IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GEOFFREY PESCE, Plaintiff, v. KEVIN F. COPPINGER, in his official capacity as Essex County Sheriff, AARON EASTMAN, in his official capacity as Superintendent of the Essex County House of Corrections - Middleton, Defendants.	C.A. No. 1:18-cv-11972-DJC LEAVE TO FILE GRANTED ON SEPTEMBER 28, 2018

PLAINTIFF'S REPLY IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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Eastman ¶ __	Affidavit of Aaron Eastman (D. 41-15)
Ex. __	Exhibit to Plaintiff's Reply in Support of Motion for Temporary Restraining Order and Preliminary Injunction, filed concurrently herewith
Faro ¶ __	Affidavit of Jason Faro (D. 41-14)
FDA	U.S. Food and Drug Administration
Ginsberg ¶ __	Declaration of Barry Ginsberg, M.D., filed concurrently herewith
Kiser ¶ __	Affidavit of Deanna Kiser, R.N. (D. 41-13)
HOC	House of Correction
MAT	Medication-assisted treatment
MacDonald ¶ __	Declaration of Ross MacDonald, M.D., filed concurrently herewith
Opposition	Defendants Kevin F. Coppinger and Aaron Eastman's Memorandum of Law in Support of Their Opposition to Plaintiff's Motion for Temporary Restraining Order and Preliminary Injunction (D. 41)
OUD	Opioid use disorder
Pesce ¶ __	Declaration of Geoffrey Pesce (D. 15)
Potee ¶ __	Declaration of Ruth A. Potee, M.D. (D. 17)
Rosenthal ¶ __	Declaration of Richard N. Rosenthal, M.D. (D. 18)
SAMHSA	Substance Abuse and Mental Health Service Administration
Walley ¶ __	Declaration of Alexander Yale Walley, M.D., M.Sc., filed concurrently herewith
Yuasa ¶ __	Declaration of Shorta Yuasa, M.D. (D.19)

INTRODUCTION

Defendants concede that if Geoffrey Pesce is incarcerated at Middleton HOC, they will halt his methadone treatment. Defendants' blanket policy refuses to provide methadone and buprenorphine, which they view not as medications but as "illegal drugs" just like heroin. *See* Opp. at 5; Eastman ¶¶ 13-14. Defendants' policies do not reflect any consideration of Mr. Pesce's medical needs; instead, they reflect stigma and moral judgment that methadone treatment is bad. But Defendants do not dispute that methadone is safely and effectively used to treat opioid use disorder ("OUD") every day, including at two Massachusetts correctional facilities where it is given to pregnant women. Nor do they dispute that halting Mr. Pesce's methadone treatment will precipitate painful withdrawal and put him at high risk for relapse and fatal overdose. Yuasa ¶¶ 20-24. Defendants have not presented a single doctor who says otherwise.

This case, therefore, is not about a "difference of opinion" grounded in reasoned medical judgment regarding the proper treatment of Mr. Pesce's OUD; it is about Defendants' decision to end Mr. Pesce's prescribed treatment based solely on their blanket prohibition against opioid agonist therapy. Mr. Pesce is likely to succeed on the merits of his claims that forcing him to withdraw from his methadone treatment violates the Eighth Amendment and the ADA. And the proven harms to Mr. Pesce—including the extreme pain of withdrawal and high risk of overdose and death—are irreparable, outweigh any generalized burden alleged by Defendants, and tilt the public interest in his favor. For these reasons, injunctive relief is not only warranted under the law, it could save Mr. Pesce's life.

I. DEFENDANTS' FACTUAL ASSERTIONS ARE CONTRARY TO THE RECORD

Defendants, throughout their Opposition, make various assertions that are not supported by the record. Most notably, Defendants claim that Middleton offers MAT "from the moment they enter the facility to the time they are released to the community." Eastman ¶ 6. But

Middleton provides only a single shot of Vivitrol (naltrexone) within 24-hours of an individual's release. Faro ¶ 9; Kiser ¶ 10; Eastman ¶ 6. The timing of the shot is based on length of sentence, not science or medical need. It does not account for an inmate's past experience with Vivitrol, and it does nothing to treat OUD during incarceration. *See* MacDonald ¶ 20.

