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Expanding Medication Assisted Treatment is Not the Answer: Flaws in the Substance Abuse Treatment Paradigm

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ABSTRACT:

As multiple stakeholders rush to address the opioid epidemic, federal policy definitively asserts Medication Assisted Treatment (MAT) constitutes the most effective solution and should be expanded to all persons with Opioid Use Disorder (OUD). This article traces how federal policy strategically collapsed different categories of persons who misuse opioids – those with physiological dependence along with persons with addiction – and why discounting relevant differences contradicts current research. Delving into controversial presumptions weaving addiction science, healthy policy, and law, this article explains the intersection between addiction and crime, personal choice and neurobiology, and analyzes how current evidence in fact demonstrates critical flaws underlying the premise of MAT. Media reports, litigation, and case law exemplify the tragic outcomes of MAT's failures when Opioid Treatment Providers offer insufficient care to address patients' underlying addiction. As a result, patients merely obtain an additional substance that fuels active polysubstance abuse, resulting in patient impairment undermining individual recovery and posing a threat to public safety and welfare.

INTRODUCTION

In 2017, media began reporting on the case *Commonwealth v. Eldred*, in which Julie Eldred pled guilty to larceny for stealing jewelry to finance her habit of abusing fentanyl.[1] As a condition of her probation, the court ordered Eldred to remain "drug free" but permitted her to utilize Suboxone, a partial opioid agonist, as part of medication assisted treatment (MAT) for her Opioid Use Disorder (OUD).[2] Several days into outpatient treatment, Eldred relapsed by abusing fentanyl.[3] Eldred violated the probation condition to remain drug free, and failed the court's drug toxicology screening.[4] Based on her probation violation, the court ordered Eldred into an inpatient facility.[5] Eldred was held in jail for several days until her attorney could find her a space in an inpatient treatment facility.[6] Eldred's attorney and media reports portrayed the case as punishing people for their addiction, asserted Eldred's relapse constituted an action she could not control, and called the court's action "cruel, arbitrary, and unfair."[7] *Eldred* represents multiple assumptions underlying the current opioid crisis from how we define substance abuse and addiction; why substance abuse intersects with crime and involves public safety; whether persons with a substance use disorder (SUD) have any control over their actions; and whether the

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[1] Deborah Becker, *Court to Rule on Whether Relapse by and Addicted Opioid User Should Be a Crime*, NPR (Oct. 26, 2017), https://www.npr.org/sections/health-shots/2017/10/26/559541332/court-to-rule-on-whether-relapse-by-an-addicted-opioid-user-should-be-a-crime; Maura Ewing, *'The Court System Shouldn't Interrupt the Treatment Process*,' THE ATLANTIC (Dec. 16, 2017), https://www.theatlantic.com/politics/archive/2017/12/opioids-massachusetts-supreme-court/548480/.

[2] *See* Brief for the Probationer on a Reported Question and On Appeal from Finding a Probation Violation, *Commonwealth v. Eldred*, No. SJC 12279, (Mass. June 2017) (hereinafter "Eldred Brief"); Brief of the Commonwealth of Massachusetts on a Reported Question and On Appeal from Finding a Probation Violation, *Commonwealth v. Eldred*, No. SJC 12279, (Mass. Aug. 2017) (hereinafter "Commonwealth Brief").

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *Id.*; Alanna Durkin, *If Addiction is a Disease, Should Relapse Mean Jail Time?*, U.S. NEWS & WORLD REPORT (Oct. 22, 2017), https://www.usnews.com/news/news/articles/2017-10-02/if-addiction-is-a-disease-should-relapse-mean-jail-time.

[7] Eldred Brief, *supra* note 2, at 6; Becker, *supra* note 1; Ewing, *supra* note 1; Maria Kramer, *SJC to Weigh if Courts Can Force Sobriety on Drug Users*, BOSTON GLOBE (Sept. 24, 2017), https://www.bostonglobe.com/metro/2017/09/24/sjc-weigh-courts-can-force-sobriety-drug-users/6a9dm1MSqufTD3I6bbuFoJ/story.html.

federal policy presumption that expanding access to MAT constitutes an effective and optimal solution for persons with OUD.[8]

In Part I, this article will summarize arguments presented in *Commonwealth v. Eldred*, which mirror many of the ongoing health policy debates relating to defining SUD, and will describe the intersection between substance abuse, public safety, and crime. Part II will outline federal policy set forth by the National Institute on Drug Abuse (NIDA) that describes SUD as a brain disease that "hijacks"[9] normal neurobiological functioning, impairs decision-making, and impedes control.[10] According to NIDA and the Substance Abuse and Mental Health Administration (SAMHSA), SUD is similar to other chronic lifelong diseases, in that it requires treatment using highly effective medication in place of punishment, and relapse constitutes an expected outcome.[11] Despite the dominant model classifying SUD as a chronic brain disease, not all health professionals and scientists agree. Part II of this article will also provide an overview of conflicting viewpoints demonstrating flaws in the current brain disease model, articulate why SUD is unlike other diseases, explain how a narrow neurobiological focus

[8] *See* Office of the Assistant Secretary for Planning and Evaluation, *Opioid Abuse In The U.S. And HHS Actions To Address Opioid-Drug Related Overdoses And Deaths - Executive Summary*, DEPT. HEALTH AND HUMAN SERVICES (Mar. 26, 2015), https://aspe.hhs.gov/pdf-document/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths-executive-summary.Drug; *Effective Treatment for Opioid Addiction*, NATIONAL INSTITUTE ON DRUG ABUSE, (Nov. 2016), https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction (hereinafter "*Effective Treatment for Opioid Addiction*"); *Medications to Treat Opioid Use Disorder*, NATIONAL INSTITUTE ON DRUG ABUSE, (Mar. 2018), https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview (hereinafter "*Medications to Treat Opioid Use Disorder*"); *FDA Takes New Steps To Advance The Development Of Innovative Products For Treating Opioid Use Disorder*, FOOD AND DRUG ADMINISTRATION (Apr. 20, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605248.html.

[9] Alan Leshner, *Addiction is a Brain Disease and Why it Matters*, 278 (5335) SCIENCE 45 (1997).

[10] *Id.*; *Drug Facts: Treatment Approaches for Drug Addiction*, NATIONAL INSTITUTE ON DRUG ABUSE (Jan. 2018), https://www.drugabuse.gov/publications/drugfacts/treatment-approaches-drug-addiction (hereinafter "*Drug Facts*"); *Drugs, Brains, and Behavior: The Science of Addiction*, NATIONAL INSTITUTE ON DRUG ABUSE (Jul. 2014), https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preface (hereinafter "*Drugs, Brain, and Behavior*").

[11] *Id.*

undermines strategies to prevent and treat SUD, and why the concept of choice and personal agency constitutes a vital part of recovery.

Part III describes the evidence behind MAT, outlines three FDA approved medications used in MAT, and provides an overview of laws governing their use in medical care. Part IV provides critical analysis of the metrics health professionals use to determine MAT efficacy, discusses the impact of MAT on quality of life and potential recovery, and why current evidence does not support expanding MAT to all persons with OUD. Finally, Part V will consider the implications of expanding MAT by examining massive shortcomings relating to regulation of Opioid Treatment Providers (OTPs), discrepancies in treatment quality and regulatory compliance, and how case law compels a fresh examination of the current treatment paradigm.

I. THE IMPACT OF DRUG ABUSE ON PUBLIC SAFETY AND WELFARE

A. *Commonwealth v. Eldred*

Julie Eldred began experimenting with OxyContin in high school, when occasional use to ease social anxiety expanded to abusing heroin and years of struggling with addiction.[12] Eldred's larceny charge was also not her first: she had been arrested previously on another larceny charge, during which she also violated her probation by abusing opioids.[13] The present case, *Commonwealth v. Eldred*, demonstrates the pervasive struggle with addiction, relapse, and the intersection of SUD and crime.[14] Persons with SUD are not punished for their status of having an addiction, but instead for specific criminal acts that impact public welfare and safety.

[12] Ewing, *supra* note 1.
[13] *Id.*
[14] *See also* Eric Westervelt, *To Save Opioid Addicts, This Experimental Court is Ditching the Delays*, NPR (Oct. 5, 2017), https://www.npr.org/sections/health-shots/2017/10/05/553830794/to-save-opioid-addicts-this-experimental-court-is-ditching-the-delays, (discussing crimes such as petty larceny as a means to obtain money to purchase drugs and a new model of diversion into rapid treatment).

Eldred raised controversial questions and attracted national attention. Multiple interested parties filed amicus briefs on behalf of each party attempting to distill the answers to murky questions in the realm of penalties, addiction, and treatment. If SUD constitutes a brain disease and relapse is inevitable, then may the court impose a probation condition for Eldred to remain drug free (in this case, permitting prescribed Suboxone)? Is her compulsion to continue to abuse illicit drugs so overwhelming that she cannot resist? If she violated her probation by abusing fentanyl, may the court find she violated the conditions of her probation? *Eldred* raises questions not only of the parameters of criminal responsibility, but also fundamental questions of choice, agency, and the extent of compulsion. The resolution of this case, and how the court views relapse (even when receiving treatment) and a condition to remain drug free will have significant consequences for the ability to sanction criminal acts committed by persons with SUD to protect public safety. It also raises broader questions of what constitutes effective treatment for persons with SUD in a manner that advances compassion and aids in successful recovery.

Eldred's Arguments

In appealing the probation violation, counsel for Eldred asserted a variety of claims premised on the brain disease model of addiction. Adopting former NIDA Director Alan Leshner's terminology, Eldred argued drug abuse hijacked her brain, initiating a series of modifications to brain structure and learning that impaired her ability to control her actions.[15] Marked by an overwhelming desire to continue abusing drugs, Eldred asserted she experienced intolerable distress if she stopped using.[16] This prompted a vicious cycle of drug seeking that

[15] Eldred Brief, *supra* note 2, at 1, 8-9, 11-12, 27.
[16] *Id.* at 8-9.

overpowered her and undermined her ability to control her impulse to use fentanyl despite the threat of negative consequences.[17]

Eldred also used NIDA's metaphor that SUD is like other diseases, such as diabetes or hypertension, because these diseases have both physiological and behavioral aspects involved in their progression and management.[18] Based on this comparison, a person with hypertension who experiences high blood pressure also experiences a relapse of a disease, but we view the state of high blood pressure as an involuntary medical condition, an inherent symptom of the disease, and the patient cannot control the disease symptoms. Just as we would not punish a person with hypertension who experiences high blood pressure, Eldred argued relapsing and abusing fentanyl constitutes a symptom of SUD – a symptom that she cannot control and the court cannot penalize.[19] Eldred further asserted that finding a relapse violated her probation constituted an ineffective and counterproductive threat that merely attempted to shame Eldred for a medical disorder that eliminated her capacity to exert any free will over her actions.[20] According to Eldred, that amounted to criminalizing her addiction under a different name, which is "cruel, arbitrary, . . . unfair," unconstitutional, and "shocks the conscience."[21]

Eldred's articulation of the brain disease model garnered the support of multiple parties including the Massachusetts Medical Society and the American Civil Liberties Union of Massachusetts, both submitting amicus briefs echoing Eldred's arguments.[22] The Massachusetts Medical Society further issued a public statement on the case, urging the court to adopt Eldred's

[17] *Id.* at 1, 8-9.
[18] *Id.* at 11-12, 14.
[19] *Id.* at 11-12, 14, 33, 37.
[20] *Id.* at 32-33.
[21] *Id.* at 6, 37.
[22] Amicus Curiae Brief of the American Civil Liberties Union of Massachusetts et al., *Commonwealth v. Eldred*, No. SJC 12279, (Mass. Sept. 2017); Amicus Curiae Brief of the Massachusetts Medical Society et al., *Commonwealth v. Eldred*, No. SJC 12279, (Mass. Sept. 2017).

arguments proffered in the appeal. The Massachusetts Medical Society asserted the medical community operates with a "clear scientific consensus" that SUD is a chronic condition, relapse is an "almost inevitable" symptom of the disease, and an order to refrain from abusing drugs during treatment as a condition of probation "condemns patients for living with a chronic disease."[23] The American Civil Liberties Union of Massachusetts similarly declared enforcing a drug free condition of probation is "dangerous and unjust." [24]

The Commonwealth's Arguments

The Commonwealth's arguments supported the court's finding that Eldred's decision to abuse fentanyl violated her probation and described pertinent nuances between SUD, choice, and punishable offenses.[25] As a preliminary note, the Commonwealth clarified that Eldred's involvement in the criminal justice system arose from her admission of guilt to a larceny charge.[26] In lieu of incarcerating Eldred for larceny, the court offered probation and treatment with a condition to refrain from abusing illicit substances. According to the Commonwealth, drug free conditions on probation enforced through periodic drug testing are designed to promote compliance and further public safety: in Eldred's case, treatment compliance to assist in her recovery and reduce her potential of future involvement in the criminal justice system.[27]

The Commonwealth noted that the brain disease model of addiction is not only controversial and contested by scientists and health professionals, but also fails to support the principle that persons with SUD lose their free will and are completely unable to exert control

[23] *Id.*; MMS Releases Statement Regarding Amicus Brief in *Commonwealth v. Eldred*, MASSACHUSETTS MEDICAL SOCIETY (Sept.19, 2017), http://www.massmed.org/News-and-Publications/MMS-News-Releases/MMS-Releases-Statement-Regarding-Amicus-Brief-in-Commonwealth-v--Julie-Eldred/#.WzJPxKdKg2w.
[24] *Id.*
[25] The Commonwealth asserted although people with SUD may face difficulties with addiction, they do not lose their free will to make alternate choices toward recovery. Further, courts do not punish people for the state of having an addiction, but instead for specific crimes that impact public safety and welfare.
[26] Commonwealth Brief, *supra* note 2, at 2-3.
[27] *Id.* at 2, 15-16.

over their actions.[28] The Commonwealth rejected Eldred's assertion that SUD is similar to other chronic diseases because persons with SUD can and do respond positively to contingency management plans (giving patients tangible reinforcement for positive behaviors and sanctioning negative behaviors), which would have no impact on a disease such as cancer or Alzheimer's disease.[29] Even if drug abuse induces neurobiological changes, the Commonwealth clarified it is unlike other brain diseases, such as Alzheimer's disease, where the person loses genuine capacity to control the disease by acts of will.[30] The distinguishing feature of SUD compared to another diseases, such as Alzheimer's disease or cancer, lies in Eldred's capacity to exert control over her actions.

Thus, although Eldred's decision-making may be impaired, she is not a powerless automaton.[31] Imposing a condition to remain drug free as part of probation can motivate engagement in treatment because successful recovery relies on the person's individual commitment to refrain from drug abuse.[32] Indeed, according to the Commonwealth, *no court* has found that drug use by a person with SUD is involuntary, because this would undermine the court's ability to assign culpability for drug-related crimes.[33] Most importantly, the court's finding of a probation violation was not punishing Eldred for her mere *status* as a person with addiction, but for a specific act – a willful violation of probation corresponding to her criminal penalty for larceny.[34]

[28] *Id.* at 5-6, 12.
[29] *Id.* at 7.
[30] *Id.* at 11.
[31] *Id.* at 37-38.
[32] *Id.* at 11, 32, 34.
[33] *Id.* at 36.
[34] *Id.* at 21, 34.

B. The Intersection of Drug Abuse and Crime

Some media and legal scholarship decries a failed war on drugs, portraying drug abuse and addiction as senseless incarceration of persons merely based on their addiction.[35] Yet as the Commonwealth noted, many cases, including Eldred's, are not punishing persons for having an addiction but involve a specific crime that directly impacts the welfare of society, which may be motivated or influenced by the individual's drug abuse. Illicit drugs are costly to both the individual and society: they decrease individual and societal productivity, increase medical costs, contribute to mental distress, and can result in death.[36] Crimes connected to drug use include offenses such as distributing the drug to others, crimes related to attempting to obtain money to purchase drugs (such as larceny), offenses associated with a lifestyle of associating with illicit markets, and public safety (driving under the influence, neglect of dependents, and interpersonal violence).[37] Political scientist James Q. Wilson aptly argued the notion that drug abuse is a victimless crime "is not only absurd by dangerous" because we "all have a stake in ensuring each of us displays minimal levels of dignity, responsibility and empathy."[38] This translates to an

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[35] *See* Marc Kupanski, *It's Time to Kick Our Addiction to the War on Drugs*, STAT NEWS (Apr. 25, 2017), *available at* https://www.statnews.com/2017/04/25/opioids-war-on-drugs-harm-reduction/ (asserting punishment for crimes relating to possession and sale of drugs do not deter such crimes, and advocates for supervised drug consumption sites); Don Stemen, *Beyond the War on Drugs*, 11 HARVARD LAW & POLICY REVIEW 375, 375-377 (2017) (calling the war on drugs an "utter failure" that ravaged and further marginalized impoverished communities); David Lebowitz, *Proper Subjects for Medical Treatment? Addiction, Prison-Based Drug Treatment and the Eighth Amendment*, 14 DEPAUL JOURNAL OF HEALTH CARE LAW 271, 273 (2012) (asserting it is "*uncontroversial* that many Americans are in prison because they are addicted to drugs").

[36] Barbara Andraka-Christou, *Improving Drug Courts through Medication-Assisted Treatment for Addiction*, 23 VIRGINIA JOURNAL OF SOCIAL POLICY & LAW 179-181 (2016); Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, Office of the Surgeon General, DEPT. HEALTH AND HUMAN SERVICES (2016) at 1-12, *available at* https://addiction.surgeongeneral.gov/ (discussing costs and consequences of substance abuse) (hereinafter "Surgeon General's Report).

[37] *Principles of Drug Abuse Treatment for Criminal Justice Populations - A Research-Based Guide*, NATIONAL INSTITUTE ON DRUG ABUSE (Apr. 2014), https://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/introduction (hereinafter "*Principles of Drug Abuse Treatment for Criminal Justice Populations*").

[38] James Q. Wilson, *Against the Legalization of Drugs*, COMMENTARY MAGAZINE (Feb. 1, 1990), *available at* https://www.commentarymagazine.com/articles/against-the-legalization-of-drugs/.

ethical responsibility to offer care and compassion to persons with addiction while also maintaining the public safety and welfare.

NIDA acknowledges the connection between drug abuse and crime is well known, and the Federal Bureau of Investigation using Uniform Crime Reports provides statistics for the intersection of drug abuse and specific categories of crimes.[39] To illustrate: 30% of state prisoners reported they committed property theft for the reason of obtaining money to purchase illicit drugs, and approximately 37% of state prisoners committed the crime while under the influence of a drug, which may impair decision-making, decrease impulse control, and diminish sound judgment.[40] In the context of persons with opioid addiction specifically, the media has covered a variety of criminal allegations, such as diversion and sale of prescribed opioid medications (including medications intended for MAT),[41] fatal motor vehicle accidents caused by a driver impairment by persons receiving MAT,[42] and child neglect or abuse by persons struggling with OUD.[43]

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[39] *Principles of Drug Abuse Treatment for Criminal Justice Populations*, *supra* note 37; *Drug Use and Crime Facts, Bureau of Justice Statistics*, U.S. DEPARTMENT OF JUSTICE, https://www.bjs.gov/content/dcf/duc.cfm.

