Testimony on H. 162 Before the House Committee on Human Services
House of Representatives, State of Vermont

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by

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Thank you for the opportunity to testify before the Committee on Human Services of the Vermont House of Representatives in support of H. 162, which would decriminalize possession of small amounts of non-prescribed buprenorphine.

In our testimony, we plan to (1) provide a brief background on the opioid crisis in Vermont; (2) review two facts about buprenorphine; (3) explain our position; (4) respond to concerns that have been raised; and (5) suggest an approach to monitoring the implementation of this legislation.

We acknowledge the assistance of two medical and public health students, Jia Ahmad and Jenny Wen, and an addiction medicine physician, Dr. Yngvild Olsen, in the preparation of this testimony. This testimony reflects the views of the two of us alone; we are not representing the views of Johns Hopkins University.

The Opioid Epidemic in Vermont

The opioid epidemic in Vermont is an ongoing public health emergency. According to the most recent state report, from 2015 to 2018, opioid-related deaths among Vermonters have increased 49% to a total of 110.[1] This toll has contributed to a decline in life expectancy at birth in the state over the last several years.

The high rate of death from overdose reflects the lethality of the drug supply. Three of four overdose deaths in Vermont are the result of illicit fentanyl and associated chemicals -- substances which have never before been so prevalent in the drug supply.

[1] Vermont Department of Health. Opioid-Related Fatalities Among Vermonters. February 14, 2019. Available at http://www.healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf. Accessed April 25, 2019.

To respond to these unprecedented risks, Vermont has taken several important steps, including the Hub-and-Spoke model for improved access to evidence-based care and the recent expansion of medication therapy for opioid use disorder in the criminal justice system.

These steps are saving lives. Yet the unprecedented nature of the fentanyl threat -- and the ongoing high rate of overdose death -- raise the question of what else can be done.

To assess the value of innovative approaches to novel challenges, the standard should not be, “Has this intervention already been well studied and well proven elsewhere?”

Rather, the standard should be two questions:

- Is there a strong justification for taking this step? and
- Can we monitor its implementation to be sure it is working as intended?

Two Facts about Buprenorphine

Before turning to the legislation, we would like to review two facts about buprenorphine, the chemical at the heart of the state’s discussion.

First, buprenorphine treats the neurobiological dysfunction in the brain associated with opioid addiction. On March 20, 2019, the National Academies of Science, Engineering, and Medicine released a consensus committee report entitled “Medications for Opioid Use Disorder Save Lives.” A major focus of the report is buprenorphine. The report states that “opioid use disorder is a treatable chronic brain disease resulting from the changes in neural structure and function that are caused over time by repeated opioid use” and that “medications are intended to normalize brain structure and function.”[2]

The report also found that “the risk of opioid overdose death declines immediately when patients initiate buprenorphine treatment” and that “expanding access to [treatment with buprenorphine] reduces the number of deaths due to opioid overdose.”

Second, buprenorphine acts differently than other opioids on the brain. Buprenorphine is known as a “partial opioid agonist” that has what is called a “ceiling effect,” meaning that the effects of the chemical at the opioid receptor reach a plateau and do not increase with higher doses.[3] This is unlike other commonly used prescription and illicit opioids -- including heroin and fentanyl -- that are” full agonists” and so do not have a ceiling effect. One result of this difference is that buprenorphine poses a lower risk of respiratory depression and therefore

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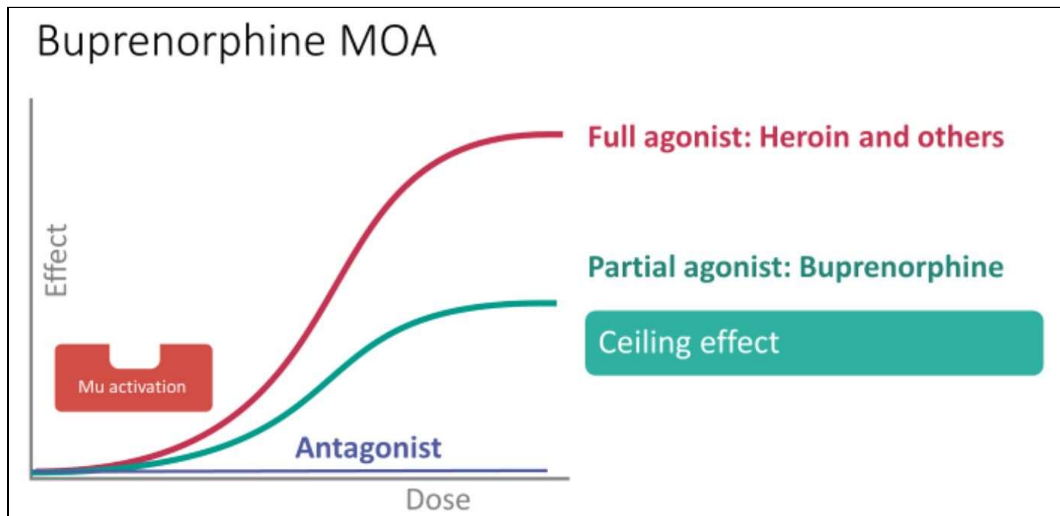
[2] National Academies of Sciences, Engineering, and Medicine 2019. *Medications for Opioid Use Disorder Save Lives.* Washington, DC: The National Academies Press. https://doi.org/10.17226/25310.

