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2ND DISTRICT, ARKANSAS



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October 21, 2019

Norman Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave Bldg 2346
Silver Spring, MD 20993-0002

Dear Dr. Sharpless:

I write regarding frustrations I have heard from first responders and educators in my district regarding the approved shelf life of the drug Narcan. Specifically, I have been informed that though the approved shelf life is 18 months, there is significant research showing that the drug remains stable for 10 months after the approved expiration date.¹

Having to replace unused Narcan 10 months before its actual expiration date has created a significant cost burden for the emergency services and schools that keep this product on hand in case of overdoses. This money could be better used for prevention efforts and increased staffing. At a time when 130 Americans are dying each day from opioid usage, I would encourage the Food and Drug Administration (FDA) to consider extending the approved expiration date of Narcan after a thorough evaluation of the existing research on this subject.

I understand that the FDA similarly extended the expiration date of the EpiPen when patients experienced a shortage of that product in 2018. In my opinion, our current opioid crisis is more severe than the EpiPen shortage and requires a comparable response.

I request that you follow up with my office to address these concerns. I thank you for your consideration and look forward to working with you to address this important issue.

Sincerely,

French Hill
Member of Congress

cc: Joe Grogan, Domestic Policy Council

¹ American Association of Pharmaceutical Scientists. "Opioid overdose reversal products chemically stable past expiration date, study indicates: Extended shelf-life has potential for stockpiles and communities." ScienceDaily. www.sciencedaily.com/releases/2018/11/181106123939.htm (accessed October 20, 2019).