

# Congress of the United States

Washington, DC 20510

May 24, 2022

The Honorable Christi A. Grimm  
Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC 20201

Dear Inspector General Grimm:

We request that the Department of Health and Human Services (HHS) Office of Inspector General (OIG) conduct an audit to determine whether fetal tissue research funded by HHS at the University of Pittsburgh violated federal law.

Between fiscal years 2016 and 2020, the National Institutes of Health (NIH) provided approximately \$1.5 million to the University of Pittsburgh as the GenitoUrinary Developmental Molecular Anatomy Project (GUDMAP) Tissue Hub and Collection Site.<sup>1</sup> The University of Pittsburgh had stated in its funding application that, to assist with the study of the “congenital diseases of the genitourinary tract (kidneys, bladder, ureter, uretha),” its Health Sciences Tissue Bank (HSTB) could provide tissue from unborn babies 6-24 weeks old and its partner, the International Institute for the Advancement of Medicine, could provide tissue from unborn babies 25-42 weeks old.<sup>2 3 4</sup>

The University of Pittsburgh’s application emphasized that “warm ischemia time is minimized.”<sup>5</sup> It stated, “We record the warm ischemic time on our samples and take steps to keep it at a minimum to ensure the highest quality biological specimens [30, 31]. We get feedback from our users and utilize this feedback to tailor our collection processes on a case-by-case basis to maximize the needs of investigators.”<sup>6</sup> “Warm ischemia time” refers to the amount of time the baby’s body part would remain at body temperature after blood supply had been cut off but before it was cooled.<sup>7</sup>

The university’s assertions raised two questions.

First, did the University of Pittsburgh and its recipients and subrecipients of HHS funding violate federal law prohibiting the alteration of abortion procedures solely for the purpose of obtaining fetal tissue? [42 U.S. Code § 289g-1](#) states that the tissue of aborted babies may only be used in research if the abortion provider signs a written statement that “no alteration of the timing, method, or procedures used to

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<sup>1</sup> NIH RePORT Project Details. “University of Pittsburgh as the GUDMAP Tissue Hub and Collection Site.” Abstract Text. [https://reporter.nih.gov/search/p3w-bb6YsECf3hOTrF\\_iLA/project-details/9944639#history](https://reporter.nih.gov/search/p3w-bb6YsECf3hOTrF_iLA/project-details/9944639#history)

<sup>2</sup> University of Pittsburgh. Application for Federal Assistance SF 242 (R&R). Page 7. <https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

<sup>3</sup> University of Pittsburgh. Application for Federal Assistance SF 242 (R&R). Page 7. <https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

<sup>4</sup> University of Pittsburgh. Application for Federal Assistance SF 242 (R&R). Page 60. <https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

<sup>5</sup> University of Pittsburgh. Application for Federal Assistance SF 242 (R&R). Page 62. <https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

<sup>6</sup> University of Pittsburgh. Application for Federal Assistance SF 242 (R&R). Page 62. <https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

<sup>7</sup> NIH National Cancer Institute. “Warm ischemia time.” Accessed February 10, 2022. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/warm-ischemia-time>

terminate the pregnancy was made solely for the purposes of obtaining the tissue.”<sup>8</sup> The University of Pittsburgh’s statement, as noted above, that it will “tailor our collection processes on a case-by-case basis” is not clearly consistent with the requirement of federal law and merits further investigation.<sup>9</sup>

Second, has the tissue being used for research been derived from aborted babies who were born alive and then killed by organ or tissue harvesting? The University of Pittsburgh and its partners provide tissue from aborted babies old enough to survive outside the womb with appropriate care. Babies born at younger than 22 weeks gestation have been known to survive and thrive.<sup>10</sup> If the babies are born alive after surviving an abortion, are the university and its recipients and subrecipients of HHS funding reducing “warm ischemia time” by keeping the babies alive until their organs or tissues have been harvested to provide blood flow to the organ or tissue for as long as possible? If infanticide by organ or tissue harvesting is occurring, it is a crime under Pennsylvania state law.<sup>11</sup> It is also a violation of federal regulation, which requires, among other things, that “there will be no added risk to the neonate resulting from the research.”<sup>12</sup>

When we raised these concerns with HHS, we received an unacceptable response that failed to substantively address either question. (Both letters are attached for your reference). We were told, because of these concerns, the NIH Office of Extramural Research had “been in discussions” with the University of Pittsburgh that had resulted in the commissioning of an “independent, third-party firm.” NIH then advised us that we could find the report publicly posted on the university’s website. Rather than conduct an independent evaluation of its own, NIH chose to accept and endorse a report that had been paid for by the institution it had been asked to investigate. This outsourcing of duties further raises concerns regarding how commonplace this practice is, warranting further oversight of HHS.

