

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

_____)	
GEOFFREY PESCE,)	
)	C.A. No. _____
Plaintiff,)	
)	
v.)	
)	
KEVIN F. COPPINGER, in his official)	
capacity as Essex County Sheriff,)	
AARON EASTMAN, in his official)	
capacity as Superintendent of the Essex)	
County House of Corrections - Middleton,)	
)	
Defendants.)	
_____)	

DECLARATION OF RICHARD N. ROSENTHAL, MD

Pursuant to 28 U.S.C. § 1746, I, Richard N. Rosenthal, M.D., declare as follows:

I. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

1. I received my undergraduate degree from Oberlin College in 1973. I then received a Master’s degree from the Department of Physiology and Pharmacology at Duke University. During that time, I also received a Neurosciences Training Grant Award from the National Institute of Health. I attended medical school at State University of New York Downstate Medical Center, where I received my medical degree in 1980.

2. From 1980 to 1984, I worked in psychiatry at Sinai Hospital in New York City, beginning as an intern, then resident, and ultimately chief resident of the department. I became a Diplomate of the National Board of Medical Examiners in 1981 and I received my license to practice medicine from the New York State Department of Education Office of the Professions in 1982. In 1985, I was certified by the American Board of Psychiatry and Neurology and in 1993, I received a subspecialty certification in addiction psychiatry.

3. Since becoming a licensed physician, I have worked and taught on substance use disorders (“SUDs”) and addiction at various medical schools, including Beth Israel Medical Center, Albert Einstein College of Medicine, Columbia University College of Physicians and Surgeons, Icahn School of Medicine at Mount Sinai, and Stony Brook University School of Medicine, where I currently work as Professor of Psychiatry and Director of Addiction Psychiatry at Stony Brook University Medical Center.

4. I have received several grants for research on alcohol and drug addiction, including research on the effectiveness of buprenorphine to treat opioid use disorder (“OUD”). I have also written numerous peer-reviewed articles, editorials, and book chapters on the treatment of opioid dependence and the opioid addiction crisis generally.

5. I am a distinguished life fellow of the American Psychiatric Association (“APA”), having been a member since 1981, and served on its Council on Addiction Psychiatry for a number of years. I have also been a member of the New York Society for Clinical Psychiatry since 1985, where I served on the Committee on Alcoholism and Drug Abuse for five years, whereupon it became the NY State Psychiatric Association Committee on Addiction Psychiatry that I continue to serve on. I served as a delegate to the Governor’s combined Psychiatric and Addiction/Abuse Task Force from 1987 to 1989. In 1986, I was a founding member of the American Academy of Addiction Psychiatry and served as that organization’s president from 2001 to 2003. I have since served as the head of its Public Policy Section and Public Policy Committee—a position I have held since 2004. I have also been a member of the American Society of Addiction Medicine (“ASAM”) since 1990, and have served as an editor on several editions of ASAM’s textbook, the *ASAM Principles of Addiction Medicine*.

6. I have also been honored to receive a number of awards for my work in the area of substance abuse and addiction psychiatry. In 2005, I received the ASAM Medical-Scientific Program Committee Award. In 2008, I received the American Academy of Addiction Psychiatry Founder's Award. And in 2010, I was named The American Journal on Addictions' Distinguished Clinical Research Scholar on the Addictions.

7. A copy of my *curriculum vitae* further detailing my expertise, qualifications, and list of publications is attached to this report as Exhibit A.

II. OPIOIDS AND ADDICTION

8. Opioids are a class of drugs that inhibit pain and have euphoric side effects. Some opioids, such as OxyContin® and Vicodin®, are prescribed for pain management purposes; others, such as heroin, are illicit. All opioids are highly addictive.

