FDA Admits That Government Is Recommending Untested, Unlicensed Vaccines for Pregnant Women

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

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."

CDC data show that women who received certain flu shots from 2010 to 2012 had a 7.7 times greater risk of miscarriage than women who did not receive those vaccines. CDC published the study in *Vaccine* but omitted those findings from its press release, leaving pregnant women ignorant of the vaccines' true risks. CHD's Chairman Robert F. Kennedy, Jr. notes that most flu shots given to pregnant women still contain a mercury-based preservative thimerosal. Thimerosal is acknowledged by Proposition 65 in California as a reproductive toxicant and exposure during pregnancy can cause learning and behavioral problems. Tdap contains aluminum, which FDA regulates as a toxin in parenteral nutrition but not in vaccines.

The fact that CDC is recommending vaccines that the FDA has not licensed for use in pregnant women comes on the heels of another disclosure forced by an ICAN/CHD lawsuit. The earlier lawsuit requested HHS documentation of compliance with statutory requirements for regular childhood vaccine safety reviews and reports to Congress. HHS's response, "searches did not locate records responsive to your request," indicates that

HHS has not once complied—in over 30 years—with the requirements for regular vaccine safety reviews nor reported to Congress on measures to improve vaccine safety. The National Childhood Vaccine Injury Act established the requirements while essentially eliminating manufacturers' legal liability for childhood vaccine injuries.

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