Covid-19 Vaccine Pregnancy Exemption Letter

This letter is to certify that Ms. XXXX XXXXX has disclosed to be pregnant.

Given that: 1. the majority of pregnant women have asymptomatic COVID-19; 2. asymptomatic women are not at an increased risk of severe COVID-19 outcomes; 3. mRNA COVID-19 vaccines increase the risk of severe adverse outcomes in healthy adults; 4. there is a lack of both short and long-term randomized safety data for use of these vaccines in pregnant women and their unborn children; and 5. safe and effective therapy is available, I advise against the use of COVID-19 vaccines in pregnancy. The scientific rationale supporting my advice is outlined below.

Healthy asymptomatic women are not at an increased risk of severe disease from COVID-19

The seminal analysis by Zambrano et al. (2020) indicating that symptomatic pregnant women are at a higher risk of severe diseases from COVID-19 than non-pregnant symptomatic women was conducted in predominantly white, symptomatic women and relied on a databases that had <30% pregnancy status and hospitalization event data.[1] Whereas, a number of small retrospective studies of obstetrics units, conducting universal testing showed that the majority of pregnant women testing positive for COVID-19 were asymptomatic (n = 33 to 46, 72% to 98%).[2-4] A further retrospective analysis conducted by Delahoy et al. (2020) that analyzed 598 hospitalized pregnant women with COVID-19 found that asymptomatic women had no ICU admissions, invasive ventilation requirements, or deaths.[5] Taken together, the available evidence does not support an increased risk of severe COVID-19 outcomes among asymptomatic pregnant women.

Phase III randomized trials in healthy adults show that COVID-19 vaccines are associated with an increased risk of severe adverse outcomes

A recent article by Thomas *et al.* (2021) reporting data for the BNT162b2 mRNA COVID-19 vaccine through 6 months[6] showed that the mRNA COVID-19 vaccine increased treatment-related adverse (predominantly COVID-like symptoms) by 298% relative to placebo. There was an increase in the absolute risk of COVID-like symptoms in 18% of recipients. The study also reported an increased risk of severe adverse events of 71% relative to placebo. When both severe COVID-19 cases and severe adverse events were considered, the likelihood of experiencing any severe event increased by 49% with receipt of the vaccine relative to placebo translating into an absolute increased risk of severe effects of 0.4%. When deaths after crossover were considered, there were numerically more deaths on the vaccine arm compared to the placebo arm (20 vs 14). Therefore, phase III randomized trials demonstrating that COVID-19 vaccines increase the risk of adverse outcomes in healthy adults **do not support safe use in pregnant women**.

There is an unmet need for randomized controlled trials that monitor the potential impact of mRNA COVID-19 vaccines on fetal and neonatal development, including teratogenicity, oncogenicity and genotoxicity studies as well as safety and development milestones up to 2-years

Administration of mRNA COVID-19 vaccines results in the production of the spike protein, which

has been implicated in pathogenic mechanisms that affect the uterus, placenta, and possibly the fetus.[7-17] Moreover, the Vaccine Adverse Event Reporting System (VAERS) has detected cardiovascular, neurological and immunological safety signals in adults.[18] It is therefore reasonable to suspect that mRNA COVID-19 vaccination may impact fetal and neonatal development through a variety of mechanisms. The desired goal of the mRNA COVID-19 vaccines is to drive an anti-viral cell-mediated immune response against SARS-CoV-2 via pro-inflammatory cytokines. Some of these same inflammatory cytokines can also lead to adverse fetal outcomes.[19-25]

Moreover, according to the Developmental Origins of Health and Disease (DOHaD) Hypothesis,[25-27] subtle multi-organ developmental changes that may occur in the fetus during an adverse vaccine reaction (AVR) could lead to increased risk of disease. As a result, studies that examine mRNA COVID-19 vaccine outcomes like teratogenicity, oncogenicity, reprotoxicity and genotoxicity are needed, in addition to those that assess shorter-term extreme outcomes during pregnancy (e.g. miscarriage, stillbirth, preeclampsia, gestational diabetes) and long-term safety and development milestones up to two years in newborns within a randomized context (e.g. preterm delivery, poor growth, birth defects) within a randomized context. Available short and long-term randomized safety data do not sufficiently prove the safety of mRNA COVID-19 vaccines in pregnant women.

There is inadequate evidence to rule out mRNA COVID-19 vaccination as an underlying contributor to spontaneous abortions. Retrospective cohort analyses should be hypothesis generating at best

As pregnant women were excluded from the Phase III randomized controlled trials there is no compelling data to support CDC recommendations for the use of these biologically active vaccines in this population. On September 10th, 2021, an article by Shimabukuro *et al.* (2021) presented preliminary safety outcomes from this registry.[28] A total of 1,982 women were vaccinated at <20 weeks gestation and of the women who had completed their pregnancies at the time of the analysis, <127 were miscarriage-eligible. A total of 104 of miscarriages were reported for an event rate among eligible women of >82% and a miscarriage rate of 5.24% of the total participants. A follow up sensitivity analysis conducted by Zauche *et al.* (2021) in 2,052 pregnancies at <20 weeks gestation showed that the cumulative miscarriage rates followed the upper most boundary of the risk range, which supports a potential association between the vaccines and observed miscarriage rates.[30] Given the lack of appropriate controls in this analysis and the homogeneity of the study population, these findings do not rule out concerns regarding increased risk of miscarriage in the wider population and do not support use of these vaccines in pregnant women outside of clinical trials.

Established treatment for COVID-19 in pregnant women is safe and effective

There are early treatment options available for women with symptomatic COVID-19 or those at increased risk of illness from COVID-19.[31] Hydroxychloroquine is a well-established and widely available therapy against COVID-19, including in pregnant women. Given the particularly favorable risk-benefit profile of this established agent, I cannot recommend the use of an experimental mRNA COVID-19 vaccine that has questionable safety data in pregnant women.

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