UNITED STATES DISTRICT COURT
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.	)	Civil Action No. 18-cv-11972

MOTION OF MASSACHUSETTS MEDICAL SOCIETY *ET AL* FOR LEAVE TO FILE *AMICI CURIAE* BRIEF IN SUPPORT OF PLAINTIFF'S EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

As preeminent associations comprised of leaders in the field of medicine, behavioral health, and addiction medicine, *Amici* respectfully seek leave to file the attached *Amici Curiae* brief ("Brief") in support of plaintiff's motion for a temporary restraining order and preliminary injunction.

Amici believe their expertise regarding the treatment of Opioid Use Disorder ("OUD") with medication-assisted therapy ("MAT") would provide the Court with detailed understanding of the state of research into the relative benefits and risks associated with various types of OUD treatment, including the scientific consensus on the efficacy of methadone maintenance programs and the defendants' current treatment.

Amici briefs are appropriate when the *Amici* have unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide. *See* Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE AND

PROCEDURE § 3975 (4th ed.). This Court has inherent authority to accept *amici* submissions, and the Brief of these *Amici* meets these standards. *See, e.g., Verizon New England, Inc. v. Maine Pub. Utils. Comm'n*, 229 F.R.D. 335, 338 (D. Me. 2005).

Amici have limited their Brief to fewer than 6,500 words. Counsel for *Amici* have conferred with counsel for both the plaintiff and defendant per Local Rule 7.1(a)(2); the plaintiff consents to this motion, but the defendants do not.

Granting leave to file this Brief will not prejudice the defendants, as the results of evidence-based clinical research cannot, by nature, be prejudicial to the truth. Thus, based upon the insights these *Amici* are able to share, this Court should grant *Amici's* motion for leave to file their Brief.

Respectfully Submitted,

MASSACHUSETTS MEDICAL SOCIETY ET AL

By Their Attorneys,

/s/ Joel K. Goloskie
Joel K. Goloskie (BBO# 675806)
PANNONE LOPES DEVEREAUX & O'GARA LLC
One International Place, Suite 1400
Boston, MA 02110
Ph: 617.535.7724
Fax: 866.353.5020
jgoloskie@pldolaw.com

CERTIFICATE OF SERVICE

I certify that on November 19, 2018, I submitted the foregoing to the Clerk of Court for the U.S. District Court for the District of Massachusetts and all counsel of record using the Court's electronic case filing system.

/s/ Joel K. Goloskie
Joel K. Goloskie

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INTRODUCTION

Amici are preeminent associations comprised of leaders in the fields of medicine, behavioral health and addiction medicine. They have knowledge and expertise relevant to the interface of criminal justice and Opioid Use Disorder ("OUD"), and seek to educate the Court about the most current medical science and professional standards that inform the issues presently before this Court.

Our nation is gripped by an opioid epidemic that claimed a stunning 115 lives per day in 2016. Drug overdose is now the leading cause of death for those under 50. A disproportionately large percentage of incarcerated persons have opioid use disorder, many with a co-occurring mental illness. There is medical consensus that OUD is a chronic brain disease that is characterized by continued use of opioids despite negative consequences, and that ineffectively-treated OUD results in a high rate of relapse and overdose. Decades of research shows that Medication Assisted Treatment ("MAT") is the most effective treatment modality for OUD, and that opioid agonist maintenance therapy, using a medication such as methadone or buprenorphine, is far more effective at preventing relapse and saving lives than are withdrawal programs. Furthermore, there is no research supporting withdrawal or detoxification programs alone, especially those that do not include MAT (such as that run by the defendants) as sufficient treatment for opioid use disorder.

Three FDA-approved drugs currently exist to provide MAT, and the current standard of research and clinical guidelines states that the most effective MAT modality varies from person to person. Accordingly, altering an individual's prescribed course of MAT for nonclinical reasons (including by substituting one medication for another) could result in the individual receiving substandard treatment, and thus facing an increased risk of relapse. This is particularly true where, as here, prior treatment regimens using different medications have

failed the plaintiff, and resulted in relapse. Simply put, ceasing ongoing methadone treatment and imposing the defendants' non-MAT based, forced withdrawal program on this plaintiff is entirely contrary to the current research and clinical standards.

