

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

BRENDA J. SMITH,

Plaintiff,

v.

AROOSTOOK COUNTY AND SHAWN
D. GILLEN,

Defendants.

CIVIL NO. 18-cv-00352-NT

DECLARATION OF ROSS MACDONALD, MD

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

1. I am an expert 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. I manage an average daily population of more than 8,000 individuals incarcerated in NYC jails, including approximately 50,000 admissions per year in 11 jail facilities. Each facility has 24-hour clinics staffed by, at various times, 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.

2. The opioid treatment program in New York City jails provides medication-assisted treatment—also referred to as agonist medication—to prisoners with opioid use disorder. I have overseen the opioid treatment program at the Rikers Island jail in New York City since

2013. I am board certified in Internal Medicine, and a buprenorphine provider licensed by the U.S. Drug Enforcement Agency (“DEA”) and New York State.

3. 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. 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**.

5. 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 implementing MAT programs in correctional settings.

6. As described in further detail below, it is my understanding that Aroostook County Jail generally refuses to provide medication-assisted treatment for prisoners with opioid use disorder, even for patients who are on maintenance medication for opioid use disorder at the time they enter the facility. It is my opinion that this policy is medically unsupported and does not provide appropriate treatment for a patient in maintenance medication-assisted treatment (“MAT”).

7. Based upon my experience in implementing medication-assisted treatment programs in a correctional setting, as well as collaboration with medical leadership of jails and prisons around the country, security concerns such as drug trafficking and diversion are not sufficient barriers to treatment. Rather, there are numerous effective methods to reduce the risks

of diversion, and providing treatment for opioid use disorder may, if anything, help ameliorate the underlying cravings that underlie drug trafficking in jails.

Opioid Use Disorder

8. Opioid use disorder (“OUD”) is a serious and potentially deadly disease. Symptoms of the disease include uncontrollable cravings for opioids, loss of control, increased tolerance to opioids, and withdrawal. Complications of OUD include overdose and death. Hundreds of people in Maine die each year from opioid overdose, with more than 400 dying in 2017.¹

9. Withholding medication from someone with OUD generally triggers symptoms of withdrawal and increases risk for relapse into active OUD. Both withdrawal and relapse are serious and potentially dangerous medical conditions.

10. There is significant suffering associated with withdrawal. Symptoms of withdrawal include muscle pain, vomiting, diarrhea, depression, insomnia and anxiety. Even if the patient is not actively vomiting or otherwise exhibiting obvious symptoms, he or she could still be in serious pain from withdrawal and experiencing other damaging psychological symptoms. Maradiaga, et al., “*I Kicked the Hard Way. I Got Incarcerated.*” *Withdrawal from Methadone During Incarceration and Subsequent Aversion to Medication Assisted Treatments*, J. Subs. Abuse Treat., 62: 49-54 (2016 March). These symptoms are exacerbated by co-occurring disorders such as depression, anxiety and post-traumatic stress disorder (PTSD), which are common among patients with OUD.

¹ Attorney General Janet Mills Releases 2017 Maine State Drug Death Statistics, <https://www.maine.gov/ag/news/article.shtml?id=788298> (Feb. 22, 2018).

11. Withdrawal symptoms can last up to several weeks, and after withdrawal, patients with OUD do not return to their pre-OUD baseline, often experiencing symptoms of OUD such as cravings, which can continue indefinitely.

12. Relapse into active OUD is a potentially life-threatening condition, and can result in overdose and death, either during incarceration or after release.

13. According to a Bureau of Justice Statistics study published in August 2015, nearly 7 percent of inmate deaths in local jails from 2000 to 2013 were caused by drug or alcohol intoxication. *Mortality in Local Jails and State Prisons, 2000-2013 – Statistical Tables*, U.S. Dep’t of Justice, Bureau of Justice Statistics (Aug. 2015) (925 deaths out of 13,728). Although lower, the rate of deaths from drug or alcohol intoxication was still significant in state prisons—at 546 deaths out of 42,157 from 2001 to 2013. *Id.* at 20. This data shows that illicit drugs are available in prison, and, for a person suffering from opioid use disorder, could pose a risk of relapse, overdose, and death.

14. 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). 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). 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.* Drug overdose was one of “the leading causes of death

among former inmates.” *Id.* Specifically, there were 181 overdose deaths out of 777 for former inmates. *Id.* at 164. For current inmates, moreover, there was 1 overdose death out of the 201 deaths during the study period. *Id.* at 164.

