Congress of the United States
House of Representatives
Washington, DC 20515-0906

January 21, 2022

The Honorable Janet Woodcock
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock,

On January 1, 2022, *The New York Times* published a deeply troubling article highlighting the concerning high level of false-positive results from non-invasive prenatal testing (NIPT).[1] We write to you today because it is our understanding that many of these tests have not been approved by the Food and Drug Administration (FDA), and we seek further clarification from the agency on this important matter.

While breakthroughs in genetic sequencing have provided Americans and their health care providers with new tools, there must be proper oversight of these new technologies to protect vulnerable populations like persons with disabilities, pregnant mothers, and their unborn children. NIPT became commercially available in the U.S. in 2011 as a screening tool to analyze DNA in a mother's blood to estimate the likelihood that her child will be born with certain genetic abnormalities.[2] Since then, the prevalence of NIPT has steadily increased, and several NIPT options are currently recommended by the American College of Obstetricians and Gynecologists (ACOG) and American College of Medical Genetics (ACMG) for use by pregnant women. Although the NIPT industry now performs tests on more than one-third of all pregnant women in the U.S.,[3][4] NIPT has largely escaped FDA regulatory review.

Companies that market and sell these products continue to see their profits grow and more products enter the market. According to a Pew Trust report from January of 2021, more than 40 non-invasive prenatal tests are now available on the market.[5] Unfortunately, many of the test manufacturers do not publish data on the accuracy of their tests, and others point to less than satisfactory studies to support their products.[6]

An examination of NIPT by *The New York Times* casts doubt on the efficacy of these tests. According to analysis conducted by *The New York Times*, positive results on certain tests were incorrect approximately 85 percent of the time. This is particularly troubling as NIPT is often

[1] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4303457/pdf/ijwh-7-113.pdf
[3] https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4303457/pdf/ijwh-7-113.pdf
[5] https://www.pewtrusts.org/-/media/assets/2021/01/clinical_lab_tests_need_stronger_fda_oversights.pdf
[6] https://www.nytimes.com/2022/01/04/podcasts/the-daily/prenatal-tests-pregnancy-birth.html?showTranscript=1

recommended to parents as a way of detecting certain rare disorders such as DiGeorge syndrome, 1p36 deletion, Cri-du-chat syndrome, Wolf-Hirschhorn syndrome, and Prader-Willi and Angelman syndromes. While these tests can help parents prepare for the arrival of their child, we are concerned that they could be a predatory financial windfall for manufacturers and directly result in the termination of innocent human life.

We respectfully request a response to the following questions related to non-invasive prenatal tests:

1) Is the FDA aware of the efficacy of these tests as reported by *The New York Times* and validated in published literature such as *The New England Journal of Medicine* and *Prenatal Diagnosis*?[7][8][9]
2) To what extent and under what circumstances does the FDA review the safety and efficacy of these tests?
3) What additional tools or authorities does the FDA need to evaluate and review the efficacy, including the validity, of these tests?
4) If the FDA is aware of a safety concern regarding tests currently on the market, what authority, if any, allows the FDA to take action on such tests?
5) What, if any, labeling requirements does the FDA require for these tests regarding safety or efficacy and the likelihood of potential adverse events?
6) How does the approval process differ between laboratory developed tests and medical devices?
7) Why are non-invasive prenatal tests regulated through the laboratory developed tract rather than the medical device tract?
8) Is the FDA considering evaluating the accuracy of claims made by the manufacturers of non-invasive prenatal tests?
9) Is the FDA considering requiring that manufacturers report adverse outcomes related to non-invasive prenatal tests?
10) Is the FDA considering taking any action to monitor the quality of non-invasive prenatal tests?
11) What data, if any, is the FDA examining or collecting related to non-invasive prenatal tests?
12) What steps can the FDA take to regulate non-invasive prenatal tests through department action?
13) Can you please provide us with data regarding which (if any) of the prenatal genetic screening tests are FDA approved?

Thank you for your attention to this issue.

Chip Roy
Member of Congress

Steve Daines
U.S. Senator

Michelle Fischbach
Member of Congress

[7] https://pubmed.ncbi.nlm.nih.gov/24571752/
[8] https://www.nejm.org/doi/full/10.1056/nejmoa1407349
[9] https://pubmed.ncbi.nlm.nih.gov/26715197/

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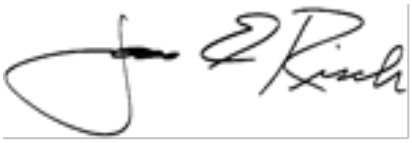

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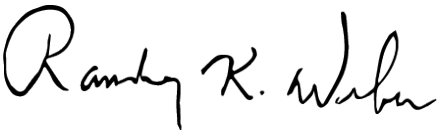

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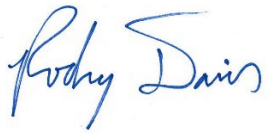

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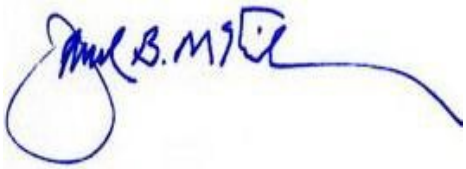

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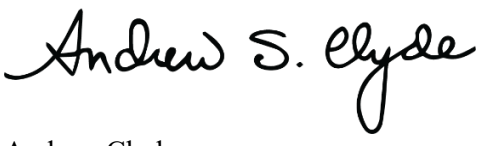

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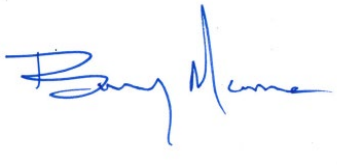

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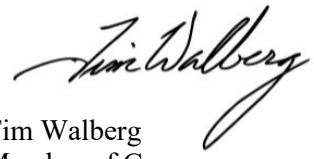

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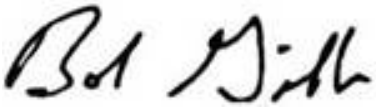

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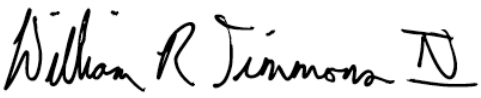

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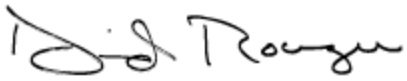

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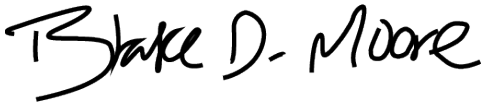

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