact that drug dependence likely results from several causes, including heredity, voluntary and involuntary behavior, and one's environment, suggests that in many ways it is very similar to other chronic diseases.⁴¹ Drug dependence etiology is frequently compared to that of diabetes because of the confluence of factors that influence both diseases' progression.⁴² Despite

drug dependence's similarity to other chronic diseases, a popular cultural myth suggests that drug dependence is not a disease but rather stems from immorality or lack of willpower to conform to social norms.⁴³ These misconceptions stigmatize individuals with drug dependence, hinder their access to treatment, and prevent society from investing sufficient resources into researching and developing more SUD treatment methods⁴⁴.

C. Treatment for Opioid Dependence

In 2011, only 11% of individuals needing SUD treatment received it.⁴⁵ Many reasons exist for the under treatment of addiction, including a lack of treatment capacity within most states⁴⁶, a cultural stigma that discourages help-seeking behavior for drug dependence, and attribution of addiction to immorality rather than disease⁴⁷. Because a majority of individuals with drug dependence who undergo treatment relapse⁴⁸, a cultural misconception also exists that SUD treatment is unsuccessful⁴⁹.

However, evidence-based drug dependence treatment has comparable success rates to diabetes treatment.⁵⁰ A common problem among individuals with drug dependence is lack of compliance, sometimes due to co-existing mental health conditions or living in an environment that makes treatment difficult, such as homelessness.⁵¹ Those individuals that do comply with evidence-based treatment guidelines tend to do well.⁵² As in diabetes treatment, lack of compliance with addiction treatment is a major predictor of recurrence of distressing symptoms.⁵³ Finally, like diabetes, drug dependence has no "cure," but can be managed successfully through evidence-based treatment.⁵⁴ As in diabetes treatment, over the long-run relapse may sometimes occur; but as long as relapse becomes less frequent and less severe, then treatment should be considered effective.⁵⁵

Multiple evidence-based treatment methods exist for opioid dependence (i.e. treatment methods validated in scientific studies).⁵⁶ They include medication-assisted treatment (MAT), psychological counseling, contingency management, and support groups. MAT is the use of FDA-approved pharmaceuticals for treating drug dependence. According to the World Health Organization (WHO), the U.S. Department of Health and Human Services (DHHS), the American Medical Association (AMA), the ASAM, and the American Association for the Treatment of Opioid Dependence (AATOD), MAT is the most effective treatment for opioid dependence. Despite MAT's effectiveness, it is severely underused in U.S. treatment settings, including physicians' offices, hospitals, the Veterans Administration,⁵⁷ residential treatment centers, prisons,⁵⁸ and drug courts.⁵⁹

Access to MAT is limited in the U.S. Health policy scholars refer to two kinds of health access: potential access and realized access.⁶⁰ Potential access is the percentage of individuals with the resources or ability to receive treatment, including health insurance, income, physician availability (such as the number of specialists in a given city), available treatment slots per capita, transportation to treatment, and knowledge about the treatment method.⁶¹ Simply by examining the number of MAT providers in the U.S., it is clear that potential access is very low. Less than 45% of SUD treatment centers in the U.S. provide even a single form of MAT.⁶² A 2012 study found that 80% of Opioid Treatment Programs (i.e. methadone clinics) were operating at 80% capacity and 96% of states and the District of Columbia lacked sufficient buprenorphine treatment capacity.⁶³ Only 46% of counties have at least one physician certified to provide buprenorphine treatment; and only 2% of all U.S. physicians have and 3% of primary care physicians (the nation's largest and most accessible group of physicians) are certified to provide buprenorphine.⁶⁴ In terms of insurance, only a few states' Medicaid programs cover

every form of MAT, some states have life-time limits (meaning maximum coverage periods) for MAT, and many commercial insurance carriers create prior authorization and "fail first" barriers.⁶⁵ One study found that less than one-third of states had wide-spread MAT implementation (meaning sufficient infrastructure, staff, and funding for MAT provision).⁶⁶ The most widespread implementation of MAT existed with respect to methadone.⁶⁷

Realized access refers to the percentage of individuals who actually receive the treatment.⁶⁸ In 2012, of the 2.5 million Americans who needed treatment for opioid abuse or dependence, fewer than one million received MAT.⁶⁹ Even within SUD treatment centers that offer at least one form of MAT, only approximately one-third of patients with opioid dependence receive MAT prescriptions.

Scholars have reported several reasons for low potential and realized access to MAT: cultural bias against MAT; bias from Narcotics Anonymous (NA) and other 12-step groups; bias and lock of MAT education among mental health therapists; an undersupply of physicians treating addiction; regulatory barriers; cost; and concerns over illicit diversion.⁷⁰ In 2012 the National Center on Addiction and Substance Abuse at Columbia University published a report that the U.S. treatment system needed "significant overhaul" and suggested that the "low levels of care that addiction patients usually do receive constitutes a form of medical malpractice."⁷¹

D. A Note on Prevention

This dissertation focuses on opioid dependence treatment rather than prevention, although prevention is extremely important and deserves more scholarly attention. The traditional preventative method of warning children that drugs are "bad" is insufficient for preventing drug dependence and overdose⁷². Opioid addiction often stems from physicians overprescribing painkillers for chronic or acute pain rather than from individuals who

consciously deciding to "get high."⁷³ The spike in opioid addiction and overdoses in the U.S. over the last decade can be directly attributed to the over-prescription of prescription painkillers, largely due to federal agencies encouraging the treatment of pain as a "fifth vital sign"⁷⁴ as well as unscrupulous marketing practices by Purdue Pharma, the maker of OxyContin.⁷⁵ The number of prescriptions for opioid pain killers in the U.S. nearly tripled between 1991 and 2013⁷⁶, with the U.S. currently accounting for almost 100% of the hydrocodone and 80% of the oxycodone market.⁷⁷

Unfortunately, while MAT is over-regulated in the U.S., the prescription of opioids for chronic pain is under-regulated.⁷⁸ For example, 49 of 50 states have instituted Prescription Drug Monitoring Programs (PDMP), allowing physicians to look up patients in a database to determine whether they have already received opioid painkillers elsewhere; but only 22 states mandate that physicians examine the database.⁷⁹ As a result, only about 35% of physicians who issue a controlled substance examine a PDMP.⁸⁰ Physicians also do not have patient limits or special certification requirements for prescribing opioid painkillers, as they do for buprenorphine. Methadone cannot be prescribed in physicians' offices for addiction treatment; although lower dosages can be prescribed in physicians' offices for pain management.⁸¹ Thus, regulations for accessing opioid painkillers (the source of much opioid addiction) are looser than regulations for accessing pharmacological addiction treatment.

III. Evidence-Based Treatment Methods

The success rate for opioid dependence treatment with appropriate treatment is similar to other chronic diseases.⁸² Not all treatments for opioid dependence are equally effective, however, and many common misconceptions exist about what constitutes effective treatment.⁸³ The four primary types of treatment for opioid dependence in America are 12-step groups and

other support groups, counseling, contingency management, and MAT. This chapter describes each treatment option in turn, including a discussion of residential treatment and detoxification treatment. The chapter ends with a brief discussion of treatment integration.

A. Narcotics Anonymous and Twelve-Step Groups

Support groups are the most common and accessible treatment for drug dependence in

the U.S. Twelve-step groups are the most popular drug dependence support groups, of which

Alcoholics Anonymous (AA) and Narcotics Anonymous (NA) are the most well-known and

widely attended. NA is the primary form of treatment in over 90 percent of inpatient

rehabilitation settings as well as within prisons and drug courts. NA is available in most major

U.S. cities and many smaller cities as well.

Active participation in NA consists of regular (sometimes daily) group meetings,

guidance from a sponsor within the group, and following the "twelve steps" of recovery⁸⁴:

- 1. We admitted that we were powerless over our addiction, that our lives had become unmanageable.
- 2. We came to believe that a Power greater than ourselves could restore us to sanity.
- 3. We made a decision to turn our will and our lives over to the care of God as we understood Him.
- 4. We made a searching and fearless moral inventory of ourselves.
- 5. We admitted to God, to ourselves, and to another human being the exact nature of our wrongs.
- 6. We were entirely ready to have God remove all these defects of character.
- 7. We humbly asked Him to remove our shortcomings.
- 8. We made a list of all persons we had harmed and became willing to make amends to them all.
- 9. We made direct amends to such people wherever possible, except when to do so would injure them or others.
- 10. We continued to take personal inventory and when we were wrong promptly admitted it.
- 11. We sought through prayer and meditation to improve our conscious contact with God as we understood Him, praying only for knowledge of His will for us and the power to carry that out.
- 12. Having had a spiritual awakening as a result of these steps, we tried to carry this message to addicts, and to practice these principles in all our affairs.⁸⁵

The twelve steps of recovery illustrate a number of themes, including regular group communication, dependence on a Higher Power, striving for moral purity, seeking forgiveness, helping others stay drug-free, and admitting the nature of one's problem.⁸⁶ The steps are followed chronologically, with individuals spending varying amounts of time on each step with a sponsor's assistance.

NA developed from Alcoholics Anonymous (AA) and is identical to AA in all respects except for its target audience, which is individuals dependent on drugs, not alcohol. AA began in the 1930s as part of the Oxford Group, an evangelical Protestant church.⁸⁷ Bill W., a member of the Oxford Group, formed AA in order to share the method he used to obtain sobriety: a spiritual experience aided by the support of fellow sufferers.⁸⁸ Based on his personal experience of recovery, Bill W. believed that sobriety could be achieved by anyone who shifted his or her dependence away from chemicals and towards a Higher Power.⁸⁹

Even though NA is the most common drug dependence treatment in the U.S., studies about its effectiveness at promoting abstinence have mixed results. Many studies purporting to prove its effectiveness have failed to distinguish between causation and correlation.⁹⁰ According to the National Institute on Drug Abuse, fewer studies of NA exist than of AA, so studies of AA may serve as a useful analog.⁹¹ The *Journal of Addiction* published the results of four rigorous, experimental studies of AA; only two found that AA had a significant positive effect on abstinence, one found a negative effect, and one found no effect.⁹² A comprehensive review of studies from 1966 to 2005 regarding AA's effectiveness at improving abstinence reports, "experimental studies have on the whole failed to demonstrate their effectiveness in reducing alcohol dependence or drinking problems when compared to other interventions."⁹³ The National Longitudinal Alcohol Epidemiologic Survey found that AA's retention rate is

approximately 30%.⁹⁴ Those members who remain tend to be highly motivated, and some of them will be active members for life. Some randomized control trials of AA have found that it is efficacious in promoting abstinence and psychosocial health for those individuals who continue to attend meetings (despite the large drop-out rate), but those studies have not specifically examined the context of opioid dependence.

AA and NA may be a helpful supplement to mental health therapy and/or MAT, so long as NA does not discourage individuals from using other treatment methods,⁹⁵ but unfortunately evidence exists that it may discourage attendees from utilizing MAT.⁹⁶ Some twelve-step groups restrict MAT patients' ability to claim clean time, speak at meetings, or be a sponsor.⁹⁷ One study found that 25% of NA patients failed to disclose that they were undergoing MAT for fear of incurring stigma from their group. Future studies should estimate the efficacy of NA and AA in promoting abstinence while considering their discouragement of MAT, which has higher rates of efficacy.

B. Mental Health Therapy

U.S. treatment providers use multiple methods of mental health therapy or psychological counseling for treating opioid dependence. Mental health therapy may be provided in group or individual settings, with group therapy being more common for drug dependence treatment; it is the primary form of treatment provided within the criminal justice system, inpatient rehabilitation centers, hospitals, and outpatient settings. Even though group therapies for drug dependence differ widely by content and context, goals typically include education about drug dependence, providing motivation to stop drug use, overcoming denial, teaching recovery and coping skills, and resolving life problems that may be contributing to drug use.⁹⁸ A group

typically includes six to 12 participants.⁹⁹ A group leader serves as a discussion facilitator and is less active than a therapist in an individualized session.¹⁰⁰

Despite the widespread use of group therapy, a paucity of research exists on its effectiveness, largely due to inherent research difficulties.¹⁰¹ Research suggests that group therapy should be combined with individual therapy.¹⁰² Also, preliminary controlled studies suggest that group therapy may increase adherence to medication.¹⁰³ Therefore, for some populations, MAT and group therapy should be combined.

Mental health therapy may also be provided in an individualized setting. Effective individualized therapy for drug dependence typically includes a focus on problems caused by drug dependence, enhancing motivation to change, developing coping skills, reinforcement, managing pain, improving interpersonal skills, and forging an alliance between the therapist and client.¹⁰⁴ Motivational interviewing, supportive-expressive therapy, and cognitive behavioral therapy are three evidence-based methods of providing individual mental health therapy.

Motivational interviewing increases client commitment to stop drug use and begin recovery; it is collaborative, aims to respect the client's autonomy and values, expresses empathy, and identifies and elicits the client's desire to change.¹⁰⁵ The role of the therapist has been described as "a good salesman, who keeps the client talking and thinking while moving the client toward a decision to buy [recovery]."¹⁰⁶ A variety of randomized controlled trials have shown motivational interviewing to be effective for treating SUD. Evidence of motivational interviewing's success, however, is stronger for nicotine and alcohol abuse than for drug abuse.¹⁰⁷

Supportive-expressive therapy analyzes the client's drug use in relation to his or her interpersonal and cognitive world.¹⁰⁸ The therapist helps the client express reasons for drug use

and how it has proved problematic.¹⁰⁹ The therapist assists the client in working through interpersonal issues that may be related to drug abuse¹¹⁰ and explore the meanings he or she has ascribed to drug abuse and form solutions to interpersonal problems.¹¹¹ Supportive-expressive therapy may be most effective when combined with additional treatment methods;¹¹² controlled trials demonstrate that it may increase the medication adherence of individuals suffering from opioid dependence.¹¹³

Cognitive behavioral therapy is the most studied form of mental health therapy for drug dependence; here, the therapist and client analyze and review the "sequence of thoughts, feelings, behaviors, and circumstances that lead to substance abuse" in a structured and usually time-limited sequence.¹¹⁴ Components of cognitive behavioral therapy include recognizing triggers, avoiding risky situations, and using psychological approaches to manage cravings.¹¹⁵ The therapist teaches the client specific skills, such as recognizing and counteracting painful feelings without the use of drugs.¹¹⁶

C. Contingency Management

Contingency management involves giving individuals tangible rewards for desired behavior, such as abstaining from drug use.¹¹⁷ Rewards depend on the context. I observed one drug court hearing where participants earned a raffle ticket if they attended counseling sessions and tested negative for drugs during the previous week. At the end of the drug court hearing, there was a prize drawing where participants could win gift cards to restaurants and movie theaters. In methadone clinics, participants who successfully follow protocols for a long time may eventually be given "take home" privileges allowing them to take home a few days of medication so that they do not need to attend the clinic daily. Eventually, take home privileges

may be extended to a few weeks (depending on state law and clinic policies), contingent on participant adherence to clinic rules.¹¹⁸

Contingency management has been tested in numerous settings and with different types of addiction, including drug and gambling addiction; studies have found it increases abstinent time and treatment adherence when used with other treatments, such as counseling and/or MAT.¹¹⁹ In particular, it can be used to reinforce participation in other treatment programs.

D. Medication-Assisted Treatment (MAT)

MAT is the use of FDA-approved medications for treating drug dependence. According to the DHHS¹²⁰ and the WHO,¹²¹ MAT is the most effective opioid dependence treatment. Professional medical associations such as the AMA, ASAM, CDC, SAMHSA, the Institute of Medicine, the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and NADCP.¹²² According to SAMHSA, patients receiving MAT cut their risk of death from overdose in half.¹²³ The three medications most commonly used within MAT are buprenorphine (commonly known by the brand name Suboxone®), Vivitrol® (extended-release naltrexone), and methadone.¹²⁴ Each has been proven significantly more effective at preventing drug use relapse than a placebo in rigorous, double-blind experimental studies.¹²⁵ Also, the MAT retention rate is greater than that for either counseling or 12-step groups.¹²⁶ Unfortunately, all medications for treating opioid dependence are underutilized and under-prescribed, and rarely available within inpatient rehabilitation centers.¹²⁷ rarely used within prisons, and underused within drug courts.¹²⁸ Buprenorphine, methadone, and extended-release naltrexone are each described in more detail below.

1. <u>Methadone</u>

Methadone is the oldest FDA-approved medication for treating opioid dependence.¹²⁹ It works by activating the brain's opioid receptor, called the mu-receptor.¹³⁰ Methadone is a complete mu-agonist, meaning that it completely activates the mu-receptor.¹³¹ As a result, it prevents cravings for opioids, while allowing individuals to stop using heroin and painkillers without experiencing withdrawal.¹³² Because methadone has a higher selectivity for the mu-receptor than heroin or painkillers, it methadone prevents euphoria or a "high" if a person abuses substances while undergoing methadone treatment.¹³³ A person taking methadone can function normally and does not feel or appear "high."¹³⁴ Methadone treatment has been proven to decrease death rates, relapse, drug-related crimes, HIV/AIDS from shared needles, medical costs, and unemployment.¹³⁵ According to the National Institute on Drug Abuse, every dollar invested in methadone treatment saves society \$38.¹³⁶ Lower programmatic restrictions on methadone provisions and higher dosages are predictors of positive outcomes.¹³⁷

Methadone can be dangerous if diverted and improperly used, but most individuals who obtain methadone use it for treatment and do not abuse it.¹³⁸ Because methadone has a high potential for physical and psychological dependence, it is a Schedule II narcotic under the Controlled Substances Act (CSA), where Schedule I is the most legally restrictive and Schedule V is the least restrictive.¹³⁹ In order to prevent illicit diversion, methadone is only available at certified methadone treatment centers, to which the patient must usually return daily to continue treatment.¹⁴⁰ These treatment centers are often heavily visible and stigmatized by city governments and residents.¹⁴¹ Additionally, some cities and a handful of states lack a single methadone clinic.

If an individual has commercial health insurance or Medicaid, the generic version of

methadone can be quite affordable. In some states (such as Indiana, however, methadone is not covered by state Medicaid, making it unaffordable for many individuals in need. Likewise, the cost of daily transportation to a methadone clinic may be a financial barrier to low-income individuals.

2. <u>Vivitrol (Extended-release naltrexone)</u>

Vivitrol has been approved for treating both opioid dependence and alcoholism.¹⁴² Unlike methadone or buprenorphine, it does not contain any opioid ingredient.¹⁴³ Instead, it contains extended-release naltrexone, which is a complete mu-receptor antagonist, meaning it completely blocks the mu-receptor.¹⁴⁴ Vivitrol prevents an individual from experiencing euphoria if he or she abuses any opioid,¹⁴⁵ making the medication very effective at preventing relapse.¹⁴⁶ But a patient must undergo complete detoxification before receiving Vivitrol; if opioids have not yet been naturally flushed out of his or her system, the individual will experience immediate and painful withdrawals.¹⁴⁷ ¹⁴⁸

Vivitrol is not a controlled substance, so it can be prescribed by any licensed physician.¹⁴⁹ The medication is given as a monthly injection that lasts for 30 days.¹⁵⁰ Unfortunately, it is very expensive, costing around \$1,000 per month for individuals without health insurance¹⁵¹ as many individuals with dependency do.¹⁵² Some but not all Medicaid programs cover Vivitrol. Even if an individual has commercial insurance, the copayment can be quite expensive and be a treatment barrier.

There are some benefits of Vivitrol that are distinct from buprenorphine and methadone. Some individuals who fear being stigmatized for taking an opioid medication may be more comfortable taking Vivitrol. The lack of an opioid ingredient also makes it practically impossible for patients to abuse or overdose on it, unlike buprenorphine and methadone.¹⁵³. In

addition, because Vivitrol is a monthly injection, patients may find it easier to adhere to treatment. Some physicians say that patients on Vivitrol just need to make one good decision per month. Buprenorphine patients could simply decide to stop taking the daily pill or sublingual film on any day.¹⁵⁴ Likewise, patients may fail to visit a methadone clinic daily.

3. <u>Buprenorphine</u>

Buprenorphine is a partial mu-agonist.¹⁵⁵ It prevents an individuals with opioid dependence from going into withdrawal or experiencing cravings.¹⁵⁶ An individual taking buprenorphine can feel, act, and appear completely normal.¹⁵⁷ Unlike methadone, the opioid in buprenorphine is not very potent, so it is less likely to be abused or cause an overdose. Because Buprenorphine has higher selectivity for the mu-receptor than any other opioid, including methadone, it prevents a "high" if the individual takes another opioid¹⁵⁸ and so, individuals who take it daily have little incentive to abuse opioids.¹⁵⁹ Moreover, unlike methadone, buprenorphine has a "ceiling effect"; after a certain dosage, the patient feels no additional physical sensations from additional buprenorphine, deterring them from taking too much. The naloxone in the buprenorphine-naloxone serves as an abuse deterrent, because naloxone when injected causes painful withdrawal symptoms.

Buprenorphine can be prescribed by any licensed physician in an office setting, as long as the physician obeys DEA rules for Schedule III substances and has obtained a waiver from SAMHSA as required under the Drug Addiction and Treatment Act of 2000.¹⁶⁰ This waiver is commonly referred to as a DATA Waiver or an "X number" because it appears as the physician's DEA number preceded by the letter "X."

A patient undergoing buprenorphine treatment typically receives a monthly prescription, which he or she fills at a local pharmacy. The patient then takes the medication at home daily in

the form of a pill or sublingual film.¹⁶¹ The DEA limits automatic refills on Schedule III narcotics to five refills or six months (whichever comes first).¹⁶² However, physicians commonly require patients on buprenorphine treatment to return monthly for an appointment to obtain a new prescription.¹⁶³

Numerous studies have documented buprenorphine's effectiveness at preventing relapse, euphoria, and drug cravings.¹⁶⁴ Increased access to buprenorphine has been associated with a decrease in mortality from opioid overdose.¹⁶⁵ For example, in France, increased buprenorphine treatment was associated with an 80% decrease in opioid overdoses.¹⁶⁶ Increased access to buprenorphine lowers medical costs by preventing the need for expensive in-patient treatment or emergency room visits and is also associated with increased employment and fewer drug-related crimes.¹⁶⁷ As patients' buprenorphine dose and length of time in treatment increases, their risk of relapse decreases.¹⁶⁸

Buprenorphine also increases compliance with mental health therapy regimens.¹⁶⁹ Individuals treated with buprenorphine are more likely to participate regularly in out-patient mental health counseling than non-users,¹⁷⁰ perhaps because individuals can more easily focus on behavioral and psychological changes if their physical cravings are controlled. Finally, buprenorphine has been used effectively and safely in pregnant women¹⁷¹ and adolescents.¹⁷²

In 2008, buprenorphine prescriptions cost about \$120 to \$570 per month (depending on the dose) without health insurance.¹⁷³ However, the FDA recently approved two generic versions of Suboxone (buprenorphine-naloxone), potentially decreasing its cost.¹⁷⁴ Commercial health insurance carriers¹⁷⁵ and all state Medicaid programs cover buprenorphine treatment, although some Medicaid programs have coverage time limits.¹⁷⁶ Some buprenorphine manufacturers provide discount cards for low-income individuals, which may decrease cost.¹⁷⁷

In May 2016, the FDA approved Probuphine, a six month surgical buprenorphine implant embedded in the arm.¹⁷⁸ Probuphine is implanted in a minor surgical procedure performed in physicians' offices.¹⁷⁹ The implant slowly releases buprenorphine and will likely eliminate the potential for diversion. Physicians who prescribe and administer Probuphine must complete an additional certification in Probuphine Risk Evaluation and Mitigation Strategy (REMS).¹⁸⁰ Because Probuphine was only recently made available, long-term studies of its efficacy are not yet available.¹⁸¹ However, preliminary studies look very promising. According to the FDA,

A response to MAT was measured by urine screening and self-reporting of illicit opioid use during the six month treatment period. Sixty-three percent of Probuphine-treated patients had no evidence of illicit opioid use throughout the six months of treatment – similar to the 64 percent of those who responded to sublingual (under the tongue) buprenorphine alone."¹⁸² The National Institute on Drug Abuse calls Probuphine "a game-changer" in opioid dependence treatment.¹⁸³

4. <u>Comparing the Medications</u>

As compared to methadone, buprenorphine and Vivitrol may carry less cultural stigma because they can be prescribed in physician offices rather than a specialized clinic.¹⁸⁴ Appointments for Vivitrol and buprenorphine may also offer patients more privacy than visiting a methadone clinic.¹⁸⁵ If a co-worker sees a patient on buprenorphine entering a primary care physician's office, that co-worker does not know the reason for patient's visit; entering a methadone clinic, however, is a sure sign an individual suffers from drug dependence.

Unlike Vivitrol, buprenorphine does not require complete detoxification prior to the first dose.¹⁸⁶ Rather, treatment begins when the patient is in mid-withdrawal.¹⁸⁷ The complete detoxification required prior to Vivitrol treatment may serve as a disincentive to some individuals, because opioid withdrawals are very painful and commonly include multiple days or weeks of diarrhea, muscle aches, excessive sweating, jerking or twitching muscles, fatigue, and nausea.¹⁸⁸ Complete detoxification from opioids without relapse is extremely difficult, often

requiring multiple attempts. One study of patients treated with methadone, for example, found that 25% had a phobia of detoxification.¹⁸⁹ As a result, individuals sometimes enroll in in-patient rehabilitation centers to detox, which cost approximately \$31,500 for 30 days.¹⁹⁰

Finally, both Vivitrol and buprenorphine are less time-consuming than methadone, because patients can obtain a 30-day supply of buprenorphine from a local pharmacy and take them at home daily and a Vivitrol injection is only needed once per month.¹⁹¹ But methadone treatment generally requires daily travel to a methadone clinic;¹⁹² many individuals with dependency are low-income¹⁹³ and find it especially difficult to afford daily transportation to a methadone clinic or take time off of work to attend.

In terms of effectiveness, no randomized controlled study has compared methadone, buprenorphine, and naltrexone. However, studies have found that buprenorphine and methadone are approximately equally effective¹⁹⁴, with the exception that severely dependent individuals may do better on methadone. No study has compared methadone to Vivitrol or buprenorphine to Vivitrol.¹⁹⁵ It appears that buprenorphine and methadone may be more effective at managing cravings relating to opioid use as well as responses to stress.¹⁹⁶ More cross-medication studies are needed.

5. <u>How Physicians Choose One Medication Over Others</u>

If a physician can prescribe either Vivitrol or buprenorphine or refer a patient to a methadone clinic, she will need to choose which medication is most appropriate for a particular patient. This is a highly individualized decision. Each of the medications has been proven effective at preventing relapse, lowering the risk of mortality and morbidity, decreasing criminal recidivism and decreasing unemployment. But not every medication is right for a particular patient.

During interviews with physicians, including primary care physicians and psychiatrists, I discovered certain trends regarding Vivitrol prescription. Physicians were more likely to recommend Vivitrol to individuals with opioid dependence for a shorter time or who had a low-level of dependence. Because full detoxification is required before starting Vivitrol, patients who have used opioids for a long time or are severely dependent may not be able to complete full detoxification, especially outside of a residential setting, hospital or prison. On the other hand, some physicians mentioned that patients forced to detox through incarceration may be ideally positioned to begin Vivitrol despite long-term use. Physicians are also more likely to recommend Vivitrol for patients with financial resources to pay for the medication. Finally, patients who are actively participating in the criminal justice system (e.g. in drug court or probation) may be prohibited from taking any medication with an opioid ingredient, leaving only Vivitrol as a viable option.

Other factors might lead physicians to recommend buprenorphine. It might be a good option if a patient has successfully tried buprenorphine before or if a patient is unwilling to try Vivitrol because of personal reasons such as a fear of commitment. Moreover, it might be appropriate for patients who have been unable to abstain from opioids while on Vivitrol or those who are unlikely to successfully complete full detoxification. Patients are likely to prescribe buprenorphine to patients for whom it is affordable; the medication's greater affordability is particularly important in some states, like Indiana, where state Medicaid does not cover methadone for addiction treatment and Vivitrol copayments remain cost-prohibitive for many.¹⁹⁷ Finally, the medication may be better for patients suffering from depression, since there is some evidence that buprenorphine effectively treats depression, even though it has not been FDA-approved for this purpose. Additionally, because buprenorphine contains an opioid ingredient, it

may be more appropriate for individuals who suffer from acute pain. But this may not be so for chronic pain patients; many medical studies do not support the efficacy of using opioids to treat chronic pain.¹⁹⁸

Physicians stated that they would be most likely to recommend methadone for patients who have used opioids for a significant period of time or are severely dependent, those with acute pain, and who did abstain from opioid abuse on Vivitrol or buprenorphine. Additionally, multiple physicians mentioned that some patients need the accountability of a daily clinic visit to obtain a prescription, such as patients with serious co-occurring mental health conditions like schizophrenia or bi-polar disorder who may be unlikely to consistently take buprenorphine daily at home. However, a few physicians mentioned that whether they referred patients to a methadone clinic would partially depend on how well that clinic was managed. Some methadone clinics have historically provided doses that are too low¹⁹⁹, or have served as a central point for illicit drug dealers to convene, targeting patients outside the clinic²⁰⁰. Additionally, some physicians have complained of overpopulated methadone clinics with inadequate staff. For example, physician 4 once worked at a methadone clinic in the North East with 400 patients, and sufficient staffing. But she feels differently about the methadone clinic nearest to her office in the Midwest, which has approximately 2,000 patients, many of whom are not carefully monitored and do not receive enough counseling.

All physicians emphasized that they strongly consider their patients' wishes and opinions about the choice of medication. They agreed that patients were more likely to ask for buprenorphine than Vivitrol because full detoxification is not required, they may have already started buprenorphine after purchasing it on the streets if a doctor appointment was physically or financially inaccessible, and they fear the long-term commitment Vivitrol requires. But

physicians also agreed that few patients have heard of Vivitrol before speaking with a physician, while almost all have heard of buprenorphine and methadone. Therefore, a lack of information about Vivitrol may explain why fewer request it. Likewise, patients are more likely to ask for buprenorphine than methadone because they do not want the hassle of travelling to a clinic daily, feel that methadone is more stigmatizing, or do not want to take a full agonist.

D. Detoxification Alone

Detoxification is sometimes considered "treatment,"²⁰¹ but alone it is almost always ineffective, especially for opioid dependence, because physical changes in the brain from opioid-dependence persist post-detoxification.²⁰² The social, psychological and occupational difficulties associated with drug-dependence also do not immediately cease upon detoxification.²⁰³ In fact, the chance of death from overdose is highest immediately following detoxification, because an individual's psychological and physical cravings persist, but physical tolerance for opioids is low.²⁰⁴ Therefore, detoxification should always be combined with another form of treatment. Additionally, detoxification tends to be more successful if completed in a controlled environment, such as a residential treatment facility or under a relative's watchful eye.

The false assumption that detoxification alone is sufficient may arise from the cultural misunderstanding that addiction is an acute rather than a chronic disease.²⁰⁵ An acute disease, such as a broken arm, may require only a short-term treatment to restore the body to its healthy state. A chronic disease, however, requires long-term care, meaning that relapse is possible; therefore, even an individual who is not actively abusing drugs may need to continue counseling, MAT, or support groups.

E. Residential Facilities

Some individuals with opioid dependence choose to enter or are referred to a residential treatment facility. Residential treatment can be short-term (such as for one month) or long-term (six months to one year). Long-term residential treatment centers attempt to resocialize the patient in a community where "other residents, staff, and the social context [are] active components of treatment."²⁰⁶

Residential treatment centers frequently provide a range of services, including mental health counseling, self-help groups, and detoxification services. According to the National Institute on Drug Abuse, short-term residential treatment centers typically use a 12-step recovery model.²⁰⁷ Unfortunately, surveys have found that most residential treatment facilities do not offer MAT. But there is no reason why residential facilities could not introduce patients to buprenorphine or Vivitrol treatment assuming physicians at the facility have the appropriate credentials and that the facility then connects patients with community providers after residential treatment.

Scholars find it difficult to accurately assess residential treatment's effectiveness compared to community-based or outpatient treatment, because residential treatment center programming differs dramatically. One study found that residential treatment participants showed greater improvement on social factors and co-occurring mental health conditions,²⁰⁸ but no benefits superior to community-based treatment in drug use.²⁰⁹ It is likely that participating residential treatment facilities did not offer MAT; therefore, we do not know the success rate for addiction treatment in those offering MAT. Another study found that 80% of individuals who underwent residential treatment for opioid dependence relapsed within 2 years, regardless of whether residential treatment was voluntary or compelled.²¹⁰

Policymakers and criminal justice administrators should know that residential treatment, especially short-term, is rarely sufficient treatment for opioid addiction. Ongoing community-based care after release is essential for full recovery. Gossop et al. examined abstinence rates of 242 heroin users from 23 U.S. residential centers; they found that 60% of heroin users relapsed within 12 months of release from the residential center, with most relapsing shortly afterwards.²¹¹ Smyth et al. studied 101 opioid-abusing individuals in Ireland and found a relapse rate of 91%, with 59% of relapses occurring within one week of release.²¹² These studies strongly imply that residential treatment should be followed by regular outpatient treatment.

A primary purpose of residential treatment is detoxification; patients may find it easier to complete detoxify in a controlled environment rather than at home. As painful withdrawal symptoms increase during detoxification, individuals benefit from community support and are unlikely to access drugs. But if treatment does not continue following release, the individual is at risk of relapse and death from overdose due to decreased physical tolerance.²¹³ Prison or jail may serve the same purposes as a residential detoxification facility, but overdose is the number one cause of death following release, again attributed to low physical tolerance and a lack of follow-up treatment.²¹⁴

E. Treatment Integration

Up to this point, I have discussed treatments for opioid dependence separation. However, every physician whom I interviewed has mentioned the need for treatment combinations and flexibility. Unfortunately, few studies have been done comparing treatment combinations. Instead, one treatment is usually compared to a placebo. This fact reflects the problematic segregation of treatment fields, including insufficient collaboration between psychiatry and psychology, and between mental health and addiction treatment.
Existing studies provide inconsistent results about the effectiveness of different treatment combinations. Although they form the bulk of opioid addiction treatment in the U.S., behavioral interventions (e.g. counseling and 12-step groups) have poor treatment in opioid treatment if provided without MAT (one study estimates that 80% of those who receive behavioral interventions only relapse).²¹⁵ Therefore, behavioral interventions should be supplemented with MAT, which has significantly lower relapse rates. Relatedly, some studies suggest that relapse rates are lower for those who receive both MAT and behavioral interventions rather than behavioral interventions alone. Therefore, DHHS, ASAM, and WHO all recommend complementing MAT with behavioral interventions.²¹⁶ However, a meta-analysis of 65 studies found no improvement in treatment retention or abstinence when MAT was supplemented with behavioral interventions, suggesting that more research on the topic is needed.²¹⁷ The relatively difficulty of designing behavioral intervention studies relative to medication intervention studies may explain the greater heterogeneity of behavioral study results. For example, even though cognitive behavioral therapy is a standard method of mental health counseling, it is not applied in exactly the same way by every therapist; on the other hand, medication provision is more likely to be uniform across physicians. Additionally, therapists' empathy, interpersonal skills, and other personal characteristics may have a strong effect on treatment efficacy; such factors likely influence medication efficacy less. According to a study published in Psychiatric Services, "[The field] psychosocial treatments is heterogeneous, and there is a lack of sufficient, high-quality studies to assess which psychosocial interventions have the most success in various populations."²¹⁸ The difficulty of assessing treatment combinations, such as the combination of medication and behavioral treatment, increases in the context of dual-diagnosis patients.

The correlation between SUD and other mental health disorders (MHDs) is very high, with 17-40% of SUD patients also suffering from mood disorders, anxiety disorder, posttraumatic stress disorder, severe mental illness, antisocial personality disorder, or borderline personality disorder.²¹⁹ Individuals suffering from SUD are twice as likely to suffer from anxiety or mood disorders as the general population; and individuals suffering from anxiety or mood disorders are twice as likely to suffer from an SUD.²²⁰ Some hypothesis for the high rate of cooccurrence of MHD and SUD have been proposed, including similar brain circuitry involved in SUDs and many MHDs, self-medication of MHD using drugs, and (in some cases) symptoms of MHDs caused by drug use.²²¹

Obviously, health practitioners treating SUDs or MHDs should be aware of their cooccurrence and should attempt to treat both types of disorders together, especially if SUDs may increase MHD symptoms or vice versa. Yet, addiction treatment centers rarely provide mental health treatment; and mental health treatment centers rarely provide addiction treatment.²²² A multi-state study published in 2009 found that 18% of addiction treatment centers and 9% of mental health centers had dual-diagnosis treatment capability.²²³ Many SUD treatment centers fail to assess patients for MHD, and many mental health centers fail to assess patients for SUDs. Even if a treatment center only offers SUD or MHD, failure to assess a patient as a dualdiagnosis patient may result in ineffective treatment. Instead of inefficient segregation, SUD treatment centers and MHD treatment centers should be integrated into dual-diagnosis treatment centers. Infrastructure development for dual-diagnosis treatment is badly needed (e.g. for clinic integration and cross-training of providers in SUD and MHD treatment).

F. Summary

Opioid addiction requires long-term treatment, often using a combination of treatment methods. Behavioral interventions alone, such as counseling and 12-step groups, have poor outcomes, with more than 80% of patients returning to drug use.²²⁴ Likewise, detoxification alone results in poor outcomes. MAT is the most effective treatment for opioid dependence, especially when provided in combination with counseling. The three forms of MAT for opioid dependence (methadone, buprenorphine, and extended-release naltrexone) have each been demonstrated to lower overdose rates, mortality, morbidity, and recidivism. Despite the effectiveness of MAT for maintenance-treatment, it is highly stigmatized in the U.S., overshadowed by abstinence-only philosophy (formed around the hegemonic 12-step program), and strictly regulated. The following chapter applies this background information by examining the cultural bias against MAT.

CHAPTER 1: CULTURAL BIAS AGAINST MAT

The U.S. has an unusual cultural bias against the use of FDA-approved medication for treating drug dependence,²²⁵ especially given the fact that medication is commonly used to treat other illnesses. Americans consider pharmaceuticals to be a normal part of life, as the frequency of television advertisements for such products pharmaceuticals demonstrates. So why is medication for treating drug dependence so heavily stigmatized?

The chapter begins with a brief history of addiction treatment in the U.S. It then discusses misconceptions surrounding addiction in light of addiction treatment history. Specifically, two misconceptions are examined: the idea that willpower and self-control should be sufficient to end addiction;²²⁶ and the idea that addiction is related to immorality, requiring spiritual treatment. The chapter ends by examining abstinence-only treatment (meaning treatment without the use of MAT), which has been strongly influenced by misconceptions of opioid addiction treatment and cultural biases against MAT.

I. <u>A Brief History of Addiction Treatment in the U.S.</u>

Perceptions of addiction treatment have changed over time in the U.S. However, some addiction treatment practices that are common today can be traced back to attitudes that are decades' or even centuries' old, such as the incorporation of religious practices into treatment protocols. Other attitudes towards addiction are more modern, such as the understanding of addiction as a chronic disease rather than an acute disease. Chronic diseases are long-lasting complex diseases, often affecting many bodily systems; whereas, acute diseases are sudden, severe, short-term diseases, often isolated to one part of the body.²²⁷ Due to their complexity, chronic diseases are typically more difficult to treat than acute diseases.²²⁸

Favored addiction treatment methods relate to societal and professional assumptions about addiction's etiology. For example, individuals who perceive addiction as a form or symptom of spiritual deprivation likely support spiritual reformation as a form of addiction treatment; those who perceive addiction stems from a lack of self-control likely support treatments that teach self-control, such as psychotherapy; and those who understand addiction to result from low dopamine levels are likely to support treatments that increase dopamine production. Therefore, in order to understand modern addiction treatment, it is helpful to review historical assumptions about addiction's nature and related treatments.

A. Views of Substance Dependence in Early American History

In the U.S., self-control is both a practical ideal and a moral ideal that can be traced back to America's Protestant foundations. For the Puritans, self-control was a sign of morality. Moderation in everything, including alcohol, was heavily emphasized in Biblical readings. For example, Puritans were encouraged to forgo luxury, wear simple clothes, be abstemious in food and drink, and live in simple houses. Churches had minimal décor. Lacking a conception of addiction as a disease, excessive alcohol or drug use was perceived as sinful, gluttonous or self-centered behavior. In the late 1700s, around the time of the American Revolution, self-control was considered an essential component of citizenship. A citizen lacking self-control could not be trusted to vote in an election; he might commit any number of acts including offenses, such as voting for a politician whose platforms would benefit himself but harm others.

Alcohol use was common in the American colonies; it was used regularly in daily cooking, as a home remedy for illnesses, in ceremonies, and as part of social events. However, the overuse of alcohol was considered gluttonous and sinful, in violation of the Puritan ethic of

self-control. Treatment for dependence was rare and largely consisted of attending religious services.

In the late 1700s, arguments surfaced that substance-dependent individuals suffered from a disease needing treatment. Benjamin Rush, a signer of the Declaration of Independence who is often deemed "the father of psychiatry," argued that alcoholism was a progressive medical condition.²²⁹ His writings on this topic were reprinted thousands of times and widely distributed. Rush also claimed that alcoholism had a genetic component, observing that it seemed to run in families.²³⁰ Some of his writings were medically flawed, at least in light of today's science. For example, Rush argued that individuals suffering from alcohol dependence should be given opioids as a replacement maintenance therapy, arguing that opioids were less addictive than alcohol.²³¹ But Rush's recommendations demonstrate that maintenance treatment for substance dependence treatment is not a new concept, even though the types of maintenance treatments used have changed over time.

Rush observed that incarceration was ineffective for treating substance dependence, and argued that Sober Houses should replace jails as residences for individuals with alcohol dependence.²³² Sober houses were necessary, because individuals with alcohol or drug dependence were barred or discouraged from receiving treatment in public hospitals or psychiatric institutions, as were others with diseases considered immoral (e.g. venereal diseases). ²³³ Interestingly, Rush suggested that these Sober Houses should be funded through a percentage of alcohol sales.²³⁴

Even though Sober Houses developed during the 1700s and 1800s described addiction as a disease, their daily programs centered on moral and religious education. ²³⁵ Daily religious devotions, for example, were considered critical for rebuilding weak characters. Unfortunately,

Rush's understanding of addiction as a disease was not shared by many Americans. Some religious groups continued to view addiction as a sin, and some clergy viewed the disease theory of addiction as an excuse to engage in sinful behavior.²³⁶

In the 1800s, many treatment centers (e.g. Sober Houses) hired physicians to provide "medications," most of which would not be considered scientifically-valid today. Treatment centers also provided recreation, rest, nutrition, massage, and other activities designed to improve one's physical and psychological health. Some treatment centers operated like luxurious spas for wealthy individuals, while others resembled poorly-run hospitals and were called "asylums." Individuals were encouraged to reside at treatment centers for many months, and sometimes years. Because alcohol and drug-dependence were perceived as being part of the same disease (insobriety), individuals with both alcohol and drug dependencies attended treatment centers.²³⁷ Aftercare consisted of church membership, involvement in fellowships,²³⁸ or other community associations for individuals with dependencies.

B. The Temperance Movement

In the early 1800s, the U.S. witnessed the beginning of the temperance movement²³⁹, which ultimately influenced societal perceptions of individuals with dependency. Even though alcohol use had been widespread and generally accepted in American society since colonial times, by the early 1800s many Americans feared that alcohol use was increasing significantly, especially on the Western frontier. Some saw alcohol use as part of an immoral tavern culture common among single men and cowboys in the Wild West that threatened the fabric of civilized community life.²⁴⁰ Originally the temperance movement sought to promote moderate alcohol use, not to eliminate alcohol use altogether.²⁴¹ By the 1850s, however, the temperance movement

promoted complete abstinence from alcohol; and advocated legal prohibition as the best method for accomplishing this goal.²⁴²

The temperance movement took a particularly cruel view of individuals with alcohol dependence. Some leaders of the temperance movement suggested that individuals with alcohol dependence should be left to die, so that heredity would stop being a cause of alcohol dependence.²⁴³ Temperance movement leaders also assumed that individuals with alcohol dependence would not need treatment, because legal prohibition would supposedly forever end alcohol use, and thus dependence.²⁴⁴ Eventually, when state governments (and later the federal government) criminalized alcohol-related activity, governments slashed funding for existing treatment initiatives (e.g. asylums) in the expectation that treatment would no longer be needed.²⁴⁵ The misunderstanding that complete abstinence from a substance is sufficient for ending dependence continues today, as does the belief that simply criminalizing a substance will end dependence.

Shortly after the nationwide prohibition of alcohol began, individuals with alcohol dependence who continued to seek and use alcohol were relegated to prisons, because most public and private treatment centers had closed.²⁴⁶ According to historian William White, the collapse of private alcoholism treatment facilities "was mirrored by the progressive collapse of the addiction treatment field as a professional area."²⁴⁷ Although treatment centers in the early 1900s had few medically-valid treatments, their mere existence had suggested that drug dependence was a disease requiring treatment. In contrast, the jailing of substance-dependent individuals suggested that dependence was a sign of immorality. Moreover, although few professional standards existed for addiction treatment,²⁴⁸ the decline in the numbers of practicing addiction treatment professionals contributed to the perception that the new treatment field was

unnecessary. But psychiatric institutions--which largely excluded individuals suffering from addiction-- continued to receive government funding.²⁴⁹

Prohibition of alcohol led to calls for prohibition of other addictive substances, including opioids and cocaine. Fear and bias against Chinese immigrants who were perceived as opioid users encouraged Congressmen to limit opioid access. In 1915, the U.S. Congress passed the Harrison Anti-Narcotics Tax Act (Harrison Act), which regulated the use, sale, manufacture, and distribution of narcotics (including opioids and cocaine), effectively making them illegal for most uses.

C. The Washingtonian Movement, Fraternities and Alcoholics Anonymous

In the late 1800s, fellowships for individuals recovering from alcohol dependency began and spread quickly. The Washingtonian movement (a predecessor to AA) was the most popular fellowship, until it fizzled out in the early 1900s. It focused on rebuilding character and increasing self-control to abstain from alcohol.²⁵⁰ Washingtonian meetings required participants to admit their addiction, promise to abstain from the addictive substance, share stories, and pray. Members met regularly at each other's homes. Other fellowships were called "fraternities" and catered to wealthy individuals, involved numerous symbols and ceremonies, relied on motivational speeches and prayer, and also required complete abstinence from the abused substance. Members who were caught using substances were forced out of the organization. Like the Washingtonian movement, fraternities decreased in popularity during the early 1900s.

After the temperance movement led to the closing of most SUD treatment facilities, a new fellowship organization, AA, filled the void. AA evolved from the Oxford Group, an evangelical spiritual organization. Member Bill W., a co-founder of AA, developed the famous AA "12-steps" after experiencing what he called a "spiritual awakening," which, in combination

with sharing his experiences, allowed him to remain sober. He sought to share his sobriety method with others suffering from alcoholic dependence in anonymous groups whose meetings were modeled after the Washingtonian movement. After receiving positive media and movie coverage,²⁵¹ AA spread like wildfire and became the only source of widely-accessibly addiction treatment. Eventually, other support groups modelled on AA developed, including NA. Even today, most professional treatment centers design their programs around the philosophy of the 12-steps.²⁵²

D. Psychoanalysis and Psychological Therapy

During the early 20th century, the psychoanalysis movement also influenced perceptions about the nature of addiction and addiction treatment. Psychoanalysis construes addiction not as a primary disease in its own right but a symptom of neurosis or a disordered personality. Addiction was also viewed as a maladaptive strategy for dealing with psychological problems, including emotional immaturity. Some leading psychoanalysis practitioners perceived addiction as a suicidal flight from an inner conflict. Therefore, according to psychoanalytic theory, the only effective treatment for addiction was complete reconstruction of the personality²⁵³ with the goal of enhancing emotional maturity through developing self-control.²⁵⁴ Interestingly, psychoanalytic theory did not demand complete abstinence because a restructured personality might allow for moderate alcohol use.²⁵⁵

Psychoanalysis was available to few individuals, namely wealthy urbanites, and became discredited as a treatment modality in the latter half of the 20th century.²⁵⁶ But it continues to influence addiction attitudes, including the common misunderstanding that individuals suffering from addiction are emotionally and psychologically immature. Psychoanalytic theory also contributed "a model of outpatient psychotherapy that focused on character reconstruction"²⁵⁷

that remains influential in contemporary treatment practices. Sigmund Freud also popularized the belief that lay individuals trained in psychoanalysis theory (as opposed to physicians) could effectively provide therapy, increasing the involvement of non-physicians in addiction treatment.²⁵⁸

By the 1960s, cognitive therapy had replaced psychoanalysis as the dominant psychological treatment for addiction. Cognitive therapy was used to discover and correct automatic negative thoughts, such as those related to drug use triggers or cravings. In the 1970s, professionals combined cognitive therapy with behavioral therapy to form cognitive behavioral therapy (CBT), creating what some describe as a revolution in psychological practice. Counselors were (and continue to be) the primary health practitioners involved in CBT, while physicians receive little training in its techniques.

E. Modern MAT

1. Aversion Therapy

One early use of medication in addiction was aversion therapy, primarily used for treating alcohol dependence .Aversion therapy causes association of the substance of abuse with an unpleasant sensation, such as nausea or an electric shock. Aversion therapy relies on the Pavlovian principle that, after repeated exposure to a stimulus, an unconscious response will occur. If individuals repeatedly experience alcohol in conjunction with nausea, for example, they may experience aversion (e.g. nausea) at the mere sight or thought of alcohol. Thereby, one can be trained to dislike a substance that one formerly used. As early as the 1800s, aversion therapies using chemical tinctures and electric shots were used in some treatment centers. The first medication to be widely used in aversion therapy was disulfiram (Antabuse), which was FDA-approved in 1951. Later aversion therapies for alcohol dependence included naltrexone²⁵⁹

(approved in 1994) and acomprosate (approved in 2004). However, each of these prescription medications is seriously underused for treating alcohol dependence, just as other medications are under-prescribed for treating opioid dependence. For example, current estimates suggest that Antabuse is used by only 120,000 individuals worldwide.²⁶⁰

2. Morphine Maintenance Therapy and Methadone

In the late 1800s and early 1900s, physicians prescribed morphine to individuals with opioid dependence as a maintenance treatment. An estimated 200,000 to 4,000,000 individuals received maintenance treatment, primarily in large cities.²⁶¹ Physicians assumed that regularly providing a small dosage of morphine would prevent dependent individuals from experiencing withdrawal symptoms, prevent criminal activity, and prevent opioid overdoses from using higher dosages. However, the Harrison Anti-Narcotics Tax Act (Harrison Act) effectively ended the practice of morphine maintenance treatment. The Act also represented the first major federal intrusion into medicine, formerly regulated entirely by states.²⁶² Even though the Act did not specifically state that maintenance treatment was illegal, the Narcotics Division of the Prohibition Unit of the Department of the Treasury (the predecessor to the DEA) interpreted the Harrison Act as barring maintenance therapy. The Commissioner of the Narcotics Division, Henry Anslinger, was notorious for his belief that drug users were bad characters and insisted that addiction was a criminal rather than a public health problem.²⁶³ The Treasury adopted Anslinger's view of individuals suffering from drug dependence and interpreted a part of the act stating that physicians could prescribe opioids "in the course of his professional practice only" as barring maintenance therapy.²⁶⁴ According to the Treasury, because drug dependence was not considered a disease, treatment for drug dependence was not in the course of a physician's professional practice.²⁶⁵

In 1919, in *Webb v. United States*, the U.S. Supreme Court further clarified that the Harrison Act prohibited physicians from prescribing narcotics for maintenance treatment.²⁶⁶ Some physicians continued to prescribe morphine for maintenance treatment after the Harrison Act. They were targeted by the Treasury, leading to the largest government raid on physician offices in U.S. history. According to Richard Boldt, "In the decades that followed passage of the Harrison Act, the moral meanings that attached to the use of narcotics in the United States underwent a dramatic shift." As a result of the raids, physicians largely existed the addiction treatment field and the general public saw physicians prescribing maintenance treatment as bad actors rather than healers.²⁶⁷ Like the general public, policy makers continued to view maintenance treatment as immoral. While discussing maintenance treatment, a U.S. Senate committee in the 1950s stated that "it would be absolutely immoral to give in to drug addiction" and that the government "should not adopt any program to give the drug addict "sustaining' doses of narcotics."²⁶⁸

The Harrison Act largely restricted research on maintenance treatment for several decades. In the 1960s, two researchers working at the U.S. Public Health Hospital in Lexington, Kentucky discovered that methadone was effective for easing withdrawal of individuals suffering from opioid dependence (methadone had been discovered as a pain management medication in Germany two decades earlier).²⁶⁹ Having learned of the research on methadone, the AMA, ABA, and the Kennedy administration recommended prescribing methadone on an experimental basis in clinics associated with hospitals.²⁷⁰ During a study at Rockefeller University, researchers (led by Vincent P. Dole) found that methadone could be used not only for treating withdrawal symptoms but for long-term maintenance treatment.²⁷¹ Dole's research team experienced harassment from the Federal Bureau of Narcotics, but Dole argued that methadone

maintenance treatment should be considered within the scope of physicians' professional practice; he did not face legal consequences. ²⁷² By the late 1960, methadone maintenance treatment was expanding to clinics affiliated with hospitals across the U.S. At proper dosages, methadone blocked cravings, preventing individuals from attaining a "high" from other opioids, and had minimal side effects. ²⁷³ Studies also demonstrated that methadone helped patients hold jobs and rebuild relationships with family and friends who had become estranged. ²⁷⁴ However, physicians generally continued to be uninterested in addiction treatment. In the late 1970s, the U.S. House of Representatives recognized the fear the Harrison Act had instilled in physicians when it said, "There 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 addicted patients."²⁷⁵

In the early, 1970s, methadone was approved by the FDA for treatment of opioid dependence, and the federal government created a complex system of regulations for methadone distribution in a closed network.²⁷⁶ For three decades, methadone was the only FDA-approved medication for addiction treatment. Then in 2002, the FDA approved the U.S.'s second pharmacological treatment for opioid dependence, known as buprenorphine (in the forms of Subutex and Suboxone, which also contains naloxone as an abuse deterrent). Foreseeing buprenorphine's FDA approval, the DEA moved buprenorphine (previously approved as a painkiller at a different dosage) from Schedule V to a more restrictive schedule III substance under the Controlled Substances Act. Also foreseeing buprenorphine's FDA approval, in 2000 Congress passed the Drug Addiction Treatment Act (DATA), requiring certification of physicians and patient limits for office-based prescriptions.²⁷⁷

In 2010, the FDA approved a third pharmacological treatment for opioid dependence: extended-release naltrexone (Vivitrol), a monthly injection.²⁷⁸ Most recently, in May 2016, the FDA approved a surgically implantable version of buprenorphine, Probuphine, which lasts up to 6 months at a time.²⁷⁹ Despite existence of these effective treatment methods, 12-step groups continue to be the most common form of addiction treatment in the U.S., followed by mental health therapy.²⁸⁰

In recent years, professional health organizations and U.S. government agencies have encouraged the simultaneous use of multiple treatment modalities for addiction (a "multiple paths approach").²⁸¹ For example, a health practitioner might encourage individuals with dependencies to undergo buprenorphine treatment and cognitive behavioral therapy and to attend a support group. In some treatment facilities, these different treatment models are even beginning to overlap to the point of integration.²⁸² For example, while support groups and MAT have rarely overlapped historically, Methadone Anonymous, a support group for methadone treatment patients using a 12-step program, spread in the 1990s. As a result, "recovery" from addiction may now mean participation in any number of treatment modalities.²⁸³ Additionally, government descriptions of addiction as a neurological disease and the re-characterization of addiction as a chronic disease by the AMA may have somewhat improved public perceptions of MAT.²⁸⁴

D. The War on Drugs

In 1971, President Nixon declared a War on Drugs, largely in reaction to Vietnam veterans returning to the U.S. using heroin.²⁸⁵ Nixon also created the DEA to coordinate antidrug efforts by federal agencies.²⁸⁶ However, Nixon believed that addiction treatment was as important as prosecution of drug-related crimes. Under Nixon, more federal funds were allocated

to addiction treatment than had ever been before in U.S. history.²⁸⁷ Importantly, more funds were devoted towards treatment than towards law enforcement.²⁸⁸

Nixon established a two-pronged approach to eradicating drugs: cutting supply and decreasing demand.²⁸⁹ Cutting supply consisted of going after big-time drug dealers, primarily those who brought drugs into the U.S. from abroad. Decreasing demand consisted of treating the addiction that was driving so many drug purchases at home. Methadone treatment was encouraged.²⁹⁰ During their tenure in the years following Nixon, Presidents Ford and Carter largely followed the path Nixon had laid out for the War on Drugs.²⁹¹

Reagan became president in an era when a subset of society viewed addiction as a treatable disease but growing numbers feared and stigmatized drug addicts due to the supposed "crack epidemic". In the 1980s, media reports sensationalized crack-induced violence in innercities, further solidifying the public's belief that drug use was always immoral. Federal agencies and Congress enhanced criminal penalties.²⁹² At the same time, Reagan slashed the federal funds allocated to addiction treatment and significantly expanded the budget for drug-crime prosecutions.²⁹³ The demand side of Nixon's original War on Drugs policy was largely ignored. State politicians followed suit, not wanting to be considered "soft on crime."²⁹⁴ Many presumed that severe criminal punishments would provide a strong disincentive, making addiction treatment programs unnecessary, an attitude reflective of the Prohibition era.

Most infamously, in 1984 Congress passed the Anti-Drug Abuse Act, including mandatory minimum sentencing guidelines.²⁹⁵ These guidelines bound judges to what many contemporary scholars view as unjustly severe sentences for simple drug possession and lowlevel drug trafficking. Prior to mandatory minimums, judges were permitted to consider circumstances of the crime when sentencing a defendant but no longer. Mandatory minimums

led directly to exploding prison populations, such that the U.S. has more prisoners per capita than any country in the world. In some cases, mandatory minimum sentences for drug trafficking were higher than for murder.

In 1984, Nancy Reagan began her "Just Say No" campaign, which inadvertently reinforced the idea that addiction is a matter of choice rather than a disease.²⁹⁶ The movement focused on protecting white, middle-class children from drugs. However, once a child became addicted to drugs, the "Just Say No" campaign offered no solutions. Even today, public schools routinely invite speakers to talk to children about the dangers of drugs but rarely explain medical options for treating addiction.

Under President George H. W. Bush, less than 1/3 of the Federal War on Drugs budget was allocated for treatment²⁹⁷, in sharp contrast to the Nixon era's funding priorities. Even though funding for treatment slightly increased under President Clinton, the bulk of funding continued to be directed towards law enforcement. However, cognizant of the racial discrepancies in mandatory minimum sentencing guidelines, Clinton signed a law decreasing the ratio of mandatory minimum sentences for crack (used predominantly by blacks) versus cocaine (used predominantly by whites).

George W. Bush's presidency continued to approach the War on Drugs through "tough on crime" policies. Aware of rising overdoses from opioid painkillers, the federal government took little action. Rather than focusing on treatment, the U.S. Drug Czar, the head of the Office of National Drug Control Policy, targeted marijuana-related crimes and encouraged widespread drug testing for disciplinary, not medical, reasons (as opposed to medical reasons). At the same time, federal and state drug enforcement agencies underwent a significant militarization.

