

United States Senate

WASHINGTON, DC 20510

October 8, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Slavitt:

We write today to express our concern regarding biosimilar reimbursement policies set forth in the Centers for Medicare & Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule (MPFS) proposed rule. Given that the pipeline and market for biosimilar drugs remain under development, we ask you to withhold the proposed Medicare reimbursement policy for biosimilars until the Food and Drug Administration (FDA) has completed regulations for these drugs and the biosimilar drugs pipeline and market are safe and stable.

The emergence of biosimilar drugs has the potential to revolutionize the treatment landscape for many patients by offering them more treatment options at a lower cost. By developing drugs based on the human body's own biological processes, life science companies have been able to create therapies with treatment possibilities previously unattainable through traditional drug development. It's critically important that the FDA and CMS work with patients, health care providers, and other stakeholders to ensure that the pipeline and market for biosimilar drugs are both safe and robust.

We have heard concerns from patient and physician groups, pharmacy organizations, biosimilar manufacturers, and other stakeholder organizations that reimbursement for biosimilar drugs may be important for tracking usage of these drugs for purposes of patient safety and research, medical innovation, and increasing patient access to biosimilar treatments. Accordingly, we urge CMS to withhold all formal reimbursement proposals for biosimilar drugs until the FDA has issued regulations for these drugs to help ensure the safety and stability of the biosimilar drugs pipeline and while the market for biosimilars develops.

Biosimilar drugs hold enormous promise for improving health care outcomes for patients and reducing costs for both patients and health care payers such as Medicare and Medicaid. We urge you to allow the biosimilar pipeline and market to stand up and continue to develop before implementing a final Medicare reimbursement policy.

Sincerely,



Pat Roberts
United States Senator



Thomas Carper
United States Senator

Michael B. Enzi

Michael B. Enzi
United States Senator

Robert Menendez

Robert Menendez
United States Senator

John Cornyn

John Cornyn
United States Senator

Debbie Stabenow

Debbie Stabenow
United States Senator

Johnny Isakson

Johnny Isakson
United States Senator

Michael F. Bennet

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United States Senator

Rob Portman

Rob Portman
United States Senator

Dianne Feinstein

Dianne Feinstein
United States Senator

Jerry Moran

Jerry Moran
United States Senator

Mazie Hirono

Mazie K. Hirono
United States Senator

Mark Kirk

Mark Kirk
United States Senator

Gary Peters

Gary C. Peters
United States Senator

John Hoeven

John Hoeven
United States Senator

Joe Donnelly

Joe Donnelly
United States Senator

David Vitter

David Vitter
United States Senator

Cory Booker

Cory Booker
United States Senator

John Barrasso
John Barrasso
United States Senator

Steve Daines
Steve Daines
United States Senator