

**Congress of the United States**  
**Washington, DC 20515**

September 16, 2019

Norman E. “Ned” Sharpless, M.D.  
Acting Commissioner of the Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Sharpless:

We write to you today about the recent increase in the number of drug shortages in the United States. Specifically, in 2018 there were 186 shortages of new drugs, a 27% increase from 2017, and the most shortages in the last five years.<sup>1</sup>

While we appreciate the ongoing efforts of the Food and Drug Administration (FDA) to prevent these shortages, it is imperative that FDA balance shortage prevention programs with similar efforts to respond expeditiously to new shortages. This is especially important given the number of factors that can contribute to drug shortages, ranging from environmental disasters to issues with manufacturing quality standards. We recognize that many shortages require case-specific solutions, which require the agency to be flexible in its response. Recent shortages of common drugs that are critical for patient care, including epinephrine, lidocaine, and ketamine have raised the public’s awareness of these challenges.

As you know, Congress provided the Food and Drug Administration (FDA) with new authorities to resolve drug shortages in the Food and Drug Administration Safety and Innovation Act of 2012.<sup>2</sup> This law required manufacturers to provide earlier notification to FDA about events or incidents that could lead to drug shortages. More recently, we were pleased to see then-FDA Commissioner Scott Gottlieb build upon these efforts and increase coordination by establishing the interagency Drug Shortages Task Force.<sup>3</sup>

It is our understanding that the Task Force convened a series of stakeholder listening sessions in September and October of 2018, followed by a public meeting with Duke University’s Margolis Center for Health Policy on November 27, 2018, and kept a docket open for public comment until January 19, 2019.<sup>4</sup> We were pleased to hear of this engagement with stakeholders and we would like to have a better understanding of the information the agency was able to obtain

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<sup>1</sup> Silverman, N. (2019, January 17). *New drug shortages rose in 2018 after three years of relative stability*. Retrieved from <https://www.statnews.com/pharmalot/2019/01/17/drug-shortages-injectables-fda/>

<sup>2</sup> 112<sup>th</sup> Congress. (2012, July 9). *Public Law 112-144*. Retrieved from <https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf>

<sup>3</sup> Gottlieb, S. & Woodcock, J. (2018, November 19) *FDA is Advancing New Efforts to Address Drug Shortages*. Retrieved from <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-advancing-new-efforts-address-drug-shortages>

<sup>4</sup> Kux, L. (2018, September 10) *Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comment*. Retrieved from <https://www.federalregister.gov/documents/2018/09/10/2018-19612/identifying-the-root-causes-of-drug-shortages-and-finding-enduring-solutions-public-meeting-request>

through this process. Given the detrimental impact drug shortages can have on patient care, we write to urge the FDA to prioritize the release of the Drug Shortages Task Force report.

We would appreciate FDA's prompt response to this inquiry. In addition, we ask that FDA include in its response the date when the Drug Shortages Task Force will submit its report to Congress.

Sincerely,

*Eliot L. Engel*

Eliot L. Engel  
Member of Congress

*Brett Guthrie*

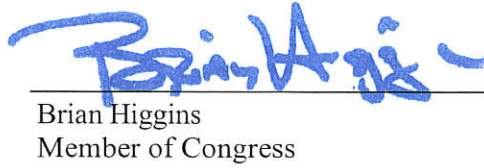
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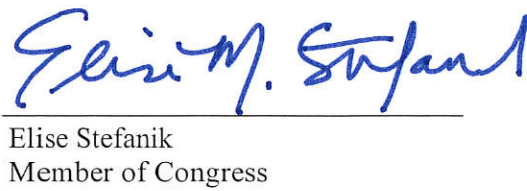
  
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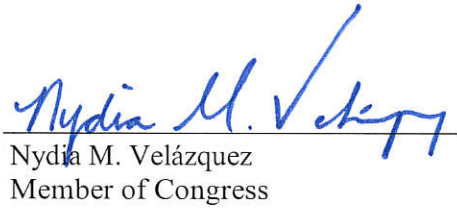
  