STATEMENT OF INTEREST OF AMICI CURIAE

The ***Massachusetts Medical Society***, with some 25,000 physicians and student members, is dedicated to educating and advocating for the patients and physicians of Massachusetts, with a strong emphasis on supporting evidence-based, patient-focused approaches toward battling the opioid crisis in the Commonwealth and across the country. Founded in 1781, MMS is the oldest continuously operating medical society in the country. The Society, under the auspices of NEJM Group, publishes the New England Journal of Medicine, a leading global medical journal and web site, and Journal Watch alerts and newsletters covering 13 specialties. The clinical research on OUD treatment published in the Journal represents the most current and methodologically sound findings in this important field of medicine.

The ***Association for Behavioral Healthcare*** (ABH), located in Natick, Massachusetts, is a preeminent voice in the field of behavioral healthcare, with four decades of experience advancing, promoting and preserving community-based mental health and addiction services for individuals and families. ABH creates strategies that positively change public policy through legislative, budgetary and regulatory advocacy. ABH identifies and impacts emerging issues relating to mental health and addiction treatment services. ABH has 86 member organizations across the Commonwealth, many of whom provide a continuum of addiction treatment services.

The ***Massachusetts Society of Addiction Medicine (MASAM)*** is a statewide medical organization providing education, leadership, and support for physicians, trainees and allied

health professionals in support of excellence in care of people with substance use disorders and of access to such care for all. MASAM is a chapter of the American Society of Addiction Medicine, the flagship organization in the field of addiction medicine and the publisher of *The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*.

STATEMENT OF THE ISSUE

Whether a correctional facility's policies for patients with Opioid Use Disorder, which unilaterally impose a non-MAT, forced withdrawal program on all incarcerated individuals with Opioid Use Disorder, and which impose cessation of all existing MAT regimens, is commensurate with modern medical science and of a quality acceptable within prudent professional standards.

SUMMARY OF THE ARGUMENT

There is consensus within the global medical community that OUD is a disease involving alteration of neural circuitry in the brain. There is medical consensus that the most effective treatment regimens for OUD include MAT, and there is incredibly robust data demonstrating the effectiveness of methadone maintenance programs in reducing mortality. As many persons with OUD fail to recover on originally-prescribed medications, there is also medical consensus that the most effective form of MAT varies from person to person.

While research shows that MAT-based withdrawal programs are largely ineffective in preventing relapse and are thus not within the standard of care for OUD treatment, no research has found non-MAT based withdrawal programs, like that operated by the defendants, to have any meaningful success in preventing relapse. Here, the defendants do not utilize any MAT during detoxification, and only give patients one dose of extended-release naltrexone the day prior to release, thereby requiring the cessation of all existing

MAT regimens upon entry to the facility. Patients do not leave the facility with additional medication, a referral to a physician providing MAT for their opioid use disorder, or even a prescription.

The plaintiff has relapsed prior on other MAT medications; whereas, he has remained in remission and recovery while on his currently-prescribed regimen of methadone. This is consistent with the literature, which shows methadone and buprenorphine are first-line treatments that are proven to reduce mortality, and that extended release naltrexone should not alone be considered a medically appropriate treatment program. In fact, the literature shows that the odds of relapse from the defendants' type of "one and done" antagonist dosing, rather than allowing continuation of a clinically appropriate MAT such as methadone, make it likely that the plaintiff will relapse shortly after being released back into the community, if he does not do so even before leaving the correctional facility.

Accordingly, *Amici* believe that the defendants' opioid use disorder program which provides non-MAT detoxification, and which prohibits methadone or buprenorphine prescribing, and which only allows for an extended-release naltrexone shot at discharge, places the plaintiff at significant, unnecessary risk of relapse, and thus is not commensurate with modern medical science or of a quality acceptable within prudent professional standards.