President Obama's presidency began to reorient the U.S. towards a public health approach to the drug problem.²⁹⁸ The current Office of National Drug Control Policy describes itself as pursuing "a public health approach," sending a strong message that addiction is a medical rather than a moral problem.²⁹⁹ The President's 2016 Budget Submission to Congress requested historic levels of funding for "health responses to illicit drug use."³⁰⁰ The Obama administration has heavily criticized mandatory minimums, but Congress has yet to completely eradicate them, although it has persuaded Congress to repeal mandatory minimum sentences for simple crack possession and to further diminish the discrepancy between other crack and cocaine punishments.³⁰¹ Significantly, the Department of Justice has told federal prosecutors to avoid pursuing charges that would trigger mandatory minimums for low-level offenses, giving federal prosecutors the official "go ahead" to circumnavigate them.³⁰² President Obama has also pardoned numerous incarcerated, non-violent drug offenders.³⁰³ Finally, the administration created a Recovery Branch within the Office of National Drug Control Policy to focus on expanding addiction treatment and decreasing addiction-related stigma.³⁰⁴ Though the tide is finally turning towards prioritizing public health measures for addiction, the scars left by the War on Drugs will take a long time to heal.

The War on Drugs has focused government resources on prosecuting drug offenders rather than treating dependence, perpetuating the common misconception that drug dependence is a personal choice and a personal failing.³⁰⁵ The U.S. has spent billions of dollars annually on the War on Drugs and dedicates a tremendous amount of prison space to drug offenders.³⁰⁶ According to the Federal Bureau of Prisons, in December 2014, 48.7% of individuals in federal prisons were incarcerated for drug offenses.³⁰⁷ Incarceration of drug offenders, especially non-violent individuals, is one reason why the U.S. has the world's highest incarceration rate.³⁰⁸

II. Addiction, Self-Control and Willpower

A. American Values and Addiction

As described above, addiction has been stigmatized since the time of the Puritans, in part because addiction appears to contradict the value of self-control. Addiction today continues to be associated with immaturity, because control of one's feelings and behavior is an important mark of adulthood in American culture.³⁰⁹ Individuals are expected to "exercise invisible surveillance of themselves and others" and to constrain their own desires, whether for food, drugs, or money.³¹⁰ Likewise, moderation continues to be a revered ideal in American culture. For example, politicians still praise the American middle class more so than the lowest or highest socioeconomic classes. Individuals with drug dependence, however, are unable to exert self-control while using drugs due to their disease symptoms (e.g. severe psychological and physical cravings, inhibited dopamine production). As a result, they are socially stigmatized by a public who perceives lack of self-control as a character flaw.³¹¹

Individuals with drug dependence are also unfairly characterized as lacking willpower, or the desire to stop using drugs.³¹² For example, a Gallup poll of individuals with an addicted family member reported that most respondents believed that a lack of willpower was the main cause of addiction, even though they also believed that addiction is a disease.³¹³ Unfortunately, those who hold this perception are less likely to recommend treatment to their family members, perhaps because they assume that merely deciding to stop using drugs is effective.³¹⁴ Even individuals who obtain treatment often do not understand addiction is a disease and feel guilty for being unable to follow through on their desire to stop using drugs.³¹⁵

Why is willpower insufficient for overcoming addiction? "Addiction" comes from the Latin root "addicere," which means "to surrender to a master." According to modern science,

this is exactly what happens to the brain: it is hijacked by the abused substance (the master). Neural networks reform, physical tolerance builds, and natural dopamine production declines. The individual becomes unable to feel average levels of euphoria without the drug, even from activities that had previously produced euphoria naturally, such as spending time with lovedones or eating a favorite food. Regardless of how the addiction started (e.g. whether by choosing to "get high" or by being prescribed an opioid painkiller for chronic pain), the individual experiences a physical and psychological compulsion to take drugs. Eventually the drug use stops being about "feeling good" and starts being about "not feeling bad." When the individual abstains from drugs, he or she feels psychologically and physically miserable, experiencing painful withdrawal symptoms.

The combination of withdrawal symptoms, cravings, and low natural dopamine levels leads the individual to desperately seek more drugs. Environmental stress or triggers may increase the desperation. As a result, medical organizations rigorously oppose the idea that addiction is a voluntary state. According to Thomas McLellan, Editor-in-Chief of *The Journal of Substance Abuse Treatment* and a former U.S. Drug Czar, "At some point after continued repetition of voluntary drug-taking, the drug 'user' loses the voluntary ability to control its use. At that point, the 'drug misuser' becomes 'drug addicted' and there is a compulsive, often overwhelming involuntary aspect to continuing drug use and to relapse after a period of abstinence."³¹⁶ Nora Volkow, the Director of the National Institute on Drug Abuse, has most succinctly described the relationship between addiction and choice:

Choices do not happen without a brain—it is the mechanism of choice. The quality of a person's choices depends on the health of that mechanism. However much we may wish that a person's choices were free in all instances, it is simply a fact that an addicted person's failures in the realm of choice are the product of a brain that has become greatly compromised—it is readily apparent when we scan their brains.³¹⁷

The common perception that addiction is a "choice" is psychologically harmful and stigmatizing. Individuals with opioid dependence cannot merely exert self-control over their dependency. They may have the willpower to stop using drugs but lack the physical and psychological ability to accomplish this desire. The conception that addiction is a choice also leads to the general public and policy makers being less willing to help those who are dependent on drugs.³¹⁸

It is dangerous to encourage individuals with drug dependence to recover through willpower alone. If individuals with drug dependence merely abstain from drug use (applying willpower alone) their tolerance lowers, significantly increasing the risk of dying from an overdose if they resume drug use. And studies show that individuals with opioid dependence who apply willpower alone (without other evidence-based treatment) almost always relapse. Even if they do not overdose as a result of relapse, they are likely to experience low self-esteem and guilt for having failed. Low self-esteem is related to low self-efficacy³¹⁹; and low self-efficacy may be related to lower rates of help-seeking behavior.³²⁰

B. The Relationship between Pharmaceuticals and Willpower

Americans have a complex relationship with pharmaceuticals. Despite being relatively healthy (especially compared to individuals in many developing nations), they take more pharmaceuticals than citizens of any other nation and yet sometimes fiercely judge one other for taking pharmaceuticals. Such social judgments depend largely on what condition the pharmaceutical is meant to treat, including whether that condition is seen as "voluntary" or "involuntary." Americans assume that "voluntary" conditions do not need to be treated with a pharmaceutical since a resolution to fixing this negative voluntary behavior should be sufficient. For example, someone who created a problem through lack of self-control presumably should develop the willpower to resolve the problem through self-control and then follow-through.

Obesity is a classic example of a condition for which Americans have a negative opinion of pharmaceutical usage. Culturally, obesity is constructed as a condition for which one is personally to blame, even though it can result from medical conditions such as hypothyroidism and genetic predisposition. Thus, it may be that any medicalized obesity treatment may attract societal disapproval. For instance, Americans have negative views of gastric bypass surgery despite the fact that gastric bypass surgery has been shown to extend the life-expectancy of morbidly obese individuals and to prevent many harmful diseases.³²¹ Instead, friends and relatives may advise morbidly obese individuals to lose weight through behavioral change. One study of patient behavior towards patients with asthma found that physicians were more likely to receive advice about losing weight).³²² On the other hand, Americans have few qualms about an individual taking pharmaceuticals to treat a genetic disease such as cystic fibrosis, even if behavioral or dietary changes could alleviate symptoms.

Like obesity, Americans tend to misconstrue addiction as an individual's fault that originates solely from a lack of willpower or from misapplied will power; an individual with the ability to choose not to be an addict in fact chose to do so.³²³ From this vantage point, addiction treatment is not necessary; addicts simply need to make a different choice. Even some Americans who claim to support addiction "treatment" assume that treatment means increasing willpower—not an outlandish assumption, given the "12-steps" of AA and NA that stress taking responsibility and abstinence. An Indiana prosecutor recently announced a new "treatment" for incarcerated individuals with dependency consisting entirely of education about why drug use is harmful. These treatment models presume that individuals are dependent because they are did not know enough to make a right choice and so chose wrongly out of ignorance. This means, of

course, that an individual's tendency to make wrong choices can be easily corrected with education.

If drug addiction is the result of poor choices, then counseling and support groups are acceptable treatments because they teach skills that one can use to make a different choice to avoid drugs. But pharmaceutical treatments are an ill fit for this paradigm of increasing willpower because they do not incorporate education and skill building. Following this logic, pharmaceuticals may even prevent individuals from learning to make the right choice by simply eliminating their drug cravings! Essentially pharmaceuticals are perceived as too easy a solution to a problem that a person must "work" to overcome. The idea of taking a pharmaceutical (e.g. buprenorphine) indefinitely without doing the real "work" to overcome addiction is perceived as especially problematic. For example, some individuals describe methadone as merely a "crutch."³²⁴

In summary, even Americans who view addiction as a disease may also assume that addiction originates from misapplied willpower, implying that education and willpower building is the best or only appropriate treatment. Many Americans also view pharmaceuticals as a "cop out," preventing the individual from learning how to choose to properly apply willpower. But every element of this American is false. First, addiction is not a disease of misapplied willpower; even though drug abuse may start voluntarily through misapplied willpower, eventually cravings and behaviors become compulsive, illustrating that willpower is actually minimally involved). ³²⁵ Second, there is no scientific basis for believing individuals with drug dependence must be forced to work harder to overcome the disease rather than taking the supposedly "easy way out" through pharmaceuticals. The amount of effort an individual puts into overcoming addiction is

irrelevant if the disease is compulsive since by definition compulsion is an irresistible urge which effort cannot overcome.

Rather than a disease of misapplied willpower, addiction is a disease of *lack of control* regarding drug use, primarily due to severe physical and psychological cravings and withdrawal symptoms.³²⁶ Even if an individual possesses willpower, she may lack self-control around drugs. Interestingly, MAT can actually be seen as a way of *increasing* self-control as it blocks compulsive cravings, allowing individuals to focus on other activities and to more easily acquire and apply skills learned through counseling.

III. Immorality and Drug Addiction

Today, professional medical organizations and the U.S. government call addiction a disease, but much of the public continues to perceive it as a moral failing—a perception that is shockingly held by many health practitioners and criminal justice administrators. The link between addiction and morality persists today in addiction treatment facilities and providers who center treatment on the twelve-step philosophy, in which MAT is often perceived as irrelevant or harmful.

A. Legacies of the War on Drugs

The War on Drugs also delays help-seeking behavior for addiction in at least three ways: stigmatizing individuals with drug dependence, causing them to hide their illness; causing treatment delays out of fear of being caught; and minimizing ability to pay for treatment. Because drugs are illegal, many Americans believe that drug dependence and individuals with drug dependence are immoral.³²⁷ This conception causes society to stigmatize the individuals with drug dependence, and individuals with drug dependence may internalize this stigma, possibly resulting in self-isolation and depression.

Individuals with stigmatized medical problems are particularly likely to hide these diseases and not seek medical treatment,³²⁸ as with HIV/AIDS.³²⁹ Persons with dependence problems do not want their friends, family, and physicians to think of them as criminals or moral failures.³³⁰ Those who do not understand privacy laws may be afraid to admitting drug dependence to a doctor or a counselor. Individuals convicted of drug possession, including marijuana, are ineligible for food stamps, public cash assistance, student educational loans, and (in some states) a driver's license, so the stakes may be very high.³³¹ Additionally, individuals convicted of drug possession have a criminal record, making it difficult to find employment, especially with health insurance. And in most states at least one form of MAT is not covered by Medicaid, requiring individuals to pay out of pocket. Ironically, some individuals unable to obtain jobs due to criminal records may feel that they have no other option than to sell drugs illicitly. Some physicians whom I have interviewed describe knowing patients who sell drugs in order to afford treatment for drug addiction.

B. Treatment and Morality

AA and NA fit comfortably within the idea of morality-related abstinence and perpetuate the assumption that, unlike other diseases, addiction is related to morality.³³² Even though AA and NA officially call addiction a disease, these groups encourage their members to seek forgiveness, strive for moral purity, and forge a relationship with a Higher Power.³³³ Several tenets of NA have strong moral undertones:

4. We made a searching and fearless moral inventory of ourselves.
5. We admitted to God, to ourselves, and to another human being the exact nature of our wrongs.
6. We were entirely ready to have God remove all these defects of character.
7. We humbly asked Him to remove our shortcomings.
8. We made a list of all persons we had harmed and became willing to make amends to them all.
9. We made direct amends to such people wherever possible, except when to do

so would injure them or others.

10. We continued to take personal inventory and when we were wrong promptly admitted it. 334

AA describes its treatment as based on a "spiritual awakening" (e.g. in step 12). Members appear to concur. A study of over 500 AA members found that the most common perception of AA's purpose was "to help alcoholics develop a spiritual way of life" (80.2% of respondents), while the second reason was "to help alcoholics not to drink" (64.4%). Furthermore, over 90% believed that developing a relationship with a higher power was necessary to be sober. Members most often described the "higher power" in AA discourse as a Judeo-Christian god, but non-religious understandings of this term also exist. Given AA's clear emphasis on spirituality, it is interesting that over 90% of respondents described alcoholism as a progressive disease.³³⁵

Relationships are also important to recovery in AA and NA, implicating the moral dimensions. Just as sin is separation from God in Christianity, separation from a Higher Power in AA both causes disease and further separation.³³⁶ Recovery involves repairing this relationship through improving personal character, including reforming relationships. It is insufficient to merely abstain from the abused substance. According to AA tenets, an alcoholic who continues to exhibit character defects such as self-centeredness is not truly sober but merely not drinking.³³⁷ Other character defects that might preclude real sobriety include self-pity, anger, and resentment, which suggest that members have not turned their lives over to a Higher Power.³³⁸ Recovery also requires service to others (see Step 12). Within AA and NA, resuming substance use is a moral action because it may harm relationships with others, the fellowship between members, and the relationships between members and a Higher Power.³³⁹ AA literature includes the following statement: "So our troubles, we think, are basically of our own making. They arise out of ourselves, and the alcoholic is an extreme example of self-will run riot"—meaning

following one's own desires rather than relying on a Higher Power. According to historian Ernest Kurtz, "AA does not treat alcoholism, it treats the alcoholic."³⁴⁰ AA's and NA's focus on morality makes it particularly attractive to criminal justice administrators who are trying to transform "criminals" into moral citizens.

Some studies have shown that NA and AA may help individuals to avoid drug use, especially those who are highly motivated. However, one study found that psychological wellbeing and decreased craving is correlated with regular attendance in the support group, not with following the spiritual steps.³⁴¹ Therefore, a support group that was not centered on morality might also help increase abstinence. Other support groups do exist, but they are few and far between. Unfortunately, the morality-focused principles of NA and AA reinforce the notion that, even if addiction is a disease, it is somehow very different from other chronic diseases. Addiction is the only disease called a "disease" but treated with morality-based principles. Imagine, for example, if individuals with STDs were encouraged to attend morality-based support groups. In the 21st century, most Americans would be outraged! However, treating addiction as a morality-based disease does not seem strange.

C. MAT and Morality

Many Americans continue to assume that drug dependence is a sin and dependent individuals are immoral.³⁴² Even many Americans who regard substance dependence as a disease believe that it is also a moral condition.³⁴³ Therefore, treating drug dependence appears to require treatment reforming morality, not medication. Obtaining a prescription from a physician does not require seeking forgiveness, making amends, or developing relationships or improving spirituality. If one understands addiction primarily as immorality, then prescriptions are superfluous at best or harmful at worst if they prevent the person from reforming her morals.

In NA philosophy, for example, an individual should replace her dependence on drugs with dependence on a Higher Power; therefore, some NA members may fear that accepting MAT is equivalent to replacing one drug dependence with another, preventing individuals from forming an ideal relationship with a Higher Power.

Thus, individuals who perceive drug use as immoral and MAT as "just another drug" are also likely to regard MAT as immoral. Despite methadone's proven benefits, in the 1990s in New York City, then-Mayor Rudy Giuliani called methadone treatment an "immoral solution" to opiate dependence.³⁴⁴ But MAT is not "just another drug." One reason for this misconception is the perception that patients undergoing MAT are "drugged" and that they will appear sluggish and non-functional. This image of methadone patients may be spread by movies. Studies show, however, that patients properly maintained on methadone do not appear drugged and that their motor skills and reflexes are not impaired, so that they can drive and operate heavy machinery.³⁴⁵ Additionally, some methadone clinics have gained notoriety in the public eye for being badly managed, with participants receiving insufficient doses (allowing them to "get high" from another drug only a few hours later) or attracting drug dealers just outside the front door. Because methadone clinics are isolated from the general practice of medicine, most Americans have had no experience seeing methadone patients, creating fertile ground for misconceptions to spread.

Conflation of addiction with immorality may negatively affect treatment professionals as well as patients. Physicians who primarily treat individuals with drug dependence are sometimes stigmatized as if they aided and abetted criminal activity. Such stigmatization discourages physicians from entering the addiction treatment field. Studies also show that some physicians harbor biases against their own patients who suffer from SUD since they presume that these

patients are making an immoral choice to remain addicted rather than to improve their health.³⁴⁶ When physicians harbor such biases, they may be unlikely to pursue addiction treatment-related education, such as training required for buprenorphine certification, and may unconsciously discourage patients from asking about MAT or being honest regarding relapses.

D. Eliminating the Link between Addiction and Immorality

1. <u>Reforming Criminal Law</u>

The federal government must change its battle tactics in the War on Drugs, focusing instead on public health initiatives rather than law enforcement. In fact, the government should stop referring to a "war" at all. Even though drugs are the supposed enemy in the war, by association individuals with drug dependence become considered the enemy as well, rather than individuals suffering from a disease. Little empirical evidence exists that the War on Drugs has been effective at lowering drug use, while significant evidence suggests it has increased the stigma of drug dependence.³⁴⁷ Currently, addiction treatment is severely underfunded within every criminal justice institution, including drug courts, prisons and jails. Money saved from slashing War on Drugs law enforcement funding could be used to expand quality treatment programs in the federal criminal justice system as well as to provide grants to states for developing their own treatment initiatives. Financial savings could also be used to develop incentives for private sector and academic development of drug dependence treatments, such as grants to pharmaceutical developers and universities. Currently only three FDA-approved treatments for opioid dependence exist, and no treatments exist for cocaine, marijuana, or methamphetamine dependence; significantly more research and development in addiction treatment is needed. Finally, funds could be used to educate the general public about evidencebased treatment, including public service announcements.

Prosecutors should also stop targeting low-level drug offenders. Throughout the War on Drugs, the DEA has targeted low-level drug offenders in the hopes that they will reveal the names of higher-level traffickers through plea bargains. This strategy, however, has overwhelmingly failed because individuals at these lower levels of simple drug possession are unlikely to have information about higher-level dealers. Instead, these low-level offenders obtain a criminal record, hampering their ability to obtain treatment if they are unable to obtain a job with health insurance or to afford treatment. Furthermore, targeting low-level drug offenders reinforces the public perception that drug dependents are immoral. Multiple judges whom I interviewed stated that low-level drug traffickers commonly sell drugs to fund their own drug habits, suggesting that many of these individuals need treatment more than prison time.

2. Changing How We Talk About Addiction

Over centuries, references to describe dependent individuals have been morality-laden. In the mid-1890s, the term "dope fiend" became common, with "fiend" being a German derivative meaning "wicked" or "hated person."³⁴⁸ Historically, individuals who recovered from drug dependence were described as "redeemed", "repentant", "straight", and "reformed," and many treatment centers were referred to as "reformatories."³⁴⁹ Today, Americans routinely perceive individuals with drug dependence as immoral.

The idea that individuals with dependence are immoral is reinforced through various means, including discourse. According to William White, "The language of addiction is a coded language. Each word emerges as a means of signaling nuances of one's personal, professional and political values and affiliations. The rhetoric chosen…rationalizes particular types of interventions into their lives."³⁵⁰

In the past and present, the words "clean" and "dirty" have been used to refer to individuals with drug dependence. Cleanliness has been synonymous with moral purity and dirtiness with moral impurity. Even today, treatment professionals and criminal justice administrators" sometimes refer to drug screens as "clean" (meaning drug-free) or "dirty" (meaning suggesting drug use). In the medical context, such language is improperly used to refer to drug use. For example, a diabetic whose urine is screened for sugar does not have her urine referred to as "clean" or "dirty."

Some addiction terms, however, have had a disease connotation, such as "cured," "recovered," and "recovering". Today the preferred language is "recovered" or "recovering," in keeping with the medical understanding of addiction as a chronic disease that is rarely cured but can be effectively managed.³⁵¹ Professional health organizations and the government should strongly encourage treatment professionals and criminal justice administrators to use medical rather than moral terms when discussing drug dependence instead of "clean" and "dirty" in reference to drug screenings.

3. <u>Decreasing Stigma</u>

Mental health disease are usually more stigmatized than physical diseases, possibly because the root MHDs is more difficult for the public to see or understand; and among MHDs, addiction is one of the most stigmatized diseases.³⁵² Even persons who believe that addiction is a disease continue to stigmatize individuals with drug dependence by, for example, not wanting to marry them out of fear of passing a genetic predisposition onto children.³⁵³ Changing cultural biases takes time, but steps can be taken to begin the process of destigmatizing drug dependence and MAT.

Three primary modes for fighting stigma exist: advocacy, public and professional

education, and increasing inter-personal contact between stigmatized and non-stigmatized groups. Public service announcements efficiently provide information to the public and may influence public attitudes. The federal government has funded numerous public service announcements for preventing drug use (most famously Nancy Reagan's "Just Say No Campaign"). These announcements uniformly provide information about prevention only; they do not provide information about treatment. The model is wrong, especially while we are in the midst of the opioid overdose crisis. Public service announcements should provide information about prevention and treatment. For example, the announcement could direct individuals to a website with a range of evidence-based treatment methods. Ideally, the website should also include a searchable database of treatment providers for each zip code or city.

Increasing inter-personal contact between stigmatized and non-stigmatized groups is important for decreasing stigma for the stigmatized group. The contact often encourages the nonstigmatized group to humanize the stigmatized group. Unfortunately, open inter-personal contact is particularly difficult in the context of addiction. Unlike members of some other stigmatized groups (e.g. individuals with darker skin), individuals with drug dependence are not easily recognizable. They can easily hide the source of their stigma from co-workers, friends, and family.

Additionally, exposing the general public to individuals with drug dependence in "active addiction" (meaning currently using drugs) is not sufficient; the public should also be exposed to individuals with drug dependence who are undergoing treatment or are in long-term recovery. If the public is only aware of individuals in active addiction, then the public is unlikely to appreciate the benefits of treatment. The public is also more likely to see someone in the midst of cravings or engaging in actions not considered socially acceptable (e.g. prostitution or theft in

order to purchase more drugs). Such exposure could further increase stigma of individuals with drug dependence rather than decreasing it. Unfortunately, unless addiction is quickly destigmatized (unlikely), most individuals suffering from drug dependency will continue to hide their status and contact between the stigmatized group and non-stigmatized group will remain minimal. Fortunately, celebrities who voluntarily "come out" as being individuals with drug dependence undergoing treatment or being in long-term recovery can form a source of exposure between the stigmatized and non-stigmatized groups. If the celebrities' stories are discussed in the mass media, then information can be quickly diffused to the general public. Ideally, such stories would include information about prevention and treatment. In other words, such stories could serve as "public service announcements" as well.

IV. Abstinence-Only Treatment

Today abstinence-only treatment is the norm in the U.S and is deeply entrenched in U.S. culture.³⁵⁴ While studies suggest that abstinence-only treatment may be effective for 30-50% of long-term dependent cocaine users, studies suggest that it is significantly less effective for individuals with opioid dependence.³⁵⁵ In general, studies estimate that behavioral treatment without medication prevents relapse in only 20% of individuals with drug dependence.³⁵⁶ Abstinence-only treatment goes hand-in-hand with sociocultural and individual biases against MAT. Abstinence-only treatment can refer to treatment without any form of MAT, or treatment without agonist MAT (in which buprenorphine and methadone are prohibited, but Vivitrol is allowed). Abstinence-only treatment facilities typically provide mental health therapy and support group participation but not MAT. Such facilities may also prohibit patients from starting MAT elsewhere or refuse to accept patients currently undergoing MAT. Individual practitioners

such as counselors often have an abstinence-only treatment philosophy, and will not recommend any form of MAT or agonist MAT to patients.

This section begins by discussing why abstinence-only treatment is the dominant treatment in the U.S., and examines the discourse associated with this philosophy. It then argues that the conflict between abstinence-only treatment and MAT stems from differing notions of sobriety and recovery, and fears about MAT grounded in inaccurate information. Finally, the chapter examines how abstinence-only treatment stigmatizes MAT patients.

A. Comparing the Frequency of MAT versus Abstinence-Only Treatment

Abstinence-only treatment is the norm in SUD treatment in the U.S.; less than 45% of all treatment programs (private and public) offer any form of MAT.³⁵⁷ Even among treatment centers that offer MAT, its actual implementation remains very low. Knudsen et al. found that only 34% of opioid-dependence patients in programs that offer MAT actually receive MAT. Naltrexone treatment is particularly limited.³⁵⁸

Treatment program administrators and staff have widespread distrust of MAT, contributing to its under-provision.³⁵⁹ Counselors form the majority of professional SUD treatment providers, but a large minority also philosophically oppose MAT. One study found that approximately 50% of SUD counselors either have not heard of MAT or are philosophically opposed to it. In another study of all U.S. state agencies responsible for funding SUD treatment, one state agency director explained, "[Barriers to MAT adoption] are mostly cultural with some of the substance abuse providers ...saying clients should just quit and shouldn't have to be on naltrexone...or people should just quit and not be on methadone and buprenorphine."³⁶⁰

Over 90% of treatment organizations programs are centered on the 12-steps of AA and NA, known as the Minnesota Model of treatment organization. Unfortunately, 12-step centered

programs tend to prohibit MAT. The hegemony of abstinence-only and 12-step discourse (in SUD treatment centers throttles any chances for MAT discourse. Treatment programs provide limited or no information about MAT to patients. One study found that patients tended to learn about MAT from other patients for whom abstinence-only treatment had failed, rather than from practitioners or treatment programs.³⁶¹ Information patients learned about MAT from 12-step groups is often inaccurate, such as the idea that MAT is just a "crutch" rather than a treatment.³⁶² Some patients know that abstinence-only treatment is not working, but continue to participate due to ignorance of or lack of access to MAT.³⁶³ In one study where individuals with opioid dependence were interviewed about their treatment pasts, the researcher concluded:

[Dominance] of the discourse was evidenced throughout the subject's [sic] treatment histories by the preponderance of references to NA, AA, or other 12-step recovery groups. In nearly every case, whenever the possibility of attending "treatment" became an option it was inevitably 12-Step based, and those who were seeking alternative treatment models were consistently faced with a lack of access and information.³⁶⁴

B. Differing Conceptions of Sobriety and Recovery

Understandings of sobriety and recovery differ between abstinence-only philosophy and medical (MAT-accepting) treatment philosophy differ. Although "sobriety" is a commonly used term, it lacks a standard definition.³⁶⁵ Abstinence-only proponents view sobriety as complete abstinence from any mind-affecting substances, including MAT or agonist MAT. In contrast, medical view proponents understand sobriety as "control, balance, and moderation" (which is similar to the dictionary definition of sobriety).³⁶⁶ The medical treatment philosophy regards MAT as an appropriate treatment because it improves individuals' functionality so that they can express control, balance, and moderation.

The meaning of "being in recovery" is likewise disputed. According to the abstinenceonly philosophy, being in recovery means abstaining from any mind-affecting substance, including opioids in agonist MAT. Therefore, one cannot be in recovery while using agonist MAT. At most, one could be making a step towards recovery. ³⁶⁷ Interestingly, many abstinenceonly treatment centers do permit pharmacological treatments for other MHDs, such as SSRIs for depression. On the other hand, within the medical view, recovery more commonly means "not abusing substances." Therefore, MAT is permitted so long as it is taken as prescribed and no substances are abused. Given that addiction is a disease, taking a medication for addiction as prescribed falls within the colloquial definition of recovery.

"Recovery" can also be understood as a broader concept than just abstinence from mindaltering substances or drug abuse. It sometimes takes on a more holistic definition, meaning that a recovering individual is no longer abusing substances, has improved overall health, and is reintegrating into the community.³⁶⁸ Many organizations and practitioners accept this broader understanding of recovery, whether or not they adhere to an abstinence-only philosophy. In AA and NA, recovery includes an additional component--spirituality, defined as being in a relationship with a Higher Power). Treatment organizations and practitioners whose treatment is centered on AA/NA likely include spirituality in their definition of recovery as well.

In another semantic complication, treatment facilities and practitioners sometimes distinguish between "remission" and "recovery." Remission is the *decline* in pathological symptoms, here, drug abuse. Recovery, on the other hand, is the *addition* of positive health and integration into community life, as well as the decline in pathological symptoms.³⁶⁹ Practitioners who believe that remission and recovery are different concepts may believe that MAT can cause remission but not recovery, perhaps unless support groups and/or counseling are used as well.³⁷⁰ Obviously, if spirituality is a necessary component of recovery, as understood within NA and AA, then MAT alone is insufficient. But MAT alone could be understood to improve community
integration and overall health by decreasing drug abuse and recidivism.

C. MAT and "Recovery"

Many organizations and practitioners who provide MAT encourage counseling and/or support group involvement, assuming that MAT alone is insufficient for complete recovery. They are probably correct in many, but not all, cases. For example, a patient whose drug dependence is related to his PTSD is more likely to completely recover when MAT and counseling for PTSD are provided together. Otherwise, without counseling for PTSD, the patient may try to self-medicate with other drugs like cocaine, methamphetamines, or other drugs whose effects are not blocked by MAT for opioid addiction.

However, interviews with health practitioners and administrators, I have often heard about policies that coerce MAT patients into other treatments under the guise that recovery is impossible without them. For example, treatment centers tell patients that they can only receive MAT *if they also attend counseling and/or support group treatment*. Patients who disagree with the policy are not provided with MAT. Such policies take the ideal of recovery to an extreme. It is contrary to harm-reduction principles and patient-centered care, both of which suggest that practitioners should meet a patient "where he or she is." Such policies also unfairly imply that counseling/support groups are more important for recovery than MAT; because patients are not required to undergo MAT in order to participate in them.

Three physicians whom I interviewed in Indiana stated that the treatment facility in which they work required patients to attend counseling and support groups to access MAT. If patients failed to attend sessions, they cannot access MAT. The policy applies even if urine screenings indicate abstinence from drug abuse, suggesting that MAT is working. Each of the three physicians expressed discomfort with the policy, because when they cancel MAT

appointments they worry that the patient is at greater risk of relapse and overdose.

In light of MAT's validated effectiveness, providers and facilities should encourage rather than coerce patients into using additional treatment modalities. Multiple arguments against coercion in counseling and support groups exist. First, coercion into multiple treatment modalities is rare (or non-existent) for other chronic diseases. For example, diabetes patients are not told that their insulin treatment will cease if they fail to see a nutritionist and exercise regularly. Primary care physicians do not withhold antidepressants from patients who fail to attend counseling. Second, studies show that MAT may improve patients' ability to partake in counseling and support groups at a later date by stabilizing physical cravings and preventing euphoria from drug use. Therefore, patients may be better off in the long-run if they begins MAT and then later add additional treatment modalities. Third, even without supplementary treatments, MAT is effective. In fact, as compared to counseling alone, MAT by itself is more effective at promoting abstinence from drug abuse. But if treatment organizations only allow MAT for patients in counseling and support groups, then patients who resist these methods will be left with no treatment at all, . Finally, I have never heard of requirements that patients attending counseling or support groups must also participate in MAT. Therefore, MAT as a treatment modality is singled out unfairly.

DATA requires buprenorphine providers to have the *capacity* to refer patients for counseling, but it does not require patients to attend counseling in order to access treatment. It is possible that some health practitioners are confused and assume that MAT provision is illegal without counseling. Clarification of this point in widely-read professional literature and MAT trainings help dispel misconceptions.

D. Other Misconceptions about MAT

In addition to the misconception that MAT hinders sobriety, I have encountered other common misconceptions about MAT among practitioners, treatment organizations, criminal justice administrators, and policy makers. These common misconceptions are assumptions that MAT prevents autonomy, concern about long-term use of MAT, and fear of illicit activities related to MAT (i.e. diversion or abuse of MAT).

1. <u>MAT and Autonomy</u>

According to Gomart, conventional addiction discourse frequently positions the drug user as a slave of the drug in contrast to an abstinent "autonomous liberal agent."³⁷¹ Practitioners who adhere to abstinence-only philosophy may assume that individuals cannot make autonomous decisions and are "slaves" unless they are abstinent from all opioids, including agonist MAT. The notion of "freedom" (without opioids) versus "slavery" (with opioids) obscures the complicated way in which medications and individuals interact to encourage agency and autonomy.³⁷² Because MAT reduces cravings and eliminates rewards from opioid abuse by activating the opioid receptor and preventing a "high", one could say that MAT encourages freedom rather than slavery; MAT ends physical cravings, a source of compulsion or "slavery." The individual has greater agency because he can focus on non-drug-seeking tasks.

Some journalists and scholars have called methadone "liquid handcuffs," because once the individual ceases taking methadone for addiction, cravings and the ability to "get high" return. This argument is unfair, because many (if not most) medications for chronic diseases could be interpreted as "handcuffs." Schizophrenia medication could be described as "handcuffs" for schizophrenia patients, because when they stop taking the medication negative symptoms recur, or one could describe insulin as "handcuffs" for diabetes patients, because when they stop taking insulin, negative symptoms will recur. However, our culture seems far more concerned

about medication for addiction treatment. Why?

The Protestant work ethic has been improperly applied to chronic diseases, especially addiction. It suggests that one should overcome addiction by "working harder," not by taking medication, which can be seen as laziness and inauthentic sobriety. If a dependent individual takes a medication indefinitely, the misconception goes, then when will they ever do the "real work" of overcoming addiction? Many counselors whom I interviewed implied that the "real work" of overcoming addiction was going to counseling and support groups rather than taking medication. I have also routinely heard this sentiment in interviews with criminal justice administrators.

The American public seems to project the Protestant work ethic onto addiction even more so than other chronic diseases, assuming that addiction stems from a lack of willpower³⁷³, correlated with laziness. They assume that if addicted individuals "willed" themselves to stop using drugs, they would be able to stop; when addicted individuals cannot stop using drugs, they are thought too lazy to apply willpower.³⁷⁴ MAT is perceived as a crutch, allowing addicted individuals to remain lazy and not do the real work of recovery. The longer the individual remains on MAT, the lazier he or she appears.

2. <u>Concerns Regarding Long-Term Use of MAT</u>

One of the most common questions I receive about my research is, "Will people who take MAT need to be on it for their entire lives?" People usually ask me this question with profound concern, as if the thought of someone being on medication for life is extremely distressing, even though it is common for other diseases. The short answer to this question is that it depends on the person. Some patients will need medication for a long-time; others will not. A consensus exists in the medical literature that long-term use of MAT agonists is better than short-term use

(few studies regarding long-term use of Vivitrol exist yet due to its recent FDA approval). Even though buprenorphine and methadone significantly reduce illicit opioid use, 90% of patients relapse after tapering from buprenorphine³⁷⁵, and 80% of patients relapse within one year after tapering from methadone.³⁷⁶

According to interviews I conducted, physicians are not typically worried about longterm use of MAT; if they are, it is typically a question of whether MAT has long-term *physiological side effects of the medication* (e.g. liver damage). On the other hand, criminal justice administrators (e.g. drug court judges) and counselors routinely worry about long-term use of MAT due to concern that it delays "real" recovery or sobriety. When I ask drug court judges whether participants can graduate from drug court while under treatment with agonist MAT, a large minority say "no," because they believe that the participant is not yet "sober."

3. <u>Concerns of Diversion and Abuse of MAT</u>

This section will discuss how patients, professionals and criminal justice systems address the problem of diversion of buprenorphine and methadone.

i. Buprenorphine

Like any medication with an opioid ingredient, buprenorphine can be abused and cause overdoses. As buprenorphine use has increased in recent years, so has the risk of accidental overdose or accidental ingestion by children.³⁷⁷ However, buprenorphine overdoses are rare relative to heroin, oxycodone, or methadone overdoses,³⁷⁸ and the majority of persons prescribed buprenorphine do not abuse or divert it. There are two reasons for this. First, the partial muantagonist nature of buprenorphine prevents the patient from experiencing euphoria from taking any additional opiate, including extra buprenorphine).³⁷⁹ Second, buprenorphine is far less potent than heroin, oxycodone, methadone, and other common opiates.³⁸⁰ Unfortunately,

negative media articles that have "overstated the medication's risk and overhyped the tendency of it to be sold on the black market" have caused some policy makers to become suspicious of expanding access to buprenorphine.³⁸¹

Policy makers are particularly concerned that individuals who illicitly access buprenorphine, such as by purchasing it on the street, are at greater risk for overdose for many reasons, including not knowing what ingredients it has been mixed with and what dose is safe. They are also concerned that individuals who purchase buprenorphine on the street may be using buprenorphine to "get high" in contrast to individuals seeking buprenorphine treatment through legal channels. Some major newspapers have published articles regarding buprenorphine's diversion and abuse, possibly discouraging physicians from prescribing it and policymakers from making it more widely available.³⁸²

Law enforcement agencies across the nation have encountered increasing amounts of diverted buprenorphine being sold on the streets. Like policymakers, law enforcement may assume that such buprenorphine is purchased primarily for the purpose of "getting high." But recent studies have found that black market purchasers are more likely to buy to help themselves become sober, seeking treatment rather than to a "high"³⁸³; epidemiologic evidence suggests that injection drug users and heroin users are more likely to illicitly purchase buprenorphine as self-treatment.³⁸⁴ These individuals may find it easier to purchase buprenorphine illicitly than to obtain a doctor's appointment.³⁸⁵ The bizarre fact that a black market has developed for treatment medication points to the high demand for treatment relative to the number of available providers.³⁸⁶

Health practitioners' attitudes about buprenorphine diversion are nuanced. One survey of physicians in 2003 found that 44% believed patients purchased buprenorphine illicitly to manage

withdrawal, 34% for maintenance until treatment, 17% to try it out, and 7% to "get high."³⁸⁷ A 2009 survey of 339 health practitioners working in addiction treatment programs, half of whom were physicians, found that the median response to questions of diversion concern was "neutral"; participants neither agreed nor disagreed that buprenorphine-naloxone diversion was a dangerous problem.³⁸⁸ Nearly two-thirds of clinicians believed that diverted buprenorphine-naloxone was used to prevent withdrawal or when people cannot obtain their drug of choice.³⁸⁹ Clinicians who worked with patients treated with buprenorphine-naloxone were significantly more likely to believe that diversion occurred primarily from limited treatment access³⁹⁰ and were less likely to perceive diversion as dangerous.³⁹¹ Their largest concern was that it could lead to overdose. The study authors point out that "if use of illicit buprenorphine-naloxone occurs mainly a) among treatment-seekers with history of injection drug use or with substantial physiological dependence, and b) because of inadequate access to treatment or withdrawal prevention, then diversion may ironically decrease community opioid overdoses."³⁹²

Indeed, other recent studies have found that illicit buprenorphine purchases occur primarily among treatment seekers and injection drug users³⁹³ and that treatment access is limited.³⁹⁴ A 2010 survey of illicit buprenorphine purchasers concluded, "[T]he results of this study suggest that demand for illicit buprenorphine is driven by people trying to avoid withdrawal and to reduce cravings; these results do not support the position that buprenorphine users are trying to attain euphoric effects."³⁹⁵ Another 2015 survey of legal buprenorphine patients found that 84% perceived buprenorphine diversion as mostly positive and 77% perceived it as a morally right, altruistic behavior to help others without access to treatment.³⁹⁶

Proposals for decreasing barriers to buprenorphine treatment are commonly countered with the argument that decreasing barriers will increase diversion. However, assuming that

increased diversion occurs, policy makers should ask whether diverted buprenorphine is primarily harmful or whether it serves as a stepping stone towards more legal buprenorphine treatment. A recent study found that individuals who had prior experience with non-prescribed buprenorphine were more likely to enter legal buprenorphine treatment and to remain in treatment after six months than individuals who began buprenorphine treatment while buprenorphine-naïve.³⁹⁷

ii. Methadone

As early as 1972, news articles were warning the public of methadone diversion. The tone of these articles was frequently negative, without a balanced discussion of the benefits of widely-available methadone maintenance treatment. Popular headlines from that year included "Study finds black market developing in methadone" (*New York Times*), "Curse or cure? Controversy balloons over use of methadone as a heroin substitute" (*Wall Street Journal*), and "Methadone: Will it spread addiction?" (*National Observer*)."³⁹⁸

As early as the 1970s, researchers were finding that individuals most often purchased methadone illicitly was for "self-treatment."³⁹⁹ Diversion of methadone may also allow marginalized persons to help one another. A study of methadone diversion in England found that such diversion to others was both altruistic and self-protective; a patient helped those who could not enter an OTP in case he was one day kicked out.⁴⁰⁰ The authors saw diverted methadone in the U.K. as "potentially having more value as a personal safeguard and social resource than a commodity on the black market."⁴⁰¹ A 2015 study by Johnson and Richert found similar attitudes in the U.S.⁴⁰²

Since the late 1990s, methadone diversion has significantly increased. But diverted methadone has typically been prescribed for pain treatment, not addiction treatment.⁴⁰³

Methadone pain prescriptions grew nearly eight-fold between 1998 and 2006.⁴⁰⁴ Methadone for pain treatment is typically in pill or film form, unlike methadone for addiction treatment, which is typically liquid.⁴⁰⁵ Diverting liquid methadone provided under supervision is more difficult than diverting methadone in pill form dispensed from a local pharmacy; some methadone patients in OTPs divert methadone by storing the liquid in their cheeks and then spitting it into a hidden container.

All government agencies can be expected to be concerned with buprenorphine and methadone diversion, but state law enforcement and the DEA have been particularly vocal about its dangers. In 1989, the DEA told Congress that "Methadone is an addictive, euphoria-producing drug with a high street value, and we believe it obvious that the dispensing of such a drug to an addict population, which by definition has shown itself to be more likely to abuse drugs than the general population, should be done only within a tightly regulated framework."⁴⁰⁶ The DEA has also been concerned with the possibility that poly-drug users sell methadone to fund purchases of other drugs, so that methadone programs could be indirectly subsidizing other drug abuse.⁴⁰⁷ When the DEA considered expanding take-home privileges in the late 1980s, Eugene Haislip, Deputy Assistant Administrator for Diversion Control, stated it "can only be expected to exacerbate the problem."⁴⁰⁸ Likewise, the DEA dismissed medical organizations' proposals you categorize buprenorphine in a less restrictive schedule of the Controlled Substances Act, largely due to fears of diversion.

Policy makers should acknowledge potential dangerous of buprenorphine and methadone diversion, including overdose from self-treatment with wrong doses. However, the concern should be balanced with the need for expanding legal treatment without stigmatizing or singling out addiction treatment patients from other medical patients.

E. Stigma of MAT-Patients in Abstinence-Only Treatment

The culture of abstinence-only treatment promotes stigma against individuals treated with MAT. Unfortunately, society places persons treated with MAT in a "uniquely marginal social location," seeing them as neither "the sober addict" nor the "the fantasy outlaw heroin user."⁴⁰⁹ Persons undergoing MAT sometimes do not have "the full status of patient" or are denied the ability to call themselves "in recovery."⁴¹⁰ In mainstream culture they are ostracized as addicts; in recovery culture they are stigmatized because they undergo MAT.⁴¹¹ Another study found that some patients avoid MAT out of shame, preferring abstinence-only treatment.⁴¹²

Unfortunately, stigmatization of MAT patients appears in the most popular form of addiction treatment in the U.S.: 12-step groups. NA has not officially taken a position against MAT⁴¹³ and is thus not officially an abstinence-only treatment. However, according to NA's main website, individual NA groups can decide to ban participants using MAT from meetings.⁴¹⁴ It appears that a significant percentage of groups or members adhere to an abstinence-only philosophy. Published studies report that up to 25% of members of NA and similar 12-step groups feel stigmatized if they undergo MAT.⁴¹⁵ One 2011 article states an invisible moral hierarchy of SUD treatments exists within AA and NA meeting discourse: abstinence-only treatment is better than MAT, and MAT is only marginally better than active drug abuse.⁴¹⁶ Members report not telling their sponsors about their medical treatment because sponsors might misunderstand it as substituting one chemical addiction for another.⁴¹⁷ A 2000 study by Rychtarik et al. found that only 53% of AA members believed MAT was or might be a good idea.⁴¹⁸ NA and similar groups are also unlikely to educate members about MAT.⁴¹⁹

Some MAT-prescribing physicians recognize its stigma and try to help patients navigate it. At an annual ASAM conference I attended, two speakers in two different sessions discussed

encouraging patients not to tell their NA sponsors that they were on MAT. Both believed that support groups were an important recovery tool but recognized that few non-12-step support groups exist.

Given that AA and NA is the most accessible form of addiction treatment today, their organizational headquarters have a moral obligation to prevent groups from excluding or discriminating against MAT patients. AA and NA have previously released publications explaining that one can be sober while taking mental health medication (e.g. for depression), but they have yet to do so regarding MAT. In the meantime, rumors that MAT is just another drug which one must get off of quickly continue to spread within AA and NA.

One study of methadone patients found wide-spread internalization of the idea that MAT was just another drug. Some patients planned how to get off of it before they even began and participated in methadone treatment half-heartedly, with some requesting low dosages contrary to best-practices because they perceived lower doses to be less immoral. Patients tended to view addiction as a coping strategy for a spiritual problem (a view encouraged by AA and NA) and perceived methadone as an ineffective treatment that was unrelated to spirituality).⁴²⁰ Patients believed that true happiness and recovery were impossible with MAT, even though their drug use had decreased or ceased since beginning it. The study found that, even among MAT patients, the cultural dominance of abstinence-only philosophy created cognitive dissonance and self-doubt. The mono-discourse of abstinence-only treatment strangles discourses supportive of MAT.

V. Summary

Since the time of American Puritans, the general public has interpreted drug and alcohol dependence as a sign of immorality and lack of willpower.⁴²¹ In this chapter, I have argued that Alcoholics Anonymous and the War on Drugs reinforce such inaccurate views of addiction. At the same time, some Americans have viewed addiction as a neurological disease. However, even among those Americans who call addiction a disease, many recommend treatments for increasing spirituality (e.g. 12-step groups) and willpower (e.g. motivational interviewing), while discouraging medication. As a result, addiction has become a medical anomaly: a concept recognized as a disease but treated as something other than a disease, with medication discouraged and spirituality encouraged. No other disease in America is overwhelmingly treated this way. SUD treatment centers who discourage MAT while encouraging abstinence-only treatment methods are actively preventing their patients for receiving the best-standard of care, a tragedy in light of the deadliness of opioid dependence. Additionally, some SUD treatment centers and support groups stigmatize MAT patients, claiming that they are not really in recovery.

Bias against MAT is not only culturally ingrained but due to lack of education about evidence-based treatment methods among counselors, physicians and the general public. Lack of education is compounded by inaccurate widely-held beliefs. For example, many abstinence-only treatment providers assume that MAT is just another drug (e.g. thus it cannot help one recover), or that the risk of diversion/abuse outweighs the benefits.

As the next chapter demonstrates, cultural bias, lack of education, and misunderstandings about MAT affect government regulations. In turn, government regulations minimize access to MAT and decrease the likelihood of interactions between the general public and patients who

have recovered through MAT. Even though MAT has transformed many lives, MAT patients' isolation from mainstream medical care, as well as the stigma of addiction (compelling them to be silent), prevents the general public from hearing success stories.⁴²² Therefore, I argue that decreasing regulatory barriers will encourage integration of MAT into mainstream medicine and will improve Americans perceptions of MAT.

CHAPTER 2: REGULATORY BARRIERS TO MAT

I. Introduction

Buprenorphine and methadone are both "controlled substances" under the Controlled Substance Act. The federal government more stringently regulates medications that are controlled substances than other prescription medications. Many commonly prescribed medications in the U.S. are controlled substances, including anabolic steroids, Xanax, and opioid painkillers. Physicians who prescribe controlled substances must register with the Drug Enforcement Agency (DEA), keep detailed records of their prescriptions, and provide DEA agents access to records for monitoring purposes. Similarly, pharmacies that dispense controlled substances must maintain detailed records, store the medications under specific conditions, and report prescription-dispensing rates to state and federal authorities.

Buprenorphine and methadone, however, are unique relative to other controlled substances because they are subject to additional prescription limitations. Separating the regulation of opioid addiction maintenance treatment from the regulation of other medical treatments can be traced back to the Harrison Act of 1915.⁴²³ In 1919, the U.S. Supreme Court interpreted the Harrison Act as prohibiting health practitioners from prescribing opioids to known abusers, essentially preventing practitioners from legally prescribing maintenance treatment with an opioid ingredient.⁴²⁴

Even though the Harrison Act has been repealed, statutory and regulatory restrictions are greater for buprenorphine and methadone than for other schedule II and schedule III controlled substances, contributing to the underuse of MAT in the U.S. An article published in the Journal of the American Medical Association in 2008 estimated that less than 10% of patients currently suffering from opioid dependance are receiving agonist treatment (meaning buprenorphine or methadone).⁴²⁵ Having seen the negative effects (e.g. waitlists for buprenorphine) of onerous legal barriers, numerous health organizations have called for reforming how buprenorphine and methadone are regulated. This chapter begins by examining regulatory barriers to buprenorphine and methadone and concludes with suggestions for reforming existing regulations.

II. <u>Regulatory Barriers to Buprenorphine</u>

This section begins with a general overview of the Controlled Substances Act. It then examines the history of classifying buprenorphine as a Schedule III substance, despite opposition from health organizations advocating for a less restrictive schedule. The section then discusses recent regulatory and statutory changes affecting buprenorphine and then concludes with suggestions for furthering access to buprenorphine.

A. DEA Scheduling

Under the Controlled Substances Act (CSA), Congress delegates authority to the Attorney General to classify substances or drugs within five schedules of control, with Schedule V being the least restrictive and Schedule I being the most restrictive.⁴²⁶ For example, heroin is in Schedule I and oxycodone is in Schedule II.⁴²⁷ The Attorney General's decision must be based on the substance's abuse or dependency potential, medical value, and safety.⁴²⁸ The Attorney General's findings about abuse potential must consider several factors, including actual or relative potential for abuse; scientific evidence of its pharmacological effect; current scientific knowledge; history and current pattern of abuse; scope, duration, and significance of abuse; risks to public health; psychic or physiological dependence liability; and whether it is an immediate precursor of a substance already scheduled under the CSA.⁴²⁹ The Attorney General must also consult with the Secretary of Health and Human Services before scheduling the substance; if the Secretary recommends against controlling the drug, then the Attorney General must honor that decision. Finally, rules must be made "on the record," meaning the rule-making process must adhere to certain formal requirements, including notice to the public of the proposed rule and time for public comment before the final rule is published in the Code of Federal Regulations.⁴³⁰

The more restrictive the scheduling, the less accessible the medication becomes. All physicians who prescribe controlled substances must register with the DEA, obtain a DEA number, and meet DEA reporting requirements.⁴³¹ However, under the CSA physicians may only prescribe automatic refills for Schedule III narcotics for up to six months, or five prescriptions (whichever is first).⁴³² But there are no automatic prescription limitations for prescribing Schedule V substances.⁴³³ Also, the more restrictive the scheduling, the less likely physicians may be to prescribe the medication out of fear of losing their medical license for wrong-doing.⁴³⁴

In 1981, the FDA approved the first version of buprenorphine as an injectable, hospitalbased pain killer.⁴³⁵ In 1985, the DEA scheduled that version of buprenorphine as a Schedule V narcotic under the CSA.⁴³⁶ Schedule V controlled substances have a lower potential for abuse than substances in Schedule IV; a currently accepted medical use in treatment in the U.S.; and limited potential for physical dependence or psychological dependence relative to substances in Schedule IV.⁴³⁷

In 2002, after other countries (especially France) had successful experiences with buprenorphine for treating opiate dependence,⁴³⁸ the FDA approved buprenorphine for treating this condition under the brand names Suboxone and Subutex.⁴³⁹ The Suboxone version contains an abuse-deterrent ingredient, naloxone, which causes individuals who abuse the medication through intravenous injection to experience immediate withdrawals.⁴⁴⁰ Therefore, Suboxone is even less likely to be abused than Subutex, which contains only buprenorphine.⁴⁴¹

In 2002, the DEA rescheduled buprenorphine from Schedule V to Schedule III after it became aware that the FDA would shortly approve buprenorphine for addiction treatment and after it received a recommendation to reclassify the substance from the DHHS.⁴⁴² Under the CSA, substances in Schedule III have a lower potential for abuse than substances in Schedules I and II; a currently accepted medical use in treatment in the U.S.; and the potential for moderate or low physical dependence or high psychological dependence.⁴⁴³ The American Academy of Addiction Psychiatry and the American Association of Addiction Medicine both recommended less restrictive scheduling for Suboxone.⁴⁴⁴ The organizations believed that scheduling Suboxone (which contains the abuse-deterrent naloxone) was more consistent with international data suggesting low rates of buprenorphine abuse. Also by making buprenorphine combined with naloxone less restricted then buprenorphine alone, the federal government would incentivize physicians to prescribe the abuse-deterrent version of the medication.⁴⁴⁵

In determining buprenorphine's abuse potential, the DEA considered that buprenorphine would be prescribed to "known drug abusers."⁴⁴⁶ The DEA's response to comments on the Final Rule addressing rescheduling noted, "Simply stated, providing an abusable substance to known drug abusers imparts enhanced risks [sic]."⁴⁴⁷ The DEA feared that opiate naïve (new users) or "non-dependent, opioid-experienced subjects" would obtain buprenorphine illicitly.⁴⁴⁸ It found that such individuals may feel "good drug effects"⁴⁴⁹ if they try to abuse buprenorphine. Ironically, however, opiate-dependent individuals rarely feel any "good drug effects" from buprenorphine⁴⁵⁰—instead, they simply feel normal.⁴⁵¹

In rescheduling buprenorphine, the DEA appeared to be more concerned with buprenorphine's potential to harm opiate naïve and non-opiate-dependent individuals than with its potential benefits for treating opiate-addicted individuals.⁴⁵² In its response to comments on

the Final Rule, the DEA stated that "buprenorphine has abuse potential in a wide spectrum of individuals. Vulnerable populations include drug naïve individuals (new drug abusers), opiate experienced individuals and opiate dependent individuals."⁴⁵³ Later, however, the DEA noted that, "The extent to which buprenorphine is able to produce euphoria and "good drug" effects limits its use by opiate tolerant abusers."⁴⁵⁴

Unfortunately, the DEA's findings did not consider how rescheduling buprenorphine would impact access to treatment.⁴⁵⁵ In response to a comment that rescheduling buprenorphine would make it less accessible for treating dependent individuals, the DEA remarked, "The proposed placement of buprenorphine in Schedule III was not made on the basis of making buprenorphine products available for office-based narcotic treatment. . . . The DEA did not consider the need to expand narcotic treatment as a specific factor in determining the placement of buprenorphine under the CSA."⁴⁵⁶ However, currently accepted medical use is a factor that the DEA is required to weigh in its scheduling determination, suggesting that the DEA should consider how its decision may impede access to medical use of the treatment.

B. Drug Addiction and Treatment Act of 2000

In 2000, Congress passed the Drug Addiction and Treatment Act (DATA), Foreseeing the likely FDA approval of buprenorphine, DATA modified the CSA,⁴⁵⁷ permitting physicians to prescribe Schedule III, IV, and V substances for addiction treatment, while trying to prevent their diversion and abuse.⁴⁵⁸

DATA's passed was not marked with controversy. The initial version of the Act, DATA of 1999, was introduced by Senator Hatch (R) in the Senate but was never brought to a vote.⁴⁵⁹ Representative Biley (R) then re-introduced DATA in the House of Representatives with Republican and Democratic co-sponsors as DATA of 2000.⁴⁶⁰ It easily passed in the House with

412 "yea" votes and only one "nay" vote.⁴⁶¹ The Senate then added DATA of 2000 as an amendment to the Children's Health Act of 2000,⁴⁶² which it then unanimously approved it. The amended Children's Health Act returned to the House for a final vote, where it was passed by a large majority.⁴⁶³

DATA became law two years before the DEA rescheduled buprenorphine from Schedule V to Schedule III. Although the DEA was aware of DATA and its purpose, in its Final Rule it stated that that it was not considering how rescheduling buprenorphine would impact DATA objectives, claiming that "The Drug Addiction Treatment Act (DATA) does not have an impact on DEA's scheduling responsibilities under the CSA."⁴⁶⁴

DATA eliminated the DEA registration requirement for physicians who dispense a Schedule III to V narcotic for purposes of detoxification or maintenance treatment.⁴⁶⁵ Instead, it requires physicians to obtain a waiver (colloquially called a DATA waiver or SAHMSA waiver) from the Secretary of Health and Human Services.⁴⁶⁶ To obtain a waiver, a physician must submit a notification of intent to the Secretary to begin prescribing such medications. This notification must demonstrate that the physician meets several requirements under DATA: 1) the physician is "qualified" to prescribe medication for opiate dependence treatment; 2) the physician will adhere to the patient limits in DATA; and 3) the physician has the capacity to refer patients for ancillary mental health services.⁴⁶⁷

DATA also defines "qualified physician" and imposes patient limits. A physician becomes "qualified" by meeting the requirements in section 2(a)(5)(G) of DATA. First, the physician must have a valid medical license under state law.⁴⁶⁸ Second, the physician must prove that he or she has the necessary education or experience to treat opiate-dependent individuals with buprenorphine (and similar medicines). The physician may demonstrate the

education/experience requirement in several ways: through board certification as an addiction specialist (by a major medical authority listed in the statute); by completing an addiction medicine educational course at least eight hours in length (provided by a medical authority listed in the statute); by participating as a principal investigator in a drug trial for buprenorphine or a similar medication; or otherwise convincing the state's medical board or the U.S. Secretary of Health that the physician has valid experience/education for treating opiate-dependent patients.⁴⁶⁹ Under DATA, physician assistants and nurse practitioners cannot become qualified or obtain a waiver, even if they are licensed in a state that permits physician assistants and nurse practitioners to prescribe Schedule III, IV, or V medications.⁴⁷⁰

In addition to defining "qualified physician" for purposes of obtaining a DATA waiver, DATA also restricts how many patients a qualified physician may treat at one time.⁴⁷¹ These patient restrictions have been widely criticized within the medical community.⁴⁷² Since the passage of DATA, Congress has twice amended the patient restriction to expand the number of patients a physician may treat.⁴⁷³ The original DATA Act prohibited any physician or physician practice from treating more than 30 patients with buprenorphine at any time.⁴⁷⁴ ⁴⁷⁵ Thus, if three physicians owned a group practice and one was treating thirty patients with buprenorphine, then the other two physicians could not treat any patients with buprenorphine.

