



May 12, 2017

The Honorable Thomas Price
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

via email: Thomas.Price@hhs.gov

Re: Comments on Medications to Treat Opioid Addiction

Dear Secretary Price:

On behalf of the not-for-profit Female Opioid-addiction Research and Clinical Experts (FORCE), we would like to submit this letter regarding your recent comment that medications to treat opioid addiction are “just substituting one opioid for another.”¹

FORCE is an alliance of women with scientific, health policy, and medical expertise in opioid addiction and who are well positioned to achieve FORCE’s mission of reducing the stigma and treatment barriers that people with opioid addiction face every day. These efforts will save lives by ensuring that more patients receive effective treatment.

Opioid overdose is a public health epidemic in the United States. Over 33,000 Americans died from opioid-related overdoses in 2015, with over 20,000 deaths involving prescription opioid medications and 12,989 deaths involving heroin.² An estimated 4.3 million Americans abuse opioids each year, while an estimated 2.5 million Americans are dependent on opioids.³ Additionally, nearly 830,000 people age 12 or older used heroin in 2015, with approximately 329,000 of those individuals classified as current heroin users.⁴ Opioid misuse, abuse, and dependence costs up to \$25 billion in healthcare costs, \$25 billion in workplace costs, and \$5 billion in criminal justice costs annually.⁵

Despite the increasing number of individuals with opioid use disorder and the associated cost increases, only an estimated 20 percent of individuals who need treatment receive it.⁶ If left untreated, individuals with opioid use disorder are at a higher risk of contracting and transmitting serious infectious diseases, such as HIV and hepatitis C; engaging in criminal activity; and experiencing fatal overdoses.⁷ The issue is further complicated by flawed assumptions that substance use disorders are a moral failing. Instead, science has shown that opioid use disorder is a chronic relapsing disease of the brain and should be treated like other chronic, relapsing diseases.⁸

Evidence shows that medication-assisted treatment, an evidence-based method that combines counseling, behavioral therapies, and medications approved by the U.S. Food and Drug Administration (FDA), is effective in managing opioid use disorder, reducing the risk of contracting serious infectious

BOARD OF DIRECTORS

Genie Bailey,
MD, DABAM
Brown University

Andrea Barthwell,
MD, DFASAM
Past president of ASAM
and former ONDCP
Deputy Director

Serena Kim, PharmD
SVP of Clinical
and Medical
Affairs, Braeburn
Pharmaceuticals

Shruti Kulkarni, JD
Outside Counsel, Center
for Lawful Access and
Abuse Deterrence

Behshad Sheldon
President and
Chief Executive
Officer of Braeburn
Pharmaceuticals

FORCE OFFICERS

Andrea Barthwell,
MD, DFASAM
Chairwoman

Shruti Kulkarni, JD
Secretary



diseases and criminal recidivism, and decreasing the cost of health care.⁹ In fact, literature from the Substance Abuse and Mental Health Services Administration specifically states:

Taking medication for opioid addiction is like taking medication to control heart disease or diabetes. It is NOT the same as substituting one addictive drug for another. Used properly, the medication does NOT create a new addiction. It helps people manage their addiction so that the benefits of recovery can be maintained.¹⁰

Treatment of opioid use disorder with FDA-approved medications may be medically appropriate for some individuals because such medications can reduce symptoms of withdrawal and craving, allowing the individual to focus on the lifestyle changes that lead back to healthy living.¹¹ For example, one study found opioid dependent patients receiving only psychological support were twice as likely to suffer a fatal overdose than those being treated with opioid replacement medications.¹²

Additionally, treatment with medication is vital for pregnant women with opioid use disorder. Buprenorphine is considered a first-line treatment during pregnancy,¹³ and timely treatment with buprenorphine can reduce the risk that infants will be born with neonatal abstinence syndrome (NAS), a drug withdrawal syndrome.¹⁴

Many states have seen rates of NAS increase dramatically, which causes lengthy and costly hospital stays. Nationally, the average hospital stay of an infant without NAS is 3.3 days, whereas the average hospital stay of an infant with neonatal abstinence syndrome is 16.4 days.¹⁵ The hospital costs for newborns with NAS were \$66,700 on average compared to \$3,500 for those without NAS.¹⁶

Medication-assisted treatment has the overall societal benefit of reducing the cost of health care. According to the Center for Substance Abuse Treatment, such treatment has a cost-benefit ratio of 1:7, with the largest savings found in the reduced cost of crime and increased employer earnings.¹⁷ Specifically, for every \$100,000 spent on treatment, there was a savings of \$487,000 in healthcare costs (e.g., visits to the hospital emergency department) and \$700,000 in crime costs (e.g., arrests or incarceration). Additional societal savings were found in public assistance and employer costs.

In sum, medication-assisted treatment has been shown to save lives, improve the lives of pregnant women with opioid use disorders and their newborns, reduce the spread of infectious diseases, decrease criminal recidivism, and result in significant cost-savings for the nation. For these reasons, we request that you reconsider your position and issue a new statement on the importance of medication-assisted treatment. If you would like to discuss this matter further, please contact me at drbarthwell@gmail.com.