Second, methadone treatment is not, as Defendants would have it, simply Mr. Pesce's preference. *See* Opp. at 17. Mr. Pesce's treating physician has prescribed him methadone for two years without side effects, and has determined that it remains medically necessary to treat his OUD. Yuasa ¶¶ 10-11, 17, 27.[1] He has tried naltrexone, and it both failed to curb his cravings and made him sick. Pesce ¶ 12. This is hardly surprising. Vivitrol's website acknowledges it "is not right for everyone,"[2] and Mr. Pesce's physician has concluded that he may be someone "for whom buprenorphine and naltrexone simply do not work." Yuasa ¶ 10. Defendants do not dispute any of these facts. To the contrary, Defendants' exhibits corroborate Mr. Pesce's evidence—namely, even if Defendants offered Vivitrol throughout someone's incarceration (which they do not), it would not meet medical standards in Mr. Pesce's case. For example, in Exhibit B, after 24 weeks only ***21%*** of patients receiving Vivitrol completed treatment, meaning 79% had dropped out, and 6% (3 patients) died. Def. Ex. B at 98. The troubling results caused the authors to conclude: "The striking rate of overdose deaths in patients starting treatment prior to release is also concerning, and supports the need for an availability of ***all evidence-based treatments*** prior to release, ***including buprenorphine and methadone***." *Id.* at 99 (emphasis added). Likewise, in Exhibit D, ***43.1%*** of patients taking Vivitrol experienced an "opioid-related event." Def. Ex. D at 1236. The relapse rate was even higher in Exhibit F (65%), which the

[1] Dr. Shorta Yuasa recently left Lahey to work at a different clinic. Mr. Pesce's diagnosis and treatment program have remained the same under his new treating physician. Ginsberg ¶ 4.

[2] https://www.vivitrol.com/.

authors attributed to it being "more difficult to initiate patients to [Vivitrol]." Def. Ex. F at 1.[3]

Third, Defendants claim that no HOC in Massachusetts "provides methadone to its male detainee population" (Eastman ¶ 19), leaving out the critical fact that incarcerated pregnant women at South Bay and MCI Framingham are, if diagnosed with OUD, *routinely* treated with methadone. Walley ¶¶ 6, 11-12.

II. MR. PESCE IS LIKELY TO SUCCEED ON THE MERITS

Defendants' policy will, without any individualized consideration of Mr. Pesce's circumstances, deny him the treatment his doctor has deemed medically necessary in favor of a single shot of Vivitrol near the end of his incarceration. This constitutes deliberate indifference in violation of the Eighth Amendment and, given that Middleton HOC provides continuity of care for other disabled inmates, violates the ADA. Therefore, Mr. Pesce is likely to succeed on the merits of his claim, and preliminary injunctive relief should be granted.

A. Plaintiff's Claims Are Ripe for Review

Defendants argue that "Plaintiff's request for injunctive relief is based on uncertain future events that may or may not occur." Opp. at 4. To successfully "seek[] shelter behind a ripeness defense," however, Defendants "must demonstrate more than a theoretical possibility that harm may be averted." *See Riva v. Massachusetts*, 61 F.3d 1003, 1011 (1st Cir. 1995). The harm resulting from a mandatory incarceration for a charge to which Mr. Pesce intends to plead guilty is sufficiently definite to warrant decision now. *See id.*

[3] Only ***after*** initiation did the authors conclude that Vivitrol and buprenorphine/naloxone were equally effective. Also, not one of the studies measured the efficacy of a single shot of Vivitol. *See* Def. Ex. A (12 weeks of treatment); Def. Exs. B, D, and F (24 weeks of treatment); Def. Ex. C (mean treatment duration of 95 days); Def. Ex. E (6 months of treatment). Nor did any study measure the efficacy of Vivitol in patients who were forced to withdraw from two years of successful methadone treatment.

B. Defendants' Blanket Treatment Policy, Which Ignores Mr. Pesce's Specific Medical Needs, Violates the Eighth Amendment

Defendants do not dispute that Mr. Pesce's OUD creates a "serious" medical need for Eighth Amendment purposes. The only point of dispute is whether Defendants will act with deliberate indifference to Mr. Pesce's medical need by applying a generic protocol that denies *all* inmates access to *all* of the FDA-approved OUD medications during *all but one day* of their incarceration, without regard for Mr. Pesce's individual medical circumstances.

As Defendants acknowledge, the Eighth Amendment requires that treatment provided to incarcerated individuals must be "reasonably commensurate with modern medical science." Opp. at 5 (citations omitted). Yet Defendants offer no evidence that denying Mr. Pesce his methadone treatment, thereby forcing him into withdrawal and meaningfully increasing his risk of overdose, is commensurate with current medical standards.[4] Indeed the *only* evidence in the record is that discontinuing Mr. Pesce's methadone treatment is categorically contrary to the standard of care. Rosenthal ¶¶ 36-37; Potee ¶¶ 15, 31; Yuasa ¶¶ 19-20; MacDonald ¶ 20.