[3] Walsh SL, Preston KL, Stitzer ML, Cone EJ, Bigelow GE. Clinical pharmacology of buprenorphine: Ceiling effects at high doses. *Clinical Pharmacology and Therapeutics*. 1994; 55(5):569–580.

results in lower risk of overdose than other opioids.[4,5,6] Another result is that people with opioid addiction typically prefer to use full agonist opioids like heroin to obtain euphoric effect -- not buprenorphine.[7]



Buprenorphine Mechanism of Action (MOA).
Source: Suzuki, Brigham & Women's Hospital, Psychopharmacology Institute.[8]

Evidence in Support of H. 162

The case for decriminalizing possession of small amounts of non-prescribed buprenorphine is straightforward, with three main points.

<u>First, H.162 should reduce the risk of overdose, as individuals use buprenorphine in place of of more dangerous opioids.</u>

A critical question in public health is, "Compared to what?"

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[4] Dahan A, Yassen A, Romberg R, Sarton E, Teppema L, Olofsen E, & Danhof M. Buprenorphine induces ceiling in respiratory depression but not in analgesia. *British Journal of Anaesthesia* 2006; 96(5):627–632.

[5] Paone D, Tuazon E, Stajic M, Sampson B, Allen B, Mantha S, Kunins H. Buprenorphine infrequently found in fatal overdose in New York City. *Drug and Alcohol Dependence*. 2015 Oct 1;155:298-301.

[6] Lee S, Klein-Schwartz W, Welsh C, Doyon S. Medical outcomes associated with nonmedical use of methadone and buprenorphine. *The Journal of Emergency Medicine.* 2013 Aug 1;45(2):199-205.

[7] Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. Factors contributing to the rise of buprenorphine misuse: 2008–2013. *Drug and Alcohol Dependence.* 2014 Sep 1;142:98-104.

[8] Suzuki J. Buprenorphine for opioid use disorder: mechanism of action. Psychopharmacology Institute. 9 Feb 2018. https://psychopharmacologyinstitute.com/clinical-psychiatry/substance-use-disorders/buprenorphine-opioid-use-disorder-mechanism-action/. Accessed April 27, 2019.

To the extent that non-prescribed buprenorphine replaces the use of other opioids -- whether the misuse of medications such as oxycodone or the use of illicit opioids such as heroin -- the overdose risk to individuals will be substantially reduced.

This shift has been shown to happen. As one participant in a qualitative study said of the formulation of buprenorphine known as Suboxone, use is "getting more common because people are trying to get off of Percocets and stuff, so everybody's trying to find Suboxone…"[9]

Second, H. 162 should save lives by introducing more people to buprenorphine and ultimately encouraging them to enter effective treatment.

Evidence indicates that in areas with wide access to oxycodone, heroin, and other dangerous opioids, people use non-prescribed buprenorphine primarily to alleviate opioid withdrawal and to reduce cravings for opioids. For example:

- Two studies in Baltimore, published in 2009 and 2013, found more than 9 in 10 people who use non-prescribed buprenorphine did so for self medication or to alleviate withdrawal. In one of the studies, only 2% of people reported using buprenorphine for euphoric effect; in the other study, none did.[10,11]
- A study in Cambridge, Massachusetts, published in 2010, found that the primary reasons for using non-prescribed buprenorphine among people presenting for care were for to alleviate withdrawal (72%) and reduce cravings (92%) and rarely for euphoria (4%). The researchers concluded "these data … suggest that the use of illicit buprenorphine rarely represents an attempt to attain euphoria. Rather, illicit use is associated with attempted self-treatment of symptoms of opioid dependence, pain, and depression."[12]
- A study in Providence, Rhode Island, published in 2018, found the most commonly reported motivation for using non-prescribed buprenorphine was to alleviate withdrawal (40%) and self-treatment of opioid use disorder (39%), much higher than reports of seeking euphoria (12%).[13]

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[9] Daniulaityte R, Falck R, Carlson RG. Illicit use of buprenorphine in a community sample of young adult non-medical users of pharmaceutical opioids. *Drug and Alcohol Dependence.* 2012 May 1;122(3):201-7.