[40] *Id*.; Mirko Bargaric & Sandeep Gopalan, *A Sober Assessment of the Link Between Substance Abuse and Crime – Eliminating Drug and Alcohol Use from the Sentencing Calculus*, 56 SANTA CLARA LAW REVIEW 243, 243-302 (2016).

[41] Deborah Sontag, *At Clinics, Tumultuous Lives and Turbulent Care*, NEW YORK TIMES (Nov. 17, 2013), https://www.nytimes.com/2013/11/.../at-clinics-tumultuous-lives-and-turbulent-care.html; Laura Ungar, *Rogue Doctors Exploit Loopholes to Let a Powerful Drug 'Devastate a Community*,' COURIER JOURNAL (June 8, 2017), https://www.courier-journal.com/story/news/investigations/2017/06/08/rogue-doctors-hands-medicine-designed-treat-addiction-turns-into-new-habit/98522426/; Marty Schladen, *Cash-only Suboxone Clinics Fuel Fears of New 'Pill-Mills'*, THE COLUMBUS DISPATCH (Oct. 8, 2017), http://www.dispatch.com/news/20171008/cash-only-suboxone-clinics-fuel-fears-of-new-pill-mills/1.

[42] Andrew Kruger, *Judge Allows Punitive Damages in Lawsuit Against Brainerd Methadone Clinic*, DULUTH NEWS TRIBUNE (Sept. 24, 2014), http://www.duluthnewstribune.com/news/3846521-judge-allows-punitive-damages-lawsuit-against-brainerd-methadone-clinic; Ella Nilsen, *First of Four Parts: A Life Changer: Effects of Methadone Treatment Extend Beyond Users*, THE KEENE SENTINEL (Nov. 7, 2014), http://www.sentinelsource.com/news/special_reports/methadone/first-of-four-parts-a-life-changer-effects-of-methadone/article_386944f2-c506-5974-ab01-14a7ab629502.html; Ella Nilsen, *Fourth of Four Parts: A Stage Set for Disaster*, THE KEENE SENTINEL (Nov. 11, 2014), *available at* http://www.sentinelsource.com/news/special_reports/methadone/methadone_day_4/fourth-of-four-parts-a-stage-set-for-disaster/article_9da5f51c-a255-5d9b-aec8-85d2aadd6a17.html.

[43] Michael Levenson, *Concern Mounts on Opioid Crisis' Toll on Children*, BOSTON GLOBE (Oct. 17, 2015), https://www.bostonglobe.com/metro/2015/10/17/concern-mounting-about-opioid-crisis-toll-

Criminal law scholars Mirko Bagaric and Sandeep Gopalan acknowledge that many persons with an addiction likely do not consciously choose a life of despair and may not weigh the impact of their actions (such as theft, impaired driving, or child neglect).[44] People born into a life of social disadvantage, poverty, or unspeakable emotional and physical trauma expertly chronicled by physician Dr. Gabor Mate may be more likely to engage in drug abuse and suffer from addiction.[45] But Bagaric and Gopalan assert that even if negative life events predispose certain possibilities, this does not foreclose individual choice of alternatives.[46] Importantly, the damage caused by these crimes, and the consequences of drug abuse, reverberate significant harm to surrounding persons in society which is not diminished simply because the person committing the crime was impaired by the influence of drugs.[47]

Legal scholar and former prosecutor Susan Broderick notes the intersection of crime and addiction requires policymakers to consider both public health and public safety considerations when determining appropriate policy measures relating to SUD.[48] The law, according to Broderick, serves as leverage to hold people accountable for their actions.[49] When addiction

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children/bbKXGdk4iKry1l6vAcb4hO/story.html; Whitney Wetzel, *Surge in Child Abuse and Neglect Cases*, WCHS EYEWITNESS NEWS, http://wchstv.com/features/eyewitness-news-i-team-investigations/surge-in-child-abuse-neglect-cases-as-opioid-epidemic-worsens; *see also* Troy Quast et al., *Opioid Prescription Rates and Child Removals*, 37(1) HEALTH AFFAIRS (2017) https://doi.org/10.1377/hlthaff.2017.1023 (finding a correlation between increased opioid prescribing and an increase in child removal by the Florida Department of Child and Family Services due to neglect or abuse.)

[44] Bargaric & Gopalan, *supra* note 40, at 244, 264.

[45] *See generally* Gabor Mate, *In the Realm of Hungry Ghosts* (2008). Mate chronicles his patients' life histories and stories of addiction, asserting "drug addiction is a matter of brain chemistry gone askew under the influence of a substance and, as we will see, even before the use of mind-altering substances begins…people's brain physiology doesn't develop separately from their life events and emotions." Mate at 30. Mate describes neglect and severe physical and sexual abuse of his patients, many of who are intractable polysubstance abusers, homeless, unemployed, and are cycles in and out of the criminal justice system. Many began using drugs as "emotional anesthetic" and "antidote" to the pain and trauma of their lives. Mate at 33.

[46] Bargaric & Gopalan, *supra* note 40, at 288-289. *See generally* Cart Hart, *High Price: A Neuroscientist's Journal of Self-Discovery* (2013) (describing lack of options for persons in economically and socially disadvantaged areas and rational choice to abuse drugs).

[47] Bargaric & Gopalan, *supra* note 40, at 244.

[48] *See* Susan Broderick, *The Law and the Criminal Justice System*, RECOVERY RESEARCH INSTITUTE (June 26, 2017), https://www.recoveryanswers.org/blog/recovery-answers-from-an-criminal-justice-public-policy-expert/.

[49] *Id.*

intersects with crime, this may take the form of several options, such as drug courts that refer offenders with true addiction to appropriate and effective treatment. [50] This raises pertinent questions of how to determine whether a person needs treatment, and whether certain types of treatment promoted by NIDA and the Office of National Drug Control Policy, such as MAT, are supported by adequate evidence.[51] Finally, not all drug-related offenders require treatment, and for offenders who may not have an addiction, providing an alternate model that uses the lever of the law to encourage responsible behavioral choices should be explored.[52] As a model, Hawaii's Opportunity Probation with Enforcement (HOPE) program employs swift, certain, and fair sanctions to motivate behavioral outcomes. [53] The HOPE program has demonstrated measurable statistical success and has been implemented in forty jurisdictions across eight states showing reduction in crime.[54]

II. CRITICAL ANALYSIS OF THE BRAIN DISEASE MODEL

Considering solutions to address substance abuse and finding answers to the controversial questions raised in *Commonwealth v. Eldred* requires examining the state of substance abuse in the United States and how federal policy defines and characterizes persons with SUD. This

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[50] *See* Treatment Courts Work, NATIONAL ASSOCIATION OF DRUG COURT PROFESSIONALS, https://www.nadcp.org/treatment-courts-work/; Paul Larkin, *Swift, Certain and Fair Punishment: 24/7 Sobriety and HOPE: Creative Approaches to Alcohol and Illicit-Drug Using Offenders*, 105 JOURNAL OF CRIMINAL LAW & CRIMINOLOGY 39, 79-80 (2015) (discussing how participation in drug treatment can substantially reduce drug use and crime).

[51] Michael Botticelli, Memorandum: Changing Federal Terminology Regarding Substance Use and Substance Use Disorders, OFFICE OF NATIONAL DRUG CONTROL POLICY (Jan. 9, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Memo%20-%20Changing%20Federal%20Terminology%20Regrading%20Substance%20Use%20and%20Substance%20Use%20Disorders.pdf (hereinafter "ONDCP Memo").

[52] Larkin, *supra* note 50, at 75.

[53] *Id.* Larkin provides an overview of the shortcomings used in traditional substance abuse testing, outlines the model for probation with frequent substance testing back by the possibility of flash incarceration for noncompliance. Larkin at 66-67, 71-72. Statistics from HOPE are promising, demonstrating the program had an 80% decrease in positive drug tests among participants, participants were 52% less likely to be arrested for a new crime, and 72% less likely to use drugs. Larkin at 73. *See also* Beau Kilmer et al., *Back in the National Spotlight: An Assessment of Recent Changes in Drug Use and Drug Policies in the United State*s, BROOKINGS INSTITUTE (Aug. 2016) at 16, https://www.brookings.edu/wp-content/uploads/2016/07/Kilmer-United-States-final-2.pdf.

[54] Kilmer, *supra* note 53, at 16.

section will provide an outline of the dominant brain disease model of addiction in federal policy set forth by NIDA that characterizes SUD as a chronic and relapsing medical disorder marked by fundamental changes in neurological functioning. It will next provide critical analysis of the dominant brain disease model based on evidence showing why SUD is unlike a chronic disease, how neurological changes do not preclude choice, and discuss the importance of recognizing individual agency in recovery. Lastly, this section will explain the significance of recognizing distinct populations of persons with OUD ranging from physiological dependence to addiction.

A. The Impact of Drug Addiction and the Brain Disease Analogy

SUD related to opioids affects a significant portion of the population in the United States: in 2016, 2.1 million persons had an opioid use disorder.[55] U.S. annual spending on drugs has remained relatively stable, but the compositions of drugs of abuse has shifted, where more persons are abusing opioids (both prescription opioids and heroin) and marijuana.[56] The Centers for Disease Control and Prevention has called opioid abuse a fast moving epidemic, and in 2017 the Secretary of Health and Human Services declared the opioid crisis a public health emergency.[57] These trends closely follow political and prescribing changes: as more physicians began writing more prescriptions for opioids, rates of overdose and death also skyrocketed.[58] From 1999 to 2013, the rate of overdose from OxyContin increased five-fold.[59]

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[55] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 3.
[56] *See* Kilmer, *supra* note 53, at 4-9.
[57] Rose Rudd et al., *Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014*, 64(50) MORBIDITY AND MORTALITY WEEKLY 1378 (Jan. 1, 2016); *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, DEPT. HEALTH AND HUMAN SERVICES (Oct. 26, 2017), https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.
[58] Andrew Kolodny, *The Opioid Epidemic: How Marketing and Regulatory Failure Led to a Public Health Crisis*, PHYSICIANS FOR RESPONSIBLE OPIOID PRESCRIBING, http://www.pharmedout.org/pdf/R3DSlides/Kolodny.pdf (hereinafter "Kolodny"); Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: a Public Health Approach to an Epidemic of Addiction*, 36 ANNUAL REVIEW OF PUBLIC HEALTH 559 (2015) (describing the link between the increase in prescriptions for opioids and rising rates of overdose).
[59] Kilmer et. al., *supra* note 53, at 9.

The "Hijacked Brain": Neurological Changes and Choice

NIDA defines drug addiction as "compulsive, or uncontrollable, drug seeking use despite harmful consequences and changes in the brain, which can be long lasting."[60] People may initially abuse drugs for a variety of reasons, classified broadly as seeking euphoria or relief from dysphoria,[61] including as a remedy to address "psychic pain, existential maladies, emptiness, lack of purpose, or isolation."[62] Although initial drug use begins as a voluntary action, as a person continues using the drug, it creates neurological changes in how the brain learns, remembers, and functions.[63] Use of the drugs releases dopamine in the brain, which reinforces the pleasurable effects of the drug as a reward with each subsequent use.[64] Repetition of these patterns induces neuroplastic changes in the brain, strengthening the association between the drug and euphoria, reinforcing the drug as a habit, and bolstering the expectation of pleasure.[65] Positron emission tomography (PET) scans show progressive changes in areas of the brain such as the prefrontal cortex that affect judgment, self-control, and decision-making and gradual loss of gray matter in the brain.[66]

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[60] *Drug Facts*, *supra* note 10; *see also* Nora Volkow & Ting Kai Li, *Drug Addiction: The Neurobiology of Addiction Gone Awry*, 5 NATURE REVIEWS NEUROSCIENCE 963 (2004).
[61] *The Definition of Addiction*, AMERICAN SOCIETY OF ADDICTION MEDICINE (Apr. 12, 2011), https://www.asam.org/docs/default-source/public-policy-statements/1definition_of_addiction_long_4-11.pdf?sfvrsn=a8f64512_4.
[62] Sally Satel & Scott Lilienfeld, *Calling it a 'Brain Disease' Makes Addiction Harder to Treat,* BOSTON GLOBE (June 22, 2017), https://www.bostonglobe.com/ideas/2017/06/22/calling-brain-disease-makes-addiction-harder-treat/ehaJs5ZYIXpPottG89KOGK/story.html.
[63] *The Science of Drug Abuse and Addiction*, NATIONAL INSTITUTE ON DRUG ABUSE, https://www.drugabuse.gov/publications/media-guide/science-drug-abuse-addiction-basics.
[64] *Id*.; *Neuroscience of Psychoactive Substance Use and Dependence*, WORLD HEALTH ORGANIZATION (2004) at 58-59, http://www.who.int/substance_abuse/publications/en/Neuroscience.pdf (hereinafter "WORLD HEALTH ORGANIZATION"); *see also* Rita Goldstein & Nora Volkow, *Dysfunction of the Prefrontal Cortex in Addiction: Neuroimaging Findings and Clinical Implications*, 12 NATURE REVIEWS NEUROSCIENCE 652 (2011).
[65] Nora Volkow & Marisela Morales, *The Brain on Drugs: From Reward to Addiction*, 162 CELL 712 at 712, 715 (2015); *see also Neuroscience of Psychoactive Substance Use and Dependence*, WORLD HEALTH ORGANIZATION (2004), http://www.who.int/substance_abuse/publications/en/Neuroscience.pdf at 58-59 (discussing the repeated association between drug and reward, reinforcing effects of drug abuse, and biobehavioral learning processes).
[66] *Drugs, Brains, and Behavior*, *supra* note 10.

These neurological changes, according to NIDA Director Nora Volkow, impair neural scaffolding that enable self-control, undermining the person's ability to resist abusing drugs.[67] Psychiatrist, Colm Connolly and colleagues demonstrated duration of substance abuse correlates with decreases in gray matter in the brain in areas associated with executive functioning, judgment, decision-making and reward processing.[68] The longer a person abuses substances, the greater the negative impact to both neurological structure and functioning.[69] Persons with SUD experience both altered sensitivity to negative reinforcers (consequences of their addiction, such as economic loss, criminal involvement, loss of child custody etc.) and also attribute excessive salience to the drug itself.[70] Behaviors relating to drug seeking and consumption become main motivational drivers at the expense of other activities and responsibilities present in daily life.[71]

These adaptations are what compromises a person's ability to choose, resulting in compulsive drug use, which invokes Leshner's concept of the "hijacked brain."[72] According to the American Society of Addiction Medicine, after continued drug abuse, a person develops a tolerance to the drug and "needs" the drug not to experience euphoria, but to avoid feeling the distress of withdrawal and associated dysphoria.[73] The American Society of Addiction Medicine asserts, without continuing to abuse the drug of choice, the individual feels "flat, lifeless, and depressed."[74]

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[67] Ruben Baler & Nora Volkow, *Drug Addiction: The Neurobiology of Disrupted Self-Control*, 12(12) TRENDS IN MOLECULAR MEDICINE 559 at 559, 562 (2006).
[68] Colm Connolly et al., *Dissociated Gray Matter Changes With Prolonged Addiction and Extended Abstinence in Cocaine Users*, 8(3) PLOS ONE 1 (2013) e59645.
[69] *Id*. at 3.
[70] Goldstein & Volkow, *supra* note 64, at 652.
[71] *Id.*
[72] Leshner originally coined the metaphor that drug abuse "hijacks" normal neurobiological functioning. *See* Leshner, *supra* note 9; *see also* World Health Organization, *supra* note 64.
[73] American Society of Addiction Medicine, *supra* note 61; *see also Drugs, Brains, and Behavior*, *supra* note 10, at 18 (stating a person with SUD "needs" to keep abusing drugs to try to bring dopamine functioning back to normal).
[74] American Society of Addiction Medicine, *supra* note 61.

A Diseased Brain: Addiction is Similar to Other Chronic and Relapsing Diseases

Federal policy maintains substance abuse should be treated as a medical condition and is similar to other chronic diseases such as heart disease or diabetes.[75] Indeed, NIDA compares temporal neurological modifications for persons with addiction visually represented by PET scans (a "diseased brain") to images of a patient with heart disease (a "diseased heart").[76] Extending these comparisons, federal policy set forth by NIDA,[77] the Surgeon General,[78] and the President's Commission on Combatting Addiction and the Opioid Crisis[79] classifies SUD as chronic and relapsing disease. Viewing SUD as a chronic disease, relapse is not only possible, but likely and may be triggered by exposure to environmental cues or reminders of the drug.[80] Volkow asserts relapse does not indicate a failure of treatment, but an indication that the person requires an adjustment in treatment or needs treatment reinstated.[81] Classifying SUD as a chronic neurological disease means persons with addiction will require long-term, repeated, and even life-long treatment.[82] Only about 10% of persons with SUD receive treatment, which the Surgeon General identifies as a substantial treatment gap, calling for expanded access to treatment.[83] Treatment should address not only substance abuse, but additional co-morbid disorders: approximately forty-one percent of persons with SUD also present with a co-occurring

[75] Surgeon General's Report, *supra* note 36, at i; Baler & Volkow, *supra* note 67, at 563.
[76] *Drugs, Brains, and Behavior*, *supra* note 9, at 5.
[77] *Id.*
[78] Surgeon General's Report, *supra* note 36, at i, iv, 6, 18.
[79] Chris Christie et al., *The President's Commission on Combatting Drug Addiction and the Opioid Crisis*, EXECUTIVE OFFICE OF THE PRESIDENT (Nov. 1, 2017) at 7, 15, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[80] *Drugs, Brains, and Behavior*, *supra* note 10, at 20, 26; Baler & Volkow, *supra* note 67, at 563.
[81] *Drugs, Brains, and Behavior*, *supra* note 10, at 26; Baler & Volkow, *supra* note 67, at 563.
[82] Baler & Volkow, *supra* note 67, at 563; *see also Drug Facts*, *supra* note 9.
[83] *Id.*

mental health conditions such as depression, anxiety, or ADHD, which requires additional strategies for successful treatment.[84]

B. Re-Examining the Brain Disease Model

Despite NIDA's characterization of substance abuse as a chronic and relapsing brain disease that fundamentally impairs individual choice, not all addiction scientists concur. In *Commonwealth v. Eldred*, Assistant Attorney General Maria Granik compiled materials from neuroscientists, psychologists and psychiatrists specializing in addiction that highlight flaws in the brain disease model, which impacts not only future legal precedent but addiction medicine and public health approaches to addiction. The Commonwealth's brief and a supporting amicus brief note central assumptions within the brain disease model – that SUD is similar to other chronic diseases, persons with addiction experience dramatic neurological changes that undermine their ability to resist the compulsion from abusing drugs is not universally shared among experts.[85] Psychologist Gene Heyman notes how we define addiction is critical for devising strategies to reduce its harm through effective health policy, which should include recognizing the role of personal agency and empowerment for recovery.[86]

Addiction is Distinct from Chronic Diseases

Classifying addiction as a brain disease began as a noble strategy to extricate persons with addiction from punitive moral judgment, expand research funding while legitimizing addiction research, and allocate treatment coverage from insurance.[87] Yet the current model

