Congress of the United States
Washington, DC 20515

March 4, 2014

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Ms. Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Sebelius and Administrator Tavenner,

Congress created the Medicare Part D program in 2003 with an emphasis on creating a prescription drug benefit that would provide access to prescription medications for all Medicare beneficiaries. Congress deliberated over this policy for many years before finally enacting the Medicare Modernization Act. While Part D was not originally supported by all Members of Congress, it has in time demonstrated the ability to provide access to important life-saving and life-enhancing medications for the vast majority of America's seniors and non-elderly people with severe disabilities.

A critically important component of what has made Part D successful over the past eight years is the six protected classes policy. Created by CMS in 2005 through subregulatory guidance, and later codified by Congress in 2008, the six protected classes policy has enjoyed strong bipartisan, bicameral support. The six classes of medications were deemed by Congress to be the correct classes for inclusion in 2008 and that position was reaffirmed in 2010.

For this reason, we are extremely troubled by the proposed rule CMS issued regarding Medicare parts C & D on January 6, which removed the protections for anti-depressants, immunosuppressants used for organ rejection and anti-psychotics. We believe this proposed policy will place harmful limits on Medicare beneficiaries' access to necessary medications that would otherwise be covered by protected status.

We also believe these policy changes will inextricably tie the hands of physicians who treat these individuals, many of whom have complex medical needs. For instance, limiting the type of immunosuppressants a physician can prescribe places a transplant patient at risk for organ rejection or other health complications. Similarly, hindering access to anti-depressants, and eventually anti-psychotics, may put someone with mental illness at greater risk for suicide and destabilization of their condition. These restrictions on appropriate access also impact persons with other challenging health conditions like cancer, HIV or epilepsy that have higher rates of depression as a comorbidity.

Furthermore, the proposed rule relies upon what is widely known to be ineffective exceptions, appeals, and grievance processes to ensure sick individuals enjoy timely access to necessary medications. Removal of protected status for the anti-psychotic, anti-depressant and

immunosuppressant classes and allowing coverage of as few as two medications in these classes is certain to overwhelm an already overburdened process under Part D.

Finally, given the broad public support for increasing patient access to care, especially in the area of mental health, and recognizing further the significant challenges your Department faces in its efforts to implement healthcare reform, we are perplexed by your decision to move forward with such a proposal. Given the overwhelming evidence that all six classes of the current six protected classes policy are appropriate and necessary to ensure clinically necessary access to needed medications, we urge you to maintain this important policy and not finalize this proposed rule.

Thank you for your prompt attention to this critical matter. We look forward to your response.