ARGUMENT

I. Withdrawal Programs Lead to Avoidably High, Unacceptable Rates of Relapse, Overdose and Death

A. OUD is a Chronic Brain Disease

Prevailing understandings of neuroscience continue to support the brain disease

model of addiction.[1] In fact, the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders – the leading authority on mental disorders – states that "[a]n important characteristic of substance use disorders is an underlying change in brain circuits."[2] In the introductory page to a 2016 report on alcohol, drugs and health by the U.S. Surgeon General, no less than the Secretary of the U.S. Department of Health and Human Services states that "addiction is a chronic neurological disorder and needs to be treated as other chronic neurological conditions are."[3] OUD is similar to that of other chronic relapsing conditions such as diabetes and hypertension.[4]

B. Detoxification-alone is a Dangerously Outdated Model

The clinical course of OUD involves periods of exacerbation and remission, but the underlying vulnerability never disappears.[5] The concept of an OUD sufferer "getting clean" by detoxication alone after a period of withdrawal is an outdated model, inconsistent with the current literature.[6] Accordingly, the underlying change in brain circuitry arising from OUD carries a grave risk of potentially-fatal relapse if ineffectively treated: the opioid epidemic, as noted, claimed an average of 115 lives a day in 2016.[7]

C. MAT-assisted Programs are Effective in Avoiding Relapse and Saving Lives

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[1] *Volkow et al., Neurobiological Advances from the Brain Disease Model of Addiction, N Engl J Med* 2016;374:363-71.
[2] *American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (5th ed.)*, p. 483 (2013) (commonly referred to as the "DSM-5").
[3] U.S. Department of Health and Human Services. *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, 2016*, Intro. by Secretary Sylvia Mathews Burwell, p. I, avail. at: https://www.surgeongeneral.gov/library/2016alcoholdrugshealth/index.html.
[4] Shukit MA. Treatment of opioid use disorders. *N Engl J Med* 2016; 375;4(357).
[5] *Id.* (citing O'Brien CP. Drug addiction. In: Brunton L, Chabner B, Knollman B, eds. Goodman & Gilman's the pharmalogical basis of therapeutics. 12th ed. New York: McGraw-Hill, 2011:649-66).
[6] *See id.*
[7] Samet JH, Botticelli M, Bharel M. Methadone in primary care – one small step for Congress, one giant leap for addiction treatment. *N Engl J Med* 2018; 379;1:7.

MAT is an evidence-based approach to OUD treatment that focuses on medical therapy , in the form of an opioid agonist or antagonist, often combined with counseling and recovery support.[8] Decades of research have demonstrated the efficacy of medications such as methadone and buprenorphine in improving remission rates and reducing both medical complications and the likelihood of overdose death.[9]

Methadone and buprenorphine are opioid agonists: they substitute themselves for the more dangerous and addictive forms of opioids in a manner that helps the patient's re-wired brain avoid relapse. Opioid agonists are commonly used in both maintenance and detoxification purposes.[10] Antagonist medications, by contrast, reduce a OUD patient's "high" from opioid ingestion, and thus attempt to weaken the stimulus-reward mechanism leading to continued use.

D. Maintenance Programs Save Lives While Withdrawal Programs are Largely Ineffective

MAT maintenance programs, the gold standard in OUD care, prescribe a steady dose of methadone or buprenorphine, such that the patient can avoid the craving for illicit opioids and successfully engage with the activities of daily life. Maintenance programs using an agonist like methadone or buprenorphine have demonstrably better outcomes than withdrawal ("detox") programs for important patient-centered outcomes such as overdose death, rates of communicable disease, retention in treatment, and relapse.[11] Multiple studies

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[8] Dunlap B, Cifu AS. Clinical management of opioid use disorder. *JAMA Clinical Guidelines Synopsis. JAMA* Vol. 316, No. 3. (July 19, 2016)
[9] Wakeman SE, Barnett ML. Primary care and the opioid-overdose crisis – buprenorphine myths and realities. *N Engl J Med* 2018 379;1(1).
[10] Stotts AL, Dodrill CL, Kosten TR. Opioid dependence treatment: options in recovery. *Expert Opin Pharmacother*, 2009 Aug; 10(11):1727.
[11] Dunlap B, Cifu, AS. Clinical management of opioid use disorder. *JAMA Clinical Guidelines Synopsis. JAMA* Vol. 316, No. 3. (July 19, 2016) (citing Mattick RP, Breen C,Kimber J, Davoli M. Buprenorphine maintenance vs placebo or methadone maintenance for opioid dependence.

