IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

STEPHANIE DIPIERRO,

Plaintiff,

v.

HUGH J. HURWITZ , in his official capacity as Acting Director for the Federal Bureau of Prisons, and DR. DEBORAH G. SHULT, in her official capacity as Assistant Director of the Health Services Division of the Federal Bureau of Prisons

Defendants.

CIVIL NO. _____

DECLARATION OF RUTH A. POTEE, M.D.

Pursuant to 28 U.S.C. § 1746, I, Ruth A. Potee, M.D., declare as follows:

A. Qualifications

1. I am the Medical Director of the Franklin County House of Correction and a specialist in Addiction Medicine. I have been a speaker on the topic of addiction at multiple conferences, including trainings for judges, lawyers, correctional staff, drug court staff, teachers, and community members.

2. I am submitting this affidavit to provide the Court with information concerning the use of medication for addiction treatment (MAT) in patients suffering from opioid use disorder in correctional facilities. I have not treated or met the defendant in this case.

3. I am board certified in both Addiction Medicine and Family Medicine. In addition to my work with the Franklin County Sherriff's Office, I am Medical Director of the Franklin Recovery Center, and Chair of the Healthcare Solutions Committee of the Opioid Taskforce of Franklin County. I am the School Physician for the Pioneer Valley School District,

as well as a family physician with Valley Medical Group. For eight years, I worked as an assistant professor of Family Medicine at Boston University, where I did my residency. In 2015, I was named the Franklin County Doctor of the Year by the Massachusetts Medical Society. My curriculum vitae is attached to this affidavit as Exhibit A.

4. From 1999-2002, I trained at Boston University, an international center for addiction medicine, and I have cared for people with addiction every working day since. In my primary care practice, I take care of people who struggle with alcohol, prescribed opioids, heroin, benzodiazepines, cocaine, and methamphetamine. I run a 64-patient drug treatment center where patients come for more intensive interventions.

5. I have worked with over 500 people with various substance use disorders (SUD) prosecuted in the criminal justice system. At the Franklin County House of Correction, approximately 85% of the 250 inmates carry a SUD diagnosis. I train medical students and residents from Boston University, Harvard, and Tufts. I also train Addiction Medicine Fellows from Boston University who work with me at the jail and the detox facility.

B. Substance Use Disorders

6. SUD, including opioid use disorder, is a brain disease defined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) as "a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems."[1]

7. The three primary risk factors for developing a SUD are genetic predisposition, early exposure while the brain is developing, and childhood trauma.

[1]American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 483 (5th ed. 2013), Exhibit B. The DSM-5 is a comprehensive, authoritative volume that defines and classifies mental disorders based on the work of hundreds of international experts in all aspects of mental health.

8. When a person starts down the path of addiction, the neurochemistry of the brain shifts in ways both dramatic and subtle. Many neurotransmitters — the "telephone wires" linking different parts of the brain — are impacted by addiction, but the one that is most damaged is dopamine. Dopamine is the chemical in the brain that tells the body to survive: find food, water, and a way to send your DNA forward to create another generation. It is the most ancient and elemental part of the brain and every living creature on the planet has this deeply housed reward center driving survival.[2]

9. With addiction, the damage to the dopamine system triggers a cascading chemical cycle telling the brain that, in order to survive, it needs to continue the addictive behavior because it feels as though its survival depends on it. Despite clear evidence of harm to themselves, people they love, and society, individuals suffering from a SUD have unrelenting perseverative thoughts and compulsion to continue to use the drug. This is driven by the broken dopamine system and seems counter-intuitive until one understands the physiology of the disease.

10. The survival part of the brain wants to achieve a sense of normalcy. Non-addicted brains have a set dopamine level racing through the synaptic cleft. After exposure to huge dopamine spikes through use of heroin, cocaine, methamphetamines, or another addictive substance, the brain down regulates and stops making enough dopamine. Dopamine levels in the addicted brain are less than half that of the non-addicted brain. In order to achieve homeostasis — i.e., to "feel normal" — the brain needs to continue to use the drug.

C. Medication for Addiction Treatment for Opioid Use Disorders

[2] *See* U.S. Department of Health & Human Services, Facing Addiction: The Surgeon General's Report on Alcohol, Drugs, and Health, 2-5 (2016), available at https://addiction.surgeongeneral.gov/sites/default/files/chapter -2-neurobiology.pdf, Exhibit C.

11. In order to recover from SUD, the brain needs to rebuild its broken dopamine system. The recovery process for SUD is not one-size-fits-all. A comprehensive assessment of clinical needs (including trauma and co-occurring disorders) by a qualified professional should guide treatment planning to meet the specific needs of the person.

12. Components of comprehensive addiction treatment include:

(a) individual counseling with a licensed clinician trained in addiction;

(b) evidence-based therapy — e.g. cognitive behavioral therapy (CBT), motivational enhancement therapy (MET), dialectical and behavioral therapy (DBT), eye movement desensitization and reprocessing (EMDR), and acceptance commitment therapy (ACT);

(c) case management (especially for high risk patients with co-occurring medical, housing and employment needs)[3]; and

(d) mutual peer support — e.g. Twelve-Step programming or recovery coaches.

13. In addition, for most patients suffering from opioid use disorder, an essential component of an effective recovery program is the administration of medication for addiction treatment (MAT), the use of FDA-approved prescription drugs in conjunction with counseling, behavioral therapy, and other interventions. The use of MAT is the medical standard of care for the treatment of opioid use disorders.

14. The medication component of MAT helps to suppress withdrawal, reduce cravings, and prevent users from experiencing a "high" after taking opioids by binding to dopamine receptors and preventing opioids from activating on them. In particular, the opioid agonists buprenorphine and methadone activate the opioid-receptors while binding to them,

[3]*See* SAMSHA, Comprehensive Case Management for Substance Abuse Treatment: Treatment Improvement Protocols (TIP) Series 27 (2015), available at https://store.samhsa.gov/shin/content/SMA15-4215/SMA15-4215.pdf, Exhibit D.

providing for a steady flow of dopamine to the brain. This conditions the brain away from further illicit opioid use and allows patients to resume healthy, functional behaviors and activities. Buprenorphine and methadone have been clinically proven to reduce opioid use compared to treatment without medication.[4]

15. Patients who successfully begin their recovery on MAT often need to maintain their course of treatment for many years, and tapering of medication should only be considered as part of a gradual and comprehensive plan established by the patient and physician. Sudden, involuntary withdrawal of medication from such patients for reasons other than medical necessity causes severe and needless suffering, jeopardizes the patient's long-term recovery, and is inconsistent with sound medical practice. Where a patient is on a successful course of medication for opioid addiction, and there are no contraindications or adverse effects warranting discontinuation, it is contrary to prudent professional standards and modern medical science to abruptly withhold treatment from the patient against the patient's will.

