UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

M[redacted] C[redacted] and T[redacted] G[redacted], on behalf of themselves and all similarly situated individuals,

Plaintiffs,

v.

JEFFERSON COUNTY, NEW YORK, et al.,

Defendants.

Case No. 6:22-cv-190 (DNH/ATB)

DECLARATION OF RICHARD N. ROSENTHAL, M.D.

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 medical degree from the State University of New York Downstate Medical Center in 1980. I received a master's degree from the Department of Physiology and Pharmacology at Duke University. During my master's program, I also received a Neurosciences Training Grant Award from the National Institutes of Health. From 1980 to 1984, I worked in the department of psychiatry at Mount Sinai Hospital in New York City, beginning as an intern, then becoming a resident and ultimately chief resident of the department. I became a board-certified physician in 1981, and I received my license to practice medicine from the New York State Department of Education Office of the Professions in 1982.

2. I have been retained by Plaintiff's counsel as an expert in addiction medicine. In 1985, I was certified by the American Board of Psychiatry and Neurology and in 1993, I received a subspecialty certification in addiction psychiatry. Since becoming a licensed

physician, I have worked and taught on substance use disorders ("SUDs") and addiction at various medical schools and teaching hospitals, including Albert Einstein College of Medicine, Columbia University College of Physicians and Surgeons, Icahn School of Medicine at Mount Sinai, Beth Israel Medical Center, St. Luke's-Roosevelt Hospital Center, and Stony Brook University School of Medicine, where I currently work as Professor of Psychiatry and was Inaugural Director of Addiction Psychiatry at Stony Brook University Medical Center.

3. 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.

4. I am a distinguished life fellow of the American Psychiatric Association, having been a member since 1981, and having 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. The committee was then renamed the New York State Psychiatric Association Committee on Addiction Psychiatry, after which I served on it for many years. I served as a delegate to the New York 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 served as the head of its Public Policy Committee 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*.

5. I have also been honored to receive a number of awards for my work in the area

of substance use disorder and addiction psychiatry. In 2005, I received the ASAM Medical-Scientific Program Committee Award. In 2008, I received the American Academy of Addiction Psychiatry Founders' Award. And in 2010, I was named The American Journal on Addictions' Distinguished Clinical Research Scholar on Addictions.

6. 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

7. Opioids are a class of drugs that inhibit pain and produce 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.

8. Although many opioids have legitimate medical uses, most opioids can halt breathing at high enough doses, creating a risk of death or irreversible brain damage from oxygen deprivation.[1] Chronic opioid use leads to physical dependence: withdrawal symptoms can be excruciatingly painful, and include severe dysphoria, craving for opiates, irritability, depression, suicidal ideations, anxiety, sweating, nausea, tremor, hypothermia, hypertension, tachycardia, bone and joint aches, vomiting, and muscle pain.[2]

9. 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

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[1] *See* Ex. 1, Centers for Disease Control and Prevention (CDC), *Prescription Opioids Addiction and Overdose* (Aug. 29, 2017), https://www.cdc.gov/drugoverdose/opioids/prescribed.html.
[2] *See* Ex. 2, American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders 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; 56(4):569–76.

addiction is seen in people from all educational and socioeconomic backgrounds.[4]

10. Opioid use disorder ("OUD") is a chronic brain disease that some people develop from frequently taking opioids, and is sometimes referred to as opioid dependence or opioid addiction. This disease leads to craving opioids, not being able to stop using opioids, and can cause major problems in social functioning such as difficulty in job function and maintaining healthy family relationships.[5] Signs of opioid use disorder can include craving for opioids, increasing tolerance to opioids (needing more drug to obtain the same effects), withdrawal symptoms, and a loss of control over the frequency of use of opioids or the amounts taken.

11. 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 rarely able to control their use of opioids, often resulting in physical harm or premature death, including due to accidental overdose. Opioid use disorder is progressive and can result in disability or premature death.

