IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

STEPHANIE DIPIERRO, Plaintiff, v. HUGH J. HURWITZ, in his official capacity as Acting Director of the Federal Bureau of Prisons, DR. DEBORAH G. SCHULT, in her official capacity as Assistant Director of the Health Services Division of the Federal Bureau of Prisons, Defendants.	C.A. No. 1:19-cv-10495

COMPLAINT
AND REQUEST FOR EMERGENCY INJUNCTIVE RELIEF

Plaintiff Stephanie DiPierro ("Plaintiff") complains against Defendant Acting Director of the Federal Bureau of Prisons ("the Bureau") Hugh J. Hurwitz, and Defendant Assistant Director of the Health Services Division of the Bureau Dr. Deborah G. Schult (collectively, "Defendants"), as follows:

INTRODUCTION

1. This civil rights action challenges the life-threatening and discriminatory denial of adequate medical care in Bureau of Prisons facilities overseen by Defendants Hurwitz and Schult. Government officials must meet the medical needs of people in their custody. Yet when it comes to opioid use disorder, a deadly disease that afflicts people across the United States, the Bureau's actions match neither its legal obligations nor the federal government's own admonishments to state and local prisons and jails.

2. The medical standard of care to treat opioid use disorder is “medication for addiction treatment” (also known as “medication-assisted treatment,” or “MAT”), which utilizes FDA-approved medications like methadone or buprenorphine. In recent years, the U.S. Attorney has investigated Massachusetts prisons and houses of correction for denying MAT to inmates. But the Bureau itself does exactly that; defying medical consensus, it prohibits *all* of its non-pregnant inmates from accessing methadone to treat their opioid use disorders. As applied to Plaintiff Stephanie DiPierro, whose opioid use disorder is being successfully treated with methadone, and who is slated to begin a 366-day federal sentence on April 8, 2019, the Bureau’s methadone policy violates the Eighth Amendment to the U.S. Constitution, the Rehabilitation Act, and the Administrative Procedures Act (“APA”). It also places her in grave and immediate danger.

3. Ms. DiPierro lives with her father in Everett, Massachusetts. She works every day as a personal care assistant for a woman with cerebral palsy who needs daily assistance to live independently.

4. Ms. DiPierro has been diagnosed with bipolar disease, anxiety and opioid use disorder. She began using heroin as a teenager in the mid-1990s, soon after her mother died. For many years Ms. DiPierro unsuccessfully attempted to overcome her addiction through multiple detoxification programs. She finally achieved active recovery in the late 2000s, when she was prescribed the correct dose of liquid methadone as part of an opioid use treatment program. This is the only treatment that has worked for her.

5. With the help of her prescription methadone, Ms. DiPierro has been in active recovery for many years. This recovery has involved long stretches of sobriety and, as is common for people in recovery, a few short relapses. Because of her methadone treatment

program, these relapses did not plunge Ms. DiPierro back into sustained active drug use. If she had not been prescribed methadone, Ms. DiPierro would likely be dead.

6. Ms. DiPierro is proud of the help she provides as a personal care assistant, but she failed to report her employment to the agencies from which she received benefits. Accepting responsibility for that mistake, she pled guilty to several federal offenses relating to benefits fraud. On February 25, 2019, Ms. DiPierro was sentenced to a year and one day of federal imprisonment, to be served at an as-yet-designated Bureau facility. She is scheduled to self-surrender to the Bureau on April 8, 2019.

7. Bureau facilities do not provide methadone maintenance treatment to any non-pregnant inmates with opioid use disorder. This policy applies even where, as here, a person is already taking prescribed methadone when they enter custody, and their doctor's professional opinion is that involuntarily ending that treatment would violate the standard of care.

8. If Ms. DiPierro is denied her prescribed methadone while she is incarcerated, she will inevitably suffer and possibly die. To begin, she will enter an acute and extremely painful period of withdrawal, which carries a heightened risk for numerous serious medical conditions. She will also experience a heightened probability of relapsing into opioid use, both during her year-long incarceration *and* upon her release, which can result in overdose and death. Involuntarily removing Ms. DiPierro from her medication is particularly dangerous given her bipolar disease, as it could trigger suicidal ideation and self-harm.

9. As applied to Ms. DiPierro, Defendants' methadone policy violates her legal rights in three ways. First, it reflects deliberate indifference to her serious medical need, to her suffering, and to the long-term consequences of forced withdrawal. Defendants' actions therefore violate Ms. DiPierro's Eighth Amendment right to be free from cruel and unusual

punishment. Second, the denial of necessary medical care violates Ms. DiPierro's right, under the Rehabilitation Act, to be free from discrimination based upon her disability. Finally, the Bureau's refusal to provide Ms. DiPierro with access to medically-necessary treatment and its blanket denial of methadone maintenance treatment to all non-pregnant inmates also violate the APA because these final agency actions are arbitrary, capricious, and unlawful under the Rehabilitation Act.