Defendants' practice reflects their strict adherence to a "one size fits all" policy of forced withdrawal, comfort drugs, and a single shot of naltrexone within 24 hours of release. This practice is expressly nonresponsive to each inmate's particularized needs and medical history. Courts in this district have consistently held that the Eighth Amendment requires decisions made

[4] Defendants' citation to a decision from 1979 (*see* Opp. at 11), and a district court decision based thereon (*see* Opp. at 12 (citing *Love v. Thompson*, 2016 WL 6991202, at *5, (W.D. Pa. Nov. 28, 2016)), hardly reflect current medical standards. Nor are Defendants' other cases persuasive, as they found no Eighth Amendment violation where a treatment decision was made by medical staff based on an *individual assessment*, rather than a blanket policy. *See Gaston v. Patel*, 2013 WL 6070053, at *3-4 (E.D. Cal. Nov. 18, 2013); *Corley v. Prator*, 290 F. App'x 749, 752-53 (5th Cir. 2008). Defendants also misstate *Davis v. Carter*, 452 F.3d 686 (7th Cir. 2006), which found disputed issues of fact as to the Eighth Amendment issue, where an inmate had made repeated requests for methadone during his incarceration, never received methadone, and died of a cerebral aneurysm shortly thereafter.

about the treatment of prisoners to be based on an individualized assessment of medical need.[5] Whatever general accolades it may have received, Defendants' blanket policy cannot pass constitutional muster on the facts of *this* case. No policy can justify denying Mr. Pesce what is for him the only effective treatment of a dangerous disorder that puts his life at risk.

C. Defendants' Anti-Methadone Policy Does Not Constitute a "Reasoned Medical Judgment" Immune from Scrutiny Under the ADA

Defendants limit their discussion of Mr. Pesce's ADA claim to a single paragraph. Opp. at 13. Defendants readily admit they will deny Mr. Pesce the benefit of continued access to his prescribed methadone treatment during his incarceration. But they assert that this denial reflects a "reasoned medical judgment" about the appropriate course of treatment. Opp. at 13 (citing *Kiman v. N.H. Dep't of Correction*, 451 F.3d 274, 285 (1st Cir. 2006)).

That assertion is incorrect. In *Kiman* and other decisions deferring to prison staff, the challenged course of treatment reflected an independent assessment of the inmate's condition made by *medical professionals*. *See Kiman*, 451 F.3d at 285 ("As the district court noted, prison medical staff sought Kiman's medical records, arranged an outside specialist consultation, and made reasoned medical judgments about the types of treatment and physical therapy that they thought were appropriate in his case."). Defendants offer no such "reasoned medical judgment" here. They rely instead on a blanket policy under which all inmates suffering from OUD who

[5] *See, e.g.*, *Soneeya v. Spencer*, 851 F. Supp. 2d 228, 242 (D. Mass. 2012) (Under the Eighth Amendment, "[a]dequate care is based on an individualized assessment of an inmate's medical needs in light of relevant medical considerations."); *Battista v. Dennehy*, 2006 WL 1581528, at *9 (D. Mass. Mar. 22, 2006) ("[T]he medical care of prisoners must be based on an individual professional evaluation, not a blanket rule."); *Kosilek v. Maloney*, 221 F. Supp. 2d 156, 160 (D. Mass. 2002) ("Adequate care is tailored to an inmate's particular medical needs and is based on medical considerations."); *see also De'Lonta v. Angelone*, 330 F.3d 630, 635 (4th Cir. 2003) (inmate stated Eighth Amendment claim where "refusal to provide hormone treatment to De'lonta was based solely on [a] Policy rather than on a medical judgment concerning De'lonta's specific circumstances").

are prescribed opioid-agonist therapy will be forced to withdraw from their prescribed medication upon incarceration. This effectively precludes any individualized medical assessment of an appropriate course of treatment. Such a blanket denial of continuity of care and access to prescribed medication does not apply to inmates suffering from any other chronic condition and constitutes unlawful discrimination under the ADA. *See Postawko v. Missouri Dep't of Corr.*, 2017 WL 1968317, at *12-13 (W.D. Mo. May 11, 2017) (policy "effectively prohibit[ing] medical professionals from making independent medical decisions about whether to provide" new antivirals discriminated against individuals with chronic HCV by denying them "access to life-saving medications for their disability" while providing medications to inmates with other disabilities); *McNally v. Prison Health Servs.*, 46 F. Supp. 2d 49, 58-59 (D. Me. 1999) (holding that a jury could find that a disparate policy for HIV medications violates the ADA).