12. According to ASAM, 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]

13. The brain-reward element of opioid use disorder involves the brain's dopamine neurotransmitter system that is the primary neurotransmitter involved in reward. Opioids directly

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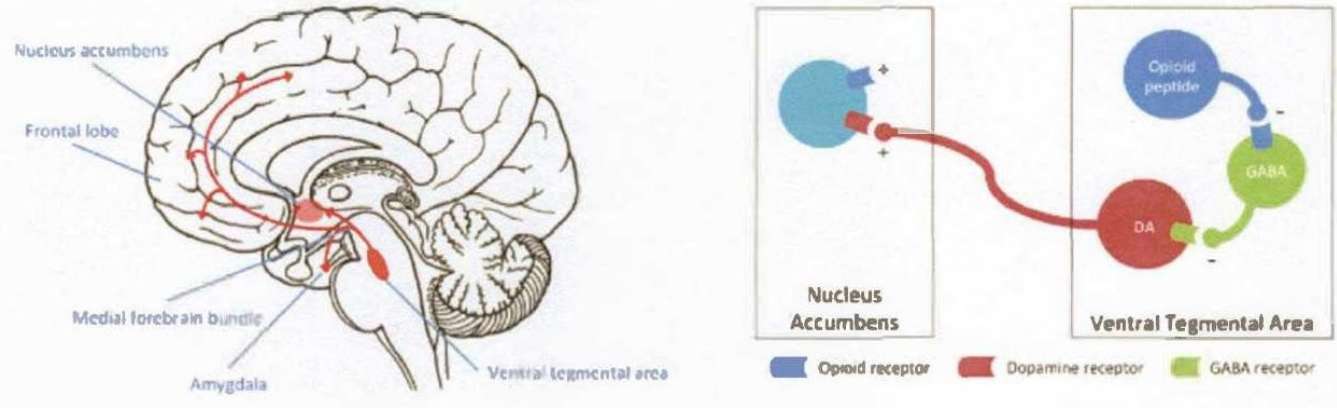
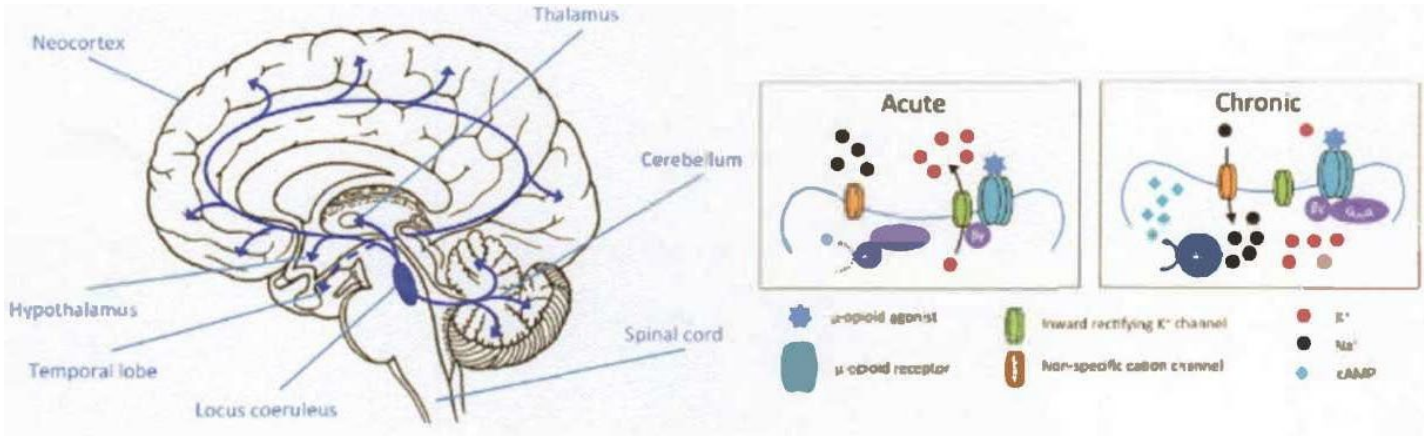
[4] Ex. 3, Schuckit at 357.
[5] Ex. 5, Centers for Disease Control and Prevention, *Opioid Overdose Commonly Used Terms*, https://www.cdc.gov/drugoverdose/opioids/terms.html.
[6] Ex. 6, American Society of Addiction Medicine, *Definition of Addiction*, https://www.asam.org/quality-practice/definition-of-addiction.

or indirectly enhance dopamine release within the nucleus accumbens, which is responsible for regulating motivation, reward, and reinforcement.[7]



14. Because opioid addiction fundamentally alters the brain's reward system, the disease makes it difficult for individuals to stop taking opioids even when they experience negative consequences and have stopped feeling the drug's pleasurable effects due to increased tolerance.

15. Opioid use disorder also changes the circuitry in the brain for regulating arousal



[7] Ex. 7, Fellers, Management of Addiction Issues in Complex Pain 9 (Oct. 2, 2016), *available at* https://www.acponline.org/system/files/documents/about_acp/chapters/me/management_of_addiction_issues_in_co 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), 445-9))).

and psychological stress. Specifically, the cycle of addiction, including withdrawal, leads to hyperactivity of the locus coeruleus noradrenergic system, which is responsible for regulating attention, cognitive control, decision-making, and emotions.[8] This leads to people with OUD having more difficulty managing life stressors without turning to drug use.

