SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF CLINTON

THE PEOPLE OF THE STATE OF NEW YORK

- against -

[redacted]

Index No. [redacted]
Hon. Timothy J. Lawliss

AFFIDAVIT OF
DR. GEORGE E. WOODY

COMMONWEALTH OF PENNSYLVANIA)
) SS:
COUNTY OF PHILADELPHIA)

George E. Woody, M.D., being duly sworn, deposes and says that:

Background & Credentials

1. I am a Doctor and Professor of Psychiatry at the Perelman School of Medicine, at the University of Pennsylvania. I have been a professor of psychiatry for more than 20 years. I have held a medical license issued by the State of Pennsylvania since 1966, and I am certified by the American Board of Psychiatry and Neurology.

2. I have specialized for more than 35 years in the treatment of addiction, and in particular in the use of medication-assisted treatment, known as MAT, for the treatment of opioid and other substance-abuse addictions. As I discuss in greater detail below, MAT is a form of treatment that uses medications, such as methadone, buprenorphine (which when combined with naloxone is commercially marketed and sold as Suboxone), and injectable naltrexone (commercially marketed as Vivitrol) to treat opioid addiction.

3. As a specialist in the treatment of addiction, I am a member of the Addiction Treatment and Research Center at the Perelman School of Medicine, and have been Principal

Investigator for the Delaware Valley Node of the National Institute on Drug Abuse's Clinical Trials Network. I am also a founding member of the Board of Addiction Psychiatry of the American Psychiatric Association. I have previously served twice as a member of the Board of Directors of the College on Problems of Drug Dependence, was a member of the working group on substance use disorders for the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), and participated on the Drug Abuse Advisory Committee for the federal Food & Drug Administration (FDA).

4. I have conducted dozens of clinical studies on the treatment of opioid addiction, including on the use and efficacy of methadone, Suboxone as well as oral and extended release naltrexone.. These studies have been published in peer-reviewed publications including the Journal of the American Medical Association, the Journal of Addiction Medicine, the Journal of Nervous & Mental Disease, and the Journal of Substance Abuse Treatment.

5. In addition to studies, I have authored or co-authored more than 300 scholarly articles, book chapters, and other publications concerning opioid addiction and its treatment, and have lectured both nationally and internationally on the subject. I have previously acted as a co-editor for Treatment Improvement Protocols for methadone maintenance, and participated as a committee member in helping develop the National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use, published by the American Society of Addiction Medicine. A complete list of my publications is attached as Exhibit A.

6. On several prior occasions, I have been qualified and provided expert testimony on the subjects of psychiatry and substance abuse in state administrative hearings dealing with impaired health professionals, and in federal courts.

Overview of Opioid Use Disorder

7. Opioid use disorder, commonly referred to as opioid addiction, is a chronic, relapsing disease that has significant economic, personal, and public health consequences. It is characterized by intense and at times uncontrollable drug craving, along with compulsive drug seeking and use that persist even in the face of severe adverse consequences.[1]

8. Opioid use disorder affects multiple brain circuits including those involved in reward and motivation, learning and memory, and inhibitory control over behavior. Individual vulnerability to opioid use disorder can vary, and depends upon the interplay between genetic makeup, age of first exposure, psychiatric problems, and other environmental influences.[2]

9. Over time, the effects of prolonged exposure to opioids on the brain compromise an individual's ability to choose, and the urge to seek and consume opioids becomes compulsive. Once in this state, an individual's self-control or willpower often are unable to overcome his or her compulsion to seek and consume.[3] As a result, an individual suffering from opioid use disorder cannot simply stop using opioids for a few days and expect to be cured.

10. Opioid use disorder is associated with increased mortality. The leading causes of death in people using opioids for non-medical purposes are overdoses and trauma.[4] Injection of opioids and other drugs also increases the risk of being exposed to HIV, viral hepatitis, and other infectious agents.[5]

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1 The American Society of Addiction Medicine ("ASAM"), *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, at 3 (adopted June 1, 2015), *available at* http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf.

2 National Institute on Drug Abuse ("NIDA"), *Principles of Drug Addiction Treatment: A Research-Based Guide* (3d ed. 2015), *available at* https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/preface.

