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About the Naloxone Request

The Baltimore City Health Department and Public Citizen jointly sent a letter to Kellyanne Conway on May 3, 2018, requesting that the federal government use its authority to expand access to the opioid overdose reversal drug naloxone by facilitating generic competition on patented naloxone products.

The opioid epidemic is the largest public health crisis in the United States. In 2016, more than 63,600 people died from overdose – more than the number of people killed by gun homicide and in car accidents combined. More than six-in-10 of the deaths from drug overdose involved an opioid. In 2017, there likely were even more opioid-related deaths.

Increasing the availability and distribution of easy-to-use naloxone treatments is a vital component of responding to the opioid addiction epidemic and saving lives.

High prices of naloxone treatments indicated for community use – Narcan and Evzio – contribute to the rationing of treatment. Naloxone and its delivery devices are inexpensive to manufacture; excessive prices of these treatments are rooted in government-granted patent monopolies.

The federal government can authorize competition to help ensure that health programs and first responders are able to obtain the naloxone needed to respond to the opioid addiction epidemic and that price does not pose a barrier to treatment.

In Baltimore, everyday residents have used naloxone to save more than 1,800 lives since 2015 and first responders have reversed 10,000 overdoses over the same time period. But despite the health department spending approximately \$1,000,000 annually, there is still significant unmet demand.

If, for example, the price of naloxone were cut in half, Baltimore would be able to purchase twice as many doses and plausibly save hundreds more lives every year. Lower naloxone prices would translate directly into more naloxone to distribute in the community, which would mean that fewer people die from opioid overdose.

Existing law, 28 U.S.C. § 1498(a)¹, gives the U.S. government the authority to make or purchase a patented invention without the permission of the patent holder in exchange for reasonable compensation. This “government use” would authorize generics manufacturers to produce patented naloxone treatments, allowing cost-lowering generic competition, which in turn would facilitate wider naloxone distribution.

The Trump Administration has declared the opioid addiction epidemic a public health emergency. But that declaration is empty unless it is followed by action. Exercising this authority is a clear action that the administration can and should take without delay.

¹ For a more thorough exploration of 28 U.S.C. § 1498(a), see Brennan, Hannah; Kapczynski, Amy; Monahan, Christine H.; and Rizvi, Zain. "A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health," *Yale Journal of Law and Technology*: Vol. 18 : Iss. 1 , Article 7. Available at: <http://digitalcommons.law.yale.edu/yjolt/vol18/iss1/7>. This fact sheet relies heavily on the article.