9. Although many opioids have legitimate medical uses, all opioids can halt breathing at high enough doses, risking death or irreversible brain damage from oxygen deprivation.¹ Chronic opioid use leads to physical dependence: withdrawal symptoms include severe dysphoria, craving for opiates, irritability, sweating, nausea, tremor, vomiting, and muscle pain.²

10. Roughly 21 to 29 percent of patients who are prescribed opioids for chronic pain use them other than as prescribed, and between 8 and 12 percent become addicted.³ Opioid use disorder is seen in people from all educational and socioeconomic backgrounds.⁴

¹ See Ex. 1, Centers for Disease Control and Prevention, *Prescription Opioids Addiction and Overdose*, available at <https://www.cdc.gov/drugoverdose/opioids/prescribed.html> (last updated Aug. 29, 2017).

² Ex. 2, American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* at 547-48 (5th ed. 2013); Ex. 3, Schuckit, MA, *Treatment of Opioid-Use- Disorder*, 375 *New Engl. J. Med.* 357, 358-59 (2016) ("Schuckit").

³ See Ex. 4, Vowles KE, et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*. *PAIN*. 2015;156(4):569-576.

⁴ Ex. 3, Schuckit at 357.

A. The Science of Opioid Addiction

11. Opioid use disorder is a chronic brain disease that some people can get from frequently taking opioids, and is sometimes referred to as opioid dependence or opioid addiction. This type of disease leads to craving opioids, not being able to stop using opioids, and can cause major life problems.⁵ Signs of opioid use disorder can include craving, increasing tolerance to opioids, withdrawal symptoms, and a loss of control over the frequency of use or the amounts taken.

12. Like other chronic diseases, opioid use disorder often involves cycles of relapse and remission. Without treatment or other recovery, patients with opioid use disorder are frequently unable to control their use of opioids. Opioid use disorder is progressive and can result in disability or premature death.

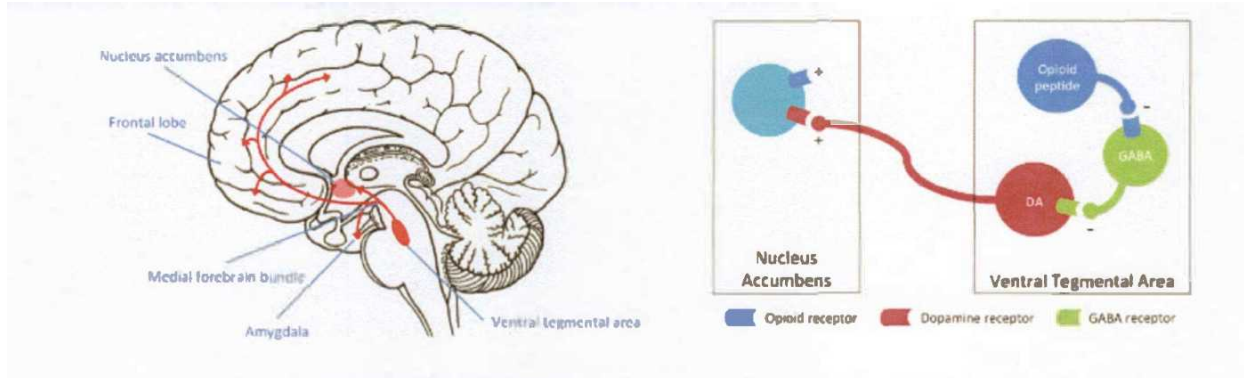
13. According to the American Society of Addiction Medicine, addiction (including opioid use disorder) “is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.”⁶

14. The brain reward element of opioid use disorder involves the brain’s dopamine neurotransmitter system that is the primary neurotransmitter involved in reward. All drugs of abuse, including opioids, directly or indirectly enhance dopamine release within the nucleus accumbens.⁷

