MARCH OF DIMES

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December 22, 2021

The Honorable Diana DeGette
U.S. House of Representatives
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
Washington, DC 20515

Dear Representatives DeGette and Upton:

In response to your request for comments on the Cures 2.0 Act (H.R. 6000), March of Dimes appreciates this opportunity to provide feedback. As you work to advance this bill, we urge you to amend the legislation to enhance vaccination efforts focused on pregnant women and children and include provisions to ensure that research protocols for clinical trials include pregnant and lactating people.

March of Dimes was founded more than 80 years ago as an organization dedicated to eradicating polio in the U.S., a goal that we achieved. We continue that fight today as we work to address some of the biggest threats to moms and babies, such as premature birth and maternal mortality, through research, education, programs and advocacy.

Our ongoing work to improve maternal and infant health is more important than ever as our nation faces a dire maternal and infant health crisis. Although preterm birth rates declined slightly in 2020, the U.S. remains one of the most dangerous places to give birth in the developed world, and there are unacceptable disparities in birth outcomes between women and infants of color and their White peers.

We know the pandemic has only worsened this crisis. According to the Centers for Disease Control (CDC) data, expectant mothers with COVID-19 had a 50 percent higher chance of being admitted to intensive care and a 70 percent higher chance of being intubated than non-pregnant women in their childbearing years.[i] The data also shows pregnant Latina and Black women were infected at higher rates than White women. As we know, COVID-19 strikes the respiratory and cardiovascular systems, which are two systems that are impacted by changes during pregnancy.

VACCINES PLAY A CRITICAL ROLE PROTECTING THE HEALTH OF PREGNANT WOMEN AND THEIR BABIES

Vaccines are considered one of the greatest public health successes of modern medicine. It is estimated that from 1994 to 2016, the U.S. childhood immunization program prevented 381 million illnesses, 855,000 deaths, and nearly $1.65 trillion in societal costs.[ii] Adult immunizations have similarly prevented millions of fatalities and illnesses from diseases like influenza and pneumococcal disease.[iii]

Immunizations play an especially critical role in the health of pregnant women and young children. For pregnant women, rubella (or German measles) is among the most dangerous infectious diseases. Rubella can cause stillbirth, miscarriage, or severe birth defects that can affect almost every part of the newborn's body, including deafness, cataracts, heart defects, intellectual disabilities, and liver and spleen damage.[iv] During the last major rubella epidemic in the United States, which took place 1964-1965, an estimated 12.5 million people contracted rubella, 11,000 pregnant women miscarried their pregnancies, 2,100 newborns died, and 20,000 babies were born with congenital rubella syndrome. Today, congenital rubella syndrome in newborns is all but unknown in the United States due

to the incredible success of the measles, mumps and rubella (MMR) vaccine. Rubella was declared eliminated in the United States in 2004.[v]

Influenza can also have disproportionate dangers for pregnant women compared to other individuals. Due to changes in their immune system, heart, and lungs during pregnancy, pregnant women and women up to two weeks postpartum are more vulnerable to severe illness from flu, including illness requiring hospitalization.[vi] During the H1N1 pandemic influenza outbreak of 2009, several studies indicated that pregnant women were at increased risk of hospitalization, admission to an intensive care unit, death, and other severe outcomes related to that strain of influenza.[vii] Data from the first month after the appearance of 2009 H1N1 showed that pregnant women were four times more likely to be hospitalized than the general population.[viii] Although pregnant women represent only 1 percent of the U.S. population, they accounted for about 5 percent of all 2009 H1N1-related deaths.[ix] Influenza vaccination plays a critical role in protecting the health of both pregnant women and their babies.

It is imperative that our nation move aggressively to protect public health by ensuring that all Americans receive the full schedule of recommended vaccinations as medically appropriate. The rise of non-medical exemptions in some communities is allowing dangerous infectious diseases to gain a foothold from which they can spread. The resulting reduction in herd immunity endangers not only pregnant women and children, but those who cannot be vaccinated, such as those with medical conditions that compromise their immune systems.

IMPROVING HEALTH OUTCOMES FOR PREGNANT AND LACTATING PEOPLE

Each year, nearly four million people in the U.S. give birth[x] and more than three million breastfeed their infants.[xi] Although more than 90 percent of pregnant people report taking a medication during pregnancy, only 1 percent of clinical trials mention the words pregnancy or pregnant and only 0.5 percent mention breastfeeding or lactation.[xii] Not enough is known about the effect of most drugs on a woman or a pregnancy, or the ways in which pregnancy may alter the uptake, metabolism, and efficacy of medication. For example, the rate at which certain drugs are excreted through the kidney may increase by 50 percent during pregnancy. People with chronic diseases, such as diabetes, hypertension, depression and asthma, are becoming pregnant, and they need safe and effective medications to manage these ongoing conditions throughout their pregnancy and beyond. In the context of COVID-19, pregnant and lactating people were largely excluded from clinical trials for treatments and vaccines, leaving them and their clinicians without clear evidence on safety and efficacy to guide clinical decision-making.