[84] Surgeon General's Report, *supra* note 36, at 2-22.
[85] Commonwealth Brief, *supra* note 2, at 8, 12, 18 (the brain disease model is "subject to vigorous debate in the scientific community.")
[86] Gene Heyman, *Do Addicts Have Free Will? An Empirical Approach to a Vexing Questions*, 5 ADDICTIVE BEHAVIOR REPORTS 85, 86 (2017).
[87] Anke Snoek, *How to Recover from a Brain Disease: Is Addiction a Disease, or Is There A Disease-like Stage in Addiction?*, 10 NEUROETHICS 185, 186 (2017); Sally Satel & Scott Lilienfeld, *Addiction and the Brain-Disease Fallacy*, 4 FRONTIERS IN PSYCHIATRY 1, 4 (2014); Satel & Lilienfeld, *supra* note 62; Amicus Curiae Brief of Eleven Addiction Experts, *Commonwealth v. Eldred*, No. SJC 12279, (Mass. Sept. 2017) at 7-9.

asserting addiction can be classified as a chronic relapsing disease similar to other diseases presents a variety of detrimental constraints when considering precipitating factors of addiction and the most appropriate methods of treatment. Psychologist and legal scholar Stephen Morse notes unlike other chronic diseases such as cancer, hypertension, or diabetes, the primary criterion for the addiction is behavioral.[88] Addiction scientists note a person with other diseases such as cancer cannot suppress the signs ("I will not have cancer today"), or a person with a brain disease such as Alzheimer's disease cannot will one's self to remember on call.[89] Unlike a person struggling to manage cancer or Alzheimer's disease, no amount of reward or punishment can alter the course of their disease.[90]

Proponents of the brain disease model are correct in asserting many chronic diseases involve individual choice in the progression of the disease (e.g. diet, exercise, stress management for some conditions).[91] Yet pharmacological strategies alone are insufficient to address any conditions that may have a behavior component whether addiction, hypertension or diabetes, because they downplay the impact of social and psychological factors driving maladaptive or destructive behavior. Narrow medical models of treating chronic disease are expensive, largely ineffective, and constitute a poor model of effective medical intervention.[92] Truly successful

[88] Stephen Morse, *Addiction Choice and Criminal Law*, ADDICTION & CHOICE: RETHINKING THE RELATIONSHIP (Oxford University Press, 2016).
[89] *Id.* at 428 (asserting persons with addiction act intentionally to satisfy their desire to seek and use drugs and this is not an involuntary action); *Id.* at 432 (discussing addiction is not involuntary in the sense that a muscle reflex is involuntary); Satel & Lilienfeld, *supra* note 62 ("we don't expect people to say 'stop having cancer'); Commonwealth Brief, *supra* note 2, at 11 (asserting it is not like other brain diseases such as Alzheimer's disease).
[90] Satel & Lilienfeld, *supra* note 62; Commonwealth Brief, *supra* note 2, at 12 (no amount of sanctions would impact truly involuntary conditions such as the symptoms of asthma).
[91] CNR'S FOR DISEASE CONTROL & PREVENTION, *Chronic Disease Overview*, https://www.cdc.gov/chronicdisease/overview/index.htm.
[92] *See, generally* Andrew Weil, WHY OUR HEALTH MATTERS (2009) (discussing disease prevention and health promotion as crucial missing components from the management of chronic disease); *see, generally* Jeffrey Bland & Mark Hyman, THE DISEASE DELUSION: CONQUERING THE CAUSE OF CHRONIC ILLNESS FOR A HEALTHIER, LONGER AND HAPPIER LIFE (2015) (describing functional medicine as a system that addresses the root causes of disease to prevent and reverse disease); *see generally* Mark Hyman, ULTRAMIND SOLUTION (2010) (discussing the connection

interventions for many chronic conditions – along with addiction – also require a new framework, such as the pioneering field of functional medicine that examines how to best intervene to prevent and reverse disease by looking at correlations between choice and empowering the public with strategies to take control of their health.[93] Independent of how we classify addiction, effective health policy should examine whether the dominant model sufficiently addresses the complexities involved in conditions with a behavioral component.

Addressing the behavioral component in addiction presents a distinct challenge because abuse of illicit substances, unlike chronic diseases, presents a substantial health and safety hazard not only to the person with SUD, but the general public.[94] A decision to repeatedly indulge in doughnuts and a disdain for exercise may impact the progression of diabetes, but unlike a person abusing illicit substances, it does not correlate to crimes affecting public safety and welfare such as larceny, motor vehicle impairment, or child neglect and abuse. When a person's behaviors and choices directly impact public safety and welfare, then it is appropriate for social norms to reproach actions that are reckless or harmful toward others.[95] In instances such as *Commonwealth v. Eldred*, when persons with SUD like Julie Eldred commit a crime, the law (including drug-free conditions of probation) can be an effective tool for motivating people to remain committed to stop using illicit substances and or engage in treatment.[96] Yet this is only

between physical health and mental well-being which impacts co-morbid mental health conditions that often occur with substance abuse).

[93] *Id.*

[94] Commonwealth Brief, *supra* note 2, at 26.

[95] Satel & Lilienfeld, *supra* note 87, at 8; *see also* Kilmer, *supra* note 53, at 17 (stating that individuals' actions threaten public health and safety it may be in society's interest to reduce their consumption of illicit substances).

[96] Not all people who abuse substances suffer from addiction, and some may benefit from probation with a condition to remain drug free that utilizes swift, certain, and fair sanctions. Other people who abuse substances and suffer from addiction may benefit from evidence-based treatment. *See* Larkin, *supra* note 50, at 71-73 (discussing the model of swift, certain, and fair sanctions), at 75 (discussing how some offenders in the criminal justice system may not require treatment but would respond to probation with a system of accountability through frequent drug screening).

the first part of the inquiry because compassion for persons suffering from addiction also requires examining whether the current model to explain addiction captures its complexities, and whether treatment interventions recommended in federal policy demonstrate successful outcomes.

A Neurocentric View Minimizes the Importance Of Psychological And Social Factors Precipitating Addiction

Psychiatrist Dr. Sally Satel and psychologist Scott Lilienfeld refer to the brain disease model as "dogma," and it constitutes the foundational message from NIDA and forms the basis of medical school education and addiction counselor training.[97] According to Satel and Lilienfeld, the brain disease model has dominated the field based on the assumption that if scientists can identify biological roots, then a person has a disease.[98] Critics of the brain disease model argue that designating the brain as the seat of addiction is "rooted in the dubious assumption that neurobiology is destiny"[99] and the neurocentric view of addiction problematically downplays psychological and social factors that contribute to addiction.[100] Though NIDA acknowledges stress constitutes a risk factor for substance abuse,[101] focusing on neurobiology ignores people's reasons for abusing drugs, such as scare opportunity for educational and economic growth,[102] pessimism, a culture that normalizes drug use, emptiness, isolation, or lack of purpose.[103] Indeed, the World Health Organization cautions that medical

[97] Satel & Lilienfeld, *supra* note 87.
[98] *Id*.
[99] Satel & Lilienfeld, *supra* note 62.
[100] Satel & Lilienfield, *supra* note 87, at 5.
[101] *Common Co-Morbidities with Substance Use Disorders*, NATIONAL INSTITUTE ON DRUG ABUSE, https://www.drugabuse.gov/publications/drugfacts/comorbidity-addiction-other-mental-disorders (discussing how "stress, trauma -- such as physical or sexual abuse -- and early exposure to drugs are common environmental factors that can lead to addiction and other mental illnesses").
[102] John Tierney, *The Rational Choice of Crack Addicts*, NEW YORK TIMES (Sept. 16, 2013), https://www.nytimes.com/2013/09/17/science/the-rational-choices-of-crack-addicts.html.
[103] Satel & Lilienfeld, *supra* note 62.

models of substance abuse may not be a wholly positive development if it oversimplifies the role of social policy in addressing risk factors of addiction.[104] In the case of Opioid Use Disorder, focusing on circumstance and reason for use may also uncover a distinct category of persons with physiological dependence rather than addiction. Reducing addiction to a neurobiological flaw directly informs the basis for the dominant treatment model, which focuses on and searches for a pharmacological cure.[105]

Not all persons who initially use drugs develop an addiction, and both animal and human studies demonstrate situational factors exert substantial impact.[106] Based on both animal and human models, Volkow and Morales estimate about 10% of persons exposed to a drug will develop an addiction.[107] Drug abuse may be precipitated by abuse, social isolation, or extreme stress, which may remit with the removal or alternate management of those stressors. One of the most frequently cited examples is the case of opiate addiction among U.S. Army personnel during the Vietnam War. Critics of the brain disease model note that during the Vietnam War, 10-25% of U.S. Army enlisted personnel were addicted to opium or heroin.[108] To board the plane and return from Vietnam, the U.S. Army required personnel to demonstrate a negative urine screen.[109] The majority of personnel passed the screen and boarded to return home on the first or second try.[110] According to follow up studies by sociologist Lee Robbins, only 5% of those who displayed addiction while in Vietnam relapsed within 10 months, and 12% relapsed

[104] WORLD HEALTH ORGANIZATION, *supra* note 64, at 231.
[105] Satel & Lilienfield, *supra* note 87, at 8.
[106] *Id.*
[107] Volkow & Morales, *supra* note 65, at 715.
[108] Satel & Lilienfield, *supra* note 87, at 8; Marc Lewis, THE BIOLOGY OF DESIRE: WHY ADDICTION IS NOT A DISEASE (2015) at 21-22.
[109] *Id.*
[110] *Id.*

within 3 years.[111] This example illustrates the principle that addiction may be tied to situation, circumstance, and context.

In addition to situational stressors, addiction scientists posits that addiction correlates to developmental time frames relating to age and coping mechanisms.[112] Adolescents are more likely to try illicit substances,[113] and both neuroscientist Marc Lewis and psychologist Gene Heyman suggest substances initially provide an attractive balm to life's obstacles or internal conflicts by providing pleasure and relief.[114] This may constitute a self-destructive or maladaptive strategy for addressing stressful circumstances or pressures that initially appears appealing in the short term.[115] The difficulty, according to Satel and Lilienfeld, is that most people would not express wish for the self-destruction that accompanies addiction: no one "chooses" to become a person with drug addiction.[116] Yet people do make a series of incremental choices leading to a habit[117] that grows into an undesirable outcome of having an addiction.[118]

Neurological Changes Do Not Preclude Choice and Change

The trajectory of drug abuse does modify neurological structure and function, but disagreement exists in the scientific community of how to characterize the significance of these differences. Some addiction scientists posit that the modifications in neurological structure and

[111] *Id.*
[112] Lewis, *supra* note 108, at 21-22; Gene Heyman, *Quitting Drugs: Quantitative and Qualitative Features*, 9 ANNUAL REVIEW OF CLINICAL PSYCHOLOGY 29, 31 (2013) (discussing aging-out and spontaneous remission following developmental stages); Snoek, *supra* note 87, at 187-188 (discussing development of one's identity, purpose, self-concept, and alternate coping strategies as the development required for moving beyond addiction).
[113] *Drugs, Brains, and Behavior*, *supra* note 10, at 21.
[114] Lewis, *supra* note 108, at 92; Gene Heyman, *Addiction and Choice: Theory and New Data*, 4 FRONTIERS IN PSYCHIATRY 1 AT 2-3 (2013).
[115] Lewis, *supra* note 108, at 23; Satel & Lilienfeld, *supra* note 87, at 3; Heyman, *supra* note 114, at 2.
[116] Satel & Lilienfeld, *supra* note 87, at 3.
[117] Ted Fenton & Reinout Wiers, *Free Will, Black Swans and Addiction*, 10 NEUROETHICS 157 (2017).
[118] Satel & Lilienfeld, *supra* note 87, at 3 (stating "no one 'chooses' to be an addict, but choosing to continue getting high makes one an addict.")

function arise in response to choice behavior and habit formation.[119] The initial decision to abuse substances constitutes a narrow impulsive choice that focuses on immediate reward, referred to as delay discounting (immediate rewards of pleasure and relief take precedence over long term goals and considerations).[120] Every subsequent decision to use the drug strengthens the synaptic connections of impulsivity and the compulsion to continue using the drug.[121] This reinforces short-term gratification over long-term global consequences that include legal concerns, familial consequences, economic pressure, or a desire for respect.[122]

Even if subsequent decisions impact neural circuitry (or even impairs individual choice), some addiction scientists distinguish this does not negate individual agency. Satel and Lilienfeld acknowledge that SUD may constrain or impair a person's capacity for choice, but it does not destroy it.[123] This distinction is critical: in *Commonwealth v. Eldred*, Eldred's arguments rested on the assertion that her SUD as scientific fact precluded her ability to refrain from substance abuse – that is, she could not control her subsequent relapse with fentanyl despite the court's order to refrain from abusing illicit drugs while in treatment on probation for larceny. Some addiction scientists convincingly demonstrate that persons with SUD do retain free will, can reflect on multiple conflicting allegiances, and engage in self-reflection.[124]

Addiction science set forth in publications by NIDA and the World Health Organization recognizes that contingency management (giving patients tangible rewards to reinforce positive

[119] Lewis, *supra* note 108, at 83-84.
[120] *Id.* at 83-84; Fenton & Wiers, *supra* note 117, at 157.
[121] Fenton & Wiers, *supra* note 117, at 158; Satel & Lilienfeld, *supra* note 87, at 3.
[122] Heyman, *supra* note 114, at 1; Heyman, *supra* note 86, at 87, 89.
[123] Satel & Lilienfeld, *supra* note 87, at 3; Snoek, *supra* note 87 (Snoek posits addiction may present challenges to control, but asserts a person can overcome addiction with techniques of self-control, self-concept, and engaging in meaningful changes to environment and habits).
[124] Heyman, *supra* note 86, at 87, 90; Heyman, *supra* note 114, at 2; Morse, *supra* note 88, at 428, 436, 440; Satel & Lilienfeld, *supra* note 87, at 1-2; Fenton & Wiers, *supra* note 117, at 157-159.

behaviors such as abstinence) are highly effective.[125] In the alternative, the threat of negative consequences such as professional sanction or legal repercussions can also motivate individual choices.[126] Heyman posits that persons with addiction reach a threshold of mounting consequences and encounter psychological changes which include reflecting on identity, familial role, legal concerns, and economic constraints that make heavy drug use no longer bearable.[127]

Not all Persons with Addiction Require Treatment

Addiction scientists have found rates of remission are strongly influenced by multiple external factors, most persons with SUD quit on their own without treatment, and SUD for most people is not chronic and relapsing.[128] Persons who are married, more highly educated, or concerned about negative legal repercussions are more likely to enter remission from substance abuse.[129] Rates of remission also correlate with external factors such as legal penalty, substance availability, and ethical concerns.[130] To illustrate, according to historians the Harrison Narcotics

[125] *See Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition)*, NATIONAL INSTITUTE ON DRUG ABUSE at 44-45 (Jan. 2018), https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/preface; *see also* WORLD HEALTH ORGANIZATION, *supra* note 64, at 59-60 (discussing contingency management and cognitive behavioral therapy as effective strategies to unlearn dependence behavior and learn more adaptive responses). *See also* August Holtyn et al., *Behavioral Factors Predicting Response to Employment Based Reinforcement of Cocaine Abstinence in Methadone Patients*, 2(2) TRANSLATIONAL ISSUES IN PSYCHOLOGICAL SCIENCE 122 (2016) at 2, 7 (discussing contingency management as one of the most effective psychological approaches in treatment).

[126] Amicus Curiae Brief of Eleven Addiction Experts, *supra* note 87, at 25-27 (discussing contingency management and the example of pilots and physicians with addiction who must remain abstinent and are subject to random drug screenings to retain their professional license), at 28-30 (discussing *Powell v. Texas*, 292 U.S. 514 (1968) wherein Powell, an alcoholic who had been arrested 100 times for public intoxication made a conscious decision to have only one drink the morning before his court appearance because he did not want to "pass out or be picked up" and miss the court appearance); *see also* Larkin, *supra* note 50, at 71-73 (discussing the efficacy of Hawaii's Opportunity Probation with Enforcement Program).

[127] Heyman, *supra* note 86, at 89.

[128] Lewis, *supra* note 108, at 15 (stating addiction is not lifelong, but most persons quit substance abuse on their own); Stanton Peele, *No Matter How Much the "Chronic" Brain Disease Model of Addiction Indicates Otherwise, We Know that People Can Quit Their Addictions – With Special Reference to Harm Reduction and Mindfulness*, 4 ADDICTIVE BEHAVIORS REPORTS 97, 98 (2016) (stating every year a constant proportion of persons with addiction remit); Heyman, *supra* note 114, at 1-2 (most persons with addiction quit on their own by age 30); Heyman, *supra* note 112, at 31 (describing aging out and maturing out of addiction); Heyman, *supra* note 86, at 87 (most persons with addiction to not seek treatment).

[129] Heyman, *supra* note 112, at 51.

[130] *See, generally* Heyman, *supra* note 86.

Tax Act reduced opiate use and addiction by as much as 50% on the population level, demonstrating the impact of legal availability and price.[131] Availability also subjectively influences craving: in one study, subjects with heroin addiction who knew they could obtain the drug reported higher levels of craving than subjects who did not have access to heroin.[132] According to the National Epidemiologic Survey on Alcohol and Related Conditions, drug availability also impacts both the length of addiction and the likelihood of remission from substance abuse.[133] Persons who have an addiction to licit substances, such as alcohol or tobacco, demonstrate longer periods of substance abuse and are less likely to stop using the substance.[134] Each of these suggests persons with addiction make evaluations based on legality, availability, access, and price which also strongly influences rates of remission.

Most people with an addiction stop on their own without treatment by the age of thirty[135] and addiction scientists note that entering remission constitutes the rule rather than the exception.[136] Annually, the proportion of persons with addiction remit on their own without intervention and rates of asymptomatic recovery exceed 90%.[137] Rates of recovery remain constant over time regardless of the time a person has engaged in substance abuse, which supports the hypothesis that a lengthy period of addiction does not necessarily constitute a barrier to remission. For most people, addiction is not chronic, and most persons with addiction do not relapse.[138] However, within the population subset that seeks treatment, the rates of relapse remains high which skews subsequent studies examining remission, recovery, and relapse

[131] *Id.* at 87.
[132] *Id.* at 87, 90.
[133] *Id.* at 88.
[134] *Id.*; Heyman, *supra* note 112, at 49.
[135] Heyman, *supra* note 112, at 1-2.
[136] Satel & Lilienfeld, *supra* note 87, at 4.
[137] Heyman, *supra* note 86, at 87; Peele, *supra* note 128, at 98.
[138] Heyman, *supra* note 112, at 51.

rates.[139] The small subset of the this population with SUD often presents with additional confounding issues, such as psychological co-morbid conditions, demographic differences, and legal concerns.[140] Addiction scientists note that the population seeking treatment often represents the sickest subset with people, and cautions that health policy decisions that generalize this population are neither reflective nor accurate of the population of persons with SUD as a whole.[141]

Careful assessment of these nuances should guide significant modifications in public health approaches pertaining to treatment. If available research shows most persons with SUD remit on their own without treatment, then treatment should not be mandated (for example, in the criminal justice system) but rather offered to persons based on a tailored assessment of their needs and how much and what type of treatment would be most appropriate.

