

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:

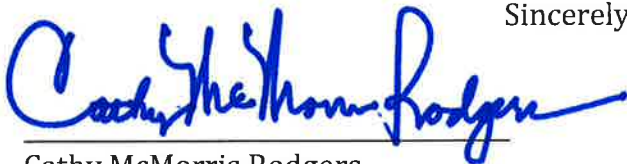
- 1) Sec. 1834(a)(19) of the Social Security Act already provides the Secretary with the authority to create a process for patients to be able to upgrade their DME items and caps Medicare spending at the rate of the base covered item. Why has this not been utilized for patients who need to utilize SGDs 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,



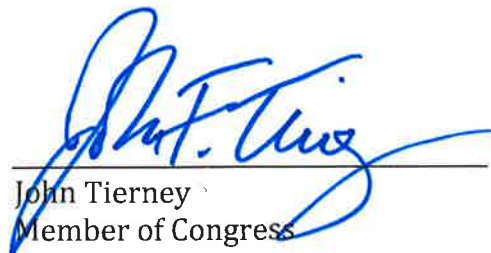
Cathy McMorris Rodgers
Member of Congress



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



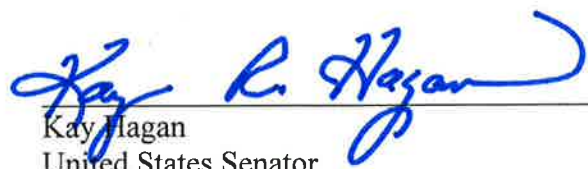
David Vitter
United States Senator



Sherrod Brown
United States Senator



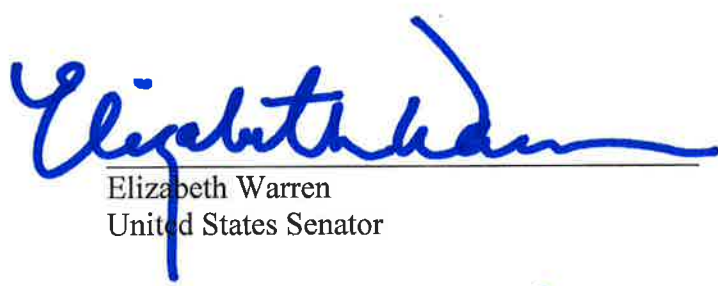
Roy Blunt
United States Senator



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



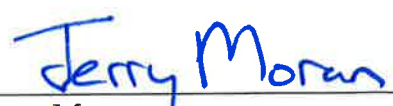
Edward Markey
United States Senator



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



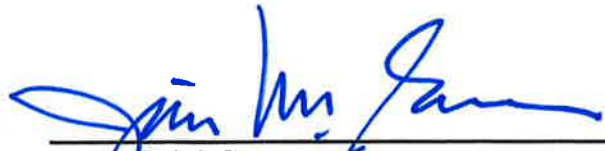
Johnny Isakson
United States Senator



Kelly Ayotte
United States Senator



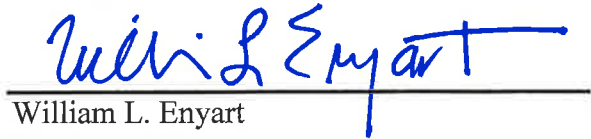
Patrick Meehan
Member of Congress



James P. McGovern
Member of Congress



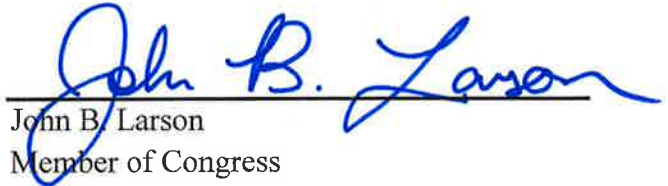
Lee Terry
Member of Congress



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



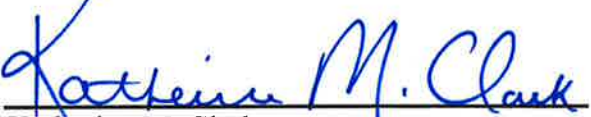
Jim Gerlach
Member of Congress



G.K. Butterfield
Member of Congress



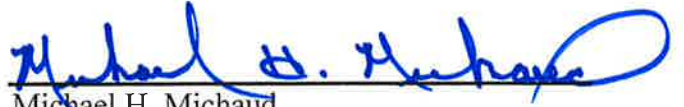
Gregg Harper
Member of Congress



Katherine M. Clark
Member of Congress



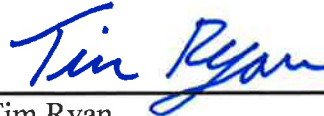
Peter T. King
Member of Congress



Michael H. Michaud
Member of Congress



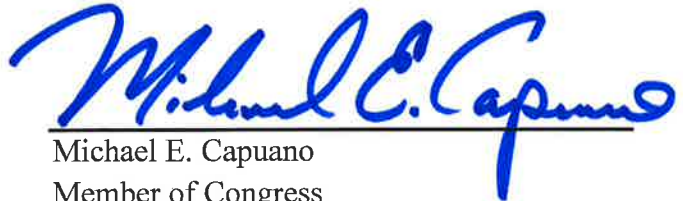
Kevin Yoder
Member of Congress



Tim Ryan
Member of Congress



Bradley Byrne
Member of Congress



Michael E. Capuano
Member of Congress



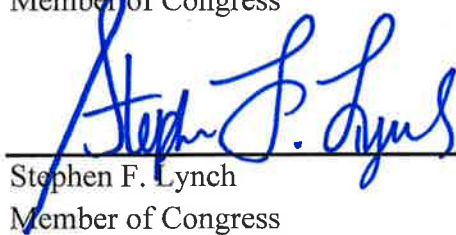
David P. Joyce
Member of Congress




Carol Shea-Porter
Member of Congress



Christopher P. Gibson
Member of Congress



Stephen F. Lynch
Member of Congress



Christopher H. Smith
Member of Congress



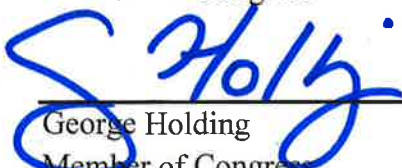
Paul D. Tonko
Member of Congress



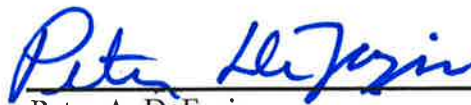
Tim Walberg
Member of Congress



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 Ruppersberger
Member of Congress