Worse yet, Defendants' policy is discriminatory on its face, because it invokes outdated stigmas about people with OUD and those prescribed MAT. Far from advancing a *medical* judgment that Mr. Pesce would fare just as well by going without methadone, Defendants express the *moral* judgment that recovery is not worthwhile unless it is "drug free," and that methadone treatment "continu[es] a user's addiction by simply switching to another dangerous drug." Opp. at 5. This insistence on "drug free" recovery would not justify forcing a person with diabetes to forgo insulin, and it is an equally unlawful basis to force someone with OUD to forgo methadone. And, as SAMHSA admonishes, "[a] common misconception associated with MAT is that it substitutes one drug for another," but "MAT programs provide a safe and controlled level of medication" that has "no adverse effects on a person's intelligence, mental capability, physical functioning or employability."[6] Under the ADA, a treatment determination

[6] https://www.samhsa.gov/medication-assisted-treatment/treatment

may be facially discriminatory when "it rest[s] on stereotypes of the disabled rather than an individualized inquiry into the patient's condition." *Kiman*, 451 F.3d at 284-85 (1st Cir. 2006) (quoting *Lesley v. Chie*, 250 F.3d 47, 55 (1st Cir. 2001)). That is the case here.

III. THE COURT SHOULD NOT DEFER TO UNSUPPORTED SECURITY CONCERNS

Defendants argue that the Court must defer to their assessment that the administration of methadone in their correctional facility is precluded by "safety and security problems." *See* Opp. at 7-8, 15-18. However, the Court should not defer to such assertions where, as here, they are grounded upon irrelevant, inaccurate, or unreliable evidence. *See Battista v. Clarke*, 645 F.3d 449, 454-55 (1st Cir. 2011) (no deference owed to "a composite of delays, poor explanations, missteps, changes in position and rigidities"); *cf. Kosilek v. Spencer*, 774 F.3d 63, 92 (1st Cir. 2014) (en banc) (determinations must be "within the realm of reason and made in good faith").

Defendants' arguments are based entirely on the Affidavit of Superintendent Aaron Eastman, plus a news article and a YouTube video. *See* Opp. at 7-8. Mr. Eastman only speaks in generalities, without addressing the key questions in *this* case: Can Middleton safely and securely store Mr. Pesce's methadone in its infirmary? Do protocols exist to safely and securely administer prescription methadone to Mr. Pesce without diversion? Can Mr. Pesce be safely and securely transported to a methadone clinic when necessary to obtain his medication? On this record, where Mr. Pesce has no history of violence and receives methadone from a clinic near the Middleton HOC, the answer to each question is undeniably "yes."

In fact, Massachusetts correctional facilities *already* administer methadone safely and securely to pregnant inmates on a daily basis. Dr. Walley has supervised the administration of methadone to incarcerated pregnant women at the South Bay HOC since 2007. *See* Walley ¶ 6. Once a week, a corrections officer and nurse transport these inmates to a nearby methadone

clinic, where they are evaluated and receive a dose of methadone. *See id.* ¶ 7. The clinic then provides six take-home doses of methadone in a locked container to the corrections officer, for storage in South Bay's secure infirmary area. *See id.* ¶ 7. For the next six days, the inmates self-administer a daily dose of medication in the infirmary under the supervision of a nurse. *See id.* ¶ 8. Because methadone is a liquid that is administered orally, there is a simple and well-established protocol to ensure the dose is fully ingested—the inmates must drink a glass of water after the dose and then speak to the nurse. *See id.* at 8; *see also* MacDonald ¶¶ 12, 18. The medication has been safely and securely delivered in this fashion for many years. *See* Walley ¶ 11. Superintendent Eastman seems to be aware of such programs. *See* Eastman ¶ 19. Yet he offers no explanation for why medication that is routinely administered to pregnant female inmates must be categorically denied to all male inmates.

