

Pfizer Works to Fast-Track More Vaccines for Pregnant Moms, Despite Mounting Evidence Rushed COVID Shots Harmed Babies

By Children's Health Defense

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Buoyed by the successful global marketing of its COVID-19 vaccines, Pfizer is teeing up to dominate the maternal vaccine market even as OB-GYNs on the front lines of maternal care sound the alarm about the COVID-19 shots' infanticidal fallout.

On Nov. 1, Pfizer issued a press release about an investigational <u>vaccine for pregnant</u> <u>women</u> the company said will protect babies from respiratory syncytial virus (RSV).

Not coincidentally, RSV is the <u>latest viral bugaboo</u> to hit the headlines, with frantic news accounts of <u>"overwhelmed" hospitals</u> sounding eerily reminiscent of the early <u>coronavirus</u> fear-mongering.

Buoyed by the successful global marketing of its $\underline{\text{COVID-19}}$ jabs — an estimated $\underline{\text{49\% of}}$ pregnant women worldwide reportedly views the vaccines favorably and almost $\underline{\text{1 in 4}}$ pregnant women in the U.S. took them — Pfizer is hoping to hit another home run with the RSV vaccine.

The vaccine maker said it intends to seek U.S. Food and Drug Administration (FDA) approval by the end of the year.

The FDA, meanwhile, has been busy handing out "<u>Breakthrough Therapy</u>" designations to Pfizer as if they were papal dispensations, signaling a regulatory willingness to <u>speed up approval</u> not only for <u>Pfizer's RSV vaccine</u> but also for a <u>maternal Group B Streptococcus</u> (GBS) vaccine the company is developing.

To this expedient end, the FDA allowed Pfizer to "stop the [RSV] study short," halting enrollment at about 7,400 participants — though the trial was supposed to involve 10,000

Region: **USA**

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<u>pregnant women</u>.

<u>Researchers</u> devoted to <u>vaccine orthodoxy</u> pay lip service to the need for an extra-high evidentiary bar for pregnancy vaccines — stating that such vaccines should not only prove they reduce illness, with minimal <u>reactogenicity</u> in the woman, the fetus and the neonate, but should also "<u>demonstrate safety</u> or lack of evidence of harm."

However, those turn out to be empty words.

In fact, the influenza and Tdap (tetanus-diphtheria-acellular pertussis) vaccines that public health agencies have long recommended for pregnant women never underwent any clinical trial safety testing in that population, and the <u>FDA never licensed</u> those vaccines specifically for pregnant women.

Moreover, <u>flu shots</u> and Tdap shots have never even resulted in <u>any statistically significant</u> reduction in the outcomes they are supposed to address.

With the advent of Emergency Use Authorization COVID-19 vaccines, the FDA, Pfizer and other manufacturers barely made any pretense of <u>assessing maternal safety</u>, and likely "colluded together to conceal damaging data" about <u>high rates of fetal death</u>.

Other researchers, however — and even vaccine insiders — began to speak out in 2021.

For example, Canadian researchers writing in late 2021 worried that many of the systemic reactions commonly reported after COVID-19 vaccination might be "sufficient to affect fetal/neonatal development."

Those authors included vaccinologist Byram Bridle, Ph.D., who earlier in 2021 characterized the COVID-19 vaccines' disturbing biodistribution and accumulation in vital organs as "a big mistake," and neurology professor Dr. Steven Pelech, who expressed repeated concerns about myocarditis and the vaccines' risks to young people.

Now, as horrified pregnant women who took the COVID-19 jabs experience <u>skyrocketing</u> <u>miscarriages</u>, stillbirths and fetal malformations, they are wondering why regulators issued no warnings.

But as Pfizer's exuberant RSV press release and the FDA's complacent endorsement of clinical trial shortcuts suggest, vaccine makers and regulators not only intend to ignore or bulldoze even the most outsized safety signals but are clearly positioning themselves to go after pregnant women in an even bigger way.

'Quibbles' and questions

The details provided — or omitted — about Pfizer's RSV clinical trial exemplify manufacturers' and regulators' cavalier approach toward pregnant women.

Commenting on Pfizer's announcement, family physician <u>Dr. Buzz Hollander</u> — who clarified that he is predisposed to celebrate the new RSV vaccine offering — nonetheless <u>noted a number of serious criticisms</u>:

 Pfizer released "just a press release" but no data, making it "impossible to pick [the vaccine's declared efficacy] apart."

