UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

JOSEPH SCLAFANI, MICHAEL FEINSTEIN, and BRET CAPPOLA,

Plaintiffs,

CAROL A. MICI, in her official capacity as Commissioner of the Massachusetts Department of Corrections, DOUGLAS DEMOURA, in his official capacity as Superintendent of MCI-Cedar Junction, and STEVE SILVA, in his official capacity as Superintendent of MCI-Norfolk,

Defendants.

C.A. 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 am board certified in both Addiction Medicine and Family Medicine. In addition to my work with the Franklin County Sheriff'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 the director of Substance Use Disorders at Behavioral Health Network. 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 1.

3. From 1999 to 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.

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4. I have worked with over 1000 people with various substance use disorders (SUD) prosecuted in the criminal justice system. At the Franklin County House of Correction, approximately 85% of the 200 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

5. 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 Its symptoms include cravings, increasing tolerance to opioids, withdrawal symptoms and a loss of control.

6. More than half a million people have died from opioid overdose in the last 20 years, and the death toll from opioid use has risen exponentially since 2013.² In 2017, more than 70,000 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.³ Every day, more than 130 American die after overdosing on opioids—equivalent to one person every 11 minutes.⁴

7. The numbers are particularly stark in Massachusetts. According to the Massachusetts Department of Public Health (DPH), there were 2,033 confirmed and estimated

² See Centers for Disease Control and Prevention, *America's Drug Overdose Epidemic: Data to Action, available at* https://www.cdc.gov/injury/features/prescription-drug-overdose/index.html (CDC, Overdose Epidemic), Exhibit 3. ³ Id.; see Ashley Welch, *Drug Overdoses Killed More Americans Last Year than the Vietnam War*, CBS News (Oct.

¹ American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, 483 (5th ed. 2013), Exhibit 2. 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.

^{17, 2017),} *available at* https://www.cbsnews.com/news/opioids-drug-overdose-killed-more-americans-last-year-than-the-vietnam-war/, Exhibit 4.

⁴ CDC, Overdose Epidemic.

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opioid-related deaths in Massachusetts in 2018.⁵ While this represented a slight decrease from 2017, it still translates to an average of more than 5 opioid-related deaths per day in the Commonwealth.

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

9. 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.⁶

10. 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.

⁵ See Massachusetts Department of Public Health, *Data Brief: Opioid-Related Overdose Deaths Among Massachusetts Residents* (Nov. 2019), *available at* https://www.mass.gov/doc/opioid-related-overdose-deaths-among-ma-residents-november-2019/download, Exhibit 5.

⁶ See U.S. Department of Health & Human Services, *Facing Addiction: The Surgeon General's Report on Alcohol, Drugs, and Health*, at 2-5 (2016), *available at* https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf, Exhibit 6.

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11. The survival part of the brain wants to achieve a sense of normalcy. Nonaddicted 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

12. 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.

13. 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, which can be used in conjunction with counseling, behavioral therapy, and other interventions. The medication component of MAT is the primary driver of its efficacy, as the medications 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. The use of MAT is the medical standard of care for the treatment of opioid use disorders.

14. Naltrexone works as an agonist by blocking opioids from producing their euphoric effects and thus reducing a desire for opioids over time.⁷

15. The opioid agonists buprenorphine and methadone activate the opioid-receptors while binding to them, providing for a steady flow of dopamine to the brain and reducing both

⁷ Substance Abuse and Mental Health Services Administration, *Naltrexone, available at* https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone (last updated Sep. 27, 2019), Exhibit 7.

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cravings and withdrawal symptoms.⁸ 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,⁹ and both have been deemed "essential medicines" by the World Health Organization.¹⁰

16. 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. Standard practice dictates against tapering or cessation of buprenorphine therapy before patients have had at least one year of treatment, have attained clinical stability, and wish to discontinue treatment.¹¹

17. It is common for some patients to need to remain on buprenorphine for many years to treat their OUD. The Substance Abuse and Mental Health Services Administration emphasizes that "[p]eople may safely take medications used in MAT for months, years, several years, or even a lifetime."¹² I have prescribed buprenorphine since 2004 and have had patients remain on that medication for that entire time with excellent results.

⁸ Substance Abuse and Mental Health Services Administration, *Medication and Counseling Treatment, available at* https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat (last updated May 7, 2019) (hereinafter "SAMHSA, Medication & Counseling"), Exhibit 8.

