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ONE HUNDRED SEVENTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

February 8, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure,

On January 11, 2022, the Center for Medicare and Medicaid Services (CMS) issued a proposed National Coverage Determination (NCD) decision memorandum that would set a new precedent for restricting coverage of all Food and Drug Administration (FDA)-approved drugs using monoclonal antibodies directed against amyloid for Medicare beneficiaries suffering from Alzheimer’s Disease (AD). We have significant concerns about what this decision, if finalized, could mean for the more than 6 million American families suffering from AD, including those with other neurological or medical conditions such as Down Syndrome, who may be effectively prohibited from receiving the drug under the proposed process.

Unfortunately, this proposed action is not an isolated instance of CMS restricting access to breakthrough medical innovations. Last December, the Agency also repealed a final rule to provide for Medicare coverage of FDA-approved breakthrough medical devices for up to four years.¹ Similarly, we are hopeful that as the Department carefully reviews comments from the affected AD community, especially from underrepresented individuals and families who are impacted by the proposed policy, you will revise or replace the proposed decision and allow more Americans, in consultation with their doctors, to access these FDA approved AD treatments.

¹ CMS Rule to Repeal Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”, 86 FR 62944. *Available at* <https://www.federalregister.gov/documents/2021/11/15/2021-24916/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and>

The impacts of AD and dementia diseases on patients and their families is tragic and they continue to grow. Last May, President Biden stated that “diseases like Alzheimer’s, diabetes, cancer – they’re all on the cusp of being able to be dealt with . . . You know, if we don’t do something about Alzheimer’s in America, every single, solitary hospital bed that exists in America . . . every single one will be occupied in the next 15 years with an Alzheimer’s patient.”² While this statement by the President may be exaggerated, the number of Americans with AD is expected to more than double by 2050 to nearly 13 million.³ Today, about one in three seniors die with AD and other forms of dementia.⁴ More than 11 million Americans provide unpaid care for people with AD or other dementias, and in total, these caregivers provided an estimated 15.3 billion hours of care – or the rough equivalent of nearly \$257 billion worth of care.⁵ It has been estimated that AD and other dementias will cost our nation more than \$355 billion, including \$239 billion in Medicare and Medicaid patients combined.⁶ Absent significant and widely applicable treatments to halt this trend, AD is projected to cost over a trillion dollars annually by 2050.⁷ Moreover, AD disproportionately impacts women as well as black and Hispanic Americans and according to the Alzheimer’s Association only 53 percent of black Americans trust that a future cure for AD will be shared equally among races and ethnicities.⁸ Lastly, it is estimated that greater than 90 percent of people with Down Syndrome over the age of 60 develop AD.⁹

The CMS proposed NCD covers “FDA approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer’s disease (AD) under Coverage with Evidence Development (CED) in CMS approved randomized controlled trials” that meet certain coverage criteria for CMS-approved clinical studies and in trials supported by the National Institutes of Health (NIH).¹⁰ Under the proposal, all trials are to be conducted in a hospital outpatient setting and “the diversity of patients included in each trial must be representative of the national population diagnosed with AD.”¹¹ Covered patients are only to include those enrolled in clinical trials with mild cognitive impairment or dementia due to AD and evidence of AD-related amyloid pathology and will *not* include those who have neurological or other medical conditions (other than AD) that significantly contribute to cognitive decline or adverse events. This appears

²Business & Politics. “Biden says Alzheimer’s patients will fill ‘every single, solitary hospital bed that exists in America.’ Hmm. You sure? (May 28, 2021). Available at <https://www.bizpacreview.com/2021/05/28/biden-says-alzheimers-patients-will-fill-every-single-solitary-hospital-bed-that-exists-in-america-hmm-you-sure-1080396/>

³ Hebert L, Weuve J, Scherr P, Evans D. Alzheimer disease in the United States (2010-2050) estimated using the 2010 census *Neurology*. (May 2013). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3719424/>

⁴ Alzheimer’s Association. *2021 Alzheimer’s Disease Facts and Figures* report. Available at <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>

⁵ Ibid.

⁶ Ibid.

⁷ Ibid.

⁸ Ibid.