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. This is in part why vulnerability to developing substance addiction runs in families.

17. Additionally, adverse childhood experiences create a two- to four-fold increase in 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 NEW YORK

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 enormous and increasing number of lives over the past 30 years. The crisis is the result of a dramatic increase in overdose deaths from commonly prescribed opioids, such as OxyContin and Vicodin, and a concomitant increase in overdose deaths from a secondary

[8] *Id.*; Ex. 8, Nestler, E.J., Alreja, M., & Aghajanian, G.K. (1999). Molecular control of locus coeruleus neurotransmission. Biol Psychiatry; 46(9),1131–39; Ex. 9, 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.

[9] Ex. 10, 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. 14 Am. J. Prev. Med. 245, 245–58.

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 fentanyl, an extremely potent synthetic opioid: Since around 2013, there has been a sharp increase in overdoses attributed to the illicit use of, or accidental exposure to, this drug. *See* ¶ 21, *infra*. Accidental exposure to fentanyl can occur because fentanyl is frequently mixed with heroin and other drugs without the user's knowledge. The following figure compares a lethal dose of heroin (left) with a lethal dose of fentanyl (right).[11]

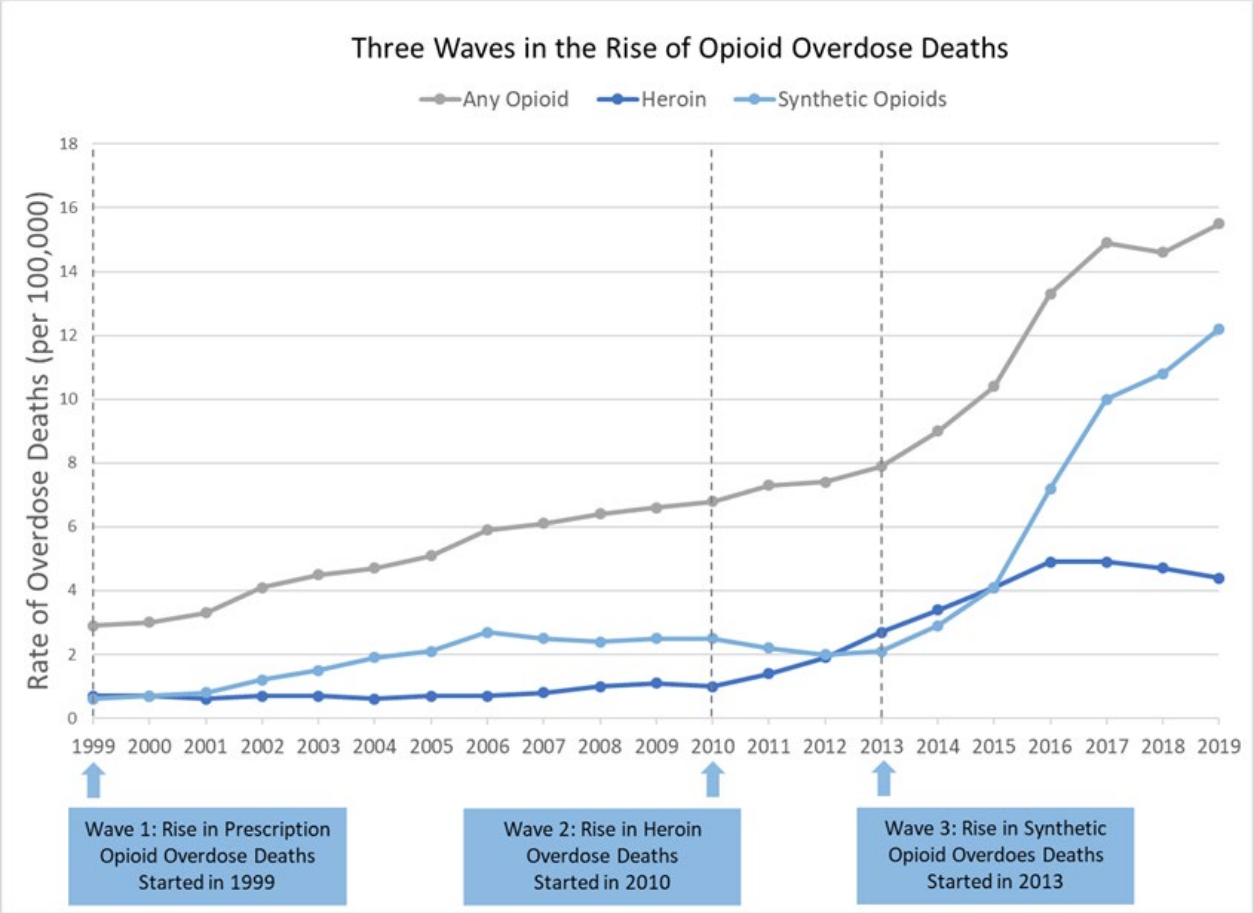
[10] Ex. 11, Nat'l Academics of Sciences, Engineering, Medicine, Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use (Bonnie, EJ et al., eds.) (2017), at 2, *available at* https://www.ncbi.nlm.nih.gov/books/NBK458660/pdf/Bookshelf_NBK458660.pdf ("NASEM Report").