- Pfizer offered no explanation as to how it defined "severe" disease, its primary endpoint.
- A year into the trial, Pfizer fishily altered an important endpoint, defying a fundamental clinical trial design principle that "involves <u>setting out in advance</u> the endpoints that will be assessed."
- In Hollander's words, Pfizer "switched their secondary (critical!) endpoint of RSV hospitalizations to 360 days from 180 days... and then inspired my suspicion by not reporting any hospitalization data, interim or otherwise, in their breathless press release."
- Researchers have published only one small safety study for the RSV shot, about which Hollander said: "I quibble with studies finding >40% of placebo participants reporting systemic symptoms; when queried enticingly enough, half of us might recall a headache or some fatigue the day after our placebo shot, and that can bury a difference in real adverse reactions compared to the vaccine group."
- Curtailing study enrollment was unwise, Hollander said, because "bigger is better when it comes to ... finding safety signals."
- Earlier this year, GlaxoSmithKline (GSK) "stopped cold" a three-times-bigger trial of a similar RSV vaccine for pregnant women after <u>detecting a safety signal</u>, yet there has been no discussion as to why Pfizer's maternal RSV vaccine is "fine" while GSK's was deemed "untouchable."

Hollander's modest conclusion: "We should have all learned by now that even the appearance of cutting corners in the vaccine approval process will carry its own unknown costs."

Readers reacting to Hollander's post were less circumspect. One acerbically remarked, "The problem here is Pfizer. They've paid <u>billions in fines</u> for shady practices and data manipulation. And that was before the Covid vaccines (for which they're indemnified)."

Another reader expressed his reservations even more succinctly: "Trust Pfizer numbers? You must be joking."

Adverse pregnancy outcomes after COVID vaccination — no joke

As Pfizer, with the FDA's help, tees itself up to "dominat[e] the <u>maternal RSV vaccine</u> <u>market</u>," OB-GYNs on the front lines of maternal care are stepping forth to <u>sound the alarm</u> about the COVID-19 shots' infanticidal fallout.

<u>Dr. Kimberly Biss</u> recently <u>tweeted</u>, "Since the vaccine rollout started, we have seen in our practice a decrease in new OB numbers, which would be infertility, by about 50%; we've also seen an increase in miscarriage rate by about 50%, and ... probably about a 25% increase in abnormal pap smears as well as cervical malignancies."

Similarly, <u>Dr. James Thorp</u>, in multiple interviews, described an "off-the-charts" <u>rise in sudden fetal death</u> and other adverse outcomes, including fetal malformation and fetal cardiac arrest.

Asked to comment on information recently <u>leaked from a California hospital</u>, Thorp characterized the uptick in fetal deaths — from under 6 per 1,000 in 2020 to more than 29 per 1,000 following the rollout of COVID-19 injections — as being "<u>way way beyond</u>" what

the Centers for Disease Control and Prevention ordinarily would consider a safety signal.

<u>Thorp published a preprint</u> in September (along with co-authors who include Children's Health Defense's <u>Megan Redshaw</u>) describing "significantly more frequent" pregnancy-related adverse events reported to the Vaccine Adverse Event Reporting System, or VAERS, after COVID-19 shots than in the aftermath of flu shots — which themselves are <u>far from benign</u>.

Cataloging significant increases in "miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal arrhythmia, fetal cardiac arrest, fetal vascular mal-perfusion, fetal growth abnormalities, fetal abnormal surveillance, fetal placental thrombosis, low amniotic fluid, and fetal death/stillbirth" and also menstrual abnormalities, Thorp and co-authors called for a "worldwide moratorium on the use of COVID-19 vaccines in pregnancy."

For children who survive, Thorp suggested they may suffer from lifelong "<u>vaccine-induced</u> acquired immune deficiency syndrome."

In <u>Scotland</u>, meanwhile, the government ordered an investigation into the "<u>spike in newborn</u> <u>baby deaths</u>" in 2021 and 2022, an increase "larger than expected from chance alone."

Even in a gerrymandered study clearly designed to exonerate the <u>COVID-19 shots during</u> <u>pregnancy</u> — focusing on immediate reactions after a first or second dose and hampered by "limited perinatal outcome assessment" — researchers found that 4.4-7.5% of pregnant women reported obstetrical symptoms.

Careless and worse

As Substack writer <u>Etana Hecht wrote</u> last May, "The topic of pregnant and nursing moms getting vaccinated under encouragement and coercion is painful," particularly once one becomes aware of "how carelessly the most precious among us are being treated."

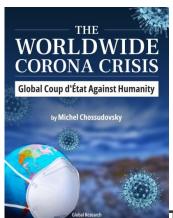
That carelessness is evident as we witness some of the same players involved in the COVID-19 vaccine fiasco now circling back around to help <u>build the case</u> for Pfizer's RSV vaccine.

That includes figures such as Dr. Robert Frenck, the Pfizer-beholden principal investigator of the <u>Cincinnati Children's Hospital clinical trial</u> that tested the company's COVID-19 shot in children. Frenck reported <u>12-year-old Maddie de Garay's</u> serious vaccine injuries to the FDA as a mere "<u>stomachache</u>."

<u>Graphs</u> clearly show that none of the vaccines pushed on pregnant women are safe for babies or moms — but given that from <u>one-fourth</u> to <u>one-half of pregnant women</u> acquiesce to getting them, those who know the truth need to work even harder to get the word out.

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