⁹ American Society of Addiction Medicine, *Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment*, at 13-15 (2013), *available at* https://www.asam.org/docs/default-

source/advocacy/aaam_implications-for-opioid-addiction-treatment_final.pdf, Exhibit 9.

¹⁰ 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), Exhibit 10.

¹¹ See Martin et al., The Next Stage of Buprenorphine Care for Opioid Use Disorder, Annals of Internal Medicine, 4-5 (2018), Exhibit 11.

¹² SAMHSA, Medication & Counseling *supra* note 8.

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18. The specific medication, dosing and length of treatment on MAT cannot be standardized across patients. Instead, these decisions must be based on a doctor's individualized assessment of a particular patient's medical needs.

19. During the early stages of MAT treatment, it is very typical for an individual to continue to use illicit opiates at the same time as their prescribed treatment before fully entering active recovery. This is a part of the process of recovery, and does not mean that the medication is not working.

20. Based on an individualized assessment of medical needs, it is appropriate to prescribe buprenorphine to an individual for MAT even if they have previously been unable to achieve active recovery on buprenorphine. A medical provider can retry medications at a different time and expect a different result. For similar reasons, based on an individualized assessment of medical needs, it is also appropriate to prescribe buprenorphine for MAT for an individual who has previously used buprenorphine at a different time to get high.

21. 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 taper the patient off this treatment against the patient's will.

22. 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

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makes treating an already complicated disease even harder. Dual diagnoses are not simply additive, they can be amplifying—patients with mood disorders are able to achieve prolonged periods of recovery using MAT but have to work extremely hard to do so.

23. In my experience, the primary driver of treatment efficacy in MAT regimens is medication. Attempts at other addiction-treatment regimens, such as abstinence-or twelve-step-type programs that have been successful in other contexts (such as alcohol addiction) have not been successful in treating opioid addiction.¹³

D. Current State of Opioid Use Disorder Treatment in Department of Corrections Facilities

24. Despite the overwhelming medical evidence supporting MAT as the standard of care in the treatment of opioid use disorder, MAT is not currently available to the vast majority of incarcerated patients suffering from opioid addiction in Department of Correction (DOC) facilities.

25. It is my understanding that the only DOC correctional facility for criminally sentenced men that provides buprenorphine is MCI-Cedar Junction ("Cedar Junction"), and individuals at Cedar Junction are only allowed to continue their buprenorphine prescriptions for a short period—typically around 90 days—at the beginning and end of their sentence.

26. This stands in contrast to the continuity of care DOC typically provides to inmates suffering from other chronic illnesses or mental health conditions that require a continuous course of medications which allows individuals to remain on their prescribed medications without generalized temporal limits.

¹³ See Marc A. Schuckit, Treatment of Opioid-Use-Disorder, 375 New Engl. J. Med. 357, 358-59 (2016), Exhibit 12.

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27. In my practice, I have personally witnessed the excruciating symptoms experienced by patients undergoing an accelerated buprenorphine 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.

28. Even if a patient was detoxed from their buprenorphine treatment over 90 days, this would still trigger significant and painful withdrawal symptoms. In my experience, a patient who has been on a stable buprenorphine program should be detoxed at a rate of 1-2 mg every month. At any point, were cravings to return, the dose should be returned to the previous most effective dose. The rate of taper needs to be particular slow when a patient reaches 2 mg a day dosing, as this is especially challenging for the patient. In my experience, decreasing someone off of 2 mg a day can take several months, as we would slowly taper someone from 2 mg to 1.5 mg to 1.0 mg to .75 mg to .5 mg to .25 mg to every other day before removing the prescription entirely. For these reasons, in my medical opinion and experience, a patient who is detoxed from 16 mg per day over 90 days would likely still suffer from the withdrawal symptoms described above.

29. Short-term buprenorphine dosing for incarcerated individuals is inconsistent with sound medical practice and can have catastrophic effects, including relapse, overdose and death.¹⁴ Buprenorphine is not a short-duration treatment, and from a medical perspective, there are no general temporal limits on buprenorphine treatment. Determining an individual's medical care based on a generally applicable temporal limit on buprenorphine is inconsistent with sound

¹⁴ See Martin, supra note 11, at 4-5.

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medical practice. Indeed, forcing incarcerated individuals to cease buprenorphine dosing after a generally set period of time, especially one as short as 90 days, is against the standard of medical care. Studies show the poor efficacy of limiting buprenorphine dosing to short periods of time.