Appropriate Treatment for Opioid Use Disorder

15. Medication-assisted therapy using agonist medication, such as buprenorphine and 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.

16. 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.

17. I have reviewed medical records from Ms. Smith, and it is my opinion that Ms. Smith suffers from opioid use disorder that requires ongoing treatment with medication-assisted treatment. Given Ms. Smith’s history of maintenance treatment on buprenorphine, it is also my opinion that forcing Ms. Smith to withdraw from her medication-assisted treatment **(A)** would cause dangerous and painful withdrawal symptoms, **(B)** would place her at greater risk of relapse into active symptoms of opioid use disorder, and **(C)** would increase the risk of a dangerous or deadly overdose upon her release from jail.

18. I also note that Ms. Smith has co-occurring diagnoses of opioid use disorder and bipolar disorder. This places her at greater risk of a complex withdrawal, with potential side effects including suicidal ideation and decomposition.

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

20. 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. *See Binswanger, et al., supra* ¶ 14. The study concluded that treatment with agonist medication during prison and post-release “appears to reduce mortality in the immediate post-release period.” *Id.*

21. Another 2014 study from Australia found that the availability of medication-assisted treatment reduced the likelihood death *in prison*. Larney, *et al., Opioid Substitution Therapy as a Strategy to Reduce Deaths in Prison: Retrospective Cohort Study*, *BMJ Open*, 2014:4 1-8 (2014). 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.

22. 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](http://dx.doi.org/10.1016/S0140-6736(14)62338-2) 1 (May 29, 2015). 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.

23. 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). 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.*

24. The most recent paper is a research letter from the United States, studying the frequency of post-incarceration fatal overdose after 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). 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.

25. 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); Manhapra, *et al.*, *Opioid Substitution Treatment is Linked to Reduced Risk of Death in Opioid Use Disorder*, *BMJ* 2017 (Apr. 26, 2017); Sordo, *et al.*, *Mortality Risk During and After Opioid Substitution Treatment: Systemic Review and Meta-analysis of Cohort Studies*, *BMJ* 2017 (Apr. 26, 2017).

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

27. 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.

28. There is a strong body of evidence that forced withdrawal has serious psychological effects and increases the risk of relapse and overdose. As detailed above, post-release overdose risk has been well established in prison and jail data from the United States.

29. Likewise, counseling or therapy alone, without accompanying medication-assisted treatment, is not supported by the evidence.

30. A study published in 2010 compared three groups that all experienced pre-incarceration heroin dependence. The groups included the following treatments: **(1)** counseling only, in which prisoners received counseling in prison, with passive referral to treatment upon release, **(2)** counseling plus transfer, in which prisoners received counseling in prison, plus a referral to a methadone treatment program in the community upon release, and **(3)** counseling plus methadone in prison, in which prisoners received both counseling and methadone treatment in prison, continued in the community upon release. See Kinlock, *et al.*, *A Randomized Clinical Trial of Methadone Maintenance for Prisoners: Results at Twelve-Months Post-Release*, *J. Subs. Abuse Treat.*, 37(3): 277-285 (Oct. 2009). The success of retention in treatment was highest in

the methadone-treatment group, with 166 days in treatment—a statistically significant difference with the 23 days (for counseling only) or 91 days (for counseling plus transfer). Prisoners in the methadone-treatment group were also less likely to test positive for illicit opioids or cocaine. Accordingly, this study supports that medication-assisted treatment, such as methadone maintenance, is more effective than counseling alone, or counseling plus referral upon release.

31. Another study likewise found that post-release care alone was statistically less effective than consistent MAT throughout prison and following release. Degenhardt, *et al.*, *supra* ¶ 14.

32. Furthermore, post-release care alone would do nothing to address the risk of relapse and overdose during the prisoner’s time in prison.

Security Risks Identified By Defendants

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

34. Agonist therapy 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, Philadelphia and Chicago. Additionally, some states have implemented access to agonist therapy across state jail and prison systems, including Rhode Island’s entire Department of Corrections system. Connecticut has also implemented MAT in its combined prison and jail system, as have some facilities in New Jersey. The feasibility of this treatment in prison is also shown by the wide

acceptance of agonist medication for pregnant inmates with opioid use disorder. Almost all correctional systems provide medication-assisted treatment when necessary to continue care for pregnant women.

