AMCP Academy of Managed Care Pharmacy®

February 2, 2014

The Honorable Barbara Mikulski
Chairwoman
Committee on Appropriations
United States Senate

The Honorable Hal Rogers
Chairman
Committee on Appropriations
United States House of Representatives

The Honorable Richard Shelby
Ranking Member
Committee on Appropriations
United States Senate

The Honorable Nita Lowey
Ranking Member
Committee on Appropriations
United States House of Representatives

The Honorable Mark Pryor
Chairman
Subcommittee on Agriculture, Rural Development and Food & Drug Administration
United States Senate

The Honorable Robert Aderholt
Chairman
Subcommittee on Agriculture, Rural Development and Food & Drug Admin.
United States House of Representatives

The Honorable Roy Blunt
Ranking Member
Subcommittee on Agriculture, Rural Development and Food & Drug Administration
United States Senate

The Honorable Sam Farr
Ranking Member
Subcommittee on Agriculture, Rural Development and Food & Drug Admin.
United States House of Representatives

Dear Chairs Mikulski, Rogers, Pryor and Aderholt and Ranking Members Shelby, Lowey, Blunt and Farr:

On behalf of more than 7, 000 pharmacists and other health care practitioners of the Academy of Managed Care Pharmacy (AMCP or Academy), we wish to express our sincerest appreciation for your prioritization of the U.S. Food and Drug Administration (FDA) in the Consolidated Appropriations Act of 2014. Your efforts and leadership in ensuring that the FDA received an appropriate level of funding is appreciated by the Academy's members. AMCP worked with the Alliance for a Stronger FDA and its 180 consumer, patient and industry groups toward achieving this greatly needed level of funding.

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 appreciates the final FY 14 appropriated amount for FDA at $ 2.561 billion, which is an increase of $175 million compared to FY 13 actual. In addition, AMCP is pleased that the appropriators also released sequestered user fees in the amount of $84 million, which will allow that funding to go to its intended purpose.

AMCP recognizes the vital role that the FDA plays in protecting the health of all Americans. Historically, the FDA as an agency 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. 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.

An adequately-funded FDA will lead to a more efficient drug approval process. One of the byproducts of the agency's underfunding has been unnecessary delays in the approval of generic drug products. Since generic drugs almost always offer a cost-savings over their brand-name counterparts, every day that a generic drug application goes unapproved costs patients, payers and the federal government untold financial resources.

This function becomes even more critical since the authorization of the development of an approval process for biosimilar biologic products. Biologic products are often prohibitively expensive for patients and payers alike, and biosimilar products carry the potential to ease the burden of these costs. AMCP is concerned that without adequate funding, the FDA will not be able to approve these products in a timely manner.

Finally, adequate FDA funding will enable the agency to better protect patient safety. 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.

While AMCP is cognizant of the pressures that face appropriators in today's challenging fiscal environment, we are pleased that you recognized the importance of the FDA with regard to future cost-savings and patient safety. Please do not hesitate to contact the Academy if we can be of further assistance. AMCP's members look forward to working with you in the future.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer