Legislative Summary

Drug Shortages Provisions within the Food and Drug Administration Safety and Innovation Act (S. 3187)

(May 9, 2012)

The Food and Drug Administration Safety and Innovation Act includes reauthorization of the Prescription Drug User Fee Act (PDUFA). PDUFA, which was first passed in 1992 and must be reauthorized every two years, allows the Food and Drug Administration (FDA) to collect fees from drug manufacturers to fund new drug approvals. The 2012 reauthorization, PDUFA V, contains several provisions that will help alleviate the ongoing drug shortages crisis.

Early Notification

Drug manufacturers would be required to notify FDA as soon as possible if they experience a production interruption and six months in advance if a product will be discontinued. The bill allows the FDA to use its discretion to include biologics in the reporting requirement. Early notification is a critical element in alleviating shortages. In 2011, the FDA was able to avoid 195 shortages because they had advance notice from manufacturers.

Expedited Review

S. 2516 codifies FDA authority to expedite the review of products and new drug applications.

Generic User Fee

The legislation creates a generic user fee program that will help speed FDA approval of generic applications and will help encourage additional manufacturers to enter the market place.

Other Provisions

S. 2516 would also require FDA to:

- Clarify its guidance to allow hospital pharmacies to **repackage and transfer** drugs to a hospital within the same health system.
- Form a **task force** to develop and implement a strategic plan to prevent and mitigate drug shortages. The task force would be required to consult with external stakeholders in the development of the strategic plan.
- Maintain **records related to drug shortages** for each calendar year that would include the number of shortages, factors contributing to the shortage, the number of manufacturers that submitted notification, and the steps that the agency has taken to

prevent or mitigate shortages. The bill would also require FDA to include in the recordkeeping a listing of the manufacturers who did not comply with the notification requirements.

Next Steps for ASHP

ASHP worked closely with a bipartisan workgroup of the Senate Committee on Health, Education, Labor, and Pensions as they developed the legislation and will advocate along with you for its passage.