35. 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. Rather, appropriate treatment of OUD will reduce illicit opioid use and therefore the desire for illicit opioids on a population level. As such, treating the underlying addiction appropriately could mitigate, though is unlikely to eliminate, the drug trafficking experienced in prisons and jails. 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 medication-assisted treatment, given the risks of overdose and potential death during incarceration.

36. 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.

37. Diversion has been cited as a reason not to provide agonist medication in the Aroostook County Jail. Although diversion can occur, in my experience, it is absolutely manageable and is not so frequent to provide a reason for refusing to provide MAT. Diversion does not undermine the effective implementation of MAT programs in the locations where it has been tried.

38. There are numerous methods to greatly reduce the possibility of diversion, including different formulations of medication, nursing protocols, and the combination of nursing and correctional staff to minimize the risk of diversion. Methods include:

- a. Administration of medication by nurses, who are trained to perform an oral check after administration to ensure the medication has dissolved;
- b. Having patients sit at desk with their hands on the desk while the medication is administered and dissolves under the tongue;
- c. Using a crushed formulation of generic buprenorphine, or liquid buprenorphine that is poured under the tongue, which has little chance to be diverted;
- d. Using the combination of nursing staff and a correctional officer to administer and observe the process;
- e. Using methadone, which is difficult to divert in liquid form.

39. In the New York City jails, we have started using a formulation of rapid dissolving tablets that dissolve quickly in the mouth and make it hard for medication to be diverted.

40. Buprenorphine, because of its unique properties as a *partial* opioid agonist, is far less likely to result in overdose even when used illicitly when compared to other opioids (especially illicit fentanyl which is now widely available across the nation). As a reflection of this property, buprenorphine has been shown to be infrequently present in overdose deaths. Paone, *et al.*, *Buprenorphine Infrequently Found in Fatal Overdose in New York City*, Drug and Alcohol Dependence 155: 298-301 (2015). Even if small amounts of opioid agonist therapies were diverted despite the strategies described above, they would be far safer when abused than the illicit substances likely to be available today.

41. Additionally, certain formulations of the medication are more difficult to smuggle than others. One particular formulation of Suboxone makes it very amenable to smuggling because the very thin strips can more easily be hidden than pills. Because the thin-strip Suboxone is taken sublingually (under the tongue), it is the only opioid (though it is not technically a full

opioid) that comes in such a formulation. This formulation is preferentially smuggled along with other easy-to-smuggle substances like fentanyl, a highly concentrated powder. As discussed above, other types of Suboxone, buprenorphine, and methadone are not easily hidden or smuggled.

42. Further, smuggling Suboxone occurs on 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. If standard medications for the treatment diabetes or HIV were to be prohibited in the jail, a market and process for smuggling these medications would likely develop over time, which would not in turn justify their continued prohibition. Studies have shown that the majority of diverted buprenorphine among opioid users is used only rarely to “get high” (12%) and more commonly for the self management of opioid use disorder or withdrawal (79%). Carroll, *et al.* *The More Things Change: Buprenorphine/naloxone Diversion Continues While Treatment Remains Inaccessible*, Journal of Addiction Medicine. 2018 Aug 7. [Epub ahead of print].

43. I am not aware of evidence to support the assumption that providing MAT would exacerbate drug trafficking in prison. To the contrary, treating opioid use disorder would actually reduce cravings for illicit drugs, and, thus, may reduce drug trafficking.

44. Far from providing a reason against providing MAT, the drug trafficking problem shows that it is *more dangerous* to withhold necessary treatment in prison. The fact that correctional institutions are secure facilities does not guarantee that illicit substances are unavailable. The uncontrollable cravings that are symptoms of OUD could explain some of the demand for these illicit drugs. Withholding MAT and forcing prisoners into withdrawal and relapse poses the risk of overdose and death because of the illicit drugs that are readily available in the prison.

45. In this era of illicit fentanyl, small (and easily smuggled) amounts can be lethal, which exacerbates an already appreciable risk of overdose while incarcerated. Denying appropriate medication increases the risk for relapse and death while incarcerated, upon release and unnecessarily exposes patients to physical and psychological suffering.

46. I am providing this declaration in my personal capacity, 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 November 2, 2018

/s/ Ross MacDonald, M.D.
Ross MacDonald, M.D