South Bay's successful methadone program is no outlier. MCI-Framingham has secured its own opioid treatment provider license, so its staff now directly administers methadone to pregnant inmates. *See* Walley ¶ 12. Prisons in Rhode Island have routinely administered all three FDA-approved medications to inmates with OUD since 2016.[7] Similarly, Rikers Island in New York has administered methadone since at least 2013. MacDonald ¶ 5. Correctional facilities in California, Illinois, Connecticut, and New Jersey have also deployed MAT using the opioid agonists methadone and buprenorphine. MacDonald ¶ 10.[8] Indeed, the National

[7] Joseph, "One state takes a novel approach to opioid addition: access to treatment for all inmates," Stat News (August 3, 2017), available at https://www.statnews.com/2017/08/03/opioid-treatment-prisons/; Arditi, "U.S. drug czar Michael Botticelli calls RI a national leader in treating drug-addicted inmates," Providence Journal (July 26, 2016), available at http://www.providencejournal.com/news/20160726/us-drug-czar-michael-botticelli-calls-ri-national-leader-in-treating-drug-addicted-inmates.

[8] Additionally, the Maine Department of Corrections recently entered into a settlement agreement to provide MAT to an inmate after it had initially raised generalized security concerns similar to Defendants. *See Smith v. Fitzpatrick*, No. 1:10-cv-00288, D. Maine, ECF Nos. 21, 30.

Commission on Correctional Health Care recommends continued methadone treatment for inmates, particularly for those facing incarceration of less than six months.[9] The same deployment could occur for Mr. Pesce at Middleton, particularly given that his clinic stands ready to assist and is less than two miles away.[10] Moreover, offering agonist therapy to inmates may reduce the risks of illicit opioid use complained of by Defendants.[11]

Accordingly, this Court is not being asked to pit its own judgment against that of the prison administrators. *See Kosilek,* 774 F.3d at 94. Rather, Middleton officials are rejecting widespread correctional medical practices based on the misapprehension that FDA-approved opioid agonist therapies are "forms of illegal drugs," *see* Eastman ¶¶ 12-13, and "do[] not get the user closer to being drug-free." *See* Opp. at 5. Defendants have not pointed to a single diversion or security problem caused by these programs. Instead, they rely exclusively on generalized diversion and transport-safety concerns—none of which apply to the specific facts of this case—to justify the application of their blanket treatment program here. Eastman ¶¶ 14-18. It is difficult to understand how the liquid methadone dosing protocol could allow for diversion (MacDonald ¶¶ 17-19), or why Mr. Pesce, who is facing a 60-day sentence, would risk up to ten years imprisonment for an attempted escape. *See* Mass. Gen. Laws Ch. 268 Sec 16.

IV. THE OTHER FACTORS FAVOR INJUNCTIVE RELIEF

Consistent with their failure to address the specific facts of this case, Defendants do not meaningfully contest that Mr. Pesce will suffer irreparable injury absent a preliminary injunction.

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[9] National Commission on Correctional Health Care, Position Statement on Substance Use Disorder Treatment for Adults and Adolescents, available at https://www.ncchc.org/substance-use-disorder-treatment-for-adults-and-adolescents# ("NCCHC Statement").

[10] *See* Yuasa ¶ 25; NCCHC Statement (recommending strategy of "transport[ing] inmates to community OTPs or a hospital" for treatment).

[11] *See* MacDonald ¶¶ 15-16, 21-25; NCCHC Statement.

It is undisputed that forced withdrawal from methadone is painful; symptoms include bone and joint aches, vomiting, diarrhea, hypothermia, hypertension, and tachycardia. Rosenthal ¶ 34.

Unfortunately, physical pain is not the only harm. Defendants do not rebut Mr. Pesce's evidence that forcing him into methadone withdrawal will also increase his risk of relapse, overdose, and death. *See* Rosenthal ¶ 36; Potee ¶ 22; Yuasa ¶¶ 18-19, 21; MacDonald ¶ 20. To the contrary, their own evidence demonstrates that these risks are all too real. Illicit drugs circulate at Middleton HOC, Eastman ¶¶ 14-15, and last year 10 inmates overdosed while in the custody of the Sheriff's Department. *See* Def. Ex. I at 1. Mr. Pesce and his treating physician fear that he will meet the same fate if he is forcibly withdrawn from methadone. Pesce ¶¶ 3, 29-32; Yuasa ¶¶ 22-24, 26-27. Significantly, this risk will continue even if Mr. Pesce survives Middleton. As Defendant Coppinger has acknowledged, "without proper planning in place, [our inmates with addiction issues] are 58 times at a greater risk to overdose than those not previously incarcerated." D. 41-14 at 44. But Mr. Pesce *has* a proper plan; it's the one prescribed by his doctor. It is Defendants' policy, not the mere fact of incarceration, that is risking is life.