The Role of Neuroplasticity in Recovery

Research on recovery and remission also demonstrates neuroplastic modifications (changes in brain structure and function) from substance abuse in most instances are not permanent.[142] Instead, current scientific research shows persons with addiction can not only make alternative choices[143] and relearn mechanisms to respond to triggers of drug use, but recovery creates novel neurological changes in the brain.[144]

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[139] Heyman discusses one sample from military personnel with addiction during the Vietnam War. In that sample, in Group 1 6% of persons sought treatment, and 70% of Group 1 relapsed. In Group 2, 94% did not seek treatment. Less than 12% of Group 2 relapsed. *See* Heyman, *supra* note 112, at 42-43.
[140] *See generally* Heyman, *supra* note 112.
[141] Satel & Lilienfeld, *supra* note 87, at 4.
[142] Fenton & Wiers, *supra* note 117, at 157 (asserting only a small subset of rare cases have enduring neurological damage from severe long term addiction).
[143] Satel & Lilienfeld note people with addiction can and do identify triggers and practice self-binding (making choices to avoid triggers such as locations, other persons with addiction, etc.) to manage cravings and can learn to identify the reason for using substances as a method for self-soothing. *See* Satel & Lilienfeld, *supra* note 87, at 5.
[144] *Id. But see* Fenton & Wiers, *supra* note 117, at 157-158 (Fenton & Wiers describe neuroplasticity and new cognitive abilities, and the rare cares of what they term "black swans," or persons who have suffered severe brain damage from excessive and lengthy periods of drug abuse. Most persons with addiction according to Fenton &

Within the brain disease model, NIDA asserts substance abuse fundamentally modifies the brain's structure and function.[145] Yet the same principles of conditioned learning (repetitive behaviors, association with reward, and new pathways in the brain) means therapies that target biobehavioral learning processes also produce and correspond to neuroplastic modifications.[146] Current research demonstrates abstinence from substance abuse starts to produce changes in the brain within a month.[147] Continued abstinence does not merely restore gray matter volume, but in clinical human research it increased gray matter volume *beyond the control comparison*.[148] Connolly and colleagues explain that abstinence requires reassertion of cognitive control and behavioral monitoring that was diminished during substance abuse.[149] Elevated volume of gray matter in these areas of the brain, according to Connolly and colleagues suggest that the brain is not only capable of compensating in response to new demands such as maintaining abstinence, but gray matter development in new areas suggests recovery constitutes more than merely reversing gray matter loss and damage: people can guide their brains to learn and grow new pathways.[150]

Self-Efficacy is a Crucial Component to Recovery

Classifying SUD as a chronic and relapsing brain disease potentially hinders recovery because it fails to account for each person's ability to exert control over his or her own life.[151]

Wiers reflect some type of neurological modifications that can be unlearned and modified, and cases of severe true "brain disease" are rare).

[145] *Drugs, Brains, and Behavior*, *supra* note 10, at 5.

[146] WORLD HEALTH ORGANIZATION, *supra* note 64, at 59-60; Lewis, *supra* note 108, at 89-91 (discussing how a period of self-reflection can induce changes in the brain to permit new connections), at 131(discussing the loss of gray matter in the brain), at (137-138 (discussing how recovery not merely returns the brain to a pre-addiction state, but changes in the brain from extended periods of recovery correspond to new areas of growth)).

[147] Xuyi Wang et al., *Changes In Brain Gray Matter In Abstinent Heroin Addicts*, 126 (3) DRUG AND ALCOHOL DEPENDENCE 304 (2012).

[148] Connolly, *supra* note 68, at 3, 5.

[149] *Id*. at 5.

[150] *Id.* at 5-6.

[151] Snoek, *supra* note 87, at 185; Peele, *supra* note at 126, 98; Lewis, *supra* note 108, at 89-91.

Designating that all persons with SUD have an irreversibly diseased brain and will face a lifetime of struggle is not only unsupported by current evidence, but may contribute to helplessness and despair.[152] Reframing expectations with hope can assist persons with SUD to see a valuable future, view themselves as agents of change, and believe they can develop the skills for reflection to "reverse, reknit, and regrow" new neurological pathways through alternate routines and habits leading to recovery.[153] Research suggests multiple effective therapies such as contingency management, therapeutic communities, and social support programs may help patients reconnect with their vision for a valued future.[154]

Agency, neurological recovery, and the concept of self-efficacy are crucial ingredients for persons with SUD to themselves believe in a different future.[155] While intended as an extension of compassion, harm reduction policies that promote the use of alternate illicit substances such as marijuana or supervised consumption sites not only undermine the concept of self-efficacy and facilitate the circumstances for persons with SUD to continue inflicting self-harm, but also relay the destructive and potentially self-fulfilling message that some persons with addiction are beyond recovery. [156]

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[152] *Id.*

[153] Lewis, *supra* note 108, at 89-91 (discussing imagining a future valuable enough to pursue), 137-138 (compulsion and neurological changes in addiction are not immutable), at 159 (persons with addiction need motivation, insight, and perspective to *want* to move beyond addiction and reconnect with their lives).

[154] August Holtyn et al., *Employment Based Abstinence Reinforcement Promotes Opiate and Cocaine Abstinence in Out-Of-Treatment Injection Drug Users*, 47 JOURNAL OF APPLIED BEHAVIORAL ANALYSIS 681 (2014); Holtyn, *supra* note 125.

[155] Peele, *supra* note 126, at 100.

[156] Considering the impact of both availability and legal penalty, health policy that favors increasing access to other classes of recreational substances such as marijuana or advocates for "safe injection" facilities are not supported by current data. Instead, both epidemiological research and addiction psychology suggests increasing legal permissibility and availability will increase rates of substance abuse and lower the probability of remission. *See* Nicholas Lau et al., *A Safer Alternative: Cannabis Substitution as Harm Reduction*, 34(6) DRUG AND ALCOHOL REVIEW 654 (2015) (discussing cannabis as an effective harm reduction method for persons who do not want to stop abusing drugs); *see also* Michelle Chen, *New York Could Open the First Safe Injection Site in the U.S.*, THE NATION (Apr. 24, 2018), https://www.thenation.com/article/new-york-could-open-the-first-safe-injection-site-in-the-us/ (describing potential plans to open supervised injection facilities in New York City).

C. Why Terminology Matters: Physiological Dependence, Addiction, and Substance Use Disorder

The considerations of whether persons with SUD would benefit from treatment, whether they relapse, and what factors influence these questions requires greater precision when describing both the population and the condition. Research suggests not all persons with SUD progress to unremitting addiction, and not all persons with OUD specifically should be swept into the category of persons with an addiction but may encompass distinct populations that compels a different approach.

Shifts in the Diagnostic and Statistical Manual: No More Distinct Categories to Describe Addiction

Both federal policy and diagnostic classifications have addressed the matter of terminology and how to address the concept of addiction and terminology. Until recently, addiction scientists distinguished between physiological dependence and substance abuse or addiction. Drugs including opioids may cause physical and psychological dependence resulting in symptoms of withdrawal which is distinct from addiction, or a compulsive and intense desire to continue using the drug even at the expense of serious adverse consequences. [157] Reuben Baler and Nora Volkow of NIDA also recognize that only a small portion (about 10%) of persons who abuse substances progress to addiction.[158]

Although addiction is not a diagnostic classification, until 2013 the American Psychiatric Association in the Diagnostic and Statistical Manual (DSM) recognized two distinct categories

[157] Volkow & Li, *supra* note 60, at 963 (distinguishing between "drug dependence" as physical dependence as distinct from "addiction").
[158] Volkow & Baler, *supra* note 67, at 559.

of substance abuse and substance dependence.[159] Criteria for substance abuse entailed harmful use of substances that resulted in harm to others, such as neglecting life roles, hazardous use, legal problems, and interpersonal or social problems.[160] To compare, substance dependence referred to harm to one's self resulting from physical and physiological dependence, such as tolerance, withdrawal, using larger amounts of a substance, devoting more time to using the substance, experience of physical or psychological problems from using the substance, and repeated attempts to quit.[161]

In 2013, The American Psychiatric Association published the DSM V, which merged two previously distinct categories into a singular category of substance use disorder,[162] vastly increasing the breadth of the persons who may have developed a tolerance to a drug, experience withdrawal, and are trying to stop using the drug into the same broader category of a person with intractable addiction who experiences social and legal problems and may have no desire to discontinue the addiction.

The Office of National Drug Control Policy's Memorandum on Addiction Terminology

In 2017, Director of the Office of National Drug Control Policy (ONDCP) Michael Botticelli issued a Memorandum calling to modify key terminology relating to addiction.[163] According to ONDCP, the public associates disfavor with the terminology "substance abuser," it provokes negative attitudes among health professionals, and it may deter persons who need treatment.[164] Referencing the modification in the DSM, ONDCP asserted "substance use disorder" is the clinically accurate term, because drug "habit" and "drug abuse" incorrectly imply

[159] Michael Norko & W. Lawrence Fitch, *DSM-5 and Substance Use Disorders: Clinicolegal Implications*, 42(4) THE JOURNAL OF THE AMERICAN ACADEMY OF PSYCHIATRY AND THE LAW 443 at 443-444 (2014).
[160] *Id.*
[161] *Id.*
[162] *See Substance Related and Addictive Disorders*, AMERICAN PSYCHIATRIC ASSOCIATION, http://appi.org.
[163] ONDCP Memo, *supra* note 51.
[164] *Id.*

the person has a choice to stop, which causes confusion because the person instead requires treatment to stop or reduce his or her substance use to a "safer level."[165]

Both the modification in the DSM and the ONDCP's call to relabel previously distinct categories has dramatic implications for considering how to address patient populations accurately and determining as a matter of health policy what course of clinical intervention is appropriate. For example, the term opioid use disorder collapses both persons with intractable addiction to heroin and prescription opioids versus persons who developed physiological dependence to prescription opioids. This has significant impact for the scenario when a person was prescribed an opioid and is unsuccessfully attempting to discontinue using it, but faces painful physical and physiological withdrawal and the prescribing clinician is unable or lacks appropriate resources to assist the patient to discontinue the medication.[166] Physician Dr. Andrew Kolodny notes opioids produce both physical and psychological symptoms when a patient attempt to discontinue the medication.[167] A patient may experience physical withdrawal symptoms such as nausea, vomiting, sweating, muscle aches, but also agitation, anxiety, insomnia and a feeling of "impending doom."[168]

Accurately Identifying the Patient Population and Its Needs: Iatrogenic Opioid Dependency

ONDCP's Memorandum also discounts pertinent differences among population groups based on type of substance abuse. NIDA recognizes that heroin use is rare in prescription drug users, and only a very small percent (4%) of persons who have prescription opioid dependence

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[165] *Id.*

[166] *See* Sontag, *supra* note 41 (Sontag describes various patients who sought medical care for ailments including back pain, sports injuries, fibromyalgia, and kidney surgery, received a prescription for opioids from their physician, attempted to stop the prescription, and struggled with withdrawal based on prescription dependence. Sontag also details how one patient requested help from his physician, who could not provide guidance on detoxification.)

[167] Kolodny, *supra* note 58, at 14.

[168] *See Opiate and Opioid Withdrawal*, MEDLINE PLUS MEDICAL DICTIONARY, https://medlineplus.gov/ency/article/000949.html; Kolodny, *supra* note 56, at 14 (referring to a sense of "impending doom" and the patient's feeling like he is "losing his mind" if he tries to discontinue taking the drug.

begin abusing heroin.[169] Of this population that switches from heroin from prescription opioids, these persons are frequently polysubstance abusers of other illicit drugs.[170] Of persons who misused prescription opioids in the 2000s, 75% reported their first opioid was a prescription drug.[171] Demographic characteristics based on race and socioeconomic status on a population level differ among persons abusing heroin and other opiates (younger men from minority races living in urban areas) versus persons with prescription opioid dependence (older white persons in rural and suburban areas).[172] These demographic shifts have led to outcry in the media alleging racial bias as a motivating reason for approaching opioid dependency as a medical condition requiring treatment rather than a matter of public safety and crime.[173] As described *supra* in Part I, even though substance abuse and crime may be interrelated, persons are not penalized for either physiological dependence on a substance or having an addiction, but their decision to commit a crime.

These claims further ignore the crucial distinction the healthcare system played in creating a class of patients with iatrogenic opioid dependency. Patients use of, and dependence on, prescription opioids in many cases began with a legitimate therapeutic prescription after seeking medical care from a physician.[174] As prescriptions for opioids nearly tripled from 1991

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[169] *Prescription Opioids and Heroin*, NATIONAL INSTITUTE ON DRUG ABUSE (Jan. 2018) at 4,7, https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-abuse-heroin-use/introduction.
[170] *Id.* at 7.
[171] *Id.* at 5.
[172] *Id.* at 8.
[173] Brian Broome, *Amid The Opioid Epidemic, White Means Victim, Black Means Addict*, THE GUARDIAN (Apr. 28, 2018), https://www.theguardian.com/us-news/2018/apr/28/opioid-epidemic-selects-white-victim-black-addict; German Lopez, *The Deadliness Of The Opioid Epidemic Has Roots In America's Failed Response To Crack*, VOX (Oct. 5, 2017), https://www.vox.com/identities/2017/10/2/16328342/opioid-epidemic-racism-addiction. *But see* Kolodny, *supra* note 58, at 6 who calls race a protective factor against overprescribing of opioids leading to prescription opioid dependence.
[174] Kolodny, *supra* note 58, at 6, 11; *see, generally* Kolodny, *supra* note 58 (describing the link between the increase in prescriptions for opioids and rising rates of overdose); *see also* Mary Wickersham & Stephanie Basey, *The "Regulatory Fog" of Opioid Treatment*, 22(3) JOURNAL OF PUBLIC MANAGEMENT & SOCIAL POLICY Art. 6 at 14 (2016).

to 2011, overdose deaths also near tripled over the same time period.[175] Physician Dr. Anna Lembke aptly describes the confluence of factors stemming from industry exerting influence on physicians to overprescribe opioids to more patients.[176] This led to creating a new class of patients with iatrogenic opioid dependence: what Kolodny describes as a "perfect patient" attempting to discontinue a prescribed medication experiences who not only experiences acute withdrawal, but months of extended withdrawal with difficulty sleeping, irritability, and unrelenting depression.[177] Without assessing the patient population and its specific needs, expanding the current treatment model would entail sweeping persons with iatrogenic physiological dependence into the same treatment category as persons with addiction.

Parallels Between Opioid Marketing and Claims Relating to MAT

Lessons from drug marketing promises that led to the opioid crisis highlight a number of considerations that are directly relevant when asking whether prescribing a different class of medications in MAT constitutes the most appropriate policy response. In 2007, Purdue Frederick Company pled guilty to criminal charges of misbranding OxyContin with the intent to defraud or mislead, which is considered a felony under the Federal Food, Drug and Cosmetic Act, wherein Purdue paid $634.5 million in monetary sanctions.[178] Though the substantive details of this case and allegations of ongoing deception[179] are outside the scope of this

[175] *Id*. at 14.
[176] Anna Lembke, DRUG DEALER, MD: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT'S SO HARD TO STOP (Johns Hopkins University Press, 2016).
[177] Kolodny, *supra* note 58, at 14.
[178] *U.S. v. Purdue Frederick Company*, 495 F.Supp.2d 569 (W.D. Va. 2007).
[179] Senator Edward Markey, Letter to U.S. Attorney General Loretta Lynch (May 27, 2016), https://www.markey.senate.gov/imo/media/doc/DOJ%20Purdue%20Oxy%20investigation%20letter.pdf (Senator Markey asks U.S. Attorney General and the Department of Justice to investigate ongoing false claims by Purdue relating to illegally misbranding OxyContin).

discussion, the case raises salient parallels of how financial interests can shape medical practice and perception of what constitutes appropriate medical care.[180]

Purdue proffered a variety of claims that bear striking similarity to claims currently percolating in scientific and scholarly literature relating to maintenance medications utilized in MAT. First, corporate interests expand the pool of potential patients and designate treatment as a medical need that should not be denied.[181] This ignores research that shows pharmacological intervention may not be effective while other less risky modalities may provide benefit.[182] Second, corporate interests assert pharmacological intervention constitutes the most effective solution and downplay risk. In educational materials, manufacturers may bolster these claims by specific promises that the medication is less likely to cause tolerance and withdrawal compared to other substances, is "less addictive," does not cause euphoria, and is less likely to be abused or diverted.[183] In the case of medications used in MAT, these are exactly the terms NIDA and SAMHSA uses to describe two medication used in MAT, methadone and buprenorphine, and distinguish them from other prescription opioids. Few ask the pertinent question of whether the evidence indeed exists to support claims of appropriateness, safety, and perceived benefit.[184]

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[180] *See, generally* Kolodny, *supra* note 58, at 12 (describing the "opioid lobby" and industry funding for organization such as the American Pain Society); *see also* Ameet Sarpatwari et al., *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARVARD LAW & POLICY REVIEW 463 (2017) at 464-466 (describing how using pain as the fifth vital sign corresponded to a rise in prescription of opioids).

[181] *Id*.; *see also* Sarah Vander Schaaff, *Amid The Opioid Crisis, Some Seriously Ill People Risk Losing Drugs They Depend On*, CHICAGO TRIBUNE (July 16, 2018), http://www.chicagotribune.com/lifestyles/health/ct-opioid-crisis-seriously-ill-risk-losing-drugs-depend-20180716-story.html#.

[182] AHRQ data shows there is no evidence opioids are effective for chronic pain over long term use, may lead to dependence, and may in fact make pain worse. *See* Kolodny, *supra* note 58, 16. Similarly, calls for treatment both in federal policy and scholarly literature does not acknowledge the significant shortcomings of MAT nor emphasize the success of less risky alternatives such as forms of contingency management and counseling. *See* Roger Chou et al., *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, AGENCY FOR HEALTHCARE, RESEARCH, AND QUALITY (Sept. 2014).

[183] *U.S. v. Purdue Frederick Company*, *supra* note 178 at 571; *see also* Kolodny, *supra* note 58.

[184] Kolodny, *supra* note 58, at 17 (discussing how one decades old case study in the *New England Journal of Medicine* formed the evidentiary basis of Purdue's claims that OxyContin would not result in dependence for most people); *see generally* Lembke, *supra* note 176.

In January 2019, media outlets published a full unredacted complaint Massachusetts Attorney General filed against Purdue Pharma.[185] This lawsuit alleges, among other claims relating to fueling the opioid epidemic in the U.S., that Purdue Pharma actively formulated a strategy to capitalize on expanding into the "attractive market" of selling treatments for patients with OUD.[186] Notably, Richard Sackler part of one of the co-founding families behind of Purdue Pharma, is listed as joint patent holder on a new formulation of buprenorphine.[187] According to the State's Complaint, Purdue Pharma planned for "a joint venture controlled by the Sacklers to sell the addiction medication suboxone," outlining Purdue Pharma's business strategy Project Tango: "patients on opioids could now be used to sell treatment for opioid addiction."[188] Based on Project Tango's projections, 40-60% of patients would relapse, which translated to long term use of a buprenorphine formulation.[189] This unconscionable conflict of interest merits further scrutiny when examining the scope, prominence and promises of MAT.