In 2005, Congress passed the Drug Addiction Treatment Expansion Act, which eliminated the 30-patient limit on group practices, but left it in place for each individual qualified physician.⁴⁷⁶ Under this law, in a three-physician group practice, each physician within the group could now treat up to 30 patients at any time with buprenorphine.⁴⁷⁷ The legislative history of the Drug Addiction Treatment Expansion Act demonstrates that Congress was concerned with how the group practice prescription limit restricted patient access. Rep. Mark

Souder (R-Ind.) advocated for the Drug Addiction Treatment Expansion Act, stating:

"According to the American Medical Association, the current 30-patient cap has limited access to effective substance abuse treatment services. . . . Lifting the cap would enable group practices to treat more patients with this highly effective drug."⁴⁷⁸

By 2006, the growing demand for buprenorphine was stymied by access barriers in the form of long wait times to see qualified physicians. In response, Congress passed the Office of National Drug Control Policy Reauthorization Act,⁴⁷⁹ which established the patient limits that are currently in effect. Title XI of the Act permits physicians who have had a DATA waiver for at least one year to treat up to 100 patients beginning in the second year, after notifying the Health Secretary of their intent to do so.⁴⁸⁰ When the Act passed, Senator Hatch gave a congratulatory speech:

It is clear this [30 patient] cap needs to be raised. To make an analogy, a doctor [] would not turn away a broken arm because he or she had already fixed 30 arms that month! The doctor would not stand for it, and neither would society. The same should be true for physicians treating drug addiction. Given that the destructive effects of drug addiction are so much greater than a broken arm, we should strive to ensure that the healing hands of doctors are not bound by unintended mandates.⁴⁸¹

Nonetheless, access remains scarce. In 2012, only 46.6% of U.S. counties had at least one physician with a DATA waiver.⁴⁸² Only 2% of all U.S. physicians have a DATA waiver, and only 3% of primary care physicians, the largest group of physicians in the nation, have obtained a DATA waiver.⁴⁸³

The AMA and the ASAM have repeatedly criticized the patient limits in DATA⁴⁸⁴ as being arbitrary and causing unnecessary waitlists for patients.⁴⁸⁵ Such patient limits do not exist for other Schedule III narcotics.⁴⁸⁶ They do not even exist for oxycodone, a Schedule II narcotic and drug of choice for many opiate-dependent individuals.⁴⁸⁷ In cities with buprenorphineprescribing physicians, patient limits may cause long waitlists that sometimes include hundreds of patients.⁴⁸⁸ Buprenorphine is an effective maintenance treatment that can be used indefinitely, and so once patients begin buprenorphine treatment, they are likely to have regularly scheduled appointments for a long time. As a result, persons on waitlists may need to wait many months until someone else stops treatment.⁴⁸⁹

C. Regulatory and Statutory Changes in 2016

1. Buprenorphine Patient Limit Regulation Change: July 2016

According to the Controlled Substances Act (which was modified by DATA), the Secretary of Health may change patient limits for buprenorphine.⁴⁹⁰ In July 2016, DHHS released a final rule (which I will refer to as the *DHHS Final Rule*) allowing "eligible practitioners" to treat up to 275 patients under the Controlled Substance Act.⁴⁹¹ In the Final Rule, the DHHS justified patient limit changes by stating: "Given the evidence supporting buprenorphine-based MAT as an effective treatment for opioid use disorder and the magnitude of the opioid crisis, this rule is intended to increase access to buprenorphine-based MAT, prevent diversion, and ensure quality services are provided."

Practitioners may be eligible by virtue of having special credentials (e.g. board certification in addiction medicine).⁴⁹² Practitioners may also be eligible if they work in a "qualified practice setting" (described in the next paragraph).⁴⁹³ Regardless of whether the practitioner is board certified in addiction medicine or practices in a qualified practice setting, the practitioner must have already obtained DHHS permission for at least one year to treat 100 patients, the practitioner cannot have had Medicare enrollment billing privileges revoked, or have been found to have violated CSA.⁴⁹⁴ All practitioners must apply for renewal of the 275 patient limit every three years.

A "qualified practice setting" is narrowly defined. It is a setting that includes the following features: professional coverage for patient emergencies when the practice is closed (e.g. at night); provides access to case management services, including referral and follow-up for medical, behavioral, social housing, employment, or educational services or related services; uses health IT systems; is registered for their states' prescription drug program (there are slightly different rules for contractors of Federal agencies); accepts third party payment or Federal benefits.⁴⁹⁵

Interestingly, the rule allows for practitioners who are otherwise ineligible for the 275 patient limit to apply for temporary (6-month) emergency permission to treat up to 275 patients.⁴⁹⁶ The application requires the practitioner to describe the public health emergency in detail, as well as the practitioners' proposed method for addressing the health emergency. In some situations, DHHS may provide an extension beyond 6 months.⁴⁹⁷ Although the regulation does not provide examples of emergency situations, one could imagine that a natural disaster destroying other treatment centers might qualify as an emergency.

In the Final Rule, DHHS responded to comments received from practitioners and interested individuals.⁴⁹⁸ In comments supporting the proposed rule, practitioners had cited buprenorphine's lifesaving potential, as well as the need for parity between addiction treatment and treatment of other conditions. In comments opposing the rule, practitioners claimed that increases in buprenorphine limits were worthless without increases in specialty practitioners. Practitioners also argued that the definition of a qualified health setting is too vague and that reimbursement levels for addiction treatment must increase.

2. Comprehensive Addiction Recovery Act of 2016

As of the writing of this dissertation, both houses of Congress have passed the

Comprehensive Addiction Recovery Act (CARA).⁴⁹⁹ President Obama is expected to sign CARA, having been a key supporter since the beginning, although the President has called for greater funding for addiction treatment.⁵⁰⁰ CARA addresses many topics, including grants for education and prevention, access to naloxone for opioid overdose reversal and improving access to MAT. Section 303 amends CSA to allow for nurse practitioners (NPs) or physicians assistants (PAs) to be "eligible practitioners" for provision of buprenorphine. Under DATA, NPs and PAs were prohibited from prescribing buprenorphine, despite the fact that many states allow NPs and PAs to prescribe schedule III medications. As a result, CARA may significantly increase access to buprenorphine. Under CARA, NPs and PAs are considered "qualified practitioners" if they meet the following criteria.⁵⁰¹ First, they must complete at least 24 hours of specialized training in addiction treatment (in contrast to physicians, who typically need 8 hours). Second, NAs and PAs must be licensed under State law to prescribe Schedule III medication. Third, they must be supervised by or work in collaboration with a qualifying physicians.⁵⁰²

In my interviews with physicians, I have heard overwhelming support for allowing NAs and PAs to prescribe buprenorphine. Physicians routinely state that they encounter NAs and PAs better educated about addiction than physicians. One physician effectively summarized the sentiment shared by many other physicians whom I interviewed by saying, "95% of the time, NAs and PAs would do a great job prescribing buprenorphine; 5% of the time the patients' situation would be complicated, making NAs and PAs feel out of their depth." (physician 19) But so long as a supervising physician is available, those more complicated situations would be well-managed.

D. Probuphine: A New Buprenorphine Treatment

In May 2016, the FDA announced its approval of Probuphine, a surgical implant that

slowly releases buprenorphine into the arm and lasts six months.⁵⁰³ Probuphine administration is a minor, office-based surgical procedure. Therefore, the FDA has required physicians who administer Probuphine to become "certified implanters" by completing a program in Probuphine Risk Evaluation and Mitigation Strategy (REMS), which teaches how to implant and remove the rods containing buprenorphine. Patients must be seen at least once per month by a physician after receiving the implant. REMS has been required by the FDA for a few other medications, including a seizure medication and a diabetes medication.⁵⁰⁴ For Probuphine, the REMS requirement is unique in so far that it is necessary in addition to the other buprenorphine certification requirements under DATA.

A few days after the FDA announcement, I contacted Titan Pharmaceuticals (the makers of Probuphine) to request information on the distribution of physicians certified in the REMS program. I was told that 5000 physicians had already signed up. Physicians who prescribe Probuphine must conform to DATA requirements (i.e. buprenorphine certification, patient limits) or work within an OTP. But prescribers need not be the ones who actually implant Probuphine. For example, in educational material about Probuphine, the FDA describes a scenario in which a DATA-waivered psychiatrist prescribes Probuphine but a different physician who is a certified Probuphine implanter visits the office to implant the rods in the patient.⁵⁰⁵

According to Titan Pharmaceuticals, Probuphine is intended for patients who have already achieved stability on low to moderate doses of oral buprenorphine.⁵⁰⁶ Such stability may be necessary to ensure that individuals do not attempt to remove the implant from their arm, which could cause nerve damage and other serious medical problems. Additionally, some individuals may require high doses of buprenorphine before they are stabilized, which the implant does not provide.

Probuphine will also be subject to a "closed distribution system," meaning that Titan Pharmaceuticals will ship Probuphine directly to physicians who have received REMS certification. The physician will then store the REMS in the office, rather than requiring patients to pick up the product from a pharmacy. The closed distribution system is likely meant to prevent patients from trying to implant Probuphine into themselves. The closed distribution system will benefit patients by eliminating the step of a visit to a pharmacy. However, the additional paperwork and storage requirements required for physicians to maintain the medication in the office may serve as a deterrent to physicians prescribing Probuphine.

III. Regulatory Barriers to Methadone Treatment

A. Opioid Treatment Programs

Methadone was FDA-approved for pain treatment in 1947. In the 1960s, it was found to be effective for treating opioid withdrawal symptoms and as a long-term maintenance treatment. Methadone's regulatory history is significant for the numerous barriers to access put in place by three agencies: the DEA, the FDA, and the DHHSA (and their precursors). Since the early 20th century, regulatory decisions relating to pharmaceuticals were made by a law enforcement division of federal government. During that time, the federal law enforcement agency interpreted the Harrison Act as banning opioid-based maintenance treatment, creating hurdles for researchers of maintenance treatments.

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (CDAPCA), which moved treatment decisions away from law enforcement to the Department of Health, Education and Welfare (the precursor of DHHS).⁵⁰⁷ The Act also consolidated the Controlled Substances Act and the Controlled Substances Export and Import Act, which became

Titles II and III, respectively, of CDPCA.⁵⁰⁸ In 1970, Methadone was classified as a Schedule II narcotic, the second most restricted category of controlled substances.⁵⁰⁹

In 1972, the FDA-approved methadone for treating opioid dependence.⁵¹⁰ The FDA established a framework for distributing methadone at dedicated sites now known as methadone treatment medication units (MTMUs).⁵¹¹ Medical treatment programs (which would provide counseling and other social services) were required to oversee MTMUs; but MTMUs were required to be located separately from medical treatment programs.⁵¹² The physical separation of medical treatment programs (which were often part of hospitals) from MTMUs (which administered the methadone) began the current separation of methadone treatment from mainstream medical practice. Interestingly, while methadone for pain management initially fell within the same segregated regulatory scheme, starting in 1976 the FDA allowed regular pharmacies to prescribe methadone for pain management.⁵¹³ The change followed a lawsuit initiated by the pharmaceutical industry, which wanted to be involved in methadone distribution.⁵¹⁴ Methadone for addiction treatment, on the other hand, continues to be prescribed and distributed in a closed network.⁵¹⁵

In 1974, Congress passed the Narcotic Addict Treatment Act, in which the federal government explicitly recognized methadone maintenance treatment (MMT) as effective.⁵¹⁶ But rather than allowing all physicians to prescribe MMT, Congress restricted this ability to physicians registered with the DEA.⁵¹⁷ Because the 1972 FDA regulations remained in effect, physicians still could only prescribe in federally regulated-treatment centers rather than in general office-based practices.⁵¹⁸ By that point, methadone was regulated by the DHHS, the FDA, and the DEA, causing administrative hurdles to opening new methadone clinics.

According to Adam Yarmolinsky and Richard Rettig, experts on the history of methadone regulation, the Congressional restrictions in the Narcotic Addict Treatment Act existed because of fears that users would divert prescribed methadone—so much so that the Senate Bill was originally titled The Methadone Diversion Control Act of 1973.⁵¹⁹ In the early 1970s, the *New York Times* and other print news media published articles warning the public of the dangers of methadone diversion.⁵²⁰ Then, during Congressional hearings for the Narcotic Addict Treatment Act, the DEA presented evidence of widespread methadone illicit purchasing.⁵²¹ However, the DEA did not clarify that, according to a contemporary study, individuals who purchased methadone illicitly primarily did so for self-treatment rather than to "get high."⁵²² Additionally, the DEA presented emergency room data related to methadone overdoses and stories of opportunistic physicians who were overprescribing methadone for financial gain.⁵²³ As a result, Congress had little reason to simplify the FDA's regulatory structure.

Access to methadone treatment for addiction is more heavily restricted in the US than in any other developed nation.⁵²⁴ Methadone treatment for addiction (as opposed to pain) is also one of the most heavily regulated medical treatments within the U.S.⁵²⁵ It is regulated by the Substance Abuse and Mental Health Services Administration (SAMHSA), the DEA, and individual states. With few exceptions, MMT may only occur within certified opioid treatment programs, which are almost always isolated from other medical practices. An Opioid Treatment Program (OTP) is defined as "a program or practitioner engaged in opioid treatment of individuals with an opioid agonist medication." All OTPs must be certified by SAMHSA. OTPs must also be licensed in their states, and registered with the DEA.⁵²⁶ To become certified by SAMHSA, the OTP must meet regulations within 42 CFR § 8. Since 2001, certified OTPs must

also become accredited by a SAMHSA-approved accrediting body, such as the Joint Commission (one of the largest health care accreditation organizations in the U.S.).⁵²⁷ Today, IOPs represent 8% of all SUD treatment centers.⁵²⁸ They are separated from mainstream medical treatment. The ASAM says, "Addiction treatment is often criticized as being a separate "silo" from medical care, but OTPs are like silos within silos."⁵²⁹

Individuals undergoing methadone treatment must travel to an OTP daily where they receive methadone while supervised by OTP staff. OTPs are also required to provide mental health counseling and to conduct urine screenings. Daily travel to an OTP may be difficult for many individuals, especially those without transportation and low-income individuals who cannot afford to miss work. The National Institute on Drug Abuse recommends that individuals receive at least one year of methadone treatment,⁵³⁰ so travel to OTPs may constitute an ongoing, sometimes onerous, time commitment. According to SAMHSA, in 2009 there were approximately 1,200 OTPs operating in the U.S.⁵³¹ However, Montana, Wyoming, North Dakota, and South Dakota did not have any OTPs.⁵³² Patients in those states must cross state borders daily if they hope to legally obtain MMT.

Sometimes OTPs permit take-home doses. Whether a patient is eligible for take-home doses depends on whether individual patients have certain characteristics and state law. For example, in West Virginia, whether a patient may obtain a take-home dosage depends on the length of time the patient has participated in treatment at the OTP; the patient's absence of criminal activity, serious behavioral problems, and drug abuse; the capacity to safely store medication at home; the stability of home and environmental relationships; the patient's work, school and other daily activities; and the patient's hardship travelling to the OTP.⁵³³ In West Virginia, the allowable take-home dosage increases gradually over time, resulting in a maximum

one month supply after two years of continuous treatment.⁵³⁴ In contrast, in Kentucky, the maximum take-home allowance is 3 doses per week.⁵³⁵ Therefore, OTP patients in Kentucky must still return weekly under the maximum take-home allowance.

The isolation of OTPs from other medical practices causes problems for methadone patients and local communities. OTPs force methadone patients to congregate in a single area where they are easily recognized as opioid addicts, making it easy for local communities to stigmatize them. In addition, they are more visible to drug dealers; numerous law enforcement personnel, judges, and physicians whom I interviewed stated that drug dealers target methadone clinics, especially those known to provide such low dosages that patients are craving opioids by midday. For decades, academics have expressed concern over this failure to integrate methadone patients into mainstream medicine,⁵³⁶ yet it is rarely discussed as a pressing issue in public discourse.

E. Methadone Treatment for Addiction versus for Pain

Between 1972 and the late 1990s, methadone was primarily used to treat opioid dependence. In the late 1990s, however, more physicians began prescribing it for pain management,⁵³⁷ encouraged in part by new guidelines from national pain-related organizations and pain treatment standards implemented by the Joint Commissions. Many physicians chose to prescribe methadone over other opioids for pain because it is relatively inexpensive and available in a variety of doses and formats.⁵³⁸

Methadone is less efficient as a pain management aid than as an addiction treatment medication. When prescribed for pain, methadone suppresses pain for only approximately four hour, and patients sometimes need a minimum of five days to achieve full pain relief. But when prescribed at appropriate dosages for addiction treatment, methadone suppresses opioid

withdrawal symptoms for a day or more. Although it appears logical to assume that patients would have more difficulty accessing methadone for pain than addiction treatment, but the opposite is true. MMT regulations are significantly more stringent than for prescribing methadone for pain management. Yet methadone overdoses overwhelmingly occur using methadone prescribed for pain, not addiction treatment.⁵³⁹

Under federal law, when methadone is prescribed for pain treatment, the health practitioner must follow general regulations for Schedule II controlled substances. Schedule II controlled substances may be prescribed by any physician registered with the Attorney General in accordance with state law. The physician must re-register with the Attorney General every three years.⁵⁴⁰ In practice, this is referred to as obtaining a "DEA number." Some states allow nurse practitioners or physician assistants to prescribe methadone (and other schedule II controlled substances) for pain relief when supervised by a licensed physician. Physicians may legally prescribing Schedule II controlled substances in an office setting. But methadone prescribed for addiction treatment must be prescribed and dispensed within a certified and accredited Opioid Treatment Program (OTP). In other words, even if a physician is legally able to prescribe methadone for pain treatment in an office setting, he or she cannot legally prescribe methadone for addiction treatment in that same environment. Furthermore, methadone may not be dispensed by a local pharmacy for addiction treatment, even if that pharmacy may legally dispense methadone for pain management.

Clearly, methadone for addiction treatment is singled out as a "special case" that must be heavily regulated. On the other hand, methadone for pain treatment is treated comparably or identically to other Schedule II controlled substances.⁵⁴¹ Methadone has the same ingredients whether it is prescribed for addiction treatment or pain treatment. Dosages for addiction and pain

treatment are different, but they may also dramatically differ within pain treatment. Therefore, the only true difference between the two treatment contexts is the patient population: addicted patients versus pain patients.

Even though the government treats both patient populations as unique, they may in fact significantly overlap. One widely-cited study estimates that 4 to 25% of patients receiving opioid pain management treatment in primary care settings are addicted to opioids. Although some physicians continue to ignore the overlap between the two populations, in recent years many are realizing that their pain patients are actually suffering from opioid dependence as well.

The treatment of pain and addiction patients contributes differently to the stigma of addiction. The general public may misinterpret the reasons why addiction patients are segregated from other patient populations and assume that they are dangerous, difficult to manage, or somehow abnormal. Because the general public does not see methadone maintenance treatment in general practice settings, the public may assume methadone is ineffective. Additionally, other patients have no opportunity to see and interact with methadone treatment patients. Separating MMT patients from other patients also reinforces stigma and misinformation among health practitioners. Most physicians have never prescribed MMT or personally witnessed another practitioner administer MMT. A physician may feel uncomfortable referring a patient to an OTP which she has never visited or knows little about. Perhaps most importantly, physicians with little experience of MMT may fail to provide information about MMT to patients in need, possibly indicating failure of informed consent.

IV. <u>Reforming Buprenorphine Regulations</u>

A. Going Further than CARA and the DHHS Final Rule

Utilization of buprenorphine is very low in the U.S.,⁵⁴² partly due to restrictions placed

on prescribers under DATA.⁵⁴³ Today many cities do not have a single physician with a DATA waiver, ⁵⁴⁴ and many physicians with DATA waivers have very long waitlists. The Huffington Post recently stated that one Ohio county clinic has a waitlist of over 500 patients.⁵⁴⁵ In theory, Americans should be deeply concerned about the waitlists that many opiate-dependent individuals must face when seeking treatment. After all, the popular media criticizes waitlists in other countries, even when those waitlists are for elective procedures.⁵⁴⁶ Buprenorphine, on the other hand, is life-saving, essential medicine.⁵⁴⁷ Furthermore, buprenorphine treatment has been found to reduce drug-related crime, ⁵⁴⁸ health care costs (particularly for emergency room visits), and unemployment.⁵⁴⁹

Patient limits can result in tragedy. The point at which an opiate-dependent individual recognizes that he or she has a problem and seeks help is an absolutely critical window that can quickly disappear.⁵⁵⁰ The cravings for opiates and the withdrawal symptoms a person experiences when they try to become sober may quickly overcome the desire to seek treatment if an appointment with a physician cannot be obtained, potentially leading to overdose (especially if the individual has lowered tolerance following detoxification). The tragedy does not affect the patients alone; families frequently bear the financial and emotional burden of having to support individuals struggling with drug dependence.

The passage of CARA and the new DHHS Final Rule should be applauded for their potential to increase access to this life saving treatment by decreasing waitlists and increasing the number of eligible practitioners. Not surprisingly, CARA and the DHHS Final Rule were strongly supported by the American Medical Association and the American Society for Addiction Medicine. Despite the passage of CARA and the Final Rule, more changes should be made to increase access to buprenorphine.

First, given that DATA patient limits were created with the primary purpose of preventing diversion of buprenorphine, Congress or the DHHS should, at the minimum eliminate patient limits for Probuphine, because Probuphine has a low risk of diversion. Additionally, elimination of the patient limit could serve as an incentive for physicians to switch patients to Probuphine after they have achieved stability on oral buprenorphine. Given that Probuphine has a lower likelihood of diversion and a higher likelihood of compliance relative to oral buprenorphine, physicians should be incentivized to switch eligible patients from oral buprenorphine to Probuphine. Eliminating the patient limits for Probuphine would also allow physicians to accept new buprenorphine patients without the need to discharge stable patients (a situation which currently creates long wait lists).⁵⁵¹

Second, oral buprenorphine-naloxone and future buprenorphine formulations with deterrent-formulations should not be included in patient limits. Naloxone prevents a "high" if buprenorphine is injected. By leaving the patient limit in place for pure buprenorphine but not for buprenorphine-naloxone, physicians will be incentivized to prescribe the latter. Third, and perhaps most importantly, the Federal government should actively work towards a lack of limitations on buprenorphine in order to reach true parity between buprenorphine and other treatments. No other medication has a patient limit and special educational certification is not even required for prescribing prescription pain medication. While the idea of eliminating these restrictions remains controversial, Congress initially enacted them almost fifteen years ago, when U.S. office-based physicians had no experience with buprenorphine for addiction. Fifteen years later, education and experience remains low but buprenorphine can no longer be treated like an experimental medical treatment.

Congress should immediately, significantly increase funding for addiction education in

medical schools and residency programs or provide funding incentives for schools to include comprehensive addiction diagnosis and treatment education. Once the nation reaches the threshold (whatever that may be) when physicians generally have good education about addiction treatment, then the restrictions on buprenorphine should disappear, as they continue to perpetuate the myth that addiction treatment is significantly different from treatment of other chronic diseases.

B. Reforming Medicaid Life-Time Limits

According to SAMHSA, eleven states' Medicaid programs set lifetime limits on buprenorphine treatment.⁵⁵² Medicaid programs rarely set lifetime limits on medications for other chronic diseases, suggesting institutional bias against individuals with drug dependence.⁵⁵³ In the case of buprenorphine, lifetime limits negatively affect patient safety.⁵⁵⁴ According to a study published in Health Affairs, "mortality rates were... more than twice as high among those receiving no treatment, compared to those receiving buprenorphine [through Medicaid]."⁵⁵⁵ Medical studies show that drug abuse relapse is most effectively prevented by long-term buprenorphine maintenance treatment, not short-term treatment.⁵⁵⁶ For example, a randomized study found that 90% of patients relapse if buprenorphine treatment stops after 12 weeks.⁵⁵⁷ Therefore, individuals who lose Medicaid coverage for buprenorphine treatment have a high risk of relapse.⁵⁵⁸

Not only is relapse harmful to the individual, it is bad for the state budget. When individuals relapse, they are more likely to need expensive emergency room treatment, in-patient rehabilitation, and/or hospital treatment due to opiate overdose. ⁵⁵⁹ According to the CDC, every day approximately 7,000 individuals seek emergency room treatment for substance abuse-related medical emergencies.⁵⁶⁰ Additionally, individuals who relapse are more likely to become

unemployed than those who do not relapse,⁵⁶¹ causing a loss in economic productivity. Finally, individuals who relapse are more likely to commit drug-related crimes,⁵⁶² draining state law enforcement resources.

The federal government should encourage Medicaid programs to cover buprenorphine indefinitely for Medicaid eligible individuals who have a formal medical diagnosis of opiate dependence. For example, the federal government could agree to bear part of the cost of Medicaid beneficiaries' generic buprenorphine prescriptions, while prohibiting the state from placing lifetime limits on buprenorphine maintenance treatment. Such limitations would actually benefit state budgets. According to the National Institute on Drug Abuse (NIDA), approximately 12% of Medicaid beneficiaries over the age of eighteen have a substance abuse disorder.⁵⁶³ When Medicaid beneficiaries with substance abuse problems receive MAT, including buprenorphine, Medicaid spends 33% less on their health care costs over the first three years, and costs continue to decline thereafter.⁵⁶⁴ Medicaid is a block-grant program between the federal government and state governments. Medicaid accounts for the single largest expenditure of states' revenues, so increasing access to MAT could significantly decrease total state Medicaid costs, pleasing both cultural liberals and fiscal conservatives.

V. <u>Reforming Methadone Treatment Regulations</u>

One often voiced criticism for stringent government regulation of methadone is that regulations fail to keep up with best medical practices, which can change more quickly than regulations. As a result, in 2001 SAMHSA changed its requirements for opening an OTP. To begin operating as an OTP, a facility must first obtain government certification. Then within one year of certification, the OTP must obtain accreditation from a government approved third-party
accreditation organization.⁵⁶⁵ Accreditation standards can change more quickly than government regulations, so the shift to accreditation may better allow OTPs to keep up with best-practice standards.

Unfortunately, the accreditation requirement does nothing to remedy the fact that OTPs are outside of "mainstream" medicine, both literally (in that few doctors or patients have experience with OTPs) and figuratively (in that the general public views OTPs more negatively than other medical facilities). One way to integrate methadone into mainstream medicine would be to allow physicians to prescribe methadone in regular offices (e.g. similarly to how buprenorphine is currently prescribed). Other nations already allow general practitioners to initiate and prescribe methadone treatment for addiction with good results and greater patient access.⁵⁶⁶ For example, after Canada made methadone treatment available form general practitioners, access increased by a factor of 5 in British Columbia and a factor of 30 in Ontario.⁵⁶⁷ Only a few feasibility of methadone treatment for addiction in office settings have been conducted in the U.S. (partly due to the difficulty of obtaining a federal exemption to conduct such studies).⁵⁶⁸ These studies demonstrate potential efficacy of allowing physicians to prescribe methadone for addiction treatment in regular offices.

A study by Merill et al. (2005) suggests that methadone treatment in general practice settings could be an effective option for expanding access to methadone, especially for patients without other severe mental health conditions who have already achieved stability in OTPs. The study recruited patients from methadone clinics who had negative urine results for at least one year, reliable methadone treatment attendance, no outstanding legal issues, or major psychiatric problems. The study found high satisfaction rates among physicians and patients, as well as high rates of abstinence from opioids among patients. Because patients received methadone treatment

in primary care settings, they also benefited from treatment of other health conditions provided in the same setting. For example, patients were also treated by primary care physicians for (or referred to specialists for treatment of) Hepatitis C, tobacco use, hypertension, and psychiatric disorders.⁵⁶⁹ Physicians' attitudes towards methadone for addiction treatment were measured at the beginning and end of the study; every physician viewed methadone treatment more favorably at the end of the study than at the beginning and supported expansion of methadone treatment to primary care settings.⁵⁷⁰ Interestingly, physicians in the study were general internists with an average of ten years of practice in medicine and no prior addiction medicine training. The study provided only 6 hours of training in methadone treatment, suggesting that even minimal education about methadone treatment may be sufficient for treating stable patients suffering from opioid addiction.

Physicians' main complaint during the study was dislike of segregating records relating to methadone treatment from other primary care records (as required by federal authorities who granted permission for the study). Physicians also stated that those patients who did not do well in office-based methadone treatment overwhelmingly suffered from co-existing severe mental health conditions, for which the physicians had little training. Note, there is no evidence to support that such patients would fare better in OTPs. Physicians overwhelmingly reported good rapport with physicians, in contrast to widely held views among physicians that addiction patients are "difficult." According to the study authors, "Comparing them to other patients in their public hospital practices, physicians generally viewed the methadone medical maintenance patients as equally or more compliant, equally or less in need of emotional support, and the same or lower on acuity of psychosocial stressors. Physicians were gratified to witness how patients benefited from the program, and all indicated willingness to care for additional methadone

medical maintenance patients."571

A study by Harris et al. (2006) of methadone patients with diverse socioeconomic backgrounds treated in office-based settings found illicit opioids in less than 1% of patients during the three year program and retention of over 98% of patients for the length of the program.⁵⁷² Eligible study participants were required to have been enrolled in OTPs prior to beginning the study with at least three years of stability (i.e. no urine screenings indicating opioid use, no recent criminal activity, and regular attendance at OTPs), making study results only generalizable to very stable patients. In another study, King et al. segregated 92 patients into three groups: OTP methadone treatment, office-based methadone treatment, and routine officebased treatment (i.e. physicians see patients but no MAT is prescribed). Eligible participants had at least 1 year of abstinence from opioids. The study found significantly higher rates of retention in the office-based methadone treatment group (91% retention at twelve months) compared to the other groups. The study also found significantly lower rates of positive urine drug screens in the office-based methadone treatment group (where only 1.3% tested positive) compared to the other groups.⁵⁷³ Other studies of office-based methadone treatment show similar positive results. But currently all such studies occur as a result of researchers or legislators seeking FDAexemptions; therefore, office-based methadone treatment is still rare.⁵⁷⁴

ASAM has issued a policy statement recommending that methadone be made available to stable patients in office-based practices, with the option of moving less stable patients or those needing more structure to OTPs.⁵⁷⁵ Specifically, the ASAM recommends that all patients in OTPs be given the option of "graduating" into office-based methadone treatment. ASAM also recommends that OTPs and office-based providers create collaborative relationships (currently rare), so that back and forth referrals become the norm.⁵⁷⁶

However, physicians need increased levels of medical school and residency education in in addiction medicine in order to become interested in office-based prescribing of methadone. Even though buprenorphine may be prescribed in office-based settings in the U.S., most physicians feel under-qualified or express low self-efficacy as a barrier to initiative buprenorphine treatment. Physicians who did not obtain some medical school or residency training in addiction medicine are unlikely to self-select into voluntary MAT training programs (such as the 8-hour course required for buprenorphine certification). The same problem would exist if methadone treatment for addiction were legal within office settings.⁵⁷⁷

VI. Summary

Statutes and regulations limit access to buprenorphine and methadone for addiction treatment and are more stringent than those applied to the most widely abused prescription opioids, such as oxycodone. Substance dependent individuals are a stigmatized group; individuals suffering for pain are less stigmatized and commonly include a large voting block senior citizens. Therefore, for example, it is unsurprising that methadone for addiction is relegated to OTPs, while methadone for pain management may be prescribed in general physicians' offices. Similarly, patient limits have been applied to buprenorphine but no other FDA-approved medication.

Patient limits, take-home limits, and methadone patient relegation to OTPs all reflect misinformation about MAT, especially overblown fears of divergence and abuse. Yet multiple studies and physicians whom I have interviewed suggest that difficulty of accessing MAT from physicians contributes to divergence; and MAT abuse is far more likely by non-dependent individuals than by dependent individuals.

Law affects culture, reinforcing biases held by the general public. For example, laws that

separate methadone patients from mainstream medical treatment reinforce the conception of addiction as different from other diseases.⁵⁷⁸ Culture affects law, because policy makers bring biases with them to the drafting table. Policy makers in the criminal justice system are likewise influenced by cultural misunderstandings surrounding MAT.

CHAPTER 3: THE UNDERUSE OF MAT IN THE CRIMINAL JUSTICE SYSTEM

I. Introduction

There is a well-known connection between drug use and criminal behavior. According to the National Institute on Drug Abuse, drug use is implicated in at least five common criminal offenses: drug possession or distribution, offenses related to obtaining drugs (such as stealing), offenses related to associating with other individuals involved in drug-related crimes (such as gang membership), abusive and violent behaviors related to drug-use (such as domestic violence while "high"), and offenses related to driving under the influence.⁵⁷⁹

Just as opioid addiction has become more prevalent among the general U.S. population, however, it has become more prevalent among the criminal justice population.⁵⁸⁰ A 2004 survey found that 53% of state and 45% of federal prisoners suffered from substance abuse disorder.⁵⁸¹ Approximately 24 to 36% of all heroin addicts enter the criminal justice system each year⁵⁸² and 20% of prison inmates have a history of injecting drugs.⁵⁸³ A 2009 study of arrestees in Cook County, Illinois found that 82% tested positive for one illegal addictive substance at time of arrest; the rate in North Carolina at time of arrest was 56%.⁵⁸⁴ During the last year, only 1-10% of the arrestees who reported drug use had received any outpatient treatment.⁵⁸⁵ Among pre-trial detainees suffering from opioid dependence, psychological and physical trauma from forced acute withdrawal may increase the risk of self-incrimination.⁵⁸⁶

Individuals convicted for drug-related crimes may be diverted along a number of different paths through the criminal justice system, including incarceration, probation, or drug court. The prevalence of addiction and treatment methods available vary among these various options. The chapter opens with a brief description of MAT underuse in prison. The chapter then focuses on underuse of MAT in drug courts and veterans courts, because these courts' explicit

purpose is to treat SUD and MHD. Unfortunately, the arm of the criminal justice system that should be most actively pursuing evidence-based treatment methods is failing to provide them. The chapter ends with suggestions for improving addiction treatment in drug and veterans courts.

II. Opioid Dependence Treatment in Prison

Relapse rates of substance dependent individuals upon release are very high, which indicates that substance abuse treatment in prison has been largely ineffective or under-provided. One-third of individuals incarcerated for drug-related crimes relapse within two months of release, 80% relapse within one year; and 95% relapse within three years.⁵⁸⁷

Failure to treat drug addiction in prison or to provide referral for treatment post-release can have deadly consequences. Prisoners face a high risk of overdose following release, especially within the first few weeks, because tolerance has declined but physical cravings and environmental triggers may still remain.⁵⁸⁸ A study found that the general overdose risk for recently-released Washington state prisoners was 12 times higher than the overdose risk for the general public; in particular, the overdose risk in the first week following release was 127-times higher than the overdose risk for the general public.⁵⁸⁹ Overall, 25% of post-release deaths occur due to accidental drug overdoses.⁵⁹⁰

According to multiple studies, MAT treatment in prison prevents relapse, reincarceration, and HIV/AIDS.⁵⁹¹ Gordon et al. (2008) and Kinlock et al. (2009) demonstrated that methadone initiated in prison or post-release when inmates have integrated back into the community was superior to counseling alone with respect to heroin use and treatment retention; moreover, health outcomes were better for inmates whose methadone use was initiated in prison than those whose use began post-release.⁵⁹² Some MAT therapies may also be more effective than others; a study of New York City heroin-dependent inmates found that inmates treated with buprenorphine were more likely to enter community treatment post-release than inmates treated with methadone.⁵⁹³ However, inmates treated with buprenorphine were also more likely to divert their medication than those treated with methadone.⁵⁹⁴ Thus, it should come as no surprise that the WHO (which views addiction as an international public health issue) recommends that all nations make methadone and buprenorphine widely available within prisons. Recently, the National Commission on Correctional Health Care also recommended that methadone and buprenorphine treatment increase in prisons.⁵⁹⁵

Yet, MAT is underused within U.S. prisons.⁵⁹⁶ In a 2009 study, Nunn et al. surveyed 50 departments of corrections (one in each state and the District of Columbia except North Dakota) regarding their use of methadone and buprenorphine to treat opioid addiction. The authors found that only 14% of prisons offered buprenorphine; 55% of prisons offered methadone under some conditions, but primarily for special circumstances like pregnancy or pain relief. The authors estimated that only 2,000 prisoners in the entire U.S. receive ongoing methadone or buprenorphine treatment while incarcerated. Prisons in Southern states were significantly less likely to offer the medications. Buprenorphine therapy was only common in the Northeast, where one-third of prisons offered it. In general, 45% of systems referred inmates for methadone treatment after release, and 29% referred them for buprenorphine. As compared to previous years, more departments of corrections were permitting inmates to take methadone and buprenorphine and providing referrals post-release.

A lack of knowledge about MAT's effectiveness, however, remains widespread within departments of corrections. The 2009 Nunn et al. study found that 49% of respondents were unsure whether buprenorphine was an effective treatment, and 27% were unsure whether methadone was an effective treatment. Among those departments of corrections that do not

provide inmates with access to buprenorphine or methadone, 57% said it was due to a preference for detoxification followed by abstinence-only treatment, and 20% cited security concerns about having opioids available within prisons.

III. Opioid Dependence Treatment in Drug Courts

A. What are Drug Courts?

Due to high relapse rates and overcrowded prisons in the late 1980s and early 1990s, legislatures around the country established drug courts as an alternative to incarceration for individuals convicted of drug-related crimes. Drug courts serve both punitive and rehabilitative purposes. In June 2010, there were 1,372 adult drug courts in the U.S, along with 365 hybrid courts for DUI and drug offenses.⁵⁹⁷ Fifty-five percent of U.S. drug courts are in rural regions, 18% are in suburban regions, and 27% are in urban regions.⁵⁹⁸ According to the U.S. Department of Criminal Justice's Drug Court's Program Office, "[d]rug courts leverage the coercive power of the criminal justice system to achieve abstinence and alter criminal behavior through the combination of judicial supervision, treatment, drug testing, incentives, sanctions, and case management."⁵⁹⁹

Two primary drug court models exist: pre-plea and post-plea. In pre-plea drug court, the arrestee enters drug court before pleading guilty to the charge. In post-plea drug court, the arrestee must first plead guilty to the charge before entering drug court; the sentence is then deferred while the defendant participates in the drug court program. In post-plea drug court, if the defendant graduates from drug court, then his or her criminal record is expunged or the sentence is waived. If the defendant fails to graduate from drug court, however, then the defendant is incarcerated. Fifty-eight percent of adult drug courts are post-plea drug courts.⁶⁰⁰

Drug courts vary tremendously from jurisdiction to jurisdiction in terms of eligibility criteria, program requirements, and treatment methods. In many jurisdictions, to be eligible for drug court the participant must have been charged with drug possession, have no record of dealing drugs or violent crime, and no history of violent behavior. As a result, repeat offenders and those charged with the most serious offenses cannot opt to participate in drug court as an alternative to incarceration. Typically, a drug court judge decides whether or not to accept a potential participant into the drug court program based on an array of factors, including the number of spaces available, an entry interview with the judge, the criminal record, an assessment of a potential participant's motivation, and need for treatment.⁶⁰¹ If approved for drug court participates in a program that typically lasts at least one year.⁶⁰²

Drug court programs usually consist of regular drug testing, court appearances, treatment (most often in the form of mandatory counseling and support groups), and short-term punishment for failure to meet program requirements. In my study of Indiana drug courts from 2015 to 2016, 19 of 20 courts required counseling and the same number required support group attendance. Although participants are not required to attend 12-step groups due to First Amendment concerns, most participants choose to participate in 12-step groups rather than other support groups. I found that two reasons account for this fact: other support groups' have limited availability and drug court participants' generally accept 12-step groups. In my study, no court required participants to undergo any form of MAT.

In drug courts, the defense attorneys, prosecuting attorneys, and judges work together to determine the best course of treatment for the defendant.⁶⁰³ Judges use a "hands on approach," forging personal relationships with clients that may lead them judge to be more empathetic

towards some than others.⁶⁰⁴ Drug court staff consists of treatment staff (e.g. therapists and case managers) and court officials (e.g. attorneys and the judge). However, drug court judges hold a unique and significant power in the drug court, and may override physician-recommended treatment plans whether or not the judge has medical experience.⁶⁰⁵

If defendants do not comply with any part of the drug court program, then graduated sanctions are used, including more frequent probation officer meetings, status hearings, and/or drug testing. Participants who commit severe violations have their participation terminated and their original sentences re-imposed.⁶⁰⁶ Participants who successful complete the drug court program can participate in a graduation ceremony.⁶⁰⁷

B. The Prevalence of Opioid Dependence in Drug Courts

A 2008 study found that 19 percent of drug court participants primarily abused opiates, a sharp increase from six percent in 2005.⁶⁰⁸ Between 2015 and 2016, I interviewed 17 judges serving in 20 Indiana drug and veterans courts to understand how their institutions treat opioid dependence. 59% of judges stated that opioid addiction was either very prevalent or the most prevalent type of drug addiction in their courts; only five judges stated that opioid addiction was not common. However, two of those five judges believe that opioid addiction is prevalent in their geographic areas, but noted that few individuals suffering from opioid addiction are admitted into their courts.

In my study, 53% of judges stated that heroin has become more common than prescription pain pills among program participants, primarily because heroin costs less and is more widely available. Judge 7 stated that a DEA raid on a local pain clinic has led to an explosion of heroin use in the community:

We have had some difficulties with the over prescription of opioids in our community; they can't get the opioids anymore because the specific doctor's clinic has been closed down by the feds, so those folks turn to the street, and they turn to street Opana or Fentanyl and then they end up on heroin, and it's the worst heroin of all that they're ending up on.

However, one judge perceived that heroin use was more prevalent than prescription pain pill abuse among program participants; this judge also believed that law enforcement targets heroin abusers more than prescription pain pill abusers. My Indiana-based study differs from results in a national study by Matusow et al., which found that prescription pain pills are used by individuals with opioid dependence in drug courts 66% of the time, whereas heroin was used 22% of the time.⁶⁰⁹ The higher rate of heroin use in Indiana drug courts may reflect the relatively recent shift from prescription pain pills to heroin as heroin has become more accessible.

C. The Effectiveness of Drug Courts

Studies of drug courts' effectiveness at preventing recidivism and drug use have been generally positive, but some criticisms exist.⁶¹⁰ Marlowe reviewed five meta-analyses of drug courts and concluded "drug courts significantly reduce crime by an average of approximately 8% to 26%, with most estimates falling around 14%."⁶¹¹ Similarly, the Sentencing Project found that drug courts reduce recidivism by 8% on the low end to 13% on the high end.⁶¹² In 2005, the Government Accountability Office (GAO) conducted a meta-analysis of methodologically sound drug court studies, pursuant to a Congressional mandate.⁶¹³ The GAO reported that most studies of drug court effectiveness carried out prior to 2002 lacked methodological rigor⁶¹⁴ due to selection bias, lack of randomized samples, lack of a control group, and failure to account for socioeconomic factors.⁶¹⁵ The GAO study concluded that the evidence of drug court success at reducing recidivism was "limited and mixed."⁶¹⁶

GAO authors found a wide variation in drug court graduation rates, ranging from 27% to 66%, with graduates demonstrating lower recidivism rates than dropouts.⁶¹⁷ The factor most

correlated with program completion was compliance with drug court procedures. Interestingly, the severity of sanctions for failure to comply with drug court procedures did not predict completion rates.⁶¹⁸ However, participants with "relatively fewer prior involvements in the criminal system and who were older were more likely to graduate than were other participants."⁶¹⁹ The GAO authors said that "those participants who were better able to recognize their problems, recognize external problems, and were ready for treatment, were more likely to complete the drug court program."⁶²⁰This is consistent with other literature that suggests participants should be matched to treatments based on their level of risk, responsibility, ability and learning style.⁶²¹ Dropouts had a recidivism rate comparable to persons who were not in drug court.⁶²²

Drug courts are highly selective in determining which offenders are permitted to enter the program, and frequently indirectly exclude the most severely-dependent individuals who often have multiple prior convictions. As a result, studies of drug courts' effectiveness are likely skewed to reflect the success of less-dependent individuals.⁶²³ In general, different techniques work for the two populations; while drug testing and drug treatment appear to be most effective at reducing drug use among severely dependent drug court participants, judicial hearings are most effective at reducing drug use among less dependent participants.⁶²⁴

D. Frequency of MAT and Attitudes towards MAT in Problem Solving Courts

Few studies have examined use of MAT and attitudes towards MAT in problem solving courts. However, existing studies have found widespread policies limiting MAT access, such as policies forbidding participants from starting MAT while in the court program, requiring patients to quit MAT in order to graduate, and barring patients utilizing MAT from entering the court program. On the other hand, mental health counseling and twelve-step groups are almost always

required for participants, with sanctions in place for participants who fail to participate in those treatment methodologies.

1. <u>Matusow et al., A National Study of MAT in Drug Courts (2013)</u>

The most comprehensive study to date was conducted by Matusow et al. in 2013 using online surveys. ⁶²⁵ Respondents included administrators working within 93 drug courts in 47 states, plus Washington D.C. and Puerto Rico. ⁶²⁶ Matusow found that half of drug courts did not provide agonist medications (methadone or buprenorphine) to participants suffering from opioid dependence under any circumstances, ⁶²⁷ and that only 34% of drug courts allowed such participants to use agonist medications. ⁶²⁸ Drug courts provided buprenorphine treatment (40%) more often than methadone (26%) or naltrexone treatment (18%). ⁶²⁹ Only 40% of drug courts allow participants already using agonist therapy prior to entering drug court to continue this usage as a maintenance treatment; all other courts required clients to quit agonist therapy before entering these programs. ⁶³⁰ Moreover, although MAT is the medical standard of care for treating pregnant women with opiate dependence, only 26% of drug courts provide these women with MAT. ⁶³¹

Matusow et al. found that even among those drug courts open to MAT, practical barriers sometimes prevented courts from referring patients to MAT. Urban courts that allowed MAT but failed to refer patients to buprenorphine treatment cited cost as the primary barrier 43% of the time. Rural courts that allowed MAT but failed to refer patients to buprenorphine treatment cited lack of local buprenorphine-prescribing physicians as the primary barrier 74% of the time. Surprisingly, 21% of respondents did not know why their drug court prohibited methadone.⁶³² Similarly, when asked their opinions about MAT's efficacy, the most common answer for was

"uncertain" (58% of respondents), signaling drug court professionals' lack of education about MAT.⁶³³

Shockingly, more than 10 percent of respondents said that methadone or buprenorphine "rewards criminals for being drug users."⁶³⁴ Predictably, negative attitudes towards MAT and misinformation about its effectiveness were most pronounced in those drug courts that banned MAT.⁶³⁵ Interestingly, no significant associations were found between a) professionals' knowledge of and attitude towards MAT and b) the professional's discipline, role in the drug court, education, or years of experience. Rather, "[t]he most significant differences in knowledge and attitudes about MAT were between courts that permit MAT and those that do not."⁶³⁶ Furthermore, professionals' attitudes towards MAT did not depend on the type of medication that the drug court used, but rather were related to respondents' attitudes towards MAT in general.⁶³⁷ In that vein, the survey asked professionals in drug courts that prohibited MAT whether they might introduce agonist medication "if evidence were available that methadone or buprenorphine improved outcomes for drug court participants." Almost half of the respondents answered "yes" (49%).

2. <u>Andraka-Christou, A Study of Indiana Drug and Veterans Courts (2016)</u>

According to my study of 20 Indiana drug and veterans courts, serious discrepancies exist between drug courts' adoption of MAT and the medical standard of care. Policies towards MAT vary widely between courts in my sample. Some courts did not explicitly permit any form of MAT; some courts explicitly permitted one or two medications but not three; and a few courts permitted all three medications. While all judges were very familiar with mental health counseling and self-help groups as treatment methods (including their methodologies and

purposes), one judge expressed lack of familiarity with buprenorphine and four expressed lack of familiarity with Vivitrol.

Every court in the study allowed participants to enter the program while undergoing MAT. However, courts differed significantly in whether they allowed participants to continue MAT upon entry. Such policies were usually medication-specific; for example, a court might forbid participants from continuing methadone while in court but might permit them to continue Vivitrol.

On a related note, courts also differed significantly in terms of whether they permitted participants to begin MAT after entry. Again, relevant policies were often medication-specific. Almost all courts (17 of 20) explicitly permitted participants to begin Vivitrol while in the program, but one court did not permit participants to graduate from the program while on that medication. Two judges who had never heard of Vivitrol prior to the interview assumed that participants would be able to begin it while in the program because Vivitrol lacks an opiate ingredient. Almost all courts (16 of 20) explicitly permitted participants to use buprenorphine while in the program; but seven courts only permitted participants to use buprenorphine for a short period of time ranging from two weeks to 30 days). Half of the courts (10) permitted participants to begin methadone while in the program. Interestingly, every court that allowed participants to begin methadone also permitted them to begin buprenorphine and Vivitrol, suggesting that courts open to methadone are more open to MAT in general. On the other hand, some courts that permitted participants to use Vivitrol or buprenorphine did not permit them to use methadone, reflecting the fact that judges are generally most ambivalent about methadone.

Table 1: Can participants enter court whi	le using MAT?	P If participants	enter court	while using	MAT, can
they continue it?					

			Can use				
		Enter while	methadone		Can use	Enter	Can use Viv.
Court	Type of	on	in court	Enter while on	bupr. in court	while on	in court
#	Court	methadone?	program?	buprenorphine?	program?	Vivitrol?	program?
1	Drug	Yes	Yes	Yes	Yes	Yes	Yes
2	Veterans	Yes	Yes	Yes	Yes	Yes	Yes
3	Drug	Yes	No	Yes	Probably	Yes	Probably
4	Veterans	Yes	Yes	Yes	Yes	Yes	Yes
5	Drug	Yes	No	Yes	Yes	Yes	Yes
N/A	Prison-based	N/A	N/A	N/A	N/A	N/A	N/A
6	Drug	Yes	No	Yes	Yes	Yes	Yes
7	Drug	Yes	No	Yes	Yes	Yes	Yes
8	Drug	Yes	Yes	Yes	Yes	Yes	Yes
9	Drug	Yes	Yes	Yes	Yes	Yes	Yes
10	Veterans	Yes	Yes	Yes	Yes	Yes	Yes
11	Veterans	Yes	No	Yes	Yes	Yes	Yes
12	Drug	Yes	No	Yes	No	Probably	Probably
13	Drug	No	No	Yes	Yes	Yes	Yes
14	Veterans	Yes	Yes	Yes	Yes	Yes	Yes
15	Drug	Yes	Yes	Yes	Yes	Yes	Yes
16	Drug	No	Yes	No	Yes	No	Yes
17	Veterans	Unsure	Unsure	Unsure	Unsure	Unsure	Unsure
18	Drug	Yes	Yes	Yes	Yes	Yes	Yes
19	Drug	No	No	Yes	Yes	Yes	Probably
20	Drug	Yes	No	Yes	No	Yes	Yes
Overall	% Yes	84.2%	52.6%	94.7%	88.9%	94.4%	100%

Court	Type of	Can start Methadone in	Can start bup. In	Can start Vivitrol in	
#	Court	court?	court?	court?	
1	Drug	Yes	Yes	Yes	
2	Veterans	Yes	Yes	Yes	
3	Drug	No	Probably	Probably	
4	Veterans	Yes	Yes	Yes	
5	Drug	No	Yes	Yes	
N/A	Prison-based	No	No	No	
6	Drug	No	Yes	Yes	
7	Drug	No	Yes	Yes	
8	Drug	Yes	Yes	Yes	
9	Drug	Yes	Yes	Yes	
10	Veterans	Yes	Yes	Yes	
11	Veterans	No	Yes	Yes	
12	Drug	No	No	Probably	
13	Drug	No	Yes	Yes	
14	Veterans	Yes	Yes	Yes	
15	Drug	Yes	Yes	Yes	
16	Drug	Yes	Yes	Yes	
17	Veterans	Unsure	Unsure	Unsure	
18	Drug	Yes	Yes	Yes	
19	Drug	No	Yes	Yes	
20	Drug	No	No	Yes	
Overall	% Yes	50%	84.2%	94.4%	

Table 2: Can participants begin MAT after starting the court program?

Even though all judges expressed positive views of counseling and support groups, their

overall opinions about MAT (as opposed to a specific medication) ranged from distrust to

ambivalence to excitement. While many judges primarily discussed MAT in negative terms,

focusing on the risks of abuse or diversion, other judges discussed MAT's usefulness. Judges

most commonly displayed ambivalence towards MAT in general, especially in courts where they

had approved use of one MAT medication while banning other medications. Examples of

ambivalence towards MAT include the following:

I would just say we're guarded when it comes to medication-assisted treatment. (Judge 8)

The other drug-assisted therapies [buprenorphine and Vivitrol] ... I wouldn't say that we would be totally against it, but it would be something that would be limited use, because . . . my feeling is, you're trading one addiction for the other, and yeah it's legal and so forth, but our push is more away from [MAT] rather than towards it. (Judge 6)

We don't emphasize [MAT], but ... there's some individuals for whom medication-assisted treatment is appropriate. Now I'm willing, personally, as a judge, to have pretty, pretty much an open mind about, if I can find a provider who will give me good, evidence-based reasons for using a particular drug-assisted or medicine-assisted kind of intervention, I'm willing to consider it. That's fine. (Judge 2)

a. Attitudes Towards Methadone

Judicial attitudes towards methadone were either neutral (in courts that permitted participants to begin methadone after entry) or overwhelmingly negative (in those courts that banned methadone.) Of the three medications, methadone inspired the most negativity from judges. For example, one judge who allowed buprenorphine and Vivitrol (but only for shortterm use) stated, "The methadone I find to just be a hideous, awful thing." (Judge 7) While judges generally did not explain their negativity towards methadone, their attitudes likely reflect American society's negativity towards methadone. In light of these negative judicial attitudes towards methadone, it is unsurprising that only half of courts permitted participants to begin methadone while in the program. Three of twenty courts prohibited participants from entering the program while undergoing methadone treatment. Sixteen courts permit participants using methadone to enter the program, but six of those courts required participants to stop the methadone treatment once in the program.

Judges' most common criticisms of methadone treatment were related to its addictive nature, distrust of methadone clinics, claims of methadone's ineffectiveness at promoting abstinence, the possibility of overdose, the likelihood of diversion, and cost (methadone is not covered by Indiana's Medicaid program). One judge was aware of research indicating that methadone was effective in reducing recidivism and illicit drug use, but believed that research was outdated on methadone's efficacy as compared to abstinence-only treatment in drug court. He believed that researchers are not comparing apples to apples but rather apples to oranges, especially in light of emphasis on evidence-based counseling. Because of ambivalence towards methadone, that judge neither banned nor encourage its use, choosing to approach methadone use on a case by case basis. Even though the judge's desire to learn more about MAT is impressive, the fact that the judge is relying on self-education rather than deferring to a physician is disconcerting.

Multiple judges expressed concern with management of methadone clinics. Even one judge who stated that "methadone is shown to be very effective" by research believed it to be only "marginally effective" when provided through poorly managed methadone clinics. This judge described poorly managed methadone clinics as those that met only minimum federal requirements, gave increasing methadone dosages, did not supervise patients, and did not provide counseling. Three judges analogized poorly managed methadone clinics to drug dealers.

For example: "It seems like drug dealing to me too, in terms of what behaviors that we see and the treatment failures and the people turning to criminal activity when they don't have the money to pay for the methadone. (Judge 1)."

Two judges did not believe methadone to be an effective addiction treatment. One claimed to have seen urine test results where a participant using methadone still has other opiates in his or her system, such as oxycodone. But the presence of other drugs has other explanations; participants who fail to remain abstinent while undergoing methadone treatment may be receiving too low a dosage, causing them to experience cravings after the methadone wears off and to other seek readily available opioids that would then show up in participants' urinalysis results.

Those judges who strongly distrusted methadone may be discouraged from learning about buprenorphine or Vivitrol. Methadone appeared to be a kind of baseline pharmaceutical to which judges compared buprenorphine and Vivitrol. One judge explained how members of the local criminal justice system had a difficult time accepting buprenorphine treatment because they had seen overdoses involving methadone.

b. Attitudes towards Buprenorphine

Attitudes and policies towards buprenorphine were somewhat less negative than attitudes towards methadone. Sixteen of twenty courts permitted participants to begin buprenorphine in the program, but seven courts required participants to wean off of buprenorphine to graduate from the program. Two judges stated that they accepted new participants undergoing buprenorphine treatment through a physician into the drug court but then required or strongly encouraged participants to wean off of buprenorphine after entry. Judges supposedly deferred to physicians' decisions about buprenorphine treatment but in fact held pre-existing opinions about

the treatment and for how long the treatment should be allowed. Distrust of physicians' roles in the treatment process was palpable. Rather than perceiving physicians recommendation to maintain patients on MAT long-term as being based on medical research (which clearly concludes that long term is better than short term treatment), judges perceived physicians recommendations as being motivated by financial gain.

So, it's interesting; our team battles whether or not we feel that medically assisted treatment is appropriate. I can tell you *I* think it is, provided you have the right professional administering it and working to wean them off of it. One of the problems that we saw was that we didn't feel like the people administering them were trying to wean . . . or cut back and slowly get 'em off of this medically assisted treatment, and wanted to keep 'em on it for, I hate to say it, but basically their financial gain.

Yeah, it's not a deal where they take it [they can take suboxone] for 90 days, I mean I don't pretend to be a doctor, but our theory is you can't substitute one drug for another...Well, it's up to the doctor, but . . . we want them off as soon as they can get off...I wouldn't see more than the thirty days at most, typically it's two to three weeks.

Even two judges who claimed to look at participants' situations on a case-by-case basis expressed a preference for weaning participants off of buprenorphine. One judge only allowed buprenorphine for detoxification purposes, contrary to best medical practices. That judge's court did not allow buprenorphine use for more than two weeks. Courts' short-term requirements for buprenorphine are an unfortunate example of judges and treatment teams (usually without physicians) making medical decisions contrary to best medical practices. Medical studies demonstrate that short-term buprenorphine use is less effective at preventing relapse and mortality than long-term use.⁶³⁸ In fact, the ASAM strongly discourages policy makers from setting treatment term limits for buprenorphine, such as Medicaid coverage limits.⁶³⁹

Access to buprenorphine varied considerably depending on court location. One judge in a rural area knew of only one buprenorphine provider in the whole county, while a second judge knew of multiple buprenorphine providers in city. A third judge stated that the one

buprenorphine provider in that city had reached maximum patient levels (as delineated under the

Drug Addiction and Treatment Act). A fourth judge said, "It's readily accessible to addicts and

it's readily accessible from addicts."

Even though 16 courts permitted buprenorphine use for at least a short time period, only one judge spoke overwhelmingly positively of the medication: "The [local] VA Medical Center has just been hitting the ball outta the ball park. We've had soldiers that are on Suboxone in particular that're just doing incredibly well" (Judge 9). In contrast, eight judges spoke overwhelmingly negatively of buprenorphine. Judges most frequently criticized buprenorphine for its abuse potential. Some judges distrusted buprenorphine-prescribing clinics because they were allegedly poorly managed or improperly supervised participants:

You know, Suboxone doctors who, you know, they're doctors, but, you know, all you have to do is show up at their office and pay them some money and you could walk away with however much supply of Suboxone they'll give you. (Judge 18)

What we've found in the past in our community, the people on, on Methadone, and now Suboxone, is that at the health clinics, or the pain clinics, or the clinics that're administering this, we don't get the monitoring that, that we feel is needed, and my case workers feel that there's more abuse, or a, a high, than there is use for treatment. (Judge 12)

It's one of those minute clinics, one of those doc in a box type clinics. I don't know about you, but as a judge, I'm sitting there from the outside thinking, "okay. This is a med check clinic. It's not an addictions treatment program, but nine doctors in that facility are prescribing, have the ability to prescribe Suboxone. (Judge 8)

[The local buprenorphine provider] is sitting in jail ... for drug dealing, for the way he was operating his clinic. (Judge 4)

Multiple judges believed participants sometimes purchased buprenorphine illicitly.

Studies suggest, however, that some drug users who purchase buprenorphine illicitly often do so

in an attempt to self-treat when they lack access to a legitimate medical provider, often for

reasons such as care expenses or because there is no local buprenorphine provider.⁶⁴⁰ Interestingly, one judge described a participant who purchased buprenorphine illicitly in an attempt to quit using heroin. According to the judge, the participant no longer used heroin as a result:

He had actually got [suboxone] illegitimately from somebody and, and he understands if, if he continues to use heroin, he's probably not gonna live too much longer, so he had made this conscious decision that okay, well, I'm gonna get Suboxone. I can't afford it [through a physician] so I can get it from other people. (Judge 16)

Those judges whose primary opposition to buprenorphine was its potential for abuse and diversion (as opposed to philosophical disagreement with MAT) were optimistic about Probuphine, a six-month surgical implant of buprenorphine that received FDA approval in May 2016.

c. Attitudes towards Vivitrol

Vivitrol was the form of MAT that drug court judges viewed most positively. In my research, I found that 16 of 20 courts explicitly permitted Vivitrol; two judges believed their courts would probably permit Vivitrol but had not yet had to decide what to do about that issue, and one judge was "unsure" of the court's policies towards Vivitrol. Judicial attitudes towards Vivitrol were fairly consistent: either judges knew about the medication and thought it was good, or else they knew little about it but were very interested in learning more. The three benefits of Vivitrol judges most often cited were its inability to be abused or diverted and its effectiveness at preventing relapse. As one judge enthusiastically remarked: "I am all in on Naltrexone!" (Judge 1) When asked whether the judge had seen benefits from Vivitrol among drug court participants, another judge asserted: "Oh, absolutely!" (Judge 18) That judge liked to ask participants "how

it's going on the Vivitrol" during court hearings in front of other participants in the hopes that others will become interested in the medication.

