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 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 19 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. I have experience treating patients with all three FDA-approved medication for opioid use disorder (MOUD). MOUD is sometimes referred to as medication for addiction treatment or medication assisted treatment (MAT), but I prefer to use the term MOUD because when people use the term MAT, they mean medication for opioid use disorder and not other addictions. I have prescribed buprenorphine and naltrexone to hundreds of patients through

my primary care practice at Boston Medical Center. In my capacity as a physician working in opioid treatment programs, I have also treated hundreds of patients with methadone. We now know that the primary driver in MAT's efficacy is the medication itself.

6. Numerous government entities have recognized the necessity of MOUD, including: the Department of Health and Human Services, the FDA, the National Institute on Drug Abuse, the President's Commission on Combatting Drug Addiction and the Opioid Crisis, the Office of National Drug Control Policy, SAMHSA, and the National Academies of Science, Engineering and Medicine. The medical consensus is clear that the standard of care for opioid use disorder, both in community and criminal justice settings, is long-term maintenance medication for opioid use disorder. A recent consensus report by the National Academies of Sciences, Engineering, and Medicine establishes unequivocally that "[w]ithholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment."[1]

7. While each of the three FDA-approved medications for opioid use disorder is 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. Once they do, it is against the medical standard of care to involuntarily remove a patient from a medication that is helping them reduce their risk of fatal overdose or other complications of opioid use and any dosing changes must be based on individual medical needs.

8. Achieving abstinence typically takes multiple treatment trials. Thus, it is typical for patients

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[1] National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives*, 3 (2019), *available at* https://doi.org/10.17226/25310.

with severe opioid use disorder to continue to use illicit opioids during initial treatment trials with buprenorphine before being able to achieve long-term abstinence during subsequent buprenorphine maintenance treatment.

9. Abstinence from illicit opioids is only one of several positive outcomes from MOUD. Even before someone achieves long-term abstinence, reduction in use, without complete abstinence, substantially reduces the functional disruption in patients' lives from illicit opioid use and the risk of the medical complications, especially for those who inject illicit opioids. In addition, buprenorphine reduces the risk of fatal overdose among those who continue to use illicit opioids.

10. An individual who has previously used buprenorphine and experienced euphoria can still successfully achieve abstinence, reduction in opioid use, functional benefit and overdose risk reduction with the assistance of buprenorphine when it is prescribed for the purpose of treating opioid use disorder.

11. The length of time a patient receives buprenorphine treatment must be based on a prescriber's individualized assessment of a particular patient's medical needs. Some patients who suffer from opioid use disorder, and who are being successfully treated with buprenorphine, will need to continue buprenorphine treatment indefinitely, even for life. Some of my patients have been taking buprenorphine for opioid use disorder for over twelve years. I expect some of these patients to continue their buprenorphine treatment for many years to come. A longer treatment period is especially typical for someone with a longer history of addiction.

12. Forced withdrawal of medication from patients on a successful course of medication for opioid addiction for reasons other than medical necessity is inconsistent with sound medical

practice. No physician, acting within prudent professional standards and in a manner reasonably commensurate with modern medical science, would arbitrarily discontinue the administration of MOUD to a patient in treatment for opioid use disorder, where the treatment is resulting in reduced risk of death, reduced medical complications, and increased likelihood of abstinence, unless there were significant adverse side effects or contraindications.

13. When a patient wants to discontinue buprenorphine treatment, or must discontinue treatment due to medical necessity, it is critical to taper buprenorphine or methadone as slowly as possible. A patient who tapers too quickly will experience withdrawal symptoms such as severe craving, diarrhea and vomiting, abdominal cramps, restless legs, excessive dehydration, and insomnia, and, thus, is at high risk of relapse, overdose, and death. For a patient who needs to discontinue treatment and who is taking 16 mg of buprenorphine per day, I would recommend tapering as slowly as possible, leaving a substantial fraction of the available tapering time for the period when the dose is tapered from 8mg to 0mg.
14. Patients who are tapering off of buprenorphine treatment often experience the most difficult withdrawal symptoms when they taper from 2 mg to 0 mg per day. Relapse is common when they discontinue the medication after having taken a daily dose of 2 mg. For this reason, in my experience it is especially important to decrease the dose at this stage at a slower pace.
15. Offering a patient buprenorphine for an arbitrary period of time does not constitute maintenance MOUD. At most, this would constitute medically managed withdrawal. Medically managed withdrawal does not treat opioid use disorder or its symptoms; it simply provides some comfort to patients while they withdraw from a prescribed or illicit opioid.
16. Unlike maintenance MOUD, medically managed withdrawal does not address a patient’s

cravings and has not been shown to improve long-term outcomes for patients' recovery.

17. A policy that requires a 90-day maximum dose of buprenorphine for every patient is a policy that denies maintenance MOUD and instead provides only medically managed withdrawal.

18. Like the length of time of buprenorphine treatment, a patient's dose of buprenorphine must be based on a prescriber's individualized assessment of a particular patient's medical needs. I generally prescribe patients suffering from opioid use disorder between 2 and 24 mg of buprenorphine per day. If a patient taking less than 24 mg per day of buprenorphine experiences symptoms of opioid use disorder, like cravings or withdrawal symptoms, a higher dose is warranted. In my experience, the most commonly prescribed dose of buprenorphine is 16 mg per day.

19. Setting an indiscriminate maximum dose of anything less than 24 mg per day would violate the medical standard of care. Likewise, without an individualized assessment of medical needs, refusing to prescribe a higher dose of buprenorphine to a patient who tolerates the medication but is continuing to experience symptoms of opioid use disorder on a dose of less than 24 mg per day is contrary to prudent professional standards.

20. 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. Abstinence is only one of several important outcomes for MOUD. Other important outcomes that occur, even among patients who are not completely abstinent from illicit opioids while taking buprenorphine are reduction in fatal overdose risk and a reduction in the medical complications of ongoing use. Access to the medication empowers patients to limit a relapse

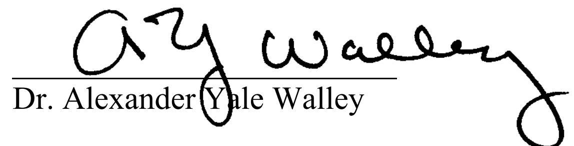
to a brief period of time, because re-engagement in treatment is more readily accessible than the routes that require a physical and mentally stressful detoxification taper in an inpatient setting.

21. I have provided buprenorphine maintenance treatment to many patients struggling with opioid use disorder who have been removed from their medication during incarceration. In my experience, most of these patients who were involuntarily withdrawn from their MOUD, relapse when they are released. Those who return to our clinic for continued treatment immediately when they are released are the exception rather than the rule.

22. Recently, however, I have had an increasing number of patients who have been able to remain on buprenorphine maintenance treatment throughout their incarceration. In these instances, the reverse is true: those who return to our clinic for continued treatment when they are released are the rule rather than the exception.

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 December 17, 2019.



Dr. Alexander Yale Walley