

**Congress of the United States**  
**Washington, DC 20515**

September 11, 2014

Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244

Dear Administrator Tavenner:

We are writing today with questions regarding recent changes to CMS' policy and Durable Medical Equipment Medicare Administrative Contractor (DME MAC) actions regarding speech generating devices (SGDs) and SGD-related accessories. We have heard from many constituents about these issues including patients living with serious conditions that require the use of SGDs such as cerebral palsy, amyotrophic lateral sclerosis (ALS), Rett Syndrome, muscular dystrophy, multiple sclerosis, Parkinson's disease, brain stem stroke, locked-in syndrome, and traumatic brain injury.

Recently, DME MACs have issued a significant policy change through a "Coverage Reminder" stating that if patients wish to expand the functionality of the device after Medicare coverage and that device can in fact be "unlocked" that the device will not be covered at all by Medicare. This change would also dictate patients' choices regarding functionality of the devices even after ownership of the device has transferred to the patient.

In addition, several DME MACs have started to issue routine denials for eye tracking technology even with required professional documentation showing the technology is medically necessary. For patients, like those living with ALS, who have lost the ability to control most if not all of their bodies with the exception of their eyes, eye tracking or eye gaze technology is their only means of utilizing an SGD.

Finally, CMS recently reclassified SGDs as a "Capped Rental." One of the implications of the "Capped Rental" designation is that Medicare will cease making rental payments for the device if the patient requires a hospital, hospice, or other facility admission forcing these patients who would otherwise be eligible for coverage to pay out of pocket.

It is our understanding that after outreach by stakeholders, CMS has declined to modify the aforementioned policies, in some instances suggesting that statute

prevents changes. With that in mind, we respectfully request your responses to the following questions regarding these changes:

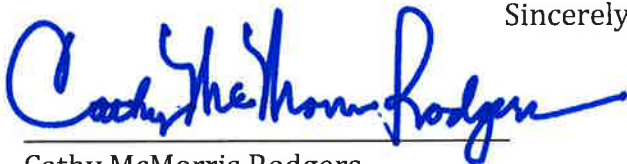
- 1) Sec. 1834(a)(19) of the Social Security Act already provides the Secretary with the authority to create a process for patients to be able to upgrade their DME items and caps Medicare spending at the rate of the base covered item. Why has this not been utilized for patients who need to utilize SGDs to communicate and want to be able to expand the functionalities of these devices?
- 2) Why is Medicare pursuing a policy of preventing unlocking of devices, which will restrict patients' ability to expand the functionality of these devices when Medicare is not being asked to cover or pay for those expanded functionalities?
  - a. Has Medicare contemplated the patient impact of dictating the patient's ability to upgrade a device even after the patient then owns the device?
  - b. How much does Medicare expect to save by restricting the unlocking of devices?
  - c. How much did Medicare spend in FY 2013 for the unlocking of these devices? How much did Medicare spend on maintenance costs that specifically related to the unlocking of the device in FY 2013? If data for FY 2013 is not available, please provide information from the most recent claims data CMS has available.
- 3) When eye tracking technology is the only option for patients with paralysis to use their device and all DME MAC Local Coverage Determinations (LCDs) state that SGD accessories that meet criteria of reasonableness and necessity are covered, why are CMS and the DME MACs denying claims for the technology and viewing it as not medically necessary or not covered when the required healthcare professional documentation has been provided?
  - a. How much did Medicare spend in FY 2013 on eye-tracking additions that were deemed medically necessary? If data for FY 2013 is not available, please provide information from the most recent claims data CMS has available.
- 4) While inappropriate denials can often be addressed as part of the Medicare appeals process, the appeals process is experiencing a backlog of *multiple years*. How does CMS plan to quickly address appeals of inappropriate denials of eye tracking given this technology is the only way for these patients to communicate?

- 5) Section 1834[a][4] allows for the purchase of items that are “uniquely constructed or substantially modified to meet the specific needs of an individual patient ...” Because SGDs are programmed specifically for each individual and modified to meet their unique needs, why has CMS determined that they do not meet this qualification and instead decided to implement the capped rental policy for SGDs?
- 6) Given that patients who require SGDs regularly require inpatient, nursing facility care, or hospice stays, does CMS plan to enforce that facilities must provide the patient with a device, especially one that involves the customization and training required to provide the correct SGD, while the beneficiary is admitted ?