Some judges voiced criticisms of buprenorphine, however. Cost was the most common criticism; two courts were currently getting free Vivitrol samples or discounts through a state-funded study and the manufacturer. Some judges reported that few physicians in their areas prescribed Vivitrol; according to one judge, only a single doctor in the entire county prescribed the medication. Another judge said, "I'm *very* interested in Vivitrol, but we haven't found anyone yet who has been prescrib[ing] it." One judge is actively trying to educate other judges and even *physicians* about Vivitrol.

Furthermore, four judges reported limited or no knowledge of Vivitrol. After I briefly described Vivitrol, three of the four judges appeared interested in learning more about the medication. The interest was always in relation to its lack of an opioid ingredient. For example, the following exchange occurred with one judge:

Interviewer: Does that fact that [Vivitrol] lacks an opiate ingredient and is not a controlled substance make it, in your opinion, something that your drug court would be more willing to refer patients for, than say Suboxone or Methadone, which have an opiate ingredient?

Judge 13: Just on what you told me, yes, without a doubt. I don't know what the downside is; I'm assuming . . . there may be some downside, but no; we would be very, very interested in using something like that.

Those judges who were informed Vivitrol mentioned a handful of informative sources,

including trainings, particularly at the annual National Association of Drug Court Professionals

conference; direct communication from the pharmaceutical manufacturer; other criminal justice

system administrators; the VA; and medical literature. But two sources of information about

Vivitrol were conspicuously missing from this list: physicians and counselors.

Strangely, four courts that allow participants to start Vivitrol in court also require participants to wean off prior to graduation, contrary to best medical practices. One judge said he refused to permit Vivitrol until he found a Vivitrol provider who promised to actively wean participants off of the medication:

We have a private doctor that we're working with that administers the Vivitrol, monitors our participant, gives us feedback, and works to, to, to wean them off of the, the medically assisted treatment...It's interesting, our team battles whether or not we feel that medically assisted treatment is appropriate. I can tell you *I* think it is, provided you have the, the right professional administerin' it and workin' to wean them off of it. One of the problems that we saw was that we didn't feel like the, the people administering them were trying to wean the, or cut back and slowly get 'em off of this medically assisted treatment, and wanted to keep 'em on it for, I hate to say it, but basically their financial gain. (Judge 12)

Two judges stated that while they do not have bright line rule prohibiting graduation on Vivitrol, they encourage participants to get off Vivitrol prior to graduation. One judge believes participants should be off Vivitrol within 18 months, while the other believes participants should be off Vivitrol within 24 months.

d. Misunderstanding Sobriety

The Matusow et al. study and my own dissertation research reveal that the problemsolving courts' definition of sobriety often differed from the medical definition. Some judges explained that sobriety meant both living life without drug abuse and without the assistance of MAT. For those judges, a participant who tested negative for opiates was not considered "sober" if treated with MAT. In other words, *how* one achieved a series of negative urine tests was most important, not *whether* the urine tests were negative for opioids in the first place. In contrast, other judges believe that participants who did not abuse drugs were "sober," regardless of whether they were treated with MAT. In my study, five judges expressed some version of the view that abstinence while on

MAT was not "complete" sobriety because MAT merely replaced one drug with another.

Fascinatingly, even though studies overwhelmingly show that MAT leads to treatment success

(i.e. lower relapse rates, overdoses, HIV-rates), one judge described MAT as a sign of "defeat" in

treatment, as if success through MAT is worth less than success through abstinence-only

treatment:

Certainly all of these options [methadone, buprenorphine, and Vivitrol] are better than buying the crack cocaine, methamphetamines, and heroin off the streets, but as pharmacological responses being, addiction we need to see the bigger picture of public policy to ultimately get our clients to live drug free, or we're simply trying to maintain the population with something other than heroin. *I don't want to be a defeatist and say that we can't get our clients completely drug free*. I think we should instruct our clients and have a goal towards a life, the life that I have, that's what they're entitled to, so I think moderately drugging is not the right answer, except in those, like I said, exceptions where a physician or a psychiatrist says this person is bipolar. (Judge 11, italics added)

Some judges equated buprenorphine and methadone to other illegal drugs:

What we focus more on, in our treatment is keeping them sober. You know what I mean? And, and, and keeping them and, and we focus, sobriety-focused, as opposed to giving them a drug to replace a drug. It's to try to, try to, try to get them to where they don't, that they, they won't need to use it, like dealing with underlying issues and things of that nature... Our goal is to rehabilitate people so that they would be clean and sober. And so we would want them, by the time they graduate, to be off Jack Daniels, off the heroin, off the Soboxone, off the Methadone, and leading a completely clean, sober life. (Judge who oversees prison treatment program)

We don't want 'em jackin' off for three years, you know it's a drug program, doesn't mean you're supposed to be on drugs, supposed to be off drugs. (Judge 17)

You know, there are drug courts who are, who are happy to have their people on Methadone, there are drug courts who are happy to have their people on Suboxone. We just think that's another form of addiction. (Judge 18)

I mean I don't pretend to be a doctor, but our theory is, you know, you can't substitute one drug for another. (Judge 19).

Relatedly, many judges assume that MAT "simply substitute[s] one addiction for another."⁶⁴¹ As Matusow et al.'s study demonstrates, some individuals even believe that MAT is a "reward" for bad behavior. This belief completely ignores the fact that MAT allows individuals with drug dependence to function normally and prevents them from "getting high." The AMA and other professional scientific and medical organizations have vigorously opposed the idea that MAT is "just another drug." Ignoring the medical community's expertise, many drug courts force patients to cease MAT as a precondition of participation.⁶⁴² Such policies may harm dependent individuals; studies show that when individuals are forced to stop agonist treatment before they are ready, relapse is extremely likely.

Some judges also incorrectly assume that individuals cannot lead normal, functional lives while undergoing MAT. For example, one judge stated that individuals on MAT are "zombies." Another judge stated that individuals cannot safely drive while being treated with methadone. However, individuals can drive while undergoing any form of MAT. Even methadone, a full agonist, does not impair intellectual functioning, reaction-time, or perceptual-motor skills.⁶⁴³ Misconceptions about how participants feel and act while undergoing MAT contribute to the notion that recipients cannot truly be "sober."

e. Treating MAT differently from other Mental Health Medications

While some courts discourages MAT for addiction treatment, they encourage medication for treating other mental health conditions, such as bipolar disorder.⁶⁴⁴ This discrepancy between court-approved treatment for addiction and other psychiatric conditions (e.g. bipolar disorder) can be interpreted in a few ways. First, it suggests that some judges do not view addiction as a medical condition with a strong biological component, but regards addiction as fundamentally a psychosocial condition where the biological component is non-existent or minimal. In contrast,

the same judge believes bipolar disorder is a biopsychosocial condition.⁶⁴⁵ This perspective downplays addiction's biological component but not the biological components of other mental health conditions. Because MAT addresses addiction's physical symptoms (e.g. cravings), those who lack an accurate understanding of addiction's biological component may regard the medication as superfluous. The fact that judges hold such beliefs suggests a need for increased education about addiction's biological dimensions, in particular the physiological effects of opiates on receptors in the brain and the dopamine system.

Second, the disparate treatment of addiction and mental illnesses such as bipolar disorder may signify that some judges are more familiar with using medications to treat mental illness and less familiar with pharmaceutical treatments for addiction. Judges may be unaware that medications for treating addiction are effective, even though they know that pharmaceutical interventions for mental illness are effective. Again, this belief suggests the need for increased education about the nature of addiction and research on MAT's efficacy.

Third, the disparate treatment of addiction and bipolar disorder may be based on fear of participant abuse and diversion of addiction medication, which does not exist for pharmaceutical mental illness interventions. Even if judges feel that MAT may be useful for treating addiction, just like medication is useful for treating bipolar disorder, they may believe the risk of abuse or diversion is simply too great. In this case, a drug court should not restrict MAT but instead should carefully monitor participants on MAT and develop working relationships with treating physicians. Even so, however, some courts may feel unable to properly monitor participants using MAT due to funding constraints and limited staffing.

Due to the discrepancy in attitudes towards MAT and other mental health medications, the court may be less likely to refer participants suffering from addiction without other co-

occurring mental illness to a psychiatrist than participants battling both addiction and mental illness. One judge explicitly stated that participants without co-occurring mental disorders are never referred to psychiatrists, and that only those with co-occurring mental disorders would be referred.

f. MAT is more accessible in Veterans Courts

Throughout the interviews it became evident that the Veterans Administration (VA) views MAT favorably and recommends it in cases of opiate addiction. The pro-MAT attitude of the VA seems to infiltrate veterans' courts. When I asked one judge who oversees both a drug court and a veterans' court whether the VA is open to MAT, he responded:

Very, the VA is extremely open. We invited the person that oversees the program [locally], I can't think of her name, but she came and spoke to all of our community corrections and probation officers, kind of explaining how it works, so they're, they're proponents for it. They don't force it, obviously, but they'll educate the participant as to, here are the pros and cons, you know, but I would say they're very pro. (Judge 9)

Perhaps equally importantly, the VA covers the cost of MAT for qualified veterans, and the VA provides relatively easy access to physicians who prescribe MAT within VA facilities. Most, but not all, veterans' court participants are VA-eligible and thus have access to MAT through the

VA.

Veterans court's different because we have the services of [the local] VA Medical Center. I always call it drug court in heaven because, if you're a veteran eligible, you know, benefit eligible, they can provide *everything* – the, the medications, psychologists, psychiatrists, housing, transportation, food. I mean, the VA right now is well funded. (Judge 9)

According to one judge who oversees both a veterans' court and a regular drug court, a veterans'

court participant will access MAT much faster than a drug court participant. Another judge who

also oversees a veterans court and a drug court stated the participants in the drug court only

obtained access to Vivitrol six months ago due to a state research grant, but participants in the

veterans' Court have had access to Vivitrol for years. One judge who oversees both a drug court and a veterans' court has two different policies with respect to methadone in the clinics, because the judge trusts methadone providers in the VA system more than the local non-VA methadone clinic.

We're still in a position where we're not accepting people that're on Methadone [in the drug court], although we do in our veterans treatment court...where we have, what I feel...are physicians that're properly prescribing it, and monitoring it. We don't on the non-veteran side because we didn't have a trustworthy relationship in [our county] with the clinic that was prescribing it. (Judge 12)

IV. How are Treatment Decisions Made in Drug Courts?

Very few studies have examined problem solving court MAT treatment policies, including how courts pick one treatment over another. In my study of 20 Indiana drug and veterans courts⁶⁴⁶, every judge stated that the court's treatment team makes treatment decisions. I gathered complete team member information for 18 of 20 problem-solving courts. Treatment teams typically consisted of the following members: the judge (the official head), the prosecutor, a defense attorney, at least one counselor, and at least one case manager. Additionally, 13 of 18 court treatment teams included a police officer, 12 included a probation officer; and two included a physician. Veterans' court teams typically included a Veterans Administration (VA) representative or outreach officer. One court's treatment team also included a representative from a women's homeless shelter and a representative from a veteran's charity (non-VA affiliated). Six court teams included a court director or administrator. Overlap may exist between some positions; for example, in at least two courts the probation officers also served as case managers.

										Court
			Defense		Case	Police	Probation		VA	Director
Court	Judge	Prosecutor	Atty.	Counselor	manager	Officer	Officer	Physician	Rep.	(Admin.)
Drug	Y	-	-	Y	-	-	-	-	-	-
Veterans	Y	-	-	Y	-	-	-	-	-	-
Drug	Y	Y	Y	Y	Y	Y	Y	N	n/a	N
Veterans	Y	Y	Y	Y	Y	N	N	N	Y	N
Drug	Y	Y	Y	Y	Y	Y	Y	Y	n/a	N
Drug	Y	Y	Y	Y	Y	Y	Y	N	n/a	N
Drug	Y	Y	Y	Y	Y	Y	N	N	n/a	Y
Drug	Y	Y	Y	Y	Y	Y	Y	N	n/a	N
Drug	Y	Y	Y	Y	Y	Y	Y	N	n/a	N
Veterans	Y	Y	Y	Y	Y	Y	Y	N	Y	N
Veterans	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Drug	Y	Y	Y	Y	Y	Y	Y	Ν	n/a	N
Drug	Y	Y	Y	Y	Y	N	Y	N	n/a	Y
Veterans	Y	Y	Y	Y	Y	Ν	Y	N	Y	Y
Drug	Y	Y	Y	Y	Y	N	Ν	Y	n/a	Y
Drug	Y	Y	Y	N	Y	N	Ν	N	n/a	N
Veterans	Y	Y	Y	Y	Y	Y	Ν	Ν	Y	N
Drug	Y	Y	Y	Y	Y	Y	Y	N	n/a	Y
Drug	Y	Y	Y	Y	Y	Y	N	N	n/a	N
Drug	Y	Y	Y	Y	Y	Y	Y	N	n/a	N
Overall (% Yes)	100%	100%	100%	95%	100%	72.2%	66.7%	16.7%	(100%)	33.3%

Table 3: Participants on Court Treatment Teams

Judges always led the treatment teams, but every judge stated that he or she tended to defer to the

treatment professionals. For example, Judge 11 stated:

When it comes to treatment protocol, that's actually made by the treatment professionals, and I suppose, in theory, you know, we have the option as a team arguing those type things, and then having the judge ultimately say yes or no, but it's a practical matter. We let the treatment people do the treatment thing. (Judge 11)

If there are ten people on the team, oh there are, let's see, there are eleven people on the team that have to have a vote, then I have eleven votes I guess, so yeah, but, you know, I'm not certainly one that has the extensive knowledge of, of treatment services and, and things like that, so we all, all the non-mentalhealth professionals and non-substance-abuse treatment professionals are certainly gonna rely on the experts for their recommendations. (Judge 3)

As a judge, it's not my role to make a decision in terms of appropriate treatment, but you know, it is my role to be part of the conversation when, you know, we talk about the all kinds of different needs that the person has in staffing, one of which is treatment too, and also to share information that I have. (Judge 1)

Some of these treatment professionals on court treatment teams have private practices.

Most, however, provide counseling through a local health agency to whom the court treatment team refers participants. Therefore, treatment providers on the team frequently serve as liaisons between the court and the health agency, sharing information between the two entities. In 18 of 20 courts, the treatment professionals on the treatment team are exclusively counselors, either psychologists or social workers, and not physicians.

If non-physician treatment professional predominantly make decisions on drug court treatment teams, then in practice most treatment decisions are made by counselors, who compose the vast majority of such professionals. Naturally counselors should make decisions regarding the courts' use of counseling therapies. But policy makers should consider whether counselors are the appropriate decision-makers with respect to MAT policies. Because counselors cannot legally prescribe MAT, they are unlikely to be extensive educated about such therapies. Furthermore, approximately 50% of SUD counselors in general in the U.S. are undereducated about or biased against MAT according to a national study.⁶⁴⁷ Counselors' lack of education and bias against MAT combined with counselor-centered decision-making on treatment teams may contribute to the widespread underuse of MAT in American drug courts. In a majority of courts, at least one team counselor was a representative of a local treatment provider (e.g. the local mental health agency). Interestingly, three treatment team counselors were themselves in recovery from drug addiction, with one having previously graduated from drug court.

Only two problem-solving court treatment teams included a physician; of the two physicians, one was an OB-GYN who sometimes counsel drug court participants and the other was retired and practiced in an unknown area. Physicians' scarcity on court treatment teams is unfortunate but unsurprising. Physicians have historically been under-involved in addiction treatment in the U.S.,⁶⁴⁸ and few drug courts can afford to compensate physicians in light of their limited funding. Finally, as one judge stated, most physicians do not have free time to voluntarily donate to a drug court. One of the two judges whose drug court treatment team included a physician stated that having a physician was very valuable because that person both assisted with decision-making and served as a liaison between the court and other physicians who provide treatment to participants. One judge whose team lacked a physician would "love" to have one with whom the team could discuss MAT options and provide health assessments. Even though all problem-solving court judges stated that they have only a small role in treatment-decision making, subtle comments during the interviews revealed that judges may

have more persuasive power on treatment teams than they realize. For example, consider the

following statements, in which judges discuss their own views in relation to court policies:

Well, probably up until this year, we've had a pretty strong bias against medication-assisted treatment, and that's probably been largely because of my biases... [But] as it stand now, I suppose that if, if the, the treatment folks are recommending medication-assisted treatment *and* the participant is open to the treatment, then I'm probably gonna go along with it. (Judge 10, whose court did not allow MAT until recently)

I, we, we allow the clients to use [Suboxone] short term to age them from a more serious drug and addiction process, and kinda bring them down slowly. But whether it's Suboxone or whether it's Methadone, I am not a fan of marginalizing our clients for life and saying that we're going to cast them away as lost souls, and we're just basically going to drug them for life, that if you're going to use Suboxone, or you're going to use Methadone, you're going to use some type of pharmacological response to addiction, it needs to be short term to bring it down from their level of drug usage with counseling, to have a life of sobriety, as opposed to a life of moderately, chemically maintained with Suboxone or Methadone. (Judge 11, whose court only permits short-term use of MAT)

Many of [the medications] are addictive, that's, you know, that's the problem I have with some of those, they're addictive themselves. And you're just substituting one for another; it can be used for a double weaned it off, but just like with Methadone. I mean that just it.... There's this one in Indianapolis and there's one in Muncie locally, so I always wonder they go up there and they come back under the influence, or driving to those clinics, they take their dose and...I mean, how's that good for anybody? (Judge 17, whose court does not permit buprenorphine or methadone)

Nobody's on Methadone in drug court. I don't allow that. (Judge 17, whose court does not permit methadone)

Now I'm willing, personally, as a judge, to have pretty, pretty much an open mind about, if I can find a provider who will give me good, evidence-based reasons for using a particular drug-assisted or medicine-assisted kind of intervention, I'm willing to consider it. (Judge 2, whose court does not ban any form of MAT)

V. <u>Relationships with Treatment Providers</u>

Most court treatment teams in the study send participants for counseling to outside

agencies, private counselors or physicians. Only one court provides treatment "in house,"

through court staff members. Even when courts send participants to outside agencies for counseling, those agencies are represented by one or two treatment providers on the court treatment team.

Information sharing about participants is an important part of partnering with another treatment provider. Every court in the study requires participants to sign an information release form as a condition of court program participation. The extent to which information is shared about individual participants between the court treatment team and outside providers differs from court to court. In some courts, information sharing with counselors is fairly minimal, consisting of a bi-weekly or monthly list of treatments the participant has attended and the counselors' brief opinion of whether the participant is making progress. If the counselor tests urine, then urine results are also included. Such information sharing is typical of veterans' courts and VA relationships. However, some drug court judges also described relatively minimal information sharing with outside counselors.

We get weekly updates on if they made their meetings, and then those agencies also drug screen, so we find out whether or not they did drug screen, the results. So drug court team, as a whole, gets updated and we monitor the weekly activity. (Judge 13)

I don't think that the case managers who are supervising our participants are getting, like, weekly progress reports but they do get regular progress reports and they do, and they do check with the treatment providers regularly to see how things are going with the treatment, with the particular participant. (Judge 18)

In a few courts, information sharing includes detailed notes of sessions in which the participant participated, including statements made by the participant to the counselor. Counselor notes are then reviewed by the court treatment team. One court requires every participant's counselor to attend weekly staff meetings at the drug court, a requirement the judge admits is too onerous for most counselors in the area to want to participate in drug court treatment. The
counselor that does attend weekly staff meetings gives the staff a "play-by-play" of what the participant said and felt during recent counseling sessions. According to that judge, detailed information sharing keeps the participant honest.

But, these people, in order to hold them accountable, I think it's only fair that they recognize that their treatment provider is going to come into court and hold them accountable in court, just like they would hold them accountable in a treatment setting, so that they're not allowed to get away with tellin' me false things in court that they, you know, told the, told the counselor something contrary throughout the week...We're also getting comments from participants that said, "Hey, I really like the fact that my treatment provider is there in court and can confirm the things that I'm telling you." (Judge 8)

The information sharing goes in the reverse direction as well. For example, during a weekly staff meeting the case manager (who always works for the court) will tell the team which participants had positive urine tests and other information acquired by the case manager during the week. Treatment providers on the team or their representatives use such information to address problem areas or relapses of which they might otherwise be unaware.

[W]e talk about the, all kinds of different needs that the person has in staffing, one of which is treatment too, and also to share information that I have that may make a treatment provider say, "Well, I didn't know about that". Maybe, you know, this thing that came out in, in probation or came out in court might indicate that this, that we've got some trauma here and so we may want to add, you know, some additional treatment that we didn't know was necessary at this time because I didn't have this information, so that's really sort of the function of staffing is that sharing of information so that we can align the treatment and all the other interventions that we provide most appropriately. (Judge 1)

Information sharing between court treatment team and outside treatment providers

sometimes leads to adjustment in treatment plans by the court treatment team. For example, a counselor from the treatment agency may discover during the course of counseling that the participant suffers from post-traumatic stress disorder (PTSD). The counselor, who is also a member of the court treatment team, will report the diagnosis of PTSD to the court treatment team the following week during the weekly staff meeting. The court treatment team will then

decide whether or not to require or recommend that the participant attends a self-help group for PTSD in addition to a self-help group for addiction.

Typically, treatment teams defer to recommendations by counselors on the team, especially recommendations about counseling. On the other hand, court teams are less likely to defer to physicians prescribing MAT, at least not without careful consideration of the physician's practice and recommendations. For example, in an interview one judge disagreed with the physicians' prescribed dosages at the local methadone clinic:

Just from our local experience, a lot of our clients, they don't try to wean off, matter of fact, they go up in dosage. That's true. They've been on it for six months and . . . they increase it, it's like, this is crazy. In fact, . . . it's a lack of trust, on the client's part and on the clinic...We try very hard to rely on the experts in the field, but at the same time, I mean, I have to tell you that we have not had success with methadone, so no matter what the experts are telling you, just through our personal results, we definitely wean. Now the other two [Suboxone and Vivitrol], I'm sure because we have zero familiarity with it, we would do whatever the experts tell us to do. (Judge 13)

Significantly, too low a methadone dosage can lead to relapse; as cravings and withdrawal symptoms will appear prior to the next methadone dosing. Another judge described clear expectations for physicians who prescribe buprenorphine: "What I expect to see is a plan where they will be weaned off the Suboxone at some point." Fortunately, multiple judges state that they defer to physician recommendations when designing MAT policies or applying policies to a participant's particular situation:

We haven't named [weaning off MAT] specific criteria for graduation, but I think for as long as our program's gonna be, and, and maybe, maybe this is naïve, or just uninformed, I think it's reasonable for them to be drug-free by the time they graduate. Now if a medical or treatment professional comes in and says that that's not feasible for this person, that this is the best we're gonna get, then, and, and if they've shown that they can manage that, then maybe not, but I would hope that they would be off of all the substances by the time they graduate. But I can't say; ... I might be naïve. (Judge 16)

Information sharing with physicians seems to be tinged with distrust in some cases as compared to information sharing with counselors. In information sharing with counselors, the focus is on monitoring the patient, not the counselor. But when sharing information with physicians, judges frequently discuss the need to know if the physician is doing an adequate job—which entails monitoring the physician along with the participant:

I never want to take the place of a doctor, but I have to be assertive enough in dealing with a doctor who[], I believe, understands what the person's actually going through and making a medical decision to prescribe that medication consistent with someone . . . who's gonna be held accountable to manage the environment and is gonna be actually be working with the program, besides just going to a clinic to take a pill or get an injection. (Judge 8)

That judge also expressed concerns that physicians might not really understand the goals of drug

court and addiction recovery:

If we have a doctor who's recommending that [MAT] to a participant, . . . we want to make sure that we're in communication with that doctor to make sure that they understand . . . that the person is in a recovery program, and make sure that they understand what the program requirements are. . . . I just would say in general, it's very difficult to establish quality working relationships with doctors in a drug court setting, and what I mean by that is that *I think I have found challenges in finding doctors who really understand about addiction and recovery*. (Judge 8) (italics added).

This quote suggests that the judge believes many (if not most doctors) fail to understand addiction or recovery. However, physicians who self-select to treat addiction (especially in light of how few physicians actually treat addiction) likely have significant understanding of addiction. At the minimum, those physicians prescribing buprenorphine require eight hours of training in buprenorphine. Drug court judges, on the other hand, have no addiction education requirement to maintain their position. It is quite shocking that a treatment team primarily composed of members without formal medical (or even health-related) backgrounds may require a physician to conform *to the team*'s understanding of addiction and recovery. Not surprisingly, in this case the team's understanding of addiction and recovery was based on abstinence-only philosophy.

When a participant needs a new counselor, such as upon entry into the drug court program, the court will typically defer to its partnering local health agency to provide a counselor for that participant. Delegating this task to the local health agency illustrates that the court trusts that this counselor is "good" in the sense of possessing the requisite credentials and adhering to the court's philosophy and policies. In contrast, when a participant needs or wants to begin MAT, courts are more likely to carefully investigate the physician and his or her methods. For example, consider the following exchange, which illustrates a court's distrust of MATprescribing physicians in contrast to deference to a mental health counselor:

Interviewer: If [the participant] were to request the ability to be on one of the medications...

Judge 13: We haven't had that issue come up, but I know the answer. We would allow a consultation, but . . . because this would happen so rarely, we would probably require that my drug court director, who is the therapist, substance abuse therapist, to attend.

Interviewer: To attend the consultation with the doctor?

Judge 13: Yeah, I'm sure we would require that, because again, we've never had it happen, but if somebody wanted to do that, we would, to absolutely be ensured of everyone being on the same page. I would require my drug court director to attend.

One wonders how exactly the mental health counselor with no medical training will

judge the physician's medical ability and motivations. Additionally, the involved process

described by the drug court judge may a chilling effect among patients desiring access to MAT.

Not surprisingly, some physicians dislike non-medical professionals interfering in the practice of

medicine, potentially pushing physicians away from treating drug court participants. For

example, according to one judge:

I don't think physicians enjoy having their clients be part of our program. I think they find that . . . it puts them in a [difficulot] position where we ask that we're permitted to be able to access all the [participant's records on] treatment and monitoring. We require our participants to sign a release, and I'm not sure that the doctors appreciate us snooping around, or looking at what's going on. So . . . we don't have a real good relationship . . . throughout the community. (Judge 12)

Distrust of physicians but not counselors is quite pervasive and striking throughout the interviews, particularly given judges' non-medical training and the lack of physicians on the court treatment teams. In light of the egregious actions of doctors who prescribed oxycodone in "pill-mill" settings over the last two decades, judges' caution is justified, for example, if the physician has had DEA action against him or her. However, the distrust appears primarily to stem not because of "bad doctors" in the area, but because court treatment teams misunderstand MAT. For example, judges described doctors as bad apples simply because patients were kept on MAT-long-term (exactly as they should be according to medical literature!) With practically no physicians on court treatment teams, misunderstandings about MAT are not surprising. For judges used to an abstinence-only paradigm of SUD treatment, education from a physician may be critical for dispelling rumors.

Interestingly, veterans' courts appear to defer to treatment providers, whether counselors or physicians, more than do drug courts. Specifically, a high level of deference to any treatment provider in the VA was evident. In veterans courts most participants are VA-eligible, meaning they can receive health benefits and treatment from the VA. Rather than making treatment decisions, veterans' court treatment teams usually focus on monitoring VA-created treatment plans, for example, by conducting random urine analysis and ensuring that participants attend counselor and physician appointments. Veterans' courts also assist VA-eligible participants in accessing VA treatment services. Court personnel serve as liaisons between the court

participants and the VA system. Sometimes a VA outreach officer is on the court treatment team. Trust exists between veterans' courts and providers in the VA system.

Specifically with the veterans court, then the case manager teams up with [the] veterans' justice outreach officer, who works for the Veterans Administration who basically operates as sort of a case manager on the veterans side of things, which handles the treatment, medical services, psychiatric services, drug-related services. So the the participants in the veterans court receive all those services through the Veterans Administration and are kinda jointly then supervised and monitored by the Veterans Administration official and our local case manager. (Judge 3)

Greater deference towards providers in the VA may exist for a number of reasons. Courts may trust treatment providers within government-led institutions more so than in nongovernment led institutions. After all, problem solving courts are government institutions as well. Courts may also assume that greater oversight of treatment providers exists in the VA, making VA treatment providers appear more trustworthy. Additionally, courts may view veterans with drug dependence more positively than non-veterans with drug dependence, as if veterans' problems are truly medical whereas non-veterans problems are more "criminal." For example, one judge stated that veterans had earned their medical treatment, while no judge described drug court participants as deserving treatment.

That's part of the services we offer, they're entitled to benefits, and they're getting the benefits that they're entitled to. They go hand-in-hand with, with, you know, the treatment aspect as well, so, you know, these people have earned it. (Judge 15)

III. Encouraging Addiction Treatment within Drug Courts

Ultimately, it appears that American drug courts have appropriated the medical rhetoric about addiction but have ignored medical expertise on appropriate treatments.⁶⁴⁹ One might say that American drug courts have not been sufficiently medicalized, even though they term addiction a medical condition. According to sociologist Peter Conrad, there are three levels of

medicalization: conceptual, institutional, and interactional.⁶⁵⁰ The conceptual level is characterized by medical rhetoric but no medical intervention.⁶⁵¹ The institutional level occurs when institutions adopt medical rhetoric and some medical approaches, but medical experts do not directly intervene or have control.⁶⁵² The final level occurs when medical experts, such as physicians, directly intervene and control the social action.⁶⁵³ Despite professionals' use of medical rhetoric in drug court, medicalization remains at the conceptual level.⁶⁵⁴ Judges and nonmedical staff, rather than physicians, diagnose and decide the appropriate treatment for the disease. ⁶⁵⁵ In most drug courts, judges may even override physicians' advice.⁶⁵⁶ As a consequence, treatment staff may have their treatment suggestions second-guessed by judges with no medical training.⁶⁵⁷ One might even argue that some judges are practicing medicine without a license.

Even though both drug court programs and new medication addiction treatments are revolutionary developments in substance abuse, these spheres remain like oil and water; according to one journal, "any hope of these two trends building off and complementing each other continues to go largely unrealized."⁶⁵⁸ For example, one author writes that at an annual drug court conference "several judges looked squarely at the mounting evidence about medication effectiveness and still professed skepticism."⁶⁵⁹ Even after being presented with evidence that methadone, buprenorphine, and naltrexone were all effective, some judges stated that their drug courts would continue to bar defendants currently using methadone from participating in the drug court "in keeping with the judicial system's drug-free bent."⁶⁶⁰ Mark Parrino, president of the American Association for the Treatment of Opioid Dependence, reported, "[t]here are judges who say, 'I don't believe in it." Parrino retorts, "This is not a belief system."⁶⁶¹ Some judges fail to acknowledge MAT's existence. In one recently published

overview of drug courts written by a former drug court judge, the author discussed multiple methods for treating drug dependence but failed to mention MAT's existence at all, despite the existence of such medication for over 30 years.⁶⁶² Fortunately, my study of Indiana courts revealed signs of shifting attitudes in favor of MAT (at least in some courts), largely due to education about MAT received from physicians or training courses. Additionally, the federal and some state governments are enacting legal and policy changes to encourage MAT. However, more state-led MAT initiatives are needed.

A. Changing attitudes towards MAT in Indiana

Five judges stated that their attitudes towards MAT have changed fairly recently. In each of these cases, the changing attitude was attributable to greater understanding of the science behind MAT and awareness of scientific studies about MAT's effectiveness. Understanding the reasons for attitude changes in problem-solving courts may help the government design more effective policies for promoting MAT. The reasons for these attitude changes are described below.

For one judge, the turning point was education through a "very confident" psychiatrist sent by the VA who explained the dynamics of MAT and its value.

Well, probably up until this year, we've had a pretty strong bias against medication-assisted treatment, and that's probably been largely because of my biases...However, some folks at the VA felt equally strongly that medicationassisted treatment is worthwhile, in some cases, not in every one, and a very confident psychiatrist came and visited us, spent about three hours explaining the dynamics of medication-assisted treatment and why it does have value, so I've come about a hundred eighty degrees this year on medication-assisted treatment, and we, we do use it now, on a very much a case-by-case basis, just kind of based upon the individual's perceived needs. (Judge 5)

Interestingly, another judge who is currently "on the fence" about MAT admitted that a good discussion with a physician might persuade him:

Now I'm willing, personally, as a judge, to have pretty, pretty much an open mind about, if I can find a provider who will give me good, evidence-based reasons for using a particular drug-assisted or medicine-assisted kind of intervention, I'm willing to consider it. That's fine. (Judge 2)

Physicians, unsurprisingly, can be persuasive proponents of MAT. After all, they are often the most knowledgeable about MAT and have the ability to prescribe it. However, as discussed in Section III, court treatment teams virtually never include physicians due to funding constraints. For another judge, education provided at the National Association of Drug Court Professionals (NADCP) annual conference changed his mind about MAT.

The National Association for Drug Court Professionals have come out, and they, they have taken the stand that it's essential, it's an essential part of treatment, to, for your best practices in drug courts, okay so, our national association, our national leaders have, have come to the conclusion that it should be, it should be done. So, we have to look at their leadership and, and say, hey, we need to look into this because it's been proven that it's successful. (Judge 13)

The NADCP is one of the most important sources of addiction treatment information for judges in problem-solving courts. Its potential to change values, attitudes, and behaviors of judges should not be underestimated. When I asked judges how they learned about the latest addiction treatment methods, almost every judge described the NADCP annual conference as being either their primary source of information about addiction treatment or an extremely persuasive source of information about addiction treatment. However, attendance at the NADCP annual conference is voluntary, neither the federal government nor the state government requires attendance for drug court certification. Additionally, even within the conference, attendance at information sessions about MAT is voluntary.

Training about MAT, whether from a physician or through a national conference appears to be a viable way of changing attitudes about MAT. As one judge said,

I think the teams came a long way through training, you know, they put up the charge that substitute therapy versus no substitute therapy, and I think the team has come a long way with understanding, hey, this isn't just tradin' a drug for a drug, this is evidence-based and it's working. (Judge 10)

One drug court treatment team has changed its philosophy towards buprenorphine after seeing it

work in their "sister" veterans' court (run by the same judge), suggesting that courts learn from

each other:

I've always been more on board than a lot of the team, with the replacement drug, seein' some success, so they're startin' to kinda warm up with, hey, you know, maybe this is better than the cold turkey, cause there's so many overdoses when, when you do the cold turkey, they may make it, you know, a month, six months, a year, whatever, but then when they relapse, the overdoses are so horrific because their tolerances are low. Anyways, we do allow that in all of our programs, and I think the team is warmin' up to seein' some of these successes that people are just doin' great, you know, if they take it as prescribed, and they're getting' counseling on top of just eatin' the pill, you know. (Judge 9)

In some cases, finding a reputable provider of MAT is the missing ingredient to allowing

MAT in court. Two judges who had previously prohibited MAT now allow MAT after finding

providers with whom they are comfortable. One judge believes that courts are becoming more

open to MAT, because the opiate abuse crisis has reached such extreme proportions. With a

large percentage of court participants addicted to opiates, judges are starting to think critically

about what works for opiate addiction, rather than what works for treating addiction generally:

I think it's becoming so much more common just because of how opiate addicts are so much more common, that people are startin' to see [MAT] work. So I think it's an improving trend. I still think there's a stigma, but I think it's an improving trend that people are starting to become more educated on the benefits. (Judge 10)

Finally, for some judges and their teams what makes a difference is knowing a participant who has been helped by MAT. Many judges and team members have only seen the effects of abstinence-only treatment. Sometimes team members are in recovery themselves having used abstinence-only methods. If abstinence-only methods worked for them, why try something else on others? Seeing MAT work in one participant makes it more likely that MAT will be allowed for other participants. As one judge said,

I think over time, [court treatment team members are] startin' to see, you know, people use Suboxone appropriately with counseling, and I think they're like hey! This actually does work! You know, so... I think that's kinda the evolution is that, you know, they can finally put their hand on someone. Like, you know, there's people in my mind vividly right now that I can say, hey, it worked for him, you know, he's back with his wife and children, and it's okay, you know so... It's kind of an evolution of goin' from overdose deaths to seein' it work." (Judge 10)

B. Educating Drug Court Professionals

Former chair of the NADCP, West Huddleson, says that acceptance of MAT is increasing in drug courts, and that some of the progress is attributed to educating judges and other drug court professionals.⁶⁶³ Misinformation is still rampant. Few studies exist regarding the effects of education about MAT on referral practices within the criminal justice system. However, one experimental study of attitudes within correctional facility administrations found that a threehour MAT education course combined with an institutional linkage intervention (involving interagency planning and implementation) significantly improved administrators' perceptions of MAT and improved their stated intentions to refer clients to MAT.⁶⁶⁴

Part of existing federal and state drug court funding should be directed towards developing an educational program for drug court professionals using evidence-based principles and the latest scientific and medical data. Such a program should be updated regularly as new medications and scientific study results become available. Acceptance of federal or state funding for drug courts could be made contingent on the drug court's administrators completing such an educational course. Additionally, problem-solving courts should be accredited (as described below), and accreditation should require an education component.

C. National Accreditation of Drug Courts

The NADCP does not track the use of MAT or other treatment methods used in drug courts. According to a former NADCP director, "I can't tell you what's happening in all 2,800 drug courts...[t]hat's not our role. We don't track drug court operations to that level."⁶⁶⁵ Neither is the federal government systematically tracking treatment provided in individual drug courts. Instead, the federal government merely requires drug courts receiving a federal grant to complete an "outcome evaluation," in which the court describes whether or not participants are benefiting from the drug court.⁶⁶⁶ While better than nothing, this system fails to promote best practices. Furthermore, even though drug court participants are being benefitted under a current drug court program, they may experience more benefits under another program. By tracking eligibility criteria, treatment methods, and results for each drug court, the federal government could establish a more accurate list of best practices and improve the quality of drug courts.⁶⁶⁷ Considering that the federal government provides funding for drug courts, the establishment of empirically-based best practices is in its best interests.

Douglas Marlowe, an expert on drug courts, recommends the formation of a national court accreditation system to standardize drug court practice across jurisdictions. He says, "[T]he responsibility now falls to the drug court field to establish performance benchmarks and best practices for drug court programs and to develop accreditation procedures that can be used to document whether a particular program is in compliance with professionally accepted standards of practice." Accreditation is also supported by John Roman of the Urban Institute, who says that accreditation would lead to the best practices becoming institutionalized.⁶⁶⁸ While some states, such as Pennsylvania, have a state-wide accreditation program in place, this is not the case in all states. Additionally, there is no reason to believe that the best practices of drug

courts in one state should not apply to other states, suggesting that national accreditation is just as important as state accreditation.

Finally, scholars must become more interested in not only whether drug courts work in general, but specifically what *within* drug courts works. Discussing the lack of critical evaluation of drug courts to date, Judge John Bozza writes, "[t]he overall concern [currently] is with assuring access to treatment, apparently with little consideration for the nature or the quality of the change strategy undertaken."⁶⁶⁹

D. Funding Incentives

According to the director of the NADCP, the economic recession has incentivized decision-makers to think about treatment rather than incarceration, because it is cheaper.⁶⁷⁰ Hopefully, economic concern will also cause policy-makers to focus on funding evidence-based, effective treatment methods. So far, the signs are hopeful. Drug courts are also feeling more pressure to increase access to MAT and to change policies that ban MAT.

Michael Botticelli, the acting director of the Office of National Drug Control Policy, has been described as "a stalwart supporter of MAT."⁶⁷¹ In February 2015, Botticelli announced that the White House planned to strip state drug courts of federal funding if they prohibit the use of MAT. This policy would be implemented through coordination with SAMHSA. Pamela Hyde, a SAMHSA administrator, said "We are trying to make it clear that medication assisted treatment is an appropriate approach to opioids."⁶⁷² She adds, "Abstinence only ideology often obstructs appropriate treatment placement, particularly with respect to opioid addiction."⁶⁷³ At the minimum, State governments should follow in the federal government's footsteps and only provide funding to drug courts that permit MAT. I asked judges (including veterans' court judges) about their views of the federal government's new policy of tying federal funding to MAT in drug courts. Only one judge expressed pre-existing knowledge of the policy. For that judge, the new federal policy is evidence of the fact that MAT is an effective treatment:

We're all a little skeptical of [MAT] around here. But I know from, from going to the NADCP meetings and a, a lot of a, and not that we get any federal funding, but federal funding is, is tied to, I guess they, they don't allow it if, if, the, the federal government will not fund anything if we don't allow medically assisted treatment. And I don't mean that for the funding, it just means that, well, there's somebody that thinks that it's pretty important..." (Judge 16)

Judges' responses to the new policy (after I explained the policy) were mixed, but tended to be more negative than positive. According to one judge, the policy does not leave enough room for judges to make individualized decisions:

I think it's too fine-grained. That's probably well-intentioned, but I think that's something that needs examined almost case by case...I don't really have a blanket restriction on the use of drug-assisted treatment, but I'd want it very individualized. I don't want them to just use liberally because it's available. I mean, frankly, I'm a cynic. I mean, that sounds to me like the drug industry's gotten to the regulators and have them impose something that's gonna benefit them. (Judge 2)

Another judge believes the policy is too much too soon:

I don't think it's a good policy. I think they should...I'm in agreement that we should be using medically assisted treatment, and, and I'm in agreement that they should, they should push that on drug courts, and ask the drug courts use it, but I, I think they need to be little more patient, and, and forgiving, and work with programs and educate 'em on why, and what the benefits are, as opposed to just defunding them. (Judge 12)

Three judges expressed concern about policy makers interfering in treatment decisions-making:

I think its bad public policy to tie money to treatment of any kind. Treatment should be stand-alone. (Judge 7)

Well, I, I think that for a national agency to, to take that approach is not prudent. I think there is a tremendous variation across the nation in clientele, in communities and in resources. And I think that absolutes in terms of dealing with people are probably a bad public policy. I, you know I, it's, I think you can encourage it. I think you can do all kinds of things to, to try to, to foster, you know, the ends of a policy, but blanket prohibitions, or blanket requirements, either way, I think are short sighted...I think it's unwise to simply sit in Washington and mandate this, that, or the other thing. (Judge 10)

I don't think it's necessarily a good idea for politicians to make treatment decisions...I think it's probably best to keep politicians out of treatment decisions...But, on the other hand, I also don't want to give the money out to people who aren't producing some sort of results that are demonstrable. (Judge 6)

One judge does not necessarily oppose the policy but wants more public debate about it,

especially since he allows some medications for short-term use but not others.

I guess it would be something that needs to be more fleshed out and have a whole discussion as to exactly what the policy is, because our drug court program does not prohibit it, but my philosophy is that we should not medicate people for life, except when, anytime you start saying we should do this for everybody is always. (Judge 11)

Only two judges explicitly agreed with federal funding policy:

I agree with that policy. I don't think you should ever, as a drug court say that something is totally gonna be banned. I mean, I just, I think you have to take a look at each individual person and what your alternatives are, so I would not support a ban. (Judge 13)

Two judges explicitly stated that the policy is irrelevant to them, because their courts

receive very little federal funding. One of those two judges believes that most drug courts receive

little federal funding. That judge is probably correct, because most judges in the study stated that

the bulk of their funding comes from the state and local governments.

Therefore, states must also change their drug court policies to prohibit drug court from

banning MAT. In March 2015, Kentucky began allowing drug court participants to access MAT

after banning their access for decades.⁶⁷⁴ Interestingly, Kentucky changed its rules after two law firms initiated a lawsuit on behalf of a nurse who claimed that Kentucky's ban on MAT violated the Americans with Disabilities Act, a claim rendered moot by the policy change.⁶⁷⁵ Shortly afterwards, New Jersey changed its drug court policy and now also allows drug court participants to access MAT.⁶⁷⁶ The New York Senate passed a similar bill in June 2015.⁶⁷⁷

E. Incentivizing Physician Involvement

Lack of physician involvement on problem solving courts' treatment teams may largely explain misconceptions about MAT. In light of limited or no MAT education received by most mental health therapists, judges should not base court treatment policies based solely on the advice of mental health therapist. Of course, basing counseling policies on the advice of mental health therapists is logical. If governments want more physicians on court treatment teams, then funding should be allocated specifically to reimburse physicians for their time. If lower reincarnation rates and lower court program dropout rates result from physicians providing accurate medical advice, then such funding may be budget neutral.

Additionally, judges should be required to follow physicians' advice with regards to MAT unless the judge has a reason based on medical best-practices for disagreeing with a physician. For example, a notarized statement from another physician or reference to medical literature could be used to describe the best-practices on which the judge is basing his or her decision. States should require judges who refer patients to a physician to follow the advice of the physician unless the judge submits, in writing, a reason for disagreeing and points to a medical best-practice standard or disciplinary issue (e.g. the physician previously had his or her license suspended). Otherwise, judges who tell drug court participants to not follow physicians' advice may be practicing medicine without a license. The mere process of explaining in writing

why the judge is asking the patient to disregard physician advice may be enough to encourage deference to physicians.

VI. The Ethics of Providing Access to MAT in the Criminal Justice System

Ludwig and Peters identify three primary ethical considerations for criminal justice administrators with regards to substance abuse treatment: beneficence, distributive justice, and autonomy. The authors derive these principles from the influential and widely read Belmont Report, an ethics report authored by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research that has been codified in professional healthcare standards.

The ethical principles of beneficence, distributive justice and autonomy suggest that MAT should be more widely available within criminal justice systems. Beneficence requires doing good. It is related to non-maleficence, which means doing no harm. Beneficence requires providing dependent individuals with MAT, because it (especially in combination with counseling) is proven to decrease mortality, risk of relapse, and re-incarceration more than other treatment modalities. Non-maleficence requires criminal justice administrators to permit continuation of previously started MAT rather than force withdrawal, as studies show that forced discontinuation may increase future relapse risk and overdose upon release from prison. For example, the relapse rate after discontinuing methadone treatment is approximately 80%.⁶⁷⁸ According to the Drug Policy Alliance, "[t]he denial of this highly successful treatment [MAT] for opioid dependence nearly guarantees that most opioid-dependent individuals will fail in drug court."⁶⁷⁹ In my study, some judges assumed that permitting MAT was harmful to participants as it prevents them from being truly sober, but this assumption misconstrued the meaning of sobriety. Failure to allow MAT also harms participants if inadequate treatment indirectly leads to their failure in drug court. Without effective treatment, participants face a greater likelihood of relapse and eventually failing out of the drug court program after repeated relapses. When participants fail out of drug court, they return to the original court for sentencing. The National Association of Criminal Defense Lawyers has reported that individuals who fail drug court often have longer sentences imposed than if they bypassed drug court in the first place.⁶⁸⁰ Sometimes these harsher sentences are meant to "set an example" for others who remain in drug court.⁶⁸¹ Unfortunately, drug courts usually lack appeal procedures, which theoretically might allow the participant to dispute reasons for receiving a sanction or failing out of drug court.⁶⁸² Moreover, persons convicted of drug possession (including marijuana) lose significant welfare benefits by becoming ineligible for food stamps, public cash assistance, student educational loans, and (in some states) the use of a driver's license.⁶⁸³ Therefore, failing out of drug court can have extensive and significant repercussions for defendants and their families.

The ethical principle of distributive justice means equitable access to a resource (in this case, effective health care). The principle of equivalence-of-care derives from distributive justice; it requires correctional facilities to provide health care that meets the community standard of care. In the 1976 case *Estelle v. Gamble*, the U.S. Supreme Court determined that equivalence-of-care is required under the Eighth Amendment to the Constitution. The Supreme Court ruled that "deliberate indifference" to a prisoner's serious medical needs violates the Eighth Amendment. In the 1979 case *Bell v. Wolfish*, the Court applied the same standard to pre-adjudication settings, including jails, under the Fourteenth Amendment. Even a well-intentioned denial of MAT in prison or drug court would fail the equivalence-of-care standard, because

MAT (in combination with counseling) is the medical standard of care for treating opioid addiction.

Finally, the ethical principle of autonomy means that individual rights prevail over the clinical standard of care. For example, autonomy means that, even if the medical standard of care for HIV is anti-retroviral therapy, a patient cannot be forced to use this therapy if he prefers an alternative one. In practice, autonomy is applied through the process of informed consent to medical treatments. True informed consent requires capacity, disclosure, understanding, voluntariness and access.⁶⁸⁴ In the past, some scholars have argued that prisoners cannot give informed consent to MAT because they lack the capacity to voluntarily agree to undergo that therapy. According to these scholars, drug cravings destroy prisoners' physical and psychological capacity for voluntary assent to treatment. However, as Ludwig and Peters state, this argument "relies on a false dichotomy by suggesting that treatment without medication does not require the same degree of capacity."⁶⁸⁵ For example, lack of capacity arguments are rarely (if ever) applied to counseling for drug-dependence or forced detoxification in prison. Additionally, this argument falsely presumes that drug-addicted individuals are constantly incapacitated. But even if drug-addicted individuals have diminished capacity, this capacity is not wholly destroyed.⁶⁸⁶

Some bioethicists argue that offering agonist medications (like methadone or buprenorphine) to individuals with opioid dependence is *de facto* coercive, because the medication is the "next best thing" to their abused substance, so they cannot resist the option. However, when offered a choice between alternative treatment options, many individuals with opioid dependence choose to engage in multiple types of treatment, including those without opioids (e.g. counseling, and support groups); some choose not to undergo MAT at all.⁶⁸⁷ At the

minimum, providing information about MAT may bolster autonomy for inmates' and drug court participants, especially if they lack knowledge about MAT.⁶⁸⁸ One cannot make a truly autonomous treatment choice without being informed about and understanding all options.

VII. Summary

Problem-solving routinely design medication policies contrary to the best standard of medical care. According to Matusow et al. (2013), approximately half of drug courts nationwide prevent participants from engaging in agonist MAT. My study of Indiana drug and veterans courts found policies encouraging short-term MAT even though medical studies suggest long-term MAT is most effective.

Problem-solving court treatment decisions are made in treatment teams composed of criminal justice professionals and counselors, but rarely physicians. Judges head the team and defer to counselors, but sometimes appear to impose their own treatment beliefs on the treatment team. The lack of physicians on treatment teams is likely related to misinformation about MAT within courts. Such misinformation also breeds distrust of MAT-prescribing physicians. Fortunately, my study suggests that education provided by physicians and conference could encourage more accurate understandings of MAT. Because judges are not medically trained, they should refer to physicians' decisions with respect to MAT. Therefore, more physicians should be included on treatment teams; the government could encourage their inclusion through funding mechanisms or accreditation standards. More MAT-prescribing physicians are also needed in the community. Matusow et al. found that even among courts that allow MAT, many failed to refer patients due to a lack of local providers. Unfortunately, an undersupply of MAT-prescribing physicians exists nationwide.

<u>CHAPTER 4: WHY ARE SO FEW PHYSICIANS TREATING ADDICTION &</u> PRESCRIBING MAT?

I. Introduction

Demand for addiction treatment services in the U.S. increased under the Affordable Care Act (ACA), which extended insurance to many previously uninsured individuals and made substance abuse dependency treatment a mandatory ("essential") insurance health benefit. However, the numbers of physicians treating addiction has not kept up with demand and remains woefully inadequate.⁶⁸⁹ Relatedly, medical professionals' knowledge of and training in effective addiction treatments remains low, signifying an information diffusion problem. According to Saxon and McCarty (2005), "[m]any areas of medicine adopt new therapies slowly, but barriers to adoption of addiction therapies may be particularly high."⁶⁹⁰

This chapter will discuss the many reasons so few physicians treat addiction and have been slow to adopt MAT. Historically, physicians have largely been excluded from the field of addiction treatment, and until recently have not pushed for admission. This has contributed to limited physician education in addiction medicine and concerns about treatment of co-occurring conditions, which in turn has allowed several misrepresentations to continue, including the stigmatization of addiction patients and the providers who treat them, the idea that addiction is a choice rather than a disease and the belief that primary care physicians should not treat addiction. Moreover, significant regulatory and institutional barriers have been erected, leading to limited institutional support for addiction treatment, insurance and reimbursement barriers, and a lack of support from mental health counselors.

II. Physicians' Exclusion from Addiction Treatment

Physicians' exclusion from addiction treatment has its roots in social and legal developments dating back over 100 years. In the late 1800s and early 1900s, many Americans suffered from opioid dependence. Dependence developed in part from the use of morphine to treat soldiers during the Civil War, opioids' inclusion in over-the-counter cough syrup and other products, and the medical practice of prescribing morphine to women for menstrual cramps and anxiety.⁶⁹¹ At the time, some physicians were treating individuals with opioid dependence in office-based practices by prescribing maintenance doses of morphine (note: methadone, buprenorphine and naltrexone had not yet been discovered.) In fact, many physicians viewed maintenance doses as a useful tool for preventing morphine theft and overdoses from self-induction.

Then, in 1915, Congress passed the Harrison Anti-Narcotics Tax Act (Harrison Act), making distribution of morphine illegal unless it was for a valid medical purpose. Many physicians initially interpreted the Harrison Act as allowing morphine maintenance therapy However, the federal government disagreed with this interpretation and the Supreme Court ruled that the Act prohibited maintenance treatment for individuals with opioid dependence.⁶⁹²

In response, the newly created DEA began targeting physicians known to prescribe maintenance therapy, leading to the largest DEA raids on physicians in U.S. history. These raids were not always conducted pursuant to a valid search warrant, and many physicians' professional reputations were irrevocably harmed. Between 1919 and 1935, approximately 25,000 physicians were indicted, with 10% being convicted and imprisoned"⁶⁹³ As a result, even those physicians who had not engaged in maintenance treatment began to fear the legal repercussions of treating opioid addiction—after all, the best self-protection was avoiding treatment of addiction

altogether.

Thereafter, a dramatic split occurred in addiction treatment: physicians largely ceased to practice in the field of addiction treatment, leaving a void that would be filled by mental health counselors and support groups. Physicians not only feared DEA raids but found that it was difficult to assess whether medical treatment for addiction was efficacious in the first place. Few methodologically valid studies had been conducted on medical treatments for addiction, rendering uncertain the value of physicians' contributions. Some physicians referred dependent patients to psychiatric hospitals, but to no avail. Historian William White notes that psychiatrists and their staff frequently resisted integrating addiction patients with other psychiatric patients out of fears that the addiction patients from addiction patients reinforced some physicians' perceptions that addiction was a moral failing, not a disease requiring medical treatment. These perceptions were reinforced by the fact that wealthier opiate-dependent individuals would segregate themselves, and would sometimes attend rehabilitation centers that essentially functioned as luxurious spas where they could detox while hiding themselves from society.

In the time period between the passage of the Harrison Act and the widespread availability of support groups such as AA, middle-class individuals with opioid dependence had essentially two options: quitting "cold turkey" (which rarely worked) or trying "quack" treatments. Quack treatments could be bought in catalogs and in stores. Many bore the names of celebrities who had supposedly been "cured" of their addiction. Ingredients were dubious at best and harmful at worst. One popular cure consisted primarily of alcohol; another incorporated tiny amounts of gold that individuals with drug dependence swallowed. Sellers of supposedly miraculous cures preyed on individuals desperate to reclaim their lives and families. With

regulatory agencies in their infancy and no active consumer protection movement, federal and state governments intervened very rarely. Physicians may have interpreted the widespread availability of quack cures to mean that there was no possibility of any medically sound addiction treatment.

Approximately 11 years after the Harrison Act was passed, dependent individuals had a newer, far better treatment option: support groups. While support groups had existed in the late 1800s, namely the Washingtonian Houses, they became widely accessible in the 1930s with the emergence of AA. AA became the dominant support group, with chapters spreading throughout the U.S. like wildfire. Decades later, NA would form specifically for individuals with drug dependence.) The reasons why AA rose to prominence so quickly include the fact that it was free, anonymous, and was an ideal philosophical fit with American cultural norms. But as any practicing physician knew, AA and NA were not medical treatments and did not require professional involvement from physicians. Support groups' popularity as an addiction treatment and their widely-perceived efficacy further reinforced physicians' perceptions that addiction was not a disease requiring medical treatment.

As the counseling field grew more sophisticated over the next few decades, practitioners developed new counseling methods that were empirically proven to be effective, including motivational interviewing, cognitive behavioral therapy, and contingency management. Although individual counseling was only available to those who could afford it, it began to be used in combination with support groups. This combination of treatment modalities helped many dependent individuals; but a large percentage continued to relapse.

Until the early 1970s, then, physicians' role in addiction treatment was largely one of referral, encouraging patients to seek help from counseling and/or support groups. Any further

physician involvement, other than prescribing medication to ease painful detoxification symptoms, seemed superfluous and not medically necessary. Then in 1972, the FDA approved methadone for treating opioid dependence. This opened the door to increased physician involvement, for methadone treatment required physicians to prescribe and manage the medication. For the first time since before the Harrison Act, physicians played a prominent role in addiction treatment.

Physician entry into addiction treatment, however, occurred at a snail's pace. The federal regulatory structure requiring methadone to be provided within OTPs rather than regular physicians' offices, yet most physicians had never visited an OTP or to their knowledge encountered methadone patients. As a result, the majority perceived they had no reason to become involved in methadone treatment and, lacking sufficient knowledge about the medication, even failed to refer patients. Even physicians who would otherwise have referred patients for methadone treatment were sometimes prevented from doing so by the lack of local OTPs, especially in rural and suburban areas). Thus, despite the availability of an effective pharmacological treatment, physicians continued to simply refer patients to counseling and support groups without further involvement in the treatment process.

This perception that addiction treatment is the exclusive realm of counselors and support groups continues today among medical professionals. According to one recent study of medical students' attitudes when confronted with addiction patients, "[t]hey rarely mentioned addiction treatment, and when they did, they perceived it as something that was done by specialized counselors out in the community. At most, they perceived that the physicians' role was to identify and refer."⁶⁹⁴ Unlike in the 1970s, however, physicians can now prescribe in-office two pharmacological treatments for opioid dependence: buprenorphine and extended release-

naltrexone.

In my interviews with physicians, a few stated that they expected more physicians will enter the addiction treatment field as the number of pharmacological treatments increase. The increasing availability of pharmacological treatments for addiction may suggest to physicians that they have an important role to play other merely providing referrals. Furthermore, for those physicians who view addiction as a choice rather than as a disease, the availability of pharmacological treatments is persuasive evidence that addiction is a disease similar to other chronic health conditions. But without widespread physician education about addiction treatment and effective treatment methods, physicians will continue to remain disengaged from this field of practice.

III. Limited Education in Addiction Medicine

Many physicians feel unprepared to treat addiction, and a large minority have never heard of MAT, primarily due to a lack of education.⁶⁹⁵ Addiction medicine is rarely taught in medical schools, residency programs, or in continuing education courses.⁶⁹⁶ When addiction medicine is taught, it typically comprises only a very small part of the curriculum or an elective course. These minimal educational offerings in addiction medicine are disproportionate to the significant numbers of dependent patients and to the fact that addiction is a public health crisis that is still intensifying. For example, although the percentage of hospitalized patients with addiction is approximately the same as that with diabetes—25%--medical school and residency curricula devote significantly more attention to the latter.⁶⁹⁷

In a survey of internal medicine residents, 37% reported that they had not received *any* instruction related to addiction in medical school. Of the 63% who had received some addiction training in medical school, only 47% received more than a single lecture and only 25% were

exposed to an addiction patient.⁶⁹⁸ Such minimal education is shocking in light of the opioid overdose epidemic. In an interview with the *New York Times*, Dr. Seitz, from Boston University, stated, "[t]here's no word for educational malpractice, but not to train people in drug abuse when you're training them for H.I.V. or Hep C reduction is ridiculous."⁶⁹⁹

Even when physicians are provided with addiction medicine education, its quality may be woefully inadequate. In a study of internal medicine residents, 55% rated overall addiction medicine instruction in their residency programs as "poor" or "fair." ⁷⁰⁰ Physician 16, director of a medical school addiction medicine fellowship program at a medical school told me that, until a few years ago, psychiatry residents' training in addiction medicine consisted of observing 12-step groups and a brief lecture. Strongly disagreeing with this minimalist approach, the director pressured the psychiatry residency program to incorporate education about MAT, counseling, and more medicalized approaches to addiction treatment. According to the director, this prior observational approach reinforced residents' presumptions that addiction treatment is not a professional medical endeavor.

