Pharmacy Purchasing Outlook

The Official Publication of the National Pharmacy Purchasing Association

Volume XVII Issue 10, January/February 2011 Published by Summerdale Enterprises, Inc.

As printed in Pharmacy Purchasing Outlook's January/February 2011 edition
The official publication of the National Pharmacy Purchasing Association (NPPA)
Visit us online at www.PharmacyPurchasing.com

Senators Klobuchar & Casey: Bill To Address Drug Shortages

On February 5, U.S. **Senators Amy Klobuchar** (D-MN) and **Bob Casey** (D-PA) introduced legislation that would provide the FDA with key tools to help address and prevent shortages of prescription drug medications. For instance, ASHP (the American Society of Health-System Pharmacists), currently lists 150 "medically necessary" drugs that are in short supply, which is double the number of such necessary medications in short-supply as compared to 5 years ago.

The bill titled: "Preserving Access to Life-Saving Medications Act," will give the FDA the ability to require early notification from pharmaceutical companies when a factor arises that may result in a shortage. These factors may include changes made to raw material supplies, adjustments to manufacturer production capabilities, and certain business decisions such as mergers, withdrawals, or changes in output. The bill would also direct the FDA to provide up-to-date public notification of any shortage situation and the actions the agency would take to address them.

Pharmacy staff and healthcare providers have been reporting unprecedented shortages of prescription drugs, especially for chemotherapy. Experts cite a number of factors behind the shortages, including scarcity of some raw materials, manufacturing problems, and unexpected demand. Business decisions within the pharmaceutical industry are also a factor, such as cutting back on the production of low-cost generic drugs in favor of more profitable brand-name drugs.

Senator Klobuchar has already spoken to FDA officials several times about this issue, and recently sent a letter to FDA Commissioner **Margaret Hamburg**, requesting immediate action to at least ensure adequate supplies of essential chemotherapy drugs.

Senator Klobuchar said: "Physicians, pharmacists and patients are currently among the last to know when an essential drug will no longer be available, that's not right. This common-sense

solution will help set up an early warning system so pharmacists and physicians can prepare in advance and ensure that patients continue to receive the best care possible. As we move forward, it is important that we have better coordination between the pharmaceutical industry, the FDA, and healthcare providers so patients don't lose access to the medications they depend on."

Senator Casey said: "Knowledge is one of the most important tools for combating problems associated with drug shortages, which are a growing threat to public health in Pennsylvania and across the U.S. Several major hospitals in our state have experienced shortages that are jeopardizing patient care and this bill will provide the knowledge required to help address and prevent future shortages."

Editorial Note: NPPA members are encouraged to reach out to their state's representatives and request their support for Senator Klobuchar's new bill, #S296, the "Preserving Access to Life-Saving Medications Act." To find the contact information for your senators, go online, to: www.senate.gov/general/contact_information/senators_cfm.cfm.

And to help you prepare for your comments, review the summary of the legislation to familiarize yourself with the bill's provisions: http://thomas.loc.gov/cgi-bin/query/z?c112:S.296:

Both links are also provided for your convenience on our website's home page (www.PharmacyPurchasing.com), in the "What's New" area.

Report From Summit On Drug Shortages

On January 10, a summary report including proposed recommendations, was released from a November summit on drug shortages, held by a group of leading healthcare organizations. The report includes suggestions on how to develop a more coordinated effort to address the critical issue of drug shortages.

The Summit was convened by the American Society of Anesthesiologists (ASA), the American Society of Clinical Oncology (ASCO), the American Society of Health-System Pharmacists (ASHP), and the Institute for Safe Medication Practices (ISMP).

Problems caused by drug shortages have received much public attention in recent months and have caused significant disruptions in patient care. These disruptions include canceled or delayed medical treatments and procedures, as well as adverse events caused by medications that may have the potential for greater harm than the first line therapy that is unavailable due to a shortage.

The Summit included participants from health professional organizations, pharmaceutical manufacturers, and supply chain entities. Representatives of FDA and other regulatory agencies also attended portions of the meeting as observers. The goals of the Summit were to:

- Discuss the scope and causes of drug shortages;
- Shed light on the harm to patients that is occurring due to them;
- Discuss the potential need for changes in public policy and stakeholder practices to prevent patient harm from shortages; and
- Develop an assertive action plan that reflects the recommendations and intent of stakeholders to work together to stop patient harm and disruptions in patient care caused by drug shortages.

The Summit report outlines 21 proposed recommendations to improve communication among stakeholders and to remove barriers faced by FDA and drug manufacturers, including:

- Expanding FDA authority to require manufacturer notification of shortages and market withdrawals;
- Providing incentives (e.g., tax credits) to manufacturers that produce critical drug products in exchange for guarantee of continued production;
- Requiring pharmaceutical manufacturers to confidentially notify the FDA when there is a single active pharmaceutical ingredient or manufacturing source;
- Establishing a modified or reduced user fee program for the FDA approval of generic drugs that would support expedited review of applications;
- Establishing an expedited approval pathway for those unapp-roved drugs that are deemed as being critical therapies;
- Requiring manufacturing redundancies to minimize the impact of quality issues;
- Enhancing communication among healthcare providers and stakeholders in the pharmaceutical supply chain about the nature and expected duration of shortages;
- Improving adherence to the FDA's Good Manufacturing Practices (GMP);
- Evaluating and addressing the impact of just-in-time and sole-source inventory practices;
- Considering distribution options for products in short supply.

The recommendations will be further evaluated and implemented, if appropriate, based on an assessment of feasibility, impact, and resources required for implementation. Compliance with legal requirements (Federal Trade Commission regulations) and avoidance of unintended consequences (hoarding, manufacturing disincentives), will also be factored into this evaluation. The next steps for the Summit co-conveners include ongoing stakeholder collaboration, establishing workgroups to prioritize activities and create action plans, and advocacy to Congress, the FDA, and other federal agencies.

The Drug Shortages Summit Summary Report can be found online at www.ashp.org/drugshortages/summitreport. Comments on the report may be submitted to: quality@ashp.org.

Editor's Note: NPPA's 2011 Conference plans to include a symposium session on this important pharmacy purchasing topic, with NPPA President & Founder Dale Kroll and members of the NPPA Advisory Board along with invited representatives from some of the agencies represented at this Summit, such as the FDA, AHA (American Hospital Association), ISMP (Institute of Safe Medication Practices), and the office of Senator Amy Klobuchar (D-MN).