⁹ Zis P, Strydom A. Clinical aspects and biomarkers of Alzheimer's disease in Down syndrome. *Free Radical Biology & Medicine*. (Jan 2018). Available at <https://pubmed.ncbi.nlm.nih.gov/28870521/>

¹⁰ The Centers for Medicare & Medicaid Services. NCA - Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease (CAG-00460N) - Proposed Decision Memo. Available at <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&ncaid=305&fromTracking=Y&>

¹¹ Ibid.

to be an unprecedented use of the CED paradigm to restrict access to a drug by requiring additional randomized, controlled clinical trials and studies after a drug has already been approved by the FDA as safe and effective and appears to question the expertise and authority of the FDA.¹²

The FDA is responsible for protecting the public health by ensuring the safety and efficacy of drugs and medical devices. To further carry out the FDA's mission, Congress amended the Accelerated Approval pathway in 2012 to allow them to review drugs intended to treat serious conditions that fill an unmet medical need more quickly, such as drugs for AD. This pathway allows for drugs to be approved based on the effect the drug has on a surrogate or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA bases its decision on whether to accept the proposed surrogate or intermediate clinical endpoint on the scientific support for that endpoint and studies that demonstrate the drug's effect must be "adequate and well controlled" as required by the Federal Food, Drug, and Cosmetic Act (FFDCA).¹³ This process enables patients to get access to potentially life-saving and life-sustaining medicines sooner, while confirmatory studies are done to confirm clinical benefit. The safety standard in accelerated approval is no different from the safety standard in the more traditional approval, so any comments from CMS regarding the safety of Aduhelm calls into question FDA's ability to determine the safety of all drugs, not just those approved through accelerated approval.

In the case of Aduhelm, FDA has stated that its decision to grant accelerated approval was predicated on the reduction of amyloid beta plaques, which the agency determined was reasonably likely to result in clinical benefit. Further, the FDA has stated that in all of the studies in which the drug was evaluated, it "consistently and very convincingly reduced the level of amyloid plaques in the brain."¹⁴ As FDA is the agency tasked with evaluating clinical evidence, CMS' unprecedented CED confuses what clinical evidence must be obtained in order to receive Medicare coverage and undermines FDA's authority. Further, it is not clear that FDA has even been involved in deciding which randomized-controlled trials should qualify for Medicare reimbursement, or if the required postmarket study FDA required will be reimbursed by Medicare. CMS also continues to state that these studies are needed to understand performance of Aduhelm in the Medicare population, while according to CMS staff, 68 percent of participants were between the ages of 63 and 78 years.¹⁵

We are concerned that finalizing a decision to prohibit Medicare coverage for FDA-approved AD treatments outside of government sanctioned randomized controlled trials could unnecessarily deny to patients and their families the hope of breakthrough AD treatments and

¹² The Centers for Medicare & Medicaid Services. Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development. *Available at* <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27>

¹³ U.S. Food and Drug Administration. Accelerated Approval. (Jan. 4, 2018). *Available at* <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/accelerated-approval>

¹⁴ The Food and Drug Administration. FDA's Decision to Approve New Treatment for Alzheimer's Disease (June 2021) *Available at* <https://www.fda.gov/drugs/news-events-human-drugs/fdas-decision-approve-new-treatment-alzheimers-disease>

¹⁵ CMS Office of Legislation (E-mail to Grace Graham, January 18, 2022)

further eroding Americans' trust in their public health institutions. Our communities are already facing an unprecedented crisis of surging deaths of despair and a fleeting sense of community as a result of the COVID-19 pandemic response from government and public health leaders. Preventing potentially millions of seniors suffering from a deadly disease from accessing an FDA-approved treatment without a reasonable policy and explanation will send mixed signals about the respective agencies' roles and sow greater confusion.

Furthermore, it is extremely concerning and unacceptable that the proposed NCD appears entirely to exclude Americans with Down Syndrome from any form of coverage through these trials for Aduhelm and any future amyloid-related treatments. As stated in the draft decision, covered patients "must not have: any neurological or other medical condition (other than Alzheimer's disease) that may significantly contribute to cognitive decline."¹⁶ This effectively excludes patients with intellectual and developmental disabilities like Down Syndrome. This is a startling exclusion of a significant population that might otherwise benefit from coverage of Aduhelm. The link between Down Syndrome and AD is still being researched by scientists. However, there appears to be a correlation between the additional 21st chromosome present in people with Down Syndrome and the chromosome's gene that makes amyloid precursor proteins and can cause a build-up of the beta-amyloid plaques common amongst those with AD.¹⁷ There is promising research being done into the novel biomarkers of aging and dementia, and people with Down Syndrome are at a unique intersection of this research and must be included where possible to help further our understandings of both Down Syndrome and AD. More must be done to include those with Down Syndrome in research, but once approved by FDA, a doctor and patient with Down Syndrome should not be denied the hope from these treatment options. The proposed NCD discriminates against our family, friends, and neighbors who live with Down Syndrome and other neurological diseases. We urge you to correct this.