The limited addiction education in medical schools and residency programs is strongly related to the low percentage of medical school faculty who are trained in addiction medicine.⁷⁰¹ Curriculum instruction and instruction from attending physicians are both positively related to a physician's self-perceived efficacy in treating addiction.⁷⁰² Moreover, addiction medicine faculty could serve as role models for students and residents, helping them to understand negative patient-physician interactions in light of addiction symptoms.

Just as medical students and residents feel underprepared to treat addiction in general, the majority of physicians have limited knowledge about MAT specifically. In a study that provided questionnaires to 101 medical residents, no resident answered all six questions about addiction

medicine correctly, almost half failed to correctly identify the mechanism of buprenorphine treatment, and 81% failed a question regarding naltrexone treatment. Only 6% of residents answered all three questions about MAT correctly.⁷⁰³

Limited education in medical school and residency programs also translates into physicians' minimal comfort treating addiction once they are in practice, including low self-efficacy implementing MAT.⁷⁰⁴ In one study of medical residents, 25% felt unprepared to diagnose addiction and 62% felt unprepared to treat addiction. No residents reported feeling "very prepared" to treat addiction. Another study of primary care residents undergoing training in a public hospital found that the majority had low self-efficacy in addiction management.⁷⁰⁵ Shockingly, such discomfort extends to psychiatrists, the physician specialty with the most training in addiction medicine (though it is still inadequate), as well as relatively high levels of contact with patients suffering from substance abuse disorder.⁷⁰⁶ A 2004 survey of 1,203 practicing psychiatrists found that 80% felt uncomfortable prescribing buprenorphine for addiction.⁷⁰⁷ Even among those psychiatrists specializing in addiction psychiatry (i.e. having completed a fellowship in addiction psychiatry), 43% felt uncomfortable prescribing buprenorphine.⁷⁰⁸

Fortunately, implementing addiction treatment curricula in medical school or residency programs is correlated with increased physician preparedness to diagnose and manage addiction.⁷⁰⁹ Even brief educational interventions increase medical students' knowledge, attitudes and clinical skills.⁷¹⁰ A meta-analysis of addiction training found that the several features are especially helpful: exposure to patients in treatment and long-term recovery; clinical work supervised by a physician experienced in treating addiction; and integrating education interventions into the general medical school or residency curriculum.⁷¹¹ Taking time in the

curriculum for student reflection (through journaling, for example), de-briefing sessions and discussions of their feelings towards drug dependent patients can also assist in learning and empathy-building.⁷¹²

Effective training for students and residents can also be provided through innovative online modules. In one study, nursing students and medical students were provided access to an online educational platform that included case vignettes, online chat sessions with individuals pretending to be patients that allowed students to practice drug history screenings and brief interventions, and "choose your own adventure"-style case scenarios. The training led to a dramatic rise in participants' perceived self-efficacy in addiction treatment; prior to the training, only 10% of students rated their self-efficacy as "good" or "great;" while 60% did after the training.⁷¹³

The federal and state governments have historically heavily subsidized medical schools, thus playing a key financial role in curriculum expansion. In previous decades, university presidents and planners could move forward with medical expansion under expectation of federal subsidies. For example, in the mid-1960s, Federal subsidies accounted for approximately 50% of medical school revenue; medical schools also received subsidies from states. As a result, the number of medical school graduates doubled in that era.⁷¹⁴ In contrast, in recent years federal funding to medical schools has been slashed. In 2010, over 50% of American Association of Colleges of Medicine schools reported concern with economic conditions for maintaining and increasing enrollment. At the same time, the cost of medical school has increased significantly, growing at twice the rate of inflation in recent years. Even though some states are providing one-time start-up funds for medical school expansion, ongoing funding is limited. Some medical schools are able to obtain lucrative private donations, but such donations frequently come with

strings attached and rarely target psychiatry or addiction medicine. One psychiatrist told me that fundraisers for the psychiatry department at his university are some of the most difficult to get people to attend and donate to, because psychiatric issues (including addiction) are stigmatized.

In light of the U.S.'s public health needs, medical schools must expand enrollment, especially in psychiatry, primary care, and other areas of medicine with physician shortages. Likewise, medical schools must expand curricula to include more classes about addiction medicine, as well as hire more faculty members trained in addiction medicine. However, in order for such expansion to take place, the federal and state governments must increase funding for medical schools.

For physicians already in practice, online or in-person courses are shown to improve selfefficacy and desire to treat addiction. In one study, after four hours of online buprenorphine training and 3.5 hours of in-person buprenorphine training, 67% of participants intended to prescribe buprenorphine.⁷¹⁵ Prior to the training, only 2% had experience in prescribing buprenorphine.⁷¹⁶ In another study which combined four hours of online buprenorphine treatment education and a few hours of in-person training, 85% of physicians wanted to learn more about buprenorphine and observe buprenorphine treatment firsthand. In particular, meeting with patients undergoing buprenorphine treatment was shown to improve physician confidence in prescribing the medication.⁷¹⁷ During patient meetings, physicians learned about transitioning patients to buprenorphine and strategies for monitoring and relapse prevention.⁷¹⁸

Physician mentorship programs may also aid physicians beginning to treat addiction for the first time. The Physician Clinician Support System, established by SAMHSA, is a national mentoring network to assist physicians with buprenorphine treatment. In the Support System, mentors experienced in buprenorphine treatment provide assistance via phone, email or by

visiting the less experienced physician's clinic.⁷¹⁹ In-person assistance is particularly helpful for physicians who cite hesitancy with buprenorphine induction as a barrier to treatment—according to one study, approximately a quarter of physicians.⁷²⁰

Experts' educational outreach to physicians may also increase buprenorphine treatment adoption.⁷²¹ In 1998, NIDA organized a six-state educational outreach program in which physician experts in addiction medicine recruited local less-experienced physicians to attend a free regional training. After the training, recruited physicians began treating patients with buprenorphine in their offices (in what was essentially a clinical trial). Recruited physicians had access to experts in case they had questions or concerns. Ultimately, physicians only initiated expert consultations on isolated occasions, and both physicians and patients expressed high degrees of satisfaction with buprenorphine treatment.⁷²²

Federal and state departments of health should expand funding and grant opportunities for outreach programs targeting practicing physicians. Programs could be modeled on the NIDA program described above. As an additional incentive for addiction treatment, states could fund participation in the online certification courses necessary for physicians to begin prescribing buprenorphine (under DATA). States could require physicians who obtain such funding to practice addiction medicine in the state for a specified number of years and to accept Medicaid.

IV. Not Understanding Addiction as a Disease

Even though the AMA has called addiction a disease since the 1930s, some medical students hold biases towards individuals with drug dependence that mirror biases held by the American public. One survey found that medical students tended to view addiction as a dependent individual's personal choice, causing them to feel angry towards patients who continued to harm themselves with drugs.⁷²³ Medical students frequently believed that patients

suffering from addiction continued to abuse drugs because they enjoyed drugs, did not know better, or did not care about the harms that addiction could cause.⁷²⁴ These erroneous opinions prompted some medical students to express disinterest in treating addiction; as one medical student responded, "I think it will be difficult to deal with people who don't want to take an active role in improving their health." Medical students' failure to view addiction as a disease translates into poor quality physician-patient interactions. Alarmingly, the study authors stated, "[medical] students did not appear to react as physicians when confronted with addiction patients. They did not discuss clinical features, diagnosis, medical treatment, or advice. . . . They did not convey a sense of therapeutic optimism and pride in their acquisition of clinical skills needed to help addicted patients."⁷²⁵

Medical students likely carry these biases into their practice careers. Even a group as well-educated and motivated to help others is not immune to the negative sociocultural depictions of dependent individuals that appear in movies, music, and the news. Fortunately, one study found that recent medical school graduates are less likely than older graduates to hold biased views towards addiction patients, suggesting that positive changes are occurring. Primary care (family medicine) physicians have also expressed apathy towards treating drug dependence.⁷²⁶ This apathy is probably a cover for personal bias or other factors underlying their reluctance to treat addiction that they are hesitant to discuss. It is difficult to imagine a physician being genuinely disinterested in treating diabetes, asthma, or another serious chronic condition for which effective medication is available. Primary care physicians may be concerned that, once word gets around that they prescribe buprenorphine, individuals with opioid dependence will be lining up at their doors, especially given the undersupply of DATA-qualified physicians.

that the stigma surrounding SUD patients rubs off on their treating physicians, so that the public begins to stigmatize the doctor as well. The stigma of addiction is deeply engrained in American culture and will take a long time to eliminate. If more physicians begin treating dependent patients, however, then the public may increasingly view addiction as a disease rather than a personal choice.

A similar process of re-education and de-stigmatization occurred with professional and public perceptions of depression and depression treatment. As physicians began treating depression with effective pharmaceuticals, the public increasingly began to view it as a disease resulting from a neurological chemical imbalance rather than a personal or moral shortcoming. Even though depression is still stigmatized, this stigma has decreased since the disease has come to more commonly be perceived as an illness meriting medical treatment.

V. The Perception of Addiction Patients as "Difficult"

Some research suggests that physicians also do not wish to treat patients suffering from addiction because such patients are rumored to be "difficult," meaning that they act in undesirable and antisocial ways such as being manipulative and dishonest.⁷²⁷ According to physicians whom I have interviewed, many dependent patients do exhibit such negative social behaviors during appointments in order to obtain prescription drugs. However, these physicians also explained that these negative behaviors are symptomatic of the addiction disease, not as inherent and immutable personality traits. Once physicians recognize that such negative behaviors are symptoms, they can focus on treating the disease.

Understanding addiction behaviors as disease symptoms require empathy for the patient—the willingness to put themselves in the patient's shoes and to imagine how they experience the world. Studies suggest that empathy is a critical factor in treatment relationships

and enhances treatment success. According to Wakeman et al., increased exposure in residency to dependent patients may itself increase empathy.⁷²⁸ Additionally, empathy training may help physicians understand the reasons for negative interactions between dependent patients and treating physicians and learn not take them personally.⁷²⁹ Additionally, physicians should be taught communication skills to use with dependent patients so they can more readily facilitate discussions rather than being confrontational and angry.⁷³⁰ Otherwise, patients confronted with a physician who seems annoyed or hostile may feel that they are being intentionally mistreated. These modest educational innovations, including training in evidence-based addiction treatment, empathy, and communication skills, may help physicians to realize that treating addiction patients is not significantly more difficult than treating patients with other chronic illnesses.⁷³¹ Like other chronic relapsing diseases (e.g. hypertension), drug dependence can be effectively managed with monitoring, medication, continuity of care, and re-intervention when needed.⁷³² In fact, when effectively managed drug dependence has lower relapse rates than both asthma and hypertension.⁷³³

VI. <u>Negative Interactions With the Criminal Justice System</u>

A large percentage of individuals with opioid dependence are involved in some way with the criminal justice system, through mechanisms such as probation, parole, or incarceration. Individuals in drug court, on parole, or on probation may seek medical treatment in the community. When these individuals seek treatment from a physician, the physician is essentially forced to interact and coordinate care with criminal justice administrators, such as probation officers and drug court case managers. Some physicians may not wish to treat patients this extra baggage with them, which not only carries the potential of stigmatization but also means more time-intensive administrative work to complete on top of an already demanding schedule.

But physician communication with criminal justice system administrators may not only be time-consuming; it may be fraught with discord as well. Within the criminal justice system, MAT is underused and often misunderstood with abstinence-only treatment philosophy being the norm. Thus, relationships between criminal justice administrators and physicians prescribing MAT may be tinged with distrust. This discord may be compounded if physicians and criminal justice administrators approach information-sharing differently, as is often the case.

Drug court case managers and probation officers commonly want physicians to provide them with detailed treatment information about patients. Physicians I have interviewed report that such information often includes urine screening results, notes of patient-physician conversations, and appointment attendance information. However, physicians usually are averse to sharing any information besides appointment attendance records—and will share that information only after a patient signs an information release.

Physicians highly value patient data confidentiality for two reasons. First, encouraging patients to be open and honest allows physicians to obtain more information, and the more information the physician has, the better quality treatment she can provide. For example, physician 4 explained how a patient in drug court attended a medical appointment with his case manager. During the appointment, the patient answered the physician's questions in a curt and evasive manner. A few minutes after the appointment ended and the patient and case manager left, the patient reappeared alone and explained that he wanted to provide different answers to the physician's questions now that the case manager was gone. The patient's initial set of answers had been influenced by fears that the case manager would share certain details with the drug court judge, who in turn would use it to impose sanctions.

Second, physicians fear that sharing patient information with criminal justice administrators will lead to the imposition of additional punishment as opposed to improved medical treatment. For example, physician 4 is very frustrated when probation officers request urine screening results since such screening serves *medical* purposes such as assisting her in determining proper dosages and ascertaining whether she should try a new treatment. In the criminal justice system, however, urine screening serves very different purposes, namely the disciplinary aims of detecting and punishing violations. The psychiatrist described a situation where a coworker accidently revealed a patient's urine screening results in which he tested positive for drug use to his probation officer; this evidence of drug use allowed the drug court to penalize him by jailing him for one week. Because the psychiatrist could not treat the patient while he was incarcerated, this jail time was a step backward in the addiction recovery process.

But not all physicians view interactions with the criminal justice system negatively. Although no physician I interviewed ever agreed that imprisonment was an appropriate consequence of relapse, a few have remarked that requiring a patient to be accountable to someone else, whether a relative or a probation officer, can encourage treatment adherence—as a result, medical and penal goals are aligned. Thus, physician and criminal justice system interactions can be positive and mutually beneficial so long as their goals are clear: providing evidence-based treatment and encouraging treatment adherence. Additionally, such interactions should have clearly defined rules: physicians should be able to provide MAT if they feel it is medically advisable, and should not be required to share any information they feel could hurt the treatment process. Describing her annoyance at probation officer requests for urine test results, one physician quipped, "I don't work for the criminal justice system! I'm a physician!" For their part, criminal justice administrators should understand that physicians' resistance to information
sharing does not represent distrust or dislike of the criminal justice system, but rather reflects physicians' desires to safeguard patient health and adhere to their professional ethics.

VII. Concerns about Treating Co-Occurring Conditions

Opioid dependence co-occurs frequently with other medical conditions, including chronic pain and other mental health conditions (such as depression, post-traumatic stress disorder, or bipolar disorder). According to one study, 22% of primary care patients suffer from chronic pain⁷³⁴; another study estimates that 4-25% of primary care patients suffering from chronic are also opioid dependent. Moreover, some studies estimate that up to 80% of individuals suffering from addiction also suffer from a serious mental health condition, including depression, bipolar disorder, schizophrenia, and generalized anxiety disorder. Patients suffering from non-sports related trauma (e.g. sexual abuse, child abuse, domestic violence, physical abuse) are at significantly higher risk of substance abuse disorder.⁷³⁵

Opioid dependence and chronic pain patient populations often overlap. Up to 20% of primary care patients treated with opioids for chronic pain also suffer from opioid dependence. Physicians treating patients suffering from both chronic pain and opioid dependence may face particularly significant challenges; physicians report low self-efficacy for treating both addiction and for managing chronic pain (a problem particularly common for primary care physicians).⁷³⁶ These perceptions of low self-efficacy may derive from the fact that medical school and residency program curricula include only limited (if any) education about the interaction between pain management and substance abuse treatment.⁷³⁷

Physicians also face challenges when treating patients suffering from both SUD and a cooccurring mental health condition. Medical professionals, particularly those who are not psychiatrists and who lack extensive training in treating patients with co-occurring mental health

conditions, may also feel discouraged when treating patients with SUD. It is not enough for medical school, residency, and continuing education curricula to address addiction treatment, chronic pain management, and mental health conditions individually; rather, such courses must prepare physicians to treat patients suffering from combinations of these illnesses.

VIII. <u>Regulatory Concerns</u>

Buprenorphine and Vivitrol are the only two addiction treatment medications that may be prescribed in a physician's office rather than an OTP. Of the two medications, buprenorphine is arguably more accessible to patients because of its lower cost, its greater likelihood of being covered by commercial health insurance or Medicaid, and its shorter detoxification requirements (patients must detox for three days versus detoxifying completely under Vivitrol). Buprenorphine is also more readily available than methadone, which can only be prescribed in an OTP. Many cities (and, unbelievably, some states) lack OTPs. Additionally, methadone is heavily stigmatized and not always covered by Medicaid or commercial health insurance. Some studies have found that, given the choice between buprenorphine and methadone, more patients prefer buprenorphine.⁷³⁸ Therefore, while physicians should be trained to administer all of forms of MAT, it is especially crucial to prioritize buprenorphine treatment.

Unfortunately, the Drug Addiction and Treatment Act of 2000 (DATA) imposes severe restrictions on buprenorphine treatment such as 100-patient limits and physician certification requirements that do not exist for any other FDA-approved medication, including oxycodone and other pain killers.⁷³⁹

Merely knowing of these patient limits may deter medical students or residents from entering the addiction treatment field, prompting fears of profound government intrusion and low salaries due to limited patient populations. These patient limits directly interfere with physicians'

ability to meet demands for addiction treatment. In early 2016, ASAM surveyed over 1,300 addiction specialists to assess the severity of waiting lists; 66% of participants stated that they had patient demand exceeding the 100-patient limit. This means that more than half of physicians are forced to turn away patients seeking buprenorphine treatment.

Some physicians may also be deterred from prescribing buprenorphine because they assume that obtaining a DATA waiver will be too time-consuming or labor intensive.⁷⁴⁰ However, there are few ongoing, time-consuming requirements for a doctor to comply with under DATA after obtaining a DATA waiver other than an eight-hour training course, Nevertheless, the waiver requirement may filter out those physicians who are not highly motivated to treat addiction.⁷⁴¹ In an ideal world, such filtering would be a distinct advantage. But given the current realities of limited numbers of addiction treatment providers and high patient demand, such filtering harms patients by limiting provider access.

For years, professional medical associations such as the AMA and ASAM, have supported looser patient limits and allowing highly trained physician assistants and nurse practitioners to prescribe buprenorphine. In remarks to Congress, a representative of the AMA stated,

The advantages of reducing the regulatory burdens to prescribing suboxone would not only increase the availability of suboxone treatment, but would also increase clinical identification, awareness, and acceptance of opiate addiction as a disease and reduce stigma associated with opiate addiction.⁷⁴²

If the patient limit is increased, more physicians may consider entering the addiction treatment field. However, some physicians fear that increasing the patient limit will encourage so-called "suboxone mills" to spring up, wherein greedy physicians will dole out buprenorphine like candy without properly managing patients. Anecdotal evidence suggests that the few physicians operating "suboxone mills" tend to operate on a "cash only" basis, and do not accept Medicaid or even commercial insurance. Most physicians are highly skeptical of "cash only" practices; not only do "cash only" physicians price themselves out of the market for most addiction patients, they may indirectly encourage addiction patients to sell some of their medication for cash to pay for appointments. I have spoken with a few "cash only" addiction treatment physicians, and they argue that insurance reimbursement is too low to cover their appointment costs. Rather than accepting insurance, therefore, they charge patients approximately \$200 per month for a buprenorphine treatment appointment. Once the patient obtains a prescription, she then pays for the medication with Medicaid or commercial insurance at a local pharmacy.

Assuming that "suboxone mill" physicians tend to adopt "cash only" policies, the government could limit suboxone mills by only increasing patient limits for physicians who accept insurance, including Medicaid. Medicaid involvement would increase oversight of physicians' practices, and patient access would improve due to Medicaid coverage.

IX. Presuming that Few Patients Suffer from Drug Dependence

A surprising number of physicians believe that drug dependence is not widespread within their patient populations. A study of primary care physicians revealed that a significant minority stated that they do not treat addiction using MAT because they think only a few of their patients are drug dependent.⁷⁴³ Not surprisingly, physicians who believe that this crisis has affected only a few of their patients also have limited motivation to seek a DATA waiver to prescribe buprenorphine. Most physicians, however, are likely naïve in believing that so few of their patients are opioid dependent, given the recent epidemic of opioid dependence and overdoses.⁷⁴⁴ Studies have shown, for instance, that up to 25% of primary care patients prescribed opioids for chronic pain also suffer from opioid dependence.⁷⁴⁵ In outpatient settings, an estimated 10-16% of patients suffer from a substance abuse disorder, including patients without chronic pain).⁷⁴⁶ In inpatient settings, 25 to 40% of admissions are related to substance use.⁷⁴⁷ Drug use disorders are common in persons of all ages, sexes, ethnicities and socioeconomic backgrounds.⁷⁴⁸

Patients with SUD may feel uncomfortable discussing their condition with their doctors, especially if they have not received any signal from them suggesting that treatment is available or that such a conversation would be welcomed. When physicians *a priori* believe that few patients suffer from drug use disorders, they may fail to screen patients from drug use. A failure to screen patients may be due to a lack of training or simply physicians' discomfort discussing addiction with patients. Unfortunately, the SUD screening rate is currently low. A 2010 study of family physicians found that only 50% screened for tobacco use and less than 1/3 screened for alcohol use.⁷⁴⁹ Although not reported, screening for other drug use is likely even less common.

Screening refers to the combination of a carefully elicited verbal history and a urine test, the most effective process for detecting SUD.⁷⁵⁰ A urine screen alone is not enough because the patient may suffer from drug dependence but any drugs may have already left the patient's body. Additionally, if a urine test is positive for drugs, there may be a reason for the drug's presence other than an SUD. Therefore, the patient's verbal history is a particularly important part of the screening process.

In order to elicit the patient's verbal history, however, the healthcare provider must feel comfortable discussing addiction. Substance dependence is so stigmatized in American culture that some medical practitioners feel uncomfortable broaching the subject during medical appointments. In an anecdote from my own health care experiences, I remember once attending an annual primary care visit during which the nurse asked routine questions about alcohol and

drug use while laughing, which gave me the impression that she thought it ridiculous to be asking me these questions when I appeared to be a successful professional. Although I could not read the exact reason for the nurse's laughter—whether she genuinely thought drug addiction was funny or whether she was laughing to indicate her nervousness about asking me these questions for fear I would take offense – I interpreted this interaction as indicative of a judgment that certain groups of people were more likely to suffer from drug dependence than others, a lack of training in drug screening and a lack of knowledge about the full extent of drug dependence in the U.S. But such an interaction may make persons with dependency too embarrassed to disclose their drug use. Patients might not only might patients feel uncomfortable disclosing drug use in that nurse's office, but might carry the experience with them into future medical settings, convinced that all health practitioners would have such judgments.

I later recounted this story to one physician who interpreted the nurse's behavior as discomfort discussing drug use. In her opinion, nurses and physicians want to help patients with addiction, but fear that screening will initiate an uncomfortable or embarrassing interaction. As a result, they prefer to skim through screening questions or to laugh. If a patient appears to be a professional or a wealthy, powerful individual, then the nurse or physician may feel even more uncomfortable asking about drug use. Making drug screening a routine part of patients' examinations regardless of whether or not they presenting symptoms of an SUD will make patients and physicians more comfortable with the screening process.⁷⁵¹ Therefore, routine SUD screening should be encouraged as a medical best practice, especially in the fields of primary care, psychiatry, emergency care, and pain management, all of which have relatively high rates of patients with SUD).

X. Presuming that only Psychiatrists are "Qualified Physicians" to Treat Addiction

Under DATA, any physician who obtains a DATA waiver from SAMHSA, registers with the DEA, and follows patient limits may prescribe buprenorphine. However, in practice, most physicians who prescribe buprenorphine are psychiatrists. Because psychiatrists undergo significant training in neuroscience and co-occurring mental health diseases, they may receive the ideal training to prescribe buprenorphine. Many psychiatrists I have interviewed have articulated this viewpoint. But the opioid epidemic has forced practitioners and patients into an untenable position. The U.S. is facing a severe shortage of psychiatrists in combination with rising rates of opioid dependence. For this reason, we cannot rely on psychiatrists being the primary prescribers of MAT. Other more accessible providers should be involved, especially primary care physicians. Ideally, physician assistants and nurse practitioners should also be permitted to prescribe MAT.

Primary care physicians are usually the first physicians whom patients see for addiction treatment. Because commercial insurance providers such as HMOs often require a referral from a primary care doctor before a patient sees a specialist, primary care physicians are the "gateway" to medical treatment.⁷⁵² Even if referral to a specialist is not required, primary care physicians may have more appointments available. Additionally, some individuals do not know what type of specialist they should see, so they schedule an appointment with a primary care physician to obtain guidance through the maze of options. In some towns, only primary care doctors are available because the population size is too small to support specialists. One study of psychiatrists' distribution concluded that "[t]hey are rare or nonexistent in rural America."⁷⁵³

Primary doctors also typically have lower appointment fees than specialists,⁷⁵⁴ and so may be more affordable for individuals in the low-income brackets to which SUD is correlated. ⁷⁵⁵ Moreover, patients may have seen their primary care physicians as "family doctors" for

years,⁷⁵⁶ so that they might be more familiar with a patient's background, health history, and needs than a specialist whom the patient has never seen before. For example, a primary care physician may notice that a patient is behaving differently, perhaps suggesting a SUD.⁷⁵⁷ In contrast, physicians without long-term knowledge of the patient may fail to notice t addiction symptoms. Lastly, an appointment with a primary care physician provides anonymity for patients suffering from drug dependence, because primary care physicians also treat a wide variety of less stigmatized conditions. Thus, seeing a psychiatrist is more stigmatizing than seeing a primary care physician.⁷⁵⁸

The reason for low DATA waiver rates among primary care doctors is not fully understood, but published studies point to a few possible explanations.⁷⁵⁹ First, many primary care doctors feel that they know too little about drug dependence to provide adequate treatment or believe that they are otherwise underqualified.⁷⁶⁰ Some primary care physicians may assume that only psychiatrists are knowledgeable enough to prescribe buprenorphine, even after an eight-hour training course (as required by DATA). This view, however, has no empirical support. According to an article published in the Annals of Family Medicine, 54% of patients were sober following six months of buprenorphine treatment from a primary care doctor, with no difference in settings.⁷⁶¹ Primary care physicians already prescribe the majority of psychoactive substances nationally.⁷⁶² Additionally, primary care physicians may feel that they lack time to treat patients with addiction, given that these patients are more time-consuming and many primary care physicians already work late hours. They may also fear inadequate reimbursement or other patient barriers (see below).

XI. Lack of an Integrated Counselor-Physician Relationships

MAT is most effective when provided in conjunction with counseling,⁷⁶³ though the two

services need not be provided by the same individual or within the same institution. Some insurers will not reimburse physicians for MAT until they document that the patient is undergoing counseling. Furthermore, DATA requires that a physician have the capacity to refer a patient for counseling in order for to obtain a DATA waiver. Unfortunately, many physicians feel both unable able to provide counseling and unable to refer patients for counseling due not knowing the qualified counselors in their area.

Lack of support from behavioral care professionals, especially mental health counselors, is a common barrier to primary care physicians prescribing buprenorphine.⁷⁶⁴ In one study of primary care physicians, the physicians noted that a lack of support from mental health counselors was the primary reason they did not prescribe buprenorphine treatment.⁷⁶⁵ All physicians whom I have interviewed believed that buprenorphine treatment should be provided in conjunction with counseling, but many felt undertrained to provide counseling themselves. Even psychiatrists who have received training in counseling typically prefer to refer patients to another therapist for counseling.

Numerous studies have proven the efficacy of treating opioid dependence through a combination of physician-prescribed MAT and counseling provided by a mental health professional such as a psychologist or social worker. If a physician providing MAT can refer their patients to counselors, in theory this treatment should pose no problems. In some cities, however, there are not enough counselors who are experienced and/or willing to treat addiction. Even if sufficient numbers of counselors are available, they may not accept commercial health insurance or Medicaid. A primary care physician who provides buprenorphine treatment told me that he is trying to encourage other physicians in town to do so as well, but the physicians cannot find a qualified counselor who accepts Medicaid to whom they can refer patients. As a result,

these other physicians are not providing buprenorphine treatment. In response, the primary care physicians has personally called every counselor in his town and the surrounding area to create a database of counselor information to distribute to other physicians, including whether they are accepting new patients, what types of insurance they accept, whether they are willing to treat addiction, and whether they are experienced in this field

Physician No. 14 began treating addiction in Southern treatment facility that provided three services: MAT, counseling, and non-twelve-step support groups. She described this setting as an ideal "one-stop-shop" for patients. When the physician moved from the South to the Midwest, she stopped treating addiction because she no longer worked in a facility that provided patients with access to all three services, and currently only treats pain. When I asked her why she did not simply refer patients to an outside counselor, she replied that she only knew of a handful of counselors who were both willing and experienced in treating addiction but they were not accepting new patients.

In addition to increasing physician education about MAT, we must make more educational and training opportunities available to counselors and social workers as well because these mental health professionals must coordinate their addiction treatment efforts with physicians.⁷⁶⁶ These programs should be targeted towards students as well as practicing professionals, and must address the "abstinence-only" resistance to MAT that is pervasive among many mental health professionals.⁷⁶⁷

XII. <u>Lack of Institutional Support</u>

Even physicians who would like to begin treating addiction patients may find that their institutions or co-workers disapprove and prefer to refer patients outside to other programs. In a study of the barriers to buprenorphine treatment that Washington state primary care physicians

had encountered, 42% cited resistance from practice partners and 36% cited institutional resistance.⁷⁶⁸

Co-workers and administrators may fear personal stigmatization for treating addiction, just as physicians who practice addiction medicine face stigma from the public and even their colleagues in the medical community.⁷⁶⁹ This stigma is a corollary of the popular cultural phenomenon of labeling individuals with dependency as immoral and those who help them including medical professionals--as enablers. Co-workers and administrators may also fear that "difficult" addiction treatment patients will be lining up at their doors, prompting patients without dependency to seek care elsewhere.

Staff and structural characteristics both influence whether an institution is more or less likely to adopt MAT. Ducharme and Roman (2009) found that structural factors are even more predictive of MAT adoption than staff structures.⁷⁷⁰ In particular, institutions were more likely to adopt MAT if the possessed accreditation, were affiliated with a hospital, provided inpatient care, and provided detoxification services.⁷⁷¹ Not surprisingly, institutions practicing abstinence-only treatment are particularly resistant to adopting MAT. Likewise, institutions that are unaffiliated with hospitals or other medical practices are more likely to resist MAT, possibly due to less physician involvement.

When organizations accept MAT, this frequently motivates practitioners to adopt such treatment options.⁷⁷² D. Simpson, an expert on knowledge diffusion in medicine, argues that top-down, institutional change in practices requires exposure to a new practice and a perceived need to change, a decision to adopt that practice (which requires that individuals believe the practice has utility, a consensus that the product has utility, and effective organizational leadership); the implementation of the practice (including resource allocation and training); and the

institutionalization of the change.⁷⁷³ The entire process may take years from start to finish.

Staff attributes may also affect whether an institution adopts MAT. Younger individuals with more professional training are more likely to accept changes in practice than older individuals without professional training.⁷⁷⁴ A physician working in an SUD recovery center likely is part of a team of other treatment providers, including counselors. In team work settings, all members need to support MAT implementation. However, counselors who are philosophically inclined aligned with self-help or abstinence-only methods may be averse to institutionalizing MAT, even if they support the use of medications for treating other conditions.⁷⁷⁵ In organizations where staff is resistant to MAT, all staff members, including non-physicians, should receive continual MAT education and training. Education about buprenorphine, for example, has been shown to change even resistant health care providers' attitudes.⁷⁷⁶

In contrast, primary care physicians typically work in an individual clinical practice where pharmacotherapy is central to disease treatment, and thus may experience less resistance from staff regarding MAT. But staff may resist other consequences that are may be associated with MAT, including low insurance reimbursements, stigma, and bureaucratic hurdles. Smaller physician practices may worry that they lack adequate staffing to manage addiction treatment. Physician 1, a primary care physician, cited limited staffing for urine screenings as a primary point of resistance. This resistance seems odd, however, considering the frequency with which urine screenings are used in diagnosing and treating other conditions in primary care practices, such as pregnancy and urinary tract infections. Other physicians I interviewed noted concerns about the increased staff time needed to complete insurance pre-authorizations and other insurance matters. Administrators may dislike hiring additional billing staff to complete pre-

authorizations. When these hurdles are combined with other concerns such as lower reimbursement, increased governmental oversight, and potential stigma, it is easy to see how well-meaning physicians and their administrators may be reluctant to implement MAT. Many of these fears, however, are arguably unsubstantiated and may never come to pass. If physicians and administrators visit other offices that offer addiction treatment, they may learn that it is not as difficult as it may appear.

Sometimes institutional change begins at the bottom, at the provider level. Physician 4 works for a large SUD and mental health treatment organization serving thousands of patients. Until two years ago, this institution not only did not provide MAT, it was a classic "abstinenceonly" institution that explicitly banned patients undergoing agonist treatment from participation. When the psychiatrist joined this organization, she brought with her extensive experience in MAT from prior employment at a methadone clinic and in an office-based practice providing buprenorphine and Vivitrol treatment. Despite her lack of a formal leadership role within this organization, within one year she had dramatically changed institutional beliefs about MAT. She organized educational seminars about MAT for all staff members including counselors, physicians, and administrators. After she successfully petitioned the administration to permit her to provide MAT, she became the first physician to prescribe buprenorphine and Vivitrol. Coworkers and administrators saw positive results from MAT, yielding increased cultural acceptance of MAT. The psychiatrist observed, however, that there are still lingering pockets of resistance, particularly from "recovery coaches," who are counselors serving as case managers instead of providing mental health therapy. These recovery coaches tend to lack a graduate degree, are likely in recovery themselves using "abstinence only" methods, and directly interact with criminal justice administrators. Sometimes counselors improperly tell patients that they

should try to wean off MAT as quickly as possible. Thus, the psychiatrist must continually remind her co-workers that long-term use of MAT is more effective than short-term use. She stressed the importance of providing regular, ongoing education about MAT to all staff members.

State mental health authorities can also influence an organization's culture, particularly at organizations with state contracts. One study of information diffusion in 50 states and the District of Columbia found that state contracts mandating MAT use were strongly predictive of MAT implementation.⁷⁷⁷ State authorities can also encourage institutional adoption of MAT through "softer" means, such as educational outreach. The study also found, however, that state authorities sometimes fail to clearly convey their priorities to institutions, including whether or not MAT should be implemented.⁷⁷⁸ Finally, state Medicaid coverage of MAT is a significant predictor of MAT adoption among institutions and individual providers.⁷⁷⁹

XIII. Insurance Barriers

The Affordable Care Act (ACA) incorporates requirements under the Mental Health & Addiction Parity & Equity Act of 2008 (MHAPEA). The MHAPEA prohibits differences in treatment limits, cost sharing, and in-network/out-of-network coverage between treatment for physical illness and treatment for mental health or SUD treatment. Under the ACA, MHAPEA now applies to Medicaid managed care organizations, the Children's Health Insurance Program, small and large employer funded plans, commercial health insurance sold on the Marketplace, and Medicaid Alternative Benefit Plans.⁷⁸⁰ The MHAPEA does not apply to traditional fee-for-service Medicaid; however, less than 20% of Medicaid enrollees nationwide participate in fee-for-service plans.⁷⁸¹

Despite the parity required under the ACA and MHPAEA, many health insurers continue

to place onerous burdens on addiction treatment policy holders and their physicians. In interviews with 16 physicians, whenever I asked whether they believe such parity actually exists, the answer has been unanimous: no. Some physicians' responses have been tinged with anger or sarcasm, such as "Absolutely not!" and "Oh, is there supposed to be parity? I've never seen it!" When I attended an annual ASAM conference, I heard frustrated physicians from around the country airing their grievances about the lack of insurance parity and the burdens it imposed. Foremost among these burdens were time-consuming preauthorization requirements applied only to addiction treatment that struck many physicians as being medically unsound.⁷⁸²

For example, multiple physicians explained that, when completing pre-authorizations for buprenorphine, they must tell the insurance company how soon they plan to wean the patient off of the medication. Some insurance companies require physicians to promise in writing to wean the patient off after six months or one year. Medical studies clearly conclude, however, that longterm buprenorphine treatment is more effective than short-term treatment. Many frustrated physicians reported that they have informed insurance companies that they would wean off patients, but then also attach a prewritten disclaimer describing how long-term treatment is more effective than short-term treatment. After six months or one year, these physicians must once again seek preauthorization and provide these same responses. Yet, according to these physicians, insurers never ask for provider promises to wean patients off of other medications, only buprenorphine—not even prescription pain killers such as oxycodone. Therefore, these "weaning off" requirements appear to violate federal parity law.

To compound these issues, pre-authorizations are fiendishly difficult and frustrating to obtain. Although completing a preauthorization form may sound simple, they are very timeconsuming in the aggregate and are rarely required for other mental health medications. The time

commitments required to obtain pre-authorizations may deter practices from providing buprenorphine and Vivitrol treatment. According to one psychiatrist, his office hired an additional billing specialist whose only task is to complete pre-authorizations and argue with insurance companies in the event of denials. He does not know how a solo practitioner without a large staff could successfully surmount this preauthorization hurdle.

Because addiction is a chronic disease, physicians must regularly renew preauthorizations for each MAT patient. Almost every physician I interviewed was annoyed that insurers do not accept preauthorization renewals until the renewal deadline has passed. In other words, the physician cannot complete and submit the preauthorization form ahead of time. But for some patients, any delay in accessing treatment can prove deadly. If a prior authorization expires January 1st and the patient runs out of buprenorphine that same day, then he may be unable to receive a buprenorphine prescription by January 3rd unless the prior authorization is submitted immediately. Buprenorphine only remains in a patient's system for two to three days; after that, the patient begins undergoing withdrawal and cravings return. At that moment, the patient is at serious risk for relapse and overdose, which ironically are very expensive for insurance companies to treat because they commonly require emergency room treatment, ambulatory care, or in-patient hospitalization. Therefore, the insurer has little to no financial incentive to delay buprenorphine treatment and every incentive to provide renewals in a timely manner.

In 11 states, Medicaid programs impose "life-time" limits per patient for buprenorphine treatment.⁷⁸³ Such limits are heavily criticized in both medical and public health scholarship. A recent study published in *Health Affairs* found that "life-time" limits for buprenorphine treatment are dangerous to patients because they often leading to relapse once the limit is met and

moreover are financially unsound for states because relapse or overdose often require expensive medical treatment.⁷⁸⁴ Physicians working in states with life-time limits may be wary to prescribe buprenorphine to patients, not only because the state legislature is intervening so intrusively in their medical care but also because they fear patients will relapse once they reach their limit. Other medications do not have "life-time" limits under Medicaid programs.⁷⁸⁵ Therefore, many some Medicaid Managed Care Organizations (MCOs) may be violating federal parity law (which applies to Medicaid MCOs but not traditional fee for service Medicaid).

Commercial insurance providers and Medicaid programs may put other barriers in place as well, the most obvious of which is refusing to cover these medications at all. ⁷⁸⁶ For example, in multiple states, including Indiana, Medicaid does not cover methadone when prescribed for addiction treatment purposes even though it covers it when prescribed for pain management. ⁷⁸⁷ A 2013 study found that only 13 state Medicaid programs currently cover all three MAT options: methadone, buprenorphine, and Vivitrol.⁷⁸⁸ But because some medications work better for different patients, limited insurance coverage artificially restricts many physicians' treatment options if they know that their patients cannot afford medications without coverage.

Multiple physicians have also reported that their state Medicaid programs will not pay for buprenorphine or Vivitrol stored in the physicians' office, even if it is provided pursuant to a valid prescription. Instead, the patient must pick up the medication from a pharmacy. In states that impose this Medicaid barrier, new addiction treatment patients must undergo an extremely time-consuming process to receive MAT medication. First, they must attend an office appointment, where they receive a diagnosis and a written prescription for buprenorphine or Vivitrol. Then, they must leave the physician's office and pick up the medication from a pharmacy. Finally, they must return to the physician's office, ideally that same day, where they must give the medication to their physician who then "induces" the patient. For patients on Vivitrol, induction requires that the drug is administered via injection followed by an observation period. Significantly, Vivitrol patients must always receive their injection from a physician's office and hey cannot legally self-inject Vivitrol at home. For patients taking Buprenorphine, induction means that the patient swallows a pill or places a dissolving sublingual film under their tongues in the physician's office, again followed by two to four hours of observation. After the first dose, buprenorphine patients take the medication daily at home daily.

Unfortunately, requiring patients to leave the physician's office, go the pharmacy and then return, many patients will never return. The nature of addiction is such that a patient with severe cravings may leave the office but instead decide to visit a drug dealer or go home on the way to the pharmacy. Even a simple trigger, such as seeing a building where the patient has previously "gotten high," may overwhelm the patient's motivation to go to the pharmacy. In other words, addiction as a disease gives patients only a short and critical window of time during which they are willing and able to undergo treatment. If that window disappears, then it may be a long time until a new opportunity appears. In the meantime, the patient is at risk for overdose.

One physician described how his office used to provide the first Vivitrol injection immediately after it was first prescribed so long as the patient had fully detoxed) because the office stored Vivitrol. At that time, so long as a patient had a valid Vivitrol prescription in place, Medicaid covered the medication's cost. Then the state's Medicaid policy changed, and the new policy required patients to pick up Vivitrol from the local pharmacy and then return for the injection. The office saw a 50% drop in the number of patients who actually received the injection (rather than just the prescription)—meaning that 50% of the patients left the office without returning. According to the physician, this tedious Medicaid requirement would be less

problematic during a patient's second or third Vivitrol treatment, when the patient might be stabilized enough to not mind the extra trip to the pharmacy. The first Vivitrol treatment in contrast is a "golden opportunity" that cannot be delayed since another opportunity may never arise. In light of the 50% drop in Vivitrol injections, the physician and his partners decided to altruistically cover the cost of each patient's first Vivitrol injection in their office, Rather than having patients pay for the injections out-of-pocket, which most could not afford. Though very admirable, this altruistic option is not practical for most physicians' offices as few would be so selfish or could afford it.

Another of the greatest barriers is limited insurance reimbursement for addiction treatment, especially low Medicaid reimbursement levels. Medicaid pays for the majority of SUD treatment in the U.S. because individuals with dependence tend to have limited incomes; thus, individuals covered by Medicaid are more likely to suffer from opioid dependence relative to those covered by commercial health insurance.⁷⁸⁹ However, Medicaid reimbursement rates are significantly lower than those from commercial health insurance and even Medicare. In a study of practicing physicians who completed buprenorphine training, 67% intended to begin prescribing buprenorphine after the training was completed.⁷⁹⁰ Of those who completed training but did not wish to begin prescribing buprenorphine, approximately one-quarter cited low reimbursement rates as the primary barrier.⁷⁹¹ Other studies have also found low reimbursement to be one of the most frequently mentioned barriers to buprenorphine treatment.⁷⁹²

Even within commercial health insurance, addiction treatment tends to be reimbursed at a lower rate than other covered procedures. Moreover, the type of appointment that addiction medicine requires is not highly reimbursed. Procedures requiring surgery or expensive machinery (e.g. magnetic resonance imaging machines) tend to be reimbursed at higher rates

than appointments (like those utilized in addiction medicine) consisting primarily of physicianpatient counseling and pharmacological prescription. Additionally, capitation payments, a common commercial insurance payment method, dissuades primary care physicians from treating patients for addiction. Capitated payment mean that physicians are reimbursed the same amount of money per patient according to a rate negotiated with the insurance company, regardless of how much time they spend with each patient. Capitation incentivizes physicians to see as many patients as possible in one day, and time-consuming patients are barriers to this goal. But addiction treatment appointments tend to be more time-consuming than others because physicians need to take patients' complete drug use history and provide basic counseling, as well as prescribe MAT and perform urine screenings. If the patient also suffers from co-occurring mental health conditions or chronic pain, then addiction treatment appointments may last even longer, often thirty minutes to an hour. Ideally, insurers should "carve out" behavioral health treatment as an exception to regular capitation rules and reimburse physicians for the extra time they must spend with addiction patients.

Commercial insurance providers also commonly require step-therapy, in which a patient must try a cheaper medication for a period of time before trying a more expensive medication or must begin with a low dosage. For example, insurance providers may require patients to begin on a low dosage of buprenorphine, which may fail to prevent cravings and euphoria from other opioids, before covering higher dosages of buprenorphine.⁷⁹³ Although step-therapy is an important cost-saving tool, in the case of addiction it may result in increased costs if the patient overdoses due to inadequate medication. Additionally, according to the ASAM, virtually no commercial health insurance companies cover methadone in IOPs, possibly fearing adverse selection (wherein patients with SUD specifically choose that insurance) if other commercial

insurance providers do not cover IOPs.⁷⁹⁴ However, if all commercial insurance providers covered methadone in IOPs, then adverse selection would be far less of a concern.⁷⁹⁵

Some insurance barriers clearly violate federal parity laws, such as requiring physicians to commit to weaning patients off buprenorphine, limiting buprenorphine coverage time, and Medicaid Managed Care Organizations' failure to cover Methadone addiction treatment while covering it for pain treatment. These insurance policies are also contrary to best medical practices. However, because individuals with dependence have limited political power, these practices are allowed to continue as regulators maintain a hands-off approach despite the opioid epidemic. Many physicians believe that such policies would not exist if the addiction patient population were wealthier and attracted more public sympathy—and in fact these barriers do not exist for other conditions and diseases for which these wealthier patient populations may need treatment. This, of course, reinforces both the stereotype that wealth individuals do not suffer from drug dependence, and the actuality that patients with financial resources or insurance coverage can afford to evade these barriers through seeking other treatment options. Other barriers, such as prohibitions on reimbursement for medication stored in the physician's office and low Medicaid reimbursement rates, disproportionately harm addiction patients. Unlike most patients, addiction patients have a limited window of time during which they are both willing and able to seek treatment, and are also particularly likely to have Medicaid rather than commercial health insurance.

Incentivizing more physicians to treat addiction will require raising Medicaid reimbursement rates, especially in light of the opioid overdose epidemic. Likewise, Congress and state legislatures should fund studies of insurance barriers in their states affecting mental health and SUD patients. Enforcement authority depends on the type of insurance plan. In most states,

MHPAEA enforcement is delegated to the state insurance commissioner for insurance plans with less than 51 employees; the Department of Labor and the Internal Revenue Service have enforcement authority with respect to plans subject to the Employee Retirement Income Security Act; and DHHSA enforces self-funded non-governmental plans, as well as small group plans in some states. MHPAEA must be rigorously enforced to discourage insurance providers from violating parity. Furthermore, the Center for Medicaid and Medicare Services should adopt a rule that would apply MHPAEA to fee-for-service Medicaid, an existing loophole in parity law.⁷⁹⁶

VIII. <u>Summary</u>

More physicians are needed in addiction treatment; within addiction treatment, more physicians should prescribe MAT. While psychiatrists (especially those trained in both addiction and MHDs) are likely the ideal prescribers of MAT, the U.S. is facing a severe shortage of psychiatrists. Therefore, primary care physicians should become involved in addiction treatment as well.

Yet, without addiction education in medical school and residency, physicians are unlikely to begin treating addiction or to seek out addiction-related courses. Addiction treatment patients are frequently perceived as difficult and often bring co-existing health conditions (such as pain or other MHDs). Without adequate training in these diseases and evidence-based treatments, physicians may feel too intimidated to treat addiction and prescribe MAT.

The structure of the health care system and health care financing also prevents physician involvement in addiction. Insurance companies violate mental health parity; Medicaid provides insufficient reimbursement rates and, in some states, lifetime buprenorphine limits. Mental health counselors and physicians rarely collaborate, largely due to the historical separation of physicians from addiction treatment after the passage of the Harrison Act. This separation

prevents MAT from diffusing into addiction treatment centers, the majority of which follow an abstinence-only philosophy. Diffusion of MAT into addiction treatment is critically important in light of the existing opioid overdose crisis and opioid dependence epidemic.

CONCLUSION: DIFFUSION OF MAT

I. Introduction

Innovation diffusion is the process by which an innovation is communicated through social channels and adopted into practices. An innovation is simply an idea perceived as "new," meaning the individual or organization has never heard of the innovation or has not used the innovation. MAT is an innovation in the sense that it is not yet widely adopted within SUD treatment in the U.S., due to lack of knowledge about MAT, practical barriers (such as costa and few prescribing physicians) and cultural stigma. Diffusion of MAT into SUD treatment would move SUD treatment much closer to mainstream medical treatment.⁷⁹⁷ Addiction treatment historian William White predicts that "the conceptual and practice silos of medication-assisted treatment and "drug free" treatment will progressively dissipate within the addiction treatment field."⁷⁹⁸ He expects that drug dependent patients will soon be able to choose from a menu of services offered at treatment centers, including MAT.

However, other scholars are more skeptical about what future the SUD treatment field will have in the U.S., given that abstinence-only treatment is still the norm. According to scholars, innovation diffusion is slow in all medical fields; but in substance abuse treatment, innovation diffusion appears to be particularly slow.⁷⁹⁹ MAT innovations seem to have hardly diffused at all. Unfortunately, just because researchers identified an evidence-based treatment does not mean that it will be implemented in medical practice.⁸⁰⁰

A synthesis of the literature on dissemination and implementation theory found that innovative treatment methods are most likely to be successfully adopted under the following conditions: practitioners receive coordinated training, supervision and assessments; organizations provide supervision, training, and evaluations of practitioners; communities and consumers

participate in selection and implementation of the innovation; and state and federal funding, regulations and policies "create a hospitable environment for implementation and program operations."⁸⁰¹

Receipt of information about an innovation alone is rarely sufficient to lead to its sustained implementation.⁸⁰² Studies have found that health practitioners frequently disregard novel information about a treatment method. A randomized controlled study compared what happened when a managed-care organization mailed new practice guidelines to an experimental group of counselors; a control group of other counselors received no such information. Only 64% of clinicians received the guidelines, and less than 50% of recipients actually read the mailing.⁸⁰³ Researchers found no difference in practice implementation between the control and experimental groups.⁸⁰⁴ Similar studies have found minimal or no effect on practice implementation when physicians receive treatment guidelines by mail.⁸⁰⁵

Fortunately, scholars have developed theories of innovation diffusion, and empirical researchers have identified factors conducive to innovation implementation. The chapter begins by examining innovation diffusion theory and problems of innovation diffusion in the SUD treatment field. The chapter then discusses how SUD treatment organizations and individual practitioners can integrate MAT into their practices, as well as motivational factors for doing so. The chapter concludes by proffering a solution: government-level intervention in MAT diffusion.

I. <u>Effective Implementation and Organizational Change</u>

A. Innovation Diffusion and Organizational Change Theory

Some studies suggest that individuals with greater knowledge of organizational change processes find it easier to successfully implement innovations, which suggests that diffusion

theories can aid government policy makers and treatment center administrators in MAT implementation.⁸⁰⁶ Scholarly literature describes a number of widely-used theories of organizational "practice" change, including Rogers' Diffusion Theory, the Transtheoretical Model (applied both to individuals and organizations), and Simpson's Stages of Change Model (applied to organizations).

Everett Roger's Diffusion Theory is the most influential innovation diffusion theory in SUD treatment. Diffusion Theory seeks to explain how organizations (which incorporate "collective attitudes, actions and relationships" of individuals in the organization) adopt change.⁸⁰⁷ Diffusion Theory posits that organizations (meaning administrators and staff) adopt innovations by consciously or unconsciously following five steps: 1) they identify problems, creating a perceived need for innovation, and adopt an agenda; 2) they match an innovation to the relevant problem; 3) they modify the innovation and organization, addressing misunderstandings about the innovation; and 5) they make the innovation a regular part of practice. During the final practice stage, the innovation is no longer considered novel but becomes "treatment as usual." At that point, the innovation's effectiveness in real world settings should approximate its effectiveness in research settings.⁸⁰⁸

Another influential model is the Transtheoretical Model (also known as the Stages of Change Model) developed by Prochaska et al. According to this model, change requires assessing actors' readiness for change and then matching interventions to these stages of readiness. The model can be applied to organizations, practitioners or patients. The authors have identified five stages of readiness for change: 1) pre-contemplation, where actors think everything is working well and no need for change exists; 2) contemplation, where actors think

change might be a good idea, but wonder whether it is really necessary; 3) preparation, where actors want to make the change but are not yet ready to do so; 4) action (actual implementation of the change); and 5) maintenance, where actors ask whether the change is working and whether improvements could be made.⁸⁰⁹ During the initial stages, actors rely primarily on cognitive, affective and evaluative process; in later stages, they rely on conditioning and environmental support.⁸¹⁰ Interestingly, counselors often use the Transtheoretical Model to decide whether SUD clients are ready for change (e.g. beginning psychotherapy), but treatment organizations can use the same model to determine whether counselors are ready to adopt and implement new treatment methodologies in their practices.⁸¹¹ This model also explains how individuals and organizations can relapse and regress from a later to an earlier stage of change.

Simpson's Stages of Change Model (which differs from the Transtheoretical Model) include four steps: 1) exposure; 2) adoption; 3) implementation; and 4) practice.⁸¹² Exposure involves training in the new innovation; staff motivation and organizational resources are necessary for such training to "stick," however. The adoption stage requires that staff perceive a need for the change and receive training, that the change has ease of use, and has "fit" with both the accepted treatment scheme and treatment ideology. For example, if counselors adhere to a strict abstinence-only ideology and assume that MAT hinders sobriety, they will be unlikely to adopt MAT. A study by Berwick found that staff perceptions of the innovation explained 49% to 87% of the variation in innovation dissemination⁸¹³; therefore, organizations that want to successfully adopt an innovation must first increase staff members' perceptions that the innovation is useful. Issuing a top-down mandate requiring staff members to implement an innovative method without first addressing their perceptions of this innovation is likely to fail.⁸¹⁴ The implementation stage includes a usage trial, allowing for staff members to develop and share testimonies of the innovation's usefulness. This stage requires that the organization commit sufficient resources and create a climate conducive to change. For example, an addiction treatment organization may need to fund staff travel to MAT training conferences. Creating an ideal climate for change includes clarifying goals, promoting staff cohesion, and allowing space for communication of concerns and resolving misunderstandings.⁸¹⁵ At this stage, administrators should also provide formal and informal incentives for adopting a change. In the practice stage, the innovation is used regularly and is sometimes modified to better fit organizational dynamics. Maintenance of the change requires ongoing organizational supervision and support; otherwise, practitioners will likely return to formerly used methodologies with which they are still more familiar.⁸¹⁶ Even if administrator turnover occurs or political and funding climates shift, the organization must continually monitor and support practitioners' use of the new innovation.⁸¹⁷ Unfortunately, while some researchers have studied dissemination's beginning stages, few studies have examined how to sustain newly-adopted practices long-term.⁸¹⁸

According to Simpson, organizational readiness for change is critical at each step. Resistance to change is not necessarily a bad thing, however, if it helps the organization identify steps that are necessary to make the change viable.⁸¹⁹ For example, counselors who resist the adoption of MAT in a treatment facility may be basing their resistance on the organization's failure to accept Medicaid, which is an important source of coverage for MAT, leading the facility to expand its insurance acceptance policies. Or counselor resistance could be based the assumption that adopting MAT will lead to a lack of buy-in from criminal justice administrators referring patients to the treatment organization, indicating that the treatment organization should consider new, more effective means of communicating MAT's advantages and the procedures surrounding its implementation.

Organizations may require significant financial resources to advance through these stages of change. Trainings should be repeated frequently, and in-person training is more effective than general workshop training, which is more effective than training from a manual alone.⁸²⁰ But inperson training and general workshop training can be expensive, and treatment centers may lack sufficient resources for intensive training, especially if they primarily serve low-income individuals. Therefore, they may need to partner with universities or apply for government grants. Unfortunately, while grants may be available for initial stages of change, they are rarely sufficient to cover shifts in practice over a longer term, including continued trainings and evaluations.⁸²¹

B. Factors Associated with Successful Innovation Adoption

Certain factors can predict whether an organization's adoption of an innovation will be successful. They can be divided into two categories: innovation-specific factors and organizational factors.

Diffusion Theory suggests that there are five innovation-specific factors associated with successful innovation adoption: a) the innovation's perceived advantage; b) its compatibility with existing program procedures; c) low innovation complexity; d) gradual implementation ("baby steps"); and e) observability of results of the innovation. The easier it is for other practitioners to see the results of an innovation, the more likely they are to adopt the innovation and spread information about the innovation. These factors partially explain MAT's slow adoption. Staff and administrators in abstinence-only treatment centers do not perceive MAT as advantageous; they regard it as a barrier rather than a facilitator to recovery.

Studies have also examined organizational-level characteristics associated with MAT adoption, including for-profit status, large organizational size, association with a hospital,

organizational use of other types of medications (e.g. SSRIs for depression), receiving a higher percentage of revenue from private or commercial insurance, and Joint Commission accreditation.⁸²² Some of these factors also characteristic of organizations that are integrated with mainstream medicine, which suggest that MAT has a greater "fit" within a medicalized program philosophy (e.g. being associated with a hospital, using other medications, and Joint Commission accreditation).

Conversely, an organizational emphasis on twelve-step programming (i.e. NA or AA) predicts MAT resistance, as does practitioners' allegiance to such a platform.⁸²³ MAT is unlikely to fit within twelve-step programs. The percentage of organizational referrals from the criminal justice system is also predictive of MAT resistance.⁸²⁴ In light of abstinence-only treatment's dominance within the criminal justice system, such resistance can and should be expected. Finally, programs without access to a physician are less likely to adopt MAT.⁸²⁵ Such a lack of access may indicate limited organizational resources, an undersupply of local physicians, or organizational adherence to abstinence-only principles. Public programs (i.e. programs receiving at least 50% of their revenue from government grants) are less likely to have access to a physician than private programs.⁸²⁶

C. Expanding Treatment Options Within Organizations

SUD treatment organizations need not eliminate other types of evidence-based treatment when contemplating MAT implementation. Ideally, SUD treatment organizations should offer a "menu" of services, including MAT. Professionals might misconstrue the treatment role of MAT, believing that it is meant to replace other treatment modalities rather than supplement them. For example, during my interviews with counselors, some expressed concern that patients would stop attending counseling as a result of MAT. After I mentioned that studies recommend a combination of MAT and counseling, they seemed less concerned. Other studies have also found that counselors resist adopting new mental health treatments when they feel they may be forced to abandon previous treatment methods.⁸²⁷ Additionally, counselors are more likely to resist new treatment methodologies if they feel that administrators have not listened to their concerns or have been insufficiently addressed. Inviting counselor participation in the planning stages of innovation adoption can prevent such feelings.⁸²⁸

Policymakers should promote MAT as an *expansion* rather than a narrowing of available treatments and should clarify that this expansion of treatment options is good for patients. First, patients who have not been responsive to psychosocial treatments may be responsive to MAT, decreasing relapse rates. In fact, treatment centers may find patients to be more responsive to counseling and support groups when used in conjunction with MAT. Second, new patients may enter the treatment center, especially those who have been resistant to psychosocial treatment. Third, by integrating SUD treatment with MAT, SUD treatment will appear more similar to "mainstream" medical treatment, potentially decreasing its stigma.⁸²⁹ Incorporating SUD will send a clear message to patients and local communities that addiction is a medical illness that can be treated like other diseases, without morality or spirituality as a foundation of treatment.⁸³⁰

As potential treatment options increases, staff members will need to understand what types of treatments work best for what types of patients. Those who lack sufficient training may feel overwhelmed. Ideally, counselors should easily be able to consult with a physician about such matters, and vice versa. Treatment centers without a physician on staff will either need to hire one or form an association with an outside physician.

