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.”

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.

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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,

Brett Guthrie
Member of Congress

Andy Barr
Member of Congress

Ami Bera
Member of Congress

Gus M. Bilirakis
Member of Congress

Mike Doyle
Member of Congress

Joe Barton
Member of Congress

Donald S. Beyer Jr.
Member of Congress

Marsha Blackburn
Member of Congress

Earl Blumenauer
Member of Congress
Peter A. DeFazio
Member of Congress

Rosa L. DeLauro
Member of Congress

Suzan DelBene
Member of Congress

Scott DesJarlais
Member of Congress

Debbie Dingell
Member of Congress

John J. Duncan, Jr.
Member of Congress

Neal Dunn, M.D.
Member of Congress

Eliot L. Engel
Member of Congress

Anna G. Eshoo
Member of Congress

Adriano Espaillat
Member of Congress

John J. Faso
Member of Congress

Brian Fitzpatrick
Member of Congress

Tulsi Gabbard
Member of Congress

John Garamendi
Member of Congress

Paul A. Gosar, D.D.S.
Member of Congress

Josh Gottheimer
Member of Congress
Rick Larsen
Member of Congress

Daniel W. Lipinski
Member of Congress

Michelle Lujan Grisham
Member of Congress

Roger W. Marshall, M.D.
Member of Congress

Doris Matsui
Member of Congress

Jerry McNerney
Member of Congress

Devin Nunes
Member of Congress

Jimmy Panetta
Member of Congress

Robert E. Latta
Member of Congress

Zoe Lofgren
Member of Congress

Stephen F. Lynch
Member of Congress

Brian Mast
Member of Congress

David B. McKinley, P.E.
Member of Congress

Seth Moulton
Member of Congress

Pete Olson
Member of Congress

Bill Pascrell, Jr.
Member of Congress
Erik Paulsen  
Member of Congress

Mark Pocan  
Member of Congress

Bill Posey  
Member of Congress

Mike Quigley  
Member of Congress

Tom Reed  
Member of Congress

Todd Rokita  
Member of Congress

Raul Ruiz, M.D.  
Member of Congress

Pete Sessions  
Member of Congress

Chellie Pingree  
Member of Congress

Bruce Poliquin  
Member of Congress

David E. Price  
Member of Congress

Jamie Raskin  
Member of Congress

David P. Roe, M.D.  
Member of Congress

Ileana Ros-Lehtinen  
Member of Congress

Kurt Schrader  
Member of Congress

Terri A. Sewell  
Member of Congress
Cathy McMorris Rodgers
Member of Congress