The balance of equities and public interest also favor an injunction. In addition to the inapplicable generalized assertions concerning prison security and diversion addressed above (Section III), Defendants claim that an injunction will cause "undue burden" because recently-passed legislation in Massachusetts has not resulted in state-wide "best practices." Opp. at 18-19. This too is inconsistent with the actual evidence. Many correctional institutions—including Franklin and South Bay in Massachusetts—have successfully administered methadone for years, without "undue burden." MacDonald ¶¶ 8-13; Exs. 1-2. If anything, the Massachusetts legislation reflects the legislature's judgment that administering opioid agonists to incarcerated people is feasible, does not pose a security threat, and is in the public interest.

Respectfully submitted,

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Dated: October 26, 2018

CERTIFICATE OF SERVICE

The undersigned counsel certifies that on October 26, 2018, the foregoing document, filed using the CM/ECF system, will be delivered by email to the following:

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/s/ Robert Frederickson III

Exhibit 1

Commonwealth of Massachusetts
Office of the Sheriff

Franklin County

DIRECTIVE

Protocol Medically Assisted Treatment (Induction, Maintenance & Pre-Release)

DATE: **September 13, 2018**

ISSUED BY: **Superintendent Lori M. Streeter:** Lori M. Streeter

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At every intake, a substance use disorder assessment is completed. This encompasses alcohol, prescription medicines, cocaine, heroin, and other misused substances.

If an inmate, at any point during incarceration indicates they have an opioid use disorder and/or is using buprenorphine or buprenorphine/naloxone in a supervised setting and is interested in Medically Assisted Treatment (MAT), he/she may be eligible for consideration of MAT. Also, if an inmate voices interest in MAT upon admission, the medical provider will be contacted for review and possible admission to induction protocol. If an inmate voices interest in MAT for pre-release induction, the inmate will undergo an evaluation by the medical provider prior to induction.

Prior to any induction, the inmate will sign a consent for buprenorphine treatment, be educated on MAT protocol, and the Shift Commander will be notified.

The following steps will take place to ensure the inmate is eligible for MAT:

1. Medical Staff will check the Massachusetts Prescription Monitoring Program (PMP) to confirm that the patient is in treatment with buprenorphine or buprenorphine/naloxone for maintenance. Confirmation of their most recent prescription may need to be made by calling their pharmacy as the PMP data entry can be delayed by as much as 10 days.

2. Medical staff should request a Release of Information from their treatment provider and confirm with that provider that the patient is active with the clinic. This should be done on the next business day. It should be made known that the patient is currently at the Franklin Count House of Correction and that treatment will continue under our care. It should also be indicated that we want their treatment to continue without much interruption at release. Concomitant non-prescription opiate and other substance use does not disqualify a patient from MAT.

3. Medical Staff should call the on-call provider for the verbal orders for buprenorphine or buprenorphine/naloxone via their on-call contact number. As it is not a medical emergency, 8-12 hours can pass if he/she is unavailable at the first call.

4. On the morning after intake, the inmate should be given the buprenorphine or buprenorphine/naloxone with clear instructions on use. Most people will never have used this drug before in this form. The buprenorphine or buprenorphine/naloxone tablets are crushed and placed sublingually by nursing staff. If an inmate enters the facility using 24mg, the maximum dose will be the threshold dose of 16mg.

   Dosing should happen each morning and will happen once daily in accordance with Directive – Dispensing Protocol for Medically Assisted Treatment (MAT) of Opioid Use Disorder.

   Urine Drug Screens shall be performed randomly at least once a week. If any patient is suspected of diversion, they may be removed from the program at the discretion of the Medical Director or Nurse Practitioner.

   If an inmate also screens for active Alcohol or Benzodiazepine Use Disorder, they will also be treated under the current substance-specific withdrawal protocol separate and distinct from the MAT.

Exhibit 2

Commonwealth of Massachusetts
Office of the Sheriff

Franklin County

DIRECTIVE

Dispensing Protocol for Medically Assisted Treatment (MAT) of Opioid Use Disorder

DATE: **September 13, 2018**

ISSUED BY: **Superintendent Lori M. Streeter:** Lori M. Streeter

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Daily Medication call for Medically Assisted Treatment for Opioid Use Disorder

1. Medication Distribution will commence at 6:00am and will take place in the medium security library. A maximum of 15 inmates will be moved to the programs area in OMS and will be counted in the library during this time. Three security staff will be assigned at all times to monitor the medication distribution unless the group of inmates is six or less, at which time, the number of security staff can be reduced to two. Security staff will follow the direction of medical personnel.