The firm’s report itself failed to address the two main questions about whether the University of Pittsburgh and its recipients and subrecipients of HHS funding have violated the law because it stopped short of investigating the University of Pittsburgh’s sources for fetal tissue. The report explained that the university coordinates with the University of Pittsburgh Medical Center (UPMC) to obtain fetal tissue for research.<sup>13</sup> It goes on to state that the review “did not include the activities conducted by individuals acting in their capacity as a UPMC employee.”<sup>14</sup> In summary, the assessment narrowed the scope of its investigation to such an extent that it was able to sidestep the two key questions about the abortion procedures and the baby victims.

We ask for your assistance in conducting an audit, consistent with the extent of your jurisdiction, to answer the questions that the Department has failed to answer. These include the following information requests for project number 1U24DK110791, for both the University of Pittsburgh and its recipients and subrecipients of HHS funding, from the beginning of the grant project period to today:

- The number of cases at each gestational age involving abortion, miscarriage, stillbirth, and neonate utilized in the GUDMAP program during the grant project period;

<sup>8</sup> [45 C.F.R. 46.204\(i\)](#) extends to all federally-funded human fetal tissue research the statutory requirements of 42 U.S.C. 289g-1

<sup>9</sup> University of Pittsburgh. Application for Federal Assistance SF 242 (R&R). Page 62.

<https://www.centerformedicalprogress.org/wp-content/uploads/2021/08/GUDMAP2015NIHappFOIA.pdf>

<sup>10</sup> Ahmad, Kaashif A. et al. “Two-Year Neurodevelopmental Outcome of an Infant Born at 21 Weeks’ 4 Days’ Gestation.” *Pediatrics*. November 2017. <https://pediatrics.aappublications.org/content/early/2017/10/31/peds.2017-0103>

<sup>11</sup> [18 PA Cons Stat § 3212 \(2020\)](#)

<sup>12</sup> [45 CFR § 46.205](#)

<sup>13</sup> Hyman, Phelps & McNamara, P.C. “Regulatory Assessment of Human Fetal Tissue Research at the University of Pittsburgh.” December 31, 2021. Page 2. [https://humancelltissueresearch.pitt.edu/sites/default/files/Regulatory%20Assessment%20of%20Human%20Fetal%20Tissue%20Research%20\(00877347-2\)%5b4%5d.PDF](https://humancelltissueresearch.pitt.edu/sites/default/files/Regulatory%20Assessment%20of%20Human%20Fetal%20Tissue%20Research%20(00877347-2)%5b4%5d.PDF)

<sup>14</sup> Hyman, Phelps & McNamara, P.C. “Regulatory Assessment of Human Fetal Tissue Research at the University of Pittsburgh.” December 31, 2021. Page 5. [https://humancelltissueresearch.pitt.edu/sites/default/files/Regulatory%20Assessment%20of%20Human%20Fetal%20Tissue%20Research%20\(00877347-2\)%5b4%5d.PDF](https://humancelltissueresearch.pitt.edu/sites/default/files/Regulatory%20Assessment%20of%20Human%20Fetal%20Tissue%20Research%20(00877347-2)%5b4%5d.PDF)

