



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

June 30, 2004

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

Department of Health and Human Services
Division of Dockets Management
Food and Drug Administration
Electronic Submission to:
<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>

Re: Docket No. 2004S-0170 - Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Priority Topics for Research

Dear Sir or Madam:

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) authorized funding for the Agency for Healthcare Research and Quality (AHRQ) to develop an agenda for research on the comparative clinical effectiveness and appropriateness of health care items and services, including prescription drugs. The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to submit recommendations regarding the FY 2006 priority list.

BCBSA is a federation of 41 independent, locally operated Blue Cross and Blue Shield Plans that collectively provide health care coverage to over 90 million Americans. Our Plans have extensive experience in providing prescription drug coverage through a variety of products and delivery mechanisms designed to meet the quality and value demands of their customers.

BCBSA believes that comparative effectiveness studies would provide highly beneficial information to public and private purchasers, health care providers, pharmacists and patients.

Our recommendation for FY 2006 is a reiteration of our recommendation for FY 2005; recognizing the limited funds available for this purpose. We recommend that any studies be directed toward evaluating existing evidence regarding the comparative clinical effectiveness of prescription drugs focusing on therapeutic classes of drugs that include high cost and/or high utilization drugs. Specifically, we recommend the following studies:

- Studies in cardiovascular treatment, such as comparisons of generic and brand statins alone and in combination with other lipid lowering drugs and the comparison of outcomes with ACEIs and ARBs for hypertension;
- In the behavioral health area, studies of the effectiveness and adverse effect of long-term use of antidepressants, atypical antipsychotics and drugs used for insomnia;

- For diabetes, comparisons of various insulin types or other new oral agents such as glitazones when added to a sulfonylurea/metformin regimen; and
- Finally, we recommend studies comparing COX II's to standard NSAIDs with a focus on adverse effects.

BCBSA believes that AHRQ's work in comparative effectiveness research will be an important first step toward providing objective, science-based information that will better guide health care decision making. We are hopeful that HHS and AHRQ will be able to begin their work on this important initiative. If you have any questions regarding these recommendations, please contact Nan North at (202) 626-8649.

Sincerely,

A handwritten signature in black ink that reads "Alissa Fox". The signature is written in a cursive, flowing style.

Alissa Fox
Executive Director, Policy
Office of Policy and Representation