The patients who are in need of SGDs are some of Medicare’s most vulnerable beneficiaries. As we mentioned, SGDs provide often the only means of communication for patients living with cerebral palsy, amyotrophic lateral sclerosis (ALS), Rett Syndrome, muscular dystrophy, multiple sclerosis, Parkinson’s disease, brain stem stroke, locked-in syndrome, and traumatic brain injury. It is imperative that Medicare policy and DME MACs take in account the ability of these patients to communicate with their family, caregivers, and health care providers.

Because the timing of these policies is already impacting patients, we thank you for your attention to this critical matter and look forward to your response before October 1, 2014.

Sincerely,



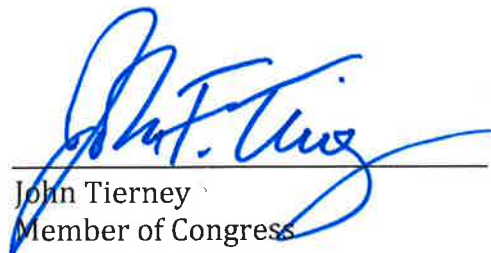
Cathy McMorris Rodgers  
Member of Congress



Susan Collins  
United States Senate



Erik Paulsen  
Member of Congress



John Tierney  
Member of Congress



Steve Scalise  
Member of Congress



Mary Landrieu  
United States Senator



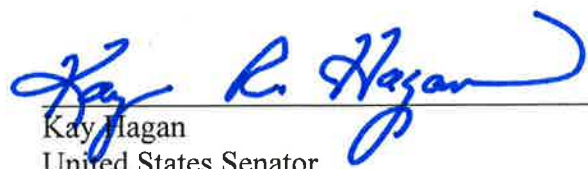
David Vitter  
United States Senator



Sherrod Brown  
United States Senator



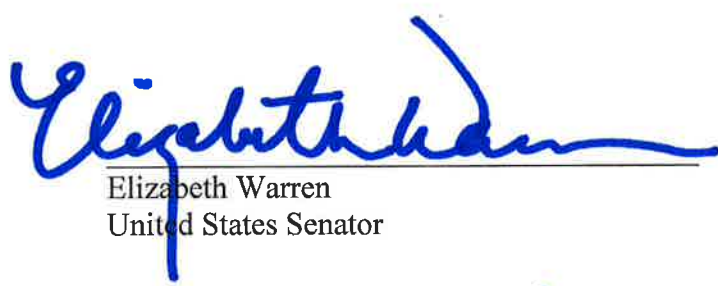
Roy Blunt  
United States Senator



Kay Hagan  
United States Senator



Pat Roberts  
United States Senator



Elizabeth Warren  
United States Senator



Lamar Alexander  
United States Senator



Angus King  
United States Senator



Richard Burr  
United States Senator



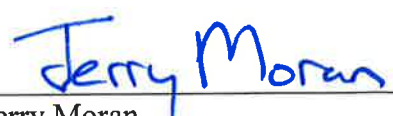
Edward Markey  
United States Senator



Mike Johanns  
United States Senator



Jeff Merkley  
United States Senator



Jerry Moran  
United States Senator



Jeanne Shaheen  
United States Senator