Without reliable data, people who are pregnant or nursing may decide to stop taking necessary medications, increasing risks for both mother and child. In other cases, people may choose not to initiate breastfeeding or may wean earlier than desired because they lack information about the extent of drug transfer into human milk, the potential impacts of the drug on milk production, and the impact of exposure to the infant. Even when drug safety data is available, such data is usually limited, and often does not address how the changes of pregnancy and breastfeeding will affect dosage. We can and must do better for pregnant and lactating people.

To address this problem, Congress established the federal Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) under the 21st Century Cures Act (P.L. 114-255) to identify and address gaps in knowledge regarding safe and effective therapies and vaccines for pregnant and lactating women. In 2018, PRGLAC released a Report to Congress that included 15 detailed recommendations to promote the inclusion of pregnant and lactating people in clinical trials.[xiii] PRGLAC

took these recommendations further in an implementation report to the Secretary of Health and Human Services (HHS) released in August 2020 (PRGLAC Implementation Plan).[xiv] We believe Congress can do more by providing adequate authority and resources for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to implement the recommendations of PRGLAC. By including new provisions in the Cures 2.0 Act specifically targeting pregnant and lactating populations, the bill could help close critical gaps in knowledge to improve the health of women and their families.

MARCH OF DIMES' RECOMMENDATIONS FOR THE CURES 2.0 Act

The following includes March of Dimes' policy recommendations for consideration of inclusion in the Cures 2.0 Act:

Improving Access to Vaccines (TITLE I, SECTION 104)

We ask that you include the House-passed H.R. 951, the *Maternal Vaccinations Act of 2021*. This bill, part of the larger package of legislation under the *Black Maternal Health Momnibus Act of 2021,* would create a national campaign to raise awareness about maternal vaccinations (including COVID-19) and increase maternal vaccination rates. Women from communities that historically have had low vaccination rates would be a particular focus, an important consideration as Black, Latino and Indigenous women are disproportionately impacted by both the pandemic and the nation's ongoing maternal health crisis. H.R. 951 would also provide evidence-based, culturally congruent resources, and build partnerships with key maternal and community-based organizations.

We also ask for inclusion of H.R. 2347, the *Strengthening the Vaccines for Children Program Act of 2021***,** in your draft bill. H.R. 2347 would greatly improve patient access and care by expanding eligibility under the Vaccines for Children program to cover more children, incentivize provider participation in the program, expand vaccine education efforts to combat vaccine hesitancy, and track immunizations to better coordinate services for underserved communities.

Proposals for Pregnant and Lactating Women (Titles IV and V)

Authorized under the first Cures Act, PRGLAC was established to provide a path forward on the inclusion of pregnant and lactating people in research. March of Dimes strongly encourages Congress to continue this work by including provisions in Cures 2.0 to implement the recommendations of PRGLAC.

We ask that language be included directing the National Institutes of Health (NIH) and Food and Drug Administration (FDA) to require clinical trial sponsors to provide justification for exclusion of pregnant or lactating people from their study design in any applications to the government.

- In January 2019, the Department of Health and Human Services (HHS) and other agencies implemented changes to the "Common Rule," regulations for the protection of human subjects in research, which included the removal of pregnant women as an example of a "vulnerable population" that requires additional ethical scrutiny prior to participating in research. While this was an important first step, more must be done to move research from a culture of protecting pregnant and lactating people *from* research to protecting them *through* research.

- In an effort to remove regulatory roadblocks, language should be included directing relevant agencies to update and implement guidance and templates surrounding the inclusion of pregnant and lactating individuals within clinical trials in order to require justification for these individuals, and to clarify that exclusion of these populations within clinical trials should not be the default practice in the development and evaluation of drugs and therapeutics.

We also request language be included directing the NIH and FDA require clinical trial sponsors to provide justification for exclusion of pregnant or lactating people from their study design in any applications to the government.

- Such guidance could shift expectations for research collaborations across federal agencies and/or with non-governmental research entities, including industry, from a culture of protecting pregnant and lactating people *from* research to protecting them *through* research. Requiring this justification may be implemented without any statutory changes and this policy change would be a clear signal that your administration is committed to tackling this issue.