Sincerely,

Leonard Lance
Member of Congress

Gene Green
Member of Congress

Diane Black
Member of Congress

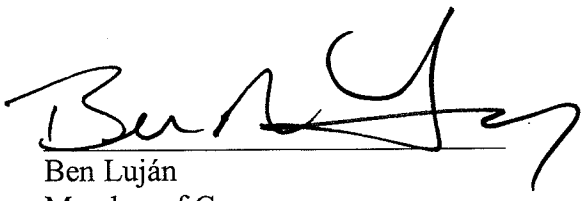
Richard Neal
Member of Congress

Mike Rogers
Member of Congress

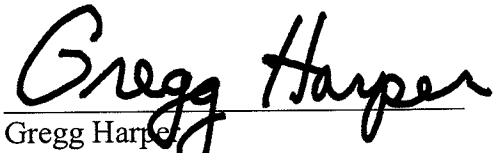
Pat Tiberi
Member of Congress

Earl Blumenauer
Member of Congress

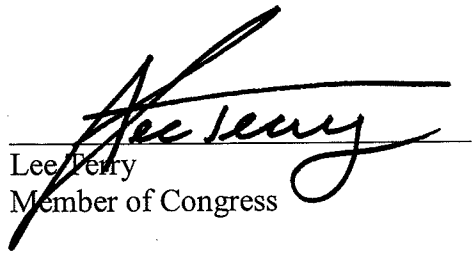
David McKinley
Member of Congress



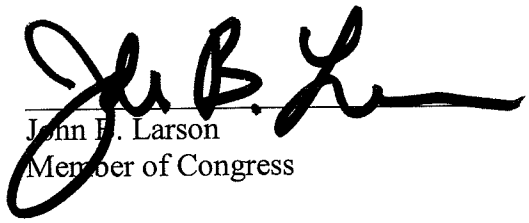
Ben Luján
Member of Congress



Gregg Harper
Member of Congress

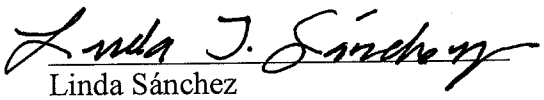


Lee Terry
Member of Congress

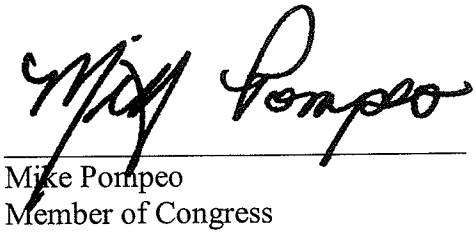


John B. Larson
Member of Congress

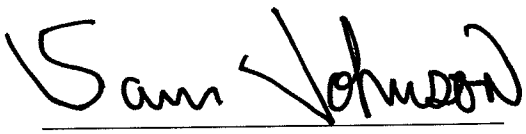
Pete Olson
Member of Congress



Linda Sánchez
Member of Congress



Mike Pompeo
Member of Congress



Sam Johnson
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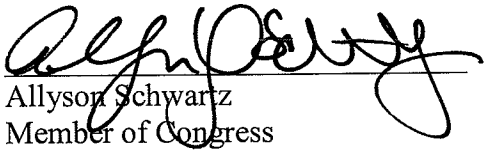

Allyson Schwartz
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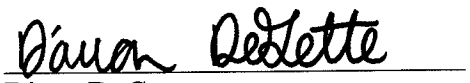
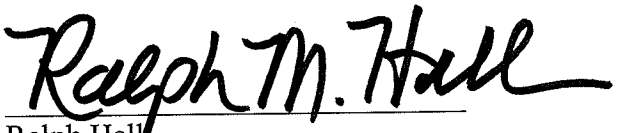
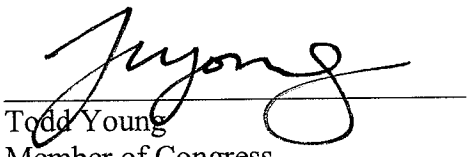