III. MEDICATION ASSISTED TREATMENT

This section will describe the view set forth by NIDA, SAMHSA, and the Office of National Drug Control Policy that MAT constitutes the most effective method of treatment for OUD. It will provide an overview of three types of FDA approved medication (1) methadone, (2) buprenorphine, (3) and naltrexone, including legal classification, prescribing requirements, and potential risks or adverse effects.

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[185] David Armstrong, *OxyContin Maker Explored Expansion Into "Attractive" Anti-Addiction Market, ProPublica* (Jan. 30, 2019), *available at* https://www.propublica.org/article/oxycontin-purdue-pharma-massachusetts-lawsuit-anti-addiction-market.
[186] Pl.'s Am. Compl. At 151-54, *Commonwealth v. Purdue Pharma Inc.*, No. 1884-cv-01808 (Jan. 2018).
[187] Armstrong, *supra* note 185.
[188] *Commonwealth v. Purdue Pharma*, supra note 186 at 154-55.
[189] *Id*. at 155.

A. The Prominence of MAT

The Surgeon General's Report on Alcohol, Drugs, and Health states there is "one clear conclusion:" if SUD constitutes a chronic but treatable disease, then it requires expanded medical intervention.[190] In the U.S., the FDA has approved three classes of medications to treat persons with OUD in MAT: methadone, buprenorphine, and naltrexone.[191] NIDA maintains medication, along with behavioral therapy constitutes the most effective treatment for opioid use disorder.[192] ONDCP goes further, asserting medication does not merely assist with psychosocial services, but *is itself a central component* of evidence-based practice.[193] The American Society of Addiction Medicine (ASAM) issued specific Practice Guidelines regarding the use of medications in treating opioid use disorder, provides dosing guidelines, and recommends implementing a plan for psychosocial treatment in addiction to pharmacological treatment.[194]

Methadone

In the 1960s, physicians Drs. Vincent Dole and Marie Nyswander piloted the use of methadone as a replacement drug for a small population of persons with intractable heroin addiction.[195] Dole and Nyswander hypothesized addiction could be reduced to biochemical deficiency, theorizing persons with intractable intravenous heroin addiction suffered from a metabolic disruption wherein they "needed narcotics in a visceral way."[196] By providing an

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[190] Surgeon General's Report, *supra* note 36 at 10.
[191] *Medications to Treat Opioid Use Disorder*, *supra* note 8 at 5-6.
[192] *Drugs, Brains, and Behavior*, *supra* note 10, at 24.
[193] ONDCP Memo, *supra* note 51 at 4.
[194] Kyle Kampman & Margaret Jarvis, *American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, 9(5) JOURNAL OF ADDICTION MEDICINE 358 (2015). Yet ASAM also asserts "it is unclear whether psychosocial interventions offer benefit" and focuses the guidelines on pharmacological interventions.
[195] Vincent P. Dole, *Implications of Methadone Maintenance Therapy for Theories of Narcotic Addiction*, 260 JAMA 3025, 3026 (1988); David Courtwright, *The Prepared Mind: Marie Nyswander, Methadone Maintenance, and the Metabolic Theory of Addiction*, 92(3) ADDICTION 257 (1997); Vincent Dole & Marie Nyswander, *A Medical Treatment for Diacetylmorphine (Heroin) Addiction: A Clinical Trial with Methadone Hydrochloride*, 193(8) JAMA 646 (1965).
[196] *Id.* at 3025.

exceptionally high dose of a substitute opioid in a clinical setting, physicians could "correct" a "neurological derangement."[197] Methadone maintenance, according to Dole, was corrective but not curative.[198]

Methadone is a synthetic full opioid agonist, which binds to and activates the same opioid receptors as heroin, morphine, and opioid pain medications.[199] It is designed for a slower and more controlled release to prevent cravings and withdrawal symptoms over a longer time duration.[200] NIDA maintains methadone does not produce euphoria at therapeutic doses, patients receiving methadone do not appear "high" based on their tolerance to the drug's effects, and are able to function normally to attend school, work, and engage in activities of daily life. [201]

Under the Controlled Substances Act, methadone is a Class II controlled substance, which means despite an accepted medical use, it has a high potential for abuse and may lead to severe psychological or physical dependence.[202] The Controlled Substances Act requires practitioners who dispense, administer, or prescribe methadone or buprenorphine to register with the Drug Enforcement Administration.[203] Practitioners also must maintain records of inventory to track prescribing for both methadone and buprenorphine as a mechanism designed to prevent diversion.[204] When used in the context of opioid treatment, practitioners may only provide methadone through an Opioid Treatment Program (OTP) that is certified and complies with

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[197] *Id.*
[198] *Id.*
[199] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 5; *see also Methadose Oral Concentrate [Package Insert]*, MALLINCKRODT PHARMACEUTICALS (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/017116s029lbl.pdf; Andraka-Christou, *supra* note 36, at 189-191 (hereinafter "*Methadose*").
[200] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 5.
[201] *Id.* at 5, 12; *see also Methadone, Medication Assisted Treatment*, SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION, https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone.
[202] Controlled Substances Act, 21 U.S.C. § 812(b)(2); *Methadone, Office of Diversion Control*, DRUG ENFORCEMENT ADMINISTRATION (March 2014), https://www.deadiversion.usdoj.gov/drug_chem_info/methadone/methadone.pdf.
[203] Controlled Substances Act, 21 U.S.C. § 822 (a) (2017).
[204] Controlled Substances Act, 21 U.S.C. § 823 (2017).

requirements set forth by Substance Abuse and Mental Health Administration (SAMHSA).[205] With limited exceptions, providers at OTPs may only administer methadone to patients at the facility. Federal regulations permit "take home" doses of methadone for weekends, holidays, and based on the provider's discretion when reviewing a record of a patient's treatment compliance.[206]

NIDA states health professionals have successfully used methadone for forty years. [207] In 2009, Richard Mattick and colleagues reviewed studies examining the use of methadone maintenance versus no methadone maintenance for persons with opioid dependence.[208] Mattick and colleagues found patients receiving methadone maintenance showed a higher rate of retention in treatment, reduced heroin use and concluded health professionals should support methadone maintenance for persons with heroin addiction.[209]

Use of methadone carries a variety side effects and risk of adverse events. Side effects may include dizziness, sedation, nausea, vomiting, sweating, confusion, agitation, dysphoria, and insomnia.[210] Risks also include life threatening QT prolongation (a heart arrhythmia) and similar to other opioid analgesics, administration of methadone even in the prescribed amount can cause respiratory depression and death.[211]

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[205] Report to the Majority Leader, U.S. Senate, Opioid Addiction: Laws, Regulations, and other Factors Can Affect Medication-Assisted Treatment Access, GOVERNMENT ACCOUNTABILITY OFFICE (Sept. 2016), https://www.gao.gov/assets/690/680050.pdf (hereinafter "GAO Report"). This report provides an overview of the multiple laws and regulations governing the prescribing and use of controlled substances used in MAT, *see* Table 2 at 10.
[206] 42 C.F.R. § 812 (2018).
[207] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 5.
[208] Richard Mattick et al., *Methadone Maintenance Therapy versus No Opioid Replacement Therapy for Opioid Dependence*, 3 COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD 002209 (2009).
[209] *Id.*
[210] *Methadose*, *supra* note 199, at 25.
[211] *Id*. at 1; *see also* AnGee Baldini et al., *A Review of Potential Adverse Effects of Long Term Opioid Therapy: A Practitioner's Guide*, 14(3) PRIMARY CARE COMPANION CNS DISORDERS (2010) PMID:23106029 (discussing the long term adverse effects of opioids as a class of medications when used in clinical care, with mention of constipation, sleep-disordered breathing, hypothalamic-pituitary-adrenal dysfunction, and overdose, finding a significant decline in patients' health related quality of life).

Methadone has unique pharmacological properties that require cautious administration. The analgesic effect of methadone lasts about 4 to 8 hours, but it remains in the body for 8 to 59 hours, binding to tissues including the brain.[212] In risk management materials, SAMHSA has warned the combination of methadone's long half-life and slow elimination can result in the fatal accumulation of methadone in patients, leading to iatrogenic overdose.[213] Methadone also may exert neurotoxic effects, reduce gastrointestinal motility leading to constipation, suppress the immune system, and impact the endocrine system which may manifest as insulin imbalances, impotence, erectile dysfunction, amenorrhea, or infertility.[214] The FDA approved package insert for Methadose, the oral liquid used by OTPs also provides a warning statement that methadone may impair the patient's ability to drive or operate heavy machinery.[215]

Despite the profile of risks and adverse events, health professionals maintain "essential questions of safety and efficacy have been definitively answered" and methadone offers a safe and effective treatment for persons with addiction because it normalizes patient function with minimal psychoactive impairment.[216]

Buprenorphine

Buprenorphine is a partial opioid agonist, and binds to the same receptors as other opioids but activates them less strongly.[217] It is also designed to reduce cravings and withdrawal

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[212] Methadone, *supra* note 201; Methadose, *supra* note 199, at 28.
[213] *Id.*; *Minimize Liability, Manage Risk, Ensure Patient Safety: Effective Strategies in Outpatient Methadone Treatment Webinar*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (Aug. 26, 2009), https://ireta.org/wp-content/uploads/2014/11/Clinical-Guidelines-and-Liability-Prevention-6.pdf (hereinafter "*SAMHSA Minimize Liability*").
[214] *Methadose*, *supra* note 199, at 1, 3-4.
[215] *Id.* at 13.
[216] Vincent Dole, *What Have We Learned From Three Decades of Methadone Maintenance Treatment?*, 13(1) DRUG AND ALCOHOL REVIEW 3-4 (1994); Herbet Kleber, *Methadone Maintenance Four Decades Later: Thousands of Lives Saved, But Still Controversial*, 300(19) JAMA 2302 (2008).
[217] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 5; *Subutex [Package Insert]*, RECKITT BENKISER PHARMACEUTICALS INC. (2010), https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020732Orig1s010lbl.pdf; Andraka-Christou, *supra* note 36, at 193 (hereinafter "*Subutex*").

at therapeutic doses, and NIDA states it does produce euphoria based on patient tolerance and dosage.[218] Some formulations of buprenorphine combine buprenorphine with naloxone, an opioid antagonist to function as an abuse deterrent.[219] As a partial agonist, it is designed to block the high from additional opiates and SAMHSA asserts buprenorphine carries a lower risk of abuse or diversion based on its "ceiling effect."[220] SAMHSA states buprenorphine assists persons with opioid abuse disorder regain normal, healthy lives, and permits patients to function normally.[221]

Under the Controlled Substances Act, buprenorphine is a Class III controlled substance, which means the DEA has determined it has less potential for abuse than a Class II substance such as methadone.[222] Buprenorphine has an accepted medical use, and abuse of it may lead to moderate or low physical dependence and high psychological dependence.[223] Buprenorphine comes in several forms, including daily pills, a sublingual film, and a sixth month injection.[224] Physicians may prescribe buprenorphine through an OTP certified by SAMHSA or through physician offices for addiction treatment pursuant to specific requirements.[225] The Drug Addiction Treatment Act of 2000 and the Comprehensive Addiction and Recovery Act permits physicians, qualifying nurse practitioners, and physicians' assistants to obtain a waiver from the Secretary of Health and Human Services to prescribe and dispense buprenorphine in outpatient

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[218] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 5, 12; *Buprenorphine, Medication Assisted Treatment*, SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION, https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine (hereinafter *SAMHSA Buprenorphine*").
[219] *SAMHSA Buprenorphine*, *supra* note 218; *see also* Andraka-Christou, *supra* note 36, at 193-194 (discussing different formulations of buprenorphine).
[220] *Id.*
[221] *The Facts About Buprenorphine*, SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION, https://store.samhsa.gov/system/files/sma14-4442.pdf at 5, 11.
[222] Controlled Substances Act, 21 U.S.C. § 812(b)(3); *Buprenorphine, Office of Diversion Control*, DRUG ENFORCEMENT ADMINISTRATION (July 2013), http://www.deadiversiontest.usdoj.gov/drug_chem_info/buprenorphine.pdf.
[223] *Id.*
[224] *Buprenorphine, Medication Assisted Treatment*, *supra* note 218.
[225] GAO Report, *supra* note 205, *see* Table 2 at 10.

settings, such as physician offices rather than traveling to receive a daily dose of medication at an OTP.[226]

Proponents of MAT and buprenorphine note that eliminating the need for daily clinic visits expands access for patient to receive medication used in MAT.[227] Patients treated with buprenorphine are more likely to stay in treatment compared to patients receiving placebo, and less likely to abuse opioids than patients receiving no form of treatment.[228] Comparisons demonstrate similar rates of efficacy for either methadone or buprenorphine when the prescribed at a sufficient dose and duration.[229]

Side effects from buprenorphine include headache, nausea, vomiting, sweating, constipation, withdrawal symptoms, anxiety, depression, and insomnia.[230] Additional adverse risks include hepatic events, respiratory depression, and overdose, which is more likely to occur if a patient combines buprenorphine with central nervous system depressants such as alcohol or benzodiazepines.[231] The FDA approved package insert for one formulation, Subutex, carries specific warnings of its potential for dependence and abuse along with a warning Subutex may impair the patient's ability to drive or operate machinery.[232]

Naltrexone

Naltrexone is an opioid antagonist, which blocks the effects of opioids by binding to opioid receptors which is designed to block euphoria from opioid drugs.[233] It may also block

[226] 21 U.S.C. § 823 (g)(2); 21 C.F.R. § 1306.07; 42 C.F.R. § 8.610 et seq.
[227] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 5-6; Andraka-Christou, *supra* note 36, at 193-194.
[228] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 8-9.
[229] *Id.* at 10.
[230] *Subutex*, *supra* note 217, at 1, 7, 8.
[231] *Id.* at 5-6.
[232] *Id.* at 4-5.
[233] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 10; *Vivitrol [Package insert]*, ALKERMES, INC. (2010), https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021897s015lbl.pdf; *The Facts About Naltrexone*, SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION, http://adaiclearinghouse.org/downloads/Facts-About-Naltrexone-for-Treatment-of-Opioid-Addiction-28.pdf

endogenous opioid peptides.[234] Naltrexone is designed to prevent relapse following detoxification from opioids.[235] If a patient begins taking naltrexone prior to detoxification, the patient may experience withdrawal symptoms.[236] Naltrexone comes in daily pill form or a once monthly injection by the brand name Vivitrol.[237] Naltrexone is not designed to stop drug cravings, is not designed as an aversive therapy, and a patient may be able to surmount the pharmacological barrier.[238] If a patient abuses opioids during treatment with naltrexone, the patient's tolerance for the opioid may decrease, which increases the risk of overdose.[239]

Naltrexone is not an opioid and is not classified under the Controlled Substances Act, so it may be prescribed by any physician, whether through an OTP or a physician office as part of MAT.

NIDA states there is insufficient evidence that oral naltrexone is an effective treatment for opioid use disorder, and instead recommends injectable naltrexone, which one clinical trial demonstrated decreased opioid abuse and improved treatment retention.[240] Research shows fewer patients utilize naltrexone compares to methadone or buprenorphine, low patient adherence to naltrexone and high rates of attrition.[241] One research study by Dr. Joshua Lee and colleagues compared the effectiveness of a buprenorphine-naloxone combination against injectable naltrexone, measuring treatment retention and opioid abuse in a research trial, finding

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at 3 (hereinafter "*Vivitrol*").
[234] *Vivitrol*, *supra* note 233, at 19.
[235] *Id.*
[236] *Id.* at 1.
[237] *The Facts About Naltrexone*, *supra* note 233 at 4.
[238] *Vivitrol*, *supra* note 233, at 1, 19; at 8-9 (discussing patients who "continue to test the blockade" by abusing opioids).
[239] *Id*. at 2.
[240] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 10.
[241] For the daily pill form, fewer than 20% of patients continued to take naltrexone at 6 months. For the injectable version, 53% of patients continued to take naltrexone at 6 months (compared to 38% receiving a placebo). *See* Gavin Bart, *Maintenance Medication for Opiate Addiction: The Foundation of Recovery*, 31(3) JOURNAL OF ADDICTIVE DISEASES 207 (2012).

similar outcomes for each metric.[242] Physicians who specialize in addiction, including Dr. Andrew Kolodny, highlight a substantial percent (28%) of study subjects withdrew from the initial clinical trial during the detoxification phase, leaving these patients susceptible to relapse and overdose and potentially misrepresents the conclusion that both medications offer similar rates of efficacy.[243]

Side effects from injectable naltrexone include nausea, vomiting, injection site reaction, muscle pain, insomnia, and hepatic abnormalities.[244] Additional adverse events include hepatic toxicity, injection site necrosis, eosinophilic pneumonia, depression, and suicidality.[245] The FDA approved package insert for one formulation, Vivitrol, also warns of risk of dizziness, sleepiness, and the potential to impair the patient's ability to drive or operate machinery.[246]

B. "Consensus" on the Efficacy of MAT

Federal policy asserts there is "consensus"[247] in the medical community that MAT plays a critical role in the treatment of persons with opioid use disorder and it constitutes the most effective form of treatment.[248] NIDA states that patients receiving MAT are more likely to reduce their use of opioids, remain in treatment, and reduce their involvement in the criminal justice system.[249] The Surgeon General notes MAT assists persons with an opioid use disorder

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[242] Joshua Lee et al., *Comparative Effectiveness Of Extended-Release Naltrexone Versus Buprenorphine-Naloxone For Opioid Relapse Prevention (X:BOT): A Multicentre, Open-Label, Randomised Controlled Trial*, 391 (10118) LANCET 309 (2018).
[243] *See* Max Blau, *Long-Awaited Study Finds Monthly Vivitrol As Effective As Daily Pill For Opioid Addiction*, STAT NEWS (Nov. 14, 2017), https://www.statnews.com/2017/11/14/vivitrol-suboxone-study-nida/.
[244] *Vivitrol*, *supra* note 233, at 1.
[245] *Id.* at 7-9.
[246] *Id.* at 4.
[247] Memorandum from Committee on Energy and Commerce Democratic Staff to Subcommittee on Oversight and Investigations Democratic Members and Staff Regarding Hearing on "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives," 113th CONGRESS (Apr. 21, 2015), https://democrats-energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Memo-OI-Opioids-2015-4-23.pdf.
[248] *Effective Treatments for Opioid Addiction*, *supra* note 8; *Medications to Treat Opioid Use Disorder*, *supra* note 8.
[249] *Medications to Treat Opioid Use Disorder*, *supra* note, at 8.

to control their symptoms of withdrawal and craving and helps patients return to a healthy life.[250] To achieve the best outcomes, providers should use MAT in conjunction with behavioral therapy measures.[251] SAMHSA recommends patients should use medications as long as it provides benefit, cautioning that patients who discontinue medication generally return to illicit opioid use and healthcare policy should prioritize patient access, utilization, and expansion of MAT. [252]

NIDA, SAMHSA, and the Office of National Drug Control Policy[253] each issued specific statements asserting it is a "misconception" that MAT substitutes one substance use disorder for another, lamenting this perspective has hindered the adoption of evidence-based treatments.[254] SAMHSA maintains patients using replacement opioids as part of MAT receive a safe and controlled level of medication and the appropriate dose exerts "no adverse effects on a person's intelligence, mental capability, physical functioning, or employability."[255] NIDA asserts patients receiving replacement opioid agonists do not experience euphoria because they have developed a tolerance.[256] In a 2016 report, the Government Accountability Office stated abstinence-based treatment often fails, is less effective than MAT, and argued hesitation or opposition to MAT indicates a "lack of understanding" of addiction and inaccurate beliefs.[257] Friedmann and Suzuki argue extensive research shows pharmacotherapy constitutes the most effective treatment

[250] Surgeon General's Report, *supra* note 36, at ES 9.
[251] *Drugs, Brains, and Behavior*, *supra* note 10, at 26.
[252] *Id.* at 1-8.
[253] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 12-13; *Medication Assisted Treatment*, SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION, https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat (hereafter "*SAMHSA Medication Assisted Treatment*"); ONDCP Memo, *supra* note 51.
[254] *Id.*
[255] *SAMHSA Medication Assisted Treatment*, *supra* note 253.
[256] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 12-13.
[257] GAO Report, *supra* note 205, at 16.

specifically for OUD and should constitute the first line standard of care, replacing any treatment programs that offer detoxification and therapy.[258]

IV. CRITICAL ANALYSIS OF THE EVIDENCE SUPPORTING MAT

MAT may indeed work for some patients, particularly if the patient tolerates the medication without adverse effects and the provider offers comprehensive behavioral treatment. But promoting MAT as blanket federal policy, or even as a first line long term treatment, requires critical analysis. This section describes how claims pertaining to MAT's efficacy are supported by partial metrics and federal policy has downplayed problematic outcomes such as high rates of continued opioid and polysubstance abuse, potential for dependence or addiction to the replacement medication, and risk of serious physical and neurological outcomes. Financial entanglements between industry and government appear to exert influence on federal policy supporting the expansion of MAT for all persons with OUD, yet an independent review by the Cochrane Collaboration distinguished little evidence exists for providing pharmacotherapy to all persons with opioid dependence.