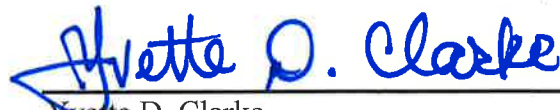
Patrick T. McHenry
Member of Congress



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



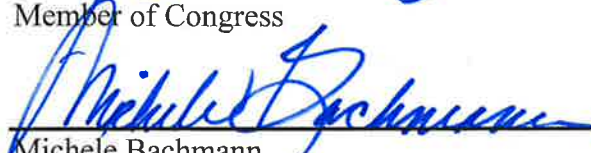
Alan S. Lowenthal
Member of Congress



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



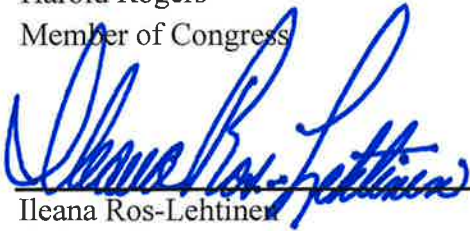
Daniel B. Maffei
Member of Congress



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



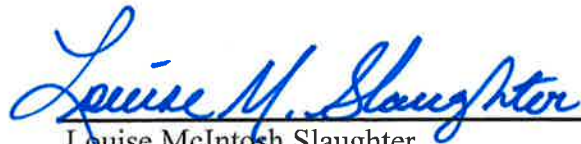
Doc Hastings
Member of Congress



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

Leonard Lance
Member of Congress

Suzan K. DelBene

Suzan K. DelBene
Member of Congress

F. James Sensenbrenner, Jr.

F. James Sensenbrenner, Jr.
Member of Congress

Michelle Lujan Grisham

Michelle Lujan Grisham
Member of Congress

Rodney Davis

Rodney Davis
Member of Congress

Eric Swalwell

Eric Swalwell
Member of Congress

Paul A. Gosar

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

Tammy Duckworth

Tammy Duckworth
Member of Congress

Gus M. Bilirakis

Gus M. Bilirakis
Member of Congress

David N. Cicilline

David N. Cicilline
Member of Congress

Tim Griffin

Tim Griffin
Member of Congress

Rick Larsen

Rick Larsen
Member of Congress

Howard Coble

Howard Coble
Member of Congress

William R. Keating

William R. Keating
Member of Congress

Michael G. Fitzpatrick

Michael G. Fitzpatrick
Member of Congress

Richard M. Nolan

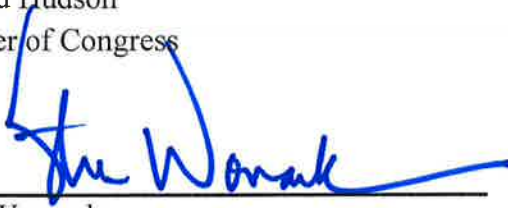
Richard M. Nolan
Member of Congress



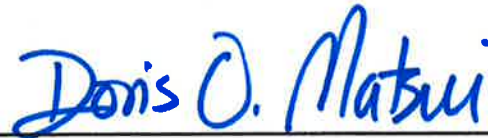
Richard Hudson
Member of Congress



David Loeb sack