of withdrawal demonstrate that the majority of patients relapse with withdrawal management alone, even with tapering with opioid agonist medications to alleviate withdrawal symptoms.[12] One 2010 prospective cohort study of 109 patients discharged from residential detoxification treatment showed that 91% of patients relapsed, with 59% relapsing in the first week.[13]

II. The Defendants' Non-MAT Withdrawal Program is Not Commensurate with Modern Medical Science or Prudent Professional Standards

A. No Research Supports the Defendants' Non-MAT Based, Forced Withdrawal Program

The defendants operate a non-MAT based, forced withdrawal program. The fact that they give each inmate a single dose of extended release naltrexone the day before they returned to the community does not make their method an MAT-based program: they force inmates through the painful withdrawal process without the titrated use of an opioid agonist or antagonist of any type. While they may give ibuprofen or other palliative medications, theirs is truly a "cold turkey" withdrawal, in keeping with an outdated—and deadly—misperception of OUD.

The defendants' non-MAT based, forced withdrawal program is not simply a case of a correctional facility using its judgment to choose among treatments that have been proven effective. *No* study has shown that detoxification programs are effective at treating OUD.[14] *Amici* must take a moment to contrast this fact to the defendants' claim in Motion Hearing

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Cochrane Database Syst Rev. 2014;(2):CD002207; also citing MacArthur GJ, Minozzi S, Martin N, et al. Opiate substitution treatment and HIV transmission in people who inject drugs. *BMJ* 2012;345(3:e5945-e5945).

[12] *Id.*

[13] *Id.* (citing Smyth BP, Barry J, Keenan E, Ducray K. Lapse and relapse following inpatient treatment of opioid dependence. *Ir Med J.* 2010;103(6):176-179.

[14] Wakeman SE, Barnett ML. Primary care and the opioid-overdose crisis – buprenorphine myths and realities. *N Engl J Med* 379;1(2), July 5, 2018.

that 13,000 people have gone through their program in the last 30 years and gone on to lead opioid-free lives.[15] Where is the documentation for this claim? Even MAT-assisted withdrawal programs lead to relapse rates over ninety percent. To claim that 13,000 people have successfully completed the defendants' non-MAT based, forced withdrawal program and remained opioid-free is unsubstantiated and reckless.

To wit, the research in this area shows that non-MAT withdrawal programs may increase the likelihood of overdose death by eliminating the tolerance that a patient has built up.[16] *Amici* believe the Court would benefit by pausing momentarily to absorb this implication: the research suggests that the defendants' program will actually increase the likelihood that the plaintiff will suffer an overdose, or even death, when he returns to the community after his sixty-day incarceration. In fact, given the availability of illicit opioids in correctional facilities, the plaintiff's may relapse and overdose while still incarcerated.

Contrast this outcome with that of the standard of clinical care: a 2017 systemic review and meta-analysis that showed a reduction in pooled all-cause mortality among people with opioid use disorder who were treated with methadone by nearly sixty-nine percent (68.7%) compared to persons not receiving methadone treatment.[17] Methadone maintenance is currently a first-line treatment for chronic opioid dependence,[18] being

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[15] *Pesce v. Coppinger*, C.A. No. 18-11972-DJC, Transcr. Of Mtn Hearing, p. 25:1-4 (Nov. 5, 2018).

[16] *Id.*; *see also* Schuckit MA. Treatment of opioid use disorders. *N Engl J Med* 375;4(358), July 28, 2016 ("However, by itself, medically supervised withdrawal is usually not sufficient to produce long-term recovery, and it may increase the risk of overdose among patients who have lost their tolerance to opioids.").

[17] Samet JH et al. *N Engl J Med* 379;1(7-8), July 5, 2018.