[11] Ex. 12, 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. Over 2.5 million Americans are addicted to opioids.[12] The harms associated with that addiction affect not only patients but also their families, their communities, and society at large.[13]

[12] Ex. 13, 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. 11, NASEM Report at 3.

21. As illustrated in the graph below published by the Centers for Disease Control and Prevention ("CDC"), the death toll from opioid use has risen dramatically in recent years. More than half a million people died from opioid overdose in the first two decades of the 2000s, and the death toll from opioid overdose has risen rapidly since 2013.[14] In 2016, a reported 64,070 people died of overdoses from all types of drugs — a larger loss of American life than in the worst year of the AIDS crisis or in the entirety of the Vietnam War.[15] [16]



[14] *See* Ex. 14, Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic*, *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Mar. 17, 2021) ("CDC, Opioid Overdose").

[15] Ex. 15, 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] Source: Centers for Disease Control and Prevention, Nat'l Ctr. for Health Stats., *Data Brief 394* (Dec. 2020), https://www.cdc.gov/nchs/data/databriefs/db394-tables-508.pdf#page=3; Centers for Disease Control and Prevention, *Understanding the Epidemic*, https://www.cdc.gov/drugoverdose /epidemic/index.html#three-waves.

22. This trend has accelerated even further during the COVID-19 pandemic. The CDC reported a record 75,673 estimated opioid-related overdose deaths in the United States during the twelve months preceding April 2021.[17] That figure is up more than 35% from the previous twelve-month period. That means 207 people on average die in America each day from an opioid-related overdose — equivalent to one person every 7 minutes. The CDC estimates that synthetic opioid deaths rose 50% during this same period.[18]

23. According to the most recent New York State Opioid Annual Report, the number of opioid overdose deaths per year in this state more than tripled between 2000 and 2017.[19] According to the New York State Department of Health, there were 11,006 emergency room visits in 2018 involving opioid overdoses.[20] There were also 2,991 overdose deaths — an average of over eight deaths per day.[21]

24. The opioid crisis has broader economic consequences as well. According to a CDC estimate, by 2013, the total economic cost 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 use treatment, and criminal justice costs.[23] The total cost of the crisis is much higher. Indeed, the White House Council of Economic Advisors estimated that in 2015 alone, the cost of the opioid epidemic (including prescription

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[17] Centers for Disease Control and Prevention, *Provisional Drug Overdose Death Counts* (Feb. 16, 2022), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#dashboard.
[18] *Id.*
[19] Ex. 16, N.Y. STATE DEP'T OF HEALTH, *New York State Opioid Annual Report 2020* 10 (2020), https://www.health.ny.gov/statistics/opioid/data/pdf/nys_opioid_annual_report_2020.pdf.
[20] *Id.* at 52.
[21] *Id.* at 10.
[22] *See* Ex. 17, 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.*

and illicit opioids) was $504 billion.[24]

25. In 2016, the Surgeon General released a report that summarized the impact of the substance use crisis in the United States 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. Medication has proven successful in treating opioid use disorder. The standard of care for the treatment of opioid use disorder is agonist or partial-agonist therapy, in combination with behavioral counseling and support. Agonists work by activating opioid receptors in the brain to relieve withdrawal symptoms and control cravings. Partial agonists work by partially activating opioid receptors. Full agonists fully activate opioid receptors, resulting in a stronger effect. The combination of medication with behavioral counseling and support is commonly referred to as "medication-assisted treatment" and more recently and more accurately referred to as "medication for opioid use disorder" (MOUD) or "medication for addiction treatment" (MAT).[26] As the Food and Drug Administration (FDA) has explained, MOUD "is a comprehensive approach that combines FDA-approved medications with counseling and other

[24] Ex. 18, 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. 19, 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. 20, Rosenthal RN. Medication for Addiction Treatment (MAT). American Journal of Drug and Alcohol Abuse, 2018;44(2):273-274.

