

# FDA Admits That Flu Vaccine Vaccines for Pregnant Women Untested, Unlicensed

The CDC and other government agencies are recommending the FLULAVAL and Tdap vaccines for pregnant women. The manufacturers of FLULAVAL and Tdap vaccines have not had any clinical safety trials with pregnant mothers and the vaccines are not licensed for use with pregnant mothers, according to the [Children's Health Defense](#).

The manufacturers warn against against vaccinating pregnant mothers:

*There are insufficient data on FLULAVAL QUADRIVALENT in pregnant women to inform."*

[Package Insert for FluLaval Quadrivalent](#)

*There are no controlled data in human pregnancy. Diphtheria/pertussis, acellular/tetanus is only recommended for use during pregnancy when benefit outweighs risk."*

[Tdap Vaccine Information](#)

A Freedom of Information Act (FOIA) lawsuit was filed by Children's Health Defense attorney, Robert F. Kennedy, Jr. on

behalf of [Informed Consent Action Network](#) to obtain clinical trial data used by FDA to approve influenza vaccines for pregnant women.

[The FDA's response:](#)

*We have no records responsive to your requests."*

The FDA is admitting that these vaccines being recommended for pregnant women have not been licensed for such use by the FDA or tested for safety for pregnant mothers in clinical trials.

*As a nation, we can no longer pretend our trusted agencies are protecting our children. It is time to hold federal agencies accountable."*

*Robert F. Kennedy, Jr.*

**Recommended:**

[\*\*How To Heal Your Gut\*\*](#)

[\*\*How To Detoxify and Heal From Vaccinations – For Adults and Children\*\*](#)

[From Children's Health Defense:](#)

WASHINGTON, D.C., Feb. 11, 2019—In response to a Freedom of Information Act (FOIA) lawsuit, the FDA has [admitted](#), for the first time, that government agencies, including the CDC, are recommending vaccines for pregnant women that have neither been licensed for pregnant mothers by FDA nor tested for safety in clinical trials. The lawsuit, filed by [Children's Health Defense](#) (CHD) attorney, Robert F. Kennedy, Jr. on behalf of [Informed Consent Action Network](#)(ICAN), a vaccine safety advocacy group, sought all clinical trial data used by FDA to approve influenza vaccines for pregnant women. The FDA's terse reply: "We have no records responsive to your requests."

The manufacturers of [flu](#) and [Tdap](#) vaccines warn against their use for pregnant mothers since their safety has never been established. Package inserts state that it is "[not known](#)" whether the vaccines "will harm an unborn baby" and there are "[insufficient data](#)" on use in pregnant women to inform vaccine-associated risks. FDA regulations strictly prohibit pharmaceutical companies from marketing products for "off-license" uses. Noncompliant companies are routinely prosecuted criminally and civilly, paying [billions](#) in lawsuits and settlements.

The CDC nevertheless has actively recommended influenza vaccination during any trimester of pregnancy since [2004](#) and has told pregnant women to get Tdap shots (for tetanus, diphtheria and pertussis) since [2011](#). The FDA is responsible for vaccine safety and licensing, but, in the just-released [court documents](#), it admits that it has no safety data to back up the CDC's "off-license" pregnancy recommendations. FDA's website [states](#) that it has never formally approved any vaccines "specifically for use during pregnancy to protect the infant."

Blanket recommendations for vaccination during pregnancy are a dangerous proposition due to vaccination's ability to activate a [maternal immune response](#) that can damage the developing fetal brain—just as infections during pregnancy sometimes do. In 2008, neuroscientist Paul Patterson warned, “Even if it happens less than 1% of the time, vaccinating an entire population of pregnant women could affect thousands of children.”

Long-term safety studies have not been designed to detect vaccine-related fetal injuries, but a 2017 Kaiser study of over 45,000 women (published in [JAMA Pediatrics](#)) showed an elevated risk of birth defects and a 20% higher risk of autism in children whose mothers received a first-trimester flu shot. After the authors applied a statistical correction that lessened the significant association, renowned UCLA statistician Sander Greenland criticized the methodologically “[inappropriate](#)” decision, noting that pharmaceutical researchers use the technique when they don't like a result and “want to see if they can get rid of it.”

[Click here to read the rest of the article on Children's Health Defense's website.](#)

Thanks to [Health Impact News](#) for bringing this story to our attention.