

GORDON SMITH, OREGON, CHAIRMAN  
RICHARD C. SHELBY, ALABAMA  
SUSAN COLLINS, MAINE  
JAMES M. TALENT, MISSOURI  
ELIZABETH DOLE, NORTH CAROLINA  
MEL MARTINEZ, FLORIDA  
LARRY E. CRAIG, IDAHO  
RICK SANTORUM, PENNSYLVANIA  
CONRAD BURNS, MONTANA  
LAMAR ALEXANDER, TENNESSEE  
JIM DEMINT, SOUTH CAROLINA

HERB KOHL, WISCONSIN, *Ranking Member*  
JAMES M. JEFFORDS, VERMONT  
RUSSELL D. FEINGOLD, WISCONSIN  
RON WYDEN, OREGON  
BLANCHE L. LINCOLN, ARKANSAS  
EVAN BAYH, INDIANA  
THOMAS R. CARPER, DELAWARE  
BILL NELSON, FLORIDA  
HILLARY RODHAM CLINTON, NEW YORK

## United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

March 22, 2006

Dr. Mark McClellan  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Dr. McClellan:

As CMS prepares to develop contracts with Medicare Part D prescription drug plans (PDPs) for 2007, I urge you to reinstate the same "all or substantially all" guidance for medications in the six classes of clinical concern that plans were required to abide by in 2006. This policy helps ensure that Medicare beneficiaries with serious health conditions, such as mental illness, epilepsy, cancer and HIV/AIDS, have access to cutting edge prescription drug therapies that come onto the market at any point during the year.

While I am encouraged that CMS' 2007 draft contract guidance proposed to renew the "all or substantially all" policy, I am concerned with a revision that would allow plans to forgo coverage of new drugs that enter the market after April 17, 2006. If a potentially life-saving or life-enhancing drug became available after that date, it would have to go through the normal Pharmacy and Therapeutic committee review process that could take several months to complete. Beneficiaries should not have to endure a potentially lengthy bureaucratic approval process to gain access to innovative drug treatments.

Additionally, as prescription drug plans have the ability to remove drugs from their formularies at any time, I feel it is a matter of fairness that the "all or substantially all" policy apply over the same time period. I understand the imposition of the new April 16 deadline would provide plans with more certainty in developing their cost-estimates, but it should not come at the expense of beneficiaries' access to medications in these critical classes of drugs. I am supportive of keeping the costs of the Medicare Part D prescription drug benefit affordable for the government and for beneficiaries, and would encourage you to explore other cost-saving options that do not unduly affect access to new prescription drugs.

Over the last several decades, pharmaceutical advances have greatly improved the lives of millions of Americans with debilitating health problems. The advent of new generation antipsychotics and antidepressants in the 1990s helped to stabilize those suffering from severe mental illness so they could be more active and productive members of their community. Such progress cannot be sustained if Medicare

beneficiaries are denied access to the cutting edge treatments of tomorrow because the “all or substantially all” policy is scaled back in future PDP contracts.

I appreciate your commitment to improving the health of America’s seniors by creating the initial “all or substantially all” formulary guidance, and urge you to reinstate the same direction to plans in the 2007 contract development process.

Warm Regards,

A handwritten signature in black ink, appearing to read "G. H. Smith", with a long horizontal flourish extending to the right.

Gordon H. Smith  
Chairman