30. The disruption of therapy has long-term consequences for incarcerated individuals during and after their incarceration. In many prisons, incarcerated individuals may have access to illicit substances, and often resort to drug use when deprived of their medication. These individuals are at a significant risk of overdose and death. Additionally, 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.

31. 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.

32. Incarcerated patients who had previously succeeded on buprenorphine are often unable to successfully resume treatment after their release from incarceration. For many patients, the experience of buprenorphine detox discourages them from reinitiating therapy.

33. 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

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compared to the rest of the adult population.¹⁵ In 2015, nearly 50 percent of all deaths among those released from incarceration were opioid-related.¹⁶ The vast majority of these deaths occurred within one month after release..¹⁷

E. Practicability and Effectiveness of MAT in Correctional Facilities

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

35. 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, they are required to sit on their hands for 10 minutes while their medication dissolves, they are required to spit out any remnants in the bathroom before they reenter general population. Random urinalysis of the inmates population is conducted to ensure that only patients on MAT are receiving buprenorphine. Thanks to this protocol, we believe diversion of buprenorphine from the MAT program is close to zero in our facility.

¹⁵ Massachusetts Department of Public Health, *An Assessment of Fatal and Nonfatal Opioid Overdoses in Massachusetts (2011-2015)*, at 50 (2017), *available at* https://www.mass.gov/files/documents/2017/08/31/legislative-report-chapter-55-aug-2017.pdf, Exhibit 13.

¹⁶ *Id*. at 51.

¹⁷ *Id.* at 52.

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36. These same strategies can be used in DOC facilities, and DOC facilities already have systems in place to provide buprenorphine dosing during the first 90 days of incarceration, as well as systems to secure other controlled substances commonly prescribed to inmates, such as benzodiazepines and prescription opioids.

37. MAT has been successfully administered in numerous jurisdictions both inside and outside of Massachusetts. Currently, Franklin, Hamden, Hampshire, Suffolk, Middlesex, Essex, and Norfolk County Houses of Correction all provide buprenorphine maintenance to inmates. In addition, inmates suffering from opioid addiction in correctional facilities throughout Rhode Island and Vermont, as well as Rikers Island in New York and King County, Washington have received buprenorphine and methadone treatment. There is no evidence that the implementation of MAT at these facilities has been unmanageable or has presented significant security concerns.

38. The administration of MAT is not cost-prohibitive. In particular, buprenorphine can be administered for less than \$2.70 per day per patient.

39. 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. Some of the biggest advocates for the MAT program at our facility are the correctional officers because it has reduced security issues.

40. 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

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facility.¹⁸ The number of recently incarcerated individuals who died from an overdose dropped from 26 in the first six months of 2016 to nine in the first six months of 2017.¹⁹ 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 1.²⁰ These findings are consistent with observations from other studies conducted in other countries.²¹

41. 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.

F. Bret Cappola

42. In my role as Medical Director of Franklin County House of Correction, I oversee the protocol for, and prescription of, buprenorphine maintenance treatment in our facility.

43. Our policy and practice is to provide an individualized assessment of medical needs, including addiction history and treatment history, before prescribing buprenorphine.

44. Our facility only prescribes buprenorphine maintenance treatment if it is medically necessary to treat a patient's opioid use disorder.

45. Based on my review of Bret Cappola's records, I can confirm that we diagnosed Mr. Cappola with opioid use disorder when he entered our facility on June 27, 2018 and that he became stable when we prescribed 16 mg of buprenorphine per day to help treat his opioid use disorder. I can also confirm that he remained on this prescription throughout his time at our

 ¹⁸ 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 14.
¹⁹ Id. at 405 tbl. 1.

²⁰ Id.

²¹ 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 15.

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facility until he transferred to Hamden County House of Correction in June, 2019. That would have occurred only if buprenorphine maintenance treatment was medically necessary to treat Mr. Cappola's opioid use disorder.

46. Individuals who are not complying with our buprenorphine protocol, or for whom buprenorphine is not working, do not stay in our buprenorphine program. That Mr. Cappola continued to remain in our buprenorphine program for his entire year at Franklin County House of Correction indicates that he was complying with our protocol and that buprenorphine maintenance treatment was helping him achieve active recovery.

47. Based on my review of Mr. Cappola's records, I can confirm that his buprenorphine maintenance treatment was medically necessary for him at the time he left our facility. Given my decades of experience in addiction medicine, I believe it would be typical for someone with Mr. Cappola's addiction history to still medically require buprenorphine maintenance treatment six months after they left our facility.

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

Executed on December <u>1</u>, 2019

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Ruth A. Potee, M.D.