The Addiction Technology Transfer Network (ATTN) is an important resource for treatment centers contemplating adding MAT to their service options. Funded by SAMHSA, the

ATTN provides web-based and in-person trainings, publications, and conferences about evidence-based SUD treatment methods. ATTN also facilitates alliances between researchers, counselors, physicians, policy makers, and patients in an attempt to unify the SUD treatment field. ATTN resources appear effective at promoting adoption of evidence-based treatments. For example, a study of ATTN-facilitated trainings for rural primary care physicians found that participants reported high levels of satisfaction, largely due to the trainings' interdisciplinary nature.⁸³¹ Importantly, primary care physicians "became more confident of their capacity to work with local drug abuse treatment centers and to care for their patients more effectively."⁸³² Furthermore, counselors developed relationships with primary care physicians in their community.⁸³³

More specifically, ATTN has published *The Change Book: A Blueprint for Technology Transfer* (now in its second edition and available online for free) to help treatment centers implement evidence-based innovations.⁸³⁴ *The Change Book* distinguishes between training and technology transfer. Training is a tool of technology transfer that tends to have short-term results; technology transfer is a broader concept that includes a desire for change, acceptance of the change, implementation, and reinforcement.⁸³⁵ Simply training counselors in a new treatment method is not sufficient to promote the use of this method long-term since individuals naturally prefer to return to more familiar methods. Therefore, treatment centers must also induce or increase staff motivation for the change and explore organizational-level issues in its adoption.⁸³⁶

D. Motivating MAT as a sound business practice

Although MAT adoption and implementation does not appear to have been economically driven, the practice is likely economically sound for treatment institutions.⁸³⁷ In a study of naltrexone adoption within 450 SUD treatment centers nationwide, organizations led by an

administrator with a medical degree or business degree were significantly more likely to adopt naltrexone, perhaps signifying a preference for practical and cost-effective results, as well as openness to medications in general.⁸³⁸ The authors reported that statistically significant variables were "consistent around the idea that a greater use of naltrexone is a sound business practice."⁸³⁹ The fact that MAT is cost- may partially explain why for-profit treatment programs are more likely to adopt it than non-profit treatment programs.⁸⁴⁰ While an important treatment method, counseling is more time consuming than providing medication, so institutions may be more cost-effective if they provide a combination of counseling and MAT.⁸⁴¹

Interestingly, policymakers appear to rarely use economic arguments in persuading organizations to adopt MAT, even though advocates routinely point to its positive health benefits. However, treatment centers trying to compete in a turbulent business environment may be more swayed by economic arguments than by arguments about adopting an effective treatment method or enhancing the societal good.

II. Change at the Practitioner (Counselor) Level

Counselors are the primary providers of professional SUD treatment in the U.S. Their knowledge and beliefs about MAT matter because they may affect organizational practices and policies. Unfortunately, SUD counselors are divided regarding knowledge of MAT and support for its use in SUD treatment.⁸⁴² For example, a large minority counselors involved in SUD treatment have either never heard of buprenorphine or oppose the use of buprenorphine.⁸⁴³ A study in 2008 by Herbeck et al. found that SUD program directors and staff (the majority of whom were counselors) viewed MAT as significantly less effective than psychological interventions for opioid dependence treatment.⁸⁴⁴ According to the study, many of the surveyed participants were unaware that buprenorphine was an effective treatment for opioid

dependence.⁸⁴⁵ In a 2005 study by Knudsen et al., more than two-thirds of counselors answered "I don't know" when asked if buprenorphine was an effective treatment for opioid dependence.⁸⁴⁶ A study of SUD counselors in Massachusetts found that 55% had never recommended naltrexone to either opioid or alcohol dependent individuals, either due to perceived cost or lack of knowledge.⁸⁴⁷

The diversity of types of SUD counselors may also explain the heterogeneity of attitudes towards MAT. Licensed counselors with graduate degrees routinely work alongside those without college degrees. State law typically only permits certain counselors to provide individual mental health counseling without supervision: licensed clinical social workers (who by definition have graduate degrees) and Ph.D.-level psychologists. However, SUD counselors without a license or college degree can provide patient support, coaching, and lead group meetings. Nationally, approximately 50% of SUD counselors lack college degrees.⁸⁴⁸ Diversity is both a strength and a weakness. It is a strength when it promotes holistic and patient-centered care; but it is a weakness when it prevents innovation diffusion due to differences in professional beliefs, attitudes, and norms.

Counselors' knowledge and beliefs about MAT are related to their formal education. Roman and Johnson (2002) found that the percentage of counselors with a master's degree or higher within an institution significantly increases the likelihood of naltrexone.⁸⁴⁹ Counselors who oppose the use of buprenorphine are unlikely to educate patients about buprenorphine's availability and benefits.⁸⁵⁰ Yet counselors have an important role to play in educating patients about effective drug dependence treatment.⁸⁵¹ Even though counselors cannot legally prescribe buprenorphine, they can refer clients to psychiatrists or other physicians for MAT. Counselors are already comfortable with referring patients for other medication, such as anti-depressants.

For example, a survey by the American Psychological Association found that 98% of psychologists have referred patients to physicians for some kind of mental health medication.⁸⁵²

SUD counselors without graduate education or licensing are more likely to resist MAT, often due to burnout and low wages, which create little incentive to learn new treatment methods. Less-educated SUD counselors are also more likely to be in recovery themselves. As far back as the early 20th century, SUD treatment programs recruited their own recovered patients as staff. Some patients may also prefer to receive counseling from a "peer" with shared experiences. But counselors in recovery themselves are likely to have been through a twelve-step program and thus to prefer such methods, and studies show that counselors philosophically aligned with twelve-step programs are particularly likely to resist MAT adoption. Counselors without college degrees are also less likely to have been exposed to accurate information about MAT.

Unfortunately, even counselors with graduate education have low knowledge of MAT. Social workers and psychologists receive minimal (or no) MAT training in graduate school, even if they specialize in addiction treatment. For example, one licensed clinical social worker whom I interviewed specialized in addiction treatment while earning an M.S.W. degree, but had only heard of methadone and naltrexone in one lecture. This counselor had never heard of buprenorphine and acknowledged having a "very low" level of knowledge about methadone and naltrexone."

Social work and counseling education programs on the levels of undergraduate, graduate, and continuing education should offer courses about MAT and widely encourage professional attendance. MAT courses should be required for social workers and counselors intending to specialize in addiction treatment. It seems absurd for a health professional to specialize in SUD

treatment without knowledge of and training in the most effective treatment for opioid dependence. Even after counselors are exposed to information about MAT, continued training and review opportunities must be made available in person or online. Equally important, managed care organizations, government agencies, professional health organizations, and other employers should provide incentives for counselors to attend these courses.

In addition to educational background, other thoughts and unconscious feelings about MAT may prevent individual mental health counselors from accepting MAT for opioid dependence. One personal concern may be that MAT is diametrically opposed to counseling, so that patients undergoing MAT will cease attending counseling. I have heard this mentioned a few times in my interviews with psychologists and social workers. However, such a fear is unfounded. Professional health organizations, the DHHS and the WHO all recommend that MAT be *combined* with counseling, especially cognitive behavioral therapy. ⁸⁵³ Additionally, DATA explicitly recognizes the concurrent roles of MAT and counseling in dependence treatment, because DATA requires a buprenorphine-prescribing physician to be able to refer a patient to ancillary mental health services.⁸⁵⁴ Likewise, methadone clinics are required to provide counseling and rehabilitative services.⁸⁵⁵ When Vivitrol was approved by the FDA, its labelling required counseling recommendations.⁸⁵⁶ Every physician I interviewed discussed the importance of both MAT and counseling together.

The Theory of Reasoned Action and Planned Behavior (TRAPB)⁸⁵⁷ can be used to understand counselors' referrals (or lack of referrals) of patients for MAT. According to TRAPB, one's behavior is dependent upon intentions; and intentions are dependent upon attitudes, norms, and perceived control.⁸⁵⁸ For adoption of an innovation, counselors' attitudes toward the innovation should be positive, counselors' should feel that their peers support the use of the
innovation, and counselors should feel that they have the ability to use the innovation.⁸⁵⁹ Multiple studies have verified that counselors' personal attitudes and assumptions about professional norms affect their intentions to inform patients about MAT. For example, in a study by Rickman et al., attitudes and norms explained 40% to 71% of intentions of counselors to tell patients about MAT.⁸⁶⁰ Another study by Kelly, Deane, and Lovett (2012) found that attitudes, norms, and perceived behavioral control explained 41% the variance between psychologists' intention to use evidence-based treatment.⁸⁶¹ According to Roberto et al., some counselors may not be referring clients to MAT because they do not feel they have the ability to refer clients to MAT.⁸⁶² Clearly, counselors' personal attitudes, assumptions about norms, and perceived control matter. In order for institutional leaders to affect counselors' behavior (in this case, referral of patients for MAT), they must address counselors' attitudes, norms and perceived control of MAT.

Institutional factors play an important role in whether or not a counselor is likely to recommend MAT. Various studies have examined institutional factors conducive to counselor support of MAT. Therapists who work in institutions with staff that already prescribe MAT or referring clients to MAT are more likely themselves to refer clients for MAT.⁸⁶³ Some institutions actively seek out evidence-based research and the latest studies more than others. Knudsen et al. refer to this practice as "screening." Screening is correlated with a higher acceptance of MAT. Other institutions are less likely to screen for new treatment methods and prefer to rely on the experience of their own staff. If an institution believes that experience is more important that research findings, then the institution may be less likely to adopt MAT (because most SUD counselors have experience in abstinence-only treatment methods but not MAT referral). One study found that 40% of administrators (the majority of whom were

counselors) believed that experience was a more important factor than research findings in guiding clinical practice.⁸⁶⁴ Such a belief may hinder counselors from seeking information about newly validated evidence-based psychological treatments and medications. The study also found that only 51% agreed or strongly agreed that the clinical staff understood the importance of evidence-based treatment.⁸⁶⁵

Though counselors cannot legally prescribe medication, their MAT education is very important; increased education about MAT may make counselors more likely to refer patients to physicians for medication. In fact, an American Psychology Association survey of counselors found that 98% of clinical psychologists routinely refer patients to physicians for medications to treat mental illness (e.g. depression or bipolar disorder). Counselors with knowledge of MAT can also better coordinate SUD treatment with a physician. Ideally, counselors and physicians would share information about patients' treatment progress and reinforce each other's methodologies. MAT-trained counselors may also be less likely to consciously or unconsciously discourage patients from participating in MAT. Finally, such counselors can influence policies within large treatment organizations, such as supporting the hiring of a staff physician or offer MAT referrals.

III. Government Initiatives

A. The "Blending Initiative"

According to Everett Rodgers' Diffusion of Innovations Theory, information diffusion flows through interpersonal networks, where it is strongly influenced by opinion leaders. End users of the innovation actively adopt and change the innovation to suit their needs.⁸⁶⁶ Publications and conferences are the traditional methods for disseminating scientific innovations, but these are typically designed to serve researchers' needs rather than practitioners, treatment

organizations or patients,⁸⁶⁷ and so they rarely allow for information to diffuse through networks of patients and practitioners quickly.

In response to limited information diffusion in addiction treatment, the National Institute on Drug Abuse (NIDA) created the "Blending Initiative" in 2001. The Blending Initiative attempts to integrate various addiction stakeholders' (e.g. patients, physicians, counselors, administrators) knowledge, skill, and resources through a variety of approaches. A key component of the Blending Initiative is the NIDA Clinical Trials Network, which leads clinical trials on existing and novel SUD treatments at practitioners' treatment sites (e.g. physician offices), allowing them to gain first-hand experience with innovations. Clinicians who see improved patient outcomes during a clinical trial are more likely to adopt an innovation and to become "ambassadors" to other clinicians.⁸⁶⁸ Additionally, because the Clinical Trials Network examines treatment effectiveness in "real world" settings, it provides important empirical data for health practitioners and researchers.⁸⁶⁹

Through the Blending Initiative, NIDA organizes conferences designed for researchers, treatment providers and policy makers. NIDA representatives also attend conferences with state-level policymakers.⁸⁷⁰ NIDA has used these approaches to diffuse information about MAT, but the number of MAT programs should increase (and be adequately funded), especially in states hit hardest by the opioid crisis.

B. Government as Opinion Leader

Opinion leaders play an important role in diffusion of evidence-based treatment. Riskaverse treatment centers wait to try a new treatment method until they have seen encouraging results or until opinion leaders or risk takers persuade them to do so.⁸⁷¹ According to Everett Rogers, 15% of organizations are "early adopters of innovation"; 34% of organizations adopt the

innovation shortly thereafter (referred to as "the early majority"), and 51% tend to be slow adopters. About 16% of organizations are particularly slow at adopting innovations, either because they are "reactionaries" (i.e. whose business model is premised around attracting consumers who disagree with mainstream treatments) or have few resources for change.

Building on Rogers' work, Berwick found that innovations in mental health treatment have a "tipping point" after which they acquires their own momentum. The tipping point occurs after approximately 20% of adoption occurs; at that time, communication typically exists between early adopters typically communicate information about the innovation with subsequent adopters. Community practitioners are more likely to look to peers for information about innovations, and learn about them through professional organizations' publications, newsletters or continuing education course rather than peer-reviewed research.⁸⁷² A 1993 study found that only 35% of practicing counselors read peer-reviewed literature.⁸⁷³ However, widespread availability of the Internet may have led to higher rates of reading peer reviewed literature since 1993. MAT advocates should encourage information diffusion through all available sources.

NIDA should serve as "the opinion leader" for treatment centers. As a well-respected government agency, NIDA can offer the widespread education, necessary to combat the many misconceptions about MAT. Organizations need a credible and authoritative information leader because they are faced with resistant abstinence-only treatment ideologies and confusing and sometimes contradictory literature. For example, misunderstandings about naltrexone may exist because its oral form has low rates of effectiveness for opioid dependence, while its injectable form (Vivitrol) has high rates of effectiveness. Some treatment program administrators may know the former fact, but not the latter.⁸⁷⁴

NIDA should also create more outreach programs for the general public, as studies suggest that the public has little knowledge about MAT. A website is unlikely to be enough to improve consumer demand for MAT; public service announcements on television and radio are needed as well, particularly in light of the absence of MAT advertisements in the mass media (television, radio, and magazines).⁸⁷⁵ Increased patient demand is likely to increase provider supply, but patients cannot demand MAT from their treatment providers if they do not know that it exists.

C. Using Government Contracts to Influence Abstinence-Only Treatment

Multiple studies have found that state-level policies influence MAT adoption at the provider and client level.⁸⁷⁶ For example, state mental health agencies, known as Single State Authorities (SSAs) provide grants to treatment centers and contract with treatment centers for service provision to low-income individuals and criminal justice system organizations.⁸⁷⁷ SSAs could impose conditions in grants or contracts that would incentivize MAT; for example, SSAs could make funding contingent on center accepting patients undergoing MAT. Also, SSAs could provide "bonus" funding to treatment centers that provide MAT to patients.

Fortunately, a study of 51 SSAs (representing each state and the District of Columbia) found that SSA prioritization of expanding MAT has increased by an average of 8% between 2007 and 2010, and MAT implementation in public treatment facilities has increased by an average of 19%.⁸⁷⁸ States with higher rates of buprenorphine and methadone implementation also had higher rates of infrastructure implementation such as strategically training physicians in addiction medication, funding addiction medication, and changes in organizational policies).⁸⁷⁹ Unfortunately, the study also found that negative attitudes of the public, practitioners, and

clients/patients served as a barrier to SSA implementation of MAT, especially the idea that MAT is "just another drug."⁸⁸⁰

Most disconcertingly, interviews with SSA directors revealed that many public officials had negative attitudes towards MAT.⁸⁸¹ One SSA director said that his state is a "very strong 12step facilitator" with a "big pocket of resistance to medication-assisted treatment."⁸⁸² Policymakers who have little time or incentive to read scientific research publications are especially likely to defer to local or regional opinion leaders, including those with abstinenceonly philosophies. These policymakers may distrust MAT if they perceive it as a challenge to established practices and beliefs.⁸⁸³

Some SSAs and municipalities impose an abstinence-only philosophy by not funding even a single methadone clinic, creating zoning barriers to methadone clinics, or prohibiting MAT in the criminal justice system.⁸⁸⁴ Government regulators and legislators who failure to provide funding for methadone or only provide limited funding for MAT despite funding abstinence-only treatment centers are likely ignorant of the benefits of MAT.⁸⁸⁵ Regulators' and legislators' limited knowledge about MAT is also unfortunate because government leaders educated in evidence-based treatment methods could serve as MAT advocates for the state. When government policies support MAT, then "core beliefs in the treatment field may shift and attitudes may become more positive." For example, legislatures can improve attitudes towards MAT by funding medications, suggesting to the public that they are effective.⁸⁸⁶ However, the federal, state and local agencies responsible for public funding of SUD treatment tend to be fragmented, making communication and information diffusion between them difficult.

D. Addressing Biases in AA and NA

NA and AA are self-sustaining, do not receive governmental funding, and strongly oppose associations with political leaders and the government. Furthermore, NA and AA are highly decentralized organizations, with most chapters groups making decisions for themselves, such as whether to accept participants undergoing MAT). The organization's national headquarters provide only minimal policy guidance to chapters. The fact that NA and AA have been self-funded and uninvolved with the government has served them well, helping their members to maintain anonymity and helping their treatment philosophy survive numerous government changes. As a result, however, the government has few options for directly encouraging MAT's acceptance within NA and AA.

The government could, however, encourage the development of alternative support groups, such as by increasing grants for development and evaluation of support group alternatives to NA and AA. These alternative groups could accept MAT as an effective treatment and not use morality-laden language. The government could also fund online support groups, which would especially help serve rural areas. Alternative support groups could continue to maintain the characteristics of NA and AA that scientific studies find most efficacious: fellowship among like-minded individuals and sponsorship. Neither component directly inhibits MAT.

Alternative groups would compete with NA and AA, and could potentially cause those in charge of AA and NA groups to change their attitudes towards MAT to retain members. Or alternative groups would simply enable more individualized treatment options: abstinence-only adherents would attend NA and AA, while individuals undergoing MAT could attend alternative

support groups. Currently, however, some alternative support groups exist, but their availability is negligible compared to that of NA and AA, especially in rural areas.

D. Educating Criminal Justice Administrators

The criminal justice community's support is particularly important for MAT implementation on the state and organizational levels.⁸⁸⁷ Most individuals enter SUD treatment through the criminal justice system. Unfortunately, treatment centers with a higher proportion of criminal justice clients are less likely to adopt MAT. My own study of drug courts—arguably the most therapeutically-oriented criminal justice institution—found that they exhibited high resistance to MAT, as did a 2013 study by Matusow et al. Only a small percentage of federal and state prisons provide prisoners with access to MAT, even though twelve-step groups are widely available in prison. The abstinence-only philosophy is deeply entrenched within the criminal justice system.

Criminal justice administrators such as drug court judges and probation officers are not health practitioners and receive little or no formal education in SUD treatment. They may receive information about SUD treatment methods from colleagues, employers, and opinion leaders. According to my study, for instance, drug court judges are most likely to learn about new treatment methods through professional conferences, in which MAT sessions are unpopular.

Criminal justice administrators play a profound role in addiction treatment despite their minimal or nonexistent training in SUD treatment methods. Drug court judges lead "treatment teams" that make SUD treatment referral decisions and design court policies regarding MAT, such as determining whether a participant can begin buprenorphine while in drug court. Probation officers communicate regularly with counselors and physicians about clients receiving SUD treatment. Prison administrators decide whether or not to permit MAT, an important

predictor of whether prisoners will be treated with MAT upon release or whether they will relapse.⁸⁸⁸ Finally, law enforcement administrators make discretionary decisions about whether to arrest individuals with drug dependence or whether instead to divert them to treatment centers.

Because criminal justice administrators make so many decisions relevant to SUD, they need greater access to education about SUD treatment. Increased education will require more local and state funding for training programs and conference travel. Because the criminal justice system relies on tax payer funding, however, the general public must first be convinced that such education is a worthwhile investment. But many members of the general public still prefer punishment without treatment, and view addicts as criminals rather than individuals coping with a disease. Therefore, decreasing public stigma of addiction and increasing public awareness of MAT's efficacy is also necessary.

IV. Summary

Abstinence-only philosophy is so deeply engrained in American culture that many SUD treatment centers, practitioners, and individuals suffering from opioid dependence assume it is the only route to recovery. Innovation diffusion models and research on institutional practices that influence innovation adoption may help policy makers change the status quo.

The time to change SUD practices is now. Skyrocketing rates of opioid dependence are making media headlines, and many Americans have become sympathetic towards the treatment of addiction rather than criminalization of drug users. In light of such social concern and the enormous individual, governmental, and social costs of opioid dependence, policy makers must prioritize formation of policies that encouraging MAT. Such policies should encourage treatment centers to approach SUD like other chronic conditions, including provision of medication and evidence-based behavioral methods. In other words, SUD treatment must be brought into the

realm of mainstream medical treatment, rather than being relegated to a spiritual disease requiring spiritual treatment peppered with counseling.

This dissertation suggested options for improving access to MAT, beginning integration of SUD patients into mainstream medical treatment, which would help debunk the notion that SUD is caused by immorality or lack of willpower⁸⁸⁹. If SUD is understood as a medical condition similar to other medical conditions, then MAT is a natural fit into treatment (after all, most disorders are treated with some medication). Similarly, individuals with SUD must be viewed as "normal" individuals suffering from a particular disease, rather than being viewed as being immoral or willfully contrarian to social norms. Like patients suffering from other chronic diseases, SUD patients deserve empathy and access to best standards of care.

In order for SUD patients to access MAT, regulatory and statutory barriers must be changed, namely existing isolation of OTPs, patient limits for buprenorphine, and inability for physician assistants and NPs to prescribe buprenorphine. For more physicians to enter the field of addiction treatment and to collaborate with existing SUD treatment centers (who rarely have an MAT-prescribing physician), medical schools and residency programs must begin widespread education about addiction medicine. Additionally, policy makers should enforce SUD and mental health parity law and raise Medicaid reimbursement rates.

Not unlike the era of alcohol prohibition, individuals with SUD today are more likely to be criminalized than to receive evidence-based medical treatment. Drug and veterans courts are an important arm of the criminal justice system that has the potential to improve lives by diverting divert individuals into treatment and away from incarceration. But courts should not bar individuals from evidence-based treatment. Fortunately, the federal government has taken notice, with recent DHHS preventing federal funding to courts that ban MAT. State funding rules

should prohibit bans on MAT as well and incentivize physician involvement in court treatment teams. National accreditation of drug courts could encourage best-practice standards.

Policy makers should develop public service announcements with messages about prevention and evidence-based treatment methods. Otherwise, individuals with drug dependence and their families will be left in a sea of abstinence-only treatment centers without the knowledge that better treatment exists. If the public demands MAT, then SUD treatment centers may be more likely to supply it. In the meantime, policy makers must realize that innovative treatment methods rarely make their way into SUD treatment centers through publication of research results alone. The Blending Initiative creates an opportunity for collaboration between researchers, practitioners, and policy makers; similar initiatives should be designed and implemented by states.

Abstinence-only treatment centers face institutional-level barriers to MAT adoption (such as limited funding for training and few or no staff physicians) and practitioner-level barriers (such as lack of education about MAT and attitudes favoring 12-step methodology over medication). For leaders of abstinence-only treatment centers to change policies and internal culture, they must provide clear goals, involve counselors in decision-making, provide ongoing (rather than short-term) training, and encourage valuing research results rather than treatment experience alone. Additionally, counseling and social work formal education programs should include information about MAT.

MAT significantly decreases the risk of death for individuals with drug dependence and saves society money that might otherwise be spent on emergency care and hospitalization. Therefore, society's failure to encourage MAT in opioid dependence treatment is unacceptable. Failure to use MAT is based outdated notions of recovery that stigmatize those individuals who

seek help despite the many barriers they already face. A national conversation about the meaning of "recovery" must begin now. Recovery does not mean abstinence from all medication; recovery means abstinence from drug abuse, often coupled with re-integration into the community and improvement in overall health. As thousands of patients have known for decades but are often too stigmatized to voice publically, MAT is literally life-saving.

ENDNOTES

DRUG ABUSE, NATIONAL INST. OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVS (May 14, 2014), http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

⁶ See SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, U.S. DEP'T OF HEALTH AND HUMAN SERVS, *Improving Access to Treatment: Expanding Reach of Buprenorphine*, (Mar. 31, 2016), http://blog.samhsa.gov/2016/03/31/improving-access-to-treatment-expanding-reach-of-buprenorphine/#.V2C8gPkrKhc.

⁷ See CENTERS FOR DISEASE CONTROL & PREVENTION, *Injury Prevention and Control: Opioid Overdose*, (Mar.12, 2016), http://www.cdc.gov/drugoverdose/data/overdose.html.

⁸ See Benzodiazepines in Combination with Opioid Pain Relievers or Alcohol: Greater Risk of More Serious ED Visit Outcomes, The DAWN Report, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, U.S. U.S. DEP'T OF HEALTH AND HUMAN SERVS (Dec. 18, 2014), http://www.samhsa.gov/data/sites/default/files/DAWN-SR192-BenzoCombos-2014/DAWN-SR192-BenzoCombos-2014.pdf.

⁹ See Overdose Rates, NAT'L INST. ON DRUG ABUSE, NATIONAL INST. OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVS (Dec. 2015), https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates [herein after referred to as Overdose Rates].

¹⁰ See CENTERS FOR DISEASE CONTROL & PREVENTION, *Morbidity and Mortality Weekly Report* (Jan. 1, 2016), shttp://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm.

¹¹ See Li Hui Chen, Holly Hedegaard, and Margaret Warner, *Drug-Poisoning Deaths Involving Opioid Analgesics: United States 1999-2011*, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEP'T OF HEALTH AND HUMAN SERVS (Sep. 2014), http://www.cdc.gov/nchs/data/databriefs/db166.htm.

¹² See Overdose Rates, supra, note 9.

¹³ See AMERICAN SOCIETY OF ADDICTION MEDICINE, Opioid Addiction 2016 Facts and Figure (2016),

http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

¹⁴ See id.

¹⁵ See id.

¹⁶ See Northern Kentucky's Collective Response to the Heroin Epidemic, DRUG FREE KENTUCKY (Nov. 14, 2013), http://drugfreenky.org/wp-content/uploads/2013/11/Northern-Kentuckys-Collective-Response-Final.pdf.

¹⁷ See Suzanne Gelber Rinaldo and David W. Rinaldo, *Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment*, AMERICAN SOCIETY OF ADDICTION MEDICINE 7 (2013),

http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final. ¹⁸ See id.

¹⁹ See AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEP'T OF HEALTH AND HUMAN SERVS, *Disparities in Healthcare Quality among Racial and Ethnic Groups*, (Sep. 2012),

http://archive.ahrq.gov/research/findings/nhqrdr/nhqrdr11/minority.html.

²⁰ See Opioid Addiction 2016 Facts and Figure, supra, note 13.

²¹ See generally SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, Substance Abuse Prevention Dollars and Cents: A Cost-Benefits Analysis, 6-9 (2008), http://www.samhsa.gov/sites/default/files/cost-benefits-prevention.pdf; HG Birnbaum et al., Societal costs of prescription opioid abuse, dependence, and misuse in the United States, 12(4) PAIN MED 657-67 (2011).

²² See Birnbaum et al., supra note 21.

²³ See id.

²⁴ See SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, Substance Use Disorders (Oct. 27, 2015), http://www.samhsa.gov/disorders/substance-use.

²⁵ See NAT'L INST. ON DRUG ABUSE, *The Science of Drug Abuse and Addiction: The Basics* (Sep. 2014), https://www.drugabuse.gov/publications/media-guide/science-drug-abuse-addiction-basics.

¹ See Appendices B-D.

² See J.W. Cresswell, QUALITATIVE INQUIRY & RESEARCH DESIGN: CHOOSING AMONG FIVE APPROACHES (2007). ³ See id.

⁴ See SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *Results from the 2013 National Survey* on Drug Use and Health: Summary of National Findings, (Oct. 16, 2014),

http://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.htm. ⁵ See Nora D. Volkow, America's Addiction to Opioids: Heroin and Prescription Drug Abuse, NAT'L INST. ON

²⁶ See NAT'L INST. ON DRUG ABUSE, NAT'L INST. OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVS, *Is there a Difference Between Physical Dependence and Addiction?*, In Principles of Drug Addiction Treatment: A Research-Based Guide (3rd ed.), (Dec. 2012), https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/there-difference-between-physical-dependence ²⁷ See NAT'L INST. ON DRUG ABUSE, *Comorobidity: Addiction and Other Mental Illness, Research Report Series* 3 (2010) [hereinafter *Comorbidity*], https://www.drugabuse.gov/sites/default/files/rrcomorbidity.pdf.

²⁸ See Nora Volkow, supra, note 5.

²⁹ See B. Martell et al., Systematic Review: Opioid Treatment for Chronic Back

Pain: Prevalence, Efficacy, and Association with Addiction, 146(2) ANNALS OF INTERNAL

Med. 116 (2007).

³⁰ See Thomas R. Kosten and Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1(1) SCIENCE & PRACTICE PERSPECTIVES 13 (2002).

³¹ See Nora Volkow et al., *Imaging Dopamine's Role in Drug Abuse and Addiction*, 56(1) NEUROPHARMACOLOGY 3 (2009).

³² See Resolution of the Board of Directors On the Availability of Medically Assisted Treatment (M.A.T.) for Addiction in Drug Courts, NAT'L ASS'N OF DRUG CONTROL PROF'LS,

http://www.nadcp.org/sites/default/files/nadcp/NADCP%20Board%20Statement%20on%20MAT.pdf (last visited Jun. 18, 2016); R. Baler and N. Volkow, *Drug addiction: The neurobiology of Disrupted Self-Control*, 12 TRENDS IN MOLECULAR MEDICINE 559 (2006); C. Dackis and C. O'Brien, *Neurobiology of Addiction: Treatment and Public Policy Ramifications*, 8 NATURE NEUROSCIENCE 1431 (2005); R. Goldstein et al., *The Neurocircuitry of Impaired Insight in Drug Addiction*, 13 CELL 372 (2009); A. McLellan et al., *Drug dependence, a chronic medical illness: Implications for treatment, insurance, and outcomes evaluation*, 284 J. AMER. MED. ASS'N 1689 (2000). ³³ See Rob Neiss, *The Role of Psychobiological States in Chemical Dependency: Who Becomes Addicted?*, 88 ADDICTION 745, 745 (1993).

³⁴ See A. Agrawal and M. Lyneskey, *Are there Genetic Influences on Addiction: Evidence from Family, Adoption and Twin Studies*, 103(7) ADDICTION 1069 (2008).

³⁵ See Tammy Saah, *The Evolutionary Origins and Significance of Drug Addiction*, 2(8) HARM REDUCTION J. (2005), available at http://harmreductionjournal.biomedcentral.com/articles/10.1186/1477-7517-2-8.

³⁶ See Adam Perry et al., *Development of Preference for Cocaine Over Food Identifies Individual Rats with Addiction-Like Behaviors*, 8(11) PLOS ONE 4 (2013).

³⁷ See B. ALEXANDER, THE GLOBALISATION OF ADDICTION: A STUDY IN POVERTY OF THE SPIRIT (2008); B. Alexander et al., *Effect of Early and Later Colony Housing on Oral Ingestion of Morphine in Rats*, 15 PHARMACOLOGY BIOCHEMISTRY & BEHAVIOR 571 (1981).

³⁸ See *What is Drug Addiction?*, Drugs, Brain and Behavior: The Science of Addiction, NAT'L INST. ON DRUG ABUSE, NAT'L INST. OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVS (Jul. 2014),

https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-abus

³⁹ See Ronald Williams et al., Use of Social Ecology Model to Address the Alcohol Use among College Athletes,

21(4) AMER. J. OF HEALTH STUDIES 228 (2006).

⁴⁰ See id.

⁴¹ See Addiction is a Chronic Disease, NAT'L INST. ON DRUG ABUSE,

http://archives.drugabuse.gov/about/welcome/aboutdrugabuse/chronicdisease/ (last visited Jun. 18, 2016). ⁴² See id.

⁴³ See Jen Simon, *Addiction, Poverty, and the Myth of Willpower*, THE HUFFINGTON POST, The Blog (Apr. 8, 2014), http://www.huffingtonpost.com/jen-simon/addiction-poverty-and-the_b_4731613.html

⁴⁴ See Dackis and O'Brien, supra note 32.

⁴⁵ See NAT'L INST. ON DRUG ABUSE, *Drug Facts: Treatment Statistics*, The Science of Addiction (Mar. 2011), https://www.drugabuse.gov/publications/drugfacts/treatment-statistics.

⁴⁶ See Brian Rush et al., *Estimating Capacity Requirements for Substance Use Treatment Systems: A Population-Based Approach*, 10(1) ADDICTION SCIENCE CLINICAL PRAC. A58 (2015).

⁴⁷ See Dackis and O'Brien, supra note 22, at 1431.

⁴⁸ See G. Vaillant, A 20-year Follow-Up of New York Narcotic Addicts, 29 ARCH. GEN. PSYCHIATRY 237 (1973); Gavin Bart, Maintenance Medication for Opiate Addiction: The Foundation of Recovery, 31(3) J. ADDICTIVE DISORDERS 207 (2012).

⁴⁹ See NAT'L INST. ON DRUG ABUSE, *How Effective is Drug Addiction Treatment?*, Principles of Drug Addiction Treatment: A Research-Based Guide (3rd ed.), (Dec. 2012) [hereinafter *How Effective is Drug Addiction*

Treatment?], https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/how-effective-drug-addiction-treatment.

⁵² See id.

⁵³ See id.

⁵⁴ See id.

⁵⁵ See *How Effective is Drug Addiction Treatment?*, supra, note 49.

⁵⁶ See NAT'L INST. ON DRUG ABUSE, *Evidence-Based Approaches to Drug Addiction Treatment*, Principles of Drug Addiction Treatment: A Research-Based Guide (3rd ed.) (Dec. 2012),

https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/evidence-based-approaches-to-drug-addiction-treatment.

⁵⁷ See M. Willenbring et al., *Beliefs about Evidence-Based Practices in Addiction Treatment: A Survey of Veterans Administration Program Leaders*, 26 J. OF SUBSTANCE ABUSE TREATMENT 79 (2004).

⁵⁸ See Catherine McKay, *Confronting Delaware's Heroin Epidemic*, 33 DELAWARE LAWYER 14 (2015).

⁵⁹ See generally Traci Rieckmann et al., Adoption of Medications in Substance Abuse Treatment: Priorities and Strategies for Single State Authorities, 6 J. PSYCHOACTIVE DRUGS, 227, 228 (2010); H. Matusow et al., Medication assisted treatment in US drug courts: results from a nationwide survey of availability, barriers and attitudes, 44(5) J. SUBSTANCE ABUSE TREATMENT 473, 473 (2013).

⁶⁰ See K. Derose et al., Understanding Disparities in Health Care Access – And Reducing Them – Through a Focus on Public Health, 30(10) HEALTH AFF. 1844 (2011).

⁶¹ See id.

⁶² See P. Roman et al., Using Medication-Assisted Treatment for Substance Use Disorders: Evidence of Barriers and Facilitators of Implementation, 36(6) ADDICTIVE BEHAVIORS 584 (2011).

⁶³ See id

⁶⁴ See id.

⁶⁵ See *infra*, Chapter 4

 ⁶⁶ See Rieckmann et al., A Longitudinal Study of State Strategies and Politics to Accelerate Evidence-Based Practices in the Context of Systems Transformation, 50(4) HEALTH SERVS RES. 1125, 1134 (2015).
 ⁶⁷ See id.

⁶⁸ See Derose et al., supra, note 60.

⁶⁹ See Nora Volkow et al, *Medication-Assisted Therapies – Tackling the Overdose Epidemic*, 370. NEW ENGLAND J. OF MED. 2063 (2014).

⁷⁰ See Roman et al., supra, note 62; William White et al., *Co-participation in 12 Step Mutual Aid Groups and Methadone Maintenance Treatment: A Survey of 322 Patients*, 8(4) J. OF GROUPS IN ADDICTION & RECOVERY 294 (2013).

⁷¹ See Jason Cherkis, Dying to Be Free, THE HUFFINGTON POST (Jan. 28, 2015),

https://projects.huffingtonpost.com/dying-to-be-free-heroin-treatment; A.J. Saxon and D. McCarty, *Challenges in the adoption of new pharmacotherapeutics for addiction to alcohol and other drugs*, 108 PHARMACOLOGY & THERAPEUTICS 119, 123 (2005).

⁷² S. Magura, *Failure of Intervention or Failure of Evaluation: A Meta-Evaluation of the National Youth Anti-Drug Media Campaign Evaluation*, 47 (13-14) SUBSTANCE USE & MISUSE 1414 (2012).

⁷³ See Volkow, supra, note 5.

⁷⁴ See N. Morone and Debra Weiner, *Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education*, 35(11) CLINICAL THERAPY 1728 (2013).

⁷⁵ See H. Griffen and J. Spillane, *Pharmaceutical Regulations and Challenges: Lessons Learned from OxyContin Abuse and Diversion*, 43(2) J. OF DRUG ISSUES 164 (2013).

⁷⁶ See Nora Volkow, supra, note 5.

⁷⁷ See Fact Sheet, AMER. SOC'Y OF INTERVENTIONAL PAIN PHYSICIANS (last visited Jun. 18, 2016), https://www.asipp.org/documents/ASIPPFactSheet101111.pdf

⁷⁸ See *Prevention and Intervention Strategies to Decrease Misuse of Prescription Medication*, AM. PUB. HEALTH ASS'N, http://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-

database/2015/12/08/15/11/prevention-and-intervention-strategies-to-decrease-misuse-of-prescription-painmedication (last visited June 14, 2016).

⁷⁹ See R. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313(9) J. OF AM. MED. ASS'N. 891, 891 (2015).

⁵⁰ See C. O'Brien et al., Myths about the Treatment of Addiction, 347(8996) LANCET 237 (1996).

⁵¹ See id.

⁸⁰ See id.

⁸² See A. McLellan et al., Drug Dependence, A Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation, 284 J. OF AMER. MED. ASS'N 1689 (2000); See Saxon and D. McCarty, supra, note 71, at 123.
⁸³ See Matusow et al., supra note 59, at 479 ("Despite evidence of the safety and efficacy of methadone and buprenorphine to improve outcomes for opioid dependence, we found that MAT has limited penetration in drug courts. Lack of adoption of an effective treatment intervention is troubling in light of the increasing problem of opioid abuse in the United States, the large body of growing evidence demonstrating MAT's efficacy in treating it, and the high relapse rates that occur when patients are withdrawn from agonist therapy even when counseling (without MAT) is still available."); Maia Szalavitz, After 75 Years of Alcoholics Anonymous, It's Time to Admit We Have a Problem: Challenging the 12-Step Hegemony, PAC. STANDARD (Feb. 10, 2014),

http://www.psmag.com/books-and-culture/75-years-alcoholics-anonymous-time-admit-problem-74268. ⁸⁴ See NARCOTICS ANONYMOUS, www.na.org.

⁸⁵ See id. at http://www.na.org/admin/include/spaw2/uploads/pdf/litfiles/us_english/misc/How%20it%20Works.pdf.
 ⁸⁶ See generally Ernest Kurtz, NOT GOD: A HISTORY OF ALCOHOLICS ANONYMOUS (1991).

⁸⁷ See id. at 9.

⁸⁸ See id. at 21.

⁸⁹ See id. at 17.

⁹⁰ See Lee and Kaskutas, Alcoholics Anonymous Effectiveness: Faith Meets Science, 28(2) J. OF ADDICTION, 42 (2009) ("What, then, is the scorecard for AA effectiveness in terms of specificity? Among the rigorous experimental studies, there were two positive findings for AA effectiveness, one null finding, and one negative finding. Among those that statistically addressed selection bias, there were two contradictory findings, and two studies that reported significant effects for AA after adjusting for potential confounders such as motivation to change. Readers must judge for themselves whether their interpretation of these results, on balance, supports a recommendation that there is no experimental evidence of AA effectiveness (as put forward by the Cochrane review).").

⁹¹ See NAT'L INST. ON DRUG ABUSE, 12 Step Facilitation Therapy, Principles of Drug Addiction Treatment: A Research-Based Guide (Dec. 2012) [hereinafter 12 Step Facilitation Therapy],

http://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/evidence-based-approaches-to-drug-addiction-treatment/behavioral-4.

⁹² See id.

⁹³ See M. Ferri, L. Amato, and M. Davoli, *Alcoholics Anonymous and other 12-step programs for Alcohol Dependence*, 3 COCHRANE DATABASE OF SYSTEMATIC REV.11 (2006).

⁹⁴ See NAT'L INST. ON ALCOHOL ABUSE & ALCOHOLISM, National Longitudinal Alcohol Epidemiologic Survey Data, Manual, (July 11, 1994); But see William White et al., Participation in Narcotics Anonymous and Alcoholics Anonymous and Abstinence Outcomes of 322 Methadone Maintenance Patients, 9 J. OF GROUPS IN ADDICTION & RECOVERY 14, 21 (2014) ("Contrary to our predicted outcome, study findings revealed that past-year continuous abstinence was related to a longer duration of time in MMT but was not related to 12-step meeting attendance.").
 ⁹⁵ See 12 Step Facilitation Therapy, supra note 91.

⁹⁶ See William White, Narcotics Anonymous and the Pharmacotherapeutic Treatment of Opioid Addiction in the United States, SUBSTANCE ABUSE & MENTAL HEALTH SERS ADMIN. 5 (2011).

⁹⁷ See William White et al., *Coparticipation in 12-Step Mutual Aid Groups and Methadone Maintenance Treatment:* A Survey of 322 Patients, 8(4) J. OF GROUPS IN ADDICTION & RECOVERY, 294, 296 (2013); "Almost a quarter (24.4%) of respondents (with current or past involvement in NA or AA) reported having had a serious problem within NA or AA related to their status as an MMT patient." *Id.*, at 301; However, White et al. note that there is some evidence that traditional 12-step groups are becoming more open to accepting people undergoing MAT. *See id.* at 296.

⁹⁸ See Dennis Daley, et al., *Group Therapies*, in THE ASAM PRINCIPLES OF ADDICTION MEDICINE, 845 (eds. Reis et al.) (2014).

⁹⁹ See id. at 846.

¹⁰⁰ See id.

¹⁰¹ See id. at 851.

¹⁰² See id. at 855; T. Gorski & J. Kelly, Counselor's Manual for Relapse Prevention with Chemically Dependent Criminal Offenders, U.S. Dep't of Health and Human Servs (1996).

¹⁰³ See Daley, supra note 98, at 850–51 (discussing increased methadone adherence for women when complemented with a women's-only group therapy).

⁸¹ See Joseph O Merrill, *Policy Progress for Physician Treatment of Opiate Addiction*, 17(5) J. GENERAL INTERNAL MED. 361 (2002).

¹⁰⁴ See Deborah Haller and Edward Nunes, *Individual Treatment*, *in* THE ASAM PRINCIPLES OF ADDICTION MEDICINE 858, 863 (Richard K. Ries et al. eds., 2014).

¹⁰⁵ See id. at 865.

¹⁰⁶ See id.

¹⁰⁷ See id. at 865–66.

¹⁰⁸ See id. at 866.

¹⁰⁹ See id.

¹¹⁰ See id.

¹¹¹ See id.

- ¹¹² See id.
- ¹¹³ See id.

¹¹⁴ *Id.* at 867.

¹¹⁵ See id.

¹¹⁶ See id.

¹¹⁷ See NAT'L INST. ON DRUG ABUSE, *Contingency Management Interventions/Motivational Incentives (Alcohol, Stimulants, Opioids, Marijuana, Nicotine)*, Principles of Drug Addiction Treatment: A Research-Based Guide (3rd ed.) (Dec. 2012), https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/evidence-based-approaches-to-drug-addiction-treatment/behavioral-0

¹¹⁸ See Jesse B. Milby et al., *Take-Home Methadone: Contingency Effects on Drug-Seeking and Productivity of Narcotic Addicts*, 3(3-4) ADDICTIVE BEHAVIORS 215 (1978).

¹¹⁹ See M. Prendergast et al., *Contingency Management for Treatment of Substance Use Disorders: A Meta-Analysis* 101(11) ADDICTION 1546 (2006); Maxine Stitzer and Nancy Petry, *Contingency Management for Treatment of Substance Abuse*, 2 ANN. REV. OF CLINICAL PSYCHOL. 411 (2006).

¹²⁰ See U.S. DEP'T OF HEALTH AND HUMAN SERVS, *Executive Summary: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths* 1, 3 (2015),

http://aspe.hhs.gov/sp/reports/2015/OpioidInitiative/es_OpioidInitiative.pdf [hereinafter EXECUTIVE SUMMARY]. ¹²¹ See WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 1, 32 (2013)

http://apps.who.int/iris/bitstream/10665/93142/1/EML_18_eng.pdf?ua=1; Andrej Kastelic et al., WORLD HEALTH ORG., OPIOID SUBSTITUTION TREATMENT IN CUSTODIAL SETTINGS: A PRACTICAL GUIDE (2008), http://www.unodc.org/documents/hiv-aids/OST_in_Custodial_Settings.pdf.

¹²² See Jag Davies, White House Takes Important First Step toward Fixing Broken Drug Court System, DRUG POL'Y ALLIANCE (Feb. 6, 2015), http://www.drugpolicy.org/blog/white-house-takes-important-first-step-toward-fixing-

broken-drug-court-system.

¹²³ See U.S. FOOD & DRUG ADMIN., *FDA Approves First Buprenorphine Implant for Treatment of Opioid Dependence* [hereinafter *FDA Approves First Buprenorphine Implant for Treatment of Opioid Dependence*], <u>http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm503719.htm</u> (last updated Jun. 8, 2016).

http://www.drugabuse.gov/publications/research-reports/heroin/what-are-treatments-heroin-addiction.

¹²⁵ See generally U.S. DEP'T OF HEALTH AND HUMAN SERVS, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS, http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf; Angela Stotts et al., *Opioid Dependence Treatment: Options in Pharmacotherapy*, 10 EXPERT OPINION ON PHARMACOTHERAPY 1727 (2009); Kimberly Kjome & F. Moeller, *Long-Acting Injectable Naltrexone for the Management of Patients with Opioid Dependence*, 5 SUBSTANCE ABUSE: RES. AND TREATMENT 1 (2011); Richard Boldt, *The "Tomahawk" and the "Healing Balm": Drug Treatment Courts in Theory and Practice*, 1 MD. L. J. OF RACE, RELIGION, GENDER, AND CLASS 45, 60 (2010) ("Indeed, methadone maintenance treatment consistently has been demonstrated to reduce drug use and criminal activity among opioid addicts far more effectively than other forms of drug-free outpatient therapy."); Laura Amato et al., *An Overview of Systematic Reviews of the Effectiveness of Opioid Maintenance Therapies: Available Evidence to Inform Clinical Practice and Research*, 28 J. OF SUBSTANCE ABUSE TREATMENT 321 (2005); Stephen Magura et al., *National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment*, 105 AM. J. OF PUB. HEALTH e55, e55 (2015) ("Opioid agonist medication-assisted treatment (OA-MAT) with methadone or buprenorphine is the most effective treatment for opioid use disorder.").

¹²⁶ See Sebastian Trautmann and Hans-Ulrich Wittchen, An Analysis of German Settings Providing Opioid Maintenance Therapy, 47 SUBSTANCE USE AND MISUSE 22, 23 (2012); John Caplehorn, A Comparison of Abstinence-Oriented and Indefinite Methadone Maintenance Treatment, 29(11) INT'L J. ADDICTIONS 1361 (1994); John Caplehorn, Donald McNeil, and David Kleinbaum, *Clinic Policy and Retention in Methadone Maintenance*, 28(1) INT'L J. ADDICTIONS 73 (1993); Mark Willenbring et al., *Variations in Evidence-Based Clinical Practices in Nine United States Veterans Administration Opioid Agonist Therapy Clinics*, 75 DRUG AND ALCOHOL DEPENDENCE 97 (2004).

¹²⁷ See Cherkis, supra, note 71 ("Peer-reviewed data and evidence-based practices do not govern how rehabilitation facilities work.").

¹²⁸ See Amy Nunn et al., Methadone and Buprenorphine Prescribing and Referral Practices in US Prison Systems: Results from a Nationwide Survey, 105(1–2) DRUG & ALCOHOL DEPENDENCE 83 (2009); NAT'L ASS'N OF DRUG CT. PROFFESSIONALS, Resolution of the Board of Directors on the Availability of Medically Assisted Treatment (M.A.T.) for Addiction in Drug Courts (July 17, 2011),

http://www.nadcp.org/sites/default/files/nadcp/NADCP%20Board%20Statement%20on%20MAT.pdf; SUBSTANCE ABUSE & MENTAL HEALTH SERVS ADMIN., Adult Drug Courts and Medication-Assisted Treatment for Opioid Dependence, 8(1) IN BRIEF 1 (Summer 2014), <u>http://dsamh.utah.gov/pdf/SAMHSA%20MAT.pdf</u> [hereinafter Adult Drug Courts and Medication-Assisted Treatment]; Drug Courts Help Break Down Barriers to MAT in Criminal Justice System, 22(42) ALCOHOLISM & DRUG ABUSE WKLY 5, 5–7 (2010); Matusow et al., supra note 59, at 475–76 (approximately half of drug courts forbid the use of M.A.T.).

¹²⁹ See generally Joseph Herman et al., *Methadone Maintenance Treatment (MMT): A Review of Historical and Clinical Issues*, 67 MOUNT SINAI J. MED. 347, 348 (2000).

¹³⁰ See generally CENT. FOR SUBSTANCE ABUSE TREATMENT, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs 28 (2012) [hereinafter Medication-Assisted Treatment For Opioid Addiction], http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf.

¹³¹ See id.

¹³² *Id*.

¹³³ See id.

¹³⁴ See Herman et al., supra note 129, at 361.

¹³⁵ See America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing on Heroin and Prescription Drug Abuse Before the Senate Caucus on International Narcotics Control (2014) (statement of Nora Volkow, Director, National Institute on Drug Abuse) [hereinafter Hearing on Heroin and Prescription Drug Abuse}, http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addictionto-opioids-heroin-prescription-drugabuse.

¹³⁶ See id.

¹³⁷ See T. D'Aunno and H. Pollack, *Changes in Methadone Treatment Practices: Results from a National Panel Study*, 1988–2000, 288(7) J. OF AM. MED. ASS'N 850 (2002).

¹³⁸ See Herman et al., supra note 129, at 354.

¹³⁹ See 21 U.S.C. § 813.

¹⁴⁰ See 42 C.F.R. 8.12 (h)-(j). If the patient has continuously undergone methadone maintenance treatment for a period of time and has met the "take-home" eligibility criteria in the D.E.A. regulation, then the methadone clinic may permit him or her to take some methadone home. The take-home amount ranges from one day's worth to one month-worth if the patient has been in treatment for at least two years. *Id.* at 8.12 (i)(3).

¹⁴¹ See, e.g., Cherkis, *supra* note 71; Herman et al., *supra* note 129.

¹⁴² See Adult Drug Courts and Medication-Assisted Treatment, supra note 128, at 4-5; SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People with Opioid Dependence, 11 ADVISORY (2012) [hereinafter An Introduction to Extended-Release Injectable Naltrexone], https://store.samhsa.gov/shin/content/SMA12-4682/SMA12-4682.pdf.

¹⁴⁵ See Adult Drug Courts and Medication-Assisted Treatment, supra note 128.

¹⁴⁶ See id.

¹⁴⁷ An Introduction to Extended-Release Injectable Naltrexone, supra note 142.

¹⁴⁸ See id.

¹⁴⁹ See id.

¹⁵⁰ See id.

¹⁵¹ See AM. ASS'N FOR THE TREATMENT OF OPIOID DEPENDENCE, AAOTD Guidelines for Using Naltrexone (Vivitrol) in OTPs (2015), http://www.aatod.org/policies/policy-statements/aatod-guidelines-for-using-naltrexone-vivitrol-in-otps/; Walter Armstrong, A Shot in the Dark: Can Vivitrol Help us Control Our Addictions, PAC.

¹⁴³ See id.

¹⁴⁴ See id.

STANDARD MAG. (May 7, 2013), http://www.psmag.com/health-and-behavior/vivitrol-help-control-addictions-57261.

¹⁵² Approximately 25% of individuals with drug dependence lack health insurance. *See Health Care Overhaul Will Add Coverage for Millions of Addicts*, CRAIN'S CHICAGO BUS. (Sept. 11, 2013),

http://www.chicagobusiness.com/article/20130911/NEWS03/130919947/health-care-overhaul-will-add-coverage-for-millions-of-addicts.

¹⁵³ See id.

¹⁵⁴ See id.

¹⁵⁵ See generally SUBSTANCE ABUSE & MENTAL HEALTH SERVS ADMIN., About Buprenorphine Treatment [hereinafter About Buprenorphine Treatment] (2016), http://buprenorphine.samhsa.gov/about.html.

¹⁵⁶ See id.

¹⁵⁷ See U.S. DEP'T OF HEALTH & HUMAN SERVS., *The Facts about Buprenorphine for Treatment of Addiction* 3 (2011), http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf.

¹⁵⁸ See id.

¹⁵⁹ See id.

¹⁶⁰ See id. at 4.

¹⁶¹ See About Buprenorphine Treatment, supra note 155.

¹⁶² See 21 C.F.R. § 1306.22.

¹⁶³ See NAT'L ALL. ADVOCATES FOR BUPRENORPHINE TREATMENT, *15 Ways to Save Money on buprenorphine Treatment* (Dec. 2014), http://www.naabt.org/buprenorphine-cost.cfm ("As the patient stabilizes, s/he can request to have less frequent office visits. Although physicians commonly require patients to come in for appointments every month to monitor the patient's progress, *schedule III medications can be refilled up to 5 times in a 6 month period*. Visit frequency is ultimately determined by the physician, but it doesn't hurt to ask, particularly for those *stable in long-term addiction remission* and those who get therapy or counseling from other sources. Some states however, overrule the physician's judgment and have set minimum periods between office visits.").

¹⁶⁴ See Declan Barry et al., Integrating Buprenorphine Treatment into Office-based Practice: A Qualitative Study, 24 J. OF GENERAL INTERNAL MED. 218, 219 (2009).

¹⁶⁵ See CENTERS FOR DISEASE CONTROL & PREVENTION, Buprenorphine Prescribing Practices and Exposures Reported to a Poison Center – Utah 2002-2011, 61 MORBIDITY & MORTALITY WKLY REP. 997, 997 [hereinafter Buprenorphine Prescribing Practices] (Dec. 14, 2012),

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6149a1.htm ("In France, widespread use of medication-assisted therapy, primarily buprenorphine treatment, was associated with an 80% decrease in overdose deaths from heroin or cocaine from 465 in 1996 to 89 in 2003."). *See also* Julien Emmanuelli & Jean-Claude Desenclos, *Harm Reduction Interventions, Behaviours and Associated Health Outcomes in France, 1996–2003,* 100 ADDICTION 1690 (2005). ¹⁶⁶ See Buprenorphine Prescribing Practices, supra note 165.

¹⁶⁷ See generally A. Khemiri, et al. Analysis Of Buprenorphine/Nalexone Dosing Impact on Treatment Duration, Resource Use, and Costs in the Treatment of Opioid Dependent Adults: A Retrospective Study of U.S. Public and Private Health Care Claims, 126 POSTGRADUATE MED. J. 113 (2014).

¹⁶⁸ See George E. Woody et al., Extended vs Short-Term Buprenorphine-Naloxone for Treatment of Opioid-Addicted Youth: A Randomized Trial, 300 J. OF AM. MED. ASS'N 2003, 2007 (2008).

¹⁶⁹ See Ryan Caldiero et al., Inpatient Initiation of Buprenorphine Maintenance vs. Detoxification: Can Retention of Opioid-Dependent Patients in Outpatient Counseling be Improved?, 15 AM. J. ON ADDICTIONS 1, 4-6 (2006) (maintenance treatment on buprenorphine leads to higher retention in outpatient counseling than detoxification treatment only.).

¹⁷⁰ See id. at 4-5

¹⁷¹ See Lori Whitten, Buprenorphine During Pregnancy Reduces Neonate Distress, NAT'L INST. ON DRUG ABUSE (July 6, 2012), http://www.drugabuse.gov/news-events/nida-notes/2012/07/buprenorphine-during-pregnancy-reduces-neonate-distress.

¹⁷² See Lori Whitten, Youth Opioid Abusers Benefit from Extended Buprenorphine-Nalexone Treatment, NAT'L INST. ON DRUG ABUSE (April 1, 2010), http://www.drugabuse.gov/news-events/nida-notes/2010/04/young-opioid-abusers-benefit-extended-buprenorphine-naloxone-treatment.

¹⁷³ See Lynn E. Sullivan & David A. Fiellin, Office-Based Buprenorphine for Patients with Opioid Dependence, 148 ANNALS OF INTERNAL MED. 662, 667 (2008).

¹⁷⁴ See Paul Jarvis & Matthew Boyle, *Reckitt Benckiser Faces Generic Threats after FDA Rejection*, BLOOMBERG BUS. (Feb. 25, 2013), http://www.bloomberg.com/news/articles/2013-02-25/reckitt-benckiser-says-fda-rejects-suboxone-safeguard-petition.

¹⁷⁵ See NAT'L ALL. ADVOCATES FOR BUPRENORPHINE TREATMENT, *Does Insurance Cover It*?, (Dec. 2008), http://www.naabt.org/faq_answers.cfm?ID=37.

¹⁷⁶ See Robin Clark et al., The Evidence Doesn't Justify Steps By State Medicaid Programs to Restrict Opioid Addiction Treatment with Buprenorphine, 30 HEALTH AFF. 1425, 1425 (2011).

¹⁷⁷ See, e.g., Savings Card May Help Reduce Costs Each Month for Eligible Patients, SUBOXONE (2014), http://www.suboxone.com/hcp/savings-card.

¹⁷⁸ See NAT'L INST. ON DRUG ABUSE, Probuphine: A Game-Changer in Fighting Opioid Dependence, Nora's Blog (May 26, 2016) [hereinafter Probuphine: A Game-Changer in Fighting Opioid Dependence],

https://www.drugabuse.gov/about-nida/noras-blog/2016/05/probuphine-game-changer-in-fighting-opioid-dependence.

¹⁷⁹See id.

¹⁸⁰ See id.

¹⁸¹ See id

¹⁸² See FDA Approves First Buprenorphine Implant for Treatment of Opioid Dependence, supra, note 123.

¹⁸³ See Probuphine: A Game-Changer in Fighting Opioid Dependence, supra, note 178.

¹⁸⁴ See Hayley Pinto et al., *The SUMMIT Trial: A Field Comparison of Buprenorphine vs. Methadone Treatment*, 39 J. SUBSTANCE ABUSE TREATMENT 340 (2010).

¹⁸⁵ See id. See also Alison Knopf, *Hoffman Death Shows Need for Methadone and Buprenorphine*. ALCOHOLISM & DRUG ABUSE WEEKLY 1, 2-3 (Feb. 10, 2014), http://www.alcoholismdrugabuseweekly.com/m-article-

detail/hoff man-death-shows-need-for-methadone-and-bupren or phine. a spx.

¹⁸⁶ For information regarding beginning buprenorphine, see Kathleen Thompson-Gargano, *What is Buprenorphine Treatment Like?*, NAT'L ALL. ADVOCATES FOR BUPRENORPHINE TREATMENT,

http://www.naabt.org/education/what_bt_like.cfm. For information regarding beginning Vivitrol, see An Introduction to Extended-Release Injectable Naltrexone, supra note 142.