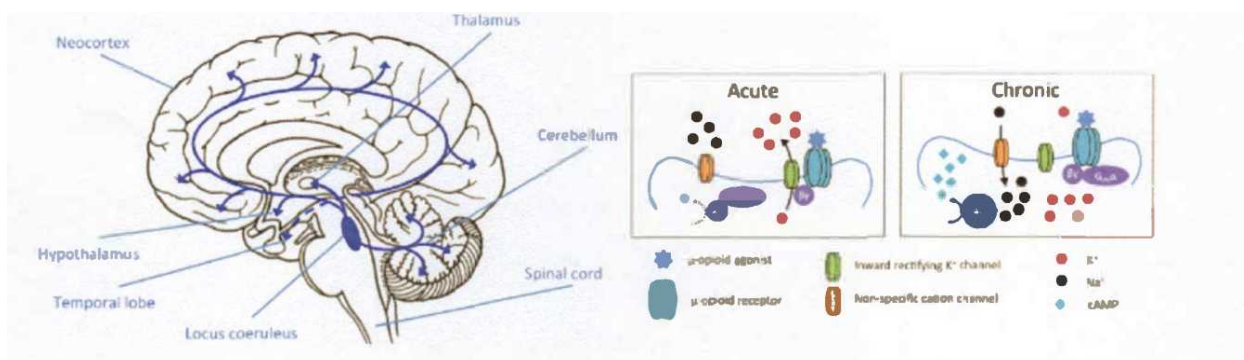
⁵ Ex. 17, Centers for Disease Control and Prevention, Opioid Overdose Commonly Used Terms, available at <https://www.cdc.gov/drugoverdose/opioids/terms.html>.

⁶ Ex. 18, Definition of Addiction, American Society of Addiction Medicine, available at <https://www.asam.org/quality-practice/definition-of-addiction>.

⁷ Ex. 19, Fellers, Management of Addiction Issues in Complex Pain at 9 (Oct. 2, 2016), available at https://www.acponline.org/system/files/documents/about_acp/chapters/me/management_of_addiction_issues_in_co



15. Opioid use disorder also changes the circuitry in the brain for regulating arousing and psychological stress. Specifically, the cycle of addiction, including withdrawal, leads to hyperactivity of the locus coeruleus noradrenergic system that regulates arousal and psychological stress.⁸



16. Genetic factors account for between 40 and 60 percent of a person's vulnerability to addiction. Those who are genetically predisposed to addiction experience an altered response to the drug and changes in drug metabolism.

17. Additionally, adverse childhood experience creates a two- to four-fold increase in

mplex_pain_j_fellers.pdf (citing Olds, J., & Milner, P.(1954). Positive reinforcement produced by electrical stimulation of septal area and other regions of rat brain. *J Comp Physiol Psychol* 47(6), 419-27; Nestler, E.J. (2005). Is there a common molecular pathway for addiction? *Nat Neurosci*: 8(11), 1445-9).

⁸ *Id.*; Ex. 20, Nestler, E.J., Alreja, M., & Aghajanian, G.K. (1999). Molecular control of locus coeruleus neurotransmission. *Biol Psychiatry*; 46(9), 1131-9; Ex. 21, Koob, G.F., Buck, C.L., Cohen, A., Edwards, S., Park, P.E., Schlosburg, J.E., et al. (2014). Addiction as a stress surfeit disorder. *Neuropharmacology*; 76 (Part B), 370-82.

the likelihood of early initiation into illicit drug use.⁹ Additional predictors of addiction include peer influence and drug availability.

III. THE OPIOID CRISIS NATIONALLY AND IN MASSACHUSETTS

18. Opioid dependence and its related public health consequences have reached epidemic proportions in this country. The United States is now in the midst of an opioid crisis that has claimed an increasing number of lives from overdose over the past 25 years. The crisis results from a dramatic increase in overdose deaths from prescription opioids and a concomitant increase in overdose deaths from a secondary epidemic of illicit opioids such as heroin and fentanyl.¹⁰

19. The harm of illicit opioid use is particularly high given the recent increased presence of illicit synthetic fentanyl: in the last five years, there has been a sharp increase in overdoses attributed to the illicit use of, or accidental exposure to, this drug, an extremely potent synthetic opioid. *See* ¶ 21, *infra*. The following figure compares a lethal dose of heroin (left) with a lethal dose of fentanyl (right):¹¹

⁹ Ex. 22, Felitti VJ, Anda RF, Nordenberg D, Williamson DF, Spitz AM, Edwards V, Koss MP, Marks JS. Relationship of childhood abuse and household dysfunction to many of the leading causes of death in adults. The Adverse Childhood Experiences (ACE) Study. *Am J Prev Med.* 1998 May;14(4):245-58.