A. Declarations of MAT's Success Downplay Important Metrics

Statements asserting that MAT constitutes the most effective treatment contains a number of potentially misleading caveats: some studies support this proposition by comparing MAT to detoxification[259] rather than treatment and do not address the significance of continued

[258] Peter Friedmann & Joji Suzuki, *More Beds Are Not the Answer: Transforming Detoxification Units Into Medication Induction Centers To Address the Opioid Epidemic*, 12(29) ADDICTION SCIENCE AND CLINICAL PRACTICE (2017) doi 10.1186/s13722-017-0092-y.

[259] Valerie Gruber et al., *A Randomized Trial of 6-Month Methadone Maintenance With Standard or Minimal Counseling Versus 21-Day Methadone Detoxification*, 94 DRUG AND ALCOHOL DEPENDENCE 199 (2008); Suphak Vanichseni et al., *A Controlled Trial of Methadone Maintenance in a Population of Intravenous Drug Users in Bangkok: Implications for Prevention of HIV*, 26(12) INTERNATIONAL JOURNAL OF THE ADDICTIONS 1313(2009) (comparing methadone maintenance to a 45-day detoxification); *see, generally* Mattick, *supra* note 208.

substance abuse.[260] One commonly cited study by Karen Sees and colleagues did compare MAT against treatment (where the detoxification group was required to attend therapy sessions) and reported MAT increased retention and reduced opioid use.[261] Yet this claim requires further examination: despite a slight decrease in opioid use among the MAT group, opioid use in both groups remained "consistently high," and both groups continued polysubstance abuse of both opioids and cocaine, which Sees and colleagues noted "remains a concern."[262] Though rates of substance abuse vary over time and by study, rates of continued opioid abuse among subjects enrolled in MAT range from over 50% to 89.5%, even after being enrolled in MAT for several months.[263] Indeed, Nielsen and colleagues concluded *there appears to be no significant difference in days of unsanctioned opioid use among study groups who receive MAT versus those who do not*.[264]

Research cited to support the efficacy of MAT also demonstrates consistently high rates of other types of polysubstance abuse across study groups, including among subjects receiving MAT.[265] Additional research shows subjects enrolled in MAT abuse multiple other licit and illicit substances in addition to opioids including alcohol, cocaine, and cannabis.[266] Sees and colleagues assert rates of polysubstance abuse do not appear to be related to inadequate dosing of

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[260] *But see* Karen Sees et al., *Methadone Maintenance vs 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence*, 283(10) JAMA 1303 (2000). Each group had disparate therapy requirements: the methadone maintenance group required 2 hours of psychosocial therapy per week, while the detoxification group was required to attend 3 hours of psychosocial therapy per week, 14 educational sessions, and 1 hour of cocaine group therapy where appropriate and therapy related to aftercare.
[261] *Id.*
[262] *Id.*at 1306 (reporting the presence of other drugs from monthly urinalysis); at 1307-1308 (a consistently high use of heroin among both groups); at 1309 (the rates of continued heroin use among both groups remain a concern).
[263] Gruber, *supra* note 259, at 203 (citing 89.5% abuse of opiates at 8.5 months); Sees, *supra* note 260, at 1308 (citing over 50% continued abuse of opiates at 12 months).
[264] Suzanne Nielsen et al., *Opioid Agonist Treatment for Pharmaceutical Opioid Dependent People*, 5 Cochrane Database of Systemic Reviews Art. No.: CD011117 at 16 (2016).
[265] *See* Gruber, *supra* note 259; Sees, *supra* note 260; *see also* Miriam Mintzer & Maxine Stitzer, *Cognitive Impairment in Methadone Maintenance Patients*, 67 DRUG AND ALCOHOL DEPENDENCE 41, 43 (2002).
[266] Mintzer & Stitzer, *supra* note, 265, at 43 (citing subjects enrolled in MAT self-reported the following polysubstance abuse: 50% continued to abuse heroin, 44% abused cocaine, and 28% abused cannabis).

maintenance medication.[267] Discounting significant continuing opioid or polysubstance abuse among persons enrolled in MAT should trigger a re-assessment of blanket declarations of efficacy.

Both media reports and case law bolster these data showing patients enrolled in MAT continue to abuse opioids and or engage polysubstance abuse. One patient who was enrolled in MAT and received a prescription for Suboxone (buprenorphine/naloxone) commented it "did nothing but prolong my death…I was just taking other drugs with it and it was really just a Band-Aid."[268] Similarly, investigations into OTPs by the *New York Times* shared a father's story, who reported despite his son's assertion that Suboxone worked for him, his son overdosed *five times* by abusing other substances while in MAT, eventually succumbing to a fatal overdose.[269]

Case law portrays similar findings: in *Taylor v. Smith,* Glenda Ennis, a patient in a methadone maintenance program, stated repeatedly she had no desire to stop any of her polysubstance abuse, and continued to abuse cannabis and illicit benzodiazepines while enrolled in MAT.[270] Similarly, in *Lingren v. Pinnacle Recovery Services*, methadone maintenance patient Vanessa Brigan continued illicit substance abuse by not only drinking her daily dose of methadone, but injecting additional doses of methadone, and simultaneously abusing cannabis.[271] The court in *Taylor v. Smith* concluded MAT facilitated Ennis to receive methadone not in *lieu* of illegal drugs, but in *addition* to them."[272]

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[267] Sees, *supra* note 260, at 1309.
[268] Ungar, *supra* note 41.
[269] Deborah Sontag, *Addiction Treatment With A Dark Side*, NEW YORK TIMES (Nov. 16, 2013), *available at* http://nyti.ms/18dv5Wb.
[270] *Taylor v. Smith*, 892 So.2d 887, 890 (Ala. 2004).
[271] *See* Order and Memorandum, *Lingren v. Pinnacle Recovery Services et al.*, No. 09-CV-13-215 and No. 09-CV-14-760 (D.Minn. Aug. 14, 2014) (on file with author).
[272] Italics in original judicial opinion. *Taylor v. Smith* italicized these terms to emphasize the patient enrolled in MAT was not being successfully treated but MAT merely provided her more drugs for abuse. *Taylor v. Smith*, 892 So.2d 887, 896 (Ala. 2004).

Many studies compare retention in treatment as a metric of success, but presuming treatment retention equates to success reveals conflicting and troubling evidence. While Mattick and colleagues review asserted that MAT constitutes an effective intervention, it found no statistically significant differences in criminal involvement or mortality.[273] Several studies conflict with the Surgeon General's claims that MAT helps persons return to a productive life, finding continued psychosocial dysfunction and rates of marginal employment or unemployment.[274] One significant barrier to employment and psychosocial functioning rests upon patients' ability to conduct activities of daily living, such as driving, working, going to school, and engaging in family life without significant impairment such as experiencing euphoria, craving, and symptoms of withdrawal.[275]

B. Evidence Does Not Support the Proposition that MAT Permits Patients to Function Normally and Promotes Recovery

*MAT **Does** Serve as Medically Sanctioned Substitute Opioid with Serious Risks for Dependency*

Despite rhetoric in federal policy asserting MAT does not constitute replacing or substituting one SUD for another, these claims are not supported by pharmacology, legal classification by the DEA, or numerous first person patient reports. As opioid agonists, both methadone and buprenorphine occupy the same receptors as other substances such as heroin or

[273] Mattick, *supra* note 208.
[274] Sees, *supra* note 260, at 1309; Julie Harris & Karen McElrath, *Methadone as Social Control: Institutionalized Stigma and the Prospect of Recovery*, 22(6) QUALITATIVE HEALTH RESEARCH 810 (2012) at 818 (discussing barriers to societal reintegration and how many MAT patients are still unemployed or marginally employed).
[275] In risk management materials designed for OTPs, SAMHSA recognizes patient impairment constitutes a significant issue. *See Effective Strategies in Outpatient Methadone Treatment: Legal and Clinical Issues*, SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION (Apr. 2, 2010) (hereinafter "*SAMHSA Effective Strategies")* (on file with author) (discussing legal definitions of impairment and how this may impact liability for the OTP); Lisa Torres, *Risk Management: Patient Safety; Public Safety and OTP Liability*, SUBSTANCE ABUSE AND MENTAL HEALTH ADMINISTRATION (hereinafter "*SAMHSA Risk Management*") (on file with author).

oxycodone.[276] Though NIDA denies patients receiving methadone and buprenorphine experience euphoria, both FDA and DEA product labeling caution against the opposite: both controlled substances *are* capable of producing significant euphoria even in persons with tolerance.[277] In a graph illustrating sustained activation of opioid receptors (euphoria), NIDA compares the relative euphoria of heroin to methadone, buprenorphine, and naltrexone.[278] The graph shows buprenorphine as a partial opioid agonist produces less euphoria relative to heroin, but also shows methadone produces the *same level of euphoria as heroin*, but sustains this activation for a longer duration relative to heroin.[279] Patient reports collected in research, SAMHSA provider educational materials,[280] and patient accounts reported in the media confirm patients request higher doses specifically to experience euphoria,[281] become "desperate"[282] in seeking more agonist medication in greater dosages, and allege "it's easy to game the system…[and receive] as much as you want."[283]

Research also supports the premise that MAT may not reduce cravings: many persons enrolled in MAT abuse the prescribed agonist itself (e.g. injecting methadone or buprenorphine)

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[276] *Methadose*, *supra* note 199; *Methadone*, *supra* note 201; *Subutex supra* note 217; *SAMHSA Buprenorphine*, *supra* note 218.
[277] *Id.*
[278] *Medications to Treat Opioid Use Disorders*, *supra* note 8, at 14.
[279] *Id*.
[280] *SAMHSA Minimize Liability*, *supra* note 213, at 21 (Patient Mary reported "she did not want an increase [in Methadone dosage] because she did not want to be like those 'other patients on high doses'].
[281] Skyler Swisher, *Methadone Treatment Raises Questions About Profit Motive, Patient Care*, DAYTONA BEACH NEWS-JOURNAl (Apr. 20, 2013), http://www.news-journalonline.com/article/LK/20130420/News/605064476/DN/ (providing a patient account from Tracy Williams, who states she asked for more methadone as a way to feel high and opines other patients are also using methadone as a way to get high); *see also* Adam Walser, *Former Methadone Clinic Doctor Says He Was 'Told To Get Them On a High Dose and Keep Them There'*, ABC ACTION NEWS (Nov. 17, 2017), https://www.abcactionnews.com/news/local-news/i-team-investigates/former-methadone-clinic-doctor-says-he-was-told-to-get-them-on-a-high-dose-and-keep-them-there (providing a physician account who stated he was instructed by OTP clinic management to place patients on a high dose and providing a patient account who stated "it was easy to game the system…they give you as much as you want"); Harris & McElrath, *supra* note 274, at 815 (providing accounts of patients receiving methadone who supplemented with heroin to achieve the desired pharmacological effect if they deemed the methadone dosage insufficient).
[282] Swisher, *supra* note 281.
[283] Walser, *supra* note 281.

in addition to continuing concurrent polysubstance abuse.[284] This suggests a deficiency in the premise of MAT – patients are still experiencing a compulsion and drive to abuse opioid agonists, including the prescribed opioid agonist, for pharmacological effect. Indeed, in 2016, an opinion piece the *New York Times* described patients attempting recovery through MAT who became dependent on Suboxone, and developed an addiction to the medication itself.[285]

Patients are also diverting the medication into the illicit market.[286] Despite NIDA's assertion that diversion is rare and merely occurs for therapeutic purposes,[287] recent research,[288] the Drug Enforcement Administration (DEA),[289] and the Department of Justice[290] suggests diversion may constitute an increasing problem.[291] In 2009, the National Forensic Laboratory Information System of the DEA published a special report demonstrating the explosion of diverted methadone and buprenorphine between 2003 and 2008 during the period when patient

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[284] *See* Hanna Uosukainen et al., *Twelve-Year Trend In Treatment Seeking For Buprenorphine Abuse In Finland*, 127(1-3) DRUG AND ALCOHOL DEPENDENCE 207 (2013) (over 80% of subjects enrolled in MAT injected buprenorphine and describes rates of concurrent polysubstance abuse); *see also* Michelle Lofwall & Sharon Walsh, *A Review of Buprenorphine Diversion and Misuse: The Current Evidence Base and Experiences from Around the World*, 8(5) JOURNAL OF ADDICTION MEDICINE 315 (2014) (citing varied research that 18-28% of persons enrolled in methadone or buprenorphine maintenance programs have shared, sold, or given away their prescribed medication).

[285] Beth Macy, *Addicted to a Treatment for Addiction*, NEW YORK TIMES (May 28, 2016), https://www.nytimes.com/2016/05/29/opinion/sunday/addicted-to-a-treatment-for-addiction.html; Brandon Stahl, *Former Patient Says Treatment Was 'Just Another Addiction*,' DULUTH NEWS TRIBUNE (Sept. 23, 2012), http://www.house.leg.state.mn.us/comm/docs/duluthnewtribunemethadone.pdf.

[286] Sontag, *supra* note 41; Ungar, *supra* note 41; Schladen, *supra* note 41.

[287] *Medications to Treat Opioid Use Disorder*, *supra* note 8, at 15 (asserting if diversion occurs, it may be for "therapeutic" use for persons who are attempting to reduce withdrawal symptoms or reduce heroin use).

[288] Lofwall & Walsh, *supra* note 284.

[289] *Methadone*, *supra* note 201; *SAMHSA Buprenorphine*, *supra* note 218.

[290] In 2013 the Department of Justice settled a case against a Metro Treatment Center in Alabama for $95,000, the largest penalty the DOJ ever collected for drug diversion arising from 3423 missing dosage units of methadone. DEPARTMENT OF JUSTICE, *U.S. ATTORNEY'S OFFICE, Huntsville Narcotic Treatment Center Agrees to Pay $95,000 Penalty* (Mar. 19, 2013), https://www.justice.gov/usao-ndal/pr/huntsville-narcotic-treatment-center-agrees-pay-95000-penalty.

[291] CENTER FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY, *The DAWN Report: Emergency Department Visits Involving Buprenorphine* (Jan. 29, 2013), https://www.samhsa.gov/data/sites/default/files/DAWN106/DAWN106/sr106-buprenorphine.htm (providing statistics that emergency department visits involving buprenorphine increased from 3161 in 2005 to 30,135 in 2010 as the availability of the drug increased) (hereinafter "*Emergency Visits Involving Buprenorphine").*

enrollment in MAT increased in response to opioid dependency.[292] During this time, diversion of buprenorphine increased 250-fold into the illicit market.[293]

Finally, patients who want to discontinue maintenance medication may find their treatment facility or individual practitioner may not provide a clear plan of how to stop.[294] SAMHSA specifically recognizes many OTPs do not provide a pathway for its patients to go medication free based on a justification of "poor outcomes" and acknowledges opioid agonists do result in patient dependence.[295] Patients feel resigned to taking a maintenance medication "maybe forever" according to one physician because if they stop, they encounter severe symptoms of withdrawal and become physically sick.[296]

MAT Can Produce Physical, Neurological, and or Psychological Harm That Hinders Recovery

The extensive and serious adverse effects for each of the three classes of medications used in MAT should not be dismissed as infrequent and may influence patients' ability to engage

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[292] DRUG ENFORCEMENT ADMINISTRATION, *Special Report: Methadone and Buprenorphine*, 2003-2008, 1-2, 4-5, 10 (2009), https://www.deadiversion.usdoj.gov/nflis/methadone_buprenorphine_srpt.pdf; *see also Emergency Visits Involving Buprenorphine*, *supra* note 291.

[293] DRUG ENFORCEMENT ADMINISTRATION, *supra*, at 1–2; *see also* Laura Ungar, *Rogue Doctors Exploit Loopholes to Let a Powerful Drug 'Devastate a Community,'* COURIER JOURNAL (June 8, 2017), https://www.courier-journal.com/story/news/investigations/2017/06/08/rogue-doctors-hands-medicine-designed-treat-addiction-turns-into-new-habit/98522426/ (quoting Kentucky Attorney General Andy Beshear who compares Suboxone clinics to the "second coming of pill mills" and reports the Attorney General's Office has more complaints than it can count relating to illegal diversion and sale of buprenorphine products used in MAT).

[294] Julie Harris & Karen McElrath, *Methadone as Social Control: Institutionalized Stigma and the Prospect of Recovery*, 22 QUALITATIVE HEALTH RES. 810, 816 (2012) (providing interviews with methadone patients stating their desire to discontinue methadone, fearing long term use of methadone and its consequences, and a desire to reduce or stop methadone but experiencing no support to do so and encountering a blanket policy of retaining patients on methadone).

[295] SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, Federal Guidelines for Opioid Treatment Programs, HHS Publication No. (SMA) PEP15-FEDGUIDEOTP, 23, 25 (2015) (opioid agonist medications will themselves produce dependence) (many OTPS do not provide a pathway for a medication free state due to "notoriously poor outcomes").

[296] Deborah Sontag, *At Clinics, Tumultuous Lives and Turbulent Care*, NEW YORK TIMES (Nov. 17, 2013), https://www.nytimes.com/2013/11/18/health/at-clinics-tumultuous-lives-and-turbulent-care.html (a physician reporting that new patients ask how long they will stay on buprenorphine, then stop asking when they realize the answer is "maybe forever"); Jose Del Real, *Opioid Addiction Knows No Color, But Its Treatment Does*, NEW YORK TIMES (Jan. 12, 2018), https://www.nytimes.com/2018/01/12/nyregion/opioid-addiction-knows-no-color-but-its-treatment-does.html (providing a quote from a methadone patient stating, "I wish I didn't have to come here every day, but I have to. If you don't, you're sick. *You wake up sick*." (emphasis added)).

in activities of daily life. In one study, over half of patients enrolled in methadone maintenance programs experienced depression, fatigue, and headaches, which negatively impact patients' subjective assessments of quality of life.[297]

Research suggests both opioid agonist and opioid antagonist medications used in MAT also pose risks to neurological and or psychological functioning.

