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January 21, 2022

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

Dear Secretary Becerra,

We write to request that you to take immediate action to address the lack of reliability of certain prenatal testing technologies. We believe administrative action to address concerns raised regarding the lack of transparency and poor performance of these prenatal testing technologies is necessary to protect life.

A recent report raised serious concerns about the lack of reliability of certain prenatal testing technologies. As a result of the inaccurate tests, some women have chosen to end their pregnancies. On January 1, 2022, *a New York Times* report found that found expectant mothers have been misled about the promise of tests that allegedly can detect developmental problems in the DNA of the fetus from a few drops of blood taken in the first trimester.¹

The *Times*' report found that these tests are frequently wrong, sometimes more than 90 percent wrong for some genetic conditions.² However, the *Times* reported that on product brochures and test result sheets, companies describe the tests to pregnant women and their doctors as near certain.³ Specifically, they advertise their findings as "reliable" and "highly accurate," offering "total confidence" and "peace of mind" for expectant mothers who want to know as much as possible.⁴ In addition, the *Times* found that some of the companies offered tests without publishing any performance data, only providing information on their best

¹Sarah Kliff and Aatish Bhatia, When They Warn of Rare Disorders, These Prenatal Tests Are Usually Wrong, *New York Times* (January 1, 2022), available at <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>

² *Id.*

³ *Id.*

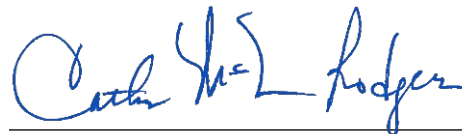
⁴ *Id.*

screenings, and leaving out weaker ones.⁵ Other companies based their claims on studies in which only one or two pregnancies actually had the condition in question.⁶

Every woman's journey to motherhood is different. Something that unites us is the uncertainty and the fear of the unknown. That should not be exploited with inaccurate tests that compound stress and anxiety during pregnancy. It is shocking that the laboratories and doctors recommended these tests without honestly communicating, or even worse, without knowing, the flaws of these tests. The testing technology in question is known as noninvasive prenatal testing, or NIPT, which apparently does not work well for less common genetic conditions, mostly caused by missing pieces of chromosomes called microdeletions. It is clear some of this testing is in widespread use. For example, the *Times* noted that, Natera, a laboratory certified under the Clinical Laboratory Improvement Amendments, said that in 2020, it performed more than 400,000 screenings for one microdeletion — the equivalent of testing roughly 10 percent of pregnant women in America.⁷ The *Times* interviewed researchers and reviewed data from multiple studies on the accuracy of the five most commonly used microdeletion tests.⁸ It found that positive results on those tests were incorrect about 85 percent of the time.⁹

You have an opportunity to raise awareness on this incredibly troubling matter by ensuring expectant mothers are fully informed with complete and accurate information about their babies, instead of relying on inaccurate and unreliable tests. These inaccurate results have led to devastating consequences. Every life should be given a chance, and I urge you to take immediate action in order to help prevent these avoidable tragedies and support pregnant women. Your consideration is greatly appreciated. We would appreciate your response by February 4, 2022.

Sincerely,



Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*