United States Senate
WASHINGTON, DC 20510

June 15, 2018

The Honorable Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
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. First, we would like to commend your recent statement regarding the FDA's efforts to mitigate shortages of intravenous drugs, shorten supply disruptions, and better predict vulnerabilities. We believe the actions you laid out and information you presented are positive steps in addressing drug shortages. As part of your efforts to resolve this critical issue, we urge the Food and Drug Administration to convene the Drug Shortage Task Force created by the Food and Drug Administration Safety and Innovation Act (FDASIA), stakeholders, and other relevant agencies to develop a report and recommendations to Congress regarding the root causes of drug shortages and the authorities FDA and other federal agencies need to address these causes and ensure that appropriate supplies of essential medications are always available.

We appreciate the work of the agency to mitigate the impact of shortages created in the wake of Hurricane Maria and recent shortages resulting from manufacturing deficiencies. However, drug shortages continue to present consistent, frequent, and significant risks for patients and threaten the stability of our health care system. These shortages are not a new issue. 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, ophthalmic diagnostics, 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

[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

by the American College of Emergency Physicians (ACEP) showed similar results, with 91 percent of respondents experiencing shortages or absences of critical medicines.

While important strides have been made since the height of the drug shortage crisis in 2012 and the subsequent enactment of FDASIA, and the number of new shortages reported to the FDA per year has decreased over time, the total number of unresolved shortages continues to be problematic to the health system according to FDA's own data[2]. The damage inflicted upon certain drug manufacturing facilities 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 improve redundancy and preparedness in our supply chain.

We recognize there are many different factors that contribute to drug shortages, and we believe that a better understanding of how these factors interact with one another and the degree to which they affect shortages can help shape policy actions. We respectfully request that the Drug Shortage Task Force work with stakeholders and federal agencies to determine the root causes of drug shortages and develop recommendations to ensure that appropriate supplies of essential medications are always available. We ask that the task force submit its recommendations to Congress no later than the end of 2019. Thank you for your consideration of this request.

Sincerely,

Christopher Murphy
United States Senator

Bill Cassidy M.D.
United States Senator

Tammy Baldwin
United States Senator

Michael F. Bennet
United States Senator

Richard Blumenthal
United States Senator

Roy Blunt
United States Senator

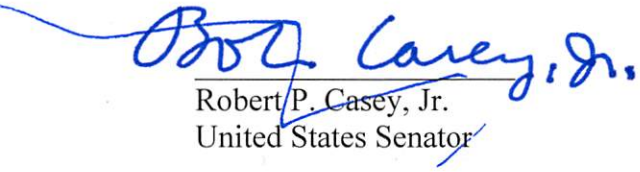
[2] https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM561290.pdf



Benjamin L. Cardin
United States Senator



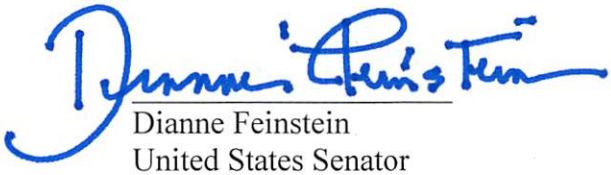
Thomas R. Carper
United States Senator



Robert P. Casey, Jr.
United States Senator



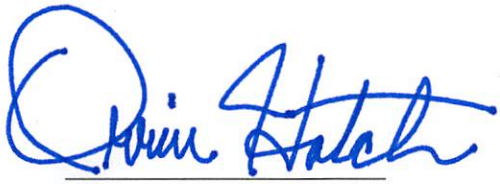
Tammy Duckworth
United States Senator



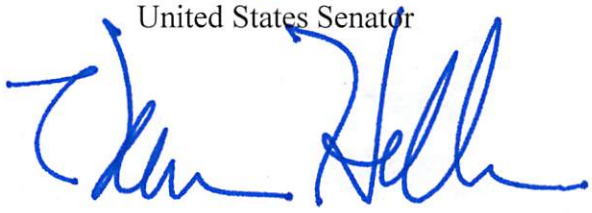
Dianne Feinstein
United States Senator



Cory Gardner
United States Senator



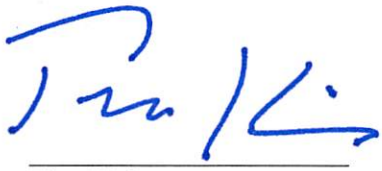
Orrin G. Hatch
United States Senator



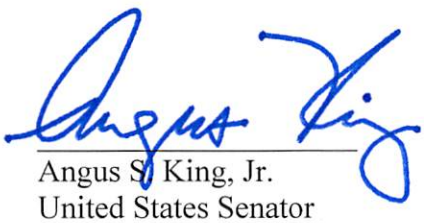
Dean Heller
United States Senator



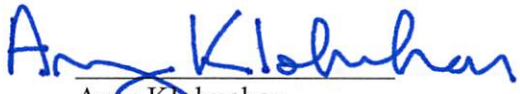
Doug Jones
United States Senator



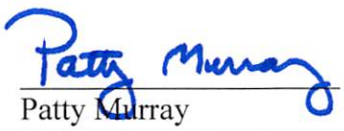
Tim Kaine
United States Senator



Angus S. King, Jr.
United States Senator



Amy Klobuchar
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Patty Murray
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Bill Nelson
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Rand Paul
United States Senator



Gary C. Peters
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Brian Schatz
United States Senator



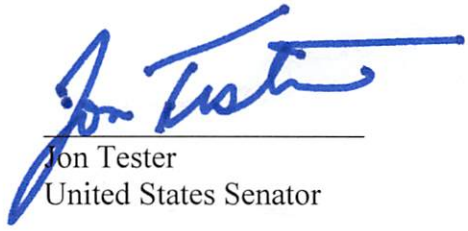
Jeanne Shaheen
United States Senator



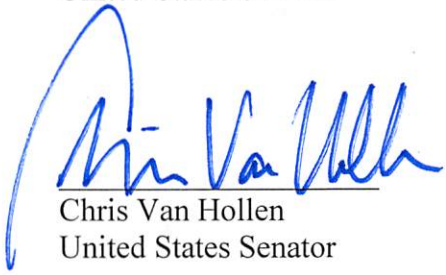
Tina Smith
United States Senator



Debbie Stabenow
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Jon Tester
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Chris Van Hollen
United States Senator



Sheldon Whitehouse
United States Senator



Todd Young
United States Senator