Wei-Che Lin and colleagues demonstrated patients enrolled in MAT who received an opioid agonist experience prominent adverse effects on multiple cognitive functions, experience increased rates of depression and suicide, and experience a lower quality of life.[298] Opioid agonists negatively impact memory processing, impair short term memory, impair visuo-spatial attention, reduce cognitive speed.[299] Research shows opioid agonists produce changes in both white matter and gray matter in the brain, resulting structural and functional abnormalities.[300] Chronic exposure to opioid agonists may lead to apoptosis (death) of neuronal cells and demyelination (impaired connectivity within the brain's synapses), which has been connected to behaviors including impulsivity, lack of self-control, and intolerance for cognitive complexity.[301] Notably, research correlates this neurological damage to duration and dose of MAT, not pre-existing differences or damage from illicit opioid abuse.[302] Wei Li and colleagues summarize

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[297] Janie Sheridan et al., *Health Problems and Help-Seeking Activities of Methadone Maintenance Clients and Aukland Methadone Services: A Potential for Community Pharmacy Expansion*, 2(25) HARM REDUCTION J. 25, 25-29 (2005).
[298] Wei-Che Lin et al., *White Matter Abnormalities Correlating With Memory and Depression In Heroin Users Under Methadone Maintenance Treatment*, 7 PLOS ONE 1, 7-8 (2012); *see also* Mintzer & Stitzer, *Cognitive Impairment in Methadone Maintenance Patients*, 67 DRUG & ALCOHOL DEPENDENCE 41, 41, 45-47 (2002) (finding patients enrolled in MAT had significantly worse performance than controls on tests for memory and cognitive speed); Shane Darke et al., *Comparative Patterns of Cognitive Performance Amongst Opioid Maintenance Patients, Abstinent Opioid Users and Opioid Nonusers*, 126 DRUG AND ALCOHOL DEPENDENCE 309 (2012) (patients enrolled in MAT had worse cognitive performance than both controls and former opioid users who were not abstinent).
[299] *Id.*
[300] Wei Li et al., *Methadone Induced Damage To White Matter Integrity in Methadone Maintenance Patients: A longitudinal Self-Control DTI Study*, 6 SCI. REPS. (2016).
[301] Li, *supra* note 300, at 2, 5; Darke, *supra* note 298, at 309; Mintzer & Stitzer, *supra* note 265, at 46-47; Lin, *supra* note 298, at 1, 7.
[302] Li, *supra* note 300, at 3-4; Darke, *supra* note 298, at 312; Lin, *supra* note 298, at 1, 7.

these findings as evidence that MAT induces a type of brain disease that may substantially impair enrolled patients.[303] This research suggests MAT does not promote neurological recovery, but rather extends neurological dysfunction and may hinder behavioral therapy options that rely on new neurological growth, cognitive judgment, and discernment.

Opioid antagonist naltrexone's inherent pharmacology likely impacts low adherence because, as an opioid antagonist, it may block the effect of endogenous opioids, endorphins, and enkephalins.[304] Patients may be more likely to experience pain, depression, and thoughts of suicidality.[305] Research shows naltrexone blocks or reduces the joy from life activities: such as the warmth of feeling connected to others, pleasure from delicious food, and a positive mood from exercise.[306] Activities that provide alternate outlets such as exercise[307] and therapeutic communities[308] show excellent promise as potential therapies to reconnect and engage. Yet, patients who adhere to naltrexone treatment may encounter difficulty in attempting to find alternate strategies, goals, and activities if they find their activities lack purpose and joy.

[303] Li, *supra* note 300, at 5.
[304] Maia Szalavitz, *How Safe Is America's Hottest Heroin Addiction Treatment?*, VICE (July 26, 2017), https://www.vice.com/en_us/article/7x9ypq/how-safe-is-americas-hottest-heroin-addiction-treatment.
[305] *Id.*; Rebecca Price et al., *Opioid-Receptor Antagonism Increases Pain And Decreases Pleasure In Obese And Non-Obese Individuals*, 233 PSYCHOPHARMACOLOGY 3869, 3869-70, 3875-77 (2016).
[306] Szalavitz, *supra* note 304; *see* Price et al., *supra note* 305, at 3869–70, 3874, 3876–77 (describing how opioid antagonists may increase pain, reduce pleasure, and contribute to depression); M. Daniel et al., *Opiate Receptor Blockade by Naltrexone and Mood State After Acute Physical Activity*, 26 BRIT. J. SPORTS MED. 111, 111, 113–14 (1992) (discussing exercise generally induces a mood state of being more calm, relaxed and pleasant, and reduces depression, anger, and anxiety, yet naltrexone blocks these positive effects of exercise on mood state); Tristen Inagaki et al., *Blocking Opioids Attenuates Physical Warmth-Induced Feelings of Social Connection*, 15 EMOTION 494, 494–500 (2015) (discussing how naltrexone reduces subjective feelings of social warmth and feelings of social connection and bonding).
[307] Mark Smith & Wendy Lynch, *Exercise and a Potential Treatment for Drug Abuse: Evidence from Preclinical Studies*, 2 FRONTIERS IN PSYCHIATRY 1 (2012).
[308] August Holtyn et al., *Employment-Based Abstinence Reinforcement Promotes Opiate and Cocaine Abstinence in Out-of-Treatment Injection Drug Users*, 47 J. APPLIED BEHAV. ANALYSIS 681, 681–82 (2014).

C. Financial Conflicts of Interest Have Significantly Driven Expansion of MAT

Benedikt Fischer of the Centre for Addiction and Mental Health highlights the impact of corporate involvement in Canadian federal policy promoting MAT as a first line treatment despite lack of evidence for this patient population and serious adverse effects.[309] In other scholarship, I've noted the strong financial conflicts of interest between clinical care standards and prescribing practices, and similar financial interests appear to influence federal policy here in the U.S.[310] The American Society of Addiction Medicine that provides clinical guidelines for three types of maintenance medications as appropriate treatment choices (rather than alternate forms of comprehensive treatment) receives industry funding from multiple manufacturers of medications used in MAT.[311] Industry funding may impact prescribing and policy to promote both opioid agonists and opioid antagonist medications.

The *New York Times* reported on the public private partnership between NIDA and Reckitt Benkiser to conduct clinical trials on buprenorphine, which NIDA and the ONDCP viewed as an improvement to methadone.[312] Charles O'Keefe, a former White House Drug Policy advisor also involved with Reckitt Benkiser, lobbied Congress to amend federal law to facilitate increased prescriptions for buprenorphine.[313] States began to offer financial incentives or subsidies to increase the pool of providers, which correlated with more individual practitioners

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[309] Benedikt Fischer et al., *Treatment of Prescription Opioid Disorders in Canada: Looking at the 'Other Epidemic'?*, SUBSTANCE ABUSE TREATMENT, PREVENTION & POL'Y (2016).
[310] Katherine Drabiak, *The Impact of a Developing Regulatory Framework Governing LDTs in Precision Oncology: Re-Envisioning the Clinical Risk Assessment Paradigm*, 13 JOURNAL OF HEALTH AND BIOMEDICAL LAW 1, 5-56 (2017) (discussing how industry shapes clinical care recommendations to use pharmacological interventions for expanded patient populations and despite serious risks), at 66 (describing how federal policy may downplay risks or issue conclusions despite lack of support from scientific evidence).
[311] ASAM's 2018 Corporate Roundtable included donations from Indivior (Suboxone), Alkermes (Vivitrol), Mallinckrodt (Methadose). *See* 2018 Corporate Roundtable Members, AMERICAN SOCIETY OF ADDICTION MEDICINE, *available at* https://www.asam.org/about-us/corporate-round-table/members.
[312] Sontag, *supra* note 269.
[313] *Id.*

and OTPs offering buprenorphine.[314] Entanglement between industry and federal policy has overshadowed concerns initially raised by the DEA and FDA pertaining to potential for dependency and diversion relating to buprenorphine.[315] MAT increases profit not only for the pharmaceutical sector,[316] but for physicians[317] and OTPs, which have emerged as one of the most profitable sectors in healthcare with high profit margins.[318]

According to the Center for Responsive Politics, in 2016 Alkermes spent $4.4 million for aggressive lobbying to brand Vivitrol (naltrexone) as a "nonaddictive medication" alternative to opioid agonists.[319] Marketing to law enforcement and policymakers, Alkermes drafted sample state legislation permitting community corrections grant priority for programs that offer alternative sentencing programs, which may include "nonaddictive medication" for opioid dependency[320] and marketed Vivitrol directly to drug court professionals as a method to directly expand its market reach.[321]

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[314] *Id*.; *see also* Christina Andrews et al., *Adoption of Evidence-Based Clinical Innovations The Case of Buprenorphine Use by Opioid Treatment Programs*, 71(1) MEDICAL CARE RESEARCH AND REVIEW 43 (2014) (finding that buprenorphine use increased 24% for detoxification and 47% for maintenance therapy between 2005 and 2011 and was correlated with coverage by private insurance or state subsidies).

[315] Sontag, *supra* note 269 (writing the FDA and DEA were not initially convinced that buprenorphine has less abuse potential than other opioid agonists, which relates to the potential for individual abuse and diversion).

[316] Christopher Moraff, *Suboxone Creator's Shocking Scheme To Profit Off of Heroin Addicts*, THE DAILY BEAST (Oct. 5, 2016), https://www.thedailybeast.com/suboxone-creators-shocking-scheme-to-profit-off-of-heroin-addicts (describing Reckitt Benkiser's advertising strategies to promote Suboxone and retain market share after the patent for Suboxone expired in 2009).

[317] *Watchdog Warns About Replacing Opioid Epidemic With a Psychotropic One*, PR NEWSWIRE (Sept. 26, 2017), https://www.prnewswire.com/news-releases/watchdog-warns-about-replacing-opioid-epidemic-with-a-psychotropic-one-300525829.html.

[318] Swisher, *supra* note 281; Wickersham & Basey, *supra* note 174, at 14; Mary Wickersham & Stephanie Basey, *Is Accreditation Sufficient? A Case Study and Argument for the Transparency When Government Regulatory Authority is Delegated*, 39(2) JOURNAL OF HEALTH AND HUMAN SERVICES ADMINISTRATION 245 (2016) at 247 (stating income and operating statistics for one clinic would yield annual revenue at $4 million).

[319] Jake Harper, *A Drugmaker Tries to Cash In On the Opioid Epidemic, One State At A Time*, NPR (June 12, 2017), https://www.npr.org/sections/health-shots/2017/06/12/523774660/a-drugmaker-tries-to-cash-in-on-the-opioid-epidemic-one-state-law-at-a-time.

[320] Naltrexone is currently the only "nonaddictive" medication. *Id.*

[321] Jake Harper, *To Grow Market Share, A Drugmaker Pitches Its Product To Judges*, NPR (Aug.3, 2017), https://www.npr.org/sections/health-shots/2017/08/03/540029500/to-grow-market-share-a-drugmaker-pitches-its-product-to-judges.

The criminal justice setting specifically warrants special consideration based on the court's influence and potential for coercion. If offenders do require treatment, it must be evidence-based on appropriate outcome data, not financial entanglements and misleading metrics. According to the World Health Organization, implementing any medication requirement in the criminal justice setting as a condition of parole or probation triggers serious human rights considerations.[322] Financial entanglements, forceful lobbying, and the unique pharmacological profiles of medications used in MAT warrant inquiry whether these medications would in fact be effective, humane, and ethically appropriate compared to alternate models for the criminal justice setting such as HOPE or treatment alternatives.[323]

D. Expanding MAT to all Persons with Opioid Use Disorder is Not Supported by Current Evidence

In Dole and Nyswander's work, MAT using methadone began an experimental method to reduce mortality and relative illicit drug abuse among persons with intractable heroin addiction. Mattick and colleague's review of research examining outcomes of patients enrolled in MAT used studies of patients with a heroin addiction, not patients with other types of OUD.[324] In 2016, the Suzanne Nielsen and colleagues published a review of studies that focus on the more precise question of whether MAT is effective for persons with OUD.[325] Nielsen and colleagues found "very limited studies" and low to moderate quality evidence supporting the use of pharmacotherapy for opioid dependence.[326] Notably, Nielsen and colleagues also reiterated that

[322] WORLD HEALTH ORGANIZATION, *supra* note 64, at 233-234 (WHO warns against legally coerced treatment and the human rights issues raised by using the state's policy power to force treatment on persons, stating the treatment must benefit the individual, be effective, and humane. WHO recommends that persons involved in the criminal justice system have constrained choices, and be permitted to choose among effective options).
[323] *Id.*
[324] Mattick, *supra* note 208.
[325] Nielsen, *supra* note 264.
[326] *Id.* Nielsen and colleagues found varied support for each outcomes measure, where some metrics were only supported by *one* study.

persons with heroin addiction appear to differ in important ways from persons with an opioid use disorder.[327]

Benedikt Fischer echoes Nielsen and colleague's finding, asserting many persons with OUD are characterized by clinically relevant differences such as short-term or tangential involvement with prescription misuse.[328] Fischer and colleagues predict adverse effects from MAT such as negative neurological changes, depression, and mortality will create a new epidemic of iatrogenic harm from medical intervention and assert evidence instead supports an individualized stepped approach where many patients would benefit from medication taper supported by behavioral therapy.[329]

The evidence described above outlines numerous deficiencies supporting the proposition that MAT constitutes a safe, effective, and appropriate solution for either addiction or physiological dependence.

V. Shortcomings Of Current Opioid Treatment Programs And Implications For Public Health And Safety

This section will consider the implications of expanding MAT to all persons with Opioid Use Disorder by examining massive shortcomings relating to the regulation of Opioid Treatment Providers (OTPs), discrepancies in treatment quality, and why case law compels a fresh examination of the current treatment paradigm.

A. Glimpses of a Problem: OTP Noncompliance and Substandard Care

Recent media report, lawsuits, and case law suggest the current framework for MAT may pose serious health risks to both patient well-being and public safety. Multiple reports describe

[327] *Id.*
[328] Benedikt Fischer et al., *Treatment of Prescription Opioid Disorders in Canada: Looking at the 'Other Epidemic'?* 11(12) SUBSTANCE ABUSE TREATMENT, PREVENTION, AND POLICY (2016).
[329] *Id.* at 3.

patients enrolled in MAT have died from either actively overdosing,[330] or died from iatrogenic overdose wherein the patient ingested an opioid agonist as prescribed and died from medication toxicity.[331] Compliance investigations and survey research of OTPs reveal some patients are enrolled in more than one OTP facility and receive multiple prescriptions, but physicians or OTP facilities do not check prescription drug monitoring databases.[332] Media reports have also highlighted concerns relating to the sufficiency of treatment provided at OTPs, such "dose and go" treatment center that line up patients to receive medication but fail to provide behavioral therapy or counseling despite a federal requirement to do so.[333] Across the country, media reports detail how patients at OTPs who receive their medication and leave the facility impaired, only to drive away and cause fatal motor vehicle accidents.[334]

Research by public policy scholars Mary Wickersham and Stephanie Basey along with the sheer amount of media reports, lawsuits, and case law suggests the reported cases of patient injury, OTP clinic mismanagement, and harm to the public constitutes the tip of the iceberg to a much larger problem. From 1996 to 2012, the number of OTPs doubled, and in June 2018 HHS announced the availability of $350 million in new funding to expand access to substance use

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[330] Sontag, *supra* note 269; Brandon Stahl, Methadone: *'60s Treatment Comes With Deadly Risks Today*, DULUTH NEWS TRIBUNE (Sept. 16, 2012), http://www.duluthnewstribune.com/lifestyle/health/2326671-methadone-60s-treatment-drug-addiction-comes-deadly-risks-today.

[331] Stahl, *supra* note 330; *SAMHSA Minimize Liability*, *supra* note 213.

[332] *See* Benjamin Schachtman, *Half of Wilmington's Private Drug Treatment Facilities Cited, Including One for a Patient's Death*, PORT CITY DAILY (Apr. 24, 2018), https://portcitydaily.com/local-news/2018/04/24/half-of-wilmingtons-private-drug-treatment-facilities-cited-including-one-for-patient-death-opiods/ (describing North Carolina Department of Health and Human Services reported that New Hanover Treatment Center was in violation of the requirement to check that clients were not dually enrolled in other treatment facilities). *See also* Wishersham & Basey's, *supra* note 174, at 13-14 (describing survey of OTPs found only about half participate in the state's prescription drug monitoring database).

[333] Swisher, *supra* note 281 (Swisher refers to the practice as "dose and go," where the patient obtains the medication, but the OTP does not provide sufficient (or any) behavioral therapy to address the reasons for the underlying addiction). *See* 42 C.F.R. § 8.12 (f).

[334] Nilsen, *A Life Changer*, *supra* note 42; Nilsen, *A Stage Set*, *supra* note 42; Kruger, *supra* note 42.

disorder and mental health services including MAT and OTPs.[335] Expanding the current model for assuring the quality of OTPs translates to the potential for more patient exposure to facilities without effective oversight to their quality.

B. Regulation of OTPs

OTPs are regulated on both the federal and state level.[336] Specific requirements set forth in 42 C.F.R. Part 8.12 designates that OTPs are required to be certified by SAMHSA and have a valid accreditation status; OTPs may be accredited by either the state or a private accreditation body, such as the Commission on Accreditation of Healthcare Facilities (CARF).[337] According to SAMHSA, the regulations set forth minimum acceptable standards for the operation of OTPs, but are not intended as the professional standard of care.[338] The regulations and corresponding guidance issued by SAMHSA outline details such as the appropriate administration and organization structure,[339] quality assurance that includes the program's goals and objectives for treatment,[340] risk management and a system to report critical incidents (such as injuries or deaths),[341] and a diversion control plan.[342] Federal regulations also require a minimum amount of annual drug screening tests for patients enrolled in OTPs, but does not condition a patient's continued enrollment or receipt of Controlled Substances with compliance.[343] Instead,

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[335] *HRSA Confronts Opioid Addiction*, HEALTH RESOURCE AND SERVICES ADMINISTRATION (Sept. 21, 2017), https://www.hrsa.gov/enews/2017/opioidaddiction.html; HHS makes $350 million available to fight the opioid crisis in community health centers nationwide, DEPARTMENT OF HEALTH AND HUMAN SERVICES (June 15, 2018), https://www.hhs.gov/about/news/2018/06/15/hhs-makes-350-million-available-to-fight-opioid-crisis-community-health-centers.html.
[336] Federal Guidelines for Opioid Treatment Providers, *supra* note 295; *see, generally* Wickersham & Basey, *supra* note 174 (discussing the intersection of federal law overseen by multiple regulatory agencies including SAMHSA, FDA, and DEA, and state licensing requirement for OTPs).
[337] Federal Opioid Treatment Standards, 42 C.F.R. § 8.12 (2015).
[338] Federal Guidelines for Opioid Treatment Programs, *supra* note 295, at 4.
[339] Federal Opioid Treatment Standards, 42. C.F.R. 8.12 (2015); Federal Guidelines for Opioid Treatment Programs, *supra* note 295, at 10-11.
[340] 42. C.F.R. 8.12; Federal Guidelines for Opioid Treatment Programs, *supra* note 295, at 15-16.
[341] Federal Guidelines for Opioid Treatment Programs, *supra* note 295, at 13-15.
[342] 42. C.F.R. 8.12; Federal Guidelines for Opioid Treatment Programs, *supra* note 295, at 15.
[343] Federal Opioid Treatment Standards, 42. C.F.R. 8.12 (f)(6) (2015).

