Federal Funding for the U.S. Food and Drug Administration (FDA)

AMCP recognizes the vital role of FDA in protecting the health of all Americans. Therefore, **AMCP supports increased federal FDA funding**. Historically, the FDA has been chronically underfunded, a situation that has led to problems with the agency being able to meet its statutory responsibilities in a timely and acceptable manner. Drug products that are subject to review and/or approval by the FDA represent one-quarter of the entire U.S. economy, yet the FDA receives an annual appropriation amount equivalent to approximately $8.00 per citizen.[1] With the recent authority granted to the agency to begin reviewing applications for "biosimilar" biologic products, it is essential that the FDA has the resources necessary to realize its mission.

- **Increased FDA funding will lead to a more efficient drug approval process, helping consumers, employers and taxpayers save money**.
    - One of the byproducts of the agency's chronic underfunding has been unnecessary delays in approving generic drug products.
    - Generic drugs almost always offer cost-savings over their brand-name counterparts, the most dramatic cost-savings typically realized after approval of the second (and subsequent) generic competitors.
    - Every day a generic application goes unapproved costs patients and payers, including the federal government, untold financial resources.
- **Increased FDA funding will enable the agency to better protect patient safety.**
    - The FDA is not only responsible for approving applications for new drug products, but also for inspecting manufacturing plants in the U.S. and abroad, and conducting post-marketing studies after drugs have been approved.
    - With the passage of the U.S. Food and Drug Administration Amendments Act of 2007 (P.L.110-85), the agency gained new authorization to require post-marketing surveillance studies and clinical trials, safety labeling changes and risk evaluation and mitigation strategies (REMS). Each of these empowers the FDA to better monitor the safety of prescription drugs after they have been introduced to the population as a whole.

- Adequate funding ensures that the FDA has the resources to carefully monitor the approval, production and performance of prescription drugs and any adverse impact they may have on patient safety.

1 Alliance for a Stronger FDA fact sheet, available at http://strengthenfda.org/. AMCP is a member of the Alliance, which has over 180 members representing patient and consumer groups; health professional organizations; trade associations; food, drug, medical device and biotechnology companies; and consultants and individuals.

August 2013

The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. AMCP will celebrate its 25th anniversary in 2013. More news and information about AMCP can be obtained on its website, at **www.amcp.org**.