

December 13, 2012

Margaret A. Hamburg, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg:

On behalf of the Premier healthcare alliance uniting more than 2,700 leading hospitals and health systems and 90,000-plus other healthcare sites to improve healthcare quality and reduce costs, we urge the Food and Drug Administration (FDA) to take advantage of the Accelerated Recovery Initiative (ARI) initiated by the generic drug industry as a means to create increased market intelligence about manufacturing capabilities to fill current gaps that exist in the drug shortage crisis.

There is no short-term silver bullet that will solve the drug shortage problem. However, we are confident that improved communications across the supply chain is an important strategy to help mitigate both production shortfalls and supply challenges. As you know, the ARI has been cleared by the Federal Trade Commission and we are hopeful that the initiative will speed solutions when a shortage occurs. The initiative also has the potential to help identify alternative sources of supply and work directly with providers to prepare for and potentially avoid a shortage from occurring in the first place. We believe that a neutral third party can work nimbly with manufacturers and the government to collect and disseminate shortage information to the stakeholders who supply medications to patients in need.

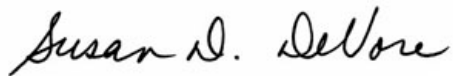
While we are hopeful that the drug shortage situation will abate in the coming years, we believe this initiative will help mitigate the shortages in the short term and, it is our hope, ultimately solve the problem over the longer term. Members of the Premier healthcare alliance are working with the Generic Pharmaceutical Association (GPhA) on this effort and with generic suppliers on longer term solutions.

Addressing drug shortages has been one of Premier's top priorities over the last several years from both a policy perspective and group purchasing standpoint. Premier, as the agent of the hospitals, continually works with our members and manufacturers to help prevent and mitigate the impact of drug shortages on patients. Premier has also been at the national forefront in partnering with the private sector, Congress and your agency to help devise legislative and regulatory solutions to address drug shortages. Our work has included researching and documenting the extent and impact of the drug shortages on hospitals and developments in the gray market; helping our hospitals manage the shortages; collaborating with the generic drug industry to find private sector solutions to reduce shortages and uneven distribution in the supply chain; and working with lawmakers and the Administration to craft policy solutions.

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We remain committed to working with our member hospitals, the industry and government to find solutions to the situation imperiling patient care. As a next step, we look forward to following up with your office on the call we had last week related to drug compounding.

Sincerely,

A handwritten signature in cursive script that reads "Susan D. DeVore".

Susan DeVore  
President and CEO