Member of Congress



Steve Womack
Member of Congress



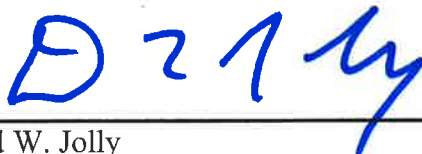
Doris O. Matsui
Member of Congress



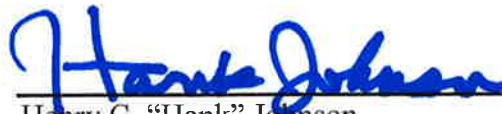
Ander Crenshaw
Member of Congress



Ron Barber
Member of Congress



David W. Jolly
Member of Congress



Henry C. "Hank" Johnson
Member of Congress



Edward R. Royce
Member of Congress



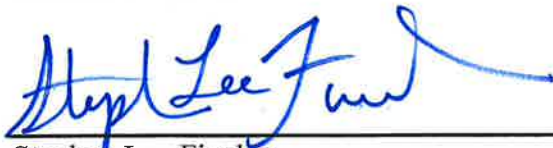
Ann Kirkpatrick
Member of Congress




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



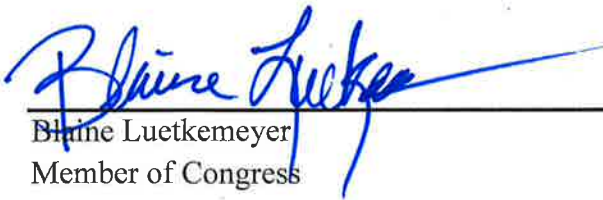
Earl Blumenauer
Member of Congress



Marsha Blackburn
Member of Congress



Corrine Brown
Member of Congress



Blaine Luetkemeyer
Member of Congress



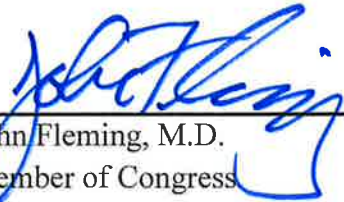
Joe Courtney
Member of Congress



Patrick J. Tiberi
Member of Congress



Marcy Kaptur
Member of Congress



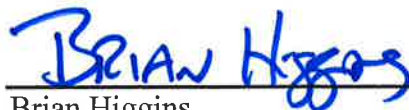
John Fleming, M.D.
Member of Congress



Timothy J. Walz
Member of Congress



J. Randy Forbes
Member of Congress



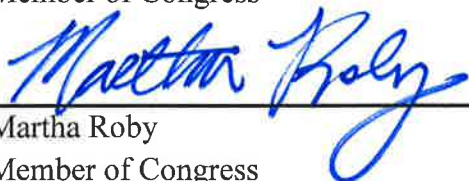
Brian Higgins
Member of Congress



Bill Johnson
Member of Congress



Frederica S. Wilson
Member of Congress



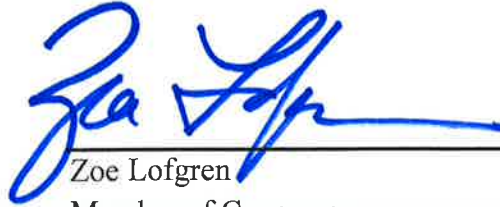
Martha Roby
Member of Congress



Marcia L. Fudge
Member of Congress



Lou Barletta
Member of Congress



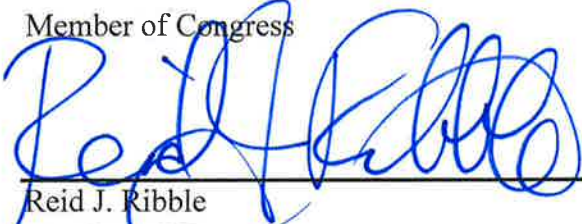
Zoe Lofgren
Member of Congress



Daniel Webster
Member of Congress



David E. Price
Member of Congress



Reid J. Ribble
Member of Congress



Daniel Lipinski
Member of Congress



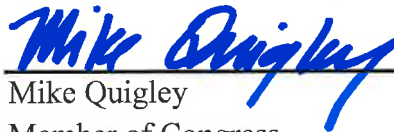
