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January 31, 2012

The Honorable John Carney
1429 Longworth House Office Building
Washington, DC 20515

Dear Representative Carney:

The American Society of Health-System Pharmacists (ASHP) is encouraged by legislation (H.R. 3839) you sponsored that would address the problem of drug shortages. We believe this bill could be a crucial step in ensuring that members of the supply chain have access to information related to drug shortages, and potentially a good compliment to an improved early warning system for the Food and Drug Administration (FDA). Prescription drug shortages have created a public health crisis forcing clinicians to scramble to find life-saving medications for their patients. We are supportive of enhancing communication between the FDA and members of the supply chain to ensure that crucial information about drug shortages is communicated in a timely and effective manner to all members of the chain.

ASHP is a 35,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams.

The establishment of a national critical drug list could be useful to identify medically necessary drugs vulnerable to a shortage, and to enable FDA to work behind the scenes with manufacturers and other members of the supply chain to address vulnerabilities. We would urge however, that the agency update the list more frequently than semi-annually, as conditions such as whether a drug is medically necessary, may change more frequently. Further, the agency must account for the variety of medical conditions that may make a drug medically necessary and therefore critical.

Creation of a national critical drug shortage list would help establish predictability in the supply chain if variables such as severity, duration, reason for the shortage, and estimated resolution of the shortage could be made available to members of the supply chain. However, we would urge the agency to consider updating the list as needed rather than monthly as market factors may necessitate the need to update sooner than once a month. In addition, the requirement that this list also identify alternate therapies would be a useful tool for clinicians as they evaluate care options for drugs in short supply. ASHP strongly urges FDA to utilize existing resources that currently identify alternate therapies. The University of Utah Drug Information Service currently tracks shortages of all drugs, not just medically necessary ones, and offers resources and information on alternative therapies. We do not believe it would be necessary to recreate a resource that is already being offered to the public.

TOGETHER WE MAKE A GREAT TEAM

ASHP thanks you for your commitment to ensuring that patients have access to the medications they need, and we look forward to working with Congress, the FDA and other stakeholders to address the problem of drug shortages. In the meantime, if you have any questions or would like additional information, please contact Joseph Hill, Director, Federal Legislative Affairs at 301-664-8710, or jhill@ashp.org.

Sincerely,

A handwritten signature in blue ink, reading "Paul W. Abramowitz". The signature is written in a cursive style with a large, stylized initial "P".

Paul W. Abramowitz, Pharm.D., FASHP
Chief Executive Officer and Executive Vice President