Regulatory and Legislative Recommendations from the Drug Shortages Summit Steering Group
[Developed with Input from the Drug Shortage Legislative-Regulatory Work Group]
American Hospital Association
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society of Health-System Pharmacists
Institute for Safe Medication Practices

1. Issue: Insufficient regulatory resources to manage rapidly escalating drug shortages

Currently, four staffers within the Food and Drug Administration's (FDA) Drug Shortage Program (DSP) handle shortages of medically necessary drugs for the entire country. As of July 2011, FDA's drug shortages website recorded 82 shortages of medically necessary drugs. The University of Utah, which maintains ASHP's listing of all drug shortages, has identified 204 new drug shortages in 2011.* By the end of the year, new shortages will surpass the 2010 total of 211. The rapidly escalating number of shortages and attendant threat to patient safety requires a sufficient number of experienced staff to manage responsibilities of the DSP.

*New drug shortages as of September 9, 2011.

Type of Action: Legislative and/or Regulatory

Proposed Solution:

- **Reallocate resources within FDA, if available, to the DSP and other specific activities that facilitate resolution of drug shortages**
- **Authorize and appropriate funding for FDA activities that prevent or mitigate drug shortages**

Impact of Solution: Increasing the FDA's capacity in activities that resolve regulatory issues contributing to shortages will facilitate reduction in the frequency and duration of shortages.

2. Issue: Inadequate and incomplete communication of drug shortage information

FDA often does not learn about problems with supply in time to implement plans to mitigate or prevent shortages. In addition, providers and patients do not receive timely sufficient information on the scope and duration of drug shortages needed to ensure continuity of patient care. Public notification of the scope and duration of shortages is based on voluntary reporting, aggregated report data, and communications with the pharmaceutical industry. Reports are usually not received until a shortage has fully evolved.

Type of Action: Legislative and Regulatory

Proposed Solution:

- **Require manufacturers to report product discontinuations and manufacturing interruptions six months in advance or upon determining that production will not meet average historic demand.**
- **Establish communications methods to provide accurate and timely information on drug shortages to healthcare providers.**
- **Establish methods to better predict the seriousness and duration of drug shortages.**

3. Issue: Lack of contingency plans for critical drugs that are vulnerable to shortages

Manufacturers do not develop continuity of supply plans for drugs vulnerable to shortages. Manufacturers do not plan for continuity of supply for drugs vulnerable to shortages. Pharmaceutical manufacturing is highly efficient in order to maximize the capacity of the facility and equipment. The same production line is often used to make multiple drug products. Changing a line to a different drug or set of drugs, known as "flipping a line," requires a great deal of time and planning on the part of the firm as well as inspection and certification by FDA. In addition, manufacturers do not make more product than the usual demand requires. Without redundancies in manufacturing processes or other continuity of supply plans, for drugs that are vulnerable to shortage, there is limited capacity to respond to unexpected increased demand.

Type of Action: Legislative and regulatory

Proposed Solution:

- **Establish criteria for determining whether a drug is vulnerable to shortage. Designate drugs that are vulnerable to shortages as part of the FDA approval process.**

- **Establish appropriate incentives for manufacturing redundancies or other means of producing emergency supplies for drugs that are deemed vulnerable to shortages. The pharmaceutical industry should collaborate with regulatory and legislative entities to identify these incentives.**

Impact of Solution: Incentives to maintain a continuity of supply strategy that can be quickly implemented provide a better business proposition for manufacturers, and may potentially alleviate acute shortages

4. Issue: Inability to quickly respond to shortages of controlled substances

Regulations for manufacturing and production quotas for controlled substances may limit the ability of the FDA and manufacturers to address drug shortages in an expedited manner. Section 306 of the Controlled Substances Act (CSA) requires that the Attorney General establish aggregate production quotas for schedule II controlled substances. Quotas are set annually in the fall based on factors such as past sales. While manufacturers can request revised quotas at any time, the process is burdensome and can prolong or exacerbate a drug shortage.

Type of Action: Legislative and/or Regulatory

Proposed Solution:

- **Require collaboration between the FDA Center for Drug Evaluation and Research divisions and the Attorney General to establish a process that would expedite the increase in manufacturing production quotas when needed in response to drug shortages of controlled substances.**

Impact of Solution: A process of rapidly increasing controlled substance quotas to firms that produce schedule drug products would allow manufacturers without shortages problems to ramp up production and help resolve shortages of scheduled drugs.

5. Issue: Disincentives to manufacturing older generic injectables

Many of the current critical shortages involve older generic injectables or unapproved drugs that are essential to care. Approval requires submission of a new drug application (NDA), which is a disincentive for manufacturers to continue their production. The NDA submission and approval process can be lengthy and expensive and is unlikely to be offset by the profitability of older generic products.

Type of Action: Regulatory

Proposed Solution:

- **Leverage current FDA pathways to expedite the approval process for medically necessary unapproved drugs that are vulnerable to shortages without compromising the quality and safety of the drug.**

Impact of Solution: Quicker approval for medically necessary unapproved drugs may incentivize manufacturers to initially enter, re-enter or remain in the market and producing such critical therapies.

More information on the Drug Shortages Summit is available here:
http://www.ashp.org/drugshortages/summitreport