Because of the significant shortcomings of this NCD, numerous patient advocacy groups and caretakers have spoken out against the proposed NCD and warned against the inevitable consequences of reduced access to treatment for millions of seniors, in particular vulnerable populations. The Alliance for Aging Research noted that the NCD's proposed CED requirements are:

Overly restrictive, medically unethical, unlikely to meet the agency's goal to address health equity, will directly compete with clinical trial recruitment for FDA-required post-market study and will ultimately prolong evidence collection. This decision is not about furthering clinical evidence, it is about CMS severely rationing Alzheimer's patients' treatment access to save Medicare costs, full stop¹⁸

¹⁶ The Centers for Medicare & Medicaid Services. Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N) – Proposed Decision Memo. (Jan. 11, 2022). *Available at* <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=305>

¹⁷ The National Institute on Aging. Alzheimer's Disease in People with Down Syndrome (November 30, 2020) *Available at* <https://www.nia.nih.gov/health/alzheimers-disease-people-down-syndrome>

¹⁸ Alliance for Aging Research. Alliance for Aging Research Responds to CMS' Proposed Medicare Coverage Policy. (Jan. 11, 2022). *Available at* <https://www.agingresearch.org/alliance-for-aging-research-responds-to-cms-proposed-medicare-coverage-policy/>

The Alzheimer's Association commented that this decision is:

[S]hocking discrimination against everyone with Alzheimer's disease, especially those who are already disproportionately impacted by this fatal disease, including women, Blacks and Hispanics. With this approach, access to treatment would now only be available to a privileged few, those with access to research institutions, exacerbating and creating further health inequities. In issuing its decision CMS has the audacity to cite the *Alzheimer's Association 2021 Alzheimer's Disease Facts and Figures* report on the challenges and barriers underrepresented communities have in participating in clinical trials, and then turn around to impose those very barriers.¹⁹

Us Against Alzheimer's Chair and Co-Founder George Vradenburg wrote:

This is absolutely unacceptable. If this decision stands, for the first time in history, millions of Americans will be denied coverage not just to a drug, but to a whole class of drugs—not by the agency that regulates drugs but by the federal insurance bureaucracy HHS is clearly at war with itself, with one agency approving this class of drugs and another slamming the door shut on treatment. It's outrageous. Does CMS no longer trust the FDA's work?²⁰

The National Down Syndrome Society explained:

Part of that CED protocol excludes people with Down syndrome and other intellectual and developmental disabilities entirely. This exclusion from coverage now will have both short- and long-term negative effects on our community because aducanumab is a breakthrough treatment, and the CED is meant specifically to help develop evidence of the drug's effectiveness. If CMS moves forward with this exclusion, whatever evidence might be developed, none of it will apply to our community, and people with Down syndrome will be no closer to gaining covered access to a safe Alzheimer's treatment. Instead, our community will be farther away than everyone else. As new developments are made based on the health outcomes of aducanumab, that gap will only widen.²¹

We urge you to abandon and re-propose the NCD to provide for reasonable access to FDA-approved AD treatments for a broader population of Medicare beneficiaries, including those Americans suffering from other neurological diseases and medical conditions such as Down Syndrome. Patient advocates have reminded you of your commitment to health care for all patients and this policy's apparent departure from that goal by preventing access to an entire class of drugs that FDA believes is safe, effective, and reasonably likely to improve the quality and lengths of their lives.

¹⁹ Alzheimer's Association. Alzheimer's Association Statement on CMS Draft Decision. (Jan. 11, 2022). Available at <https://www.alz.org/news/2022/alzheimers-association-statement-on-cms-draft-deci>

²⁰ UsAgainstAlzheimer's. Medicare Slams the Door on Alzheimer's Treatments. (Jan. 11, 2022). Available at <https://www.agingresearch.org/alliance-for-aging-research-responds-to-cms-proposed-medicare-coverage-policy/>

²¹ National Down Syndrome Society, CMS Comment Website. Available at <https://www.ndss.org/cms-comment/>

In addition to taking our comments into consideration during the open comment period, please provide the following information by February 18, 2022:

1. Is this the first time CMS has proposed CED with a randomized controlled trial requirement for a drug?
2. Please elaborate on how cost-sharing for Medicare beneficiaries will operate.
 - a. How will cost-sharing operate for the Medicare beneficiaries enrolled in CMS-approved clinical trials that are allowed to access the relevant AD treatments?
 - b. Would qualifying seniors be liable for 20 percent coinsurance on their drugs in Medicare Part B?
 - c. Would some portion of seniors become liable for 20 percent coinsurance for a placebo product while suffering from AD?
 - d. What is the ethical justification for proposing that seniors suffering from AD would pay out-of-pocket for a placebo when an FDA-approved product is currently available?
3. Please elaborate on the rationale for extending this policy across an entire class of AD treatments targeting amyloid using monoclonal antibodies.
 - a. Does CMS have the authority to restrict the NCD policy to Aduhelm instead of a class wide restricted coverage policy? If so, why did it choose not to exercise this authority and instead apply the coverage policy to an entire class of drugs without the benefit of studying the data related to these separate and distinct products?
 - b. How did CMS consider the effects of such a blanket policy on the existing pipeline of AD treatments?
 - c. Did CMS consider how such a preemptively restrictive CED policy might impact beneficiaries' timely access to future treatments, especially those for AD but also across diseases and conditions?
4. This proposed decision seems to represent at least a tacit rejection of the FDA's analysis of Aduhelm and prospectively, other monoclonal antibody treatments affecting amyloid plaque. Is it CMS' position that drugs approved under the accelerated approval pathway should be treated differently for Medicare coverage than drugs approved under the standard approval pathway?
 - a. Will CMS assess future drugs and devices coverage prospects differently based upon their respective approval pathways?
 - b. How will CMS coordinate with FDA and improve its CED coverage paradigm to avoid further confusion to prevent loss of investment in research and future treatments for Medicare beneficiaries?
5. The proposed NCD refers to CMS evaluation of all relevant publicly available evidence in crafting the proposed NCD. It would seem, however, that collaboration with FDA might have allowed CMS to review evidence that, due to various data protection laws, is not publicly available but is essential to this coverage decision.

- a. Did CMS have the opportunity—and did the Agency avail itself of that opportunity—to work directly with FDA and evaluate all relevant data, not just data that is “publicly available”?
 - b. Did CMS avail itself of the expertise of the FDA, which Congress has determined should make decisions regarding whether prescription drugs should be made available to the American public based on their safety and efficacy?
6. One finding of the COVID-19 Clinical Evaluation of Therapeutics Lessons Learned Initiative is that community partnerships and community engagement are essential to supporting community clinics in clinical trial research—and that such community efforts help integrate underserved communities into clinical trial research.
- a. How does the NCD requirement that “all trials be conducted in a hospital-based outpatient setting” align with the goal of community engagement, and what might the impact of this requirement be on furthering health disparities in underserved communities, especially rural communities?
 - b. What empirical evidence did CMS use to propose such a restriction?
 - c. How many patients have already received the NCD covered treatments in a setting other than a hospital outpatient setting?
 - d. How does CMS plan to ensure access to treatment for qualifying individuals who lack convenient access to a hospital outpatient facility?
 - e. Did CMS study the impact of such a requirement on health disparities, particularly in rural parts of the country?
 - f. How would such a requirement fulfill “The CMS Equity Plan for Improving Quality in Medicare,” in particular priority number six to “Increase Physical Accessibility of Health Care Facilities”?²²
 - i. Priority six acknowledges that:

Physical inaccessibility of hospitals and provider offices reduces access to care for people with disabilities. Despite the passage of the Americans with Disabilities Act of 1990 (ADA), national data are not available on the accessibility of health care facilities and services, and many provider offices and services are inaccessible to people with disabilities.

Since gaps in data remain, how would CMS know if potential qualifying beneficiaries actually are able to receive treatment at other safe and accessible sites of care, especially if these sites of care were already safely administering the treatment before CMS’s new requirements?

7. On its face, one might interpret the NCD as compelling Medicare beneficiaries, particularly Medicare beneficiaries with access to fewer financial resources to pay out-of-pocket for AD treatment, to participate in clinical research.
- a. Did CMS intend to marginalize individual’s decisions regarding voluntary participation in clinical trials?