We ask that language be included in the legislation that would authorize and fund a research prioritization process for pregnant women and lactating women at NICHD.

- The purposed is to allow NICHD to study existing and new medications used by pregnant women and lactating women, and the Agency will establish a research prioritization process to determine which proposed research projects should receive priority grant funding. This research prioritization process shall take into account the following factors in determining the priority:
    - Available evidence (unmet need or gaps in information);
    - Feasibility (prevalence, expertise);
    - Urgency (immediacy of obstetrical or lactation needs for therapeutic); and
    - Impact (Severity of condition, cost, frequency of use, availability of alternative treatments).

We also ask that you include legislative language authorizing HHS to create new websites to list clinical trials and registries that include pregnant and lactating people at dedicated site (e.g. preglac.clinicaltrials.gov) to connect patients and providers to opportunities.

- PRGLAC has recommended creation of a website with comprehensive listing of clinical trials eligible for pregnant and/or lactating people. It would need to be constructed in patient-friendly language and could be a resource for providers who wish to discuss participation in trials or registries with their patients. This could be a new website or possibly a tab or check box could be added to Clinicaltrials.gov.

- Separately – but relatedly – PRGLAC has recommended creation of a user-friendly website to list pregnancy and lactation patient registries that would be created and funded by a public-private partnership, involving many stakeholders. There is not currently a comprehensive list of pregnancy registries and it is often difficult for a pregnant person and their providers to locate them.

We recommend language be included authorizing a public awareness campaign to engage the public and health care providers in research on pregnant women and lactating women.

- The campaign should prioritize engagement with the general public and health care providers in research on pregnant women and lactating women, as well as highlight the importance of research on therapeutic products in pregnant women and lactating women, including the

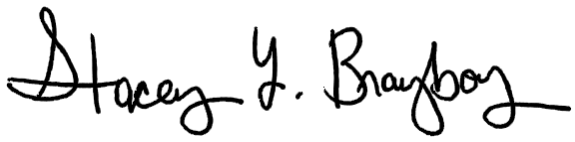
impact of not taking the medication during pregnancy and lactation, as well as the impact of not breastfeeding on mother and child.

We ask that you include language creating a new PRGLAC Advisory Committee under NICHD to monitor implementation of the PRGLAC recommendations.

- PRGLAC was established and its first charter expired in March 2019. Then-Secretary Alex Azar extended PRGLAC's charter for another two years – until March 2021 – so that PRGLAC could complete its work on the implementation report. Now PRGLAC has recommended that another committee with a similar range of stakeholders and expertise be established to monitor the implementation of the PRGLAC recommendations. We recommend the new Advisory Committee be headquartered at NICHD, but there should be involvement across the federal government and including outside stakeholders.

March of Dimes appreciates the opportunity to provide feedback and assist in the ongoing efforts to improve maternal health outcomes. If we can provide further information or otherwise be of assistance, please direct any follow-up questions to KJ Hertz, Senior Director, Federal Affairs (khertz@marchofdimes.org, 571.969.8655) or Jay Nichols, Deputy Director, Federal Affairs (jnichols@marchofdimes.org, 703.650.5627).

Sincerely,



Stacey Y. Brayboy
Sr. Vice President, Public Policy & Government Affairs

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[i] https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a1.htm
[ii] Centers for Disease Control and Prevention (CDC). (2018). VFC Infographic: 20 Years of Protection. Retrieved from https://www.cdc.gov/vaccines/programs/vfc/20-year-infographic.html
[ii] CDC. (2016). Vaccine-Preventable Adult Diseases. Retrihttps://www.cdc.gov/vaccines/adults/vpd.html. d
[iii] https://www.cdc.gov/vaccines/adults/vpd.html
[iv] CDC. (2017). Pregnancy and Rubella. Retrieved from https://www.cdc.gov/rubella/pregnancy.html.
[v] https://www.cdc.gov/rubella/pregnancy.html
[vi] Rasmussen SA, Jamieson DJ, Uyeki TM. (2012). Effects of influenza on pregnant women and infants. American Journal of Obstetrics & Gynecology, 207(3 Suppl):S3-8. Retrieved from https://www.ajog.org/article/S0002-9378(12)00722-3/pdf.
[vii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5359513/
[viii] https://www.cdc.gov/h1n1flu/in_the_news/pregnancy_qa.htm
[ix] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5823273/
[x] https://www.cdc.gov/nchs/fastats/births.htm
[xi] https://www.cdc.gov/breastfeeding/data/facts.html
[xii] https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf
[xiii] https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf
[xiv] https://www.nichd.nih.gov/sites/default/files/inline-files/PRGLAC_Implement_Plan_083120.pdf