Sincerely,

Andrea G. Barthwell, MD, DFASAM
Chairwoman

BOARD OF DIRECTORS

Genie Bailey,
MD, DABAM
Brown University

Andrea Barthwell,
MD, DFASAM
Past president of ASAM
and former ONDCP
Deputy Director

Serena Kim, PharmD
SVP of Clinical
and Medical
Affairs, Braeburn
Pharmaceuticals

Shruti Kulkarni, JD
Outside Counsel, Center
for Lawful Access and
Abuse Deterrence

Behshad Sheldon
President and
Chief Executive
Officer of Braeburn
Pharmaceuticals

FORCE OFFICERS

Andrea Barthwell,
MD, DFASAM
Chairwoman

Shruti Kulkarni, JD
Secretary



Footnotes

1. Julia Lurie, Trump's Health Secretary Says Addiction Meds Are "Substituting One Opioid For Another," MOTHER JONES (May 10, 2017), <http://www.motherjones.com/politics/2017/05/tom-price-opioid-addiction-treatment>.
2. Opioid Addiction: 2016 Facts & Figures, AMERICAN SOCIETY OF ADDICTION MEDICINE (2016), <http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>.
3. Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (Sept. 2015) <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>; Substance Use Disorders, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (Nov. 23, 2015), <https://www.samhsa.gov/disorders/substance-use>.
4. Jonaki Bose, et al., Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (2016), <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2015/NSDUH-FRR1-2015/NSDUH-FRR1-2015.htm#illicit09>.
5. H.G. Birnbaum, et al., Societal costs of prescription opioid abuse, dependence, and misuse in the United States, PAIN MED. 2011; 12(4): 657-667.
6. Number of Addicted Rises, but Shortage in Drug Treatment Remains Stagnant, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH (Oct. 13, 2015) <https://www.sciencedaily.com/releases/2015/10/151013133407.htm>.
7. Nora D. Volkow, Prescription Opioid and Heroin Abuse, NATIONAL INSTITUTE ON DRUG ABUSE (Apr. 29, 2014) <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/prescription-opioid-heroin-abuse>.
8. Drugs, Brains, and Behavior: The Science of Addiction, NATIONAL INSTITUTE ON DRUG ABUSE (July 2014) <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preface>.
9. Statement by Nora D. Volkow, M.D. on Treating Addiction as a Disease: The Promise of Medication-Assisted Recovery, DEPARTMENT OF HEALTH AND HUMAN SERVICES (June 23, 2010).
10. Medication-Assisted Treatment for Opioid Addiction, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (2011), <https://store.samhsa.gov/shin/content/SMA09-4443/SMA09-4443.pdf>.
11. Id.
12. Matthias Pierce, Impact of Treatment of Opioid Dependence on Fatal Drug-Related Poisoning: A National Cohort Study in England, (Nov. 2015), <http://onlinelibrary.wiley.com/doi/10.1111/add.13193/full>.
13. Lori Whitten, Buprenorphine During Pregnancy Reduces Neonate Distress, NATIONAL INSTITUTE ON DRUG ABUSE (June 6, 2012), <https://www.drugabuse.gov/news-events/nida-notes/2012/07/buprenorphine-during-pregnancy-reduces-neonate-distress>.
14. Jones, Hendrée E., et al., Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure, N Engl J Med. (Dec. 9, 2010); 363(24): 2320-2331, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3073631/pdf/nihms258739.pdf>.
15. Out of the Womb, into Withdrawal, NORTH CAROLINA HEALTH NEWS, (Sept. 11, 2015) <http://www.northcarolinahealthnews.org/2015/09/11/out-of-the-womb-into-withdrawal/>.
16. Dramatic Increases in Maternal Opioid Use an Neonatal Abstinence Syndrome, NATIONAL INSTITUTE ON DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome>.
17. U.S. Department of Health and Human Services: The cost offset of treatment services, CENTER FOR SUBSTANCE ABUSE TREATMENT, (2009) https://samhsa-gpra.samhsa.gov/CSAT/view/docs/SAIS_GPRA_CostOffsetSubstanceAbuse.pdf.

BOARD OF DIRECTORS

**Genie Bailey,
MD, DABAM**

Brown University

**Andrea Barthwell,
MD, DFASAM**

Past president of ASAM
and former ONDCP
Deputy Director

Serena Kim, PharmD

SVP of Clinical
and Medical
Affairs, Braeburn
Pharmaceuticals

Shruti Kulkarni, JD

Outside Counsel, Center
for Lawful Access and
Abuse Deterrence

Behshad Sheldon

President and
Chief Executive
Officer of Braeburn
Pharmaceuticals

FORCE OFFICERS

**Andrea Barthwell,
MD, DFASAM**

Chairwoman

Shruti Kulkarni, JD

Secretary