16. Two-thirds of people with SUD are considered dual-diagnosis, meaning they also carry a formal diagnosis of a major mood disorder, including, but not limited to, major depression, bipolar disease, panic disorder, post-traumatic stress disorder, and others. Successful treatment of SUD involves concomitantly managing the symptoms of the mood disorder. This makes treating an already complicated disease even harder. Dual diagnoses are not simply additive but they are amplifying – patients with mood disorders are able to achieve prolonged periods of recovery using MAT but have to work extremely hard to do so. In the example of Bipolar Illness, impulsivity, feelings of grandiosity, and uncontrolled or excessive return to experiences that are pleasurable or risky define the psychiatric illness. This means that

[4] American Society of Addiction Medicine, Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment, 13–15 (2013), available at http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addictiontreatment_final, Exhibit E.

most inmates in federal prisons receiving MAT for opioid use disorder prior to incarceration are forced to undergo a rapid "detox" process for terminating their medication regimen. Based on my understanding, a federal institution has two options. If the institution does not have a license to dispense methadone for treatment purposes, an inmate will be immediately withdrawn from their methadone treatment after three days. If the institution does have such a license, an inmate will be quickly detoxed from their methadone treatment at a rate of 10% per day after a stabilization period of a few days. I am not certain what, if any, federal facilities have a license to provide methadone treatment for opioid use disorders such that they follow this second option.

21. In my practice, I have personally witnessed the excruciating symptoms experienced by patients undergoing an accelerated methadone detox process. These patients suffer from severe diarrhea and vomiting, abdominal cramps, restless legs, excessive dehydration, and insomnia. These symptoms can sometimes lead to life threatening complications. Inmates undergoing detox require frequent surveillance and monitoring and are placed on "medical watch" by correctional officers or nursing staff.

22. Even if a patient was detoxed from their methadone treatment at a rate of 10% per day, this would still trigger significant and painful withdrawal symptoms. This rate of reduction is far outside of the normal detox procedures for someone who has been on a stable methadone program. Standard practice typically dictates that a patient who has been on a stable methadone program is detoxed at a rate of 1mg per week. For someone on a daily dose of 40 mg, this would translate into a reduction of just 2.5% per week. In my medical opinion and experience, a patient who is detoxed at the rapid rate of 10% per day would still suffer from all of the withdrawal symptoms described above.

23. The disruption of therapy has long-term consequences for inmates during and after their incarceration. In many prisons, inmates may have access to illicit substances, and often resort to drug use when deprived of their medication. When these inmates are caught for using, they are often placed in solitary confinement or terminated from other treatment programs. This isolation further impedes the inmate's prospects for recovery.

24. Moreover, for inmates subjected to forced abstinence during their incarceration, the chemical cascade of cravings to return to drug or alcohol use starts about six weeks prior to release, when addicted inmates start planning how they will use the minute they are released. Abstinence does not itself repair the broken dopamine system. Thus, even if an inmate with opioid use disorder has been abstinent during incarceration, the brain's dopamine system remains broken, and the patient's opioid-seeking behaviors continue.

25. Incarcerated patients who had previously succeeded on methadone are often unable to successfully resume treatment after their release from incarceration. For many patients, the experience of methadone detox discourages them from reinitiating therapy. Moreover, patients whose methadone treatment is interrupted are required to begin their therapy anew at low doses without the benefit of the routine and privileges they had previously established.

26. Moreover, patients subjected to forced abstinence during incarceration lose their opioid tolerance, and can fatally overdose upon re-exposure to even small amounts of certain drugs, especially in the first thirty days after returning to society. The overdose-related fatality rates among recently incarcerated individuals in Massachusetts illustrate this danger. The opioid-related overdose death rate is 120 times higher for people released from jails and prisons compared to the rest of the adult population.[5] In 2015, nearly 50 percent of all deaths among

those released from incarceration were opioid-related.[6] The vast majority of these deaths occurred within one month after release.[7]

E. Practicability and Effectiveness of MAT in Correctional Facilities

27. Administration of MAT is both practicable and effective in correctional facilities, as illustrated by its implementation in jails and prisons throughout the country.

28. At the Franklin County House of Corrections, my colleagues and I have successfully administered buprenorphine to inmates since 2016. In particular, the staff at Franklin County have implemented effective strategies to manage the risk of medication diversion. Buprenorphine and all controlled substances are stored in locked cabinets with controlled access. The supply is subject to a "count" with every shift change, along with needles, syringes and scalpels. To prevent patients from "cheeking" or diverting pills, inmates receive their medication in a crushed form, their mouths are inspected before and after administration, and they are required to eat a cracker and drink a glass of water after receiving their medication. Random urinalysis of the inmates population is conducted to ensure that only patients on MAT are receiving buprenorphine.

29. These same strategies can be used for both methadone and buprenorphine, and correctional facilities already have systems in place securing other controlled substances commonly prescribed to inmates, such as benzodiazepines and prescription opioids. Moreover, methadone is most frequently administered in a liquid or dispersible tablet form that deters diversion.

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[5] Massachusetts Department of Public Health, An Assessment of Fatal and Nonfatal Opioid Overdoses in Massachusetts (2011-2015), 50 (2017), available at https://www.mass.gov/files/documents/2017/08/31/legislative-report-chapter-55-aug-2017.pdf, Exhibit H.

[6] *Id.* at 51.

[7] *Id.* at 52.

30. MAT has been successfully administered in numerous jurisdictions outside of Massachusetts. For several years, inmates suffering from opioid addiction in correctional facilities throughout Rhode Island and at Rikers Island in New York and King County, Washington have received methadone treatment. There is no evidence that the implementation of MAT at these facilities has been unmanageable or has presented significant security concerns.

31. The administration of MAT is not cost-prohibitive. In particular, methadone can be administered for less than a dollar a day per patient. In my estimate, the cost of providing methadone treatment to a patient, particularly for an inmate serving a brief term of incarceration, is dwarfed in comparison to the cost of monitoring and caring for the patient during methadone detox.

