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March 14, 2013

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

Docket Number: FDA-2013-N-0124

Dear Dr. Hamburg:

On behalf of the nearly 12,000 fire and emergency medical services chiefs of the International Association of Fire Chiefs (IAFC), I would like to submit the following comments in reference to Docket Number: FDA-2013-N-0124. As authorized by Section 506D of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §356D), the U.S. Food and Drug Administration (FDA) has created an internal Drug Shortage Task Force to create and implement a drug shortage strategic plan.

The IAFC, through our Emergency Medical Services (EMS) Section, believes that the task force should pay particularly close attention to the impact of drug shortages on the emergency medical services (EMS). Though drug shortages in the EMS community have not received a similar amount of attention as those affecting the hospital industry, they are nonetheless having a dangerous impact on the ability of EMS personnel to provide both basic and critical patient care. Drug shortages have impacted a wide array of medications commonly used by EMS providers. Without access to the preferred or most clinically appropriate drug treatment, paramedics are forced to use alternatives, which may result in human errors when drawing up medications and lead to less effective treatment and an increased risk of adverse outcomes. Additionally, some EMS systems may not have alternative medications to treat patients.

As the task force begins to formulate plans for drug shortage response and mitigation, the IAFC would like to provide the following information in response to the FDA's recent request for information. In particular, the IAFC would like to offer the following points for consideration in response to Question 4 of the February 12 Request for Comments:

1. **Enforcement of Notification Standards:** As the task force begins its work, one of its most important goals will be ensuring that drug manufacturers comply with requirements to provide prompt notification when voluntarily discontinuing a drug or when anticipating the inability to meet average historical demand of medically necessary pharmaceuticals purchased by EMS systems. As a result of the FDA Safety and Innovation Act (P.L. 112-144), 21 U.S.C. §356C now requires manufacturers of drugs used in emergency medical care to provide at least six months' notification when the supply of such a drug will be discontinued

or otherwise interrupted. Any plan that this task force creates for mitigating drug shortages should include provisions strengthening this requirement.

2. **Communications with Other Federal, State and Local Agencies:** As part of its strategic plan to mitigate and prevent drug shortages, the task force should plan to communicate drug shortages to federal agencies that work with emergency responders, including the U.S. Fire Administration and the Office of Health Affairs in the U.S. Department of Homeland Security, and the Office of Emergency Medical Services in the National Highway Traffic Safety Administration. These federal partners play an important and active role in the development of EMS regulations and standards through their numerous partnerships with external stakeholder organizations, such as the IAFC. The task force should work with these federal partners to achieve as wide a reach as possible when disseminating information related to both anticipated and actual drug shortages. In addition, the task force should plan to use state and local health agencies to communicate drug shortages, because these agencies also work closely with emergency responders.
3. **Working with External Partners:** The task force also should maintain strong direct contact with external stakeholder organizations, such as the IAFC. These organizations represent the leadership of both the fire and emergency medical services and can be strong allies in developing mitigation strategies which are rooted in the real-world experiences of EMS providers. Also, the task force can use the relationships between these external partners and their members to ensure a wide distribution of drug shortage warnings.
4. **Task Force Membership:** The task force should consider expanding its membership to include an experienced EMS chief officer to represent the viewpoints of local EMS providers. This member can play a key role by articulating the concerns of the end-users of these pharmaceuticals in the emergency response field.

Thank you for the opportunity to provide these comments and suggestions as the task force begins its important work of addressing the dangerous drug shortages facing our nation's EMS providers and patients. If you need any further information, please contact Mr. Evan Davis, EMS Section Staff Liaison, at 703-537-4809 or edavis@iafc.org.

Sincerely,



Chief Hank C. Clemmensen
President and Chairman of the Board

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