¹⁸⁷ See What is Buprenorphine Treatment Like?, supra note 101.

¹⁸⁸ See What is withdrawal?, NAT'L ALL. ADVOCATES FOR BUPRENORPHINE TREATMENT (2008),

http://www.naabt.org/faq_answers.cfm?ID=16.

¹⁸⁹ See J. Milby et al., *Prevalence and Diagnostic Reliability of Methadone Maintenance Detoxification Fear*, 143 AMER. J. PSYCHIATRY 739 (1986).

¹⁹⁰ See Cherkis, supra note 71.

¹⁹¹ See generally Stotts et al., supra note 125.

¹⁹² See id.

 ¹⁹³ See Frank Chaloupka et al., Introduction, in THE ECONOMIC ANALYSIS OF SUBSTANCE USE AND ABUSE: AN INTEGRATION OF ECONOMETRICS AND BEHAVIORAL ECONOMIC RESEARCH 10 (Frank Chaloupka et al. eds., 1999).
 ¹⁹⁴ See R. Mattick, et al., Buprenorphine Maintenance versus Placebo or Methadone Maintenance for Opioid Dependence, 2 COCHRANE DATABASE OF SYSTEMATIC REVIEWS (2008).

¹⁹⁵ See G. Bart, *Promise of Extended-Release Naltrexone is a Red Herring*, 378 LANCET 663 (2011). ¹⁹⁶ See Bart, supra note 48.

¹⁹⁷ See *Medicaid Drug Spending on Anti-Addiction Medicine and Opioid Addiction Refresher* (Feb. 13, 2015), http://www.in.gov/fssa/files/MAC_Presentation_20150213.pdf

¹⁹⁸ See A.Trescot et al., *Effectiveness of Opioids in the Treatment of Chronic Non-Cancer Pain*, 11 PAIN PHYSICIAN OPIOIDS SPECIAL ISSUE S181 (2008).

¹⁹⁹ See Paul G. Barnett and Sally S. Hui, *The Cost-Effectiveness of Methadone Maintenance*, 67(5/6) MOUNT SINAI J. OF MED. 365, 370 (2009).

²⁰⁰ J. Inciardi et al., *Mechanisms of Prescription Drug Diversion Among Drug-Involved Club- and Street-Based Populations*, 8(2) PAIN MEDICINE 171 (2007).

²⁰¹ See Louise Baxter and Alan Stevens, *The Impact of Managed Care on Addiction Treatment: An Analysis*, AMERICAN SOCIETY OF ADDICTION MEDICINE (Sept. 25, 2012), http://www.asam.org/docs/advocacy/2012-9-25_njopioid-document.pdf?sfvrsn=2; *Integrating Treatment Continuum for Substance Use Dependence "Hub/Spoke" Initiative-Phase 1: Opioid Dependence*, VERMONT AGENCY OF HUMAN SERVICES (Jan. 2012),

http://www.healthvermont.gov/adap/documents/HUBSPOKEBriefingDocV122112.pdf ("Medication assisted therapy (MAT), such as methadone and buprenorphine in combination with counseling, has long been recognized as the most effective treatment for opioid addiction."); *What Are the Treatments for Heroin Addiction?, supra* note 55. ²⁰² See Dan Lubman et al., Addiction, a Condition of Compulsive Behaviour? Neuroimaging and

Neuropsychological Evidence of Inhibitory Dysregulation, 99(12) ADDICTION 1491 (2004).

²⁰³ See O'Brien et al., supra note 50.

²⁰⁴ See Baxter & Stevens, *supra* note 201 ("Unfortunately, too many stakeholders in addiction treatment represent that detoxification alone is treatment. "Detoxification alone" only increases the probability of relapse into active use and overdose deaths."); Matusow et al., *supra* note 7 ("In light of the ample evidence demonstrating high relapse rates following opioid detoxification, a policy mandating medical withdrawal [from M.A.T.] appears to be contrary to best practices as defined by medical evidence and the consensus of addiction experts and may represent an infringement of rights as set forth in the Americans with Disabilities Act.").

²⁰⁵ See O'Brien et al., supra note 50.

²⁰⁶ See id.

²⁰⁷ See NAT'L INST. ON DRUG ABUSE, *Types of Treatment Programs*, Principles of Drug Addiction Treatment: A Research-Based Guide (3d Ed.) (2012), available at http://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/drug-addiction-treatment-in-united-states/types-treatment-programs.

²⁰⁸ See Joseph Guydish et al., *Drug Abuse Day Treatment: A Randomized Clinical Trial Comparing Day and Residential Treatment Programs*, 66(2) J. OF CONSULTING AND CLINICAL PSYCHOL. 280 (1998). ²⁰⁹ See id.

²¹⁰ See Vaillant, supra note 48.

²¹¹ See Michael Gossop et al., *Factors Associated with Abstinence, Lapse or Relapse to Heroin Use after Residential Treatment: Protective Effect of Coping Responses*, 97(10) ADDICTION 1259 (2002).

²¹² See B. Smyth et al., *Lapse and Relapse Following Inpatient Treatment of Opioid Dependence*, 103(6) IRISH MED. J. 176 (2010).

²¹³ See J. Strang, *Loss of Tolerance and Overdose Mortality after Inpatient Opioid Detoxification: Follow up Study*, 326 BRIT. MED. J. 959 (2003) (Patients who "successfully" completed inpatient detoxification were more likely than other patients to have died within a year).

²¹⁴ See id; Ingrid Binswanger et al., *Mortality after Prison Release: Opioid Overdose and Other Causes of Death, Risk Factors, and Time Trends from 1999 to 2009*, 159(9) ANNALS OF INTERNAL MED. 592 (2013).

²¹⁵ See Vaillant, supra note 48; See Bart, supra note 48.

²¹⁶ See NAT'L INST. ON DRUG ABUSE, What is Drug Addiction Treatment, Principles of Drug Addiction: A Research-Based Guide, http://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guidethird-edition/frequently-asked-questions/what-drug-addiction-treatment (last visited Feb. 10, 2015) ("Because they work on different aspects of addiction, combinations of behavioral therapies and medications (when available) generally appear to be more effective than either approach used alone."); Morten Hesse and Mads Pedersen, *Easyaccess Services in Low-threshold Opioid Agonist Maintenance*, 6 INT'L J. MENTAL HEALTH ADDICTION 316 (2008) (study of combining methadone treatment with counseling in Europe).

²¹⁷ See Cindy Thomas et al., *Medication-Assisted Treatment with Buprenorphine: Assessing the Evidence*, 65(2) PSYCHIATRIC SERVS 158, 165 (2014); D. Drummond and K. Perryman, *Psychosocial Interventions in Pharmacotherapy of Opioid Dependence: A Literature Review*, WORLD HEALTH ORGANIZATION (2007), <u>http://www.who.int/substance_abuse/activities/psychosocial_interventions.pdf</u> (prepared for Third Meeting of Technical Development Group for the WHO "Guidelines for Psychosocially Assisted Pharmacotherapy of Opioid Dependence").

²¹⁸ See Thomas et al., supra note 217, at 165; See Drummond and Perryman K, supra note 217.

²¹⁹ See M. MGovern et al., Addiction Treatment Services and Co-Occurring Disorders: Prevalence Estimates, Treatment Practices, and Barriers, 31(3) J. OF SUBSTANCE ABUSE 267 (2006).

²²⁰ See *Comorbidity*, supra note 27, at 2.

²²¹ See *Comorbidity*, supra note 27.

²²² See H. Gotham et al., Assessing the Co-Occurring Capability of Mental Health Treatment Programs: The Dual Diagnosis Capability in Mental Health Treatment (DDCMHT) Index, 40(2) J. OF BEHAV. HEALTH SERV. & RES.234, 239 (2013).

²²³ See M. McGovern et al., *Dual Diagnosis Capability in Mental Health and Addiction Treatment Services:* An Assessment of Programs across Multiple State Systems, 41(2) ADMIN. AND POL'Y IN MENTAL HEALTH & MENTAL HEALTH SERV. RES. 205 (2014).

²²⁴ See Vaillant, supra note 48; Bart, supra note 48.

²²⁵ See generally Medication-Assisted Treatment for Opioid Addiction, supra note 27, at 8-10.

²²⁶ See Dackis and O'Brien, supra note 32, at1431.

²²⁷ See E. Murrow EJ and F. Oglesby, *Acute and Chronic Illness: Similarities, Differences and Challenges*, 15(5) ORTHOPEDIC NURSING 47 (1996).

²²⁸ See id.

²²⁹ See WILLIAM WHITE, SLAVING THE DRAGON: THE HISTORY OF ADDICTION TREATMENT RECOVERY IN AMERICA 2 (1998). ²³⁰ See id. ²³¹ See id. ²³² See id. at 4. ²³³ See id. at 4. ²³⁴ See id. at 21. ²³⁵ See id. at 4. ²³⁶ See id. at 26 ²³⁷ See id. at 34-35. ²³⁸ See id. at 39-40. ²³⁹ See id. at 4. ²⁴⁰ See id. at 4-5 ²⁴¹ See id. at 5 ²⁴² See id. ²⁴³ See id. at 5, 26. ²⁴⁴ See id. at 5. ²⁴⁵ See id. at 24. ²⁴⁶ See id. at 26. ²⁴⁷ See id. ²⁴⁸ See id. at 28. ²⁴⁹ See id. ²⁵⁰ See id. at 37. ²⁵¹ See Pekka Sulkunen, Images of Addiction: Representations of Addiction in Films, 15(6) ADDICTION RES. & THEORY 543, 544 (2007). ²⁵² Such centers follow the Minnesota Model, meaning the centering of addiction treatment around the 12-steps, even when counselors and other treatment professionals are involved. See NAT'L INST. ON DRUG ABUSE, Minnesota Model: Description of Counseling Approach, http://archives.drugabuse.gov/ADAC/ADAC11.html. (last visited Jun. 19, 2016). ²⁵³ See White, supra note 229 at 96-97.

²⁵⁴ See id. at 98.

²⁵⁵ See id.

²⁵⁶ See id. at 99.

²⁵⁷ See id.

²⁵⁸ See id.

²⁵⁹ See J. Mitchell et al., *Naltrexone Aversion and Treatment Efficacy are Greatest in Humans and Rats that Actively Consume High Levels of Alcohol*, 33(1) NEUROBIOLOGY OF DISEASE 82 (2009).

²⁶⁰ See H. Kragh, *From Disulfram to Antabuse: The Invention of a Drug*, 33(2) BULL. FOR THE HIST. OF CHEMISTRY 87 (2008).

²⁶¹ See Kurt Hohenstein, *Just What the Doctor Ordered: The Harrison Narcotic Anti-Narcotic Act, the Supreme Court, and the Federal Regulation of Medical Practice, 1915-1919*, 26(3) J. OF SUP. CT.HIST.231, 253 (2001). ²⁶² See id. at 233.

²⁶³ See Richard Boldt, Drug Policy in Context, 62 S.C. L. Rev. 261, 263 (2010).

²⁶⁴ See HARRISON ANTI-NARCOTIC TAX ACT, HARRISON NARCOTICS ACT of 1914, Pub. L. No. 63-223, 38 Stat. 785 (repealed 1970)

²⁶⁵ See R. Rettigg and Adam Yarmolinsky, *Federal Regulation of Methadone Treatment*, Committee on Federal Regulation of Methadone Treatment, INST. OF MED. (1995).

²⁶⁶ See Webb v. United States, 249 U.S. 96, 99-100 (1919)/

²⁶⁷ See Hohenstein, supra note 261 at 234.

²⁷⁰ See id.

²⁷¹ See id.

²⁶⁸ See Boldt, supra note 263 at 263, (quoting S. Comm. on the Judiciary, Subcomm. on Improvements in the Fed. Criminal Code, 84th Congress, 2d Session, Rep. on the Treatment and Rehabilitation of Narcotic Addicts 9, 12 (1956)).

²⁶⁹ See Joseph Herman et al., *Methadone Maintenance Treatment: A Review of Historical and Clinical Issues*, 67 (5&6) MOUNT SINAI J. OF MED. 347 (2000).

²⁷² See id.

²⁷⁴ See id.

²⁷⁵ See Rettigg and Yarmolinsky, supra note 265 at 123.

²⁷⁶ See infra, chapter 2.

²⁷⁷ See infra, chapter 2.

²⁷⁸ http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm229109.htm

²⁷⁹ See FDA Approves First Buprenorphine Implant for Treatment of Opioid Dependence, supra, note 123.

²⁸⁰ See David Frank, *The Trouble with Morality: The Effects of 12-Step Discourse on Addicts' Decision-Making*, 43(3) J. OF PSYCHOACTIVE DRUGS 245 (2011).

²⁸¹ See William White, *Medication-Assisted Recovery from Opioid Addiction: Historical and Contemporary Perspectives*, 31(3) J. OF ADDICTIVE DISEASES 199, 200 (2012).

²⁸² See id.

²⁸³ See id.

²⁸⁴ See id.

²⁸⁵ See Thirty Years of America's Drug War: A Chronology, FRONTLINE,

http://www.pbs.org/wgbh/pages/frontline/shows/drugs/cron/ (last visited Jun. 19, 2016).

²⁸⁶ See id.

- ²⁸⁷ See id.
- ²⁸⁸ See id.

²⁸⁹ See id.

²⁹⁰ See id.

²⁹¹ See id.

²⁹² See id.

²⁹³ See id.

²⁹⁴ See id.

²⁹⁵ See Kyle Graham, Sorry Seems to Be the Hardest Word: The Fair Sentencing Act of 2010, Crack, and Methamphetamine, 45 U. RICH. L. REV. 765, 766 (2011).

²⁹⁶ See Dackis and O'Brien, surpa note 32 at 1431.

²⁹⁷ See Thirty Years of America's Drug War: A Chronology, supra note 285.

²⁹⁸ See THE WHITE HOUSE, A Drug Policy for the 21st Century,

https://www.whitehouse.gov/ondcp/drugpolicyreform (last visited Jun. 19, 2016).

²⁹⁹ See OFF. OF NAT'L DRUG CONTROL POL'Y, THE WHITE HOUSE, 2015 National Drug Control Strategy,

https://www.whitehouse.gov/ondcp/national-drug-control-strategy (last visited Jun. 19, 2016).

³⁰⁰ https://www.incb.org/documents/Publications/AnnualReports/AR2015/English/AR 2015 E.pdf 55

³⁰¹ See A Drug Policy for the 21st Century, supra note 298.

³⁰² See id.

³⁰³ See id.

³⁰⁴ See id.

³⁰⁵ See Kalynn Amundson, Anna Zajicek, and Valerie Hunt, *Pathologies of the Poor: What do the War on Drugs and Welfare Reform Have in Common?* XLI(1) J. OF SOCIOLOGY AND SOC. WELFARE 5, 17 (2014) (A study of rhetoric used in the War on Drugs found the following: "Most references to drug addiction, in both War on Drugs and Welfare Reform documents, were largely from a punitive criminal justice frame advocating punishment, rather than a medical frame, which views addiction as a medical condition requiring treatment, although there were some mentions of treatment and rehabilitation.").

³⁰⁶ See Jeffrey Timberlake et al., *How Should We Wage the War on Drugs? Determinants of Public Preferences for Drug Control Alternatives*, 31 POL'Y STUD. J. 71, 72-73 (2003).

³⁰⁷ Offenses, FED. BUREAU OF PRISONS (Dec. 27, 2014),

http://www.bop.gov/about/statistics/statistics_inmate_offenses.jsp.

³⁰⁸ See NAT'L ASS'N FOR THE ADVANCEMENT OF COLORED PEOPLE, Criminal Justice Fact Sheet, (2015),

http://www.naacp.org/pages/criminal-justice-fact-sheet.

³⁰⁹ See T. J. Csordas, THE SACRED SELF (1994).

³¹⁰ See Sulkunen, supra note 251 at 544.

³¹² See id.

²⁷³ See id.

³¹¹ See Dackis and O'Brien, supra note 32 at 1431.

³¹³ See *Public Opinion Poll Shows Deep-Seated Conflict About Addiction as Disease*, 18(33) ALCOHOLISM & DRUG ABUSE WKLY 1, 1 (Aug. 26, 2006).

³¹⁴ See id. at 2.

³¹⁵ See id. at 2.

³¹⁶ See O'Brien et al., supra note 50.

³¹⁷ See NAT'L INST. ON DRUG ABUSE, Addiction and Free Choice, Nora's Blog (Feb. 18, 2014),

https://www.drugabuse.gov/about-nida/noras-blog/2014/02/addiction-free-choice.

³¹⁸ See P. Corrigan et al., *The Public Stigma of Mental Illness and Addiction: Findings from a Stratified Random Sample*, 9(2) J. OF SOCIAL WORK 139 (2009).

³¹⁹ See Avoidance of Counseling: Psychological Factors That Inhibit Seeking Help, 85 J. OF COUNSELING & DEV. 410 (2007)

³²⁰ See David L. Vogel, *The Role of Self-Efficacy in Achieving Health Behavior Change*, 13 HEALTH EDUC. & BEH. 73 (1986).

³²¹ See Patricia Drew, "But Then I Learned...": Weight Loss Surgery Patients Negotiate Surgery Discourses, 73(8) SOC. SCI. & MED. 1230 (2011).

³²² See S. M. Phelan et al., *Impact of Weight Bias and Stigma on Quality of Care and Outcomes for Patients with Obesity*, 16 OBESITY REV. 319 (2015).

³²³ See Dackis and O'Brien, surpa note 32 at 1431.

³²⁴ See William White, *Long-Term Strategies to Reduce the Stigma Attached to Addiction, Treatment, and Recovery within the City of Philadelphia*, PHILADELPHIA DEP'T OF BEH. HEALTH AND MENTAL RETARDATION SERV. 6 (Jun. 19, 2016), http://www.williamwhitepapers.com/pr/2009Stigma%26methadone.pdf.

³²⁵ See O'Brien et al., supra note 50.

³²⁶ See Dackis and O'Brien, surpa note 32 at 1431.

³²⁷ See generally Matthew Stanbrook, Addiction is a Disease: We Must Change our Attitudes Towards Addicts, 184 CANADIAN MED. ASS'N. J. 155 (2012); Jennifer Murphy, Drug Court as both Legal and Medical Authority, 32 DEVIANT BEH. 257, 258 (2011).

³²⁸ Id.

³²⁹ See Valerie Earnshaw et al., Drug Addiction Stigma in the Context of Methadone Maintenance Therapy: An Investigation into Understudies Sources of Stigma. 11 INT'L. J. MENTAL HEALTH ADDICTION 110, 111-12 (2013). ³³⁰ See id., at 111-12.

³³¹ See U.S. DEP'T OF HEALTH AND HUMAN SERVS., ARE YOU IN RECOVERY FROM ALCOHOL OR DRUG ADDICTION? KNOW YOUR RIGHTS 12-13, https://store.samhsa.gov/shin/content/PHD1091/PHD1091.pdf (last visited Feb. 9, 2015).

³³² See Maria Swora, *Personhood and Disease in Alcoholics Anonymous: A Perspective from the Anthropology of Religious Healing*, 4(1) MENTAL HEALTH, RELIGION, & CULTURE 1, 3 (2001).

³³³ See Murphy, supra note 326 at 258.

³³⁴ See id.

³³⁵ See Sarah Sifers and Kristina Peltz, *What Members of Alcoholics Anonymous Really Believe*, 16(7) MENTAL HEALTH, RELIGION, & CULTURE 711, 713 (2013).

³³⁶ See Swora, supra note 331 at 18.

³³⁷ See id. at 13.

³³⁸ See id.

³³⁹ See id. at 6.

³⁴⁰ See id. at 7.

³⁴¹ See John Kelley and M. Greene, *The Twelve Promises of Alcoholics Anonymous: Psychometric Measure Validation and Mediational Testing as a 12-Step Specific Mechanism of Behavior Change*, 133 DRUG & ALCOHOL DEPENDENCE 633, 639 (2013).

³⁴² See generally Stanbrook, supra note 326.

³⁴³ See id. at 4.

³⁴⁴ See id.

³⁴⁵ See O'Brien et al., supra note 50.

³⁴⁶ See Stanbrook, supra note 326.

³⁴⁷ See GLOBAL COMMISSION ON DRUG POL'Y, *The Negative Impact of the War on Drugs on Public Health: The Hidden Hepatitis C Epidemic* (May 2013), http://www.globalcommissionondrugs.org/reports/the-negative-impact-of-the-war-on-drugs-on-public-health-the-hidden-hepatitis-c-epidemic/

³⁴⁸ See White, supra note 229 at xv.

³⁴⁹ See id. at xvi.

³⁵⁰ See id.

³⁵¹ See id.

³⁵² See H. Rao et al., A Study of Stigmatized Attitudes Towards People with Mental Health Problems among Health Professionals, 16 J. OF PSYCHIATRIC & MENTAL HEALTH NURSING 279 (2009); R. Room, Stigma, Social Inequality and Alcohol and Drug Use, 24 DRUG & ALCOHOL REV. 143 (2005); G. Schomerus, The Stigma of Alcohol Dependence Compared with other Mental Disorders: A Review of Population Studies, 46 ALCOHOL & ALCOHOLISM 105 (2011).

³⁵³ See Daniel Buchman and Peter Reiner, *Stigma and Addiction: Being and Becoming*, 9(9) AMER. J. OF BIOETHICS-NEUROSCIENCE 18, 19 (2009).

³⁵⁴ See Cherkis, supra note 71; A. Thomas McLellan, What is Recovery? Revisiting the Betty Ford Institute Consensus Panel Definition, 10 J. OF SOCIAL WORK PRAC. IN THE ADDICTIONS 109, 111 (2010).

³⁵⁵ See Mary Kreek, *Extreme Marginalization: Addiction and other Mental Health Disorders, Stigma, and Imprisonment*, 1231 ANNALS OF THE N.Y. ACAD. OF SCI. 65, 69 (2011).

³⁵⁶ See id.

³⁵⁷ See Roman, supra note 62.

³⁵⁸ See Paul Roman and J. Aaron Johnson, *Adoption and Implementation of New Technologies in Substance Abuse Treatment*, 22 J. OF SUBSTANCE ABUSE TREATMENT 211, 216 (2002)

³⁵⁹ See H. Knudsen et al., *Adoption and Implementation of Medications in Addiction Treatment Programs*, 5 J. OF ADDICTION MEDICINE 21 (2011).

³⁶⁰ See Traci Rieckmann et al. (2010), *supra* note 59, *at* 232.

³⁶¹ See Frank, supra note 280.

³⁶² See id.

³⁶³ See id. at 250.

³⁶⁴ See id. at 249-50.

³⁶⁵ See McLellan, *supra* note 353 at 109.

³⁶⁶ See id. at 110.

³⁶⁷ See Magdalena Harris and Tim Rhodes, *Methadone Diversion as a Protective Strategy: The Harm Reduction Potential of "Generous Constraints"*, 24 INT'L J. OF DRUG POLICY e43, e49 (2013).

³⁶⁸ See White, supra note 281 at 201.

³⁶⁹ See id. at 202.

³⁷⁰ See generally id.

³⁷¹ See E. Gomart, *Surprised by Methadone: In Praise of Drug Substitution Treatment in a French clinic*, 10(2–3) BODY & SOCIETY 85 (2004); Harris and Rhodes, supra note 366, at e44.

³⁷² See Harris and Rhodes, supra note 366 at e44.

³⁷³ See Dackis and O'Brien, surpa note 32 at 1431.

³⁷⁴ See id.

³⁷⁵ See D. Fiellin et al., *Counseling plus Buprenorphine-Naloxone Maintenance Therapy for Opioid Dependence*, 355 New ENGLAND J. OF MED. 365 (2006).

³⁷⁶ See Merrill (2002), supra note 81.

³⁷⁷ See CENTER FOR SUBSTANCE ABUSE RES., UNIVERSITY OF MARYLAND COLLEGE PARK, Maryland U. Number of U.S. emergency department visits related to nonmedical use of buprenorphine more than triples since 2006, March 31, 2003 to December 15, 2014, CESAR Fax Buprenorphine Series (Jan. 9, 2015), available at

http://www.cesar.umd.edu/cesar/pubs/BuprenorphineCESARFAX.pdf; O. Ferrant et al., Fatal Poisoning due to Snorting Buprenorphine and Alcohol Consumption, 204 (1-3) Forensic Science Int'l e8 (2011); A. Pelissier-Alicot et al., Buprenorphine Related Deaths: Unusual Forensic Situations, 124 Int'l J. Legal Med. 647 (2010).

³⁷⁸ See generally About Buprenorphine Treatment, supra note 155.

³⁷⁹ See id.

³⁸⁰ See id.

³⁸¹ See Alec MacGillis, *The Wonder Drug: Why are Drug Courts Denying Heroin Addicts the Medicine They Need?*, SLATE, Feb. 9, 2015,

http://www.slate.com/articles/news_and_politics/politics/2015/02/suboxone_could_help_heroin_addicts.html. ³⁸² See, e.g., Deborah Sontag, Addiction Treatment with a Dark Side, N.Y. TIMES (Nov. 16, 2013),

 $http://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupe-can-be-savior-or-menace.html?pagewanted=all\&_r=0.$

³⁸³ See Z. Schuman-Olivier et al. *Self-Treatment: Illicit Buprenorphine Use by Opioid-Dependent Treatment Seekers*, 39 J. SUBSTANCE ABUSE 41, 43 (2010).

³⁸⁴ See S. Comer et al., Buprenorphine/naloxone Reduces the Reinforcing and Subjective Effects of Heroin in Heroin-Dependent Volunteers, 181(4) PSYCHOPHARMACOLOGY (Berl.) 664 (2005); See S. Comer et al., Abuse Liability of Intravenous Buprenorphine/Naloxone and Buprenorphine Alone in Buprenorphine-Maintained Intravenous Heroin Abusers, 105 ADDICTION 709 (2010); A. Hakansson et al., Buprenorphine Misuse among Heroin and Amphetamine Users in Malmo, Sweden Purpose of Misuse and Route of Administration, 13 Eur. ADDICTION RESEARCH 207 (2007); A. Bazazi et al., Illicit use of Buprenorphine/Naloxone among Injecting and Noninjecting Opioid Users, 5 J. OF ADDICTION MED. 175 (2011).

³⁸⁵ See Comer et al. (2005), supra note 384; Comer et al. (2010), supra note 384; Hakansson et al., supra note 384; Bazazi et al., supra note 384.

³⁸⁶ See Comer et al. (2005), supra note 384; Comer et al. (2010), supra note 384; Hakansson et al., supra note 384; Bazazi et al., supra note 384.

³⁸⁷ See Chris-Ellyn Johanson et al., *Diversion and Abuse of Buprenorphine: Findings from National Surveys of Treatment Patients and Physicians*, 120 DRUG & ALCOHOL DEPENDENCE 190, 193 (2012).

³⁸⁸ See Zev Schuman-Olivier et al., *Clinician Beliefs and Attitudes about Buprenorphine/Naloxone Diversion*, 22 AMER. J. ON ADDICTIONS 574, 575 (2013).

³⁸⁹ See id. at 576.

³⁹⁰ See id.

³⁹¹ See id. at 579.

³⁹² See id. at 578.

³⁹³ See Becky L. Genberg, *Prevalence and correlates of street-obtained buprenorphine use among current and former injectors in* Baltimore, Maryland, 38 ADDICTIVE BEHAVIORS 2868, 2873 (2013).
 ³⁹⁴ See Comer (2005), supra note 384; A. *Monte et al.*, *Diversion of Buprenorphine/Naloxone Coformulated Tablets*

³⁹⁴ See Comer (2005), supra note 384; A. *Monte et al.*, *Diversion of Buprenorphine/ Naloxone Coformulated Tablets in a Region with High Prescribing Prevalence*, 28 J. OF ADDICTIVE DISEASES 226 (2009); M. Lofwall et al., *Inability to Access Buprenorphine Treatment as a Risk Factor for Using Diverted Buprenorphine*, 126 DRUG & ALCOHOL DEPENDENCE 379 (2012).

³⁹⁵ See Schuman-Olivier et al., supra note 383 at 48; see also prevalence and correlates

³⁹⁶ See B. Johnson and T. Richert, Diversion of Methadone and Buprenorphine from Opioid Substitution Treatment: The Importance of Patients' Attitudes and Norms, 54 J. OF SUBSTANCE ABUSE TREATMENT 50 (2015).

³⁹⁷ See L. Monico et al., *Prior Experience with Non-Prescribed Buprenorphine: Role in Treatment Entry and Retention* 57, J. OF SUBSTANCE ABUSE TREATMENT 57, 61 (2015).

³⁹⁸ See Rettig and Yarmolinsky, supra note 265 at 94.

³⁹⁹ See id. at 97.

⁴⁰⁰ See Harris and Rhodes, supra note 366 at e47.

⁴⁰¹ See id. at e49.

⁴⁰² See Johnson and Richert, supra note 396.

⁴⁰³ See U.S. GOV'T ACCOUNTABILITY OFF., Report to Congressional Requesters, Highlights, *Methadone-Associated Overdose Deaths: Factors Contributing to Increased Deaths and Efforts to Prevent Them*, GAO-09-341 (2009). ⁴⁰⁴ See id.

⁴⁰⁵ See id. at 5.

⁴⁰⁶ See Rettigg and Yarmolinsky, supra note 265, at 100.

⁴⁰⁷ See id.

⁴⁰⁸ See id.

⁴⁰⁹ See Rebecca Tiger, Judging Addicts 85 (2011); Suzanne Fraser & Kylie Valentine, Substance and Substitution: Methadone Subjects in Liberal Societies 2 (2008).

⁴¹⁰ See White, supra note 281 at 204.

⁴¹¹ See id.

⁴¹² See Rieckmann et al. (2010), supra note 59 at 232.

⁴¹³ See NA Groups and Medication, NA WORLD SERVICES, INC. (Narcotics Anonymous, Chatsworth, Cal.), 2007, http://www.na.org/admin/include/spaw2/uploads/pdf/servicemat/Dec2011_NA_Groups_and_Medication.pdf. ⁴¹⁴ See id.

⁴¹⁵ See William White, *Narcotics Anonymous and the Pharmacotherapeutic Treatment of Opioid Addiction in the United States*, PHILA. DEP'T OF BEH. HEALTH AND INTELLECTUAL DISABILITY SERVS. (Philadelphia Department of Behavioral Health and Intellectual Disability Services and the Great Lakes Addiction Technology Transfer Center, Chicago), 2011, available at http://atforum.com/documents/2011NAandMedication-assistedTreatment.pdf.

⁴¹⁶ See Frank, supra note 280 at 250.

⁴¹⁷ See Hearing on Heroin and Prescription Drug Abuse, supra note 135 ("Medication-assisted treatments remain grossly underutilized in many addiction treatment settings, where stigma and negative attitudes (based on the misconception that buprenorphine or methadone "substitute a new addiction for an old one") persist among clinic staff and administrators.").

⁴¹⁸ See R. Rychtarik et al., *Alcoholics Anonymous and the Use of Medications to Prevent Relapse: An Anonymous Survey of Member Attitudes*, 61 J. OF STUD. ON ALCOHOL 134 (2000).

⁴¹⁹ See WHITE, supra note 415 at 22, ("Seen as a whole, NA literature defines the use of medically supervised methadone maintenance and other pharmacotherapies for opioid addiction as differing little from illicit drug use or alcohol use. It asserts that views restricting the participation of NA members on medications like methadone and buprenorphine are means of asserting NA's philosophy of complete abstinence and maintaining the recovery atmosphere of NA meetings.").

⁴²⁰ See Frank, supra note 280 at 253.

⁴²¹ See Dackis and O'Brien, supra note 32 at 1431.

⁴²² See Y. Olsen and J. Sharfstein, *Confronting the Stigma of Opioid Use Disorder and Its Treatment*, 311(14) J. Am. Med. Ass'n 1393 (2014).

⁴²³ See infra, Chapter One.

⁴²⁴ See id.

⁴²⁵ See H. Kleber, *Methadone Maintenance 4 Decades Later: Thousands of Lives Saved but Still Controversial*, 300 (19) J. AM. MED. Ass'N 2303 (2008).

⁴²⁶ See 21 U.S.C. § 812.

⁴²⁷ See id.

⁴²⁸ See 21 U.S.C. § 811(a)(1).

⁴²⁹ See id.

⁴³⁰ See id.

⁴³¹ See 21 U.S.C. § 823 (g).

⁴³² See 21 C.F.R. § 1306.22.

⁴³³ See id.

⁴³⁴ See Rob Stein, Painkiller Paradox: Feds Struggle to Control Drugs that Help and Harm, NAT'L PUB. RADIO (Jan. 23, 2013), http://www.npr.org/blogs/health/2013/01/23/169963431/painkiller-paradox-feds-struggle-to-control-drugs-that-help-and-harm.

⁴³⁵ *See* Schedules of Controlled Substances, 67 Fed. Reg. 62354, 62354 (codified at 21 C.F.R. pt. 1308) (Oct. 7, 2002).

⁴³⁶ SCHEDULES OF CONTROLLED SUBSTANCES, 50 Fed. Reg. 8104 (Feb. 28, 1985).

⁴³⁷ See 21 U.S.C. § 812 (b)(5).

⁴³⁸ See Buprenorphine Prescribing Practices, supra note 165. See also Emmanuelli & Desenclos, supra note 165 at 1696.

 ⁴³⁹ See U.S. FOOD & DRUG ADMIN, Subutex and Suboxone Approved to Treat Opiate Dependence (Oct. 8, 2012), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm191521.htm.
 ⁴⁴⁰ See 67 Fed. Reg. 62354, 62358 (Oct. 7, 2002).

⁴⁴¹ See id.

⁴⁴² See id. at 62354.

⁴⁴³ See 21 U.S.C. § 812 (b)(3).

⁴⁴⁴ See generally 67 Fed. Reg. 62354, 62355 (Oct. 7, 2002).

⁴⁴⁵ See DEPART OF JUSTICE, DRUG ENFORCEMENT AGENCY, 21 CFR part 1308, October 7, 2002.

http://www.deadiversion.usdoj.gov/fed_regs/rules/2002/fr1007.htm

⁴⁴⁶*Id.* at 62357.

⁴⁴⁷ Id.

⁴⁴⁸ *Id.* at 62358.

⁴⁴⁹ Id.

⁴⁵⁰ See id.

⁴⁵¹ See The Facts about Buprenorphine for Treatment of Opioid Addiction, supra note 157, at 3; Medication Proponents Make Pitch to Drug Court Professionals, 16 ALCOHOLISM & DRUG ABUSE WKLY 2 (Aug. 16, 2004). ⁴⁵² See 67 Fed. Reg. 62354, 62357-62358.

⁴⁵³ *Id*.at 62357.

⁴⁵⁴ *Id.* at 62359.

⁴⁵⁵ See id. at 62363.

⁴⁵⁶ Id.

⁴⁵⁷ See 21 U.S.C. § 823(g).

⁴⁵⁸ See Drug Addiction Treatment Act of 2000, 146 CONG. REC. H6374-H6375 (Rep. Gilman said the following: "[The legislation] seeks to assist qualified physicians in treating their addicted patients, to speed up approval of narcotic drugs for addiction treatment purposes, and offers treatment options for those Americans for whom other treatment programs are financially out of reach...The bill contains a number of safeguards that are designed to prevent abuses of the waiver procedure." *Id.* at H6377). The Drug Addiction Treatment Act was ultimately passed by Congress as Title XXXV, Section 3502 of the Children's Health Act of 2000.

⁴⁵⁹ DRUG ADDICTION TREATMENT ACT of 1999, S. 324, 106th Congress (1999).

⁴⁶⁰ DRUG ADDICTION TREATMENT ACT of 2000, H.R. 2634, 106th Congress (2000). Representative Bliley (R). was the main sponsor, with the following co-sponsors: Boucher (D), Green (D), Rangel (D), Norwood (R), Upton (R), Coble (R), Greenwood (R), Deal (R), Cox (R), and Oxley (R).

⁴⁶¹ See Final Vote Results for Roll Call 416 (Drug Addiction Treatment Act of 2000), Office of the Clerk of the U.S. House of Representatives (July 19, 2000). http://clerk.house.gov/evs/2000/roll416.xml.

⁴⁶² See S.Amdt. 4181 to H.R.4365, 106th Congress (2000).

⁴⁶³ See *Final Vote Results for Roll Call* 496 (Children's Health Act of 2000), Office of the Clerk of the U.S. House of Representatives (Sep. 27, 2000), http://clerk.house.gov/evs/2000/roll496.xml. There were 394 Yea votes and 25 Nay votes.

⁴⁶⁴ See Schedules of Controlled Substances, 67 Fed. Reg. 62354, 62366 (Oct. 7, 2002).

⁴⁶⁵ See DRUG ADDICTION TREATMENT ACT of 2000, 21 U.S.C. § 823(g) (2006).

⁴⁶⁶ *See id.* at § 823 (g)(2)(A).

⁴⁶⁷ Id.

⁴⁶⁸ Id.

⁴⁶⁹ *Id.* at § 823 (g)(2)(B)(iii).

⁴⁷⁰ See id. at § 823 (g)(2)(G).

⁴⁷¹ See id.at § 823 (g)(2)(B)(iii).

⁴⁷² See, e.g., Letter from Stuart Gitlow, President, American Society of Addiction Medicine, to Senator Edward J. Markey, (June 19, 2014) [hereinafter ASAM Letter], http://www.asam.org/docs/default-source/advocacy/lettersand-comments/buprenorphine-expansion-act-markey-letter.pdf ("We have at our disposal highly effective, FDAapproved pharmacotherapies to treat opioid addiction. Unfortunately, they all come with arbitrary treatment limits that have resoundingly negative effects on treatment access and outcomes."); *Medication-Assisted Treatment for Opioid Addiction, supra* note 27, at 4-5 (noting that a National Institute of Health consensus panel has called for less restrictions on medication for treating addiction).

⁴⁷³ See Drug Addiction Treatment Expansion Act, 151 CONG. REC. D877 (daily ed. Sept. 6, 2005); Office of National Drug Control Policy Reauthorization Act of 2006, Public L. 109-469 (2006) (codified at 21 U.S.C. § 1701, *et seq.*)

⁴⁷⁴ See DRUG ADDICTION TREATMENT ACT of 2000, 21 U.S.C. § 823 (g)(2)(B)(iii).

⁴⁷⁵ See id.

476 See id.

⁴⁷⁷ See id.

⁴⁷⁸ 151 CONG. REC. H6679-H6681 (daily ed. July 27, 2005) (Statement of Rep. Souder).

⁴⁷⁹ See Office of National Drug Control Policy Reauthorization Act of 2006, Public L. 109-469 (2006). ⁴⁸⁰ See id.

⁴⁸¹ 152 CONG. REC. S11703-S11706 (daily ed. Dec. 8, 2006) (statement of Sen. Orin Hatch).

⁴⁸² See Roger Rosenblatt et al., Geographic and Specialty Distribution of U.S. Physicians Trained to Treat Opioid Use Disorder, 13 ANNALS OF FAMILY MED. 23, 25 (2015).

⁴⁸³ See id.

⁴⁸⁴ See 21 U.S.C. § 823(g).

⁴⁸⁵ See, e.g., Gitlow, supra note 472 ("We have at our disposal highly effective, FDA-approved pharmacotherapies to treat opioid addiction. Unfortunately, they all come with arbitrary treatment limits that have resoundingly negative effects on treatment access and outcomes."). *See* 151 CONG. REC. H6679-H6681 (daily ed. July 27, 2005) (Statements of Reps. Deal and Souder).

⁴⁸⁶ See Melissa Ferrara, Comment: The Disparate Treatment of Addiction-Assistance Medications and Opiate Pain Medications Under the Law: Permitting the Proliferation of Opiates and Limiting Access to Treatment, 42 SETON HALL L. REV. 741. (2012); Saxon & McCarty, *supra* note 71, at 124 ("There are few, if any, other approved medications that can be prescribed only by physicians who meet certain standards.").

⁴⁸⁷ See id. at 750-52.

⁴⁸⁸ See Cherkis (2015), supra note 71.

⁴⁸⁹ See id.

⁴⁹⁰ See 21 U.S.C. 823(g)(2)(B)(iii).

⁴⁹¹ Medication Assisted Treatment for Opioid Use Disorders, 81 FR 44738 (July 8, 2016).

⁴⁹² See id.

⁴⁹³ See id.

⁴⁹⁴ See id.

⁴⁹⁵ See id.

⁴⁹⁶ See id.

⁴⁹⁷ See id.

⁴⁹⁸ See id.

⁴⁹⁹ See Comprehensive Addiction Recovery Act of 2016, S. 524, 114thCong. (2016).

⁵⁰⁰ See Jason Cherkis, Congress Finally Passes Bipartisan Legislation to Address Opioid Epidemic, HUFFINGTON POST (July 13, 2016), http://www.huffingtonpost.com/entry/congress-passes-opioid-

bill_us_5786ed5ee4b0867123dfac37.

⁵⁰¹ See Comprehensive Addiction Recovery Act, S. 524 of 114th Cong. (2016) § 303(a)(iv).

⁵⁰² See id.

 ⁵⁰³ See FDA Approves First Buprenorphine Implant for Treatment of Opioid Dependence, supra, note 123.
 ⁵⁰⁴ See A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS), U.S. FOOD & DRUG ADMINISTRATION, http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf (last visited July 21, 2016).

⁵⁰⁵http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Psychopharmacologic DrugsAdvisoryCommittee/UCM482606.pdf

⁵⁰⁶ See id.

⁵⁰⁷ COMPREHENSIVE DRUG ABUSE PREVENTION AND CONTROL ACT of 1970 (Public Law 91-513, October 27, 1970). The Act also consolidated

⁵⁰⁸ See Rettigg and Yarmolinsky, supra note 265.

⁵⁰⁹ See id.

⁵¹⁰ See id.

⁵¹¹ See id.

⁵¹² See id.

⁵¹³ See id.

⁵¹⁴ See APhA v. Mathews, 530 F.2d 1054, (1976).

⁵¹⁵ See Rettigg and Yarmolinsky, supra note 265.

⁵¹⁶ See id.

⁵¹⁷ See NARCOTIC ADDICT TREATMENT ACT of 1974. Public Law 93-282 (1974).

⁵¹⁸ Note: a minor exception exists for temporary emergency treatment in hospitals.

⁵¹⁹ See Rettigg and Yarmolinsky, supra note 265.

⁵²⁰ See id.

⁵²¹ See id. at 95.

⁵²² See id. at 97.

⁵²³ See id. at 94.

⁵²⁴ See EUR. MONITORING CENTRE FOR DRUGS & DRUG ADDICTION, *Substitution Treatment—Treatment Regimes* (2007), http://www.emcdda.europa.eu/html.cfm/index41827EN.html.

⁵²⁵ See Kleber, supra note 425.

⁵²⁶ See SUBSTANCE ABUSE & MENTAL HEALTH SERVS., *Administration Certification of Opioid Treatment Programs* (2015), <u>http://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs</u>.

⁵²⁷ See SUBSTANCE ABUSE & MENTAL HEALTH SERVS, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, A Treatment Improvement Protocol (TIP 43)*, available at http://www.ncbi.nlm.nih.gov/books/NBK64157/#A82766 (last visited Jun. 19, 2016).

⁵²⁸ See SUBSTANCE ABUSE & MENTAL HEALTH SERVS, *Similarities and Differences in Opioid Treatment Programs that Provide Methadone Maintenance or Buprenorphine Maintenance*, N-SSATS Report (Jan. 28, 2010), available at http://atforum.com/documents/225OpiodTx2k10Web.pdf.

⁵²⁹ See Addiction Treatment Forum, *ASAM: States and Insurance Companies Limit MAT in Face of Opioid Abuse Epidemic and ODs*, AMERICAN SOCIETY OF Addiction Medicine (Jul. 19, 2013),

http://atforum.com/2013/07/asam-states-and-insurance-companies-limit-mat-in-face-of-opioid-abuse-epidemic-and-ods/.

⁵³⁰ See U.S. GOVERNMENT ACCOUNTABILITY OFFICE, supra note 403 at 6.

⁵³¹ See id.

⁵³² See id.

⁵³³ See id. at 39-40.

⁵³⁴ See id. at 40.

⁵³⁵ See id.

⁵³⁶ See J. Merill et al., *Methadone Medical Maintenance in Primary Care*, 20(4) J. OF GEN. INTERNAL MED. 344, 344 (2005).

⁵³⁷ See U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 403 at 2.

⁵³⁸ See id. at 8.

⁵³⁹ See id.

⁵⁴⁰ 21 U.S.C. §§822(a)(2),823(f).

⁵⁴¹ See U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 403 at 13.

⁵⁴² See Ad Fox et al., I Heard About it from a Friend: Assessing Interest in Buprenorphine Treatment, 35 SUBSTANCE ABUSE 74, 74 (2014).

⁵⁴³ See, e.g., Gitlow, supra note 472.

⁵⁴⁴ See Rosenblatt, supra note 482, at 25.

⁵⁴⁵ See Cherkis, supra note 71.

⁵⁴⁶ See, e.g., David Frum, *How Long Do Canadians Wait for Healthcare?*, DAILY BEAST (Jun. 20, 2012), http://www.thedailybeast.com/articles/2012/06/20/canadian-healthcare.html. *See also Queue-Jumping a Fact, Alberta Medical Inquiry Finds*, CBC NEWS (Aug. 21, 2013), http://www.cbc.ca/news/canada/calgary/queuejumping-a-fact-alberta-medical-inquiry-finds-1.1393856.

⁵⁴⁷ See, e.g., WORLD HEALTH ORGANIZATION, WHO MODEL LIST OF ESSENTIAL MEDICINES 1, 32 (2013), http://apps.who.int/iris/bitstream/10665/93142/1/EML 18 eng.pdf?ua=1.

⁵⁴⁸ See Erol Digiusto et al., *Effects of Pharmacotherapies for Opioid Dependence on Participants' Criminal* Behavior and Expenditure on Illicit Drugs: An Australian National Evaluation (NEOPD), 39 AUSTL. & NEW ZEALAND J. CRIMINOLOGY 171, 172, 183-85 (2006).

⁵⁴⁹ See generally Amine Khemiri et al., Analysis of Buprenorphine/Naloxone Dosing Impact on Treatment Duration, Resource Use, and Costs in the Treatment of Opioid Dependent Adults: A Retrospective Study of U.S. Public and Private Health Care Claims, 126 POSTGRAD. MED. J. 113 (2014).

⁵⁵⁰ See Detoxification and Substance Abuse Treatment Training Manual, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. 13 (2008), http://store.samhsa.gov/shin/content/SMA09-4331/SMA09-4331.pdf; Andrej Kastelic, Jorg Pont & Heino Stover, *Opioid Substitution Treatment in Custodial Settings: A Practical Guide*, UNITED NATIONS (2008), http://www.unodc.org/documents/hiv-aids/OST_in_Custodial_Settings.pdf.

⁵⁵¹ BRAEBURN PHARMACEUTICALS, Proposed Regulation: Increase Number of Patients to Which DATA-Waived Physicians Can Prescribe Buprenorphine (Feb. 16, 2016),

http://www.reginfo.gov/public/do/eoDownloadDocument?pubId=&eodoc=true&documentID=1966 ⁵⁵² See SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., MEDICAID COVERAGE AND FINANCING OF MEDICATIONS TO TREAT ALCOHOL AND OPIOID USE DISORDERS [hereinafter MEDICAID COVERAGE AND FINANCING] 2 (2014), http://store.samhsa.gov/shin/content//SMA14-4854/SMA14-4854.pdf. ⁵⁵³ See id.

⁵⁵⁴ See Clark, supra note 176, at 1431 ("Although further studies measuring the impact of policies that restrict access to buprenorphine are needed, this analysis suggests that significant reductions in its use could have the unintended effect of increasing costs. Also, if it reduces overall use of opioid substitution therapy, a policy restricting buprenorphine use might also contribute to higher mortality among Medicaid beneficiaries with opioid addiction."). ⁵⁵⁵ *Id.* at 1425.

⁵⁵⁶ See Roger D. Weiss et al., *Adjunctive COUNSELING DURING BRIEF and EXTENDED BUPRENORPHINE-NALOXONE TREATMENT for PRESCRIPTION OPIOID DEPENDENCE: A 2-Phase Randomized Controlled Trial,* 68 ARCHIVES OF GENERAL PSYCHIATRY 1238, 1238 (2011) (explaining that relapse is prevented while patients are on buprenorphine, but significantly increases if patients taper off buprenorphine).

⁵⁵⁷ See id at 1244.

⁵⁵⁸ See id. at 1238.

⁵⁵⁹ See CENTERS FOR DISEASE CONTROL & PREVENTION, PRESCRIPTION DRUG OVERDOSE IN THE UNITED STATES: FACT SHEET, http://www.mayorsinnovation.org/images/uploads/pdf/1_-

_Prescription_Drug_Overdose_in_the_United_States.pdf (last visited Feb. 9, 2015) ("Every day in the United States, 114 people die as a result of drug overdose, and another 6,748 are treated in emergency departments (ED) for the misuse or abuse of drugs.").

⁵⁶⁰ See id.

⁵⁶¹ Regarding the relationship between addiction and unemployment, *see generally* Dieter Henkel, *Unemployment and Substance Use: A Review of the Literature (1990-2010),* 4 CURRENT DRUG ABUSE REV. 4 (2011).
 ⁵⁶² Cf. Redonna Chandler et al., *Treating Drug Abuse and Addiction in the Criminal Justice System: Improving Public Health and Safety,* 301 J. AM. MED. ASS'N 183 (2009).

⁵⁶³ See CENTER FOR MEDICAID & CHIP SERVS, Informational Bulletin, *Medication Assisted Treatment for Substance Use Disorders* 1 (July 11, 2014), http://medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-07-11-2014.pdf (citing Walter, L. et al., *Medicaid Chemical Dependency Patients in a Commercial Health Plan*, 32 J. Beh. Health Servs. & Res. 253 (2005)).

⁵⁶⁴ See id.

⁵⁶⁵ See generally 42 CFR § 8.

⁵⁶⁶ See M. Weinrich and M. Stuart, *Provision of Methadone Treatment in Primary Care Medical Practices: Review* of the Scottish Experience and Implications for US Policy, 283 J. AMER. MED. ASS'N 1343 (200); S. Hutchinson et al., One-Year Follow-Up of Opiate Injectors Treated with Oral Methadone in a GP-Centred Programme, 95 ADDICTION 1055 (2000); M. Gossop et al., Methadone Treatment for Opiate Dependent Patients in General Practice and Specialist Clinic Settings: Outcomes at 2-Year Follow-Up, 24 J. OF SUBSTANCE ABUSE TREATMENT 313 (2003); J. Brands et al., The Expansion of Methadone Prescribing in Ontario, 1996–1998, 8 ADDICTION RES. 485 (2000).

⁵⁶⁷ See J. Luce and C. Strike, A Cross-Canada Scan of Methadone Maintenance Treatment Policy Developments: A Report Prepared for the Canadian Executive Council on Addictions, CANADIAN EXECUTIVE COUNCIL ON ADDICTIONS (2011), available at http://www.ccsa.ca/ceca/pdf/CECA %20MMT%20Policy%20Scan%20 April%202011.pdf.

⁵⁶⁸ See V. King et al., *A Multi-Center Randomized Evaluation of Methadone Medical Maintenance*, 65(2) DRUG & ALCOHOL DEPENDENCE 137 (2002).

⁵⁶⁹ See Merill et al., supra note 536.

⁵⁷⁰ See id.

⁵⁷¹ See id.

⁵⁷² See K. Harris et al., *A Five-Year Evaluation of a Methadone Medical Maintenance Program, 31* J. OF SUBSTANCE ABUSE TREATMENT 433 (2006).

⁵⁷³ See V. King, A 12-Month Controlled Trial of Methadone Medical Maintenance Integrated into an Adaptive Treatment Model, 31(4) J. OF SUBSTANCE ABUSE TREATMENT 385 (2006).

⁵⁷⁴ See Merill (2002), supra note 536 at 364-65.

⁵⁷⁵ See AMERICAN SOCIETY OF ADDICTION MEDICINE, *Public Policy Statement on Office-based Opioid Agonist Treatment (OBOT)* 5, available at <u>http://www.asam.org/docs/default-source/public-policy-statements/1obot-treatment-7-04.pdf?sfvrsn=0</u> (last visited Jun. 16, 2019).

⁵⁷⁶ See id.

⁵⁷⁷ See B. Nosyk et al., A Call For Evidence-Based Medical Treatment Of Opioid Dependence In The United States and Canada, 32(8) HEALTH AFF. 1462, 1465 (2013).

⁵⁷⁸ See Olsen and Sharfstein, supra note 422.

⁵⁷⁹ See Drug Use, Crime, and Incarceration, Drug Addiction Treatment in the Criminal Justice System, NAT'L INST. ON DRUG ABUSE, NAT'L INST. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS (April 2014),

http://www.drugabuse.gov/related-topics/criminal-justice/drug-addiction-treatment-in-criminal-justice-system. ⁵⁸⁰ See A. Ludwig and R. Peters, *Medication-Assisted Treatment for Opioid Use Disorders in Correctional Settings:*

An Ethics Review, 25 Int'l J. of Drug Policy 1041, 1045 (2014).

⁵⁸¹ See Matusow et al., supra note 59, at 473.

⁵⁸² See id.

⁵⁸³ See id.

⁵⁸⁴ See Kreek, supra note 355 at 70.

⁵⁸⁵ See id.

⁵⁸⁶ See K. Fiscella et al., *Management of Opiate Detoxification in Jails*, 24(1) J. OF ADDICTIVE DISEASES 61–71 (2005).

⁵⁸⁸ See E. Merrall et al., *Meta-analysis of drug-related deaths soon after release from prison*, 105(9) Addiction 1545 (2010); S. Seaman et al., *Mortality from Overdose among Injecting Drug Users Recently Released from Prison: Database Linkage Study*, 316(7129) BRITISH MED. J. 426 (1998).

⁵⁸⁹ See I. Binswanger et al., *Release from Prison-A High Risk of Death for Former Inmates*, 356(2) NEW ENG. J. OF MED. 157 (2007).

⁵⁹⁰ See id.

⁵⁹¹ See K. Dolan et al., A Randomized Controlled Trial Of Methadone Maintenance Treatment in NSW Prisons, Technical Report No. 155., SYDNEY NAT'L DRUG AND ALCOHOL RESEARCH CENTRE (2003); K. Dolanet al. (2005). Four-Year Follow-Up of Imprisoned Male Heroin Users and Methadone Treatment: Mortality, Re-Incarceration and Hepatitis C Infection, 100 ADDICTION 820 (2005); S. Magura, et al., Buprenorphine and Methadone

Maintenance in Jail and Post Release: A Randomized Clinical Trial, 99 DRUG & ALCOHOL DEPENDENCE 22 (2009); Magura et al., supra note 125; V. Tomasino et al., *The Key Extended Entry Program (KEEP)*:

A Methadone Treatment Program for Opiate-Dependent Inmates, 68 MOUNT SINAI J. OF MED. 14 (2001).

⁵⁹² See T. Kinlock et al. (2009), 37 *Methadone Maintenance for Prisoners: Results at Twelve-Months Post-Release*, J. OF SUBSTANCE ABUSE TREATMENT 277 (2009).

⁵⁹³ See Magura et al. (2009), supra note 591.

⁵⁹⁴ See id.

⁵⁹⁵ See Nat'l Comm'n On Correctional Health Care & United States Of America, Guideline for Disease Management in Correctional Settings: Opioid Detoxification (2012).

⁵⁹⁶ See P. Friedmann et al., *Medication-Assisted Treatment in Criminal Justice Agencies Affiliated with the Criminal Justice-Drug Abuse Treatment Studies (CJ-DATS): Availability, Barriers, and Intentions*, 33(1) SUBSTANCE ABUSE 9 (2012).

⁵⁹⁷ See Matusow, supra note 59, at 475.

⁵⁹⁸ See id.

⁵⁹⁹ See U.S. DEPT. OF JUSTICE, DRUG CTS. PROGRAM OFFICE, *About the Drug Court's Program Office: Fact Sheet* (2000),

http://www.chesco.org/Doc umentCenter/View/1447.

⁶⁰⁰ See U.S. GOVERNMENT ACCOUNTABILITY OFFICE, Adult Drug Courts: Evidence Indicates Recidivism Reductions and Mixed Results for Other Outcomes, Washington D.C.: (2005), available at

http://www.gao.gov/new.items/d05219.pdf.

⁶⁰¹ See Kimberly Baker, *Decision Making in a Hybrid Organization*, 38 LAW & SOC. INQUIRY 27, 34 (2013); Denise C. Gottfredson et al., *How Drug Treatment Courts Work: An Analysis of Mediators*, 44(1) J. RES. CRIME & DELINQ. 3, 9 (2007).

⁶⁰² See Eric Miller, *Embracing Addiction: Drug Courts and the False Promise of Judicial Interventionism*, 65 OHIO ST. L. J. 1479, 1556 (2004).

⁶⁰³ See Baker, supra note 601, at 30.

⁶⁰⁴ See id.

⁶⁰⁵ See TIGER, *supra* note 409 at 4.

⁶⁰⁶ See id. at 13.

⁶⁰⁷ See id.

⁶⁰⁸ See id. at 474.

⁶⁰⁹ See id. at 475.

⁶¹⁰ See Suzanne Wenzel, Susan Turner and M. Ridgley, *Collaborations between Drug Courts and Service Providers: Characteristics and Challenges*, 32 J. OF CRIM. JUSTICE 253, 254 (2004).

⁶¹¹ See Boldt, supra note 125. See Douglas Marlowe, *The Verdict on Adult Drug Courts*, ADVOCATE (Idaho State Bar) Sept. 2008, at 14.

⁶¹² RYAN S. KING & JILL PASQUARELLA, THE SENTENCING PROJECT, DRUG COURTS: A REVIEW OF THE EVIDENCE 5-7 (2009).

⁶¹³ See U.S. GOV'T ACCOUNTABILITY OFFICE (2005), supra note 600.

⁶¹⁴ See U.S. GOV'T ACCOUNTABILITY OFFICE, GENERAL ACCOUNTING DOJ DATA COLLECTION AND EVALUATION EFFORTS NEEDED TO MEASURE IMPACT OF DRUG COURT PROGRAMS 3 (2002).

⁶¹⁵ See Boldt, supra note 125, at 52-53.

⁶¹⁶ See id. at 53.

⁵⁸⁷ See id.; Boldt, supra note 125; Steven Martin et al., *Three-Year Outcomes for In-Prison Therapeutic Community Treatment for Drug-Involved Offenders in Delaware: From Prison to Work Release to Aftercare*, 79 PRISON J. 294, 307, 310 (1999).

⁶¹⁷ *Id.* at 54; *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 614, at 62.

⁶²² See Boldt, supra note 125, at 55-56; U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 614, at 69-70.

623 See John A. Bozza, Benevolent Behavior Modification: Understanding the Nature and Limitations of Problem-

⁶²⁴ See Gottfredson, supra note 601, at 29.

⁶²⁵ See Matusow, supra, note 59.

⁶²⁶ See id.

⁶²⁷ See id. at 476. See King & Pasquarella, supra note 612 at 5-7.

⁶²⁸ See Matusow, supra, note 59.

⁶²⁹ See id.

⁶³⁰ See id.

⁶³¹ See id.

⁶³² See id. at 476-77.

⁶³³ See id. at 477.

⁶³⁴ See id.

⁶³⁵ See id.

⁶³⁶ See id.

⁶³⁷ See id. at 478.

⁶³⁸ See Weiss, et al., supra note 556; *Extended v. Short-term Buprenorphine Naloxone for Treatment of Opiate Addicted Youth*, 300 (17) JAMA 2003 (2008); Clark, et al., supra note 176; R. Clark and J. Baxter, *Responses of State Medicaid Programs to Buprenorphine Diversion: Doing More Harm than Good?*, 173 J. AMER. MED. Ass'N INTERNAL MED. 1571 (2013).

