Congress of the United States
Washington, DC 20515

June 18, 2018

Mr. Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We write to request your assistance in addressing our nation's ongoing and worsening drug shortage crisis, an issue that threatens the health and safety of our constituents and hinders the ability of health care providers to deliver high-quality care. As part of the effort to resolve this critical issue, we urge the Food and Drug Administration to convene a special meeting, or meetings, of the Drug Shortage Task Force with stakeholders and other relevant agencies to determine the root causes of drug shortages, develop recommendations for Congress to ensure that appropriate supplies of essential medications are always available, and to take appropriate action to ensure that they are.

Drug shortages present significant risks for patients and threaten the stability of our health care system. A 2014 Government Accountability Office (GAO) report noted that shortages have resulted in "delays in or rationing of care, difficulties finding alternative drugs, risk associated with medication errors, higher costs, reduced time for patient care, and hoarding or stockpiling of drugs in shortage. During a shortage, providers may have to cancel or delay procedures, which can have detrimental health effects on patients."[1]

These persistent shortages can last for months or longer and affect all classes of medications used in a variety of settings – emergency departments, hospitals, ambulatory surgical centers, among others. Shortage medications include local anesthetics, injectable opioids, and even sterile IV fluids necessary for delivering nearly every drug used in an emergency department or surgical setting. These are essential products used every day, and for many of them there are no suitable alternatives that are readily available. This can result in suboptimal pain control or sedation for patients, and ultimately limit patient access to the most appropriate care.

In fact, in a recent member survey conducted by the American Society of Anesthesiologists, 98 percent of respondents indicated they regularly experience anesthesia drug shortages, and 95 percent said the shortages adversely affect patient care. A recent member survey by the American College of Emergency Physicians (ACEP) showed similar results, with 91 percent of respondents experiencing shortages or absences of critical medicines.

[1] United States Government Accountability Office, "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," February 2014, https://www.gao.gov/products/GAO-14-194

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While important strides have been made since the height of the drug shortage crisis in 2012 and the subsequent enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA), physicians have recently noticed greater intensity of current shortages. Additionally, the damage inflicted upon the drug manufacturing industry by Hurricane Maria in 2017 not only exacerbated these existing shortages, but exposed just how fragile our current system is, highlighting the need to take action to bring drug supply levels up to where they need to be.

Patients deserve better. We recognize there are many different factors that may contribute to drug shortages, and we need a better understanding of how these factors interact with one another and to what degree they affect shortages. Once again, the undersigned Members of Congress respectfully ask you to conduct these meetings and respond with any developments that result from the meeting as soon as possible. Thank you for your consideration of this request.

Sincerely,

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Member of Congress

Mike Doyle
Member of Congress

Andy Barr
Member of Congress

Joe Barton
Member of Congress

Ami Bera
Member of Congress

Donald S. Beyer Jr.
Member of Congress

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Marsha Blackburn
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Suzanne Bonamici
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Anthony G. Brown
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Julia Brownley
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Salud Carbajal
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André Carson
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Earl L. "Buddy" Carter
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Matt Cartwright
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Kathy Castor
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Yvette D. Clarke
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Emanuel Cleaver, II
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Chris Collins
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Betty McCollum
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Cathy McMorris Rodgers
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