32. Moreover, prisons can offer inmates access to methadone without being independently licensed as an opioid treatment program (OTP) by the Federal Drug Enforcement Agency and state departments of public health. Instead, a correctional facility can contract with a local OTP to serve as the source of methadone for a jail or prison. There are two versions of this contract: one involves the OTP coming to the facility daily to administer the medicine, the other involves the facility picking up and dispensing the medicine at the facility themselves. The entire Rhode Island Department of Corrections has implemented this approach.

33. After the initial implementation of MAT in 2016, Franklin County saw a 35 percent drop in opioid overdose deaths between 2016 and 2017. We have also generally observed a decrease in behavioral problems and less illicit drug use among inmates. Based in part on the results in Franklin County, the Massachusetts legislature passed legislation to create a pilot program at five county jails (Franklin, Hampden, Hampshire, Middlesex, and Norfolk), where inmates who had a prescription before being arrested will continue to be provided their

medications during their incarceration. Suffolk and Essex County recently joined the program as well. The pilot program is expected to begin in or around September 2019.

34. The preliminary results in Franklin County are consistent with trends observed elsewhere. Recently, a statewide study in Rhode Island showed a large and clinically meaningful reduction in post-incarceration deaths from overdose among inmates released from incarceration after the implementation of a comprehensive MAT program in the statewide correctional facility.[8] The number of recently incarcerated individuals who died from an overdose dropped from 26 in the first 6 months of 2016 to nine in the first 6 months of 2017.[9] More specifically, between those two study periods, the number of individuals to die from an overdose within the first 30 days after release from incarceration decreased from 10 to 1.[10] These findings are consistent with observations from other studies conducted in other countries.[11]

35. In light of the demonstrated practicability and effectiveness of MAT in inmate populations, there are no reasoned grounds for correctional facilities to deny patients suffering from opioid addiction the same continuity of care provided to patients suffering from other medical conditions requiring medication.

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

Executed on March 13, 2019

[8] Traci C. Green et al., Research Letter: Postincarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System, 75 JAMA Psychiatry 405, 406 (2018), Exhibit I.

[9] *Id.* at 405 tbl. 1.

[10] *Id.*

[11] *See, e.g.*, John 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, 112 Addiction 1408 (2017), Exhibit J.

Ruth A. Potee, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

STEPHANIE DIPIERRO, Plaintiff, v. HUGH J. HURWITZ, in his official capacity as Acting Director for the Federal Bureau of Prisons and DR. DEBORAH G. SHULT, in her official capacity as the Assistant Director of the Health Services Division of the Federal Bureau of Prisons. Defendants.	Civ. No. _____

DECLARATION OF ALEXANDER YALE WALLEY, MD, MSc

Pursuant to 28 U.S.C. § 1746, I, Alexander Yale Walley, M.D., declare as follows:

1. My name is Dr. Alexander Yale Walley. I am a board certified physician in internal medicine and addiction medicine.
2. I received my medical degree from Johns Hopkins School of Medicine in 2000 and have more than 18 years of experience. I completed my residency at the University of California, San Francisco and my fellowship in clinical addictions research and education at the Boston University School of Medicine, including a Masters of Science in epidemiology at Boston University School of Public Health. A copy of my curriculum vitae is attached as Exhibit 1.
3. Since 2005, I have been an attending physician at the Boston Medical Center. I have also taught at the Boston University School of Medicine since 2007, first as an Assistant

Professor and then since 2016 as an Associate Professor.

4. Throughout my career, I have focused on providing primary care and treatment to individuals with substance use disorders. From 2007 to 2014, I was the medical director for the Opioid Treatment Program of the Boston Public Health Commission. Between 2014 and 2016, I was the site medical director of the Opioid Treatment Program of the Health Care Resource Centers in Boston. I have continued as a physician at the Opioid Treatment Program of the Health Care Resource Centers in Boston (23 Bradston Street clinic) since 2016.
5. In my capacity as a physician working in opioid treatment programs, I have treated hundreds of patients with medication for addiction treatment (MAT), primarily with methadone. I also prescribe buprenorphine and naltrexone, the two other FDA-approved medications for opioid use disorder, through my primary care practice at Boston Medical Center. While each of these medications is FDA approved and effective in randomized clinical trials, each medication does not work equally well for every patient. Because opioid use disorder is a highly fatal, but treatable illness, it is crucial that patients and providers are able to choose the medication best for each individual patient.
6. One indication that a patient has been particularly compliant with their treatment program is when they have earned the privilege to take methadone doses at home. By federal and state regulations, to earn take home doses it requires at least 60 continuous days of perfect clinic attendance, counseling attendance, and negative toxicology testing. An additional 60 days at a minimum is required for each additional step in take home privileges (e.g. one to two doses, two to three doses, etc).
7. That being said, I have treated patients who have worked hard to achieve long periods of sustained recovery on medication for opioid use disorder, and it is very common for such

individuals to have multiple short periods of relapse in the midst of long periods of recovery. This is a symptom of the disease of opioid use disorder and is not a sign that the medication is not working. To the contrary, access to the medication empowers patients to limit a relapse to a brief period of time, because re-engagement in treatment is more readily accessible than the routes that require a physical and mentally stressful detoxification taper in an inpatient setting.

8. Similarly, it is common for individuals in long term recovery on MAT to go through periods where they miss some of their doses. Missing occasional doses does not mean that the MAT is not working. This is especially true for my patients who suffer from a dual diagnosis of OUD and some form of mental illness like bipolar disease. The symptoms of mental illness wax and wane, and can pose additional barriers for individuals attempting to make it to the clinic on a daily basis in the early morning. It is similarly challenging for patients who are balancing work responsibilities, parenting responsibilities or other caregiving responsibilities to have perfect daily attendance at methadone programs.
9. Since 2007, I have supervised the provision of methadone to pregnant women incarcerated at South Bay House of Corrections in Suffolk County ("South Bay") who suffer from opioid use disorder. Among other things, this treatment prevents the patients from experiencing withdrawal symptoms that may jeopardize their pregnancy. Furthermore, when released from incarceration, these women are connected and engaged in existing community-based Opioid Treatment Programs, so they can continue their methadone treatment.
10. Typically, South Bay transports the incarcerated patients to the 23 Bradston Street clinic once a week. They are accompanied by a corrections officer and a nurse from South Bay's infirmary. The patients are evaluated by nurses in our clinic, who administer one dose of

methadone on site. The clinic then gives six medical exception take-home doses of methadone in a secure box to the corrections officer, who transports the box to South Bay's infirmary. Either my physician colleagues or I complete an application to the State and Federal regulators for these medical exception take-home doses, which are updated and resubmitted at least quarterly

