

Legislative Summary

Preserving Access to Life-Saving Medications Act (H.R. 2245)

(June 21, 2011)

Representatives Diana L. DeGette (D-Colo.) and Thomas J. Rooney (R-Fla.) have introduced H.R. 2245, the Preserving Access to Life Saving Medications Act. The legislation directs the Food and Drug Administration (FDA), to address drug shortages by requiring all drug manufacturers to notify FDA about manufacturing problems or when a drug product will be discontinued, requires the agency to maintain an online list of drugs in shortage situations, and institutes civil monetary penalties for manufacturers who fail to report.

Definition of Drug Shortage

The bill defines drug shortage as “period of time when the total supply of such drug available at the user level will not meet the demand for such drug at the user level will not meet the demand for such drug at the user level. “

Manufacturer Reporting

The bill requires all manufacturers, including those who share the market with others, to notify the FDA of any discontinuance, interruption or adjustment in the manufacture of a drug that may result in a shortage. If the manufacturer plans on discontinuing the drug, they must notify the FDA at least 6 months in advance. For other disruptions in manufacturing attributed to supply of raw materials, disruptions in the supply chain, output changes and other problems identified by FDA, notification will be required as soon as the manufacturer becomes aware of the problem, but within six months.

Penalties for Non Compliance

Manufacturers who do not comply with the reporting requirements are subject to civil monetary penalties of up to \$10,000 for each day the violation continues. The penalty amount is capped at \$1.8 million.

Public Notification by FDA

The bill also requires the FDA to publish information relating to manufacturing problems and drugs experiencing an actual shortage on its web site.

Develop Criteria for Drugs Vulnerable to Shortage

The bill would require FDA to implement evidence-based criteria for identifying drugs vulnerable to a shortage. This would be based upon factors such as: number of manufacturers, sources of raw material or active pharmaceutical ingredients, supply chain characteristics, and the availability of therapeutic alternatives. If FDA can determine based upon the above criteria that a drug is vulnerable to a shortage, FDA would have to publish that information on their web site. Further, for those drugs



deemed vulnerable to a shortage and medically necessary, FDA would collaborate with manufacturers to establish continuity of operations plans to address drug shortages.

FDA Reporting

The FDA will be required to provide an annual report to Congress followed by a report every five years on the actions taken to address and prevent drug shortages.

Next Steps for ASHP

ASHP worked closely with DeGette's and Rooney's offices as they developed the legislation and will strongly advocate along with you for its passage by soliciting cosponsors in the House of Representatives. The Society will also continue to work to build bipartisan support for drug shortage legislation in the Senate (S. 296) and towards a comprehensive solution that includes an early warning system.

