

United States Senate
WASHINGTON, DC 20510

March 10, 2020

Dr. Francis S. Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dr. Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Collins and Dr. Hahn:

We write regarding the work the U.S. National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) have done to prioritize the rapid development of treatments and vaccines for the 2019 Novel Coronavirus (COVID-19). As your agencies work to combat this public health emergency, we urge you to account for the unique risks and concerns of populations that have historically been excluded from pandemic research agendas and investments, including pregnant people.

Currently, our understanding of the specific impact of COVID-19 on pregnant people is limited. The latest information from a World Health Organization (WHO) investigation of 147 pregnant women infected with coronavirus indicates, “pregnant women do not appear to be at higher risk of severe disease.”¹ Still, the Centers for Disease Control and Prevention (CDC) notes that information on the susceptibility of pregnant people is limited and cautions that “[p]regnant women experience immunologic and physiologic changes which might make them more susceptible to viral respiratory infections, including COVID-19.”² According to the CDC, outcomes for other related coronavirus infections, including SARS-CoV and MERS-CoV, suggest pregnant people “might be at risk for severe illness, morbidity, or mortality compared to the general population as observed in cases of other related coronavirus infections.”³

¹ The World Health Organization, “Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19),” February 16-24, 2020, pp 32, <https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf>.

² The Centers for Disease Control and Prevention, “Frequently Asked Questions and Answers: Coronavirus Disease 2019 (COVID-19) and Pregnancy,” Accessed March 3, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/pregnancy-faq.html>.

³ *Id.*

Despite their immunologic and physiologic vulnerabilities, pregnant people have historically been left out of research agendas and clinical trials due to the added complexities of ensuring their safety and that of their children. Previous Ebola outbreaks, for example, have revealed that this is a particular problem in the midst of fast-moving pandemic response efforts.⁴ In the case of the West African Ebola Epidemic of 2013-2015, pregnant individuals were “systematically excluded from essentially all drug and vaccine clinical trials”—despite suffering from extremely high fatality rates and a WHO Ethics Working Group recommendation that it is “ethically important” to include pregnant people in clinical trials.⁵

As your agencies work with pharmaceutical companies to develop a pipeline for COVID-19 vaccines and therapeutics, we urge NIH and FDA to use their authorities to incentivize and ensure the development of vaccine and treatment candidates suitable for use in pregnancy. To do this safely and effectively, NIH and FDA should commit to investing in early non-clinical studies to provide for the eventual enrollment of pregnant people in late-stage clinical trials. Early investment in this commitment will be crucial in allowing pregnant people to have access to preventive measures in the face of this emerging pandemic threat.

We also encourage your agencies to consult with the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). Congress established PRGLAC in the 21st Century Cures Act to “advise the Secretary of Health and Human Services (HHS) regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women.”⁶ In September 2018, the Task Force released 15 recommendations for improving efforts to research and develop therapies specific for pregnant individuals, some of which may be readily applicable to the COVID-19 immunization and treatment development process.⁷

In addition, we urge NIH and FDA to increase representation of other underrepresented populations in clinical trials of treatments and vaccines for COVID-19. Both the 21st Century Cures Act and the FDA Reauthorization Act of 2017 (FDARA) included key provisions promoting equitable representation in clinical trials. FDA should encourage companies to follow its recently published guidance, *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs*, which was issued in accordance with Section 610(a)(3) of FDARA. The guidance recommends approaches that sponsors of clinical trials can take to broaden eligibility criteria and increase enrollment of underrepresented populations, including both demographic populations (e.g., sex, race, ethnicity, and age) and

⁴ David A. Schwartz, “Clinical Trials and Administration of Zika Virus Vaccine in Pregnant Women: Lessons (that Should Have Been) Learned from Excluding Immunization with the Ebola Vaccine during Pregnancy and Lactation,” December 2018, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313913/>.

⁵ *Id.*

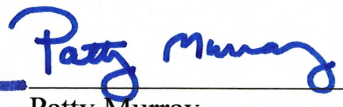
⁶ National Institute of Child Health and Human Development, “Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC),” <https://www.nichd.nih.gov/about/advisory/PRGLAC>.

⁷ National Institute of Child Health and Human Development, “List of Recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC),” <https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations>.

non-demographic populations (e.g., patients with organ dysfunction, comorbid conditions, and those at the extremes of the weight range) in their clinical trials.⁸

Thank you for your continued dedication to safeguarding the public health. We invite your agencies to stay in touch with our offices regarding Congressional actions needed to support efforts to ensuring that every American can access essential medicines, treatments, and vaccines for COVID-19. We look forward to working with you and other stakeholders on this critical issue.

Sincerely,

	
Elizabeth Warren	Patty Murray
United States Senator	United States Senator
	Ranking Member, U.S. Senate Committee on Health, Education, Labor, and Pensions

⁸ FDA Draft Guidance for Industry, “Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs,” June 2019, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial>.