11. For the next six days, the incarcerated patients go to the South Bay infirmary to self-administer the take-home doses of methadone under the supervision of a nurse. There is a well-established protocol to prevent diversion of the medication. South Bay's infirmary routinely stores many controlled medications, including methadone and opioid-based pain medications, in a secured location within the infirmary. Methadone is a liquid that is administered orally. When it is time for a patient to receive a methadone dose, the nurses require the patients to drink the methadone in front of them, followed by another cup of water, and then finally to speak to them before they are allowed to leave the infirmary. This protocol—which is also employed at the 23 Bradston Street clinic—ensures that the methadone has been ingested and is not diverted.
12. We typically administer methadone to 1 to 4 incarcerated pregnant women at any given time at our clinic. We sometimes see these patients more frequently than once a week, generally when the patient's dosage is being adjusted in the first few weeks of treatment.
13. Administering methadone to incarcerated pregnant women has not disrupted our clinic or caused any administrative difficulties.
14. To the best of my knowledge, the administration of methadone to these patients has never caused any security, safety, or diversion problems at South Bay.
15. Pregnant inmates in Massachusetts also receive methadone at the Massachusetts Correctional

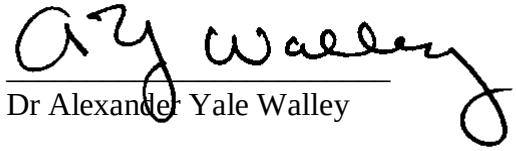
Institute at Framingham ("MCI Framingham"). Staff at MCI Framingham administer methadone directly to pregnant women incarcerated at the facility.

16. To the best of my knowledge, there is no reason why the protocol described for administering methadone to incarcerated pregnant female patients could not also be applied to other incarcerated female patients with the same high degree of safety, security, and efficacy.

17. To the best of my knowledge, the cost of methadone is approximately 1 cent per milligram. As a result, the medication typically costs between 40 and 60 cents per day.

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

Executed on March _12__, 2019.



Dr Alexander Yale Walley

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Stephanie DiPierro, Plaintiff, v. HUGH J. HURWITZ, in his official capacity as Acting Director of the Federal Bureau of Prisons, DR. DEBORAH G. SCHULT, in her official capacity as Assistant Director of the Health Services Division of the Federal Bureau of Prisons, Defendants.	C.A. No. _____

DECLARATION OF ROSS MACDONALD, M.D.

Pursuant to 28 U.S.C. § 1746, I, Ross MacDonald, M.D., declare as follows:

1. I have more than seven years of experience in correctional health and the treatment of substance use disorder in correctional settings. I currently serve the Chief Medical Officer and Senior Assistant Vice President for the Division of Correctional Health Services at New York City Health + Hospitals, which is the largest public health care system in the United States. In that role, I am responsible for medical leadership of the public hospital system's division responsible for healthcare, including substance use treatment, for those incarcerated in the NYC jail system.

2. I earned my medical degree from Weill Medical College of Cornell University, New York, and my undergraduate degree from Cornell University. My curriculum vitae is attached as **Exhibit 1**.

3. I am board certified in Internal Medicine and am a buprenorphine provider licensed by the U.S. Drug Enforcement Agency ("DEA") and New York State. I am also a Clinical Assistant Professor at the New York University School of Medicine, where I supervise and evaluate medical students, and also serve as an Attending Physician at the Bellevue Hospital Center in New York City.

4. In my capacity as the Chief Medical Officer and Senior Assistant Vice President for the Division of Correctional Health Services at New York City Health + Hospitals I manage an average daily population of approximately 8,000 individuals incarcerated in NYC jails, including approximately 45,000 admissions per year in 11 jail facilities. Each facility has 24-hour clinics staffed at various times by physicians, psychiatrists, nurses, and social workers. I supervise more than 1,100 healthcare staff overall, including the Chief Nursing Officer, Chief of Medicine, and the Chief of Psychiatry and Social Work Services.

5. The Opioid Treatment Program ("OTP") in New York City jails provides

medication-assisted treatment ("MAT")—also referred to as agonist medication (buprenorphine or methadone)—to prisoners with opioid use disorder. I have overseen the OTP at the Rikers Island jail in New York City since 2013.

6. We are facing a deadly nationwide opioid crisis. The medical consensus is clear that the standard of care for opioid use disorder ("OUD") is medication-assisted treatment using opioid-agonist medication such as buprenorphine or methadone. Although stigma against OUD and other factors have delayed access to treatments for too long, many jurisdictions are now successfully administering buprenorphine and methadone in correctional settings.

7. Based upon my experience implementing medication-assisted treatment programs in a correctional setting, as well as collaborations with medical leadership of jails and prisons around the country, it is my opinion that security concerns, including concerns regarding drug trafficking and diversion, do not warrant withholding these life-saving treatments from inmates. Rather, there are numerous effective methods to reduce the risks of diversion, and providing treatment for OUD may, if anything, help ameliorate the demand that underlies opioid trafficking in jails.

I. Correctional Facilities Successfully Administer Buprenorphine and Methadone

8. My experience with MAT in the New York City jail system dates more than seven years, and the MAT program itself dates back to the 1980s. I have collaborated with jail health experts around the country and there is now a wealth of experience with using agonist medications for MAT in correctional settings.

9. As medical and epidemiological evidence has decisively shown the life-saving benefits of medication-assisted treatment, jails and prisons across the country have started to provide methadone and buprenorphine.

10. Agonist therapy, including methadone and buprenorphine, is workable in the

numerous correctional settings where it has been tried. This includes the jails systems of many large cities, like New York City, Chicago, and Philadelphia. Additionally, some states have implemented access to methadone or buprenorphine across state jail and prison systems, notably Rhode Island's entire Department of Corrections system. Connecticut has also implemented methadone in its combined prison and jail system, and several facilities in New Jersey offer buprenorphine. I am also aware of MAT programs in Maricopa County, Arizona as well as in jails in Massachusetts and Vermont.