3 *Id.*

4 ASAM, *National Practice Guideline*, *supra* note 1, at 4.

5 *Id.*

The Use of Medication-Assisted Treatment

11. Medication-assisted treatment, or MAT, is an effective treatment for opioid use disorder.

12. Methadone and buprenorphine are each unique, but both are opioid based and perform the same core function. Specifically, these medications target the same brain circuits that are targeted by opioids themselves. In doing so, they reduce or eliminate the withdrawal symptoms and cravings (the urge to seek and use opioids) typically experienced by an individual with opioid use disorder.[6] Injectable naltrexone, the third FDA-approved medication to treat opioid addiction, blocks the effects of opioids so that patients will not experience euphoria or a "high." Individuals must be fully withdrawn from opioids before they can use injectable naltrexone or it will precipitate a clinically significant opioid withdrawal reaction.[7]

13. Methadone, buprenorphine, or injectable naltrexone are usually combined with behavioral therapy and counseling. This is because opioid use disorder has multiple dimensions and severely disrupts many aspects of an individual's life, and effective treatment must help an individual not only stop using opioids illicitly, but also change a drug-seeking life style so that they are able to function productively in society. The goals of combining medication with behavioral therapies are to normalize brain chemistry, block euphoric effects of opioids, relieve cravings, and stabilize bodily functions.

14. These medications play an essential role in achieving these goals. Methadone and buprenorphine are effective in combatting withdrawal symptoms, and, when used as prescribed, do so without also producing the feelings of euphoria or sedation caused by opioids. Though they can cause sedation and cognitive impairment if taken in high doses, persons that have

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[6] NIDA, *Principles of Drug Addiction Treatment*, supra note 2.

become addicted develop tolerance to their sedative effects and thus experience no significant cognitive impairment when taken as prescribed during maintenance treatment. This phenomenon of tolerance, combined with the suppression of withdrawal and opioid craving that occurs during untreated addiction permits individuals receiving MAT to achieve a healthy and productive lifestyle, develop supportive relationships, and reduces the risk of overdose and other adverse events that are associated with untreated addiction

15. For these reasons, the use of buprenorphine or methadone in MAT is not merely "substituting one addiction for another," a commonly held misperception. Unlike short-acting opioids, such as heroin, which go directly to the brain to produce euphoric affects and impair cognitive functions, long-acting opioid medications, such as methadone and buprenorphine, when used as prescribed, stabilize opioid addiction and increase the chances that individuals will hold jobs, avoid criminal activity, reduce exposure to HIV and other infectious diseases from use of contaminated injecting equipment, and allows individuals to more effectively participate in behavioral therapy and other supportive services, which further aids recovery.

16. Using medication solely for the purpose of managing withdrawal is not effective. Studies show that treating withdrawal alone runs a significant risk of relapse and other harm, and does not constitute a treatment method for the underlying medical disorder.[8] Treatment of opioid use disorder with counseling alone is also proven to be rarely effective.

17. In my medical judgment, the use of MAT, including Suboxone or methadone, constitutes best medical practices for treatment of opioid use disorder.

18. My medical conclusion is supported by extensive research. After an exhaustive study, the American Society of Addiction Medicine concluded that treatment of opioid use

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[7] Substance Abuse and Mental Health Services Administration ("SAMHSA"), *Naltrexone*, (last updated Sept. 9, 2016) *available at* https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone.

disorder with MAT, including the use of an opioid medication, was superior to efforts to simply manage withdrawal.[9] The Society concluded that use of MAT led to "decreased mortality, abstinence from opioids, and retention in treatment" and that there is "strong evidence supporting the superiority" of MAT over drug-free treatments for persons with opioid use disorders.[10] This conclusion has been reaffirmed by numerous studies,[11] including studies in which I have personally participated. The National Institute on Drug Abuse has also observed that MAT "decreases drug use, infectious disease transmission, and criminal activity."[12]

19. Public health officials have also endorsed the use of MAT to treat opioid addiction. The U.S. Surgeon General, for example, concluded that "[w]ell-supported scientific evidence shows that medications can be effective in treating serious substance use disorders, but they are under-used."[13] Similarly, New York's Office of Alcoholism & Substance Abuse Services makes use of an assessment tool called the LOCADTR3, which incorporates the use of MAT to treat opioid use disorder.[14]

The Use of Suboxone

20. Suboxone is a medication approved by the federal Food & Drug Administration for treatment of opioid use disorder, including as part of a MAT program.

21. Suboxone consists of two active drugs: buprenorphine and naloxone.

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9 *Id.* at 23.

10 *Id.* at 23–24.

11 For a collection of these studies, *see* Legal Action Center, *Medication-Assisted Treatment in Drug Courts*, n. 8 (observing that "dozens of studies have shown that medication-assisted treatment reduces drug use, disease rates, overdose deaths, and criminal activity among opioid addicted persons").

12 NIDA, *Medication-Assisted Treatment for Opioid Addiction* (Apr. 2012), *available at* https://www.drugabuse.gov/sites/default/files/tib_mat_opioid.pdf.

13 Dep't of Health & Human Services, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*, at 4-2, *available at* https://addiction.surgeongeneral.gov/surgeon-generals-report.pdf.