[10] Gwin Mitchell S, Kelly SM, Brown BS, et al. Uses of diverted methadone and buprenorphine by opioid-addicted individuals in Baltimore, Maryland. *Am J Addict.* 2009 ; 18(5): 346–355.

[11] Genberg BL, Gillespie M, Schuster CR, Johanson CE, Astemborski J, Kirk GD, Vlahov D, Mehta SH. Prevalence and correlates of street-obtained buprenorphine use among current and former injectors in Baltimore, MD. *Addict Behav.* 2013 Dec; 38(12)2868-73.

[12] Schuman-Olivier Z, Albanese M, Nelson SE, et al. Self-treatment: illicit buprenorphine use by opioid-dependent treatment seekers. *J Subst Abuse Treat.* 2010; 39(1):41–50.

[13] Carroll JJ, Rich JD, Green TC. The More Things Change: Buprenorphine/naloxone diversion continues while treatment remains inaccessible. *J Addict Med.* 2018 12(6): 459-465.

As a participant in a qualitative study told researchers, “I just eat Suboxone ‘cause it doesn’t necessarily give me a buzz, but it helps with the mental state, you know, it helps me feel regular and it’s not like I’m taking it to get high.”[14]

When people try non-prescribed buprenorphine to alleviate withdrawal or reduce cravings, evidence and experience indicates that they feel better and become more interested in entering treatment and obtaining both a consistent supply of medication as well as other services.

In the aforementioned Baltimore study, nearly all participants who used non-prescribed buprenorphine were interested in receiving drug treatment.[15] In the Rhode Island study, people who had sought buprenorphine treatment were also more likely to have used non-prescribed medication in the past.[16]

This effect has also been seen here in Vermont. When one of us visited Burlington in March, he heard from an emergency department physician at the University of Vermont that people were asking for treatment with buprenorphine after trying non-prescribed buprenorphine on the street.

As a participant in a 2017 qualitative study stated, “I’ve taken Suboxone illegally, and I’ve found that I’ve done very, very well on it. So, I’m looking for a Suboxone provider.”[17]

Third, H.162 should lead to fewer people being arrested due to their addiction, resulting in fewer associated adverse consequences to their health and well-being.

Arrest and incarceration have harmful health impacts. These include the risk of physical and sexual assault, poor ventilation and nutrition, overcrowding, and stress from incarceration[18]

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[14] Daniulaityte R, Falck R, Carlson RG. Illicit use of buprenorphine in a community sample of young adult non-medical users of pharmaceutical opioids. Drug and alcohol dependence. 2012 May 1;122(3):201-7.

[15] Genberg BL, Gillespie M, Schuster CR, Johanson CE, Astemborski J, Kirk GD, Vlahov D, Mehta SH. Prevalence and correlates of street-obtained buprenorphine use among current and former injectors in Baltimore, MD. Addict Behav. 2013 Dec; 38(12)2868-73.

[16] Carroll JJ, Rich JD, Green TC. The More Things Change: Buprenorphine/naloxone diversion continues while treatment remains inaccessible. J Addict Med. 2018 12(6): 459-465.

[17] Carroll JJ, Marshall BDL, Rich JD, Green TC. Exposure to fentanyl-contaminated heroin and overdose risk among illicit opioid users in Rhode Island: A mixed methods study. International Journal of Drug Policy. 2017; 46: 136-145.

[18] National Research Council and Institute of Medicine. (2013). *Health and Incarceration: A Workshop Summary.* A. Smith, Rapporteur. Committee on Law and Justice, Division of Behavioral and Social Sciences and Education and Board on the Health of Select Populations, Institute of Medicine. Washington, DC: The National Academies Press.

as well as adverse consequences from disruption of employment and health insurance,[19] impoverishment from legal fees, and difficulty obtaining housing and services with a criminal record.[20] These traumas and deprivations are likely to increase the risk for substance misuse, not decrease it. In addition, arrest of a person with opioid addiction may lead to further disruption of their treatment pathway, and may substantially elevate their risk of overdose upon release from incarceration.[21]

Responding to Concerns

We appreciate the opportunity to respond to several concerns raised about this legislation.