10. Ms. DiPierro seeks emergency, preliminary, and permanent relief to require Defendants to provide her with adequate medical care and prevent suffering. Specifically, Ms. DiPierro seeks declaratory and injunctive relief requiring Defendants to provide her with access to her medically-necessary, physician-prescribed methadone throughout her upcoming incarceration at a Bureau facility.

THE PARTIES

11. Plaintiff Stephanie DiPierro is a resident of Everett, Massachusetts.

12. Defendant Hugh J. Hurwitz is the Acting Director of the Federal Bureau of Prisons. He is being sued in his official capacity only, in which he is responsible for overseeing the operation of all 122 Bureau facilities.[1]

13. Defendant Dr. Deborah G. Schult is the Assistant Director of the Health Services Division for the Federal Bureau of Prisons. She is being sued in her official capacity only, in which she directs the Bureau's national medical program and oversees health care delivery for the Bureau.[2]

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[1] Federal Bureau of Prisons, *Hugh J. Hurwitz*, https://www.bop.gov/about/agency/bio_dir.jsp (last visited March 12, 2019).

[2] Federal Bureau of Prisons, *Dr. Deborah G. Schult*, https://www.bop.gov/about/agency/bio_hsd.jsp (last visited March 12, 2019).

JURISDICTION AND VENUE

14. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1343. The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action seeks to vindicate rights guaranteed by the Eighth Amendment to the United States Constitution, Section 504 of the Rehabilitation Act, 29 U.S.C. § 794, and the Administrative Procedures Act, 5 U.S.C. §§ 704 and 706.

15. This Court has authority to issue declaratory and injunctive relief under 28 U.S.C. §§ 2201 and 2202, 5 U.S.C. § 706, Rules 57 and 65 of the Federal Rules of Civil Procedure and the Court's inherent equitable powers.

16. Venue lies in the District of Massachusetts under 28 U.S.C. § 1391.

FACTS

A. Opioid Use Disorder Is a Life-Threatening Medical Condition and a Public Health Crisis.

17. Opioids are a class of drugs that inhibit pain and can have euphoric side effects. Many opioids have legitimate medical uses, including chronic pain management. Others, such as heroin, are not generally used in medicine in the United States, but are sold on the black market.

18. Opioid use disorder is a chronic brain disease with potentially deadly complications. Signs of opioid use disorder include cravings, increased tolerance to opioids, the inability to cut back or control opioid use, withdrawal symptoms, and a loss of control.

19. Like other chronic diseases, opioid use disorder often involves cycles of relapse and remission.

20. Without treatment or other recovery, patients with opioid use disorder are frequently unable to control their use of opioids. Opioid use disorder is progressive and can result in disability or premature death, including due to accidental overdose.

21. Opioid use disorder is a national public health crisis. As of 2016, 2.1 million Americans suffered from this disease.[3] Between 1999 and 2017, more than 700,000 people died from opioid overdose.[4] The death toll has increased exponentially in the past five years, and the number of opioid overdose deaths in 2017 was six times higher than in 1999.[5] Every day in America, an average of 130 people die after overdosing on opioids—equivalent to one person every 12.5 minutes.[6]

22. Here in Massachusetts, the Department of Health reported 2,069 confirmed and estimated opioid-related overdose deaths in 2017, or an average of almost six opioid-related overdose deaths per day.[7] The opioid-related death rate in Massachusetts has now exceeded the national average, with an especially sharp rise in the last two years.[8]

23. Opioid use disorder has impacted Ms. DiPierro's home of Middlesex County with particular severity. Among the 14 counties in the Commonwealth, Middlesex had the highest number of opioid-related deaths for the calendar year 2017, as well as for the period from 2000-2017.[9]

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[3] SAMHSA, *Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Patients, and Families, Treatment Improvement Protocol Tip 63*, at ES-2.
[4] Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic*, *available at* https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Dec. 19, 2018).
[5] *Id.*
[6] *Id.*
[7] Massachusetts Department of Public Health, *Data Brief: Opioid-Related Overdose Deaths Among Massachusetts Residents* (Aug. 2018), *available at* https://www.mass.gov/files/documents/2018/08/24/Opioid-related%20Overdose%20Deaths%20among%20MA%20Residents%20-%20August%202018_0.pdf.
[8] Massachusetts Department of Public Health, *The Massachusetts Opioid Epidemic, A data visualization of findings from the Chapter 55 Report*, http://www.mass.gov/chapter55/.
[9] Massachusetts Department of Public Health, *Number of Opioid-Related Overdose Deaths, All Intents by County, MA Residents: 2000-2017* (August 2018), *available at* https://www.mass.gov/files/documents/2018/08/24/Opioid-related%20Overdose%20Deaths%20by%20County%20-%20August%202018_0.pdf.