¹⁰ Ex. 5, Nat'l Academics of Sciences, Engineering, Medicine, Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use (Bonnie, EJ et al., eds.) (2017), at 2, available at https://www.ncbi.nlm.nih.gov/books/NBK458660/pdf/Bookshelf_NBK458660.pdf ("NASEM Report").

¹¹ Ex. 23, Allison Bond, *Why fentanyl is deadlier than heroin, in a single photo*, STAT NEWS, Sep. 29, 2016, available at <https://www.statnews.com/2016/09/29/why-fentanyl-is-deadlier-than-heroin/>.



20. Millions of Americans are addicted to opioids.¹² And the harms associated with that addiction “affect not only patients with pain themselves but also their families, their communities, and society at large.”¹³

21. As illustrated in the below graph published by the Center for Disease Control, the death toll from opioid abuse has risen exponentially just in the last 5 years. More than half a million people have died from opioid overdose in the last 20 years, and the death toll from opioid overdose has risen exponentially just in the last 5 years.¹⁴ In 2016, a reported 64,070 people died from drug overdoses—a larger loss of American life than in the worst year of the AIDS crisis or

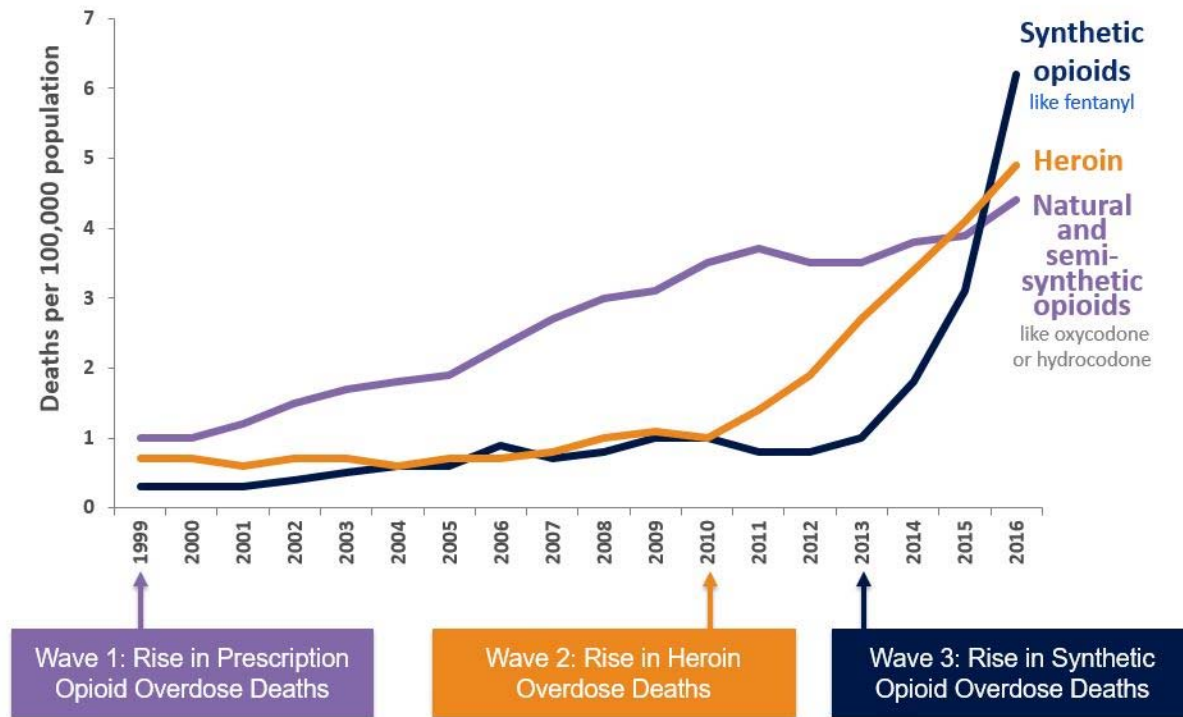
¹² Ex. 6, National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, available at <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction> (last updated Nov. 2016) (“NIDA, Effective Treatments”).