22. Buprenorphine is a synthetic opioid medication that is on Schedule III and acts as a partial agonist at opioid receptors. It reduces or eliminates withdrawal by targeting the same brain circuits targeted by full agonists such as methadone an other opioids. Unlike short-acting drugs such as heroin, buprenorphine does not produce euphoria or sedation when taken for maintenance treatment at prescribed doses. It is among the medications identified by the American Society of Addiction Medicine for treating opioid use disorder as part of a MAT program.[15]

23. Naloxone is a medication that acts as an antagonist, or blocker, at opioid receptors. When Suboxone is taken orally, as prescribed, naloxone is not absorbed into the blood and has no effect. However, if an individual with opioid use disorder injects Suboxone, the naloxone will produce significant withdrawal symptoms and thus acts to mitigate the threat that Suboxone will be dissolved and injected.

Best Practices in Treating Opioid Use Disorder

24. There is no "one size fits all" approach to the use of Suboxone, MAT, or the treatment of opioid use disorder. Each treatment plan should be tailored to the individual, including the types of opioid medication that are used, the dosage, the plan to reduce such usage, if any, and the array of behavioral therapy and other support received.

25. Individuals progress through treatment of opioid use disorder at different rates, and as a result there is no medically recommended length of treatment in a MAT program. Research has shown, however, that good outcomes from treatment are dependent upon adequate

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[14] *See* Office of Alcoholism & Substance Abuse Services, *Level of Care for Alcohol and Drug Treatment Referral 3.0*, at 21, *available at* https://oasas.ny.gov/treatment/health/locadtr/documents/LOCADTRManual.pdf.

[15] ASAM, *National Practice Guideline*, *supra* note 1, at 23–26.

treatment length, and that some individuals with opioid use disorder continue to benefit from MAT, and the associated opioid medications, for many years, even indefinitely.[16]

26. The most important factors in the treatment of opioid use disorder are (a) cooperation between the individual and the physician and (b) treatment that is consistent with the latest medical guidance. No decisions regarding treatment, including the decision to reduce the use of opioid medication, known as "tapering," should be made without agreement between the individual and the physician, or in a manner inconsistent with the latest medical guidance.

The Risks of Premature Cessation of Medication-Assisted Treatment

27. An individual who is forced to exit a MAT program that incorporates methadone, buprenorphine, or injectable naltrexone will be at a markedly increased risk of relapse and its attendant consequences, including overdose and death. Studies have shown that relapse rates are significantly higher when opioid use disorder is treated solely with withdrawal management techniques.[17] Similarly, studies have also shown that relapse rates are significantly higher for individuals who discontinue participation in MAT programs.[18]

28. In addition, immediate cessation of MAT poses particularly acute risks to health and well being, as an individual who has avoided opioids for a significant period of time will have reduced tolerance to the opioids, but not reduced cravings. As a result, individuals suffering from opioid use disorder that resort to treatment solely for reducing opioid withdrawal are at an increased risk of death as compared to those who participate in MAT.[19]

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[16] NIDA, *Principles of Drug Addiction Treatment*, supra note 2; U.S. Depart. Of Health & Human Svcs., Substance Abuse & Mental Health Admin., *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol* 43 (2005), *available at* http://store.samhsa.gov /shin/content/SMA12-4214/SMA12-4214.pdf.

[17] ASAM, *National Practice Guideline*, *supra* note 1, at 27.

[18] *Id.* at 30.

[19] *Id.* at 27.

Conclusions Based on My Review of Mr. [redacted]'s Medical Records

29. I have reviewed the past one and a half year's of Mr. [redacted]'s medical records, which I have been provided by his counsel. These medical records include (a) the file maintained by Mr. [redacted]'s current physician, Dr. [redacted], and (b) the file from the last year of his earlier treatment by Northern Tier Center for Health.

30. Based on my review of Mr. [redacted]'s medical records, I have identified no medical reason as to why the general principles of opioid use disorder and its treatment that I describe above would not apply with equal force to Mr. [redacted].

31. Accordingly, it is my opinion that:

a. There is no medical rationale for ordering that Mr. [redacted] discontinue his use of Suboxone in conjunction with his current MAT program;

b. Requiring that Mr. [redacted] discontinue his use of Suboxone poses a significant threat to his health and well-being, including a substantial increase in the risk of relapse and the attendant medical and non-medical consequences of relapse; and

c. Were Mr. [redacted] to attempt to taper down his use of Suboxone, there is no pre-determined amount of time for completion of tapering that can be deemed medically safe in advance, and any future decisions should be made only after consultation with his treating physician.

George E. Woody, M.D.

Subscribed and sworn to before me
this 21 of March, 2017.

Notary Public

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN B. NOBLE, Notary Public
City of Philadelphia, Phila. County
My Commission Expires January 15, 2019