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United States Senate

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The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

I write to encourage you to add naloxone, the opioid overdose reversal medication, to the Strategic National Stockpile (SNS) and to develop a plan for rapidly deploying this life-saving resource where most needed.

The SNS is the nation's largest stockpile of critical pharmaceuticals and medical supplies, maintained for rapid deployment during a public health emergency that strains the availability of local supplies.¹ The SNS is critical to our country's public health preparedness and response infrastructure. Given the severity of the opioid overdose epidemic that claims 115 lives every day, the U.S. Surgeon General's recent call for more Americans to carry naloxone,² and reports that the administration of and demand for this medication are increasing,³ now is the time to modernize our SNS to store and deploy naloxone.

The overarching goal of the SNS is to ensure that during a public health emergency, Americans can quickly access life-saving medical resources. As HHS has acknowledged, the nation's opioid crisis is a genuine public health emergency.⁴ Between 2015 and 2016, twenty-one states saw an

¹ Centers for Disease Control and Prevention, Strategic National Stockpile, <https://www.cdc.gov/phpr/stockpile/index.htm> (last visited May 30, 2018)

² Surgeon General's Advisory on Naloxone and Opioid Overdose, <https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html> (last visited May 30, 2018)

³ Massachusetts Opioid-Related EMS Incidents 2013-2017, <https://www.mass.gov/files/documents/2018/05/22/Emergency%20Medical%20Services%20Data%20-%20May%202018.pdf> (last visited May 30, 2018)

Alison Kodjak, *First Responders Spending More On Overdose Reversal Drug*, NPR (Aug, 8, 2017), <https://www.npr.org/sections/health-shots/2017/08/08/541626627/first-responders-spending-more-on-overdose-reversal-drug>

⁴ Declarations of a Public Health Emergency, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-20Apr2018.aspx> (last visited May 30, 2018)

increase in opioid overdose deaths from synthetic opioids.⁵ These deadly drugs, which include the highly potent fentanyl, claimed the lives of more than 19,000 Americans in 2016 alone.⁶ For many of these individuals, as well as the 42,000 people who fatally overdosed on opioids in 2016,⁶ the immediate administration of naloxone could have made the difference between life and death.

The rise of synthetic opioids is only contributing to the increased demand for naloxone, because multiple doses of this drug are often necessary to counteract a fentanyl overdose.⁷ Unfortunately, high prices of several naloxone formulations, which have increased drastically over the last several years,⁸ may hinder access to this life-saving medication.

In Massachusetts, the demand for naloxone caused the rapid depletion of a state fund used to both purchase naloxone in bulk and subsidize its cost for local communities.⁹ As a result, some local law enforcement officials and first-responders were faced with higher costs for this life-saving drug, and they were forced to purchase fewer doses of naloxone while still responding to increasing numbers of fentanyl overdoses.⁹ The Massachusetts experience is not an isolated one. The higher naloxone prices and the increase in overdoses, particularly from synthetic opioids, are preventing many communities and their first-responders from procuring naloxone in the quantities necessary to respond to this public health emergency.

Whether a single dose or multiple doses of naloxone are needed, it can save lives if swiftly administered — just like many of the medicines currently included in the SNS. By stockpiling easily administered naloxone formulations in the SNS, we can make available a sufficient supply of this life-saving medication to states and localities hit particularly hard by the opioid crisis. As the HHS Secretary, you have the authority to take immediate action to address this serious problem.

To gain an understanding of your views on your authority and willingness to stockpile naloxone in the SNS, I respectfully ask that, no later than June 14, 2018, you respond to the following questions:

1. Has HHS considered adding naloxone to the SNS? If not, why not? If yes, what have you concluded about doing so?
2. What barriers, if any, do you foresee that would hinder or prevent HHS from adding naloxone to the SNS?

⁵ *U.S. drug overdose deaths continue to rise; increase fueled by synthetic opioid*, CDC Newsroom (March 20, 2018), <https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html>

⁶ *Drug Overdose Deaths in the United States, 1999–2016*, CDC Data Brief 294, https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4 (last visited May 30, 2018)

⁷ *Increases in Fentanyl Drug Confiscations and Fentanyl-related Overdose Fatalities*, CDC Health Action Network, (Oct. 26, 2015), <https://emergency.cdc.gov/han/han00384.asp>

⁸ Ravi Gupta et al., *The Rising Price of Naloxone — Risks to Efforts to Stem Overdose Deaths*, 375 N.E.J. Med. 2213-2215 (2016)

⁹ Shira Schoenberg, *Price jumps for anti-overdose drug Narcan through Massachusetts bulk buying program*, MassLive (April 10, 2018), http://www.masslive.com/politics/index.ssf/2018/04/price_jumps_for_anti-overdose.html

3. Certain formulations of naloxone may be easier to administer in times of crisis by both first responders and members of the community, as encouraged by the Surgeon General. Given this, are there particular formulations of naloxone that would be better suited for stockpiling? Has this been considered in any deliberations you may have had on this topic?
4. How would HHS work with states to ensure that stockpiled naloxone could reach hard-hit areas in a timely manner?

Should you have any questions about this request, please have your staff contact Nikki Hurt of my staff at nikki_hurt@markey.senate.gov or 202-224-2742. Thank you for your attention to this critical public health matter.

Sincerely,



Edward J. Markey
United States Senator