¹³ Ex. 5, NASEM Report at 3.

¹⁴ See Ex. 7, Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic*, available at <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated August 20, 2017) (“CDC, Opioid Overdose”).

in the entirety of the Vietnam War.¹⁵ Every day, more than 115 Americans die after overdosing on opioids—equivalent to one person every 12.5 minutes.¹⁶

3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

22. In Massachusetts in particular, “opioid-related deaths . . . were more than four times higher in 2015 than in 2000.”¹⁷ According to the Massachusetts Department of Public Health (DPH), there were 2,069 confirmed and estimated opioid-related overdose deaths in Massachusetts in 2017, *i.e.*, an average of almost six opioid-related death per day in the

¹⁵ Ex. 8, Ashley Welch, *Drug overdoses killed more Americans last year than the Vietnam War*, CBS NEWS, Oct. 17, 2017, available at <https://www.cbsnews.com/news/opioids-drug-overdose-killed-more-americans-last-year-than-the-vietnam-war/>.

¹⁶ Ex. 7, CDC, Opioid Overdose.

¹⁷ Ex. 24, The Massachusetts Opioid Epidemic, A data visualization of findings from the Chapter 55 report, available at <http://www.mass.gov/chapter55/> (Chapter 55 Data Visualization).

Commonwealth.¹⁸ Indeed, the Bureau of Substance Abuse Services (BSAS) of DPH reports that opioid-related cases are now more than half of all admissions to substance abuse treatment centers, “overtaking alcohol as the most prevalent substance recorded by BSAS at treatment intake.”¹⁹

23. Opioid use disorder also has broader effects beyond overdoses and opioid-related fatalities; it is causing a broader public health crisis, including through the spread of infectious diseases like HIV,²⁰ and a rising incidence of neonatal abstinence syndrome—a result of chronic opioid use during pregnancy. To illustrate the scope of the broader public health impact: every 25 minutes, a baby is born suffering from opioid withdrawal.²¹

24. The opioid crisis has broader effects in economic consequences as well. According to a CDC estimate, by 2013, the total economic burden of the prescription opioid crisis (not including illicit opioids) had risen to \$78.5 billion.²² Approximately one-fourth of that cost is borne by the public sector—for example, in health care, substance abuse treatment, and criminal justice costs.²³ And the extent of the crisis has only grown in the five years since this estimate. The White House Council of Economic Advisors has estimated that in 2015 alone, the

¹⁸ See Ex. 29, Data Brief: Opioid-Related Overdose Deaths Among Massachusetts Residents, *available at* https://www.mass.gov/files/documents/2018/08/24/Opioid-related%20Overdose%20Deaths%20among%20MA%20Residents%20-%20August%202018_0.pdf

¹⁹ Ex. 24, Chapter 55 Data Visualization at 8.

²⁰ Ex. 9, Centers for Disease Control and Prevention, *HIV and Injection Drug Use*, *available at* <https://www.cdc.gov/hiv/risk/idu.html> (2017).

²¹ Ex. 10, NIH National Institute on Drug Abuse, *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, *available at* <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome> (last updated Sept. 2015).

²² See Ex. 11, Florence CS et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*. *MED CARE*. 2016;54(10):901-906.

