IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

ZACHARY J. SMITH,

Plaintiff,

v.

MAINE DEPARTMENT OF CORRECTIONS, *et al.*,

Defendants.

CIVIL NO. _____

DECLARATION OF JONATHAN C. FELLERS, MD

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

1. I am a psychiatrist and the current Director of Integrated Medication-Assisted-Treatment at Maine Medical Center in Portland, Maine. I am board certified in Addiction Psychiatry and Psychiatry. I earned my medical degree at the Cornell University Medical College, and completed residencies in the University of California San Francisco Fresno and the University of Virginia Health System.

2. I am also an Assistant Clinical Professor, Tufts University School of Medicine, a fellow of the American Psychiatric Association and a member of the American Academy of Addiction Psychiatry. In May 2018, the Department of Health and Human Services named me to an interagency task force authorized by the Comprehensive Addiction and Recovery Act of 2016 to recommend updates to best practices for managing chronic and acute pain. My curriculum vitae is attached as Exhibit 1.

Opioid Use Disorder

3. Opioid use disorder is a chronic brain disease that some people can get from taking opioids often, and is sometimes referred to as opioid dependence or opioid addiction. This

type of disease leads to craving opioids, not being able to stop using opioids, and can cause major life problems.[1] Signs of opioid use disorder can include craving, increasing tolerance to opioids, withdrawal symptoms, and a loss of control.

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

5. Opioid use disorder is a serious public health crisis in Maine, with an average of 1.14 overdose death per day reported in 2017.[2] That figure marks an 11 percent increase in opioid overdose deaths over the previous year.

Science of Addiction

6. According to the American Society of Addiction Medicine, addiction (including opioid use disorder) "is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors."[3]

7. The brain reward element of opioid use disorder involves the brain's dopamine system that is involved in reward. Drugs of abuse, including opioids, enhance dopamine release within the nucleus accumbens.[4]

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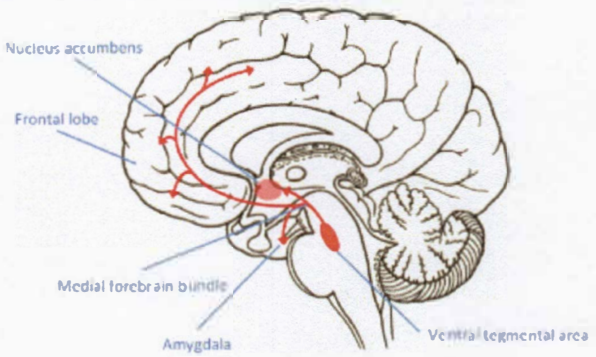
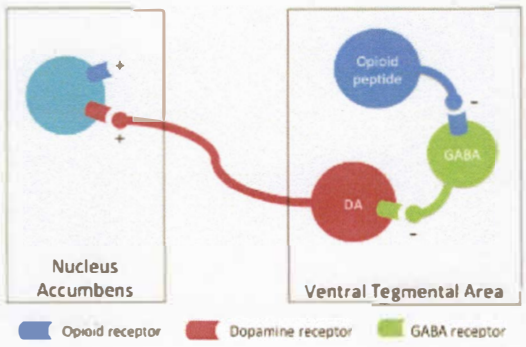
[1] https://www.cdc.gov/drugoverdose/opioids/terms.html, https://mainehealth.org/services/behavioral-mental-health/opioid-use-disorder.

[2] Attorney General Janet Mills Releases 2017 Maine State Drug Death Statistics, Office of the Maine Attorney General (Feb. 22, 2018), https://www.maine.gov/ag/news/article.shtml?id=788298.

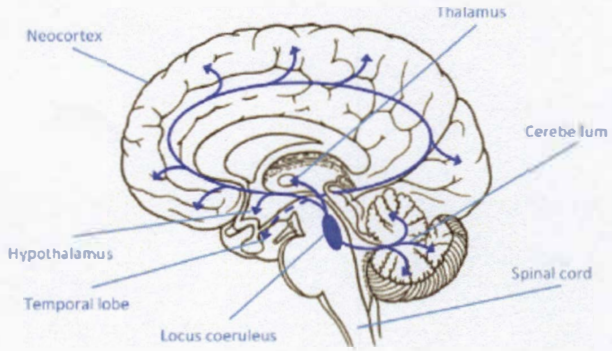
[3] Definition of Addiction, American Society of Addiction Medicine, https://www.asam.org/quality-practice/definition-of-addiction.

