

Office of the Vice President, Practice Activities Christopher M. Zahn, MD Col (Ret), USAF, MC

October 27, 2020

José R. Romero, MD, FAAP Chair Advisory Committee on Immunization Practices Centers for Disease Control and Prevention 1600 Clifton Road, N.E., Mailstop H24—8 Atlanta, GA 30329-4027

Re: Docket No. CDC-2020-0100; Advisory Committee on Immunization Practices; Notice of Meeting; Establishment of a Public Docket; Request for Comments

Dear Dr. Romero,

On behalf of the American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 physicians and partners dedicated to advancing women's health, thank you for the opportunity to submit written public comments on the upcoming meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). We appreciate ACIP's continued dedicated focus on development of a COVID-19 vaccine, and the opportunity to inform that work. Obstetrician-gynecologists, as trusted women's health physicians, are on the front lines of the response to the global COVID-19 pandemic.

ACOG is aware of and following closely the plans and discussions around COVID-19 vaccination allocation and prioritization and recently submitted comments to The National Academies of Sciences, Engineering, and Medicine (NASEM) and the Food and Drug Administration's (FDA) Vaccines and Related Biologic Products Advisory Committee.

ACOG is concerned that most, if not all, of the current Phase II/III vaccine trials exclude pregnant and lactating women, putting them at a disadvantage for protecting themselves against SARS-CoV-2. ACOG has and will continue to strongly advocate for the inclusion of pregnant women in Phase III vaccine trials to obtain the safety and immunogenicity data that will inform recommendations on vaccinating and protecting pregnant women. ACOG has urged NASEM and the FDA to recommend the establishment of pregnancy registries for those individuals who receive(d) a COVID-19 vaccine candidate in the early trial phases in order to further collect and evaluate the impact of the vaccine in pregnant women.

A growing body of evidence suggests that pregnant women are more likely to have certain manifestations of severe illness related to SARS-CoV-2 infection including ICU admission and mechanical ventilation^{1, 2}. Further, while pregnant and lactating women were a clear priority group for vaccination

José R. Romero, MD, FAAP Advisory Committee on Immunization Practices Page 2 of 2

during previous pandemics, pregnant and lactating women are noticeably and alarmingly absent from the NASEM vaccine allocation plan for COVID-19.

Pregnant and lactating women make up a significant portion of the U.S. workforce, including roles critical to the pandemic response such as health care workers. Thus, it is critical that a vaccine allocation plan explicitly outline that pregnant and lactating women who otherwise fit the criteria for inclusion in a high-priority population can be vaccinated alongside their non-pregnant peers based on shared clinical decision making with the patient and her clinician. These groups most notably include:

- a. Pregnant women and lactating women who are health care works or first responders.
- b. Pregnant women and lactating women with underlying conditions.

Women who are pregnant and/or lactating should not be excluded from what are identified as high priority populations for the COVID-19 vaccine allocation strategy. In addition to being an identified atrisk group by themselves, upwards of half of pregnant women also fall into another priority category, including frontline workers and those with underlying conditions. Women make up more than 75 percent of the health care workforce, and it is estimated that there are 330,000 pregnant health care workers^{3,4,5}. As such, ACOG urges ACIP to incorporate pregnant and lactating women clearly and explicitly into its COVID-19 vaccine allocation and prioritization framework as outlined above. Should an Emergency Use Authorization be executed for one or more COVID-19 vaccines and provide a permissive recommendation for pregnant and lactating women, pregnant health care workers, pregnant first responders, and pregnant individuals with underlying conditions should be prioritized for vaccination alongside their non-pregnant peers.

Thank you for the opportunity to submit comments and inform the critical work of your Committee. If we can provide any additional information or expertise, please contact me or Sarah Carroll at scarroll@acog.org.

Sincerely,

Christopher M. Zahn, MD Col (Ret), USAF, MC

Vice President, Practice Activities

cc: Sarah Carroll Megan McReynolds Rachel Tetlow Select staff

- Ellington S, Strid P, Tong VT, Woodworth K, Galang RR, Zambrano LD, et al. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status — United States, January 22–June 7, 2020. MMWR Morb Mortal Wkly Rep 2020; 69;769– 75. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6925a1.htm. Retrieved September 4, 2020.
- Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, et al. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. BMJ 2020;370:m3320. Available at: https://www.bmj.com/content/370/bmj.m3320. Retrieved September 4, 2020.
- 3. Rho HJ, Brown H, and Fremstad S. A basic demographic profile of workers in frontline industries. Center for Economic and Policy Research. April 2020. Available at: https://cepr.net/wp-content/uploads/2020/04/2020-04-Frontline-Workers.pdf. Retrieved October 24, 2020.
- 4. Day JC and Christnacht C. Women hold 76% of all health care jobs, gaining in higher-paying occupations. U.S. Census Bureau. August 14, 2019. Available at: https://www.census.gov/library/stories/2019/08/your-health-care-in-womens-hands.html#:~:text=Where%20Women%20Dominate,both%20of%20these%20large%20occupations. Retrieved October 24, 2020.
- Estimating the number of pregnant women in a geographic area. CDC Division of Reproductive Health. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/reproductivehealth/emergency/pdfs/pregnacyestimatobrochure508.pdf.
 Retrieved October 24, 2020.