²² The Centers for Medicare & Medicaid Services Office of Minority Health. *The CMS Equity Plan for Improving Quality in Medicare*. (September 2015). Available at https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf

- b. In what other situations might CMS envision compelled participation in clinical research?
8. Please share the clinical rationale behind the NCD parameter precluding coverage for beneficiaries with concurrent conditions that may significantly contribute to cognitive decline.
 - a. Is this intended to pre-determine the inclusion and exclusion criteria of the clinical research?
 - b. What impact might this have on the significant portion of Medicare beneficiaries with AD and other neurological or other medical conditions such as Down Syndrome?
9. Patient advocates, manufacturers, and other stakeholders have expressed growing confusion about the meaning of the respective FDA “safe and effective” definition and the CMS “reasonable and necessary” definition and how CMS has unilaterally added unpredictable, subjective criteria into the definition of “reasonable and necessary.” Occasionally, *additional* safety and effectiveness requirements have been added on top of FDA requirements to meet Medicare coverage requirements. These additional studies to demonstrate – again -- safety and effectiveness appear to be a duplicative and unnecessary use of resources that will delay necessary treatments getting to anxiously waiting patients.
 - a. How does CMS plan to address the widespread confusion about the apparent gulf between such definitions and the ambiguity of the “reasonable and necessary” standard?
 - i. Will CMS consult with FDA to align their respective definitions and cut back on redundancies and uncertainty?
 - b. What specific steps will be taken to provide clarity for the definition of “reasonable and necessary” beyond the Program Integrity Manual?²³
10. A 2021 report from the CMS Office of Minority Health²⁴ describes its CMS Disparities Impact Statement as “a quality improvement tool that enables CMS and its stakeholders to systematically evaluate the impacts of a policy or program on health disparities.”²⁵ Did any CMS or the Department of Health and Human Services staff fill out a Disparities Impact Statement for this policy?
 - a. If so, please share a copy of the statement.

²³ The Centers for Medicare & Medicaid Services. Medicare Program Integrity Manual. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf>

²⁴ The Centers for Medicare & Medicaid Services Office of Minority Health. *Paving the Way to Equity: A Progress Report: 2015-2021*. Available at <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>

²⁵ The Centers for Medicare & Medicaid Services Office of Minority Health. Disparities Impact Statement. (March 2021). Available at <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf>

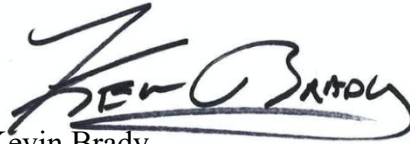
- b. If not, what other analyses were used to inform decision makers about the tradeoffs for such a restrictive coverage decision on the health of all patients affected by AD?
11. What resources will be made available to physicians who, upon studying and weighing the medical benefits and risks of one of the impacted Alzheimer's treatments, decide it is in their patient's best interest to be prescribed the drug to treat their Alzheimer's?
- a. What recourse would a physician have if they are denied the ability to reasonably provide an FDA-approved treatment for AD?

Thank you for your attention to this matter.

Sincerely,



Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce



Kevin Brady
Republican Leader
Committee on Ways and Means



Brett Guthrie
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce



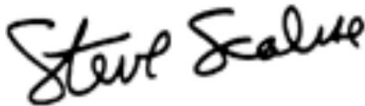
Vern Buchanan
Republican Leader
Subcommittee on Health
Committee on Ways and Means



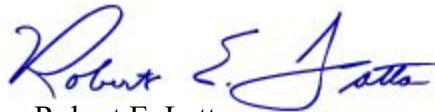
Fred Upton
Member of Congress



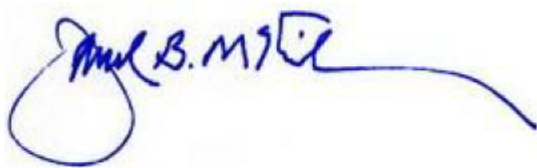
Michael C. Burgess, M.D.
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Steve Scalise
Member of Congress



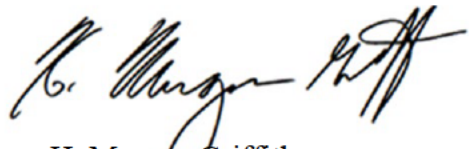
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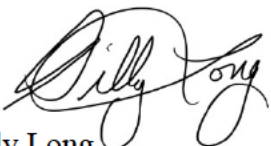
Gus Bilirakis
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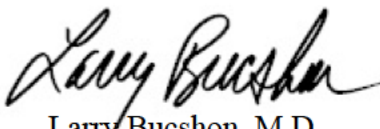
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Billy Long
Member of Congress