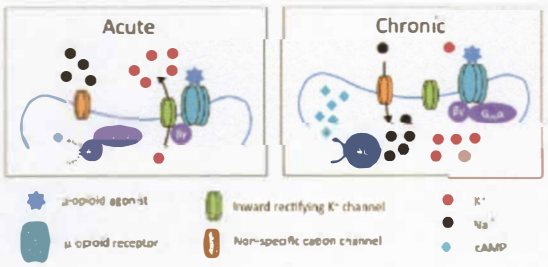
[4] https://www.acponline.org/system/files/documents/about_acp/chapters/me/management_of_addi





8. Opioid use disorder also changes the circuitry in the brain for regulating arousing and psychological stress. Specifically, the cycle of addiction, including withdrawal, leads to hyperactivity locus coereleus noradrenergic system that regulates arousal and psychological stress.[5]





9. Genetic factors account for between 40 and 60 percent of a person's vulnerability to addiction. Those who are genetically predisposed to addiction experience an altered response to the drug and changes in drug metabolism.

10. Additionally, adverse childhood experience creates a two- to four-fold increase in

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ction_issues_in_complex_pain_j_fellers.pdf (citing Olds, J., & Milner, P. (1954). Positive reinforcement produced by electrical stimulation of septal area and other regions of rat brain. J Comp Physiol Psychol 47(6), 419-27. Nestler, E. J. (2005). Is there a common molecular pathway for addiction? Nat Neurosci; 8(11), 1445-9).

[5] Nestler, E. J., Alreja, M., & Aghajanian, G. K. (1999). Molecular control of locus coeruleus neurotransmission. Biol Psychiatry; 46(9), 1131-9. Koob, G. F., Buck, C. L., Cohen, A., Edwards, S., Park, P. E., Schlosburg, J. E., et al. (2014). Addiction as a stress surfeit disorder. Neuropharmacology; 76 (Part B), 370-82.

the likelihood of early initiation into illicit drug use. Additional predictors of addiction include peer influence and drug availability.

Standard of Care for Opioid Use Disorder

11. Medication-assisted treatment is the standard of care for opioid use disorder. Although some patients can treat their opioid use disorder using only detoxification and 12-Step programs such as Narcotics Anonymous, most patients need medication-assisted treatment ("MAT") to achieve long-term recovery[6].

12. MAT is an opioid treatment that combines medication and counseling. The primary medications used in MAT are methadone and buprenorphine. Both have been approved by the United States Food and Drug Administration for treatment of opioid dependence.

13. The results of treatment with MAT is dramatically superior to other treatment options, with studies showing improved retention in treatment, abstinence from illicit drugs[7], and decreased mortality[8].

14. The medication element of MAT helps to prevent a user experiencing a "high" after taking opioids, helps to suppress withdrawal, and reduce cravings. *See* Exhibit 2. Methadone is a full agonist at the opioid receptor, and buprenorphine is a partial agonist. In other words, methadone activates the opioid receptor at 100 percent, and buprenorphine activates opioid receptors approximately 20 to 40 percent.

15. Both buprenorphine and methadone bind tightly to the opioid receptor so that

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[6] Frequently Asked Questions about Opioid Use Disorder and IMAT, MaineHealth, https://mainehealth.org/-/media/mainehealth/pdfs/opioids/frequently-asked-questions-about-opioid-use-disorder-and-imat.pdf?la=en

[7] Mattick RP, Breen C, Kimber J, Davoli M. (2014). Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev.* 2:CD002207.

[8] Kakko J, Svanborg KD, Kreek MJ, Heilig M. (2003). 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: a randomised, placebo-controlled trial. *Lancet*. 361(9358): 662-8.

someone taking one of these medications is not able to feel a "high" from taking heroin or fentanyl because those drugs are not able to activate the opioid receptor.

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. Exhibit 2.

17. Both methadone and buprenorphine also facilitate extinction learning because patients learn that they will not get the same "high" from taking drugs like heroin or fentanyl.

18. Use of buprenorphine has been supported by the American Medical Association, the American Psychiatric Association, and the American Academy of Family Physicians, among others.