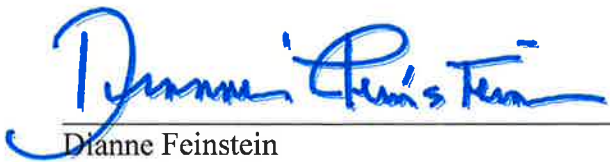
Rob Portman  
United States Senator



Kirsten Gillibrand  
United States Senator



Mark Kirk  
United States Senator



Dianne Feinstein  
United States Senator



Jeff Flake  
United States Senator



Amy Klobuchar  
United States Senator



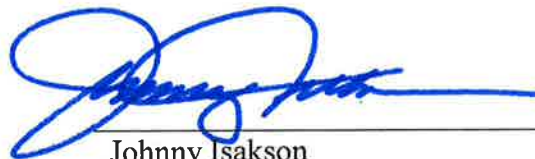
Lisa Murkowski  
United States Senator



Jack Reed  
United States Senator



Thad Cochran  
United States Senator



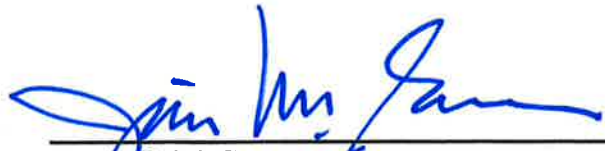
Johnny Isakson  
United States Senator



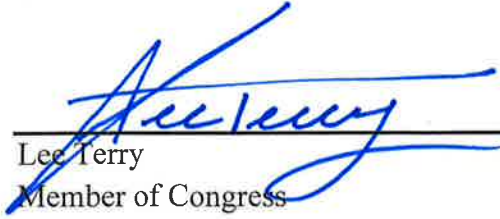
Kelly Ayotte  
United States Senator



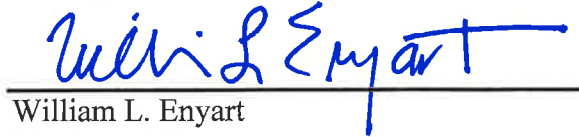
Patrick Meehan  
Member of Congress



James P. McGovern  
Member of Congress



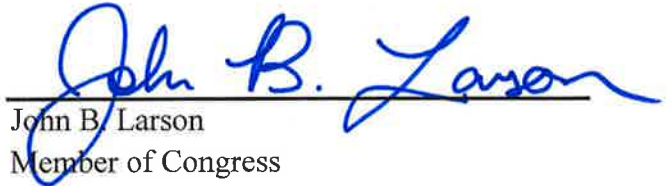
Lee Terry  
Member of Congress



William L. Enyart  
Member of Congress



Walter B. Jones  
Member of Congress



John B. Larson  
Member of Congress



Vance M. McAllister  
Member of Congress



Tony Cardenas  
Member of Congress



David "Phil" Roe, M.D.  
Member of Congress



Chellie Pingree  
Member of Congress



Steve Stivers  
Member of Congress



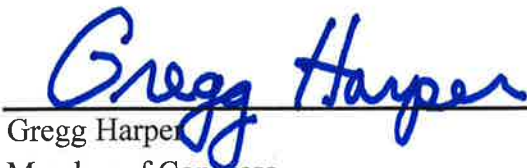
John Conyers Jr.  
Member of Congress



Jim Gerlach  
Member of Congress



G.K. Butterfield  
Member of Congress



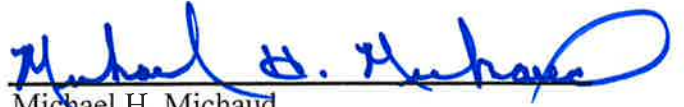
Gregg Harper  
Member of Congress



Katherine M. Clark  
Member of Congress



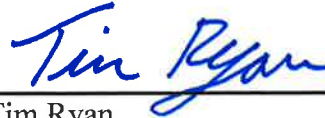
Peter T. King  
Member of Congress



Michael H. Michaud  
Member of Congress



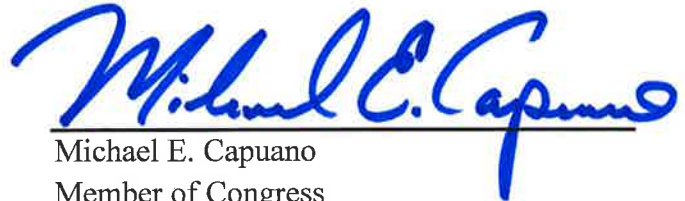
Kevin Yoder  
Member of Congress



Tim Ryan  
Member of Congress



Bradley Byrne  
Member of Congress




Michael E. Capuano  
Member of Congress