²³ *Id.*

opioid epidemic cost \$504 billion.²⁴

25. In 2016, the Surgeon General released a report that summarized the impact of the substance abuse crisis in America as follows: “The accumulated costs to the individual, the family, and the community are staggering and arise as a consequence of many direct and indirect effects, including compromised physical and mental health, increased spread of infectious disease, loss of productivity, reduced quality of life, increased crime and violence, increased motor vehicle crashes, abuse and neglect of children, and health care cost.”²⁵

IV. STANDARD OF CARE FOR OPIOID USE DISORDER

26. There are options for combating this crisis. From a treatment perspective, there are proven successes using medication to treat opioid dependence. The standard of care for the treatment of opioid dependence is pharmaceutical treatment, in combination with behavioral counseling and support—a combination commonly referred to as “medication-assisted treatment” and more recently more accurately referred to as “medication for addiction treatment” (MAT).²⁶ MAT “is a comprehensive approach that combines FDA-approved medications ... with counseling and other behavioral therapies to treat patients with opioid use disorder (OUD).”²⁷ As the FDA recently reported, “[a]ccording to the Substance Abuse and Mental

²⁴ Ex. 12, German Lopez, *White House: one year of the opioid epidemic cost the US economy more than \$500 billion*, Vox, Nov. 20, 2017, available at <https://www.vox.com/science-and-health/2017/11/20/16679688/white-house-opioid-epidemic-cost>.

²⁵ Ex. 13, U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, *Facing Addiction in America: The Surgeon General’s Report on Alcohol, Drugs, and Health*. Washington, DC: HHS (November 2016), available at <https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf>, at 1-1.

²⁶ Ex. 30, Rosenthal RN. Medication for Addiction Treatment (MAT). *American Journal of Drug and Alcohol Abuse*, 2018;44(2):273-274.

²⁷ Ex. 14, FDA News Release, FDA approves first generic versions of Suboxone® sublingual film, which may increase access to treatment for opioid dependence (June 14, 2018), available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610807.htm> (“FDA News Release”).

Health Services Administration, patients receiving MAT for treatment of their OUD cut their risk of death from all causes in half.”²⁸

27. MAT has been shown to decrease opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission.²⁹ MAT has also been shown to increase patients’ social functioning and retention in treatment.³⁰ As the FDA explained in its recent announcement of the first approvals for generic versions of Suboxone® sublingual film (buprenorphine/naloxone), one type of pharmaceutical treatment used in MAT, MAT is a focus of efforts to combat the opioid addiction crisis: “Improving access to prevention, treatment and recovery services, including the full range of MAT, is a focus of the FDA’s ongoing work to reduce the scope of the opioid crisis and one part of the U.S. Department of Health and Human Services’ Five-Point Strategy to Combat the Opioid Crisis.”³¹

28. In my experience, the primary driver of treatment efficacy in MAT regimens is medication, and recovery without MAT after detoxification from opioids is perilous by comparison.³² Attempts at other addiction-treatment regimens, such as abstinence- or twelve-step- type treatment programs that have been successful in other contexts (such as alcohol addiction) have not been successful in treating opioid addiction.³³ Studies have shown that maintenance medication treatments of opioid use disorder reduce all-cause and overdose

²⁸ *Id.*

²⁹ Ex. 15, Volkow, ND et al., *Medication-Assisted Therapies — Tackling the Opioid Overdose Epidemic.*, 370 *New Eng. J. Med.* 2063, 2064, available at <https://www.nejm.org/doi/pdf/10.1056/NEJMp1402780> (“Volkow”); Ex. 6. NIDA, *Effective Treatments*.

³⁰ *Id.*

³¹ Ex. 14, FDA News Release.

³² Ex. 31, Bailey GL, Herman DS, Stein MD. Perceived relapse risk and desire for medication assisted treatment among persons seeking inpatient opiate detoxification. *J Subst Abuse Treat.* 2013;45(3):302-305.

