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February 5, 2013

The Honorable Gene L. Dodaro
Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

On behalf of the 12,000 chief fire and emergency medical services officers of the International Association of Fire Chiefs, I am writing to provide you with additional information on the impact of drug shortages on the Emergency Medical Services (EMS). I would like to request that you take the following information into consideration as the Government Accountability Office (GAO) begins its work on the study of drug shortages which was required under the Food and Drug Administration Safety and Innovation Act (P.L. 112-144).

One aspect of the drug shortage problem to be addressed in the study and recommendations is: "To what extent are health care providers, including hospitals and physicians responding to drug shortages, able to adjust care effectively to compensate for such shortages, and what impediments exist that hinder provider ability to adjust to such shortages?" It is important that "health care providers" be interpreted as encompassing local providers of EMS, including emergency response departments operating within the public safety sphere.

At least 30 drugs on the Food and Drug Administration's (FDA) current drug shortage list are integral to EMS operations, including those used to treat cardiac, stroke, seizure, severe pain and high-risk obstetrical patients. If these drugs are unavailable there can be life-altering, potentially fatal consequences for patients in the EMS system. Additionally, certain sedatives that are used to treat combative patients are in short supply, putting both the patient and transport team at risk as they attempt to treat and transport an agitated patient.

EMS providers are working to manage their drug supplies as best they can, despite ongoing shortages, but certain stop-gap solutions that have helped in other areas of medicine are particularly difficult for EMS to implement. EMS chiefs routinely face difficult choices in directing emergency responders to make drug substitutions on-the-fly or use expired drugs. Unlike in a hospital with a more predictable population of patients, asking providers to reserve limited and essential drug supplies for patients with the greatest need is impossible in an environment with no idea of what the next call may bring. Any choice places emergency responders in the position of making decisions that are potentially medically, legally and ethically hazardous.

When therapeutic alternatives do exist for certain drugs, they are often second-line therapies or are available only in unfamiliar concentrations or vial sizes. Despite additional training, even the best

substitutions can lead to errors in any environment. This error risk is magnified in EMS when one or two professionals are moving quickly, multitasking the responsibilities of triage, treatment and transport, and operating without the backup of a pharmacist or a computerized dispensing system, rendering time sensitive treatment.

Some emergency responders, at the direction of medical directors, are disregarding the expiration dates of select drugs for lack of any alternatives. There is no formal mechanism for extending medication shelf-life in the civilian environment. Therefore, medical directors are left, at their own peril, to make individual decisions in the best interest of the patient. While most medical professionals and patients would agree that in a life-threatening emergency it is better for a patient to receive an expired drug rather than no drug at all; medical directors have been left to make these decisions without guidance or legislative backup, exposing them to legal and personal liability.

In some states, the EMS scope of practice establishes very specific drugs allowable for pre-hospital use. Certain substitutions, viable in the hospital, may involve drugs that can only be administered by a specific type of trained professional. A substitute for an approved drug not included in a state advanced life support (ALS) scope of practice, would make it illegal for an EMS provider to deliver that substitute drug. These and other "scope of practice" issues are of particular concern in the out of hospital patient care and medical transport settings.

In closing, it is imperative that the forthcoming GAO study and any subsequent recommendations address the specific challenges facing the EMS community. It is equally as important that any recommendations for other practice environments do not unintentionally exacerbate EMS issues. I encourage you to consider the IAFC to be a key resource as the GAO identifies stakeholder groups and subject matter experts for consultation.

Sincerely,

Chief Hank Clemmensen
President and Chairman of the Board of Directors

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