Tom Reed
Member of Congress



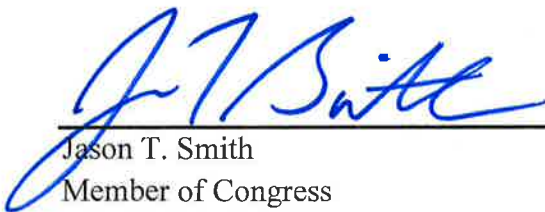
Kathy Castor
Member of Congress



Mike Kelly
Member of Congress



Mike Quigley
Member of Congress



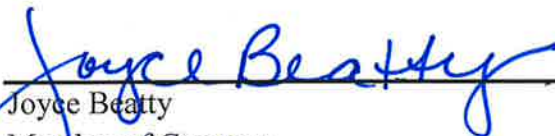
Jason T. Smith
Member of Congress



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



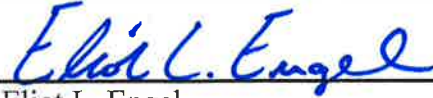
Curt Clawson
Member of Congress



Joe Garcia
Member of Congress



Ann Wagner
Member of Congress



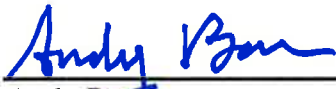
Eliot L. Engel
Member of Congress



Chris Collins
Member of Congress



Bill Foster
Member of Congress



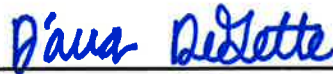
Andy Barr
Member of Congress



Mark Pocan
Member of Congress



Scott Rigell
Member of Congress



Diana DeGette
Member of Congress



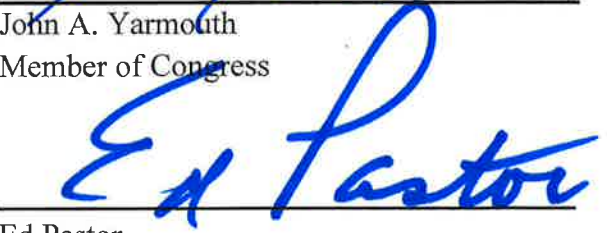
Bob Gibbs
Member of Congress



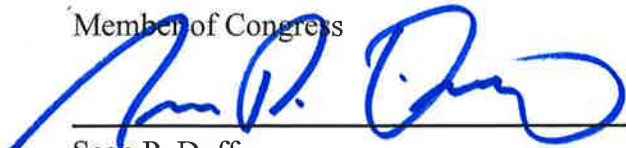
John A. Yarmouth
Member of Congress



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



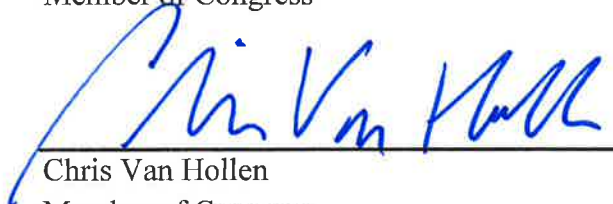
Robert E. Latta
Member of Congress



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



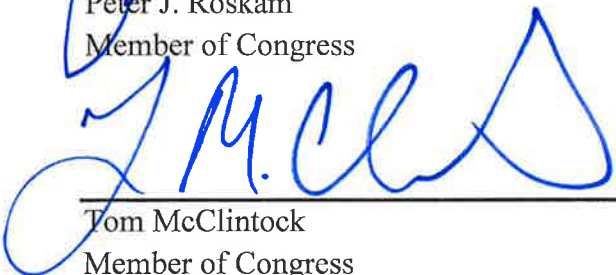
James A. Himes
Member of Congress



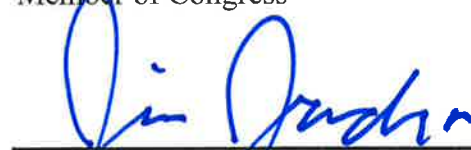
Peter J. Roskam
Member of Congress



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



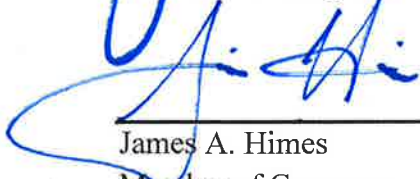
Pete Sessions
Member of Congress



Dan Benishek
Member of Congress



Janice D. Schakowsky
Member of Congress



James A. Himes
Member of Congress



David G. Valadao
Member of Congress