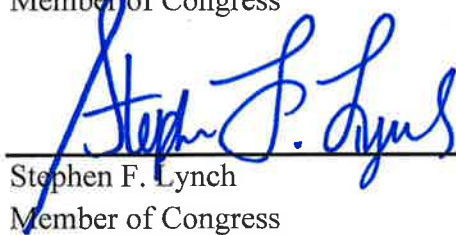
David P. Joyce  
Member of Congress




Carol Shea-Porter  
Member of Congress



Christopher P. Gibson  
Member of Congress



Stephen F. Lynch  
Member of Congress



Christopher H. Smith  
Member of Congress



Paul D. Tonko  
Member of Congress



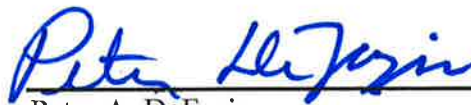
Tim Walberg  
Member of Congress



Joseph P. Kennedy III  
Member of Congress



George Holding  
Member of Congress



Peter A. DeFazio  
Member of Congress



Richard L. Hanna  
Member of Congress



C.A. Dutch Ruppertsberger  
Member of Congress



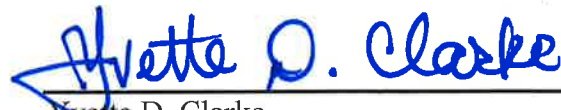
Patrick T. McHenry  
Member of Congress



Adam B. Schiff  
Member of Congress



Dennis A. Ross  
Member of Congress



Yvette D. Clarke  
Member of Congress



James Lankford  
Member of Congress



James R. Langevin  
Member of Congress



Robert J. Wittman  
Member of Congress



Raul M. Grijalva  
Member of Congress



Michael T. McCaul  
Member of Congress



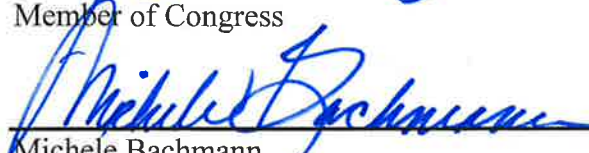
Alan S. Lowenthal  
Member of Congress



Trey Gowdy  
Member of Congress



Wm. Lacy Clay  
Member of Congress



Michele Bachmann  
Member of Congress



Bradley S. Schneider  
Member of Congress





Mark Meadows  
Member of Congress



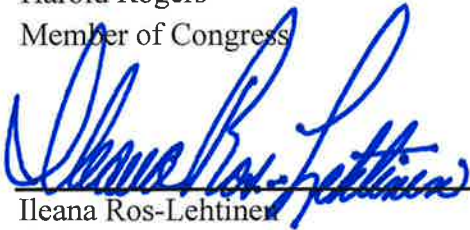
Daniel B. Maffei  
Member of Congress



Harold Rogers  
Member of Congress



Collin C. Peterson  
Member of Congress



Ileana Ros-Lehtinen  
Member of Congress



Steve Israel  
Member of Congress



Ed Whitfield  
Member of Congress



Carolyn McCarthy  
Member of Congress



Steve Chabot  
Member of Congress



Betty McCollum  
Member of Congress



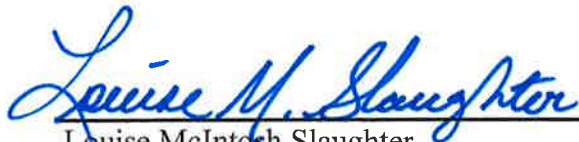
Doc Hastings  