⁶³⁹ See Rinaldo and Rinaldo, supra note 17.

⁶⁴⁰ See Schuman-Olivier et al., *supra* note 383; Bazazi et al., supra note 384; Torkel Richert and Björn Johnson, Long-Term Self-Treatment with Methadone or Buprenorphine as a Response to Barriers to Opioid Substitution Treatment: The Case of Sweden, 12 J. OF HARM REDUCTION 1 (2005); Shannon Mitchell et al., Uses of Diverted Methadone and Buprenorphine by Opioid-Addicted Individuals in Baltimore, Maryland, 18(5) AMER. J. OF ADDICTIONS 346 (2009).

⁶⁴¹ See Matusow et al., *supra* note 59, at 478.

⁶⁴² See id.

⁶⁴³ See N. Gordon and P. Appel, *Functional Potential of the Methadone-Maintained Person*, 11(1) ALCOHOL DRUGS & DRIVING 31 (1995).

⁶⁴⁴ See Andrew Wilper et al., *The Health and Health Care of U.S. Prisoners: Results of a Nationwide Survey*, 99 AM. J. OF PUB. HEALTH 666, 669 (2009) ("Among inmates with a previously diagnosed mental condition who had been treated with a psychiatric medication in the past, 69.1% (SE = 4.8%) of federal, 68.6% (SE = 1.9%) of state, and 45.5% (SE = 1.6%) of local jail inmates had taken a medication for a mental condition since incarceration."). ⁶⁴⁵ Addiction is a biopsychosocial condition, because it is caused and exacerbated by biological factors (e.g. heredity), psychological factors, and social (environmental) factors.

⁶⁴⁶ In order to examine the meaning of opiate addiction treatment in the context of problem-solving courts, I conducted semi-structured interviews with eighteen judges in Indiana between October 2015 and February 2016. Recruited judges included eleven drug court judges, three veterans' courts judges, and three judges who each oversaw a veterans' court and a drug court. Additionally, I interviewed one judge from a prison-based treatment program, the successful completion of which results in reduced sentences. Therefore, in total, I investigated policies of 20 problem-solving courts and one prison-based treatment program. Each of the veterans' courts required substance abuse treatment for participants. Generally speaking, the veterans' courts operate similarly to drug courts except that they only include veterans and require more extensive treatment for co-occurring health conditions (e.g. post-traumatic stress disorder).

⁶⁴⁷ See T. Rieckmann et al., *Client and Counselor Attitudes Toward the Use of Medications for the Treatment of Opioid Dependence*, 32 J. OF SUBSTANCE ABUSE TREATMENT 207 (2007).

⁶⁴⁸ See White (1998), supra note 229.

⁶⁴⁹ See TIGER, supra note 409, at 75.

⁶¹⁸ See Boldt, supra note 125, at 53-54; see also U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 614, at 67.

⁶¹⁹ See Boldt, supra note 125, at 55; U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 614, at 69.

⁶²⁰ See U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 614, at 69-70.

⁶²¹ See Boldt, supra note 125, at 55-56; U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 614, at 69-70.

Solving Courts, 17 WIDENER L.J. 97, 118-19 (2007).

⁶⁵⁰ See Peter Conrad, The Medicalization of Society: On the Transformation of Human Conditions into Treatable Disorders (2007).

⁶⁵¹ See id.

⁶⁵² See id.

⁶⁵³ See id.; TIGER, supra note 409, at 75–76.

⁶⁵⁴ See TIGER, supra note 409 at 76.

⁶⁵⁵ See DRUG POLICY ALL., DRUG COURTS ARE NOT THE ANSWER: TOWARD A HEALTH-CENTERED APPROACH TO DRUG USE 5–6 (2011), http://www.drugpolicy.org/docUploads/Drug_Courts_Are_Not_the_Answer_Final2.pdf ("The judge is the ultimate arbiter of treatment and punishment decisions and holds a range of discretion unprecedented in the courtroom, including the type of treatment mandated, whether methadone prescription is acceptable (and at what dosage) and how to address relapse.").

⁶⁵⁶ See id.

⁶⁵⁷ See TIGER, supra note 409 at 4.

⁶⁵⁸ See Medication Proponents Make Pitch to Drug Court Professionals, supra note 451, at 1.

⁶⁵⁹ Id.

⁶⁶⁰ Id.

⁶⁶¹ Id.

⁶⁶² See Peggy Fulton Hora, Drug Treatment Courts in the 21st Century: The Evolution of the Revolution in Problem-Solving Courts, 42 Ga. L. Rev. 717, 759 (2008).

⁶⁶³ See Drug Courts Help Break Down Barriers to MAT in Criminal Justice System, supra note 128 at 1.

⁶⁶⁴ See P. Friedmann et al., *Effect of an Organizational Linkage Intervention on Staff Perceptions of Medication*-Assisted Treatment and Referral Intentions in Community Corrections, 50 J. OF SUBSTANCE ABUSE TREATMENT 50 (2015).

⁶⁶⁵ See Alison Knopf, NADCP Supports MAT But Questions Lack of Medication Protocols, ALCOHOLISM & DRUG ABUSE WKLY (July 21, 2014), http://www.alcoholismdrugabuseweekly.com/m-article-detail/nadcp-supports-mat-but-questions-lack-of-medication-protocols.aspx.

⁶⁶⁶ See Celinda Franco, *Drug Courts: Background, Effectiveness and Policy Issues for Congress*, CRS Report for Congress, CONGRESSIONAL RESEARCH SERVICE (Oct. 12, 2010), available at

https://www.fas.org/sgp/crs/misc/R41448.pdf

⁶⁶⁷ See Holst, A Good Score? Examing Twenty Years of Drug Courts in the United States and Abroad, 45 VAL. U. L. REV. 73, 104 (2010).

⁶⁶⁸ See id., at 119.

⁶⁶⁹ See Bozza, *supra* note 623, at 107.

⁶⁷⁰ See Drug Courts Help Break Down Barriers to MAT in Criminal Justice System, supra note 128 at 5.

⁶⁷¹ See Knopf, supra note 665.

⁶⁷² See Davies, supra note 122.

⁶⁷³ See id.

⁶⁷⁴ On March 24, 2015, the Kentucky Supreme Court amended drug court policy regarding MAT. See KY ST ADMIN P XIII Sec. 23 at 18 (amended March 24, 2015)).

⁶⁷⁵ See Watson v. Kentucky, 2015 U.S. Dist. LEXIS 86998 (E.D. Ky. July 6, 2015) (Defendant's motion to dismiss granted; Court says Plaintiff should have raised the issue in State court. Parties' joint motion for oral argument is denied as moot). See also Jason Cherkis, Kentucky Reforms Drug Courts Rules to Let Heroin Addicts Take Prescribed Meds, HUFFINGTON POST, (Apr. 17, 2015, 5:21 PM), http://www.huffingtonpost.com/2015/04/17/heroin-addiction-kentucky_n_7088270.html.

⁶⁷⁶ See Assemb.B. 3723, 2014-15 Leg., 216th Sess. (N.J. 2014) (text substituted June 25, 2015).

⁶⁷⁷ See S.B. 4239b, 201st Sess. (N.Y. 2015). See also DRUG POL'Y ALLIANCE, Bill to Encourage Medication Assisted Treatment like Methadone and Buprenorphine for Drug Court Participants Passes New York State Senate (June 6, 2015) http://www.drugpolicy.org/news/2015/06/bill-encourage-medication-assisted-treatment-methadone-and-buprenorphine-drug-court-par.

⁶⁷⁸ See Medication Proponents Make Pitch to Drug Court Professionals, supra note 229, at 2.

⁶⁷⁹ See Davies, *supra* note 122.

⁶⁸⁰ See Boldt, supra note 125, at 70; NAT'L ASS'N OF CRIM. DEF. LAW., America's Problem-Solving Courts: The Criminal Costs of Treatment and the Case for Reform 14, 29 (2009).

⁶⁸¹ See Baker, supra note 601, at 70.

⁶⁸² See id. at 52.

⁶⁸³ See U.S. DEP'T OF HEALTH AND HUMAN SERVS, Are you in recovery from alcohol or drug addiction? Know your rights, 12-13, https://store.samhsa.gov/shin/content/PHD1091/PHD1091.pdf (last retrieved Feb. 9, 2015).

⁶⁸⁴ See Ludwig and Peters, supra note 580 at 1043.

685 See id. at 1044.

⁶⁸⁶ See D.Z. Buchman and B. Russell, *Addictions, Autonomy and So Much More: A Reply to Caplan*, 104(6) ADDICTION 1053 (2009).

⁶⁸⁷ See Ludwig and Peters, supra note 580, at 1044.

688 See id.

⁶⁸⁹ See Rieckmann et al. (2010), supra note 59.

⁶⁹⁰ See Saxon and McCarty, supra, note 71; J. West et al., *Challenges in Increasing Access to Buprenorphine Treatment for Opiate Addiction*, 13 AM. J. ON ADDICTIONS S8, S13. (2004).

⁶⁹¹ See Edward M. Brecher, Licit And Illicit Drugs: The Consumers Union Report on Narcotics, STIMULANTS, DEPRESSANTS, INHALANTS, HALLUCINOGENS, AND MARIJUANA - INCLUDING CAFFEINE, NICOTINE, AND ALCOHOL (1972); See White, supra note 229.

⁶⁹² See White, supra note 229.

⁶⁹³ See Kleber, supra note 425 at 2303.

⁶⁹⁴ See D. Midmer et al., *Medical Students' Experiences with Addicted Patients: A Web-Based Survey*, 29(1) SUBSTANCE ABUSE 25, 29 (2008).

⁶⁹⁵ E. Weber, Symposium: Failure Of Physicians To Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance, 13 J. HEALTH CARE L. & POL'Y 49, 69 (2010).
 ⁶⁹⁶ See id.; West, supra note 690 at \$13.

 ⁶⁹⁷ See R. Brown et al., *The Prevalence and Detection of Substance Use Disorders among Inpatients Ages 18 to 49: An Opportunity for Prevention*, 27 PREVENTATIVE MED. 101 (1998); S. Wakeman et al., Internal Medicine Residents' Training in Substance Use Disorders: A Survey of the Quality of instruction and Residents' Self-Perceived Preparedness to Diagnose and Treat Addiction, 34 SUBSTANCE ABUSE 363, 368 (2013).
 ⁶⁹⁸ See Wakeman, supra note 697 at 366.

⁶⁹⁹ See Luke Kummer, *Drug Users' Hard Lessons Become Tools to Teach Doctors*, NEW YORK TIMES, Apr. 2, 2002, available at <u>http://www.nytimes.com/2006/04/02/nyregion/drug-users-hard-lessons-become-tools-to-teach-doctors.html</u>.

⁷⁰⁰ See Wakeman, supra note 697 at 366.

⁷⁰¹ See N. Miller et al., *Why Physicians are Unprepared to Treat Patients who Have Alcohol- and Drug-Related Disorders*, 7 ACADEMY OF MED. 410 (2001).

⁷⁰² See Wakeman, supra note 697 at 367.

⁷⁰³ See id.

⁷⁰⁴ See P. O'Connor et al., *Integrating Addiction Medicine into Graduate Medical Education in Primary Care: The Time Has Come*, 154 ANNALS OF INTERNAL MEd.56 (2011).

⁷⁰⁵ See E. Gunderson et al., *The Interface Between Substance Abuse and Chronic Pain Management in Primary Care: A Curriculum for Medicine Residents*, 30 SUBSTANCE ABUSE 253, 255. (2009).

⁷⁰⁶ See West, supra note 690, at S9.

⁷⁰⁷ See id. at S10.

⁷⁰⁸ See id.

⁷⁰⁹ See Gunderson et al., supra note 705 at 255.

⁷¹⁰ See Midmer, supra note 694 at 30.

⁷¹¹ See B. Turner et al., *Barriers and Facilitators to Primary Care or Human Immunodeficiency Virus Clinics Providing Methadone or Buprenorphine for the Management of Opioid Dependence*, 165(15) ARCHIVES OF INTERNAL MED. 1769 (2005); J. Renner et al., *Training Psychiatrists to Diagnose and Treat Substance Abuse Disorders*, 7(5) CURRENT PSYCHIATRY R. 352 (2005).

⁷¹² See Midmer et al., supra note 694 at 31.

⁷¹³ See T. Tanner et al, *Web-based SBIRT Skills Training for Health Professional Students and Primary Care Providers*, 33 SUBSTANCE ABUSE 316 (2012).

⁷¹⁴ See id.

⁷¹⁵ See E. Gunderson et al., *Evaluation of a Combined and In-Person Training in the Use of Buprenorphine*, 27(3) SUBSTANCE ABUSE 39, 43 (2006).

⁷¹⁶ See id. at 42.

⁷¹⁷ See id. at 43.

⁷¹⁸ See id.

⁷²² See Saxon and McCarty, supra, note 71, at 125.

⁷²⁴ See id.

⁷²⁵ See id.

⁷²⁶ See Barry et al., supra note 164, at 221.

⁷²⁷ See E.B. Ritson, Alcohol, Drugs and Stigma, 53 INT'L J. OF CLINICAL PRAC. 549 (1999).

⁷²⁸ See Wakeman, supra note 697 at 368.

⁷²⁹ See id.

⁷³⁰ See M. Weaver et al., *Role of the Primary Care Physician in Problems of Substance Abuse*, 159 ARCHIVES OF INTERNAL MED. 913 (1999).

⁷³¹ See Miller et al., supra note 721.

⁷³² Michael Dennis and Christy K Scott, *Managing Addiction as a Chronic Condition*, 4(1) ADDICTION SCI. & CLINICAL PRAC. 45(2007).

⁷³³ See *The Science of Drug Abuse and Addiction: The Basics*, supra note 25.

⁷³⁴ See O. Gureje et al., *Persistent Pain and Well-Being: A World Health Organization Study in Primary Care*, 280(2) J. OF AM. MED. ASS'N 147 (1998).

⁷³⁵ See Weaver et al., supra note 730 at 914.

⁷³⁶ See B. Bhamb et al., *Survey of Select Practice Behaviors by Primary Care Physicians on the Use of Opioids for Chronic Pain*, 22 CURRENT MED. RES. & OPINION 859 (2006); I. Chen et al., *The EVMS Pain Education Initiative: a Multifaceted Approach to Resident Education*, 8 J. OF PAIN 52 (2007); Gunderson (2009), supra note 705 at 255.
 ⁷³⁷ See Gunderson (2009), supra note 705 at 255.

⁷³⁸ See Bobbi Yarborough et al., *Methadone, Buprenorphine and Preferences for Opioid Agonist Treatment: A Qualitative Analysis*, 160 DRUG & ALCOHOL DEPENDENCE 112, 115 (2016).

⁷³⁹ 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)).

⁷⁴⁰ Eliza Hutchinson et al., *Barriers to Primary Care Doctors, Prescribing Buprenorphine*, 12 ANNALS OF FAM. MED. 128, 131 (2014).

⁷⁴¹ See Saxon and McCarty, supra, note 71, at 124.

⁷⁴² See AM. MED. ASS'N, Statement of the American Medical Association to the Committee on Energy & Commerce Subcommittee on Oversight and Investigations United States House of Representatives 6 (Apr. 23, 2015).
 ⁷⁴³ See Barry et al., supra note 164 at 222.

⁷⁴⁴ Li Hui Chen, Holly Hedegaard, and Margaret Warner. (2014 September). *Drug-Poisoning Deaths Involving Opioid Analgesics: United States 1999-2011*, CENTERS FOR DISEASE CONTROL AND PREVENTION 2. Available at http://www.cdc.gov/nchs/data/databriefs/db166.htm.

⁷⁴⁵ In a study of 833 primary care patients suffering from chronic pain, 23% met criteria for drug use disorder. E. Meltzer, *Aberrant Drug-Related Behaviors: Unsystematic Documentation Does Not Identify Prescription Drug Use Disorder*, 13 PAIN MED. 1436, 1438 (2012).

⁷⁴⁶ See Weaver, supra note 730 at 913.

⁷⁴⁷ See id.

⁷⁴⁸ See id.

⁷⁴⁹ See J. Seale et al., *Impact of Vital Signs Screening and Clinician Prompting on Alcohol and Tobacco Screening and Intervention Rates: A Pre-Post Intervention Comparison*, 11 BIOMED CENTRAL FAMILY PRACT. 18 (2010). ⁷⁵⁰ See Weaver, supra note 730 at 914.

⁷⁵¹ See id.

⁷⁵² See L. Shi, *The Impact of Primary Care: A Focused Review*, 2012 SCIENTIFICA 1 (2012).

⁷⁵³ See Rosenblatt et al., *supra* note 482 at 25.

⁷⁵⁴ See Shi, *supra* note 752, at 10-11.

⁷⁵⁵ See Chaloupka et al., *supra* note 193, at 3.

⁷⁵⁶ See Shi, *supra* note 752, at 2 (stating that primary care "refers to family medicine services... and is personoriented, longitudinal care").

⁷⁵⁷ See Weaver et al., supra note 730 at 913.

⁷¹⁹ See J. Egan et al., *The Physician Clinical Support System-Buprenorphine (PCSS-B): a Novel Project to Expand/Improve Buprenorphine Treatment*, 25(9) J. OF GENERAL INTERNAL MED. 936 (2010).

⁷²⁰ See Gunderson et al., supra note 715 at 44.

⁷²¹ See S. Soumerai, *Improving Drug Prescribing in Primary Care: A Critical Analysis of the Experimental Literature*, 67 MILBANK QUARTERLY 268 (1989).

⁷²³ See Midmer, supra note 694 at 29.
⁷⁵⁸ See R. Bar-Leyav, *The Stigma of Seeing a Psychiatrist*, 30 AM. J. PSYCHOTHERAPY 473 (1976).

⁷⁶³ See I.D. Montoya et al., *Demographic and Practice Characteristics of Psychiatrists who Primarily Treat Patients with Substance Use Disorders*, 12 AMER. J. ADDICTION 181 (2003).

⁷⁶⁴ See C.O. Cunningham et al., *Barriers to Obtaining Waivers to Prescribe Buprenorphine for Opioid Addiction Treatment among HIV Physicians*, 22(9) J. GEN. INTERNAL MED. 1325 (2007); A. Gordon et al., *Facilitators and Barriers in Implementing Buprenorphine in the Veterans Health Administration*, 25(2) PSYCHOL. OF ADDICTIVE BEH. 215 (2011); J. Netherland et al., *BHIVES Collaborative Factors Affecting Willingness to Provide Buprenorphine Treatment*, 36(3) J. OF SUBSTANCE ABUSE TREATMENT 244 (2009); See Turner et al., supra note 711.
 ⁷⁶⁵ See Hutchinson (2014), supra note 740.

⁷⁶⁶ See West, supra note 690 at S14.

⁷⁶⁷ See Traci Rieckmann et al., A Multi-Level Analysis of Counselor Attitudes toward the use of Buprenorphine in Substance Abuse Treatment, 41 J. OF SUBSTANCE ABUSE TREATMENT 374 (2011).

⁷⁶⁸ See Hutchinson (2014), supra note 740.

⁷⁶⁹ See generally id.

⁷⁷⁰ See L. Ducharme and P., *Opioid Treatment Programs in the Clinical Trials Network: Representativeness and Buprenorphine Adoption*, 37(1) J. OF SUBSTANCE ABUSE TREATMENT 90 (2009).

⁷⁷¹ See H. Knudsen et al., *The Adoption of Medications in Substance Abuse Treatment: Associations with Organizational Characteristics and Technology Clusters*, 87(1) DRUG & ALCOHOL DEPENDENCE 64 (2007).

⁷⁷² See C. Thomas et al., *Research to Practice: Adoption of Naltrexone in Alcoholism Treatment*, 24 J. OF SUBSTANCE ABUSE TREATMENT 1 (2003); C. Thomas and D. McCarty, *Adoption of drug abuse treatment technology in specialty and primary care settings*, In H. J. Harwood and T. G. Myers (eds.), NEW TREATMENTS FOR ADDICTION: BEHAVIORAL, ETHICAL, LEGAL, AND SOCIAL QUESTIONS 140–72 (2004).

⁷⁷³ See D. Simpson, A Conceptual Framework for Transferring Research to Practice, 22 J. OF SUBSTANCE ABUSE TREATMENT 171 (2002).

⁷⁷⁴ See Saxon and McCarty, supra, note 71, at 123.

⁷⁷⁵ See id.

⁷⁷⁶ See B. Garner, Research on the Diffusion of Evidence-Based Treatments within Substance Abuse Treatment: A Systematic Review, 36 J. OF SUBSTANCE ABUSE TREATMENT 376 (2009).

⁷⁷⁷ See Knudsen et al., supra note 771.

⁷⁷⁸ See id.

⁷⁷⁹ See L. Ducharme and A. Abraham, State Policy Influence on the Early Diffusion of Buprenorphine in Community Treatment Programs, 3 SUBSTANCE ABUSE TREATMENT, PREVENTION, AND POLICY 17 (2008)
 ⁷⁸⁰ See SUBSTANCE ABUSE & MENTAL HEALTH SERVS ADMIN., *Implementation of the Mental Health Parity and Addiction Equity Act (MHPAEA)* (2016) [hereinafter *Implementation of the Mental Health Parity and Addiction Equity Act*], <u>http://www.samhsa.gov/health-financing/implementation-mental-health-parity-addiction-equity-act</u>.
 ⁷⁸¹ See Managed Care, CENTERS FOR MEDICARE & MEDICAID SERVS., <u>https://www.medicaid.gov/medicaid-chip-</u>

program-information/by-topics/delivery-systems/managed-care/managed-care-site.html (last visited Jun. 19, 2016). ⁷⁸² See e.g., Rieckmann et al. (2010), supra note 59 at 233.

⁷⁸³ See MEDICAID COVERAGE AND FINANCING, supra note 552 at 2.

⁷⁸⁴ See Clark, et al., supra note 176; R. Clark and J. Baxter, supra note 638.

⁷⁸⁵ See MEDICAID COVERAGE AND FINANCING, supra note 552 at 2.

⁷⁸⁷ See id.

⁷⁸⁸ See id.

⁷⁸⁹ See P. K. Adelmann, Mental and Substance Use Disorders among Medicaid Recipients: Prevalence Estimates from Two National Surveys, 31(2) Administration & Policy in Mental Health 111 (2003).

⁷⁹⁰ See Gunderson et al. (2006), supra note 715 at 43.

⁷⁹¹ See id.

⁷⁹² See Netherland et al., supra note 764; C. Arfken et al., Expanding Treatment Capacity for Opioid Dependence with Office-Based Treatment with Buprenorphine: National Surveys of Physicians, 39(2) J. SUBSTANCE ABUSE TREATMENT 96 (2010).

⁷⁵⁹ See Hutchinson (2014), supra note 740.

⁷⁶⁰ See Saxon and McCarty, supra, note 71, at 123; See Miller, supra note 721.

⁷⁶¹ See Saxon and McCarty, supra, note 71, at 123; See Miller, supra note 721.

⁷⁶² See Meltzer, supra note 745 at 1437.

⁷⁸⁶ See id. at 1.

⁷⁹³ See Addiction Treatment Forum, supra note 529.

⁷⁹⁶ See Implementation of the Mental Health Parity and Addiction Equity Act, supra note 780.

⁷⁹⁷ See id.

⁷⁹⁸ See White (2012), supra note 281 at 203.

⁷⁹⁹ See P. Marinelli-Casey et al., The Gap between Research and Practice in Substance Abuse Treatment, 53 Psychiatric Services 984 (2002); J. Sorensen and E. Midkiff, (2002). Bridging the Gap between

Research and Drug Abuse Treatment, 32 Journal of Psychoactive Drugs 379 (2002).

⁸⁰⁰ See T. Condon et al., Blending Addiction Research and Practice: Strategies for Technology Transfer, 35 J. Substance Abuse Treatment 156, 157 (2006).

⁸⁰¹ See Dean Fixen et al., Implementation research: A Synthesis of the Literature, University of South Florida vi (2005).

⁸⁰² See F. Azocar et al., The Impact of Evidence-Based Guideline Dissemination for the Assessment and Treatment of Major Depression in a Managed Behavioral Health Care Organization, 30(1) *Journal of Behavioral Health Services & Research* 109 (2003); F. Azocar et al. (2001). Best Practices: Dissemination of Guidelines for the Treatment of Major Depression in a Managed Behavioral Health Care Network, 52(8) *Psychiatric Services* 1014 (2001).

⁸⁰³ See Azocar et al. (2003), supra note 802; Azocare et al. (2001), supra note 802.

⁸⁰⁴ See Azocar et al. (2003), supra note 802; Azocare et al. (2001), supra note 802.

⁸⁰⁵ See M. Fine et al., Implementation of An Evidence-Based Guideline to Reduce Duration of Intravenous Antibiotic Therapy and Length of Stay for Patients Hospitalized with Community-Acquired Pneumonia: A Randomized Controlled Trial, 115(5) *The American Journal of Medicine* 343 (2003); J. Schectman, Randomized Controlled Trial of Education and Feedback For Implementation of Guidelines for Acute Low Back Pain, 18(10) *Journal of General Internal Medicine* 773 (2003).

⁸⁰⁶ See L. Bauman et al., Reinventing Fidelity: The Transfer of Social Technology among Settings, 19 American J. of Community Psych. 619 (1991); S. Winter & G. Szulanski, Replication as Strategy, 12(6) Organization Science 730 (2001).

⁸⁰⁷ See Simpson, supra note 773 at171.

⁸⁰⁸ See Fixen et al., supra note 801 at 17.

⁸⁰⁹ See ADDICTION TECHNOLOGY TRANSFER CENTER NETWORK, THE CHANGE BOOK (2d ed.) 26 (2004), available at http://www.nattc.org/pdf/The_Change_Book_2nd_Edition.pdf.

⁸¹⁰ See J. Prochaska et al., *The Transtheoretical Model and Stages of Change*, In K. GLANZET ET AL. (eds.) HEALTH BEHAVIOR AND HEALTH EDUCATION (4th ed.) 105 (2008).

⁸¹¹ See Addiction Technology Transfer Center Network, supra note 809 at 26.

⁸¹² See D. Simpson and P. Flynn, Moving Innovations into Treatment: A Stage-based Approach to Program Change, 33(2) J. of Substance Abuse Treatment 111 (2007).

⁸¹³ See D. Berwick, Disseminating Innovations in Health Care, 289 J. of the Amer. Medical Ass. (2003).

⁸¹⁴ See Shannon Stirman et al., Achieving Successful Dissemination of Empirically Supported Psychotherapies: A Synthesis of Dissemination Theory, 11(4) Clinical Psychology Science & Practice 343, 348 (2004).

⁸¹⁵ See generally ADDICTION TECHNOLOGY TRANSFER CENTER NETWORK, supra note 809.

⁸¹⁶ See Stirman et al., supra note 814 at 350.

⁸¹⁷ See Fixen et al., supra 801 at 17.

⁸¹⁸ See id. at 18.

⁸¹⁹ See Addiction Technology Transfer Center Network, supra note 809 at 27.

⁸²⁰ See Stirman et al., supra note 814 at 350.

⁸²¹ See id.

⁸²² See Roman et al., supra note 62.

⁸²³ See Knudsen et al., supra note 359.

⁸²⁴ See Roman et al., supra note 62 at 587.

⁸²⁵ See id. at 585.

826 See id.

⁸²⁷ Weisz, J., Donenburg, G., Han, S., & Weiss, B. (1995). Bridging

the gap between laboratory and clinic in child and

adolescent psychology. Journal of Consulting & Clinical

Psychology, 63, 688–701; dissemination theory synthesis 352

⁷⁹⁴ See id.

⁷⁹⁵ See id.

⁸²⁸ See K. Carroll et al., MET Meets the Real World: Design Issues and Clinical Strategies in the Clinical Trials Network, 23 Journal of Substance Abuse Treatment 73 (2002). ⁸²⁹ See Roman et al., supra note 62 at 588. ⁸³⁰ See id. at 585. ⁸³¹ See D. McCarty et al., Training Rural Practitioners to Use Buprenorphine: Using the Change Book to Facilitate Technology Transfer, 26 J. of Substance Abuse Treatment 203 (2004). ⁸³² See id. at 206-07. ⁸³³ See id. ⁸³⁴ See Addiction Technology Transfer Center Network, supra note 809. ⁸³⁵ See id. at 12. ⁸³⁶ See id. ⁸³⁷ See MCarty et al., supra note 831 at 218. ⁸³⁸ See id. at 216-17. ⁸³⁹ See id. at 217. ⁸⁴⁰ See id. ⁸⁴¹ See id. ⁸⁴² See Hannah Knudsen et al. (2011), supra note 359. ⁸⁴³ See id. ⁸⁴⁴ See D. Herbeck et al., Empirically Supported Substance Abuse Treatment Approaches: A Survey of Treatment Providers' Perspectives and Practices, 33 ADDICTIVE BEH. 699, 705 (2008). ⁸⁴⁵ See id. ⁸⁴⁶ See H. Knudsen et al., *Buprenorphine Diffusion: The Attitudes of Substance Abuse Treatment Counselors*, 29 J. OF SUBSTANCE ABUSE TREATMENT 95 (2005). ⁸⁴⁷ See Thomas et al., supra note 772. 848 See T. Backer, Dissemination & Adoption of Innovative Psychosocial Interventions, 54(1) J. OF CONSULTING & CLINICAL PSYCH. 111 (1986). ⁸⁴⁹ See Roman and Johnson, supra note 358 at 216. ⁸⁵⁰ See id. ⁸⁵¹ See A. Roberto et al., Predicting Substance-Abuse Treatment Providers' Communication with Clients About Medication Assisted Treatment: A Test of the Theories Of Reasoned Action and Planned Behavior, 47 J. OF SUBSTANCE ABUSE TREATMENT 307, 311 (2014). ⁸⁵² See Laurie Meyers, Psychologists and Psychotropic Medication, 37 MONITOR 46, 46 (2006), http://www.apa.org/monitor/jun06/psychotropic.aspx. ⁸⁵³ See BAXTER & STEVENS, supra note 201, at 2. 854 See 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)). ⁸⁵⁵ See Rettigg and Yarmolinsky, supra note 265 at 94. ⁸⁵⁶ See Food & Drug Admin., Vivitrol Medication Guide, Highlights of Prescribing Information 3 (Oct. 2010), http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021897s015lbl.pdf ("To be effective, treatment with VIVITROL must be used with other alcoholism or drug recovery programs such as counseling."). ⁸⁵⁷ See Alicia Kritsonis, Comparison of Change Theories, 8(1) INT'L J. OF SCHOLARLY ACAD. INTELLECTUAL DIVERSITY 1 (2004-2005). ⁸⁵⁸ See id. at 5. ⁸⁵⁹ See id. ⁸⁶⁰ See Reickmann, supra note 767. ⁸⁶¹ See P. Kelly et al., Using the Theory of Planned Behavior to Examine Residential Substance Abuse Workers' Intention to use Evidence-Based Practices, 26 PSYCHOL.OF ADDICTIVE BEH. 661 (2012). ⁸⁶² See Roberto et al, supra note 851 at 311. ⁸⁶³ See id. ⁸⁶⁴ See Lois Benishek et al., Beliefs about the Empirical Support of Drug Abuse Treatment Interventions: A Survey of Outpatient Treatment Providers, 107 DRUG & ALCOHOL DEPENDENCE 202, 204 (2010). ⁸⁶⁵ See id. ⁸⁶⁶ See EVERETT ROGERS, DIFFUSION OF INNOVATION (5th ed. 2003). ⁸⁶⁷ See B. Brown, From Research to Practice: The Bridge is Out and the Water's Rising, In J. Levy et al. (eds.), EMERGENT ISSUES IN THE FIELD OF DRUG ABUSE: ADVANCES IN MEDICAL SOCIOLOGY 345 (7th ed. 2000).

⁸⁶⁸ See P. Meehl, *Philosophy of Science: Help or Hindrance?*, 72 PSYCHOL. R. 707 (1993); J. Herbert et al., Science and Pseudoscience in the Development of Eve Movement Desensitization and Reprocessing: Implications for Clinical Psychology, 20 CLINICAL PSYCHOL. REV. 945 (1999). ⁸⁶⁹ See NAT'L INST. ON DRUG ABUSE, About the CTN (2015), http://www. drugabuse.gov/CTN/about.html. ⁸⁷⁰ See Condon, supra note 800 at 159. ⁸⁷¹ See Rogers, supra note 866. ⁸⁷² See L. Beutler et al., Obstacles to Disseminating Applied Psychological Science, 2 APPLIED & PREVENTIVE PSYCHOL. 53 (1993). ⁸⁷³ See id. ⁸⁷⁴ See Roman et al., supra note 62 at 587. ⁸⁷⁵ See id. at 588. ⁸⁷⁶ See Rieckmann et al. (2010), supra note 59; K. Isett et al., The State Policy Context of Implementation Issues for Evidence-Based Practices in Mental Health, 58 PSYCHIATRIC SERV. 914 (2007). ⁸⁷⁷ See Rieckmann et al. (2010), supra note 59 at 229. ⁸⁷⁸ See id. at 231. ⁸⁷⁹ See id. 880 See id. at 232. ⁸⁸¹ See id. ⁸⁸² See id. ⁸⁸³ See Addiction Technology TRANSFER CENTER NETWORK, supra note 809 at 24. ⁸⁸⁴ See Rieckmann et al. (2010), supra note 59 at 232. ⁸⁸⁵ See id. at 233. ⁸⁸⁶ See id. ⁸⁸⁷ See id. at 232. ⁸⁸⁸ See J. Rich et al., Methadone Continuation versus Forced Withdrawal on Incarceration in a Combined U.S. Prison and Jail: A Randomised, Open-Label Trial, 386(9991) LANCET 350 (2015).

⁸⁸⁹ See Dackis and O'Brien, surpa note 32 at 1431.

APPENDIX A: ACRONYMS

12-Step: Support groups and philosophy centered on the 12 step program of Alcoholics Anonymous
AA: Alcoholics Anonymous
AATOD: American Association for the Treatment of Opioid Dependence
ACA: Affordable Care Act
AMA: American Medical Association
ASAM: American Society of Addiction Medicine
CARA: Comprehensive Addiction Recovery Act of 2016
CSA: Controlled Substances Act
DATA: Drug Addiction & Treatment Act of 2000
DATA-Waiver: a waiver required by a physician in order to prescribe buprenorphine for addiction treatment
DEA: Drug Enforcement Agency
DHHS: U.S. Department of Health & Human Services
FDA: Food & Drug Administration
MAT: Medication-assisted treatment
MHAEA: Mental Health & Addiction Equity Act of 2008
MHD: Mental Health Disorder
NA: Narcotics Anonymous
NADCP: National Association of Drug Court Professionals
NIDA: National Institute on Drug Abuse
NPs: Nurse Practitioners
PAs: Physician Assistants
SAMHSA: U.S. Substance Abuse & Mental Health Services Administration
SUD: Substance Use Disorder
WHO: World Health Organization
VA: Department of Veterans Affairs

APPENDIX B: INTERVIEW INSTRUMENT - POLICY MAKERS

Thank you for taking the time to speak with me today about this important issue.

May I have your permission to record this interview?

I will ask you several questions related to opiate addiction and medication assisted-treatment. You can choose not to answer any question, and may stop the interview at any time.

- 1. How prevalent do you think opiate addiction is within your geographic locale (city, county, state) or jurisdiction?
- 2. Do you feel that opiate addiction is a serious problem within your geographic locale (city, county, state) in light of factors such as opiate overdose rates, death rates, and emergency room admissions?
- 3. How do you feel opiate addiction has affected the criminal justice system in your geographic locale (city/county/state)?
- 4. What treatment options for opiate addition exist within your geographic locale (city/county/state)?
- 5. How accessible are these treatment options (geographic access, expense, patient volume limits)
- 6. What opiate addiction prevention policies/programs exist within your geographic locale (city/county/state)?
- 7. What opiate overdose prevention policies/programs exist within your geographic locale (city/county/state)?
- 8. Now I would like to ask a few questions about the perceived effectiveness of these prevention programs.
 - a. Do you think that these prevention programs are effective? Why or why not?
 - b. Do you think that other members of your profession think that these prevention programs are effective? Why or why not?
 - c. Do you think members of the public feel that these prevention programs are effective? Why or why not?
 - d. Do you think patients struggling with opiate addiction feel that these prevention programs are effective? Why or why not?
- 9. Are you familiar with other treatment options for opiate addiction such as support groups, 12-step groups, mental health counseling and in-patient rehabilitation?

- a. Do you feel that these treatment options are safe? (go over each)
- b. Do you feel that these treatment options are effective (go over each)
- c. Do you feel that these treatment options are accessible (go over each)
- 10. The White House Office of National Drug Control Policy recently announced that it will be taking steps to expand access to medication-assisted treatment for opiate addiction. Therefore, these next questions will be asking you about your opinions, knowledge, and experiences related to medication-assisted treatment.
- 11. Are you familiar with medication-assisted therapy for opiate addiction?
- 12. What is your opinion on the safety of medication-assisted therapy for opiate addiction?
- 13. What is your opinion on the efficacy of medication-assisted therapy for opiate addiction?
- 14. Do you think it is easy for patients to access medication-assisted treatment for opiate addition within your geographic locale (city/county/state)?
- 15. In your geographic location, do you know if medication-assisted therapy is covered by Medicaid? What about other treatment options—are they covered?
- 16. Now I would like to ask a few questions about how others perceive the safety and effectiveness of medication-assisted therapy.
 - a. Do you think that other members of your profession regard medication-assisted therapy as safe?
 What about effective?
 - b. Do you think that members of the public regard medication-assisted therapy as safe? What about effective?
 - c. Do you think that patients struggling with opiate addiction feel that medication-assisted therapy is safe? What about effective?
- 17. Do you know of any existing or planned government programs that expand or limit the use of medicationassisted treatment within your geographic locale (city/county/state)?
- 18. Do you feel that medication-assisted treatment is stigmatized within your geographic locale (city/county/state)? If so, why?

- 19. Do you feel that you would face political difficulties expanding access to medication-assisted treatment within your geographic locale (city/county/state)? Why or why not?
- 20. In your opinion, what types of incentives from the federal government could lead to expanded access to medication-assisted treatment in your geographic locale (city/county/state)?
- 21. In your opinion, what types of incentives from the state government could lead to expanded access to medication-assisted treatment in your geographic locale (city/county)?
- 22. Do you think any of your constituents groups or local institutions (such as professional associations, churches or for-profit rehabilitations centers) would oppose expansion of medication-assisted treatment in your geographic locale (city/county/state)?
 - a. If so, who? Why?
- 23. Do you believe that medication-assisted treatment should be used within the criminal justice system (e.g. prisons, drug courts, or parole supervision) in your geographic locale (city/county/state)? Why or why not?
 - a. If so, what government policies could be used to incentivize its use?

APPENDIX C: INTERVIEW INSTRUMENT – CRIMINAL JUSTICE ADMINISTRATORS

Thank you for taking the time to speak with me today about this important issue.

May I have your permission to record this interview?

I will ask you several questions related to opiate addiction and medication assisted-treatment. You can choose not to answer any question, and may stop the interview at any time.

- 1. What type of criminal justice institution do you work for? (e.g. drug court, prison)
- 2. What is your role within the institution? (e.g. case manager, administrator)
- 3. How prevalent do you think opiate addiction is within your geographic locale (city, county, state) or jurisdiction?
- 4. Do you feel that opiate addiction is a serious problem within your geographic locale (city, county, state) in light of factors such as opiate overdose rates, death rates, and emergency room admissions?
- 5. How do you feel opiate addiction has affected the criminal justice system in your geographic locale (city/county/state)?
- 6. What treatment options for opiate addition exist within your geographic locale (city/county/state)?
- 7. How accessible are these treatment options (geographic access, expense, patient volume limits)
- 8. What opiate addiction prevention policies/programs exist within your geographic locale (city/county/state)?
- 9. What opiate overdose prevention policies/programs exist within your geographic locale (city/county/state)?

10. Now I would like to ask a few questions about the perceived effectiveness of these prevention programs.

- a. Do you think that these prevention programs are effective? Why or why not?
- b. Do you think that other members of your profession think that these prevention programs are effective? Why or why not?
- c. Do you think members of the public feel that these prevention programs are effective? Why or why not?
- d. Do you think patients struggling with opiate addiction feel that these prevention programs are effective? Why or why not?

- 11. Are you familiar with other treatment options for opiate addiction such as support groups, 12-step groups, mental health counseling and in-patient rehabilitation?
 - a. Do you feel that these treatment options are safe? (go over each)
 - b. Do you feel that these treatment options are effective (go over each)
 - c. Do you feel that these treatment options are accessible (go over each)
- 12. The White House Office of National Drug Control Policy recently announced that it will be taking steps to expand access to medication-assisted treatment for opiate addiction. Therefore, these next questions will be asking you about your opinions, knowledge, and experiences related to medication-assisted treatment.
- 13. Are you familiar with medication-assisted therapy for opiate addiction?
- 14. What is your opinion on the safety of medication-assisted therapy for opiate addiction?
- 15. What is your opinion on the efficacy of medication-assisted therapy for opiate addiction?
- 16. Do you think it is easy for patients to access medication-assisted treatment for opiate addition within your geographic locale (city/county/state)?
- 17. In your geographic location, do you know if medication-assisted therapy is covered by Medicaid? What about other treatment options—are they covered?
- Now I would like to ask a few questions about how others perceive the safety and effectiveness of medication-assisted therapy.
 - a. Do you think that other members of your profession regard medication-assisted therapy as safe?
 What about effective?
 - b. Do you think that members of the public regard medication-assisted therapy as safe? What about effective?
 - c. Do you think that patients struggling with opiate addiction feel that medication-assisted therapy is safe? What about effective?
- 19. Do you know of any existing or planned government programs that expand or limit the use of medicationassisted treatment within your geographic locale (city/county/state)?

- 20. Do you feel that medication-assisted treatment is stigmatized within your geographic locale (city/county/state)? If so, why?
- 21. What type of criminal justice institution do you work within? (e.g. law enforcement, prison, drug court, parole board)
- 22. Does your institution provide access to 12 step groups? Why or why not?
- 23. Does your institution require participants (e.g. drug court participants, inmates) suffering from opiate dependence to participate in 12 step groups? If yes:
 - a. How often must participants attend meetings?
 - b. Where are meetings held?
 - c. Are participants provided transportation?
 - d. What happens if participants fail to attend required meetings?
 - e. Are non-spiritual alternative meetings available for non-religious individuals?
 - f. How effective is this type of treatment, in your opinion?
- 24. Does your institution require any participants (e.g. drug court participants, inmates) suffering from opiate dependence to participate in psychological counseling? If not, why? If yes:
 - a. How often are participants required to attend appointments?
 - b. What happens if participants fail to attend required meetings?
 - c. Where are appointments held?
 - d. Does your institution cover the cost of such treatment?
 - e. How does your institution find mental health therapists with whom to collaborate?
 - f. How many mental health therapists collaborate with your institution?
 - g. What type of quality check does your institution perform with regards to the therapist who is chosen?
 - h. How effective is this type of treatment, in your opinion?
- 25. Does your institution provide access to medication-assisted treatment? If yes:

- a. What types?
- b. How is access provided? (e.g. referrals to physicians)
- c. Does your institution cover the cost of such treatment?
- d. With how many physicians does your institution collaborate in providing such treatment?
- e. How does your institution find physicians with whom to collaborate?
- f. Is such treatment supplemented with mental health counseling? With 12-step groups?
- g. How effective, in your opinion, is this type of treatment?
- h. How safe, in your opinion, is this type of treatment?
- 26. If your institution does not provide medication-assisted treatment, does your institution ban the use of medication-assisted treatment (e.g. methadone, buprenorphine, and/or naltrexone)? Why?
- 27. If your institution bans the use of medication-assisted treatment, are individuals who enter the institution required to stop using medication-assisted treatment that they were previously prescribed?
- 28. Does your institution place any individuals within residential treatment centers? If no, why? If yes:
 - a. How are such rehabilitation centers chosen? (e.g. choice may be based on cost, reputation, location)
 - b. In your opinion, how effective are the rehabilitation centers?
 - c. How long is a participant usually required to stay within the rehabilitation center?
 - d. What types of treatments are provided within the rehabilitation center? E.g. 12-step groups, art therapy, medication-assisted treatment, psychological counseling?
 - e. What types of quality checks does your institution perform with regards to the rehabilitation center?
 - f. How much does residence within the center cost? Who pays? (e.g. criminal justice institution, insurance of participant)
- 29. How does your institution match a particular participant to a particular treatment? Who makes the decision regarding treatment type? Does the participant have a say in the decision?
- Does your institution provide any mental health medications to participants? (e.g. antipsychotics, depression medication)

- 31. Does your institution view medication assisted treatments for opiate addiction (methadone, buprenorphine, and naltrexone) differently than mental health medications for depression, schizophrenia, or other mental health disorders?
- 32. Do you believe that medication-assisted treatment should be used within the criminal justice system (e.g. prisons, drug courts, or parole supervision) in your geographic locale (city/county/state)? Why or why not?
- 33. If you do believe that medication-assisted treatment should be used within the criminal justice system in your geographic locale (city/county/state), what government policies could be used to incentivize its use?
- 34. What kind of training does your institution provide to administrators regarding drug addiction treatment? Does such training include information regarding medication-assisted treatment?
- 35. If your institution does not provide training regarding medication-assisted treatment, do you think your institution would be interested in obtaining such training?
- 36. In your opinion, do you see drug addiction primarily as a moral issue, medical issue, criminal issue, or a combination of these? Why?
- 37. Do you believe that your institution sees drug addiction primarily as a moral issue, medical issue, criminal issue, or a combination of these?
- 38. Overall, do you believe that your institution provides an adequate level of treatment for opiate dependence? If not, how could treatment provided be improved?

APPENDIX D: INTERVIEW INSTRUMENT – HEALTH PRACTITIONERS

Thank you for taking the time to speak with me today about this important issue.

May I have your permission to record this interview?

I will ask you several questions related to opiate addiction and medication assisted-treatment. You can choose not to answer any question, and may stop the interview at any time.

- 1. In what institutional setting do you practice?
 - a. What types of treatment options are available to you?
 - b. What types of treatment options are not available? Please explain.
- 2. How prevalent do you think opiate addiction is within your geographic locale (city, county, state) or jurisdiction?
- 3. Do you feel that opiate addiction is a serious problem within your geographic locale (city, county, state) in light of factors such as opiate overdose rates, death rates, and emergency room admissions?
- 4. Are you familiar with other treatment options for opiate addiction such as support groups, 12-step groups, mental health counseling and in-patient rehabilitation?
 - a. Do you feel that these treatment options are safe? (go over each)
 - b. Do you feel that these treatment options are effective (go over each)
 - c. Do you feel that these treatment options are accessible?
 - d. Do you feel that members of the public are aware of these treatment options?
- 5. Do you receive promotional materials regarding these treatment options? From what sources?
- To which of these treatment options are you most likely to refer patients struggling with opiate addiction?
 Does it depend on different factors? If so, please explain.
- 7. Approximately how much do each of these treatment options cost (or how would you rank them from most to least expensive)? Do you accept Medicaid for these expenses?
- 8. What is the role of 12-step groups in your community in treatment opiate addiction? Are they a predominant treatment method? Do they influence community treatment policymaking?

9. Do you collaborate with the criminal justice system to provide treatment for prisoners or paroled individuals struggling with opiate addiction? (This includes drug courts).

a. If so, what treatment methods are commonly used in these settings?

- 10. The White House Office of National Drug Control Policy recently announced that it will be taking steps to expand access to medication-assisted treatment for opiate addiction. Therefore, these next questions will be asking you about your opinions, knowledge, and experiences related to medication-assisted treatment.
- 11. Are you familiar with medication-assisted therapy for opiate addiction?
- 12. (IF PROVIDE MAT) How expensive is medication-assisted treatment? In comparison with other treatment options?
- 13. What is your opinion on the safety of medication-assisted treatment for opiate addiction?
- 14. What is your opinion on the efficacy of medication-assisted treatment for opiate addiction?
- 15. Do you think that medication-assisted treatment is stigmatized in your professional community? If so, why?
- 16. Do you think that members of the public are familiar with medication-assisted treatment for opiate addiction? Why or why not? What about other treatment methods?
- 17. Do you receive promotional materials from pharmaceutical companies or other entities regarding medication-assisted treatment? From what sources?
- 18. Do you think it is easy for patients to access medication-assisted treatment for opiate addiction within your geographic locale (city/county/state)?
- 19. Personal use of medication assisted therapy:
 - a. THERAPISTS: Do you refer patients struggling with opiate addiction to physicians for medicationassisted therapy?
 - b. PHYSICIANS: Do you prescribe medication-assisted treatment for patients struggling with opiate addiction or refer them to other specialists for such treatment?

- 20. What government policies would effectively incentivize or de-incentivize members of your profession to provide access medication-assisted treatment?
- 21. Opinions on educational opportunities for medication-assisted treatment
 - a. THERAPISTS: How do you feel about the education and training available regarding medicationassisted therapy in graduate school and continuing education programs? Is it extensive enough? Is it effective?
 - b. PHYSICIANS: How do you feel about the education and training available regarding medicationassisted therapy in medical school and continuing education programs? Is it extensive enough? Is it effective?

EDUCATION

Member of the Florida Bar Association *Member ID #0110320 June 2014-present*

Doctor of Philosophy in Law & Social Science Indiana University Maurer School of Law - Bloomington, IN Research Focus: Regulation of Addiction Medicine *August 2013- July 2016*

Doctor of Jurisprudence Indiana University Maurer School of Law - Bloomington, IN *August 2010-May 2013*

Bachelor of Arts, Major: Economics Minor: African Studies University of Florida - Gainesville, FL August 2006-December 2008 Graduated Summa Cum Laude

PUBLICATIONS & PRESENTATIONS

Publications:

- Barbara Andraka-Christou, *What is 'Treatment' for Opiate Addiction in Problem-Solving Courts? A Study of 20 Indiana Drug and Veterans Courts*, 4 STANFORD JOURNAL OF CRIMINAL LAW AND POLICY (forthcoming 2016).
- Barbara Andraka-Christou, *Essay: Improving Drug Courts through Medication-judge Assisted Treatment for Addiction*, 23(2) VIRGINIA JOURNAL OF SOCIAL POLICY & THE LAW 179 (2016).
- Barbara Andraka-Christou, *America Needs the TREAT Act: Expanding Access to Effective Medication for Treating Addiction*, 26(1) HEALTH MATRIX: JOURNAL OF LAW AND MEDICINE 310 (2016)
- Barbara Andraka, *Public Policy Lessons from the Orphan Drug Act: Applications for Health Policy Advocates*, 4(3) JOURNAL OF ENTREPRENEURSHIP & PUBLIC POLICY 278 (2015).
- Jody Madeira and Barbara Andraka-Christou, *Paper Trails, Trailing Behind: Improving Informed Consent to IVF through Multimedia Applications*, JOURNAL OF LAW AND THE BIOSCIENCES 1 (2016).
- Barbara Andraka-Christou, A Pressing Need for Pharmacotherapy Development to Treat Drug Addiction: An Editorial from a Legal Perspective, in ANIMAL MODELS FOR MEDICATIONS SCREENING TO TREAT ADDICTION 15-38 (Richard L. Bell & Shafiqur Rahman Vol. 126) (2016). Also published as Animal Models for Medications Screening to Treat Addiction, 126 INTERNATIONAL REVIEW OF NEUROBIOLOGY 15, 15-38 (2016).

Invited Speaker Presentations:

- Invited Speaker, "IVF Law and Politics: A Comparative Perspective," *Polish Studies Center*, Indiana University-Bloomington (February 11, 2016)
- Invited Speaker, "Medical, Social and Legal Perspectives on Fetal Tissue Donation," *Mini IU*, Indiana University-Bloomington (June 2016)
- Invited Speaker, "Underuse of Medication-Assisted Treatment," *Poynter Center for the Study of Ethics and American Institutions*, Indiana University-Bloomington (January 25, 2016).
- Testified as Subject Matter Expert to Indiana State Senate Judiciary Committee regarding SB36 (January 13, 2016). An article referencing the effect of my testimony on the Senate Bill was published in *The Indiana Lawyer*.
- Resulted in press coverage about the presentation in the *Indiana Daily Student* newspaper.
- Invited Speaker, *Addiction Psychiatry Symposium*, Indiana University School of Medicine Symposium (November 17, 2015).
- Invited Speaker, *Bioethics Society*, Poynter Center for the Study of Ethics and American Institutions, Indiana University-Bloomington (October 2015)
- Invited Speaker at National Center for Research and Development, Warsaw, Poland (July 2015)

Conferences, Presentations, & Media Interviews:

- Presenter at *Social Science History Association Annual Conference*, Chicago, Illinois (November 2016)
- Presenter at American Public Health Association Annual Conference (October 2016)
- Presenter at 7th Annual Prescription Drug Abuse and Heroin Symposium, Indianapolis, Indiana (October 2016)
- Presenter at *Society for the Study of Social Problems Annual Conference*, Seattle, Washington (August 2016)
- Presenter at Annual Law & Society Conference, New Orleans, Louisiana (May 2016)
- Presenter (poster) at American Society of Addiction Medicine Annual Conference, Baltimore, Maryland (April 2016)
- Guest lecturer for *Reproduction, Childhood and the Law*, Indiana University Law School (Spring 2016)
- Guest lecturer for *Health Care in America* course, Medical Sciences Department, Indiana University (Fall 2015)
- Presenter at Annual Law & Society Conference, Seattle, Washington (May 2015).
- Presenter at *World Congress of the International Association for the Philosophy of Law & Social Philosophy*, Washington D.C. (July 2015)
- Panel Member, *Your Kids and Killer Drugs, Community Education*, Presented by the Local Council of Women (Bloomington, IN, Spring 2015)
- Guest lecturer for *Health Care in America* course, Medical Sciences Department, Indiana University (Fall 2014)
- Guest lecturer for *Law & Medicine* course, Indiana University Law School (Fall 2014)
- Presenter at McGill Annual Graduate Conference in Law, Montreal, Canada (May 2014)
- Panel Member at *LSC's Technology Innovation Grants Conference*, Jacksonville, Florida (January 2014)

In the Media:

- Megan Jula, Untreated: Indiana is hit hard by the opioid epidemic. Medical experts say medicine is the most effective treatment. Why aren't we using it? INDIANA DAILY STUDENT (April 5, 2016), <u>http://specials.idsnews.com/untreated/</u>.
- Megan Jula, *Medication-Assisted Treatments are Underused with Opioid Addictions*, Speaker Says, INDIANA DAILY STUDENT (January 26, 2016), http://www.idsnews.com/article/2016/01/drug-treatments-for-opiate-are-addiction-underused.
- Dave Stafford, *Lawmakers table easing access to gun permits for alcohol abusers*, THE INDIANA LAWYER (January 14, 2016), http://www.theindianalawyer.com/article/print?articleId=39236.
- CLAAD Recommends Policies to Combat Prescription Drug Abuse, WFHB RADIO (June 8, 2015)

AWARDS & HONORS

Indiana University Awards/Honors:

- Mattie B. Lacy Fellowship (Fall 2015-Spring 2016)
- Graduate & Professional Student Organization Travel Award Winner (Spring 2015)
- Excellence for the Future Award in Products Liability (Spring 2015)
- Excellence for the Future Award in FDA Law (Fall 2012)
- Full Maurer Scholarship (100%) (August 2010-May 2013)
- Federal Communication Law Journal Associate (August 2011-May 2012)
- Guest Moot Court Judge, Indiana University-Bloomington Law School (October 2015)

University of Florida Awards/Honors:

- Summa Cum Laude (December 2008)
- Bright Futures Scholarship (100%) (August 2006-December 2008)
- Undergraduate Honors Program
- President of UF Polish Student Association, 2007 & 2008
- Presidential Service Awards (Spring 2008, Spring 2007)
- Harriet-Irsay Scholarship from Institute of Polish Culture (2007)
- Phi Beta Kappa Honor Society
- Dean's List-Every Semester of Undergraduate Education (2006-2008)

PROFESSIONAL EXPERIENCE

Enfoglobe, Inc., Corporate Counsel

June 2014 to present

- Contract preparation and review
- Business and legal consultation
- Leading a project designing interactive, web-based informed consent for heart surgery centers
- Leading a project designing online education for drug court judges about substance dependence treatment
- Part-time; works remotely from Bloomington, IN

Gainesville, FL

Post-Doctoral Research Position - IUPUI Fairbanks School of Public Health

Beginning August 2016

Adjunct Professor, Indiana Wesleyan University

Spring 2016

- Teaches Health Policy Issues course to students in the Masters of Business Administration in Health Administration program
- Lecture preparation, teaching, and grading

Polish-American Chamber of Commerce of the Eastern U.S.A, Chair of Public Health & Charities

Apple 2014 to Program

- April 2014 to Present
 - Leads an e-health initiative between Polish medical schools, Polish local governments and American-based businesses, with the purpose of expanding public health services to remote regions of Poland for the elderly and mentally ill
 - Designing an educational initiative to increase awareness of substance abuse treatment needs in Rzeszow, Poland and Bialystok, Poland
 - Leads collaboration between the Chamber and charity organizations
 - Assisted in the development of the Sister City relationship between Gainesville, FL and Rzeszow, FL

Assistant to the Director, Polish Studies Center, Indiana University Bloomington

August 2015 to May 2016

- Organizes events at the Polish Studies Center, including student events, guest lectures, and professional development events; Responsible for planning and marketing
- Community and university outreach

Informed Consent Research for Professor Jody Madeira (IU LAW)

April 2011 to present

- Researches factors that guide patient informed-consent decision making in reproductive technology and the role that values and emotions play in patient-doctor relationships
- Researchers clinical and legal potential for multi-media, interactive informed consent contracts in the health care industry

Human Rights Violations Research for the UN via Professor Timothy Waters (IU LAW)

April 2011 to May 2011

• Researched Libyan human rights violations during the "Arab Spring" for use by the UN in its assessment of Gaddafi, NATO, and Rebel forces' activities (short term research due to compressed UN time-schedule)

Enfoglobe, Inc., Public Relations and Operations Manager

November 2009 to August 2010

- Developed and executed marketing strategies
- Assessed client requirements, served as liaison between clients and computer scientists, and directed meetings with the client throughout the product development phases; trained clients
- Initiated and led PR for development of LitigationExpert[™], legal software for litigation document and task management

John Paul II: School of Polish Language & Culture, Inc., Co-Founder and Vice Principal

March 2006 – August 2010

- Co-founded and directed the weekend school of Polish language and culture, a non-profit Florida corporation
- Responsibilities: PR, parent/student relations, accounting, events, overseeing curriculum, marketing

Indianapolis, IN

Indianapolis, IN

Gainesville, FL

Bloomington, IN

Gainesville, FL

Gainesville. FL

Bloomington, IN

Bloomington, IN professional

VOLUNTEER EXPERIENCE

Episcopal Canterbury House

January 2011 – present Bloomington, IN

- Meal ministry for the ill, elderly, and funerals
- Lector

Bloomington Animal Shelter

September 2015 – present Bloomington, IN

- Walks and cares for stray shelter dogs weekly
- Prepares stray dogs for behavioral tests, which help determine whether the dog will be put up for adoption

Little Hands, Big Hearts, Inc., Co-Founder and President

January 2008 – August 2010 Bloomington, IN

- A non-profit corporation designed to collect, purchase, and distribute toys, supplies, & clothing to underprivileged children; in coordination with local schools/businesses, increased awareness of the homeless in Gainesville, FL
- Won two Presidential Service Awards from UF for leading this organization as an unpaid volunteer

Local Council of Women, Member

Fall 2014 - present Bloomington, IN

- A non-profit advisory body to Bloomington Hospital
- Health advocacy and educational outreach

OTHER ACHIEVEMENTS

- Fluent in Polish
- Certified Pilates Instructor
- Private English Language Instructor
- Private Piano and Musical Theater Instructor (2004-2010)