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‘Sad Day for Babies and Mums’: FDA Panel Recommends Pfizer’s RSV Vaccine for Pregnant Women

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Advisers to the U.S. Food and Drug Administration (FDA) on Thursday recommended, by a vote of 10 to 4, that the agency approve Pfizer’s respiratory syncytial virus (RSV) vaccine for pregnant women, despite questions about the vaccine’s safety.

During Thursday’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting, committee members and medical experts raised concerns about premature births identified during Pfizer’s clinical trials.

The FDA is expected to issue a final decision on the vaccine in August. If approved, it would become the first RSV vaccine authorized for pregnant women.

The Centers for Disease Control and Prevention (CDC) must “sign off” on Pfizer’s vaccine for pregnant women prior to it becoming available to the public.

According to Axios, the CDC’s immunization advisory committee is likely to discuss FDA-approved RSV vaccines during its June meeting.

Dr. Meryl Nass, an internist, biological warfare epidemiologist and member of the Children’s Health Defense (CHD) scientific advisory committee, told The Defender that while the FDA is not obliged to follow the recommendations of its advisory committees, “it almost always does so.”

The appeal of a maternal vaccine like Pfizer’s is “the way it would create neutralizing antibodies in pregnant women that can be transferred to infants in the womb,” Axios reported.

However, “there are health risks, including preterm births,” Axios added, noting that

GlaxoSmithKline Biologicals' (GSK) recently halted its trial of a similar RSV vaccine for infants. According to NBC News, the GSK vaccine "showed a higher preterm birth rate among some vaccine recipients."

Commenting on the FDA's recommendation of Pfizer's RSV vaccine, Dr. Peter McCullough, a cardiologist, told The Defender:

"This product represents an unprecedented attempt to vaccinate mothers for no benefit to them and only theoretical efficacy in babies. In the trial, less than 2% of infants at any time point contracted RSV, which is easily treatable with nebulizers.

"Pregnancies should not be threatened with novel vaccines for uncommon and low-risk infantile illnesses.

"Widespread use of this reactogenic vaccine can be expected to cause fetal loss in some unfortunate women. A single case of pregnancy termination would not be worth the population being vaccinated."

> 'Nauseating' FDA VRBPAC Recommends Pfizer's RSV Vaccine for Pregnant Women Despite Premature Birth Signals + Antigen Interference
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> Ten advisors voted yes, and four advisors voted no.
>
> Chair of the Committee Dr. El-Sahly voted no and advocated for research into "vaccines that… pic.twitter.com/73VheO5EAU
>
> — Children's Health Defense (@ChildrensHD) May 18, 2023

The positive recommendation from the VRBPAC comes two weeks after the FDA approved Arexvy, the first vaccine authorized for RSV. That vaccine, produced by GSK, is intended for adults 60 years of age and older.

It also comes as Pfizer is expecting an FDA decision later this month for its RSV vaccine for adults 60 and over, with the same formulation as the one for pregnant women. The VRBPAC recommended the vaccine for this age group in February.

Pfizer is also "evaluating how its shot performs in other age groups," Axios reported.

'A sad day for babies and mums'

According to CNBC, Pfizer's RSV vaccine, marketed as Abrysvo, will be administered as a single dose to pregnant women in their second or third trimester.

NBC News reported that the shot would be given to pregnant women at 24 to 36 weeks gestation and that the "protective antibodies transfer to infants through the placenta."

The FDA advisory panel found that data from Abrysvo's clinical trial "supports the safety of the vaccine" for pregnant women, while the same panel voted unanimously "that available data supported the vaccine's efficacy for giving the shot to women in their second or third trimesters of pregnancy."

An FDA briefing document said safety data from Abrysvo clinical trials was "generally favorable."

According to the trial data, Abrysvo "had an 81.7% efficacy at protecting newborns in the first three months of life against severe illness and a 69.4% efficacy through the first six months," Axios reported.

The trial consisted of nearly 7,400 participants, according to NBC News, adding that Abrysvo "also lowered the risk of developing respiratory disease from RSV that required doctors' visits by 51% within about six months."

"After that, however, the vaccine didn't appear to make a big difference," according to the NBC News report, which also reported that "a slightly higher rate of preterm births — defined as before 37 weeks' gestation — among people who received the vaccine (5.7%) versus those who got a placebo (4.7%)" was identified.

"The difference wasn't statistically significant, however, so it's unclear whether it was vaccine-related," NBC News added. CNBC reported that both percentages were below the overall percentage for preterm births in the general population (10%).

According to CNBC, the clinical trial for Abrysvo "reported 18 peripartum fetal deaths."