24. Opioid use disorder is especially dangerous for people who are or have been incarcerated.

25. As the 2017 Final Report from the President's Commission on Combating Drug Addiction and the Opioid Crisis 2017 explained, "[i]n the weeks following release from jail or prison, individuals with or in recovery from OUD are at elevated risk of overdose and associated fatality."[10] A recent study by the Massachusetts Department of Public Health similarly found that "[t]he opioid overdose death rate is 120 times higher for those recently released from incarceration compared to the rest of the adult population."[11] The same study found that "[o]pioid-related deaths among persons recently released from incarceration [in Massachusetts] have increased 12-fold between 2011 and 2015," and, "[i]n 2015, nearly 50% of all deaths among those released from incarceration were opioid-related."[12]

B. Medication for Addiction Treatment Is the Standard of Care for Opioid Use Disorder.

26. MAT is the standard of care for opioid use disorder.

27. MAT "is a comprehensive approach that combines FDA-approved medications . . . with counseling and other behavioral therapies to treat patients with opioid use

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[10] *The President's Commission on Combating Drug Addiction and the Opioid Crisis* (Nov. 2017), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf (hereinafter "President's Commission").
[11] Massachusetts Department of Public Health, *An Assessment of Fatal and Nonfatal Opioid Overdoses in Massachusetts 2011-2015* (August 2017), *available at* https://www.mass.gov/files/documents/2017/08/31/legislative-report-chapter-55-aug-2017.pdf.
Chapter 55 of the Acts of 2015, as amended by Chapter 133 of the Acts of 2016, instructed the Secretary of Health and Human Services and the Department of Public Health to "conduct or provide for an examination of the prescribing and treatment history, including court-ordered treatment or treatment within the criminal justice system, of persons in the commonwealth who suffered fatal or nonfatal opiate overdoses." The preliminary "Chapter 55" report for years 2013-2014 was published on September 15, 2016. On August 16, 2017, the Executive Office of Health and Human Services released an updated report for years 2011 through 2015.
[12] *Id.*

disorder (OUD)."[13] Three medications used in MAT are methadone (sold under brand names such as Dolophine and Methadose), buprenorphine (sold under brand names such as Subutex, Suboxone, and Bunavail), and naltrexone (sold under brand names such as ReVia and Vivitrol). These medications have been approved by the United States Food and Drug Administration for treatment of opioid addiction.

28. Naltrexone works by blocking opioids from producing their euphoric effects and thus reducing a desire for opioids over time. Buprenorphine and methadone act through a different mechanism than naltrexone: both activate rather than block opioid receptors to relieve withdrawal symptoms and control cravings.

29. Because of this important ability to act on opioid receptors without presenting the same risk of overdose, buprenorphine and methadone have both been deemed "essential medicines" according to the World Health Organization.[14] Both methadone and buprenorphine facilitate extinction learning (a gradual decrease in response to a stimulus, such as an opioid), because patients learn that they will not get the same "high" from taking illicit drugs like heroin and fentanyl.

30. As with any prescription medication, patients' responses to these medications are individualized—a patient may find that only one of these medications provides effective treatment without significant adverse side effects.

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[13] Food and Drug Administration, *FDA approves first generic version of Suboxone® sublingual film, which may increase access to treatment for opioid dependence* (June 14, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610807.htm.

[14] *See* National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction (last updated Nov. 2016).

31. The results of treatment with MAT are dramatically superior to other treatment options.

32. Studies of MAT show improved retention in treatment, abstinence from illicit drugs, and decreased mortality. MAT has been shown to decrease opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission. [15] MAT has also been shown to increase patients' social functioning and retention in treatment.

33. The primary driver of treatment efficacy in MAT regimens is the medication.

34. Studies have shown that maintenance medication treatments of opioid use disorder reduce all cause and overdose mortality and have a more robust effect on treatment efficacy than behavioral components of MAT.[16] Buprenorphine and methadone have been clinically proven to reduce opioid use more than (1) no treatment, (2) outpatient treatment without medication, (3) outpatient treatment with placebo medication, and (4) detoxification only. One study documented the treatment outcomes from a detoxification facility and showed (1) a twenty-nine percent relapse on the day of discharge, (2) a sixty percent relapse after one month, and (3) a success rate of between only five to ten percent after one year.[17]

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[15] Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid Overdose Epidemic.*, 370 NEW ENG. J. MED. 2063, 2064 (May 29, 2014), *available at* https://www.nejm.org/doi/pdf/10.1056/NEJMp1402780; National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction (last updated Nov. 2016).

[16] *See* Laura Amato et al., *Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence*, COCHRANE DATABASE SYST. REV. 1, 2 (Oct. 10, 2011).

[17]Genie L. Bailey et al. *Perceived relapse risk and desire for medication assisted treatment among persons seeking inpatient opiate detoxification.,* 45(3) J. SUBST. ABUSE TREAT, 302, 304-05 (2013); George E. Valiant, *What does long-term follow-up teach us about relapse and prevention of relapse in addiction?* 83 BR. J. ADDICTION 1147, 1152-57 (1988).

35. Once a patient is successfully recovering from opioid use disorder through MAT, the arbitrary and sudden cessation of the medication violates the standard of care and, in the case of methadone and buprenorphine, will cause excruciating withdrawal symptoms within 48 hours of cessation.