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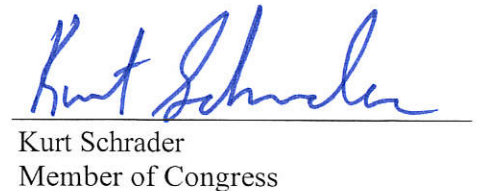
  
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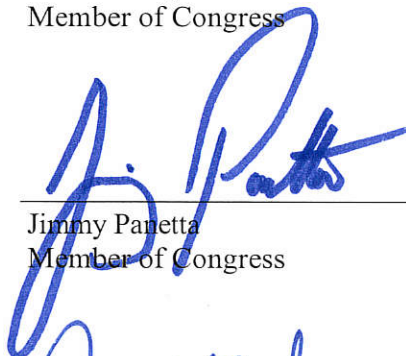
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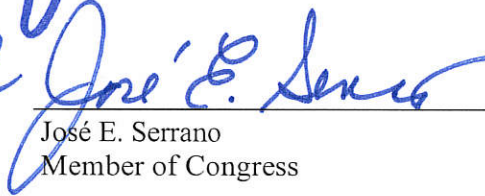
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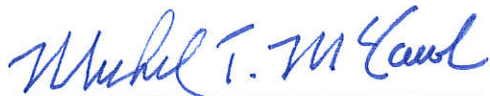
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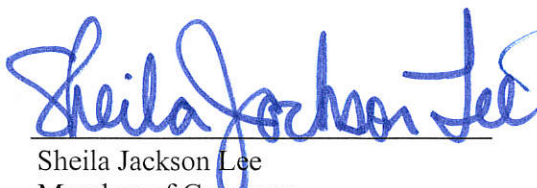
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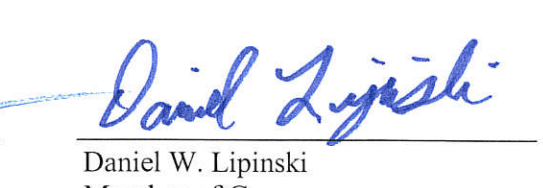
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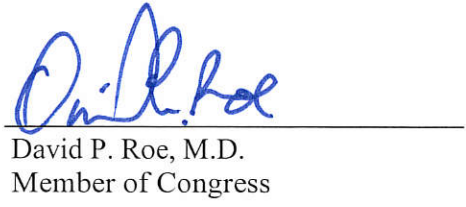
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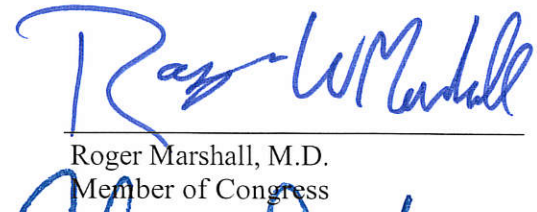
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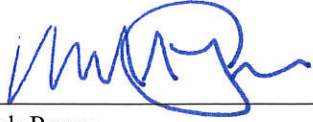
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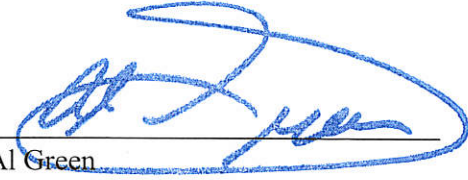
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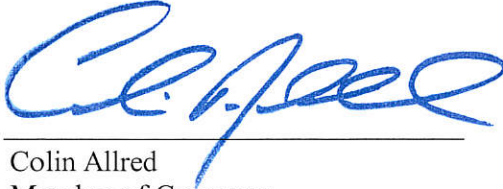
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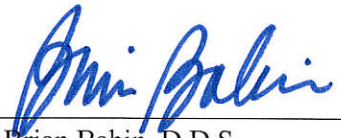
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