However, the FDA said these deaths were "unlikely" to be related to the shot. According to Axios, "The fetal deaths present in the vaccine group (0.3%) were not related to Pfizer's vaccine … Similarly, 4 out of 5 infant deaths were considered unrelated to the shot, with one being possibly connected to the shot, although that remains unclear."

Data reported by Pfizer to the CDC indicated that 14% of pregnant women who participated in Pfizer's trial sustained an adverse event, with 4.2% sustaining a "serious" adverse event, 1.7% experiencing a "severe" adverse event and 0.5% suffering a "life-threatening" adverse event.

Similarly, the same data showed that 37.1% of infants whose mothers received the experimental Pfizer vaccine experienced adverse events within one month of birth — with 15.5% classified as "serious," 4.5% as "severe" and 1% as "life-threatening," while efficacy waned within months of vaccination.

According to the National Vaccine Information Center (NVIC), "The RSV clinical trial data also included the death of one pregnant woman, 18 stillbirths (10 in vaccinated pregnant women and eight in unvaccinated pregnant women), and 17 infant deaths (five from the vaccinated pregnancy group and 12 in unvaccinated pregnancy group)."

Attorney, journalist and podcaster Daniel Horowitz, in an article published Monday in the Conservative Review, quoted Phase 2 trial data for Abrysvo. He wrote: "Pfizer reported 3 out of 116 (2.6%) premature births in the placebo group and 6 out of 114 (5.3%) in the group that received the vaccine that was chosen as Pfizer's final product," adding that Pfizer "was studying preterm birth as an 'adverse event of special interest.'"

According to NBC News, "The most common side effects of the shot reported among pregnant women were fatigue, headache, muscle pain and injection site pain."

Nass told The Defender there were essentially three problems with the Abrysvo clinical trial data, "two of which were identified by Pfizer and the FDA." She said:

"There were about 20% more preterm babies and low birth weight babies in the group, whose mothers had been vaccinated versus the group whose mothers had received a placebo. This was very concerning but was disregarded by most of the committee.

"It was unclear to me whether Pfizer had collected enough information on the health of the pregnant women after vaccination. It is hard to tell when you were studying, newborns and babies, whether they have had a side effect from their mothers' vaccination. The children weren't studied for long enough to compare their intellectual ability or other parameters."

The third problem reflected concerns arising from the problems GSK's candidate vaccine for pregnant women encountered, Nass said. However, "the FDA claimed the GSK clinical trial data were proprietary, and they were unable to provide them," even though it was pointed out that these findings had been published and were in the public domain."

"No one questioned the veracity of the data Pfizer presented, despite the fact that Pfizer repeatedly presented data on its COVID vaccine efficacy to this committee that made the vaccines appear much more efficacious than they turned out to be," Nass said.

McCullough, writing on his Substack, also questioned the Abrysvo clinical trial data. "Pfizer has aggressively advanced RCTs [randomized controlled trials] into the pregnant population with no assurances on long term outcomes. There is no direct benefit to the mothers."

"Furthermore, the sponsors moved the goal posts to make it easier to have a successful trial. We should demand long-term safety, high efficacy … and at least one year of durability, for such a rare and easy-to-treat condition in babies," he added.

Calls for 'tougher scrutiny' of the RSV vaccine ignored

Some health experts called for "tougher scrutiny" of Abrysvo leading up to Thursday's VRBPAC meeting, Axios reported, "after trials for GlaxoSmithKline halted trial for a similar shot over increased risks of preterm births and neonatal deaths."

"Pfizer has not reported similar safety concerns, but some health experts told the British Medical Journal [BMJ] that they hope FDA staff will take the GlaxoSmithKline results into consideration when reviewing the vaccine," according to Axios.

"Results have raised concerns about a possible increase in preterm births, and experts are calling for further analyses of the data and for post-approval monitoring of the vaccine, should the FDA approve it," The BMJ analysis stated.

Horowitz said the "formulations of most of these shots are likely very similar, so red flags from one cohort of the study should inform us on the problems with the other."

According to Nass, who live-blogged the meeting, one VRBPAC member, Dr. Henry H. Bernstein, a professor of pediatrics at Hofstra University, said during the meeting "he does not want another rotavirus vaccine repeat, in which the signal was known when licensed, but was not statistically significant."

The rotavirus vaccine was pulled within one year because of intussusception, she said.

Intussusception is a life-threatening illness that occurs when a portion of the intestine folds like a telescope, with one segment slipping inside another segment. This causes an obstruction, preventing the passage of food that is being digested through the intestine.

Dr. Paul Offit, a pediatrician at Children's Hospital of Philadelphia and VRBPAC panelist, was quoted by CNBC as saying that the problems with GSK's trial are "hanging over" Pfizer's RSV shot for pregnant women and infants.

