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Statement

of the

American Hospital Association

before the

Subcommittee on Health

of the

Energy and Commerce Committee

of the

United States House of Representatives

"Examining the Increase in Drug Shortages"

September 23, 2011

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the increase in drug shortages. We applaud the Committee for holding this hearing.

DRUG SHORTAGES AND THE REAUTHORIZATION OF THE PRESCRIPTION DRUG USER FEE ACT

In 2010, a record number of drug shortages – more than 200 – were reported by the U.S. Food and Drug Administration (FDA), and in the first six months of 2011, there have been more than 150 drugs reported in shortage. These shortages occurred across drug classes, including critical drugs used in surgery/anesthesia, emergency care and oncology.

Hospitals and health systems are deeply concerned about chronic and increasing drug shortages because they have serious consequences for patient safety, quality of care and access to therapies. Drug shortages lead to delays in treatment and force the use of alternative drugs with which the provider may not be as familiar. Using unfamiliar alternative drugs can result in unintended harm to the patient through errors in dosing and administration, and in unexpected side effects.

Shortages also are costly to hospitals and health systems in terms of staff time and other resources to manage the shortages and the increased cost of buying alternative drugs "off contract." Critical sterile injectible drugs, mostly older generic drugs, accounted for the majority of drug shortages in 2010 and 2011. From the hospital perspective, these shortages often came with little or no advance notice from the manufacturers.

Drug shortages are complex, with many causes ranging from raw material sourcing, manufacturing problems (quality control and compliance issues), manufacturer consolidation and business decisions that result in drugs being discontinued. While there are some steps the FDA can take to mitigate or resolve drug shortages, the agency's current statutory authority in this area is limited.

The AHA, together with other national pharmacy, physician, drug manufacturer and patient safety organizations, supports the *Preserving Access to Life Saving Medications Act* (H.R. 2245), introduced by Reps. Diana DeGette (D-CO) and Thomas Rooney (R-FL). Sens. Amy Klobuchar (D-MN) and Robert Casey (D-PA) have introduced companion legislation, S. 296, in the Senate. This legislation would help address the issues leading to shortages and provide the FDA with additional authority and information to prevent further drug shortages. Specifically, the bill would:

- Require drug manufacturers to notify the FDA at least six months prior to a planned discontinuance, interruption or other adjustment of the manufacture of a drug that would likely result in a shortage; or as soon as practicable upon becoming aware of such interruption or adjustment. The FDA may modify reporting timeframes, if appropriate.

- Require the FDA to establish a schedule of civil monetary penalties for failure to submit a notification as required.

- Ensure that the FDA protects proprietary information submitted by manufacturers.

- Require the FDA to publish on its website information about actual drug shortages and distribute such information to appropriate health care provider and patient organizations.

- Require the FDA to implement evidence-based criteria for identifying drugs that may be vulnerable to shortages. The FDA must notify and collaborate with the manufacturers of such vulnerable drugs in order to establish and improve their plans and processes for averting and addressing drug shortages.

- Require the FDA to submit annual reports to Congress describing its actions to address drug shortages.

- Require the Government Accountability Office to conduct a study and submit a report to Congress examining the causes of and FDA response to drug shortages; assessing the adequacy of stakeholder communications; and analyzing the impact of the provisions of the bill and identifying other steps to prevent drug shortages.

While this legislation is a critical first step in addressing a serious public health problem, there are many other changes that could be made to help to alleviate drug shortages. Other steps include removing obstacles so that the FDA is able to streamline approval of drugs in shortage. An example would be to develop a fast track for approval of new production lines, alternate manufacturing sites or new suppliers of raw materials for medically necessary drugs in shortage. Improved communication among stakeholders also would help. For example, more formal communication between the FDA's Drug Shortage Program, Office of Generic Drugs and the Office of Compliance could help to minimize unnecessary delays in resolving quality systems issues for shortage drugs. Further, Congress should explore establishing appropriate incentives for manufacturing redundancies or other means of producing emergency supplies as part of the FDA approval process for drugs that are deemed vulnerable to shortages. Also, the rapidly escalating number of shortages and the threat that these shortages represent to patient safety require that the FDA have adequate resources and a sufficient number of experienced staff to manage drug shortages. Therefore, Congress should authorize and appropriate funding for FDA activities that prevent or mitigate drug shortages.

The reauthorization of the *Prescription Drug User Fee Act* presents an opportune vehicle for making some of the policy changes needed to address drug shortages. The FDA has been meeting with drug industry and non-drug industry stakeholders, including the AHA, to develop recommendations for the next *Prescription Drug User Fee Act.* Initiatives to prevent and address drug shortages have been raised in this context as well as other drug-related issues of interest to hospitals.

With drug shortages becoming increasingly frequent, the AHA recently surveyed our members to assess how the shortages have impacted patient care. With 820 hospitals responding, almost 100 percent reported a shortage in the last six months and nearly half of the hospitals reported 21 or more drug shortages. More than 90 percent of hospitals reported shortages of surgery or anesthesia drugs and emergency care drugs, and two-thirds reported shortages of chemotherapy drugs.

While many hospitals were able to find alternative sources for the drugs in short supply, the AHA survey revealed that in the past six months:

- Hospitals report that they have delayed treatment (82 percent) and more than half were not always able to provide the patient with the recommended treatment.

- Patients got a less effective drug (69 percent).

- Most hospitals rarely or never receive advance notification of drug shortages (77 percent) or are informed about the cause of the shortage (67 percent).

- The vast majority of all hospitals reported increased drug costs as a result of drug shortages.

- Most hospitals are purchasing more expensive alternative drugs from other sources.

The AHA will continue to work with Congress, the FDA and with other interested organizations in effort to address the serious issue of drug shortages and keep patients safe.