36. Withdrawal symptoms include severe dysphoria, cravings for opiates, irritability, sweating, nausea, tremor, vomiting, insomnia, and muscle pain. These symptoms can sometimes lead to life-threatening complications.

37. Withdrawal is particularly dangerous for patients with pre-existing psychiatric conditions, such as bi-polar disorder, because withdrawal symptoms can exacerbate their psychiatric illness.[18]

C. The Federal Government Has Widely Adopted the Medical and Scientific Consensus that Medication for Addiction Treatment Is the Standard of Care for Opioid Use Disorder.

38. Embracing the medical and scientific consensus, numerous federal entities have expressly endorsed the necessity of MAT, including: the Department of Health and Human Services ("HHS"),[19] the Food and Drug Administration ("FDA"),[20] the National Institute on

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[18] Federal Bureau of Prisons, *Clinical Guidance on the Detoxification of Chemically Dependent Inmates* at 3 (Feb. 2014, reformatted Jan. 2018), *available at* https://www.bop.gov/resources/pdfs/detoxification.pdf (hereinafter "BOP Clinical Guidance on Detoxification").

[19] *See, e.g.*, FDA News Release, *FDA takes new steps to encourage the development of novel medicines for the treatment of opioid use disorder* (August 6, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615892.htm (Health and Human Services Secretary Alex Azar explaining "[t]he evidence is clear: medication-assisted treatment works, and it is a key piece of defeating the drug crisis facing our country.").

[20] *See, e.g.*, *id.* (FDA Commissioner Dr. Scott Gottlieb underscoring, "we're committed to doing our part to expand access to high-quality, effective medication-assisted treatments and encouraging health care professional to ensure patients with opioid use disorder are offered an adequate chance to benefit from these therapies. This work also includes improving understanding about the treatment options available for patients and countering the unfortunate stigma that's sometimes] associated with their use.").

Drug Abuse ("NIDA"),[21] the President's Commission on Combating Drug Addiction and the Opioid Crisis,[22] the Office of National Drug Control Policy ("ONDCP"),[23] and the Substance Abuse and Mental Health Services Administration ("SAMHSA").

39. For example, emphasizing that "the gold standard for demonstrating efficiency in clinical medicine," has shown that MAT is more effective in reducing illicit opioid use than no medication, SAMHSA has concluded that "just as it is inadvisable to deny people with diabetes the medication they need to help manage their illness, it is also not sound medical practice to deny people with OUD access to FDA-approved medications for their illness."[24] SAMHSA has also highlighted that "dosing and schedules of pharmacotherapy must be individualized," and that some individuals may require "lifelong treatment."[25]

40. The Department of Justice has confirmed that MAT is the standard of care for treatment of opioid use disorder.

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[21] *See, e.g.*, NIH, National Institute on Drug Abuse, *What Science tells us About Opioid Abuse and Addiction*, Nora D. Volkow Testimony to Congress (Jan. 27, 2016) (Testifying before the Senate Judiciary Committee in late January 2016, National Institute on Drug Abuse Director Dr. Nora Volkow explained that "medications have become an essential component of an ongoing treatment plan, enabling opioid-addicted persons to regain control of their health and their lives," while emphasizing "[t]o be clear, the evidence supports long-term maintenance with these medicines in the context of behavioral treatment and recovery support, not short-term detoxification programs aimed at abstinence.").

[22] *See, e.g.*, The President's Commission, *supra* note 10 at 68 (noting that treatment for opioid use disorder "should include" five elements including "[a]ccess to MAT (e.g., methadone, buprenorphine/naloxone, naltrexone). Choice of medication should be made by a qualified professional in consultation with patient, and based on clinical assessment.").

[23] *See, e.g.*, National Drug Control Strategy: January 2019, OFFICE OF NATIONAL DRUG CONTROL POLICY, at 10 ("The Administration will work across the Federal government to remove barriers to substance-use disorder treatments, including those that limit access to any forms of FDA-approved MAT, counseling, certain inpatient/residential treatment, and other treatment modalities.") (hereinafter "National Drug Control Strategy").

[24] SAMHSA, *supra* note 3 at ES-2.

[25] *Id.* at ES-2, ES-5.

41. The Department of Justice has taken the position that denying non-incarcerated individuals suffering from opioid use disorder access to MAT can constitute unlawful disability discrimination under the Americans with Disabilities Act ("ADA").

42. The Department of Justice has also taken the position that denying incarcerated individuals suffering from opioid use disorder access to MAT can constitute unlawful disability discrimination under the ADA.