11. The feasibility of providing buprenorphine or methadone treatment in prison is also shown by the wide acceptance of agonist medication for pregnant inmates with opioid use disorder. Almost all correctional systems, including federal correctional facilities and Massachusetts correctional facilities, provide methadone when necessary to continue care for pregnant women.

12. Based on my experience at Rikers Island and my conversations with other experts in the field, I am aware of a variety of protocols that can be used safely and effectively to administer buprenorphine and methadone in the correctional setting. The cornerstone of safe medication administration in correctional settings is directly observed therapy ("DOT"), which involves collaboration between health staff (typically a nurse or pharmacist) and correctional staff to carefully observe the administration of controlled substances. Such a process will universally involve observation by both parties as incarcerated patients take the medication, and may also include protocols to minimize the risk of diversion, including placing the patient's hands behind the patient's back or on top of a table for a period of time after administration.

13. Diversion of these medications is possible despite these efforts, but when properly managed, it is rare. The risk of the small amounts of medication that could be successfully

diverted pales in comparison to far more dangerous illicit substances (such as fentanyl), which remain available in correctional facilities despite security authorities' decades-long efforts at interdiction.

II. Potential Security Concerns Can Be Minimized and Effectively Managed and Do Not Justify Withholding Buprenorphine or Methadone from Inmates

14. I have communicated with healthcare leadership of many correctional institutions implementing medication-assisted treatment programs including Rhode Island, Connecticut, New Jersey, and Chicago. Their experiences, along with my own, show that perceived security risks formerly thought to preclude the administration of buprenorphine and methadone in the correctional setting can be managed and should not preclude appropriate treatment.

15. Based on my experience with medication-assisted treatment in various correctional settings, the concerns of drug trafficking and diversion do not justify withholding this potentially life-saving treatment. To the contrary, appropriate treatment of OUD may well reduce illicit opioid use and therefore the desire for illicit opioids on a population level. Most importantly, in a time when potent illicit fentanyl is driving an overdose crisis, the existing drug trafficking problems mean that jails and prisons cannot afford not to provide MAT, given the risks of overdose and potential death during incarceration.

16. A 2014 study of methadone treatment in prisons in Australia, a country with a long history of widespread access to methadone in prisons, showed an 87% lower rate of death from unnatural causes including overdose, suicide, and violent death during periods of treatment with methadone. Larney, *et al.*, "Opioid substitution therapy as a strategy to reduce deaths in prison: retrospective cohort study," BMJ Open 2014, Exhibit 2. This suggests that methadone availability can reduce these key outcomes, which are important indicators of the safety and security of a correctional facility.

A. Diversion

17. Diversion of opioid-agonist medication has been cited as a reason not to provide such medication in correctional settings. In my experience, any potential diversion can be minimized through appropriate management and does not warrant refusal to provide buprenorphine or methadone to incarcerated patients. In the locations where MAT has been implemented, diversion has not been sufficiently widespread or unmanageable to undermine the effective implementation of the treatment programs. While these programs have grown rapidly around the country in recent years, I am not aware of programs that have been ended because of diversion or for any other reason.

18. Specifically, there are numerous methods to greatly reduce the possibility of diversion, including administration of different formulations of medication, implementation of nursing protocols, and the combined vigilance of nursing and correctional staff to minimize the risk of diversion. Methods include:

a. Using methadone, which is difficult to divert as it is administered in liquid form;
b. The administration of medication by nurses, who are trained to perform an oral check after administration to ensure the medication has dissolved; nurses performing these mouth checks may use a powerful flashlight to inspect the interior of the mouth before and after medication administration;
c. Having patients sit at a desk with their hands on the desk while the medication is administered and dissolves under the tongue, in the case of Suboxone (buprenorphine/naloxone transmucosal film or sublingual tablets);
d. Using the combination of nursing staff and a correctional officer to administer and observe the process;
e. Some jurisdictions have recently begun to use crushed tablets of buprenorphine

given in thin plastic sleeves, which is then observed to be poured under the tongue by health and correctional staff.

19. Based on my experience, methadone is particularly difficult to divert because it is administered in liquid form. It is not possible for liquid methadone to be hidden in a body cavity, sewn into clothing, smuggled in dentures, diluted in adhesive strips of envelopes or letters, or "cheeked" (i.e., an inmate hiding the medication inside his or her cheek to be hoarded for later use or dissemination).

20. Medication-assisted therapy using agonist medication, such as methadone, is the standard of care for opioid use disorder. It is well established from the medical literature that access to opioid agonist medications, including buprenorphine, mitigates the risk of death.

21. There is medical consensus that medication-assisted treatment is effective at reducing opioid and other drug use and improving physical and mental health for people with opioid use disorder. Medication-assisted treatment also reduces the likelihood of overdose and death that is associated with opioid use disorder.

22. These benefits have been demonstrated for maintenance treatment with these medications, and are not expected to extend beyond the withdrawal of the medication, whereupon risks for relapse, overdose and death would increase. Management of withdrawal does not itself constitute effective treatment of OUD, which should include access to maintenance therapy when appropriate. Current federal guidance from the Substance Abuse and Mental Health Services Administration ("SAMHSA") acknowledge in a 2018 guidance document on Medications for OUD that "Many people with OUD benefit from treatment with medication for varying lengths of time, including lifelong treatment." SAHMSA, *Medications for Opioid Use Disorder For Healthcare and Addiction Professionals, Policymakers, Patients,*

and Families, Treatment Improvement Protocol TIP 63, at ES-2 (2018) ("Medications for OUD"), Exhibit 3. And "It is not sound medical practice to deny people with OUD access to FDA-approved medications for their illness." *Id.*

23. Withdrawing a medication such as methadone for a patient maintained on a stable dose will result in a withdrawal syndrome characterized by physical discomfort and psychological distress. The management of this condition is described in the Federal Bureau of Prison's ("BOP") Clinical Guidance on the Detoxification of Chemically Dependent Inmates. *See* Federal Bureau of Prison, Clinical Guidance on the Detoxification of Chemically Dependent Inmates (February 2014, reformatted January 2018), Exhibit 4. Though this protocol describes a regimen to manage the physical and psychological harms of this withdrawal syndrome in line with those historically used in incarcerated settings that prohibit maintenance medications, the syndrome itself is brought on by the denial of the medication, and could be avoided altogether by continuation of the effective treatment regimen for a patient maintained on a medication such as methadone. Many patients would experience significant psychological and physiological distress from such a protocol, especially patients who have had such experiences with attempts to taper medication in the past. The protocol itself acknowledges the risks associated with withdrawal syndromes, particularly for those with co-occurring psychiatric illness: "Inmates with pre-existing psychiatric conditions may suffer an exacerbation of their illness during detoxification. A collaborative treatment effort with psychology and psychiatry staff is warranted for management of these inmates. Inmates without pre-existing psychiatric illness may also experience significant psychological distress during detoxification, including the development of suicidal ideation, plan, and intent." *Id.* at 3.