19. There is robust scientific data showing that MAT with buprenorphine or methadone is far more effective than detoxification alone. In fact, detoxification alone produces very poor outcomes. For example, one study documented the treatment outcomes from a detoxification facility, and showed (1) a 29 percent relapse on the day of discharge, (2) a 60 percent relapse after one month[9], and (3) a success rate of between only 5 to 10 percent after one year[10].

20. For example, methadone and buprenorphine both retain patients in treatment better than a placebo treatment. On the placebo treatment, no patients remained in treatment or remained sober at six months[8]. In contrast, 50-60 percent of patients on methadone remained in

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[9] Bailey, G. L., Herman, D. S., & Stein, M. D. (2013). Perceived relapse risk and desire for medication assisted treatment among persons seeking inpatient opiate detoxification. *J Subst Abuse Treat*, 45(3), 302-5.

[10] Valliant GE. (1988). What does long-term follow-up teach us about relapse and prevention of relapse in addiction? *Br J Addict;* 83(10): 1147-57.

treatment after one year[11], and patients on buprenorphine showed similar numbers[12]. In my practice at Maine Medical Center, we see approximately 50 percent retention on patients treated with buprenorphine.

21. Results like this show that it is a disservice to refuse to offer MAT from patients with opioid use disorder, especially patients with a track record of success on MAT.

22. Both methadone and buprenorphine are also cost-effective. Methadone costs less than $5,000 per patient, per year. Buprenorphine costs approximately $5,000 to $6,000 per year for the medication alone.

23. Opioid use disorder is a chronic relapsing condition, similar to diabetes. It should not be treated differently than other chronic diseases. Both conditions require maintenance medication to keep symptoms managed. We do not withhold insulin from a person with diabetes during incarceration. We need to continue treatment with MAT for a person with the brain disease of opioid use disorder during incarceration.

Opioid Withdrawal

24. Prison policies that prohibit treatment with methadone and buprenorphine can force patients into acute withdrawal. Acute withdrawal causes symptoms including bone and joint aches, vomiting, diarrhea, excessive sweating, hypothermia, hypertension, tachycardia (elevated heart rate), and psychological symptoms like depression and anxiety.

25. Withdrawal is especially dangerous for patients with co-occurring disorders, such as depression or anxiety. For such patients, forced withdrawal may cause severe depression, suicidal ideation, and decompensation. In the psychological sense, decompensation refers to a

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[11] Sees KL, Delucchi KL, Masson C, Rosen A, Clark HW, Robillard H, Banys P, Hall SM. (2000). Methadone maintenance vs 180-day psychosocially enriched detoxification for treatment of opioid dependence: a randomized controlled trial. *JAMA;* 283(10): 1303-10.

patient's inability to maintain defense mechanisms in response to stress, which can result in uncontrollable anger, delusions, mania, and other dangerous symptoms.

26. Forced withdrawal is not medically appropriate for patients being treated with MAT. It disrupts their treatment plan[13], leading to a seven-fold decrease in continuing MAT after release. Discontinuation of MAT increases the risk of relapse into active addiction. Over 82% of patients who leave methadone treatment relapse to intravenous drug use within a year[14]. Finally, patients are more likely to suffer from overdose and potential death as a consequence of forced withdrawal. Death is three times as likely for people out of treatment versus when in treatment[15].

27. I am providing this declaration in my personal capacity, not as a representative of Maine Medical Center or MaineHealth.

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

Executed on July 20, 2018

/s/Jonathan C. Fellers
Jonathan C. Fellers

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[12] Alford DP, LaBelle CT, Kretsch N, Bergeron A, Winter M, Botticelli M, Samet JH. (2011). Collaborative care of opioid-addicted patients in primary care using buprenorphine: five-year experience. *Arch Intern Med.* 171(5): 425-31.

[13] Rich JD, McKenzie M, Larney S, Wong JB, Tran L, Clarke J. (2015) Methadone continuation versus forced withdrawal on incarceration in a combined US prison and jail: a randomised, open-label trial. Lancet; 386:350–9.

[14] Ball JC, Ross A. (1991). The Effectiveness of Methadone Maintenance Treatment. New York, NY: Springer-Verlag.

[15] Evans E, Li L, Min J, Huang D, Urada D, Liu L, Hser YI, Nosyk B. (2015). Mortality among individuals accessing pharmacological treatment for opioid dependence in California, 2006-10. *Addiction*; 110(6): 996-1005.