

December 3, 2018

Docket No. FDA-2018-N-3805 for Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee

Comments from Human Rights Watch

Dear Committee Members:

We submit these comments for Docket No. FDA-2018-N-3805 convened to address the crucial issue of increasing access to naloxone for overdose prevention in the United States. Human Rights Watch is a non-governmental organization that investigates and documents human rights conditions in more than 80 countries and advocates for change. Our researchers have reported on the issue of access to health services, including overdose prevention, for people who use drugs around the globe. Most recently, we published a report documenting four primary barriers to access to naloxone in the United States and making recommendations to state and federal government for removing or reducing those barriers in order to meet their obligation to respect the rights to health, and to life, for people who use drugs.¹

Naloxone is a generic medication that has a 20-year track record of safe administration by lay persons- indeed, current formulations are specifically designed for lay use. In the midst of what has been declared by the Trump administration to be a public health emergency, it is imperative to put naloxone into the hands of those who need it the most: people who use drugs and those most likely to be at the scene of an overdose. Equipping emergency and law enforcement responders is important, but someone has to call 911 – and since earlier administration of naloxone is associated with better health outcomes we need to make sure that person has ready access to naloxone.

People who use drugs are a criminalized, stigmatized and marginalized population who often lack health insurance or the ability to pay for health services. Experiences of having been treated badly, mistrust and shame also often prevent people who use drugs from seeking help in traditional medical facilities. Pharmacies are often in short supply in rural and underserved areas and naloxone distribution limited by lack of participation by pharmacists and lack of awareness among pharmacy customers.² In these conditions, reliance on a medical model for naloxone distribution is necessary, but insufficient, to meet the need for this life-saving medication among the people it is intended to help.

¹ Human Rights Watch, A Second Chance: Overdose Prevention, Naloxone and Human Rights in the United States, April 2017, <https://www.hrw.org/report/2017/04/27/second-chance/overdose-prevention-naloxone-and-human-rights-united-states>

² Peter Murray, “Why Spatial Analysis is Key to Ending Pharmacy Deserts and the Opioid Epidemic,” Carto, March 27, 2018, https://carto.com/blog/spatial-analysis-pharmacy-deserts-opioid-epidemic/?utm_content=69228009&utm_medium=social&utm_source=twitter (accessed November 26, 2018); Puzantian, T., et al, “Provision of Naloxone Without a Prescription 2 Years After Legislation Implementation,” JAMA Network, November 13, 2018, https://jamanetwork.com/journals/jama/article-abstract/2714519?guestAccessKey=3606cef4-6882-4177-9eb8-03d32e50c606&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jama&utm_content=etoc&utm_term=111318 (accessed November 26, 2018.)

Increased naloxone availability saves lives. While two working papers that have not been subject to peer review found that naloxone access laws were not associated with an overall change in overdose deaths, a third found them to be associated with a nine to eleven percent decrease. More importantly, the only peer-reviewed study, led by scientists at the Substance Abuse and Mental Health Services Administration, found that these laws were associated with a 14% lower incidence of opioid-related mortality for the population as a whole, and a 23% lower incidence of opioid overdose mortality among non-Hispanic Black Americans.³

Importantly, direct distribution of naloxone through front-line, community-based interventions such as syringe access programs, has been shown to reverse significant numbers of overdoses.⁴ For example, North Carolina has an extensive community-based program that since 2013 has distributed more than 80,000 naloxone kits directly to people who use drugs, their families and friends. This has resulted in more than 12,000 reported overdose reversals in North Carolina alone.⁵ In Florida, Miami's IDEA syringe exchange has distributed naloxone since March 2017, and has reversed nearly 1,000 overdoses since that time.⁶ Over the counter status would permit community organizations to more easily purchase naloxone and availability in non-pharmacy locations could, in the words of one national harm reduction advocate, "be a game-changer" in the fight against the overdose epidemic in our country.⁷

For these reasons Human Rights Watch has called upon the FDA and manufacturers of naloxone to ensure that at least some formulations of naloxone are available without the unnecessary barriers presented by prescription requirements. We applaud the FDA efforts to encourage manufacturers to move existing products OTC, but these efforts have been unsuccessful: no manufacturers have come forward to apply for OTC status. We urge the FDA to take regulatory action to move one or more existing formulations of naloxone to OTC status without further delay and to do everything possible to hasten approval of new OTC formulations. This is an extraordinary step, but as legal experts have noted in their written comments submitted to this committee, it is a step authorized by current law.⁸ And with more than 70,000 deaths from overdose in the last year in a formally declared public

³ Doleac J. The Moral Hazard of Lifesaving Innovations: Naloxone Access, Opioid Abuse, and Crime, September 30, 2018; McClellan C, Lambdin BH, Ali MM, et al. Opioid-overdose laws association with opioid use and overdose mortality. *Addict Behav* 2018;86:90-5; Rees D, Sabia J, Argys L, Latshaw J, Dave D. With a Little Help from My Friends: The Effects of Naloxone Access and Good Samaritan Laws on Opioid-Related Deaths: National Bureau of Economic Research; 2017; Erfanian E, Collins A, Grossman D. The Impact of Naloxone Access Laws on Opioid Overdose Deaths in the U.S. Morgantown, W.V.: Regional Research Institute of West Virginia University; 2018.

⁴ Wheeler, E., et al, "Opioid Overdose Prevention Programs Providing Naloxone to Laypersons- United States 2014," *MMWR* June 19, 2015.

⁵ North Carolina Harm Reduction Coalition, <http://www.nchrc.org/programs-and-services/> (accessed November 27, 2018.)

⁶ Human Rights Watch interview with Dr. Hansel Tookes, Medical Director, IDEA exchange, October 10, 2018.

⁷ Human Rights Watch email communication with Eliza Wheeler, Harm Reduction Coalition, September 17, 2016.

⁸ 21 CFR 310.200; see, e.g. comments submitted by Corey Davis, JD, of the National Health Law Project.

health emergency, extraordinary steps are not only fully justified but are a public health and human rights imperative.⁹

Thank you for your consideration. If any further information is required, please do not hesitate to contact us.

Megan McLemore, JD, LLM
Senior Health Researcher
Human Rights Watch
350 5th Avenue
New York, NY 10118
mclemom@hrw.org

⁹ CDC, “Provisional Drug Overdose Death Counts” 11/4/2018 <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (accessed November 27, 2018.)