Member of Congress



Julia Brownley  
Member of Congress



James B. Renacci  
Member of Congress



Louise McIntosh Slaughter  
Member of Congress



Kevin Cramer  
Member of Congress



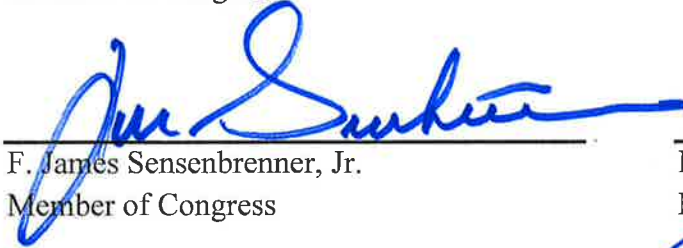
Jared Polis  
Member of Congress



Leonard Lance  
Member of Congress



Suzan K. DelBene  
Member of Congress



F. James Sensenbrenner, Jr.  
Member of Congress



Michelle Lujan Grisham  
Member of Congress



Rodney Davis  
Member of Congress



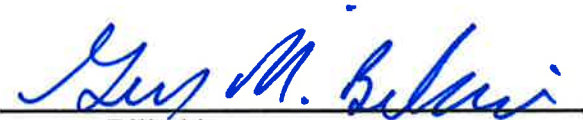
Eric Swalwell  
Member of Congress



Paul A. Gosar, D.D.S.  
Member of Congress



Tammy Duckworth  
Member of Congress



Gus M. Bilirakis  
Member of Congress



David N. Cicilline  
Member of Congress



Tim Griffin  
Member of Congress



Rick Larsen  
Member of Congress



Howard Coble  
Member of Congress



William R. Keating  
Member of Congress



Michael G. Fitzpartcik  
Member of Congress



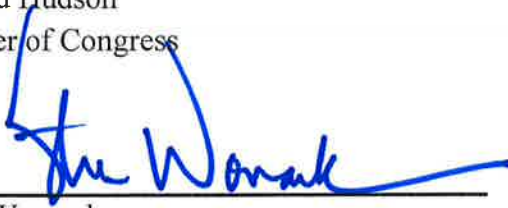
Richard M. Nolan  
Member of Congress



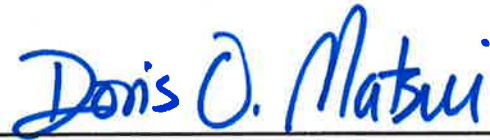
Richard Hudson  
Member of Congress



David Loeb sack  
Member of Congress



Steve Womack  
Member of Congress



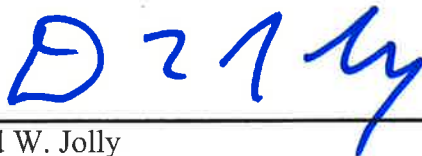
Doris O. Matsui  
Member of Congress



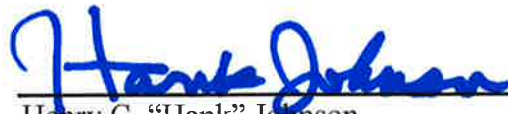
Ander Crenshaw  
Member of Congress



Ron Barber  
Member of Congress



David W. Jolly  
Member of Congress



Henry C. "Hank" Johnson  
Member of Congress



Edward R. Royce  
Member of Congress



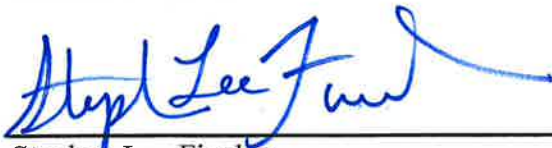
Ann Kirkpatrick  
Member of Congress



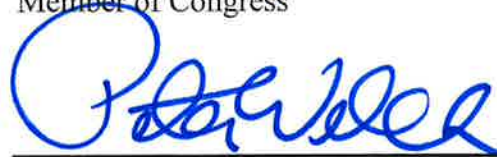
Tom Cole  
Member of Congress



Denny Heck  
Member of Congress



Stephen Lee Fincher  
Member of Congress