SAMHSA guidance warns *against* decreasing or limiting doses of maintenance medication in response to polysubstance abuse and instead suggests patient's polysubstance abuse signals the need for more intensive counseling and an *increased dose* of maintenance medication.[344]

Licensing requirements, reporting, and inspection practices within each state vary based on differing state law.[345] Not all states require annual inspections, facilities may self-report partial metrics (such as number of enrolled patients and retention in treatment) but not metrics measuring polysubstance abuse and drug screen results, or impact of MAT on employment, criminal activity, or adverse health outcomes.[346] Accordingly, measures of "success" may correspond to the number of enrolled patients, or the length of time in treatment without report of crucial outcomes such as how many patients continue to abuse illicit substances and their quality of life.[347]

The problem, according to Wickersham and Basey, is that accreditation status has become a signifier of quality but lacks uniformity and transparency.[348] Wickersham & Basey's findings provide substantive research supporting troubling media stories[349] reporting how state

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[344] Federal Guidelines for Opioid Treatment Programs, *supra* note 295, at 51-52 (asserting programs shall not adjust doses to reinforce positive behavior or punish negative behavior and positive toxicology screens may indicate the need for an increased dosage of maintenance medication), at 20(describing the appropriate response of more intensive counseling to address polysubstance abuse).

[345] Wickersham & Basey, *supra* note 174, at 2 (licensing requirements vary across state lines), at 6 (if states did not collect licensure data, then the data collection is left to the accreditation agency, at 11-12 (data on the lack of uniform performance metrics among 22 surveyed OTPs).

[346] *Id*.; Wickersham & Basey, *supra* note 318, at 258 (stating most state regulations provide requirements for OTP processes and organizational structure rather than outcome metrics related to patient success), at 269 (finding that 86% of states require reporting sentinel adverse events such as patient deaths, yet only 3 states of 22 that responded to the survey were able to provide data).

[347] Wickersham & Basey, *supra* note 318, at 260 (listing types of violations that hinder appropriate treatment such as failure to conduct drug screening, lack of treatment plans, lack of physical exam, lack of reporting patient deaths, lack of appropriate staff training).

[348] *Id.* at 249 (accreditation becomes the de factor interpreter of quality); Wickersham & Basey, *supra* note 174, at 2 (the regulation itself becomes the measuring stick rather than the appropriateness of policies or the outcomes associated with OTPs).

[349] Stahl, *supra* note 330; *Inspectors Pass Different Judgments on Duluth Methadone Clinic*, DULUTH NEWS TRIBUNE (Nov. 11, 2012), https://www.duluthnewstribune.com/lifestyle/health/2441365-inspectors-pass-different-judgments-duluth-methadone-clinic (describing how the Minnesota Department of Human Services found 56 compliance violations despite the Commission on Accreditation of Rehabilitation Facilities giving Lake Superior

health departments discovered OTPs with egregious compliance violations offering substandard patient care despite high marks from CARF.[350] Further, some states do not require annual inspections, which means no accounting of violations may exist, or alternatively, the public may only discover violations after a legal complaint or publicized crime, such as patient death or motor vehicle fatality.[351]

C. Impact on Patient Care and Public Safety

The gaps in regulation, compliance, and enforcement translates to discrepancies in provider quality, and creates a permissive regulatory environment for substandard medical care. This impacts not only the patient's life and well-being, but also public safety if patients are impaired from prescribed medication, continue to engage in polysubstance abuse, and/or divert the medication they receive into the illicit market.[352] Across the United States, patients who sought comprehensive treatment for addiction filed lawsuits against OTPs, alleging claims including negligence, medical malpractice, and fraud.[353] Former patients assert the OTP

Treatment Center high marks); *Duluth Methadone Clinic Cited for 22 New 'Serious and Substantial Violations*, PIONEER PRESS (Nov. 14, 2014), https://www.twincities.com/2014/11/10/duluth-methadone-clinic-cited-for-22-new-serious-and-substantial-violations/.

[350] Wickersham & Basey, *supra* note 318, at 253-254 (referencing the Lake Superior Treatment Facility in Minnesota and the Commission on Accreditation of Rehabilitation Facilities' statistics that 95% of facilities seeking accreditation from CARF receive it); at 246, 260 (outlining a case study of a similar case in Georgia where CARF reported high marks for an OTP, yet investigation by the Georgia Health Facility Regulators found serious and substantial violations), at 266-267 (providing a table comparison to illustrate discrepancies of accreditation status, state, and federal findings for one provider Georgia Therapy Associates).

[351] Wickersham & Basey, *supra* note 174, at 4 (after SAMHSA implemented the accreditation process, states reduced or modified state survey requirement and accreditation bodies may not communicate their findings with states, creating a disconnect between OTP noncompliance and state knowledge).

[352] *See Vincent v. Quality Addiction Management*, 2013 WL 5372336 (E.D. Wisc. 2013) (Not Reported) at 3 (Patient Madison was enrolled at an OTP and received methadone in weekly take home doses, traded methadone for what she believed was other illicit substances including Ecstasy, OxyContin, and morphine. She provided her doses of 200mg methadone to a Jamison, who overdosed and died. Plaintiff also alleged a record of previous diversion by Jamison triggering notice to the OTP to modify her take home dose privileges. Madison was initially charged with first degree reckless homicide, which was later reduced to manufacturing and delivering a Schedule I or II narcotic.) *See, generally SAMHSA Effective Strategies*, *supra* note 275; SAMHSA Risk Management, *supra* note 275; *SAMHSA Minimize Liability*, *supra* note 213.

[353] Plaintiffs' Complaint, *[Redacted Class Action Plaintiffs] v. Colonial Management Group et al.* (M.D. Ala 2010), *available at* http://www.beasleyallen.com/news/beasley-allen-files-suit-against-fraudulent-drug-treatment-centers/ (Plaintiffs allege the OTP failed to provide sufficient counseling, failed to advise on the serious adverse effects of

provided failed to provide comprehensive counseling to address the social and psychological factors underlying their addiction and instead solely prescribed methadone, which resulted in serious physical and psychological adverse effects, fueling an addiction to another Controlled Substance.[354] Patients who are enrolled in treatment at an OTP may also overdose and die,[355] but polysubstance abuse may undermine the ability to determine causality (whether the death was caused solely or partially by the prescribed opioid), creating a high bar effectively precluding legal recourse.[356] Despite reports of patient harm in media[357] and several Plaintiffs complaints,[358] there is a dearth of case law.[359]

Case law across several jurisdictions has addressed patient impairment when the patient's conduct impacts public safety and welfare. In multiple cases, patients who attended an OTP to receive methadone continued to abuse other illicit substance while enrolled in MAT.[360] Patients

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methadone, and engaged in a plan to induce patient dependence on methadone); Plaintiff's Complaint, *Shawna Palmer v. Karl Lanocha and Metro Treatment of New Hampshire*, (D.N.H. 2010) (Plaintiff alleged the OTP did not provide comprehensive addiction treatment services, but fostered Plaintiff's addiction by merely providing a new Controlled Substance in the form of methadone) (on file with author courtesy of Abramson, Brown, and Dugan, PA); *see also* Plaintiff's Complaint, *Jenna Lydon v. Dennis Swartout and Metro Treatment of New Hampshire*, (D.N.H. 2010) (where Plaintiff was a pedestrian victim of a motor vehicle accident by a patient of the named OTP and alleges the OTP failed to provide comprehensive addiction treatment services, but instead merely provided Controlled Substances to a patient who continued to engage in polysubstance abuse) (on file with author courtesy of Abramson, Brown, and Dugan, PA).

[354] *Id.*

[355] *Piscitelli v. Hospital Authority of Valdosta*, 691 S.E.2d 616 (11th Cir. 2010) (Deceased patient was enrolled in a drug and alcohol abuse treatment facility and died during the induction period four days into treatment and the medical examiner testified patient cause of death was methadone toxicity); *see also SAMHSA Minimize Liability*, *supra* note 213.

[356] *Id.*; *but see Procaccini v. Lawrence and Memorial Hospital Inc*., 168 A.3d 538 (Conn. App. Ct. 2017) (Deceased patient previously received treatment at an OTP wherein she received methadone. The OTP discharged patient, and one week after patient's last dose of prescribed methadone, the patient obtained illicit methadone and overdosed, dying of respiratory distress despite administration of naloxone and admission for emergency care.)

[357] *See* Swisher, *supra* note 281; Macy, *supra* note 285; Stahl, *supra* note 285; Sontag, *supra* note 41.

[358] *See* Wickersham & Basey, *supra* note 345.

[359] If patients are engaging in polysubstance abuse, this both convolutes potential causality, may constitute evidence of comparative negligence, and patients who are substance abusers generally may present with the stigma of being an unsympathetic plaintiff. According to a phone conversation with attorney Richard Shapiro and email communications with attorney Holly Haines, the attorneys discussed with the author how settlements not only impact lack of case law, but decrease transparency and ability to track the extent of legal complaints against OTPs.

[360] *Cheeks v. Dorsey*, 846 So.2d 1169 (4th Cir. 2003); *Taylor v. Smith*, 892 So.2d 887 (Ala. 2004); Order, *Lingren v. Pinnacle Recovery Services*, No. 09-CV-13-215, No. 09-CV-14-760 (D. Minn. 2014)(on file with author).

may explicitly disclose their intention to continue to abuse multiple substances,[361] they may demonstrate impairment (appearing disoriented, upset, red eyes, or nodding off),[362] or may have physical signs of continued substance abuse (new intravenous marks).[363]

Many patients who visit an OTP drive extensive distances (over an hour) to attend the clinic, receive their medication, then drive to work or home.[364] In *Lingren v. Pinnacle Recovery Services*, patient Vanessa Brigan arrived early at Pinnacle Recovery Services to receive her daily dose of methadone, "presented herself with fresh track marks, marijuana in her system, and nodding off in the waiting room prior to receiving her methadone dose." Pinnacle Recovery Services provided Brigan the same daily dose and provided her a "take home" dose, despite physical evidence she was injecting her take home doses while simultaneously abusing other illicit substances.[365] Brigan drove away from the facility and stopped at a gas station to inject the "take home dose."[366] Driving impaired under the influence of marijuana and two doses of methadone, Brigan crossed the center line on the highway, striking another vehicle and killing the driver.[367] If OTPs do not share metrics of continued opioid abuse, polysubstance abuse, or

[361] *Taylor v. Smith*, 892 So.2d 887 (Ala. 2004).
[362] *Cheeks v. Dorsey*, 846 So.2d 1169, 1171 (4th Cir. 2003) (describing patient Reutlinger had red eyes and looked upset and disoriented "as if he had been doing cocaine or methamphetamines); Order, *Lingren v. Pinnacle Recovery Services*, No. 09-CV-13-215, No. 09-CV-14-760 (D. Minn. 2014) at 14 (patient Brigan was nodding off in the waiting room).
[363] Order, *Lingren v. Pinnacle Recovery Services*, No. 09-CV-13-215, No. 09-CV-14-760 (D. Minn. 2014) at 15 ("Brigan presented herself to the clinic with fresh tacks marks on her arms, marijuana in her system, and nodding off in the waiting room prior to receiving her methadone doses").
[364] Order, *Lingren v. Pinnacle Recovery Services*, No. 09-CV-13-215, No. 09-CV-14-760 (D. Minn. 2014) at 14 (stating patient Brigan drove over 100 miles to and from the clinic each day); *Taylor v. Smith*, 892 So.2d 887, 891 (Ala. 2004)(stating patient Ennis drove 90 minutes to and from the clinic each day). Some patients may arrange alternative transportation or use a taxi. *See also* Del Real, *supra* note 296.
[365] Amended Plaintiff's Complaint, *Lingren v. Pinnacle Recovery Services*, No. 09-CV-13-215 (D. Minn. 2013) (on file with author) at 3 (stating Brigan "regularly and routinely injected her take-home doses of methadone intravenously," and had evidence of the injections "visible on her skin"), at 4 (Brigan injected the methadone at a gas station), at 5 (toxicology tests showed THC and methadone present in Brigan's system at the time of the motor vehicle accident).
[366] *Id.*
[367] Kruger, *supra* note 40.

track patient impairment, then it is foreseeable cases like Vanessa Brigan constitute only the tip of the iceberg.

In similar cases such as *Cheeks v. Dorsey*, the court held OTPs have a duty to screen their patients and adopt a policy for how to address when patients present with impairment at the clinic.[368] Without toxicology screening or an effective policy to monitor the patient, advise the patient against driving, or arrange for alternate transportation, the OTP creates a risk that unidentifiable third parties may become injured when the patient drives away from the clinic.[369] Some OTPs may have a drug screening policy in place and are acutely aware of patients' ongoing abuse of multiple illicit substances because patients repeatedly test positive.[370] Yet if the OTP adheres to SAMHSA's guidance stating patient noncompliance should not prompt a decrease or limitation in their maintenance medication and the OTP continues providing maintenance medication to the patient, then the OTP likely faces liability if the patients leaves the clinic impaired and causes injury to others.[371]

[368] *Cheeks v. Dorsey*, 846 So.2d 1169 at 1170, 1173 (4th Cir. 2003); *see, generally SAMHSA Effective Strategies*, *supra* note 275 (discussing patient impairment); *SAMHSA Risk Management*, *supra* note 275, at 25 (discussing multiple sources of impairment), at 26, 30 (describing foreseeable harm to third parties from patient impairment), at 27 (discussing a duty to screen for patient impairment); *SAMHSA Minimize Liability*, *supra* note 213, at 17, 24 (describing the pharmacokinetics of methadone as a central nervous system depressant that can build in tissue and cause impairment and death).

[369] *Id.*

[370] *Taylor v. Smith*, 892 So.2d 887, 888-889 (Ala. 2004). (Patient Ennis 13/14 urinalysis screens showed the presence of additional illicit substances in addition to methadone, including non-prescribed benzodiazepines and cannabis and patient reported "no desire to stop using." The OTP medical clinic director continued to provide daily doses of methadone to patient Ennis.) *But see Moore v. Western Carolina*, 182 F.Supp.3d 825, 835-836 (E.D. Tenn. 2016) (OTP may *not* have a duty to injured third parties if the methadone patient does not show signs of impairment even if methadone patient was in actuality impaired).

[371] *Id.*; Federal Guidelines for Opioid Treatment Providers, *supra* note 295, at 51-52 (asserting programs shall not adjust doses to reinforce positive behavior or punish negative behavior and positive toxicology screens may indicate the need for an increased dosage of maintenance medication), at 20 (describing the appropriate response of more intensive counseling to address polysubstance abuse).

D. The Impact of a Flawed Treatment Model

This particular component of SAMHSA's guidance constitutes a critical flaw, because it both glosses over the significance of the patient's continued drug abuse – a signal that MAT is ineffective at addressing patient's underlying addiction – and it places the public in harm's way from the conduct of the impaired patient. The effects of inadequate treatment impact the patient, who continues to suffer addiction and adverse health effects that preclude recovery and integration back to society. Presuming patients enrolled in MAT will continue to abuse illicit substances and continuing to provide opioid agonist medications for patients to engage in self-harm is neither compassionate nor ethical. Such actions signal resignation to the patient, who will suffer ongoing physical and psychological despair. In the cases describe above, patient impairment reverberates to society when patients drive away from the clinic and cause permanent and disabling injury to other motorists,[372] motor vehicle fatalities,[373] and crash into unsuspecting pedestrians.[374] Patients also faces criminal charges with incarceration for injuries and deaths that cannot be undone simply because they were impaired.[375] These outcomes compel a re-examination of how MAT impacts both patients and how supporting the expansion of MAT as a health policy strategy will magnify shortcomings of ineffective treatment and societal harm.

CONCLUSION

Julie Eldred represents only one face of persons with OUD as a patient with a history of addiction to opioids who became entangled in the criminal justice system from crimes she

[372] *Taylor v. Smith*, 892 So.2d 887 (Ala. 2004).
[373] *Cheeks v. Dorsey*, 846 So.2d 1169 at 1170, 1173 (4th Cir. 2003); Order, *Lingren v. Pinnacle Recovery Services*, No. 09-CV-13-215, No. 09-CV-14-760 (D. Minn. 2014).
[374] Nilsen, *supra* note 42.
[375] *Id*.; *Taylor v. Smith*, 892 So.2d 887 (Ala. 2004); *Cheeks v. Dorsey*, 846 So.2d 1169 at 1170, 1173 (4th Cir. 2003); Order, *Lingren v. Pinnacle Recovery Services*, No. 09-CV-13-215, No. 09-CV-14-760 (D. Minn. 2014).

committed to fuel her addiction. The amicus briefs filed in support of Eldred and rhetoric set forth by NIDA and SAMHSA portray a bleak prognosis for person suffering from addiction: Eldred suffers from a chronic, relapsing brain disease over which she has little control and enrolling her in MAT with a prescription for Suboxone constitutes the most effective form of treatment. Yet extensive research in addiction science contradicts each of these statements, showing narrow neurobiological models may undermine recovery, hinder appropriate medical care that addresses polysubstance abuse, and confuse perceptions of legal culpability. The current brain disease model of addiction constrains how we conceptualize addiction as a complex series of choices that may or may not require different levels of treatment to address the social and psychological issues underlying the patient's addiction.

Importantly, discussing OUD requires precision to separate persons with addiction who may require extensive supportive treatment from persons with physiological dependence attempting to discontinue prescribed medication but facing severe physical and psychological withdrawal symptoms. Research on MAT demonstrates an extensive profile of physical risks that negatively impact quality of life; research demonstrating neurological damage from opioid agonist maintenance treatment and risks from opioid antagonist treatment; and forceful financial entanglements promoting pharmacological solutions. Long term MAT for persons with iatrogenic opioid dependence is not only inappropriate, but as Fischer and colleagues suggested will likely create a new epidemic of impaired persons dependent or addicted to a new controlled substance.

For persons who do suffer from addiction, available research casts doubt on the efficacy of MAT because the majority of patients continue polysubstance abuse, some may develop dependence or addiction to the prescribed maintenance medication itself, and patients may

continue to struggle with activities of daily life undermining claims of reintegration and recovery. As OTPs expand, patterns from media reports, lawsuits, and case law suggest discrepancies in provider quality, portray numerous facilities as merely providing another opioid without providing comprehensive treatment, and demonstrate insufficient attention to addressing patients' extensive medical, psychological, and social needs. This model not only fails to as a policy for promoting compassionate and evidence-based care for persons struggling with addiction but places the public at risk of more crime and injury arising from patients' maladaptive actions arising from impaired decision-making.