   Medication distribution grouping will be organized by the overnight shift supervisor in accordance with the information below. If numbers dictate, all groups will be filled to capacity.

   a. Group 1 (Library)
      Court
      Community Service/Off site jobs
      Offsite morning appointments
      Security Quarantine
      All other inmates from Pod A, C, and D

b. Group 2 (Library)

Female inmates (Female inmates scheduled for court will be medicated by the 5:30am – 5:30pm nurse between 5:30am-6:00am in the Medical department.)

c. Group 3 (Library)

Segregation inmates (All segregation inmates can be grouped together unless enemy status dictates. Inmates shall remain handcuffed in the front during medication pass.)

d. Group 4

High risk group (consists of previous inmates who have been removed from the MAT program for not following the MAT protocol and have been given another opportunity to remain on MAT as continuation of treatment, as well as getting it as a pre-release induction, or maintenance if re-admitted to the facility.)

e. Any remaining inmates on the list will be incorporated into additional sessions in the library until the conclusion of the distribution process (up to 15 per session) is completed. In the event the medication distribution lasts until 8:45am, and at the direction of shift commander, inmates will be escorted to the intake/booking area (current restraint chair area) and have their medication distributed there. If the restraint chair area is in use, the medication pass will take place in the booking iso-pass area. **Distribution on Sunday can remain in library for the duration of the distribution.**

f. An officer shall be assigned to escort inmates to the intake/booking area with a nurse and remain with the nurse until distribution is completed. Once in the intake area inmates shall be seated in chairs and will adhere to the same procedures required in the library.

2. Security Staff shall call the Housing Units and request the necessary inmates to be seen.

3. The Housing Unit Officer shall log the inmate/s out to medical documenting the name and time of departure on the Unit Log.

4. In both locations, Officer will instruct inmates to sit on their hands and remain in this position for the duration of medication distribution.

5. The Nurse on duty will administer the crushed Buprenorphine or Buprenorphine/Naloxone sublingual (under the tongue) per the provider order. There will be no talking, manipulating of medication with tongue or mouth movements for the remainder of the distribution time. The nurse will visually check with a flashlight to ensure that the crushed sublingual medication remains under the tongue.

6. After all inmates have received their medication, the group will remain in the waiting area (both locations) with the Officer and Nurse for approximately 15-18 minutes. After this time has passed, the nurse will complete a final mouth check with a flashlight to determine if the crushed sublingual medication has fully dissolved. Inmates who receive their medication in both locations (library and intake/booking area) shall be individually, with their hands behind their backs, escorted to the bathroom by the Officer. Prior to being escorted to the bathroom, the inmate shall move his/her chair to the opposite side of the medication distribution line. Medical staff will instruct the inmate to begin a mouth rinse and spit the residue out, then have the inmate eat one package of saltine crackers, and repeat rinse and spit. The inmate shall then be instructed to use their fingers to open and expose their upper and lower lip, under their tongue and do a complete finger sweep of their mouth. At this time the inmates are to wash their hands. Prior to returning to the unit, the Officer shall conduct another mouth and hand check. If the inmate salivates onto any part of their jumpsuit, that piece of clothing will be removed and replaced.

7. If an inmate on MAT has dentures, the following shall apply. If the inmate is able to chew crackers without dentures, the dentures will be left in his/her cell for MAT distribution. If the patient is not able to chew crackers without dentures, the dentures may be kept on person (pocket) during MAT. After the inmate has completed the first mouth rinse/check, the dentures may be worn to proceed with the cracker consumption.

8. Once all inmates from Minimum Security/Kimball House have completed their final mouth rinse/check, they will immediately be escorted back to the minimum security building in preparation for work details. All remaining medium security inmates will wait until the rest of the group has undergone the mouth rinse/check before being transported back to the housing unit.

9. Inmates that are in Protective Custody Status will be escorted to the medication distribution area (individually or in a group of up to 15) and adhere to the procedures above.

10. If an inmate is suspected of tampering with or attempting to divert the medication, the Officer present shall follow the FCSO disciplinary procedure.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GEOFFREY PESCE, Plaintiff, v. KEVIN F. COPPINGER, in his official capacity as Essex County Sheriff, AARON EASTMAN, in his official capacity as Superintendent of the Essex County House of Corrections - Middleton, Defendants.	C.A. No. 1:18-cv-11972-DJC

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 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 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 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—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 ("MAT") 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 collaboration 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, San Francisco, 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.