[18] Stotts AL, Dodrill CL, Kosten TR. Opioid dependence treatment: options in recovery. *Expert Opin Pharmacother*, 2009 Aug; 10(11):1728 (citing Lenne M, Lintzeris N, Breen C, Harris S, Hawkin L, Mattick R, et al. Withdrawal from methadone maintenance treatment: prognosis and participant perspectives. *Australian & New Zealand J Pub Health* 2001 Apr;25(2):121-25).

commonly referred to as the "gold standard" of treatments based upon its associated reductions in intravenous drug use, crime, HIV risk behaviors and mortality, and its being well-established in community treatment programs around the world.[19] Many studies have demonstrated methadone's superiority to using abstinence-based approaches.[20]

Of particular relevance, Methadone treatment has been demonstrated to be beneficial in the prison setting. Not only do prisoners receiving methadone use a lesser amount of drugs while incarcerated,[21] prisoners treated with methadone use less drugs after release and are more likely to participate in community-based addiction treatment.[22] Treatment with methadone has been shown to lower the rate of reincarceration during the 3-year period following first incarceration.[23]

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[19] Stotts AL, Dodrill CL, Kosten TR. Opioid dependence treatment: options in recovery. *Expert Opin Pharmacother*, 2009 Aug; 10(11):1736.

[20] American Society of Addiction Medicine. *The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, p.29 (June 1, 2015) (citing Mattick R., Breen C. Kimber J., et al. Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database Syst Rev* 2009. CD002209).

[21] American Society of Addiction Medicine. *The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, p.47 (citing Dolan KA, Wodak AD, Hall WD. Methadone maintenance treatment reduces heroin injection in New South Wales prisons. *Drug Alcohol Rev* 1998;17:153-158; Darke S, Kaye S, Finlay-Jones R. Drug use and injection risk-taking among prison methadone maintenance patients. *Addiction* 1998;93:1169-1175; Dolan KA, Shearer J, White B, et al. Four-year follow-up of imprisoned male heroin users and methadone treatment: mortality, reincarceration, and hepatitis C infection. *Addiction* 2005;100:820-828; Heimer R, Catania H, Newman RG, et al. Methadone maintenance in prison: evaluation of a pilot program in Puerto Rice. *Drug Alcohol Depend* 2006;83:122-129).

[22] American Society of Addiction Medicine. *The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, p.47 (citing Bertram S GA. Views of recidivists released after participating in the NSW prison methadone program and the problems they faced in the community. Sydney, Australia, Department of Corrective Services; 1990).

[23] American Society of Addiction Medicine. *The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, p.47 (citing Bertram S GA. Views of recidivists released after participating in the NSW prison methadone program and the problems they faced in the community. Sydney, Australia, Department of Corrective Services; 1990; Canada ARCRBCS. Institutional methadone

Antagonist medications are used to accelerate the detoxification process, and are appropriately prescribed post-detoxification to assist in preventing relapse.[24] While the defendants claim that their detoxification program includes the use of Vivitrol®,[25] an extended-release naltrexone antagonist, they actually do not administer Vivitrol® during the detoxification process. Instead, they provide inmates with one dose of Vivitrol® shortly prior to their release. Further, the defendants will not be prescribing a course of Vivitrol® that the plaintiff may continue after his release. He will receive only a single dose of a medication clinically which is indicated only for repeated administration over time. Unfortunately, the literature regarding naltrexone's ability to avoid long-term relapse does not support an MAT program which relies solely upon this one drug.[26]

> The following quotation, from an article currently under review, is instructive:
>
> Opioid detoxification remains a critical area of focus. There is no consensus on the most effective pharmacological strategy to achieve complete abstinence from all opiates. Relapse either during or after detoxification occurs in the majority of patients, and, for those who have the resources, return to maintenance treatment is common. Despite the dismal rates of success, a minority of patients are able to detoxify successfully from methadone, heroin and other opiates. Research has yet to determine,

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maintenance treatment: impact on release outcome and institutional behavior. Ottawa ON, Cananda. Avail. at: http://198.103.98.138/text/rsrch/reports/r119/r119_e.pdf.).

[24] Stotts AL, Dodrill CL, Kosten TR. Opioid dependence treatment: options in recovery. *Expert Opin Pharmacother*, 2009 Aug; 10(11):1727.

[25] Vivitrol® is an extended release injectable version of naltrexone.

[26] Cousins SJ, Crevecoeur-MacPhail D, Rawson RA. The Los Angeles County hub-and-provider network for promoting the sustained use of extended-release naltrexone (XR-NTX) in Los Angeles County (2010–2015). *J Sub Abuse Treat*, 2018 Feb; 85:78; but see, Lee JD et. al. Extended-Release Naltrexone to Prevent Opioid Relapse in Criminal Justice Offenders. *N Engl J Med* 374;13(1232), March 31, 2016.