behavioral therapies to treat patients with opioid use disorder (OUD)."[27] The FDA recently reported that "patients receiving MOUD for treatment of their OUD cut their risk of death from all causes *in half*."[28]

27. MOUD has been shown to decrease opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission.[29] MOUD has also been shown to increase patients' social functioning and retention in treatment.[30] As the FDA has highlighted, MOUD is key to efforts to combat the opioid addiction crisis: "Improving access to prevention, treatment and recovery services, including the full range of [MOUD], 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 MOUD regimens is medication. By comparison, treating a patient without MOUD after detoxification from opioids is perilous.[32] Studies have shown that maintaining medication treatments of opioid use disorder reduces all-cause and overdose mortality,[33] and has a more robust effect on treatment efficacy

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[27] Ex. 21, 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").
[28] *Id.* (emphasis added).
[29] Ex. 22, 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; Ex. 13. NIDA, Effective Treatments.
[30] *Id.*
[31] Ex. 21, FDA News Release.
[32] Ex. 23, 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] Ex. 24, 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.

than behavioral components of MOUD.[34] Attempts at addiction-treatment regimens that do not include medication, such as abstinence- or twelve-step-type programs that have been popular in other contexts (such as alcohol addiction), have not been as effective in treating opioid addiction.[35]

29. The only FDA-approved medications for treating opioid use disorder are methadone, buprenorphine, and naltrexone.[36] Methadone and buprenorphine are agonists that activate the brain's opioid receptors, relieving the withdrawal symptoms and physiological cravings that cause chemical imbalances in the body.[37] Methadone is a full agonist at the opioid receptor, whereas buprenorphine is a partial agonist that has less opioid effect with higher doses. Both methadone and buprenorphine present a substantially lower risk of overdose than heroin, especially when properly administered in a clinical setting. (For ease of reference, hereinafter in this declaration I use the terms "agonist" and "agonist MOUD" to refer to both methadone and buprenorphine, as is common practice, unless otherwise noted.)

30. Because of this important ability to act on opioid receptors without presenting the same risk of overdose as other opioids such as heroin, methadone and buprenorphine have both been deemed "essential medicines" by the World Health Organization.[38] "Numerous clinical trials and meta-analyses have shown that methadone treatment is associated with significantly higher rates of treatment retention and lower rates of illicit opioid use," as well as reduced

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[34] Ex. 25, 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.
[35] *See* Ex. 3, Schuckit.
[36] *See* Ex. 26, 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] *Id.*

mortality, criminal conduct, and contraction of HIV.[39] Likewise, "[r]egular adherence to [MOUD] with buprenorphine reduces opioid withdrawal 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]

31. Naltrexone, an antagonist, works by a different mechanism: It blocks opioid receptors without activating them, preventing opioids from producing their euphoric effects and thus reducing a desire for opioids over time. To be effective, it requires patients to have completely withdrawn from opioids (including methadone and buprenorphine) before they can begin treatment, which requires three to ten days of non-use — a high hurdle in some cases.[41] Administering naltrexone to a patient who has not completely withdrawn from opioids can trigger acute and severe withdrawal, and for that reason is contraindicated. No physician, acting in accordance with reasonable judgment and professional standards, would administer naltrexone to a patient who has not completely withdrawn from opioids.

32. Studies have shown that naltrexone produces poorer outcomes in terms of treatment retention than either methadone or buprenorphine. And my clinical experience treating patients with OUD is consistent with those results. Treatment retention is crucial for MOUD because length of treatment is positively correlated with outcomes: in general, the longer a patient stays in treatment the better the treatment outcome. Because methadone and buprenorphine are better able than naltrexone to keep patients in treatment for longer periods, I

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[39] *See* Ex. 27, SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use* Disorder 3-15, *available at* https://www.ncbi.nlm.nih.gov/books/NBK535268/pdf/Bookshelf_NBK535268.pdf.
[40] Ex. 21, FDA News Release.
[41] *See* Ex. 13, NIDA, Effective Treatments.

conclude that methadone and buprenorphine are the standard of care for opioid use disorder — particularly among patients with severe opioid use disorder. Furthermore, a patient who immediately stops using naltrexone has a lower opioid tolerance — that is, their body is less able to handle a given amount of opioids without experiencing an adverse reaction — than their baseline while receiving no medication. That means that a patient who takes opioids after discontinuing naltrexone is at a higher risk of overdose than if they had taken no medication beforehand and were at their "baseline" tolerance.