Peter Welch  
Member of Congress



Bill Flores  
Member of Congress



Niki Tsongas  
Member of Congress



Bill Huizenga  
Member of Congress



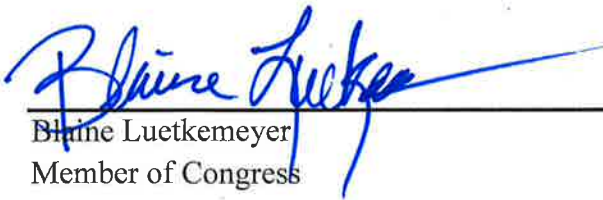
Earl Blumenauer  
Member of Congress



Marsha Blackburn  
Member of Congress



Corrine Brown  
Member of Congress



Blaine Luetkemeyer  
Member of Congress



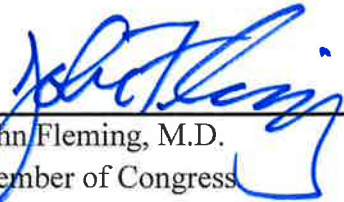
Joe Courtney  
Member of Congress



Patrick J. Tiberi  
Member of Congress



Marcy Kaptur  
Member of Congress



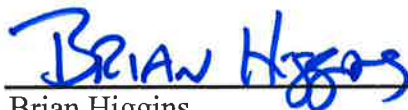
John Fleming, M.D.  
Member of Congress



Timothy J. Walz  
Member of Congress



J. Randy Forbes  
Member of Congress



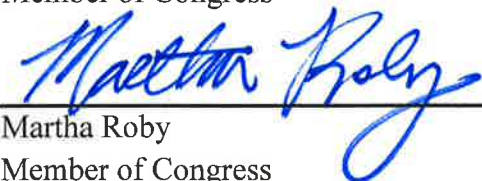
Brian Higgins  
Member of Congress



Bill Johnson  
Member of Congress



Frederica S. Wilson  
Member of Congress



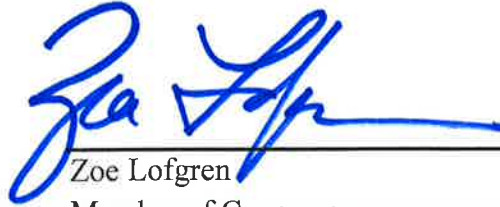
Martha Roby  
Member of Congress



Marcia L. Fudge  
Member of Congress



Lou Barletta  
Member of Congress



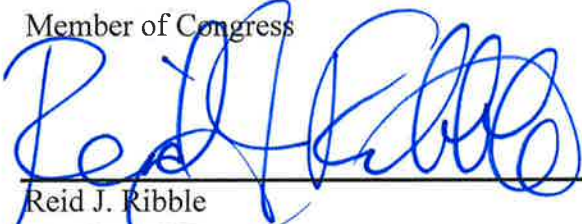
Zoe Lofgren  
Member of Congress



Daniel Webster  
Member of Congress



David E. Price  
Member of Congress



Reid J. Ribble  
Member of Congress



Daniel Lipinski  
Member of Congress



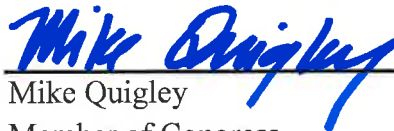
Tom Reed  
Member of Congress




Kathy Castor  
Member of Congress



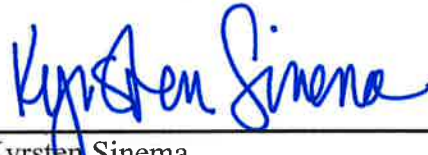
Mike Kelly  
Member of Congress



Mike Quigley  
Member of Congress



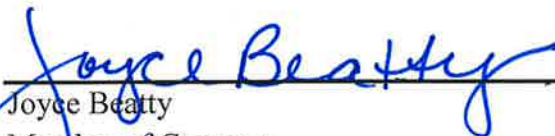
Jason T. Smith  
Member of Congress



Kyrsten Sinema  
Member of Congress



Aaron Schock  
Member of Congress



Joyce Beatty  
Member of Congress



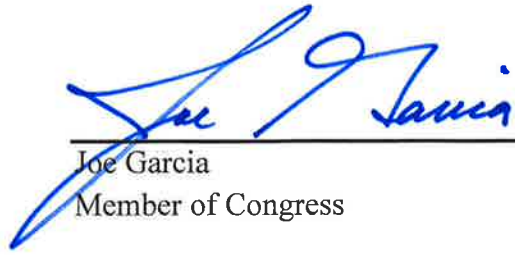
Jaime Herrera Beutler  
Member of Congress