> however, who will succeed and who will fail. In a recent manuscript reporting on a 6 month [agonist-assisted] detoxification study in which almost every participant returned to opioid use (methadone maintenance or illicit opioids), Grabowski et al. (under review) concluded that neither patients nor clinical researchers are adequately equipped to determine a patient's preparedness for complete withdrawal. For these reasons, experts understandably have recommended agonist maintenance treatment over detoxification.[27]

With no disrespect to the defendants, if highly knowledgeable clinical experts are not adequately equipped to determine a patient's preparedness for complete withdrawal, *Amici* see no possibility of the defendants successfully making this determination. Moreover, the defendants make no effort at such a determination, but impose withdrawal indiscriminately. Non-MAT based withdrawal, at that. The cited evidence shows that the defendants' choice to impose non-MAT based withdrawal on every incarcerated OUD sufferer will directly result in the irreparable harm of increased relapse and overdose for the majority of persons forced into their program. Given that the plaintiff has relapsed on non-methadone-based programs in the past, it is quite likely the plaintiff will be one of those for whom the defendants' forced withdrawal program will be the proximate cause of relapse and, potentially, overdose.

B. Substantial Deference Should Not Extend to Programs Contrary to Modern Medical Science or Prudent Professional Standards

Amici recognize that much of the case law to which defendants cite was decided

[27] Stotts AL, Dodrill CL, Kosten TR. Opioid dependence treatment: options in recovery. *Expert Opin Pharmacother*, 2009 Aug; 10(11):1737 (citing Grabowski J. Outcome of five-month open vs. blind dose reduction after LAAM maintenance: Heroin use, risks, and QTc. Under review.)

before the current opioid crisis. The vintage of these cases means that the courts were unable to benefit from the ever-growing body of clinical research demonstrating that OUD is a chronic, relapsing brain disease. However, given how ineffective and potentially dangerous the current literature indicates MAT-based withdrawal to be, the defendant's non-MAT based, one-size-fits-all program certainly must fail the test for substantial deference. It is insufficiently "commensurate with modern medical science [to be] of a quality acceptable within prudent professional standards," to quote the test for prison-based medical services articulated by the U.S. Circuit Court of Appeals for the First Circuit.[28]

As three internationally-respected entities that undertake and publish that modern medical science and establish those prudent professional standards, *Amici* feel themselves qualified to advise the Court with authoritative certainty that the defendants' program falls unacceptably short of both that science and those professional standards.

The sweep of substantial deference cannot include programs that fall below the current state of the science and professional standards, and thus must be limited to treatment regimens that the literature shows to have a reasonable probability of success. Based upon the ninety-plus percent relapse statistics of MAT-assisted withdrawal programs and the complete lack of credible research showing non-MAT, forced withdrawal programs like the defendants' to be effective for any but a random and impossible-to-predict few, *Amici* simply cannot see how this Court could hold the defendants' one-size-fits-all, forced non-MAT-assisted withdrawal program to be Constitutional when the relevant medical authorities find it to fall so far below the current state of the science and professional standards.

[28] Defendants' Memorandum of Law in Support of Their Opposition to Plaintiff's Motion for Temporary Restraining Order and Preliminary Injunction, 1:18-cv-11972-DJC, Doc 41, Filed 10/19/18, p. 5(citing *United States v. Derbes*, 369 F.3d 579, 583 (1st Cir. 2004) (citations and quotations omitted)).

Specifically, the defendants' program fails on at least two fronts: (1) it does not utilize an opioid agonist or antagonist at any time during detoxification, and (2) it does not match evidence-based interventions to individual needs at each stage of drug treatment, through the application of clinical judgment.

C. Defendants' Program is not MAT-based

As demonstrated by previously-cited research, MAT-based detoxification programs have dismal relapse statistics. Their sky-high relapse rates cost lives. Here, however, the defendants' detoxification process does not even utilize MAT. Neither an agonist or an antagonist medication is used during the detoxification process. The only time naltrexone is used is immediately prior to release back into the community. Based upon all the available research, after this short-term detox and one-and-done dose of naltrexone the day prior to release, the odds of the plaintiff suffering a relapse will be far greater under the defendants' restricted protocol than if the current standard of care—access to the three separate and distinct medication therapies for opioid use disorder—were to be offered.