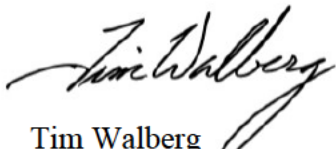
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Markwayne Mullin
Member of Congress



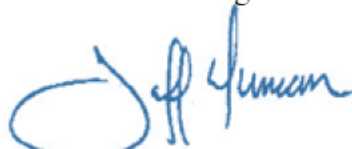
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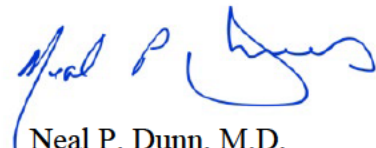
Earl L. "Buddy" Carter
Member of Congress



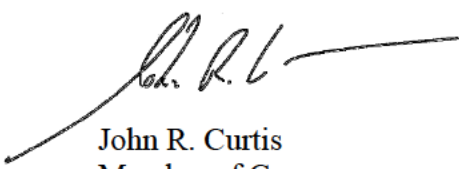
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Gary J. Palmer
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Neal P. Dunn, M.D.
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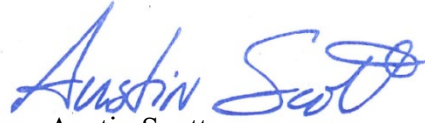
Vicky Hartzler
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Andy Harris, M.D.
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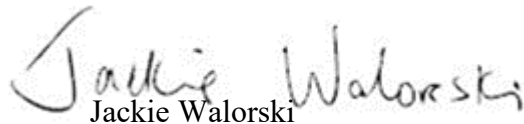
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Jason Smith
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Mike Bost
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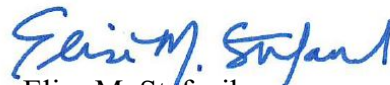
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Member of Congress



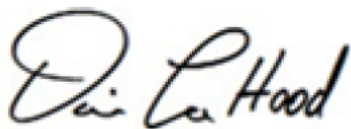
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Member of Congress



Elise M. Stefanik
Member of Congress



Darin LaHood
Member of Congress



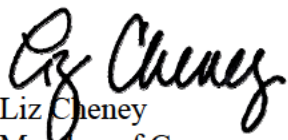
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Jim Banks
Member of Congress



Ted Budd
Member of Congress



Liz Cheney
Member of Congress




Drew Ferguson
Member of Congress



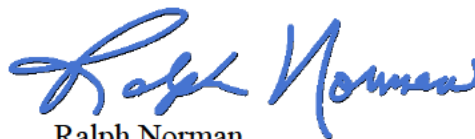
Brian Fitzpatrick
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Lloyd Smucker
Member of Congress



Ralph Norman
Member of Congress



Troy Balderson
Member of Congress



Kevin Hern
Member of Congress



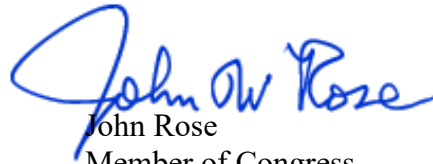
Tim Burchett
Member of Congress



Carol D. Miller
Member of Congress



Guy Reschenthaler
Member of Congress



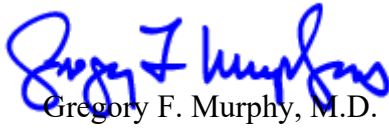
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Fred Keller
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Gregory F. Murphy, M.D.
Member of Congress



Chris Jacobs
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Cliff Bentz
Member of Congress



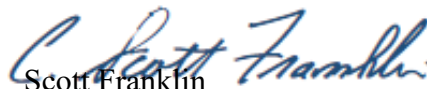
Kat Cammack
Member of Congress



Madison Cawthorn
Member of Congress



Andrew Clyde
Member of Congress



Scott Franklin
Member of Congress



Mariannette Miller-Meeks
Member of Congress



Jay Obernolte
Member of Congress



August Pfluger
Member of Congress

A handwritten signature in black ink, appearing to read "Michelle Steel". The signature is fluid and cursive, with the first name being more prominent.

Michelle Steel
Member of Congress

A handwritten signature in blue ink, appearing to read "Beth Van Duyne". The signature is cursive and somewhat stylized, with the last name being more prominent.

Beth Van Duyne
Member of Congress