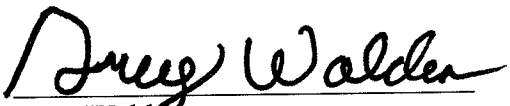
Diana DeGette
Member of Congress



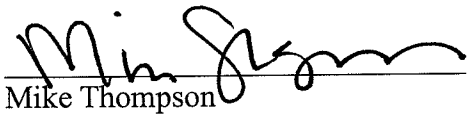
Ralph Hall
Member of Congress



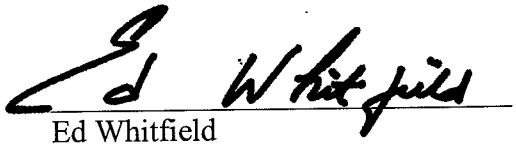
Todd Young
Member of Congress



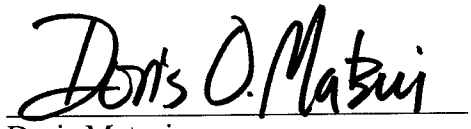
Greg Walden
Member of Congress



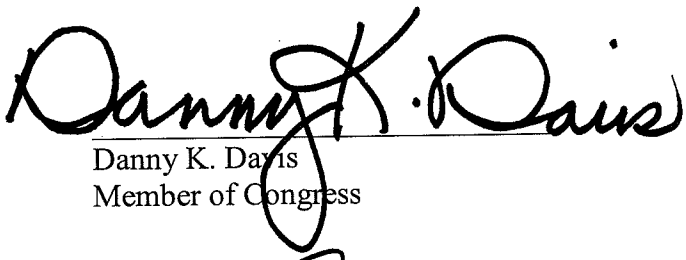
Mike Thompson
Member of Congress



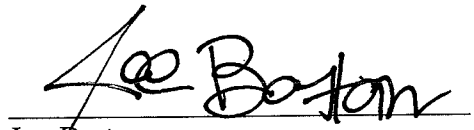
Ed Whitfield
Member of Congress



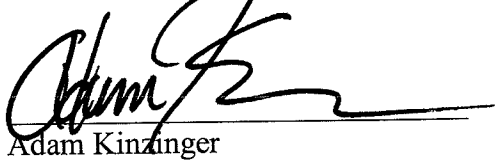
Doris Matsui
Member of Congress



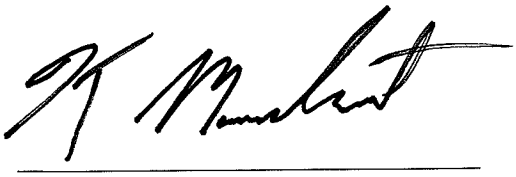
Danny K. Davis
Member of Congress



Joe Barton
Member of Congress



Adam Kinzinger
Member of Congress



Kenny Marchant
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Gus Bilirakis
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Bill Cassidy
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Lois Capps
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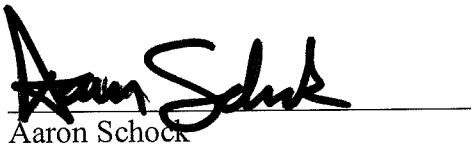

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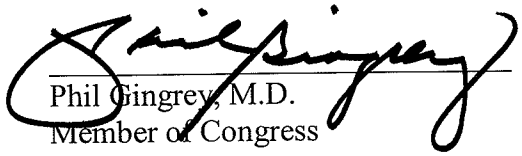
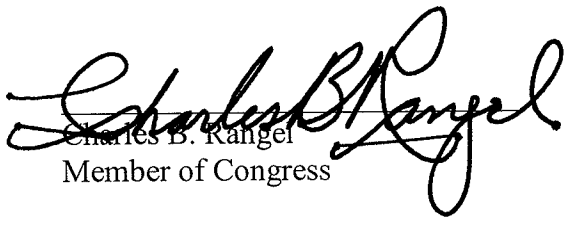
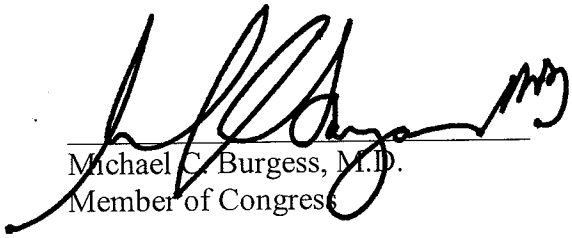
Renee Ellmers
Member of Congress



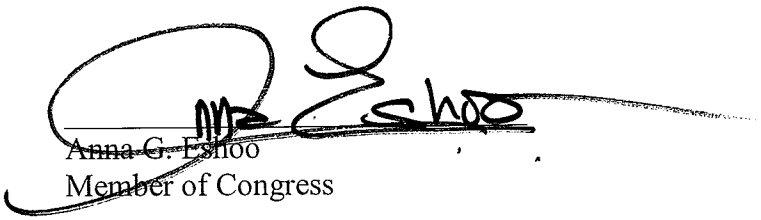
Phil Gingrey, M.D.
Member of Congress



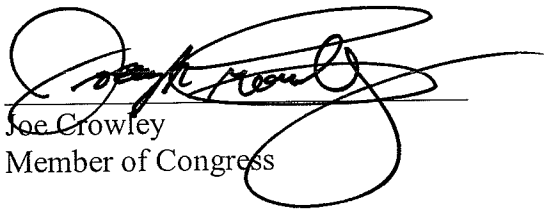
Charles B. Rangel
Member of Congress



Michael C. Burgess, M.D.
Member of Congress



Anna G. Eshoo
Member of Congress



Joe Crowley
Member of Congress