24. The risks associated with withdrawal and the increased risk of relapse, overdose,

and possible death is avoidable if the SAMHSA Medications for OUD guidance is followed by not denying access to the particular FDA-approved medication which has proven effective for the OUD patient in this case.

B. Drug Trafficking and Other Safety Concerns

25. Smuggling of buprenorphine and methadone occurs against the backdrop of the prohibition of MAT in the facility, where an estimated 15% of the population are likely to have OUD, based on national data. The withholding of medically-appropriate MAT, including buprenorphine and methadone, in this setting elevates demand for smuggled agonist medication. The resulting market for such drugs should not be used to justify continued withholding of medication. As an analogy, if standard medications for the treatment of diabetes or HIV were to be prohibited in the jail, a market and process for smuggling these medications would likely develop over time, but the existence of such a market would not, in turn, warrant the prohibition of these essential treatments.

26. I am not aware of evidence to support the assumption that providing buprenorphine and methadone would exacerbate drug trafficking in prison. To the contrary, treating opioid use disorder with medications that have been shown to reduce cravings and illicit use should reasonably reduce demand for illicit drugs among the incarcerated population.

27. Moreover, the existence of a drug trafficking problem in correctional facilities makes it more dangerous in these settings to withhold necessary medication from inmates suffering from OUD because they are more vulnerable to the risk of overdose from illicit drugs.

28. In this era of illicit fentanyl, small (and easily smuggled) amounts can be lethal, which exacerbates an already appreciable risk of overdose while incarcerated. Thus, in addition to the unnecessary physical and psychological suffering caused by withholding of MAT in prisons, denial of buprenorphine and methadone increases the risk for relapse and death in

inmates suffering from OUD both during their incarceration and upon their release.

III. Importance of Continuing Opioid Agonist Treatment During Incarceration

29. The risk of overdose and death is particularly high upon release from prison. Studies have shown "the high mortality risk that opioid-dependent prisoners face after prison release," including from accidental drug-induced deaths. *See* Degenhardt, *et al*., *The Impact of Opioid Substitution Therapy on Mortality Post-Release from Prison: Retrospective Data Linkage Study*, Addiction, 109, 1306-1317 (2014), Exhibit 5. Additionally, a prior study in the United States had found heightened risk of post-release death for inmates released from the Washington State Department of Corrections from 1999 to 2003. *See* Binswanger, *et al*., *Release from Prison – A High Risk of Death for Former Inmates*, New England Journal of Medicine 336:2 157-165 (2007), Exhibit 6. The study concluded that former prisoners had a "high risk for death after release from prison," especially in the first two weeks, when their risk of overdose death was 129 times higher than among the general population. *Id.*

30. Several studies demonstrate the increased risk of overdose and death after release from prison, plus the role of MAT in mitigating that risk.

31. For example, a 2014 study from Australia evaluated the impact of medication-assisted treatment upon mortality after release from prison, finding the lowest post-release mortality among the group that continuously remained in medication-assisted treatment with agonist medication, Exhibit 5. The study concluded that treatment with agonist medication during prison and post-release "appears to reduce mortality in the immediate post-release period." *Id.*

32. A 2014 study from Australia found that the availability of medication-assisted treatment reduced the likelihood of death *in* prison. Exhibit 2. Compared to opioid dependent prisoners not in medication-assisted treatment, the hazard of an unnatural death (including

overdose deaths, suicide, and other preventable mortality) in the first four weeks of incarceration was 94 percent lower for prisoners in medication-assisted treatment. *Id*. For any period of incarceration, the hazard of unnatural death was 87 percent lower for the group with medication-assisted treatment. In short, prisoners with opioid use disorder were less likely to die in prison when being treated with medication-assisted treatment.

33. Another study published in 2015 compared outcomes for patients who were receiving methadone maintenance treatments for opioid dependence prior to incarceration at the Rhode Island Department of Corrections. *See* Rich, *et al.*, *Methadone Continuation Versus Forced Withdrawal on Incarceration in a Combined U.S. Prison and Jail: A Randomized, Open-Label Trial*, http://dx.doi.org/10.1016/S0140-6736(14)62338-2 1 (May 29, 2015), Exhibit 7. One group was randomly assigned to continue with methadone treatment and the other group was forced to withdraw from methadone. The study found that the first methadone-treatment group was "more than twice as likely" as the forced-withdrawal group to return to treatment at a community methadone clinic within 1 month of release. *See id.* The study concluded that "[c]ontinuation of methadone maintenance during incarceration could contribute to greater treatment engagement after release, which could in turn reduce the risk of death from overdose and risk behaviors." *Id.* This study contributed to a change in policy in Rhode Island so that today all patients admitted to the Rhode Island Department of Correction have access to all forms of MAT.

34. A 2016 national study from England observed whether prison-based medication-assisted treatment reduced the acute risk of death after release. 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), Exhibit 8. The

study found that medication-assisted treatment provided in prison "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." *Id.*

35. The most recent paper is a research letter from the United States, studying the frequency of post-incarceration fatal overdose for inmates who received medication-assisted treatment in the Rhode Island Department of Corrections. *Postincarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System*, Vol. 74, No. 4 (April 2018), Exhibit 9. The letter "observed a large and clinically meaningful reduction in postincarceration deaths from overdose among inmates released from incarceration after implementation of a comprehensive MAT program" in the Rhode Island Department of Corrections. *Id.* at 2. This reduction contributed to "overall population-level declines in overdose deaths," which was remarkable given the context of a fentanyl-driven overdose epidemic during the same period. *Id.*

36. Additional studies demonstrate the mortality benefit of agonist therapy in different community settings, including studies published in 2017 and 2018. Larochelle, *et al.*, *Medication for Opioid Use Disorder after Nonfatal Opioid Overdose and Association with Mortality*, 2018 Annals of Internal Medicine, Vol. 169, No. 3 (Aug. 7, 2018), Exhibit 10; Manhapra, *et al.*, *Opioid Substitution Treatment is Linked to Reduced Risk of Death in Opioid Use Disorder*, BMJ 2017 (Apr. 26, 2017), Exhibit 11; Sordo, *et al.*, *Mortality Risk During and After Opioid Substitution Treatment: Systemic Review and Meta-analysis of Cohort Studies*, BMJ 2017 (Apr. 26, 2017), Exhibit 12.