43. The Department of Justice and its subordinates have taken concrete actions to combat this discrimination. In 2017, the Department of Justice's Civil Rights Division launched the Opioid Initiative to enforce the ADA and work with U.S. Attorney's Offices nationwide "to ensure that people who have completed, or are participating in, treatment for OUD do not face unnecessary and discriminatory barriers to recovery."[26]

44. Also in 2017, the U.S. Attorney for the Southern District of New York sent a 10-page letter to the New York State Attorney General, explaining "it has come to our attention that the Family Court and the Surrogate's Court in Sullivan County, New York, as well as the stake holders involved with those courts, may benefit from further information about the ADA's application to individuals receiving medication-assisted treatment ("MAT") such as treatment with methadone or buprenorphine, for substance use disorders."[27] Emphasizing that "MAT is a safe and widely accepted strategy for treating opioid disorders," with "broad support [] among

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[26] Charlotte Lanvers & Erin Meehan Richmond, Department of Justice, Opioid Use Disorders and the Americans with Disabilities Act: Eliminating Discriminatory Barriers to Treatment and Recovery Panel at the National Prescription Drug Abuse & Heroin Summit (Apr. 4, 2018), *available at* https://ncric.org/files/D2DF00000/037.pdf.

[27] Letter from the Department of Justice, United States Attorney for the Southern District of New York to New York State Office of the Attorney General regarding Medication-Assisted Treatment and the ADA (Oct. 3, 2017), *available at* https://lac.org/wp-content/uploads/ 2018/02/DOJ-SDNY-ltr-to-OCA-10.3.17.pdf. (hereinafter "SDNY Letter").

medical and substance use experts," the letter instructed that "the Sullivan family court and Sullivan surrogate's court should ensure that their policies and practices with respect to individuals participating in MAT . . . are consistent with ADA requirements."[28]

45. In March 2018, the U.S. Attorney for Massachusetts initiated an ADA-investigation of the Massachusetts Department of Correction for its failure to provide non-pregnant inmates who had been prescribed MAT to treat their opioid use disorder with continued access to MAT during their incarceration.[29] In so doing, the office emphasized "that all individuals in treatment for OUD, regardless of whether they are inmates or detainees, are already protected by the ADA, and [] the DOC has existing obligations to accommodate this disability."[30]

46. In October 2018, the U.S. Attorney for Massachusetts initiated an ADA-investigation of several county sheriffs for their failure to provide inmates who had been prescribed methadone or buprenorphine to treat their opioid use disorder with continued access to these medications during their incarceration.[31]

D. Providing Medication For Addiction Treatment Is Particularly Important, and Administrable, in Correctional Settings.

47. Withholding MAT from incarcerated people with opioid use disorder causes some of them to die.

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[28] *Id.*
[29] Letter from Andrew E. Lelling, United States Attorney for the District of Massachusetts to Sheriff Kevin F. Coppinger (Essex County) (Dec. 4, 2018).
[30] *Id.*
[31] *Id.*; *see also* Beth Schwartzapfel, *When Going to Jail Means Giving Up Meds That Saved Your Life*, THE MARSHALL PROJECT (Jan. 29, 2019), *available at* https://www.themarshallproject.org/2019/01/29/when-going-to-jail-means-giving-up-the-meds-that-saved-your-life.

48. As the President's Commission on Combating Drug Addiction and the Opioid Crisis has explained, "MAT has been found to be correlated with reduced risk of mortality in the weeks following release [from incarceration]," and a "large study of individuals with [opioid use disorder] released from prison found that individuals receiving MAT were 75% less likely to die of any cause and 85% less likely to die of drug poisoning in the first month after release."[32]

49. Providing MAT in correctional settings is administrable.

50. Providing MAT in correctional settings also saves lives.

51. Numerous authorities have therefore recommended providing MAT in jails and prisons to help address the serious risks the opioid crisis poses for incarcerated people.

52. For example, the Department of Justice's Adult Drug Court Discretionary Grant Program requires grantees to permit the use of MAT.[33]

53. On behalf of the Trump Administration, the ONDCP's 2019 report establishes "increasing the availability of MAT for incarcerated individuals" as a priority initiative.[34]

54. SAMSHA identifies "making treatment available to criminal justice populations" as one of the "remaining challenges" in fighting the opioid public health crisis.[35]

55. In a 2018 report, the National Sheriffs' Association and the National Commission on Correctional Health Care explain that "correctional withdrawal alone actually increases the chances the person will overdose following community release due to loss of opioid tolerance" and "[f]or this reason, all individuals with OUD should be considered for MAT" while they are

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[32] President's Commission, *supra* note 10 at 72.
[33] U.S. Dept. of Justice, Adult Drug Court Discretionary Grant Program FY 2018 Competitive Grant Announcement (June 5, 2018), *available at* https://www.bja.gov/funding/DrugCourts18.pdf.
[34] National Drug Control Strategy, *supra* note 23 at 9.
[35] SAMHSA, *Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs, A Treatment Improvement Protocol* TIP 43, at 6-8 (2017).

incarcerated.[36] They emphasize that providing MAT in jails and prisons can "contribut[e] to the maintenance of a safe and secure facility for inmates and staff" and reduce recidivism, withdrawal symptoms, the risk of post-release overdose and death, and disciplinary problems.[37]

56. The American Society of Addiction Medicine, the leading professional society in the country on addiction medicine, also recommends treatment with MAT for people with opioid use disorder in the criminal justice system.[38]

57. As recognized by these authorities, opioid use disorder is a chronic relapsing condition that requires medically appropriate treatment just like other chronic diseases.