In at least two of the cases on which the defendants rely, the court found dispositive the fact that the programs they upheld gradually weaned the plaintiff off methadone (or a similar drug) and did not force him to go "cold turkey."[29] The defendants cite to *Baker v. Stevenson*, which upheld a prison's program because "[t]he facts on hand indicate that the medical staff sought to gradually wean [Plaintiff] off Methadone rather than forcing him to go 'cold turkey.'" 605 Fed. App'x 514, 519-20 (6th Cir. 2015). Defendants also cite *French v. Daviess County, Kentucky*, wherein the court noted the prison's use of a gradual detoxification protocol so as to minimize withdrawal symptoms, and contrasted that with an

[29] Defendants' Memorandum, p. 15 (citing *Baker v. Stevenson*, 605 Fed. App'x 514, 519-20 (6th Cir. 2015); *French v. Daviess County, Ky.*, 376 Fed. App'x 519, 522 (5th Cir. 2010)).

abrupt removal of an addictive drug. 376 Fed. App'x 519, 522 (5th Cir. 2010). Here, as noted, the defendants' program provides no MAT during the traumatic detoxification process. The one dose of naltrexone they provide before the plaintiff is put back on the street comes long after the patient has gone through what is truly a "cold turkey" withdrawal. The defendants' program fails the minimum threshold articulated by the very cases the defendants cite.

Also worth noting, the cases cited by the defendants limit the irreparable harm to the patients' being forced through a cold turkey withdrawal. Given what medical science now knows about the long-term rewiring of brain circuitry that accompanies OUD, any calculation of irreparable harm arising from a withdrawal program must include the significantly-increased odds of relapse and overdose.

D. The Defendants' Program in Insufficiently Matched to Individual Needs

All persons actively suffering or recovering from OUD who enter incarceration by the defendants receive the same, one-size-fits all detoxification regimen. This is true regardless of whether they are on a prescribed MAT maintenance regimen when they present for incarceration, regardless of whether they are successfully avoiding relapse on that prescribed regime, and regardless of whether they have relapsed on other prescribed regimes in the past. The defendants even place newly incarcerated persons in their detoxification program without regard to whether the person has relapsed one or more times when attempting detoxification in the past. It is a truly one-size-fits all response to a brain-based disorder that requires an individualized treatment regimen.

The U.S. Surgeon General's 2016 report cited above states that "[t]he treatment plan and goals should be person-centered and include strength-based approaches."[30] "Tailoring

[30] *Facing Addiction in America: The Surgeon General's Report on Alcohol,*

treatment to the patient's specific needs increases the likelihood of successful treatment."[31] "[A]n abstinence-only philosophy that avoids the use of medications… [is] not scientifically supported; the research clearly demonstrates that opioid antagonist therapy leads to better treatment outcomes compared to behavioral treatments alone."[32]

The National Institutes of Health's National Institute on Drug Abuse, in its online publication entitled Principles of Drug Abuse Treatment for Criminal Justice Populations – a Research-Based Guide, advises correctional facilities that "[o]ne of the goals of treatment planning is to match evidence-based interventions to individual needs at every stage of drug treatment."[33] "[T]he effectiveness of drug treatment depends on both the individual and the program, and on whether interventions and treatment services are available and appropriate for the individual's needs."[34]

NIH also advises correctional facilities that "[w]hile individuals progress through drug abuse treatment at different rates, one of the most reliable findings in treatment research is that lasting reductions in criminal activity and drug abuse are related to length of treatment. Generally, better outcomes are associated with treatment that lasts longer than 90 days, with treatment completers achieving the greatest reductions in drug abuse and criminal behavior."[35] The defendants' forced withdrawal program lasts far less than ninety days.

Drugs, and Health, 2016, U.S. Department of Health and Human Services, Introduction by Secretary Sylvia Mathews Burwell, p. 17, avail. at: *https://www.surgeongeneral.gov/library/2016alcoholdrugshealth/index.html*.

[31] *Id.*

[32] *Id.* at 23.