Concern: *How can it be that people need to use non-prescribed buprenorphine to self-treat their withdrawal symptoms, when there is such easily available access and no waitlists for treatment in Vermont?*

Response: Vermont indeed has made significant progress in treatment capacity by expanding evidence-based care for opioid use disorder through its hub and spoke model. However, gaps in access to treatment remain.

According to a 2017 evaluation of the hub and spoke model conducted by the Vermont Center Behavior and Health, there are several reasons for remaining gaps, including long distances to clinics and other logistical barriers especially in rural areas, as well as stringent policies for new patients and remaining stigma against those seeking treatment.[22,23]

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[19] Freudenberg N, Daniels J, Crum M, Perkins T, Richie BE. Coming home from jail: The social and health consequences of community reentry for women, male adolescents, and their families and communities. *American Journal of Public Health*. 2005; 95(10), 1725-1736.

[20] Sheely A, Kneipp SM. The Effects of collateral consequences of criminal involvement on employment, use of temporary assistance for needy families, and health. *Women & Health.* 2015; 55(5), 548-65.

[21] Merrall ELC, Kariminia A, Binswanger IA, et al. Meta-analysis of drug-related deaths soon after release from prison. *Addiction*. 2010;105(9):1545–1554.

[22] Rawson, 2017; page 9. Evaluator noted "Central Vermont had most integrated and collaborative sector of the H & S system. The Northeast [the most rural region of Vermont] has suboptimal access to spoke services and is disproportionally served by hubs...there is increasing, but still insufficient spoke access, in Chittenden County, and there are only two spoke providers and no hub in Addison County….In the Southwest region...drive times to Bennington County limit the number of people receive hub services….the Southeast region has both hub and spoke services easily available."

[23] Sigmon SC. Access to Treatment for Opioid Dependence in Rural America: Challenges and Future Directions. *JAMA Psychiatry.* 2014;71(4):359–360. Residents of rural areas in Vermont struggle more with treatment access, similar to the rest of nation. Dr. Sigmon, the author of this piece and the director of the largest methadone clinic in Vermont in 2014, noted in her clinic with 52 currently enrolled patients, patients reported around 60 minutes of travel time per clinic visit and $48 in weekly transportation cost. Most (85%) had to attend clinic daily, 40% rely on public transportation, and 22% reported travel time for treatment interfered with ability to maintain employment. .

For some patients who experience these barriers, or who at the moment may not be ready for treatment in an official program, using non-prescribed buprenorphine may encourage them to give treatment a try.

Concern*: Will the availability of non-prescribed buprenorphine discourage people from seeking treatment?*

Response: This is unlikely, because as noted above, evidence points to the reverse conclusion: Non-prescribed buprenorphine is often used by people who may not have had experience with treatment or may not know where or how to access it, and trying non-prescribed buprenorphine may encourage them to seek treatment. In fact, those who have used non-prescribed buprenorphine before entering treatment have been found to have better treatment retention rates than those who did not.[24]

Concern*: Will more people become addicted to buprenorphine if possession of small quantities is decriminalized?*

Response: It is unlikely that decriminalization of small amounts of buprenorphine will lead more people to become addicted to buprenorphine. In settings where low level drug use has been decriminalized, such as Portugal, this policy has not been associated with increased use among the population.[25]

It is particularly unlikely that decriminalization of possession of small amounts of buprenorphine will have this effect. Because of its partial agonist properties and "ceiling effect" on the opioid receptor, buprenorphine is much less likely to cause euphoria than full agonist opioid medications and illicit opioids that are available in Vermont.

Concern*: Buprenorphine is more potent than morphine. Does that mean it is more addictive than morphine?*

Response: No. Potency refers to the amount of a substance that lead to its specific effect. Addictive potential depends on a number of factors including the likelihood to cause euphoria, which buprenorphine is less likely to do compared to full agonist opioids such as morphine.[26]

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[24] Alford DP, LaBelle CT, Kretsch N, et al. Collaborative care of opioid-addicted patients in primary care using buprenorphine: five-year experience. *Arch Intern Med.* 2011;171(5):425–431.

[25] Hughes CE and Stevens. A resounding success or a disastrous failure: Re-examining the interpretation of evidence on the Portuguese decriminalisation of illicit drugs. *Drug and Alcohol Review.* 2015; 31:101-113.

[26] Walsh SL, Eissenberg T. The clinical pharmacology of buprenorphine: extrapolating from the laboratory to the clinic. *Drug and Alcohol Dependence.* 2003 May 21;70(2):S13-27.