58. Once patients successfully begin using one form of MAT, they need to be maintained on that treatment under medical supervision to give them the best chance of success.

59. Forced withdrawal is not medically appropriate for patients receiving MAT.

60. Forced withdrawal disrupts their treatment plan, leading to a seven-fold decrease in continuing MAT after release. As the National Sheriffs' Association and National Commission on Correctional Healthcare emphasize, "forced detoxification of prescribed opioid medication, such as methadone, can undermine an individual's willingness to engage in MAT in

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[36] National Sheriffs' Association, *Jail-Based Medication-Assisted Treatment Promising Practices, Guideline, and Resources for the Field*, at 9 (Oct. 2018), *available at* https://www.sheriffs.org/publications/Jail-Based-MAT-PPG.pdf (hereinafter "National Sheriffs' Association"); *see also id.* at 21 ("Jails should establish systems to ensure that detainees and sentenced inmates who had been receiving MAT, particularly methadone and buprenorphine, prior to their arrest have MAT continued when feasible.").
[37] *Id.* at 5-6, 21.
[38] Kyle Kampman & Margaret Jarvis, Margaret, *American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use,* 9 J. ADDICTION MED. 1, 4-6 (2015) *available at* https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-jam-article.pdf.

the future, compromising the likelihood of long-term recovery."[39] Death is three times as likely for people out of treatment versus when in treatment.[40]

61. Reflecting this knowledge, numerous jails and prisons follow the medical standard of practice and allow prisoners to continue with MAT during incarceration. Examples include Bernalillo County Metropolitan Detention Center (New Mexico); Rikers Island Correctional Facility (New York); Kings County Jail (Washington State); Orange County Jail (Florida). The Rhode Island and Vermont Departments of Correction make MAT available to all of their prisoners, even those who were not receiving MAT before being incarcerated.

62. Following the medical standard of practice yields positive results. After the first year of the program within the Rhode Island Department of Corrections, 95% of inmates who were on MAT at the time they were incarcerated continued with their treatment after their release.[41] "Research showed that this program reduced post-release deaths by 60% and all opioid-related deaths in the state by more than 12%."[42]

E. The Federal Bureau of Prisons Categorically and Arbitrarily Denies Medication for Addiction Treatment for Inmates with Opioid Use Disorder.

63. The Bureau's National Formulary and Pharmacy Services Program Statement establish the Bureau's official prescribing policies.[43]

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[39] National Sheriffs' Association, *supra* note 36 at 21.
[40] Josiah D. Rich et al., *Methadone continuation versus forced withdrawal on incarceration in a combined US prison and jail: a randomized, open-label trial*, 386 LANCET 350, 352-59 (2015); Elizabeth Evans et al., *Mortality among individuals accessing pharmacological treatment for opioid dependence in California, 2006-10*, 110 ADDICTION 996, 1003 (2015).
[41] National Sheriffs' Association, *supra* note 36 at 29.
[42] *Id.*
[43] *See* Federal Bureau of Prisons, *Program Statement for Pharmacy Services*, P6360.01 at 37 (Jan. 15, 2005), *available at* https://www.bop.gov/policy/progstat/6360_001.pdf (hereinafter "Program Statement for Pharmacy Services"); Federal Bureau of Prisons Health Services, *National Formulary Part I* at 15 (Winter 2018), *available at* https://www.bop.gov/resources/

64. The Bureau's Formulary instructs that "ALL BOP institutions, including Medical Centers, are expected to abide by the [F]ormulary as outlined in the BOP Pharmacy Services Program Statement."[44] It further mandates that all clinical directors, health services administrators, associate wardens and wardens are "expected to support and ensure compliance with the BOP National Formulary."[45]

65. Under these mandatory policies, the Bureau denies non-pregnant inmates access to methadone treatment for opioid use disorder.[46]

66. The Bureau's denial of methadone to non-pregnant inmates with opioid use disorder is arbitrary.

67. The Bureau's denial of methadone to non-pregnant inmates with opioid use disorder is also categorical; it applies even if methadone has been prescribed by a physician as a medically-necessary treatment for someone placed into the Bureau's custody.[47]

68. The Bureau's Program Statement for Pharmacy Services restricts the dissemination of methadone within its institutions to "only three approved uses."[48] These uses are limited to "treatment of opiate addicted pregnant inmates; detoxification of opiate addicted inmates; and treatment of severe pain."[49] This policy underscores that "inmates will not be maintained on methadone with the exception of pregnant inmates."[50]

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pdfs/national_formulary-part_I-2018.pdf (hereinafter "BOP Nat ional Formulary Part I"); Federal Bureau of Prisons Health Services, *National Formulary Part 2* at 102 (Winter 2018), *available at* https://www.bop.gov/resources/pdfs/national_formulary-part_II-2018.pdf (hereinafter "BOP National Formulary Part II").

[44] BOP National Formulary Part I, *supra* note 43 at 4 (emphasis in original).