- Detailed protocols for Dilation & Curettage abortion, Dilation & Evacuation abortion, and Labor Induction abortion followed to obtain fetal tissue for the GUDMAP program;
- The detailed biospecimen collection IRB application and approval for the Health Science Tissue Bank;
- Documentation to verify the physiological status of unborn babies delivered by labor induction abortion upon tissue harvest;
- The number of fetal tissue collection procedures from babies delivered by labor induction abortion;
- Documentation of the number of babies delivered by labor induction abortion that were deceased, and documentation that cardiac activity had ceased prior to fetal organ and tissue collection;
- Documentation of when “warm ischemia” time was recorded with reference to death when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Documentation on the specific steps that were taken to minimize warm ischemic time when collecting organs and tissue from abortion, miscarriage, stillbirth, and neonate;
- Details on how specimens from abortion, miscarriage, stillbirth, and neonate are collected and transferred to the Tissue Hub and the personnel involved at each step;
- Documentation of how compliance is ensured (including any reporting and oversight mechanisms) with regard to each of the following statutes and regulations:  
The Partial-Birth Abortion Ban Act (18 U.S.C. 1531);  
Research protections for pregnant women and fetuses (42 U.S.C. 289g, 289g-1, and 45 C.F.R. 46.204);  
Research protections for neonates (45 C.F.R. 46.205); and,  
Prohibitions regarding fetal tissue (42 U.S.C. 289g-2, 45 C.F.R. 46.206).

We are cognizant that the HHS OIG has a reputation for performing thorough, non-partisan audits in pursuit of its mission to promote the economy, efficiency, effectiveness, and integrity of HHS programs. We thus await your unbiased evaluation of the serious concerns we have raised, which may either obviate or confirm the need for additional congressional oversight.

Sincerely,



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Christopher H. Smith  
Member of Congress



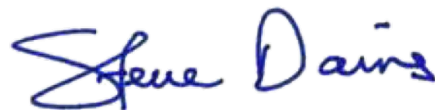
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James Lankford  
United States Senator



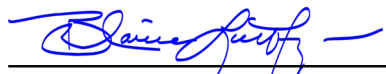
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Vicky Hartzler  
Member of Congress



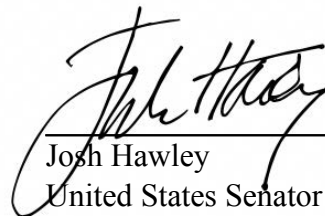
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Steve Daines  
United States Senator



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Blaine Luetkemeyer  
Member of Congress



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Josh Hawley  
United States Senator



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Lisa C. McClain  
Member of Congress



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John Thune  
United States Senator



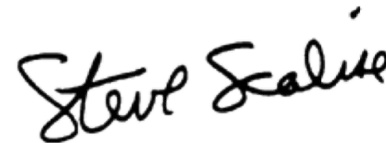
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Mike Kelly  
Member of Congress



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Ted Cruz  
United States Senator



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Steve Scalise  
Republican Whip



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James M. Inhofe  
United States Senator



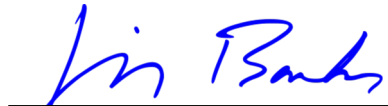
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Elise M. Stefanik  
Republican Conference Chair



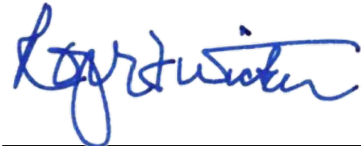
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Cindy Hyde-Smith  
United States Senator



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Jim Banks  
Member of Congress



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Roger F. Wicker  
United States Senator



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Mike Johnson  
Member of Congress



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John Boozman  
United States Senator



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Michelle Fischbach  
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Mike Braun  
United States Senator



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Andy Harris, M.D.  
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Tom Cotton  
United States Senator



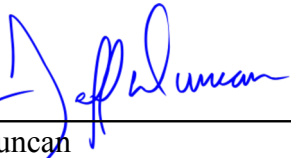
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Jake Ellzey  
Member of Congress



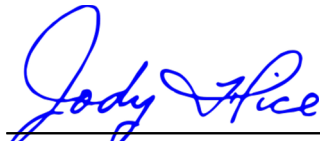
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Warren Davidson  
Member of Congress




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Jeff Duncan  
Member of Congress



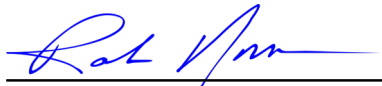
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Jody B. Hice  
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Steve Chabot  
Member of Congress




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Ralph Norman  
Member of Congress



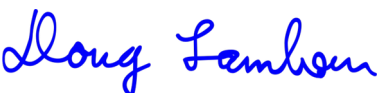
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Doug LaMalfa  
Member of Congress