"If GSK truly abandons a program on a similar, almost identical vaccine, that is going to hang over [Pfizer's] program. I think it needs to be addressed," Offit added.

Offit separately told Reuters "I worry that if preterm births are in any way a consequence of this vaccine that would be tragic in many ways."

Science magazine quoted FDA medical officer Dr. Yugenia Hong-Nguyen, who said the rate of premature births was "not statistically significant and lower than background incidence rates in the general population."

Other VRBPAC members were less concerned. Dr. Daniel Feikin, a Johns Hopkins University epidemiologist and "temporary voting member", said, "I'm not convinced that there's a clear causal relationship between this vaccine and preterm birth," Reuters reported.

Another VRBPAC panelist, Dr. Jay Portnoy, a pediatrics professor at the University of Missouri-Kansas City, said, "If the vaccine actually lives up to the data that we've seen today, I can guarantee that many infants and their parents will breathe easier in the coming years."

Pfizer representatives also sought to downplay concerns with Abrysvo. According to CNBC, Dr. William Gruber, Pfizer's senior vice president of vaccine clinical research and development, said, "Certainly in our eyes, there is no definitive evidence to suggest that there is a risk of prematurity."

"So, the question is, do you hold hostage the potential benefits of the vaccine for something which you have no statistical significance at this point?"

Dr. Anthony Fauci also raised concerns about vaccines for respiratory illnesses, Horowitz wrote in a May 4 article. A paper co-authored by Fauci and published in January in Cell Host & Microbe stated that the challenges for RSV and flu vaccines were "many and complex" and that RSV vaccines were not good at providing immunity.

In a November 2022 episode of "RFK Jr. The Defender" podcast, Robert F. Kennedy Jr., then-chairman and chief litigation counsel for CHD (now chairman on leave), described RSV as "a vehicle for re-implementing the COVID-19 playbook all over the country and responding with vaccines."

Nass characterized Thursday's VRBPAC approval of Abrysvo as "a sad day for babies and mums," adding, "Is there a reason to trust Pfizer's data on its RSV vaccine, when we could not trust its COVID vaccines?"

"Currently, pregnant women are advised (not by me!) to get the flu, TdaP [tetanus-diphtheria-pertussis] and COVID vaccines during pregnancy. This would be a fourth pregnancy vaccine," Nass wrote.

Nass said Thursday's VRBPAC meeting was held with four temporary members.

"Did FDA stuff the meeting with four new temporary members in order to get the majority yes votes it wanted?" Nass asked.

Horowitz noted in his article published Monday that Pfizer vaccines have previously been approved despite concerns about their impact on pregnant women, citing trial data from the Pfizer-BioNTech COVID-19 vaccine.

Pfizer seeks to 'offset declining revenue from its COVID-19 products'

According to Reuters, "Pfizer is counting on new medicines and vaccines to help offset declining revenue from its COVID-19 products," noting that the market for RSV vaccines is expected to surpass $10 billion by 2030 and that Pfizer is "ready to launch" its RSV vaccines for both pregnant women and older adults "later this year."

Pfizer CEO Albert Bourla said he expects increased revenue for the company in the coming years from the company's RSV and flu shots.

On her Substack, Nass noted:

> "As a consequence of the 21st Century Cures Act of 2016, all vaccines recommended by CDC for pregnant women have all manufacturer liability waived, and are placed in the national vaccine injury compensation program. This improves profitability and may result in mandates."

Several other Big Pharma drugmakers are now clamoring to enter the potentially lucrative RSV vaccine market, after decades of failed attempts to develop a vaccine.

Moderna is developing an mRNA RSV vaccine for older adults. According to Axios, it "was found to be 83.7% effective in preventing RSV with one or two more symptoms" and "The company plans to apply for FDA approval this quarter."

According to Horowitz, Moderna's candidate vaccine "openly shows 200 adverse events and 10 serious ones per mild case [of RSV] avoided."

Bavarian Nordic, known for its development of a vaccine in response to last year's monkeypox outbreak, is also developing an RSV vaccine for adults 60 and over," expecting to release Phase 3 clinical trial data by midyear.

AstraZeneca and Sanofi also are seeking FDA approval for a monoclonal antibody treatment for RSV that would be administered to infants and toddlers up to age 2. Sanofi says the antibody, nirsevimab, was found to be 83.2% effective in reducing RSV-related hospitalizations.

However, the NVIC reported that the effectiveness of nirsevimab "is not known beyond 150 days" and it is unclear if the drug prevents ICU stays or deaths.

In all, "Eleven RSV vaccines (including GSK's approved shot) are being actively studied in U.S. trials," NBC News reported. "Six are for older adults, and five are designed to protect infants or children."

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