



May 2, 2018

The Honorable Robert Kadlec, MD, MTMH, MS  
Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Scott Gottlieb, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Assistant Secretary Kadlec and Commissioner Gottlieb:

The undersigned leaders of organizations whose members are directly responsible for response to disasters, as well as daily emergency situations, write with an urgent and unified message: the current shortage of Essential Emergency Medications (EEM) is threatening lives on a daily basis and leaves the United States unprepared to respond to disasters.

Emergency medical services (EMS) agencies, emergency departments, and hospitals across the United States are currently severely restricting use of IV fluids, pain medications, anti-nausea medications, sedatives, and airway management medications. Without urgent intervention, we are concerned that these restrictions will lead to rationing and, ultimately, to complete lack of availability of EEM.

As you are both undoubtedly aware, this problem began several years ago, with a peak of shortages in 2011. A series of helpful legislative and regulatory interventions assisted with the situation and we subsequently experienced several years of improved, although never ideal, availabilities of EEM. Unfortunately, after disruption of supply from Puerto Rico as well as other production issues, we are again in a period of critical EEM drug shortages.

We sincerely appreciate the efforts of Congress and the U.S. Food and Drug Administration (FDA) to mitigate this issue over the past several years; in particular, the efforts of Captain Valerie Jensen, R.Ph., Associate Director, FDA Drug Shortages Staff and her entire team. Undoubtedly, the FDA Drug Shortages team has utilized all of the tools at its disposal to their maximum effectiveness. Despite these remarkable efforts, we nevertheless find ourselves in a dire situation with no clear resolution on the horizon.

We write to ask that you elevate attention to ensuring the availability of EEM for everyday patient needs and ensure our ability to respond to public health emergencies. We are

committed to active participation with our federal, regional, state, and local partners as we work toward a solution. Inclusion of the private sector is also welcome by our organizations. Ultimately we believe a public/private partnership between all levels of governments, clinicians and entities administering EEM, and manufacturers producing them will be required to bring lasting resolution to this issue. We do not purport to have perfect solutions, but we do encourage consideration of a national forum to facilitate communication of best practices as well as consideration of use of additional tools, such as the Strategic National Stockpile, to help mitigate this situation for public health emergencies.

We look forward to working together to solve this critical and urgent issue.

Sincerely,

American Ambulance Association (AAA)  
American College of Emergency Physicians (ACEP)  
Association of Critical Care Transport (ACCT)  
International Association of Fire Chiefs (IAFC)  
National Association of EMS Physicians (NAEMSP)  
National Association of Emergency Medical Technicians (NAEMT)  
National Association of State EMS Officials (NASEMSO)

CC: Capt. Valerie Jensen, R.Ph., Associate Director, FDA Drug Shortages Staff