[45] *Id.* at 4-5.

[46] Program Statement for Pharmacy Services, *supra* note 43 at 37.

[47] *Id.*

[48] *Id.*; *see also* BOP National Formulary Part II, *supra* note 43 at 102.

[49] Program Statement for Pharmacy Services, *supra* note 43 at 37.

[50] *Id.*

69. There are no exceptions to this blanket prohibition.

70. The Bureau's Clinical Guidance on Detoxification of Chemically Dependent Inmates instructs Bureau facilities with a methadone license to taper inmates off of methadone at a rate of 10% per day; Bureau facilities without a methadone license can provide methadone for only three days.[51]

71. The Bureau's National Formulary similarly prohibits the use of buprenorphine to treat opioid use disorder, explaining that this medication "will only be approved for detoxification, NOT for pain or maintenance therapy."[52]

72. Some Bureau facilities have begun to offer Vivitrol, but, on information and belief, they only do so immediately prior to an individual's transfer out of the Bureau facility.

73. Inmates in a Bureau facility depend upon the facility to provide them with all medical care.[53]

74. Bureau facilities provide medically-necessary care to other inmates in their custody, but not to inmates who suffer from opioid use disorder.[54]

75. For example, methadone is provided to inmates for pain management, but uniformly denied to non-pregnant inmates to treat their opioid use disorder.[55]

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[51] BOP Clinical Guidance on Detoxification, *supra* note 18 at 16.
[52] BOP National Formulary Part I, *supra* note 43 at 15.
[53] *See Custody & Care, Medical Care, Inmate Receive Essential Medical, Dental, and Mental Health Services,* FEDERAL BUREAU OF PRISONS https://www.bop.gov/inmates/custody_and_care/medical_care.jsp (last visited Mar. 11, 2019).
[54] Program Statement for Pharmacy Services, *supra* note 43, at 37.
[55] *Id.*

76. On information and belief, no non-pregnant inmate with a methadone prescription to treat their opioid use disorder has ever been permitted to continue receiving maintenance methadone treatment during their custody at a Bureau facility.

F. Without Judicial Intervention, Ms. DiPierro Will Be Denied Medically-Necessary Treatment for Her Opioid Use Disorder When She Is Incarcerated in a Federal Bureau of Prisons Facility.

77. Defendants' policies, if permitted to be applied to Ms. DiPierro, will cause her to lose access to methadone while she is incarcerated and experience what is known as "withdrawal."

78. Ms. DiPierro's methadone treatment is medically necessary. For her, forced withdrawal would be dangerous and potentially life-threatening.

79. Ms. DiPierro is diagnosed with opioid use disorder, a serious medical need and a recognized disability. If untreated, Ms. DiPierro's opioid use disorder is likely to result in relapse and potentially a fatal opioid overdose, among other things.

80. Ms. DiPierro has suffered from addiction for years. Before she was prescribed the proper dose of methadone, she tried numerous detoxification programs but none of them worked.

81. MAT with methadone has been the only treatment that has enabled Ms. DiPierro to remain in active recovery and to get her life back.

82. For several years, Ms. DiPierro has been prescribed methadone for treatment of her opioid use disorder. With the help of the proper dose of methadone, she has been in active recovery since the late 2000s. Methadone is medically necessary for the treatment of Ms. DiPierro's serious medical condition.

83. Without access to this medically-necessary treatment, Ms. DiPierro faces a high risk of relapse, overdose and death, as well as a heightened risk of suicidal ideation and acts of self-harm due to her bi-polar disorder and anxiety.

84. Ms. DiPierro is well-acquainted with the dangers associated with untreated opioid use disorder. Her brother died of an opioid overdose in 2013.

85. Ms. DiPierro is currently due to self-surrender for a sentence of one year and one day to a Bureau facility on April 8, 2019.

86. If, as the Bureau's policies mandate, Ms. DiPierro is prevented from accessing her methadone treatment when she is incarcerated, she will begin experiencing withdrawal symptoms within 48 hours. These excruciating symptoms will continue for several weeks. Reducing Ms. DiPierro's dose at a rate of 10% per day will similarly trigger withdrawal symptoms within a matter of days, as that rate is far too fast and much more accelerated than the standard protocol.

87. On February 27, 2019, Ms. DiPierro's counsel sent a letter to Defendants informing them of her serious medical need and requesting assurance that Ms. DiPierro will be provided with her physician-prescribed dose of methadone during her time in their custody.

88. On March 6, 2019, counsel for the Bureau called Ms. DiPierro's counsel and claimed that Ms. DiPierro would be given an individualized assessment of her general medical needs and would be given treatment of some kind. But the Bureau's counsel would not confirm that, in assessing Ms. DiPierro, Defendants could or would deviate from their blanket prohibition of methadone maintenance treatment for non-pregnant inmates.