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Brian Babin, D.D.S.  
Member of Congress



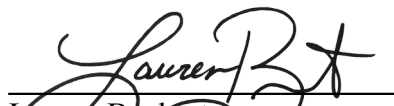
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Doug Lamborn  
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Randy K. Weber, Sr.  
Member of Congress




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Lauren Boebert  
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Richard Hudson  
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Eric A. "Rick" Crawford  
Member of Congress



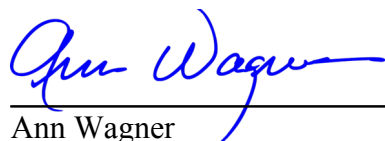
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Glenn "GT" Thompson  
Member of Congress




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John Rose  
Member of Congress



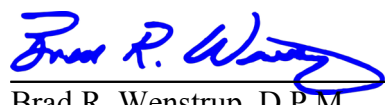
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Ann Wagner  
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Rick W. Allen  
Member of Congress




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Brad R. Wenstrup, D.P.M.  
Member of Congress



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Robert E. Latta  
Member of Congress



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David Rouzer  
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Barry Moore  
Member of Congress



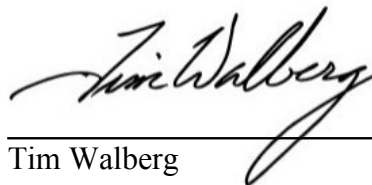
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John Joyce  
Member of Congress



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Glenn Grothman  
Member of Congress



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Tim Walberg  
Member of Congress



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Mariannette Miller-Meeks,  
M.D.  
Member of Congress



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Barry Loudermilk  
Member of Congress



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Julia Letlow  
Member of Congress



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Member of Congress



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C. Scott Franklin  
Member of Congress





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Chris Jacobs  
Member of Congress



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Mike Bost  
Member of Congress



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Bill Huizenga  
Member of Congress



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Michael Guest  
Member of Congress



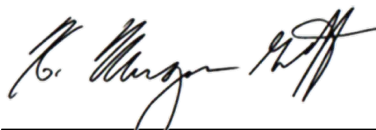
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Michael Cloud  
Member of Congress



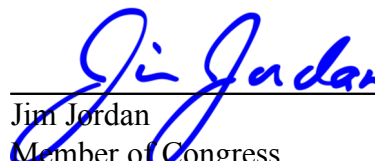
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Andy Biggs  
Member of Congress



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H. Morgan Griffith  
Member of Congress



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Jim Jordan  
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David B. McKinley  
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Bob Good  
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Ronny L. Jackson, M.D.  
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Michael Waltz  
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Steven M. Palazzo  
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Earl L. "Buddy" Carter  
Member of Congress



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Gregory F. Murphy, M.D.  
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Markwayne Mullin  
Member of Congress



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Jackie Walorski  
Member of Congress



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Ben Cline  
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Garret Graves  
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Bill Posey  
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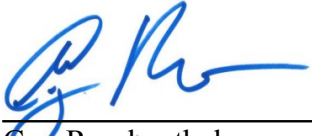
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Dan Crenshaw  
Member of Congress



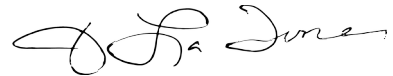
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Diana Harshbarger  
Member of Congress



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Guy Reschenthaler  
Member of Congress



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Jake LaTurner  
Member of Congress



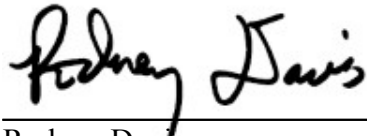
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Alex X. Mooney  
Member of Congress



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Ken Buck  
Member of Congress



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Rodney Davis  
Member of Congress



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Debbie Lesko  
Member of Congress



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Louie Gohmert  
Member of Congress



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Daniel Webster  
Member of Congress



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



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David Kustoff  
Member of Congress



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Robert B. Aderholt  
Member of Congress



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William R. Timmons IV  
Member of Congress



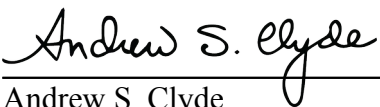
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Darin LaHood  
Member of Congress



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Randy Feenstra  
Member of Congress



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Andrew S. Clyde  
Member of Congress