33. The form and dosage of MOUD that is most appropriate to treat a particular patient may vary based on the patient's profile—including factors such as opioid use disorder severity, medication side effects profile, co-occurring other medical and mental disorders—but must be a clinical decision in consultation with the patient. While one patient may do well on any of the three FDA-approved medications, another patient may find that only one provides effective treatment without significant adverse side effects. The severity of a patient's OUD is one factor that may affect the relative effectiveness of these different medications. For example, a patient with severe OUD may require a full agonist that produces a stronger opioid effect (such as methadone) to fully suppress opioid cravings than a patient with mild OUD. A patient with more severe OUD may also require a higher dosage of a given medication than a patient with less severe OUD. For some, this means that methadone will be the treatment of choice as buprenorphine, due to its partial-agonist properties, has a ceiling at which a higher dose provides little further benefit, whereas for the full agonist methadone, general dosing procedure is to slowly titrate to a dose that actively suppresses opioid craving and/or self-administration of opioids.

34. As a result of the benefits of MOUD, government agencies and physician groups

alike have recognized the urgent need for more access to those treatment options. A growing coalition of state and federal government agencies and physician groups has advocated for increased access to MOUD 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 $2 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 recovery activities for opioid use disorder."[42] SAMHSA has also established a national training and clinical mentoring program to encourage and facilitate physicians to provide MOUD 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, as well as a $10.8 million grant for students in the medical, physician assistant and nurse practitioner fields to ensure they are trained to prescribe MOUD products in office-based settings, among others.[43]

V. FORCED WITHDRAWAL FROM MOUD

35. No physician, acting consistent with prudent professional standards and in a manner reasonably commensurate with modern medical science, would discontinue the administration of agonist MOUD to a patient in treatment for opioid use disorder, where the

[42] Ex. 28, SAMHSA, State Targeted Response to the Opioid Crisis Grants (May 30, 2017), *available at* https://www.samhsa.gov/grants/grant-announcements/ti-17-014.
[43] Ex. 29, 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. 30, 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.

treatment is resulting in active recovery or is the form of medication most effective at helping the patient reduce their cravings for and use of opioids, and there are no significant adverse side effects or other contraindications.[44] Discontinuing agonist MOUD treatment in an abrupt manner, with no or minimal tapering, would result in even more serious harm.

36. Jail policies that prohibit treatment with methadone and buprenorphine can force patients into acute withdrawal with dangerous consequences. Acute withdrawal causes physical symptoms including bone and joint aches, vomiting, diarrhea, insomnia, excessive sweating, hypothermia, hypertension, and tachycardia (elevated heart rate), as well as psychological symptoms like depression, anxiety, desperation, and suicidal ideation. Acute withdrawal can cause death, in particular due to dehydration and heart failure resulting from diarrhea and vomiting.[45] A study conducted by two leading authorities on OUD showed that withdrawal from methadone is frequently more severe than withdrawal from heroin.[46] Withdrawal symptoms occur within 24 to 48 hours of non-use, and can last for several days, weeks, or even months.

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[44] As recognized by the American Society of Addiction Medicine, there are only four contraindications that justify the forcible discontinuation of methadone: (1) where the patient has a known hypersensitivity to methadone (an abnormal response by the immune system to methadone); (2) where the patient experiences respiratory depression (an insufficient breathing rate and volume); (3) where the patient has acute bronchial asthma (a condition that typically causes recurrent episodes of acute shortness of breath) or hypercapnia (an elevated level of carbon dioxide in the bloodstream); and (4) where the patient has known or suspected paralytic ileus (a condition where the motor activity of the bowel is impaired due to something other than a physical obstruction). And there are only two contraindications that justify the forcible discontinuation of buprenorphine: (1) where the patient has a known hypersensitivity to buprenorphine or any component of the formulation; and (2) where the patient has certain severe liver impairments. *See* Ex. 31, American Society of Addiction Medicine, *National Practice Guideline for the Treatment of Opioid Use Disorder*, at 30 (2020).

[45] Ex. 32, Shane Darke et al., Yes, People Can Die from Opiate Withdrawal, 112 Addiction 199 (2017).

[46] *See* Ex. 33, Michael Gossop & John Strang, *A Comparison of the Withdrawal Responses of Heroin and Methadone Addicts During Detoxification*, 158 Brit. J. Psychiatry, No. 5, at 697–99 (1991).

37. Withdrawal without medical support, which would typically be in the form of a slow tapering of the dosage of medications over the course of several months, is particularly 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.[47] 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.