³³ *See* Ex. 3, Schuckit.

mortality,³⁴ and have a more robust effect on treatment efficacy than behavioral components of MAT.³⁵

29. The primary pharmaceutical treatments administered as MAT are buprenorphine, methadone, and naltrexone.³⁶ These drugs relieve withdrawal symptoms and physiological cravings that cause chemical imbalances in the body.³⁷ Naltrexone works by blocking opioids from producing their euphoric effects and thus reducing a desire for opioids over time; but to be effective, it requires patients to have completely withdrawn from opiates before they can begin treatment—a high hurdle in some cases.³⁸

30. Buprenorphine and methadone act through a different mechanism than naltrexone: both activate rather than block opioid receptors to relieve withdrawal symptoms. Methadone is a full agonist at the opioid receptor, and buprenorphine is a partial agonist that has less opioid effect with higher doses. In other words, methadone activates the opioid receptor at 100 percent and buprenorphine activates opioid receptors approximately 20 to 40 percent. Because of this important ability to act on opioid receptors without presenting the same risk of overdose, buprenorphine and methadone have both been deemed “essential medicines” according to the World Health Organization.³⁹

31. “Regular adherence to MAT with buprenorphine reduces opioid withdrawal

³⁴ Ex. 32, Sordo L, Barrio G, Bravo MJ, Indave BI, Degenhardt L, Wiessing L, Ferri M, Pastor-Barriuso R. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ*. 2017 Apr 26;357:j1550.

³⁵ Ex. 16, Amato L, et al., *Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence*, *Cochrane Database Syst Rev*. 2011; (10), at 13.

³⁶ See Ex. 33, Substance Abuse and Mental Health Services Administration (SAMHSA), *Medication and Counseling Treatment*, available at <https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat> (last updated Sept. 28, 2015).

³⁷ See *id.*

³⁸ See Ex. 6, NIDA, *Effective Treatments*.

³⁹ *Id.*

symptoms and the desire to use opioids, without causing the cycle of highs and lows associated with opioid misuse or abuse. At proper doses, buprenorphine also decreases the pleasurable effects of other opioids, making continued opioid abuse less attractive.”⁴⁰ Methadone has also been proven to be effective in treating opioid dependence.

32. Low accessibility to effective treatment among the OUD patient population is a major problem in treating OUD. Only 17.5 percent of people with prescription opioid use disorders received specialty treatment in 2016.⁴¹ The number of opioid treatment admissions with treatment plans that included receiving medication fell from 35 percent in 2002 to 28 percent in 2012.⁴² In 2013, only 13 percent of 11,542 outpatient addiction treatment providers offered MAT.⁴³

33. As a result, public agencies and physician groups alike have recognized the urgent need for more accessible treatment options. A growing coalition of state and federal government agencies and physician groups has advocated for increased access to MAT to combat the growing crisis of opioid addiction. For example, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) has dedicated billions of dollars to grant programs directed at increasing access to treatment of OUD. For fiscal year 2017, it offered roughly \$1 billion over two years in grants for its “State Targeted Response to the Opioid Crisis” program, which “aims to address the opioid crisis by increasing access to treatment, reducing unmet treatment need, and reducing opioid overdose related deaths through the provision of prevention, treatment and

⁴⁰ Ex. 14, FDA News Release.

⁴¹ Ex. 25, SAMHSA News, SAMHSA Shares Latest Behavioral Health Data, Including Opioid Misuse (Oct. 12, 2017), *available at* <https://newsletter.samhsa.gov/2017/10/12/samhsa-new-data-mental-health-substance-use-including-opioids/>.

⁴² Ex. 6, NIDA, Effective Treatments.

⁴³ Ex. 34, 2013 State Profile — United States National Survey of Substance Abuse Treatment Services (N-SSATS), *available at* <http://www.samhsa.gov/data/DASIS.aspx#N-SSATS>.

recovery activities for opioid use disorder.”⁴⁴ For fiscal year 2018, SAMHSA increased funding for the program to roughly \$2 billion over two years.⁴⁵ SAMHSA has also established a national training and clinical mentoring program to encourage and facilitate physicians to provide MAT to patients with opioid use disorder in various care settings. Under that program, SAMHSA has announced a \$24 million grant to ensure the provision of evidence-based prevention, treatment, and recovery programs, and a \$10.8 million grant for students in the medical, physician assistant and nurse practitioner fields to ensure they are trained to prescribe buprenorphine products in office-based settings, among others.⁴⁶

V. OPIOID WITHDRAWAL

34. Prison policies that prohibit treatment with methadone and buprenorphine can force patients into acute withdrawal. Acute withdrawal causes symptoms including bone and joint aches, vomiting, diarrhea, excessive sweating, hypothermia, hypertension, tachycardia (elevated heart rate), and psychological symptoms like depression, anxiety, and desperation.