37. In short, the medical literature clearly demonstrates that medication-assisted treatment using agonist medication is the standard of care for opioid use disorder.

38. Forced withdrawal is not medically appropriate for patients being treated with MAT because it increases the risk of relapse into active OUD and makes patients more likely to suffer from overdose and potential death.

39. Similarly, forced withdrawal from successful treatment with an agonist therapy such as methadone and subsequent treatment with an opioid antagonist such as extended release naltrexone (Vivitrol), would not be clinically appropriate alternative. Such medication may be an appropriate option for a small and selected population of OUD patients, but does not have the same robust body of medical literature to support its impact on overdose mortality and has a completely different mechanism of action, making it an inappropriate choice for a patient who has demonstrated success on an opioid agonist medication such as methadone.

40. I am providing this declaration in my personal capacity as an expert on correctional healthcare, not as a representative of New York City Health + Hospitals.

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

Executed on March 14, 2019

Ross MacDonald, M.D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

STEPHANIE DIPIERRO, Plaintiff, v. HUGH J. HURWITZ, in his official capacity as Acting Director of the Federal Bureau of Prisons, DR. DEBORAH G. SCHULT, in her official capacity as Assistant Director of the Health Services Division of the Federal Bureau of Prisons, Defendants.	C.A. No. _____

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 Institutes 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 Founders' 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, most 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]

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.

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[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").

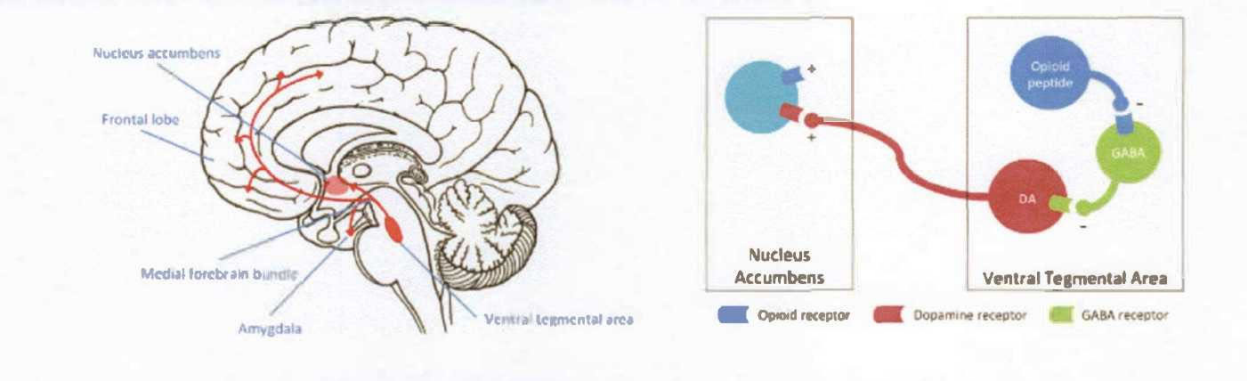
[3] *See* Ex. 4, Vowles KE, et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*. PAIN. 2015;156(4):569-576.

[4] Ex. 3, Schuckit at 357.

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

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]



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]

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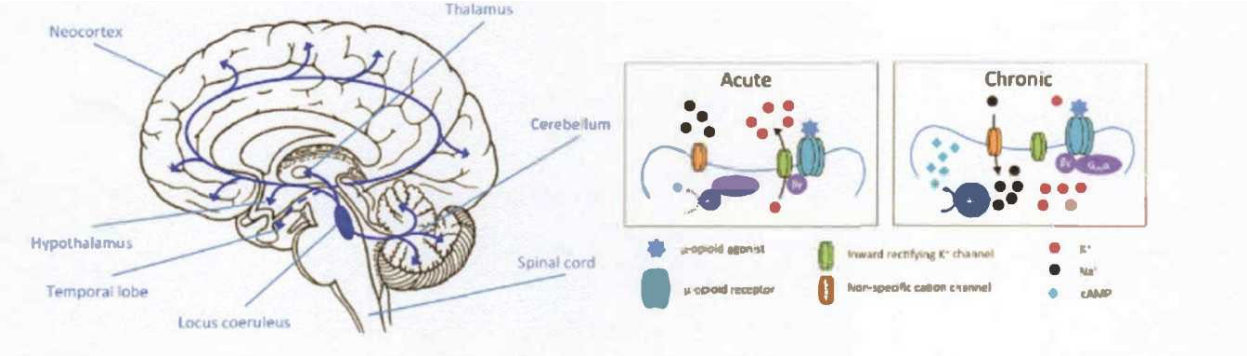
[6] Ex. 18, Definition of Addiction, American Society of Addiction Medicine, *available at* https://www.asam.org/quality-practice/definition-of-addiction.

[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_complex_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.



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 an addiction to substances runs in families.

17. Additionally, adverse childhood experience creates 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 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

[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").