38. Forced withdrawal is not medically appropriate for incarcerated patients being treated with MOUD. Whether or not patients are removed from methadone or buprenorphine through tapering, withdrawal disrupts their treatment plan and leads to a dramatically higher risk of relapse into active addiction. Patients withdrawn in jail or prison are seven times less likely to continue MOUD treatment after release.[48] Over 82% of patients who discontinue methadone treatment relapse to intravenous drug use within a year.[49] And patients who discontinue buprenorphine after opioid detoxification are far more likely to drop out of treatment, have higher symptom severity, and have a higher rate of fatal outcomes than those who are inducted and maintained on buprenorphine.[50] What is more, detoxification or forced withdrawal reduces the tolerance to high-dose opioids seen in persons with OUD, rendering them more susceptible to

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[47] Ex. 34, U.S. Dep't Justice, *Investigation of The Cumberland County Jail* 6 (Jan. 14, 2021), https://www.justice.gov/opa/press-release/file/1354646 /download.

[48] 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: 350–59.

[49] 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.

[50] Ex. 37, Kakko J, Svanborg KD, Kreek MJ, Heilig M. 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: a randomised, placebo-controlled trial. The Lancet. 2003;361(9358):662–668.

life-threatening overdose with new use. Thus, patients are more likely to die from overdose as a consequence of forced withdrawal.

39. Other non-MOUD medications are not substitutes for agonist MOUD and do not render involuntary removal from agonist MOUD safe or clinically appropriate. While there are medications that are sometimes used to attempt to mitigate the effects of withdrawal from MOUD in the short term, these medications do not mitigate the ongoing risk of relapse and overdose without agonist MOUD treatment.

40. Death is three times as likely for people out of treatment versus those receiving MOUD.[51] The risk of opioid overdose for people being released from jails and prisons is even more staggering. One study in Washington State between 1999 and 2003 found that in the first two weeks following release from prison, incarcerated people were *129 times* as likely as a member of the general public to die of a drug overdose.[52] A 2016 national study in England regarding the use of MOUD in jails and prisons found that MOUD "was associated with a 75% reduction in all-cause mortality and an 85% reduction in fatal drug-related poisoning in the first month after release."[53]

41. Because illicit drugs are commonly available in jails and prisons, the risk of overdose and death that results from forced withdrawal or medical detoxification is present both during incarceration and upon release. My understanding is that the Jefferson County Jail has a

[51] Ex. 38, 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.
[52] Ex. 39, Binswanger, et al., Release from Prison—A High Risk of Death for Former Inmates, New England Journal of Medicine 336:2 157-165 (2007).
[53] Ex. 40, Marsden, et al., Does Exposure to Opioid Substitution Treatment in Prison Reduce the Risk of Death After Release? A National Prospective Observational Study in England, Addiction 112, 1408–1418 (2017).

policy providing for the administration of Narcan[54] to people in its custody, which recognizes the danger of opioid overdose while people are serving their sentences at the facility. And given the availability of drugs in jails and prison, post-release care alone would do nothing to address the risk of relapse and overdose while a person is incarcerated.

42. Further, it is my opinion that it would be clinically inappropriate and dangerous for jail clinical staff to force a change to a different form of MOUD, such as an opioid antagonist like naltrexone, in a patient who is receiving medically necessary community treatment with an opioid agonist such as methadone or buprenorphine. Doing so would unnecessarily subject the patient to painful, potentially excruciating withdrawal symptoms. In addition, while it is known that agonist therapy has been determined to be effective at treating the patient's OUD, it is at best unknown that antagonist treatment will be as effective—and, depending on the patient's clinical history, it may be clear that antagonist treatment would be ineffective. Moreover, as discussed above, evidence shows that antagonist treatment results in poorer long-term treatment retention compared to agonist treatment, meaning that the switch to antagonist treatment would place the patient at a higher risk of relapse and overdose.

43. It is my understanding that the Jefferson County Jail prohibits the use of methadone and buprenorphine maintenance treatment for non-pregnant people incarcerated there.

44. I also understand that the Jefferson County Jail provides maintenance treatment with agonist MOUD during incarceration for pregnant people in its custody. There is no medical reason to give agonist MOUD to a pregnant person, but not to a non-pregnant person, for whom

[54] Narcan is the brand name of naloxone injection and naloxone nasal spray, which is used to block the effects of opioids in persons who may be experiencing an opioid overdose.

that medication is medically necessary.

45. The cessation of an appropriately prescribed medication for a chronic disease is unethical as it discriminates against patients with OUD as compared to persons with other chronic medical problems. Even more important than the short-term impact of detoxification from methadone or buprenorphine on an immediate or accelerated basis is the added profound risk of releasing a person with a chronic OUD after incarceration without the medical benefit and protection of MOUD.