Concern: *Is buprenorphine more likely to be injected than other opioids?*

Response: No, buprenorphine is less likely to be injected than other opioids. This is because the most common formulation that is available, often known as Suboxone, is a combination of buprenorphine and naloxone that will precipitate withdrawal and block the euphoric effects if injected.[27,28] In fact, studies show participants who have tried injecting buprenorphine combined with naloxone report aversive reactions.[29]

Concern: *Will decriminalizing possession of small amounts of buprenorphine incentivize current patients to sell their medications, undermining their treatment?*

Response: We are not aware of evidence that suggests that this is likely. The proposed legislation does not change the criminal liability for selling buprenorphine, nor does it change the importance of clinical protocols to assure that patients are appropriately taking their medications.

Concern: *Will the decriminalization of possession of small amounts of buprenorphine lead to the loss for opportunities for treatment within the criminal justice system?*

Response: Vermont has made great strides to assure evidence-based treatment is available in jails and prisons. However, treatment in the criminal justice system should not be the main avenue into care; it should be a path of last resort. Far better (and much less expensive) for individuals to obtain care in the community without enduring the adverse effects of arrest and incarceration.

Concern*:* Does H. 162 discourage law enforcement officers from referring people found with non-prescribed buprenorphine to community-based treatment?

Response: H. 162 is consistent with efforts to encourage and make it easier for persons to enter community-based treatment. There are a number of promising models within law enforcement supporting referral of people with addiction to treatment, without the need to threaten criminal charges.[30] We would recommend the adoption of such strategies that could act as a complement to H162.

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[27] Stoller KB, Bigelow GE, Walsh SL, Strain EC. Effects of buprenorphine/naloxone in opioid-dependent humans. *Psychopharmacology*. 2001 Mar 1;154(3):230-42.

[28] Yokell MA, Zaller ND, Green TC, Rich JD. Buprenorphine and Buprenorphine/Naloxone Diversion, Misuse, and Illicit Use: An International Review. *Curr Drug Abus Rev.* 2011;4(1):28-41.

[29] Moratti E, Kashanpour H, Lombardelli T, Maisto M. Intravenous Misuse of Buprenorphine. *Clin Drug Investig.* 2010;30(1):3-11.The majority who injected buprenorphine (53%) had a negative experience.

[30] Law Enforcement Assisted Diversion (LEAD), http://leadkingcounty.org/about/

Recommendations for Monitoring Implementation of H. 162

Vermont is in many ways a pioneer in its response to the national opioid crisis. H. 162 is also a novel initiative for which there are no prior examples in the United States. It is our view that this policy is likely to reduce overdose risk and improve access to treatment over time. At the same time, it is important for Vermont to monitor its implementation to be sure it is working as intended.

In particular, we recommend two focus areas for monitoring the health impacts of this legislation:

- Surveillance of hospitalizations and deaths involving opioids, including non-prescribed buprenorphine.

We recommend that Vermont actively track the number and proportion of hospitalizations and deaths that involve opioids, and understand the role of buprenorphine plays in contributing to or reducing this risk. It is critical that the state not only track the involvement of buprenorphine in these events but also detect overall increases or decreases in opioid risk and mortality across the population.

- In-depth assessments of experiences of persons who use non-prescribed buprenorphine, including their understanding of and access to treatment.

We recommend that Vermont support qualitative studies and interviews with persons who may be directly impacted by this legislation, to understand any new benefits or challenges posed by this policy. A focus on motivations for use and experiences with non-prescribed buprenorphine can help shed light on any unintended consequences of this law as well as help address ongoing barriers to accessing buprenorphine in treatment programs.

Tracking the implementation of H. 162 will not only allow the state to monitor safety and respond to any unintended consequences of this law, but also be able to inform other states who may be considering similar legislation as a step towards minimizing opioid related harms and deaths in their communities.

Conclusion

Thank you very much for allowing us the opportunity to speak with you today. In addition to these comments, we have attached two recently published papers relevant to H. 162. We look forward to your questions.

Attachments

1. Doernberg M, Krawczyk N, Agus D, Fingerhood M. Demystifying buprenorphine misuse: Has fear of diversion gotten in the way of addressing the opioid crisis?.*Substance Abuse.* 2019 Apr 19:1-6.

2. Martin SA, Chiodo LM, Bosse JD, Wilson A. The next stage of buprenorphine care for opioid use disorder. *Annals of Internal Medicine.* 2018 Nov 6;169(9):628-35.