

Recommendations from the Stakeholder Workgroup of the Drug Shortage Summit

Juliana Reed, Hospira

Jason Byrd, American Society of
Anesthesiologists

Disclosures

- Jason Byrd – no financial conflicts; employed by American Society of Anesthesiologists
- Julie Reed – no financial conflicts, employed by Hospira, Inc.

Drug Shortage Summit

- November 5, 2010
- Co-conveners:
 - American Hospital Association
 - American Society of Anesthesiologists
 - American Society of Clinical Oncologists
 - American Society of Health-System Pharmacists
 - Institute for Safe Medication Practices
- Goals: Discuss scope, causes and actions needed to address drug shortages
- Meetings: April, May, June, August 2011
- Recommendations are a work in progress and have not been finalized or approved by all participants of the summit.

Multi-Stakeholder Effort

- American College of Emergency Physicians
- American Society for Parenteral and Enteral Nutrition
- AmerisourceBergen
- APP Pharmaceuticals
- Baxter Healthcare Corporation
- Bedford Laboratories
- Cardinal Health
- Generic Pharmaceutical Association
- Healthcare Distribution Management Association
- Health Industry Group Purchasing Association
- Hematology Oncology Pharmacy Association
- Hospira
- Novation
- Pharmaceutical Research and Manufacturers of America
- Premier
- Society of Critical Care Medicine
- Teva Pharmaceuticals
- University of Utah
- University of Michigan Health System
- US Oncology
- *Centers for Disease Control and Prevention*
- *Food and Drug Administration*
- *National Institutes of Health*

Issue 1

- Insufficient regulatory resources to manage rapidly escalating drug shortages
- Proposed solutions:
 1. Reallocate FDA resources to Drug Shortage Program and other activities that facilitate resolution of shortages
 2. Authorize and appropriate funding for FDA activities that prevent or mitigate drug shortages

Issue 2

- Inadequate and incomplete communication of drug shortage information
- Proposed solutions:
 1. Require manufacturers to report product discontinuations and interruptions six months in advance or upon determining production will not meet average historic demand
 2. Establish communications methods to provide accurate and timely information on drug shortages to providers
 3. Establish methods to better predict the seriousness and duration of drug shortages

Issue 3

- Lack of contingency plans for critical drugs that are vulnerable to shortages
- Proposed solutions:
 1. Establish criteria for determining whether a drug is vulnerable to shortage and designate such drugs as part of the FDA approval process
 2. Establish appropriate incentives for manufacturing redundancies or other means of producing emergency supplies for drugs deemed vulnerable to shortages. The pharmaceutical industry should collaborate with regulatory and legislative entities to identify these incentives

Issue 4

- Inability to quickly respond to shortages of controlled substances
- Proposed solution:
 1. Require collaboration between the FDA Center for Drug Evaluation and Research divisions and the Attorney General to establish a process to expedite the increase in manufacturing production quotas when needed in response to shortages of controlled substances

Issue 5

- Disincentives to manufacturing older generic injectables
- Proposed solution:
 1. Leverage current FDA pathways to expedite the approval process for medically necessary unapproved drugs vulnerable to shortages without compromising quality and safety of the drug