[33] *Principles of Drug Abuse Treatment for Criminal Justice Populations – a Research-Based Guide,* National Institutes of Health, National Institute on Drug Abuse, (Apr. 2014) avail. at: https://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/what-treatment-other-health-services-should-be-prov.

[34] *Id.*, avail. at: https://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/how-effective-drug-abuse-treatment-criminal-justice.

[35] *Id.*, avail. at: https://www.drugabuse.gov/publications/principles-drug-

Particularly germane to the defendants' post-withdrawal, pre-discharge dose of naltrexone, NIH also advises that "[n]altrexone has been available for more than 2 decades, but poor compliance in the face of severe cravings and addiction has undermined its benefits."[36]

A recent article in the American Medical Association's AMA Journal of Ethics reinforces the dangers of forcibly withdrawing stable patients from an opioid agonist therapy.[37] As fully twelve percent of jail inmates report using opioids regularly compared to a reported non-medical use by 1.8 percent of non-incarcerated persons,[38] a program that ignores a patient's success on agonist maintenance therapy and forcibly withdraws stable patients is by all standards ethically concerning.

> This approach ignores respect for patient autonomy, limits access to evidence-based care, and results in negative outcomes for individuals, communities, and society. *** In light of the scientific evidence, withholding effective medical treatment with opioid agonist therapy from people with addiction is ethically questionable in any context. To do so during a public health crisis that disproportionately affects people experiencing incarceration is unconscionable.[39]

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abuse-treatment-criminal-justice-populations/how-long-should-drug-abuse-treatment-last-individua.

[36] *Id.*, avail. at: https://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/what-role-medications-in-treating-substance-abusing.

[37] Wakeman SE. Why it's inappropriate not to treat incarcerated patients with opioid agonist therapy. *AMA J Ethics* 2017;19(9):922-930., avail. at: https://journalofethics.ama-assn.org/article/why-its-inappropriate-not-treat-incarcerated-patients-opioid-agonist-therapy/2017-09.

[38] *Id.* (citing Substance Abuse and Mental Health Services Administration (SAMSHA). Behavioral health trends in the United States: results from the 2014 National Survey on Drug Use and Health. HHS Pub. SMA 15-4927; also citing Chandler RK, Finger MS, Farabee D, et al. The SOMATICS Collaborative: introduction to a National Institute on Drug Abuse cooperative study of pharmacotherapy for opioid treatment in criminal justice settings. *Contemp Clin Trials*. 2016; 48:166-172).

[39] *Id.*

CONCLUSION

At present, over nine out of ten participants in MAT-based withdrawal programs experience relapse, with over half relapsing in the first week. Given that no research has shown *non*-MAT based, forced withdrawal programs to be effective, and given that the literature overwhelmingly holds that treatment programs must be individually tailored to be effective, these *Amici* can state with a certainty appropriate to their positions in the international medical and scientific communities that the defendants' one-size-fits-all, non-MAT based, forced withdrawal program will result in needless episodes of relapse, overdose and – yes – death. In addition, the defendant's policy of ceasing medically indicated MAT for treatment of OUD represents yet another deviation from the medical standard of care. To quote the First Circuit again, the defendants' program is not at all "commensurate with modern medical science [or] of a quality acceptable within prudent professional standards."[40] As such, it fails the threshold for deference by this Court.

Accordingly, in the interest preventing potentially fatal overdose and relapse, the defendants should be ordered to continue the plaintiff's methadone maintenance program for the duration of his brief sixty-day incarceration.

[40] Defendants' Memorandum, p. 5(citing *United States v. Derbes*, 369 F.3d at 583).

Respectfully Submitted,

MASSACHUSETTS MEDICAL SOCIETY ET AL

By Their Attorneys,

/s/ Joel K. Goloskie
Joel K. Goloskie (BBO# 675806)
PANNONE LOPES DEVEREAUX & O'GARA LLC
One International Place, Suite 1400
Boston, MA 02110
Ph: 617.535.7724
Fax: 866.353.5020
jgoloskie@pldolaw.com

CERTIFICATE OF SERVICE

I certify that on November 19, 2018, I submitted the foregoing to the Clerk of Court for the U.S. District Court for the District of Massachusetts and all counsel of record using the Court's electronic case filing system.

/s/ Joel K. Goloskie
Joel K. Goloskie