35. Withdrawal is especially dangerous for patients with co-occurring disorders, such as depression, anxiety, psychosis or other mental disorders. For such patients, forced withdrawal may cause severe depression, suicidal ideation, and decompensation. In the psychological sense, decompensation refers to a patient’s inability to maintain defense mechanisms in response to stress, which can result in uncontrollable anger, delusions, mania, and other dangerous symptoms.

⁴⁴ Ex. 26, SAMHSA, State Targeted Response to the Opioid Crisis Grants (May 30, 2017), *available at* <https://www.samhsa.gov/grants/grant-announcements/ti-17-014>.

⁴⁵ Ex. 27, SAMHSA, State Targeted Response to the Opioid Crisis Grants (June 14, 2018), *available at* <https://www.samhsa.gov/grants/grant-announcements/ti-18-015>.

⁴⁶ Ex. 28, SAMHSA, Press Announcement, FY 2018 Opioid State Targeted Response Technical Assistance (Nov. 8, 2017), *available at* <https://www.samhsa.gov/grants/grant-announcements/ti-18-004>; Ex. 29, SAMHSA, Press Announcement, SAMHSA is announcing the availability of up to \$10.8 million for the Providers Clinical Support System – Universities program (June 4, 2018), *available at* <https://www.samhsa.gov/newsroom/press-announcements/201806040200>.

36. Forced withdrawal is not medically appropriate for patients being treated with MAT. It disrupts their treatment plan, leading to a seven-fold decrease in continuing MAT after release.⁴⁷ Discontinuation of MAT increases the risk of relapse into active addiction. Over 82% of patients who leave methadone treatment relapse to intravenous drug use within a year.⁴⁸ Finally, patients are more likely to suffer from overdose and potential death as a consequence of forced withdrawal. Detoxification or forced withdrawal reduces the tolerance to high-dose opioids seen in persons with opioid use disorders, rendering them more highly susceptible to overdose with new use. Death is three times as likely for people out of treatment versus when in treatment.⁴⁹

37. No physician, acting within prudent professional standards and in a manner reasonably commensurate with modern medical science, would abruptly and arbitrarily discontinue the administration of methadone to a patient in treatment for opioid use disorder, where the treatment is resulting in lasting recovery and there are no significant adverse side effects or other contraindications.

⁴⁷ Ex. 35, Rich JD, McKenzie M, Larney S, Wong JB, Tran L, Clarke J. (2015) Methadone continuation versus forced withdrawal on incarceration in a combined US prison and jail: a randomized, open-label trial. *Lancet*: 386: 350-9.

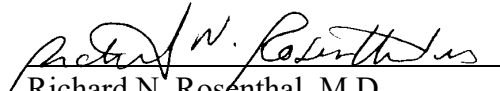
⁴⁸ Ex. 36, NIDA International Program, Methadone Research Web Guide, Part B: 20 Questions and Answers Regarding Methadone Maintenance Treatment Research, at B-10, *available at* <https://www.drugabuse.gov/sites/default/files/pdf/partb.pdf>.

⁴⁹ Ex. 37, Evans E, Li L, Min J, Huang D, Urada D, Liu L, Hser YI, Nosyk B. (2015). Mortality among individuals accessing pharmacological treatment for opioid dependence in California, 2006-10. *Addiction*; 110(6): 996- 1005.

* * *

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on September 19, 2018


Richard N. Rosenthal, M.D