89. Accordingly, the relevant officials at the Bureau have been informed of Ms. DiPierro's diagnosis and need for medical treatment, but it appears that they will not provide

such treatment while she is incarcerated in a Bureau facility. In fact, no one on behalf of the Bureau has asserted that, absent a court order, they will even consider continuing Ms. DiPierro's methadone treatment upon her placement at a Bureau facility.

COUNT I –THE EIGHTH AMENDMENT
(Deliberate Indifference to Serious Medical Need in Violation of the Eighth Amendment)

90. The foregoing allegations are re-alleged and incorporated herein.

91. The Defendants, while acting under color of federal law, deliberately, purposefully, and knowingly deny or will deny Ms. DiPierro access to necessary medical treatment for her opioid use disorder, which is a serious medical need.

92. Denying Ms. DiPierro access to her prescribed dosage of methadone will immediately cause her physical and psychological suffering, will expose her to heightened risk for other serious medical conditions, and could trigger relapse into active addiction, potentially resulting in overdose and death. It also heightens the risk of suicidal ideation and acts of self-harm.

93. As applied to Ms. DiPierro, the denial of treatment by Defendants amounts to deliberate indifference to a serious medical need, in violation of the Eighth Amendment's prohibition against cruel and unusual punishment.

COUNT II – REHABILITATION ACT
(Unlawful Discrimination Against Qualified Individuals with Disabilities)

94. The foregoing allegations are re-alleged and incorporated herein.

95. The Bureau of Prisons, which is overseen by Defendants, receives federal funding and is a federal agency that is subject to the Rehabilitation Act. 29 U.S.C. § 794(a).

96. Drug addiction is a "disability" under the Rehabilitation Act. 29 U.S.C. § 705(20)(B); 42 U.S.C. §§ 12102 and 12131(2); 28 C.F.R. § 35.108 (the phrase "physical or mental impairment includes, but is not limited to . . . drug addiction, and alcoholism.").

97. The Rehabilitation Act applies to people, like Ms. DiPierro, who are participating in a supervised drug rehabilitation program.

98. Defendants deny Ms. DiPierro the benefits of the Federal Bureau of Prison's medical programs on the basis of her disability.

99. Defendants refuse to make a reasonable accommodation for Ms. DiPierro by providing her with access to her prescribed dosage of methadone during her incarceration, thereby discriminating against her on the basis of disability, even though accommodation would in no way alter the nature of the healthcare program. On information and belief, Defendants do not deny medically-necessary, physician-prescribed medications to other inmates with serious, chronic medical conditions, such as diabetes.

COUNT III – ADMINISTRATIVE PROCEDURES ACT
(Agency Action that is Arbitrary, Capricious and Not in Accordance with the Law)

100. The foregoing allegations are re-alleged and incorporated herein.

101. The Federal Bureau of Prisons, which is overseen by Defendants, is a federal agency whose final actions are subject to judicial review under the Administrative Procedures Act. 5 U.S.C. §§ 701, 704.

102. Under the Administrative Procedures Act, a reviewing court shall "hold unlawful and set aside agency actions, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A).

103. The Federal Bureau of Prisons Pharmacy Services Program Statement No. 6360.01 and 2018 National Formulary Parts 1 and 2 are the subject of the Bureau's completed decision-making process. These documents directly affect the parties, as they bind the Defendants to prevent all non-pregnant inmates, including Ms. DiPierro, from continuing their medically-necessary methadone maintenance treatment. The Federal Bureau of Prisons

Pharmacy Services Program Statement No. 6360.01 and 2018 National Formulary Parts 1 and 2 therefore constitute final agency action.

104. This final agency action automatically denies reasonable accommodation to any non-pregnant inmate suffering from opioid use disorder with a medically-necessary methadone prescription, including Ms. DiPierro. For the reasons described in Count II, this final agency action is arbitrary, capricious, and unlawful under the Rehabilitation Act and therefore violates the Administrative Procedures Act. 5 U.S.C. §§ 704, 706

105. Defendants deny Ms. DiPierro access to her medically-necessary methadone treatment. This final agency action is arbitrary, capricious, and unlawful under the Rehabilitation Act for the reasons described in Count II, and therefore violates the Administrative Procedures Act. 5 U.S.C. §§ 704, 706.

PRAYER FOR RELIEF

Wherefore, Ms. DiPierro asks this Court to GRANT the following relief:

1. Emergency, preliminary, and permanent injunctive relief ordering Defendants to provide Ms. DiPierro with access to MAT, including the methadone dosage prescribed by her physician, during her entire term of incarceration;

2. A declaratory judgment holding that Defendants' policy denying all non-pregnant inmates access to methadone treatment for opioid use disorder, as applied to Ms. DiPierro, violates the Eighth Amendment;

3. A declaratory judgment holding that Defendants' policy denying all non-pregnant inmates access to methadone treatment for opioid use disorder, as applied to Ms. DiPierro, violates the Rehabilitation Act and the APA;

4. Award Ms. DiPierro her attorneys' fees and costs;

5. Any further relief this Court deems just and proper.

Respectfully submitted,

STEPHANIE DIPIERRO,

By her attorneys,

/s/ Robert Frederickson III

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