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 correctional facilities in Massachusetts, 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 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, San Francisco 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 medication-assisted treatment, 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.[1] 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

[1] Larney et al., "Opioid substitution therapy as a strategy to reduce deaths in prison: retrospective cohort study," BMJ Open 2014, attached hereto as Exhibit 2.

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 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 a crushed formulation of generic buprenorphine, or liquid buprenorphine that is poured under the tongue, which has little chance to be diverted;

e. Using the combination of nursing staff and a correctional officer to administer and observe the process;

f. One jurisdiction has 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. Though the opioid antagonist, naltrexone (aka Vivitrol) is often considered a form of MAT, it is the least well studied of the three forms of MAT and has not been clearly shown to

reduce risk of overdose death as methadone and buprenorphine have. It would be grossly inappropriate treatment to force a patient who is stably in treatment with either methadone or buprenorphine to transition an antagonist medication such as Vivitrol. Such a forced transition would impose unnecessary suffering associated with withdrawal (which is only partly mitigated by treatment) as well as risk destabilizing recovery, and thereby would increase the risk of relapse, infection and overdose death.

B. Drug Trafficking and Other Safety Concerns

21. 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.

22. 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.

23. 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.

24. 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.

25. 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 October 26, 2018

Ross MacDonald, M.D

CERTIFICATE OF SERVICE

The undersigned counsel certifies that on October 26, 2018, the foregoing document, filed using the CM/ECF system, will be delivered by email to the following:

Stephen Pfaff
101 Summer Street
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Boston, MA
spfaff@lccplaw.com

/s/ Robert Frederickson III

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GEOFFREY PESCE, Plaintiff, v. KEVIN F. COPPINGER, in his official capacity as Essex County Sheriff, AARON EASTMAN, in his official capacity as Superintendent of the Essex County House of Corrections - Middleton, Defendants.	C.A. No. 1:18-cv-11972-DJC

DECLARATION OF ALEXANDER YALE WALLEY, MD, MSc

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

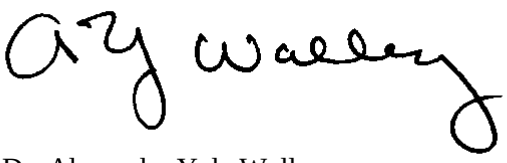
Program of the Boston Public Health Commission. Between 2014 and 2016, I was the site medical director of the Opioid Treatment Program of the Health Care Resource Centers in Boston. I have continued as a physician at the Opioid Treatment Program of the Health Care Resource Centers in Boston (23 Bradston 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. 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.
7. 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, updated and resubmitted at least quarterly
8. 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.

9. We typically administer methadone to anywhere between 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.
10. Administering methadone to incarcerated pregnant women has not disrupted our clinic or caused any administrative difficulties.
11. 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.
12. Pregnant inmates in Massachusetts also receive methadone at the Massachusetts Correctional Institute at Framingham ("MCI Framingham"). That facility applied for and received its own opioid treatment provider (OTP) license. As a result, staff at MCI Framingham now administer methadone directly to pregnant women incarcerated at the facility.
13. 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 incarcerated male patients with the same high degree of safety, security, and efficacy.
14. 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. The daily dosing rate that MassHealth reimburses methadone programs is $10.49, which covers the cost of medication, provider services and administrative expenses.

Executed on October 25, 2018



Dr. Alexander Yale Walley

CERTIFICATE OF SERVICE

The undersigned counsel certifies that on October 26, 2018, the foregoing document, filed using the CM/ECF system, will be delivered by email to the following:

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/s/ Robert Frederickson III

IN THE UNITED STATES DISTRICT COURT
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GEOFFREY PESCE, Plaintiff, v. KEVIN F. COPPINGER, in his official capacity as Essex County Sheriff, AARON EASTMAN, in his official capacity as Superintendent of the Essex County House of Corrections - Middleton, Defendants.	C.A. No. 1:18-cv-11972-DJC

DECLARATION OF BARRY GINSBERG, MD

I, Barry Ginsberg, M.D. declare as follows:

1. My name is Dr. Barry Ginsberg. I am the Chief Medical Officer at Lahey Behavioral Health Services (Lahey).
2. I oversee Lahey's Danvers Treatment Center, which currently administers Geoffrey Pesce's methadone treatment.
3. Dr. Shorta Yuasa, who had been Mr. Pesce's treating physician at Lahey, recently left our practice to work at a different clinic.
4. Mr. Pesce's diagnosis and treatment program have remained the same under his new treating physician.

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

Executed on October 26, 2018

Dr. Barry Ginsberg

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