

# **The Impact of Drug Shortages on EMS Patients**

## **Background on Drug Shortage Issue:**

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 essential emergency medications (EEM).

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.

A recent survey of physician medical directors of EMS agencies, undertaken by the National Association of EMS Physicians and summarized below, demonstrates serious and adverse impacts of drug shortages on EMS patients, including wrong dosing of a drug, wrong drug administration, and high rates of unavailability of essential medications, many with no suitable substitute. The nature of EMS medical care is such that when drugs or specific concentrations of a drug go into shortage, medical directors must continually revise their protocols based on what drugs and concentrations they may be able to secure. Paramedics must quickly adjust to alternative medications, different concentrations or no workable substitute, greatly increasing the risk of medication errors in a fast-paced environment in which time is of the essence for patients.

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 the FDA Drug Shortages Office which 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 are especially grateful for the new interagency Drug Shortages Task Force, led by FDA, and their efforts over the past year to evaluate the problem and seek solutions.

We are committed to active participation with our federal, regional, state, and local partners as we collectively work toward a solution. At the FDA Drug Shortages Task Force stakeholder meeting last October, several important ideas were discussed as potential approaches that aren't mutually exclusive. One potential approach would be to provide additional statutory authority for the Secretary of HHS to address drug shortages, which necessitates legislative action. Another potential approach is to identify the most essential or critical medications for which minutes matter and life versus death or severe disability are at stake. 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.

## **Request for Congress:**

There is clearly a market failure exacerbating EEM shortages. It is imperative that the Congress prioritize solving the drug shortage problem for those patients most at risk. We urge Congress to examine novel ways to reimburse ambulance agencies and hospitals to facilitate a market-based solution that ensures a stable, sufficient, and redundant supply of these essential medications for the protection of public health.