The recent emergency use authorization of novel mRNA vaccines to prevent COVID-19 is a triumph for science. Less than a year after the SARS-CoV-2 virus was first identified, we have a 95% effective vaccine in production. There is much to celebrate, and there is also a yawning gap: phase 3 trials of these novel mRNA-based vaccines excluded pregnant and lactating women. This void is the product of decisions made >40 years ago to exclude pregnant and lactating women from research, with the goal of avoiding any risk to the fetus or nursing child. In the short term, this strategy avoided liability; in the long term, it has left providers and patients without clinical data to make informed decisions. Without clinical data, the Academy of Breastfeeding Medicine relied on biological plausibility and expert opinion to craft a statement on considerations for mRNA COVID-19 vaccines during lactation. The available information is reassuring; however, pregnant and lactating people deserve better than plausibility to guide medical decisions. Henceforward, phase 3 clinical trials should routinely include pregnant and lactating participants. It is time to protect pregnant and breastfeeding individuals through research, not from research.

—Alison Stuebe, MD, MSc
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