FDA knew as of February 2021 that the mRNA vaccine crosses the placenta, passes into milk, and causes adverse events in breastfed infants

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FDA Report: spontaneously collected adverse events for Pfizer BNT162b2 vaccine between December 11, 2020, and February 28, 2021[1]

This is the report of adverse event reports from Pfizer's safety database until February 28, 2021: this database includes cases reported spontaneously by health authorities, in the medical literature, collected by Pfizer-funded programs, by non-interventional studies. This collection therefore concerns only a little more than two and a half months of vaccine administration (between December 11, 2020, the date of authorization, and February 28, 2021).

The report notes that the rate of spontaneous underreporting of adverse events is unknown.

458 cases of adverse events following BNT162b2 vaccine received during pregnancy were identified and 215 during breastfeeding.

210 cases following vaccine received during pregnancy were excluded as having no associated adverse event or an AE related to off-label use or use of the product, either for the mother or the child. This is confusing: why would there be people who would fill out an ADR file without mentioning an ADR? Similarly, what does exclusion for off-label compliance mean? Would the exclusion include people who could not provide the lot number of the vaccine?
Whatever the answer, these results are likely to be underestimated because of these undocumented exclusions.

Vaccine exposure during pregnancy

Of the 248 cases retained, 53 miscarriages and 6 premature deliveries were reported

Miscarriages: most were reported within 3 weeks of vaccination (it can be assumed that miscarriages occurring within a longer period were not reported).

Preterm deliveries

One premature baby developed tachycardia 7 days after the mother received the second dose of vaccine, the fate of the child is unknown.

One baby is described as having received the vaccine transplacentally by the FDA. The injection at 13 to 28 weeks' gestation resulted in early delivery and the baby did not survive, having experienced severe respiratory distress and a pneumothorax.

Another preterm delivery (vaccine received in the second trimester of pregnancy) resulted in a baby with sequelae who was treated with aspirin and heparin: did he show signs of thrombosis?

Another premature baby of a mother vaccinated in the second trimester died of severe respiratory distress and pneumothorax.

Another premature baby had been exposed to the vaccine even transplacentally, according to the FDA.

Exposure during breastfeeding

Of the 215 cases reported in 174 cases, no adverse events were reported: see note above!
On the 41 remaining cases, various adverse effects are reported, the most frequent of which are: fever, irritability, headache, rash, diarrhea, sickness, insomnia, milk drying, milk discoloration, vomiting of the baby, lethargy, pain, hypothermia, urticaria, ...
10 AEs concerning babies were reported. They all occurred within 7 days after the mother's vaccination: skin peeling and irritability of the infant, rash and urticaria, angioedema, unspecified

illness (with or without hospitalization).

Data from the April 30, 2021 full adverse event document

It should also be noted that in the full document [2] regarding all signals received as of February 28, 2021, 270 pregnancies were exposed to the vaccine and for only 32 of these pregnancies is the pregnancy outcome known. Of these 32 pregnancies, Pfizer's report shows 23 spontaneous abortions (miscarriages), two premature births with neonatal death, two spontaneous abortions with intrauterine death, one spontaneous abortion with neonatal death, and one pregnancy with "normal outcome." This means that out of 32 pregnancies with known outcomes, 28 resulted in fetal death. Pfizer's report indicates that there were five pregnancies with "pending" outcomes, as well as the 238 pregnancies with unknown outcomes. But 32 minus 28 equals four, not five.

Discussion

It should be noted that this document concerns only the first 2.5 months of the vaccination campaign: these notifications are already numerous and could therefore be a strong signal of safety not taken into account by the FDA concerning vaccination during pregnancy or breastfeeding
The FDA approved the vaccine for pregnant women on April 23, 2021, thus after this first alarming report [3].
Those who received the vaccine prior to the approval for pregnant women were mostly caregivers: caregivers were the first group of young people to receive the vaccine. Pregnant women were excluded from the clinical trials.
This document therefore confirms that the vaccine (or its product spike) can cross the placental barrier [4].
It was already known from 4 publications that the vaccine mRNA could pass into the milk during the first week after the injection [4,5]. The adverse events reported here all concern this first week and therefore confirm these publications. The pathologies described for premature babies could be due to the toxic effect of the spike protein which could have passed from the mother to the fetus or even be produced directly by the fetus after transfection of the cells. In fact, it seems to be thrombosis and heart problems which are the effects most often described in people who have directly received the vaccine.

Can we continue to recommend mRNA vaccines to pregnant and breastfeeding women?

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