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]

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]

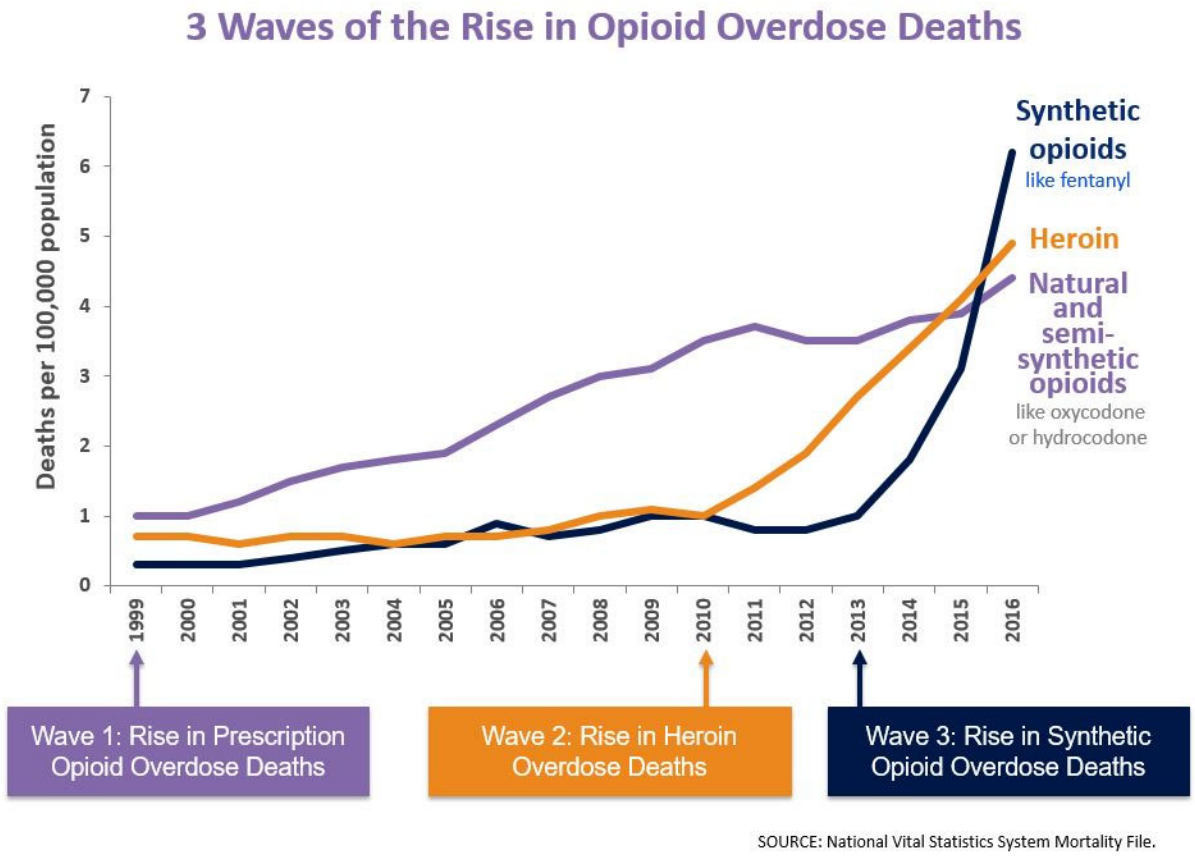
21. As illustrated in the below graph published by the Center for Disease Control, the

[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/.

[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.

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 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]



22. In Massachusetts in particular, "opioid-related deaths . . . were more than four

[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").

[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.

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 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

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[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).

[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.

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 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

[23] *Id.*

[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.

(OUD)."[27] As the FDA recently reported, "[a]ccording to the Substance Abuse and Mental 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

[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").

[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; 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.

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 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] Buprenorphine and methadone 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

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[33] *See* Ex. 3, Schuckit.

[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.

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 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

[39] *Id.*

[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.

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."[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 without medical support which would typically be in the form of a slow tapering of the dosage of medications, is especially dangerous for patients with co-occurring disorders, such as depression, anxiety, psychosis or other mental disorders. For such

[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. 42, 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.

patients, forced withdrawal, especially from a potent, long acting opioid agonist like methadone, 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.

36. Forced withdrawal and even medical detoxification 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. It is my understanding that the Federal Bureau of Prisons (BOP) Pharmacy Services Program Statement and BOP's National Formulary prohibit the use of methadone or buprenorphine maintenance treatment for non-pregnant inmates.[50]

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[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.

[50] Ex. 38 Federal Bureau of Prisons, *Program Statement for Pharmacy Services*, P6360.01 at 37 (Jan. 15, 2005), *available at* https://www.bop.gov/policy/progstat/6360_001.pdf; Ex. 39, Federal Bureau of Prisons Health Services, National Formulary Part I, *available a*t https://www.bop.gov/resources/pdfs/national_formulary-part_I-2018.pdf;

38. The BOP's Clinical Guidance on the Detoxification of Chemically Dependent Inmates permits the use of methadone for purposes of detoxification from opioids. I would assume that this protocol applies to detox patients who are being treated with methadone for OUD as well, although the document does not specifically say so. Additionally, the Clinical Guidance states that methadone detoxification treatment can only be administered in an appropriately licensed Narcotic Treatment Program.[51] Yet, the document also states "Pregnant women on methadone ordinarily should not be detoxified" and "Pregnant women taking opiates should be treated with methadone or maintained on methadone, since detoxification increases the risk of miscarriage and premature labor." As such, there appears to be precedent for maintenance of methadone treatment during incarceration for pregnant inmates.

39. The cessation of an appropriately-prescribed medication for a chronic disease is unethical and discriminatory to patients with OUD as compared to other chronic medical problems. First, the Clinical Guidance states, "Medical detoxification is considered the standard of care for individuals with opiate dependence." Given the current epidemic of opioid overdose and opioid overdose fatality, this is no longer true. Rather, the standard of care is induction and long-term maintenance on MAT. Patients maintained on methadone are routinely treated with doses higher than 40 mg daily, and frequently higher than 100 mg, but even so, it is significantly understated that the inmate after long-term acclimation to 40mg/day of methadone could be detoxified with a minimum of risk and distress in just 2-3 days or at a rate of 10% per day, as suggested in BOP's Clinical Guidance on the Detoxification of Chemically Dependent Inmates. Even more important than the short-term impact of detoxification from methadone on an

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Ex. 40, Federal Bureau of Prisons Health Services, National Formulary Part II at 102-03, *available at* https://www.bop.gov/resources/pdfs/national_formulary-part_II-2018.pdf.

[51] Ex. 41, Federal Bureau of Prisons, Clinical Guidance on Detoxification of Chemically Dependent Inmates, at 16 (February 2014, reformatted January 2018).

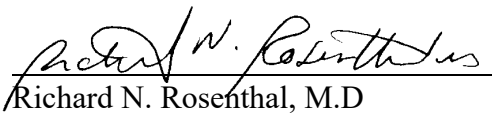
accelerated schedule is the added profound risk of releasing a person with a chronic OUD to freedom after incarceration without the medical benefit and protection of MAT.

40. 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. 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.

* * *

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

Executed on March 13, 2019



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