William L. Owens  
Member of Congress



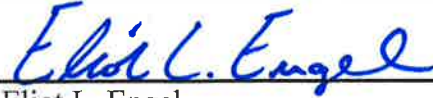
Curt Clawson  
Member of Congress



Joe Garcia  
Member of Congress



Ann Wagner  
Member of Congress



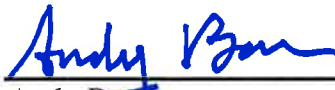
Eliot L. Engel  
Member of Congress



Chris Collins  
Member of Congress



Bill Foster  
Member of Congress



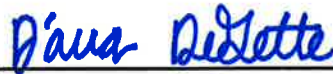
Andy Barr  
Member of Congress



Mark Pocan  
Member of Congress



Scott Rigell  
Member of Congress



Diana DeGette  
Member of Congress



Bob Gibbs  
Member of Congress



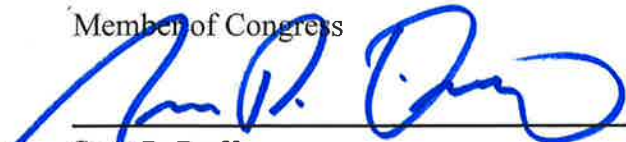
John A. Yarmouth  
Member of Congress



Dave Reichert  
Member of Congress



Ed Pastor  
Member of Congress



Sean P. Duffy  
Member of Congress



Tulsi Gabbard  
Member of Congress



Matt Salmon  
Member of Congress



John K. Delaney  
Member of Congress



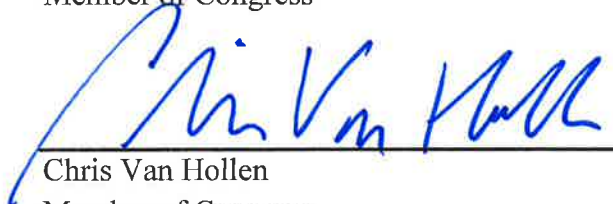
Robert E. Latta  
Member of Congress



Lloyd Doggett  
Member of Congress



Bob Goodlatte  
Member of Congress



Chris Van Hollen  
Member of Congress



Robert Pittenger  
Member of Congress



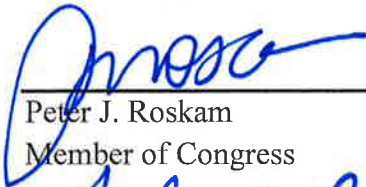
Keith Ellison  
Member of Congress



John Kline  
Member of Congress



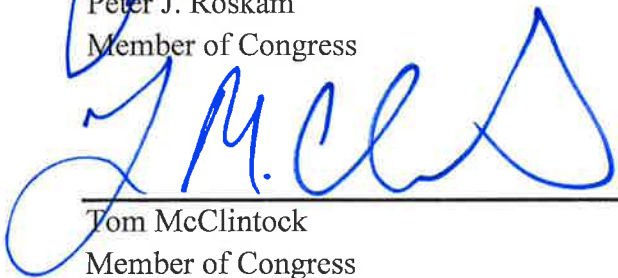
James A. Himes  
Member of Congress



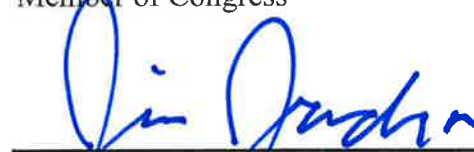
Peter J. Roskam  
Member of Congress



Markwayne Mullin  
Member of Congress



Tom McClintock  
Member of Congress



Jim Jordan  
Member of Congress



Michael R. Turner  
Member of Congress



Diane Black  
Member of Congress



Brad R. Wenstrup  
Member of Congress



Keith J. Rothfus  
Member of Congress



Tim Murphy  
Member of Congress



Renee L. Ellmers  
Member of Congress



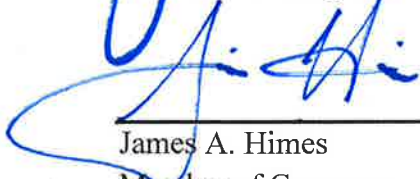
Pete Sessions  
Member of Congress



Dan Benishek  
Member of Congress



Janice D. Schakowsky  
Member of Congress



James A. Himes  
Member of Congress



David G. Valadao  
Member of Congress