46. Given the high rate of relapse to opioid use after detoxification and discharge from an institutional setting, and the high risk of fatal overdose among those who relapse and who also have no tolerance for opioids as a result of having had their maintenance medications stopped, preventing access to maintenance medication is arbitrarily withholding a life-saving medicine.

VI. M[redacted] C[redacted]'S TREATMENT

47. I have reviewed medical records of M[redacted] C[redacted]'s OUD treatment, including records from the Credo Community Center, the Conifer Park treatment facility, and the Camino Nuevo Chemical Dependency Outpatient Program.

48. It is my opinion based on those records that maintenance of [redacted]'s methadone treatment is not only appropriate but medically necessary. The records show that [redacted] has severe OUD and requires a high daily dose of methadone (185mg) to manage his opioid cravings and the effects of withdrawal. The records also show he has responded well to the medication, and that there are no contraindications. It is important that patients like [redacted] who are being treated for OUD at the time of their entry into the criminal justice system continue their treatment through incarceration as risk for relapse and overdose is particularly high in the

weeks immediately following release.[55]

49. It is particularly important that there be no interruption in [redacted]'s methadone treatment because he is diagnosed with mood, anxiety, and post-traumatic stress disorders. These conditions would likely be exacerbated by withdrawal from methadone, as well as make his withdrawal symptoms more intense.

50. In summary, the evidence I have reviewed allows me to conclude with a high degree of confidence that full agonist treatment with methadone is both medically necessary and the only medically appropriate course of treatment for [redacted] Removing him from that treatment is not only medically contraindicated, but also extremely dangerous—in addition to subjecting him to severe withdrawal, it would drastically increase his risk of relapse, overdose, and death.

51. Given the severity of [redacted]'s opioid use disorder, a partial agonist such as buprenorphine would mostly likely be inadequate to treat his addiction. The record documents that [redacted] had been treated with buprenorphine in the past and, when last treated with it, continued to demonstrate continued opioid cravings, a major factor in relapse to non-medical opioid use. Given the increased structure associated with methadone treatment, [redacted]'s better outcomes with structured approaches to treatment as documented in the record, and the inadequacy of buprenorphine treatment in stabilizing his opioid use disorder, methadone is the medically appropriate treatment. If [redacted] were switched to buprenorphine treatment from methadone, his medical records suggest that he would be at a substantially higher risk of relapse and overdose as compared to methadone.

[55] Ex. 31, American Society of Addiction Medicine, *National Practice Guideline for the Treatment of Opioid Use Disorder* (2020).

52. Antagonist treatment with naltrexone is also clearly contraindicated. If [redacted] were switched from methadone treatment—a process that would require him to be fully removed from opioids for a period of three to ten days, and to go through severe withdrawal that may last for weeks later—he would be at a dramatically increased risk of relapse and overdose either during incarceration or soon after his discharge. Relapse after discharge would be particularly dangerous for [redacted] because once a patient stops receiving naltrexone, their body has a higher sensitivity to and lower tolerance of opioids, commonly described as "reverse tolerance". *See* ¶ 32, *supra*. The risk of a life-threatening overdose is therefore heightened.

53. The significant risks to [redacted] of removal from methadone would not be meaningfully diminished by medically managing his withdrawal. For a patient, like [redacted], on a high methadone dosage, even gradual tapering off his medication is difficult to manage and leads to very painful withdrawal. Moreover, even if the tapering is managed to minimize the patient's suffering in the short term, the long-term risks to the patient of relapsing and overdosing without MOUD remain high.

54. Fundamentally, no measures aimed at managing [redacted]'s withdrawal would adequately mitigate the risks of relapse, overdose, and death that result from interrupting his methadone treatment. Without ongoing methadone therapy, [redacted] will continue to experience cravings for opioids and withdrawal symptoms, both while incarcerated and after he is released.

55. Advance transfer planning can help ensure continuity of MOUD treatment during major changes in delivery of care, and for that reason should be practiced where possible. Without such planning, treatment can lapse, unnecessarily subjecting patients to withdrawal and potential relapse. With respect to [redacted], a physical examination is not needed to determine

that the continuation of his methadone treatment is medically necessary and appropriate. He has been prescribed methadone as treatment for his OUD by a specialist in addiction medicine and has not experienced adverse side effects or exhibited contraindications. Confirmation from the current treating physician of [redacted]'s diagnosis, medication, and dosage is sufficient to continue his treatment.

Dated: February 28, 2022
Stony Brook, NY

Richard N. Rosenthal, M.D.