



### **Funding for the U.S. Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ)**

Historically, the U.S. Food and Drug Administration (FDA) has been chronically underfunded, a situation that has led to problems with the agency being able to meet its statutory requirements in a timely and acceptable manner. 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.

**AMCP supports adequate funding for the FDA.** AMCP members rely upon the agency for timely drug approvals, including approvals of generic drug applications, as well as post-marketing surveillance and monitoring of the prescription drug supply chain. AMCP is a member of the Alliance for a Stronger FDA, a coalition of over 180 patient and consumer groups, health professional organizations, trade associations and food, drug and medical device and biotechnology companies that work to ensure annual appropriations that will enable the FDA to complete its essential missions.

The Agency for Healthcare Research and Quality (AHRQ) funds important research examining the relative comparative effectiveness of treatment options, as well as outcomes associated with various pharmaceutical therapies. Patients, providers and payers rely on the results of this research to both improve the quality of patient outcomes and reduce the overall costs of care.

**AMCP supports continued funding of AHRQ.** AHRQ currently funds several unique programs which directly benefit our members, and in turn the patients that they serve. While we recognize and understand the need to control federal spending, we believe that terminating AHRQ would be a decision that will save money in the short-term, but would sacrifice quality and savings, and could have enormous detrimental effects on spending in the long-term.

- **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.
  - 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.
  - 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.
- **AHRQ funds several unique programs that directly benefit AMCP members and the patients they serve:**
  - Section 1013 of the Medicare Modernization Act authorized funding for research specifically aimed at examining the effectiveness of different medical treatments, including prescription drugs, for 10 common health conditions. AHRQ received an additional \$300 million in funding via the American Recovery and Reinvestment Act to fund similar research.
  - The Affordable Care Act (ACA) authorized a grant program for medication therapy management (MTM) pilot programs for Medicare Part D. Grants will also be available for researchers to evaluate the effectiveness of the programs and help establish best practices.
  - Under a grant from AHRQ, AMCP partnered with continuing medical education company PRIME to disseminate summaries of AHRQ research to our members via supplements to the *Journal of Managed Care Pharmacy*.
- **AHRQ is not empowered to make coverage decisions or determinations and they cannot restrict access to treatments based on the results of their research.**
  - While some research funded by AHRQ considers the cost-effectiveness of treatments under review, AHRQ merely makes the results available to patients, providers and payers, who are free to use the information in a manner they deem appropriate.
- **AHRQ’s research is distinguishable from the work of other agencies.**
  - AHRQ supports observational studies that examine the “real world” outcomes associated with two or more treatments. AHRQ’s research is intended to help patients make informed decisions and improve the quality of care. Agencies such as the National Institutes of Health (NIH) support clinical trials that examine the outcomes of one treatment compared with a placebo in a strictly controlled patient population, and are intended for use by the scientific community, not necessarily the general public.

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*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 assist patients in achieving positive therapeutic outcomes. The Academy's 6,000 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. More news and information about AMCP can be obtained on its website, at*

[www.amcp.org](http://www.amcp.org)