

Glaring Lack of Safety Testing

You have to look no further than information in the vaccine manufacturer product inserts and posted online by the U.S. Food and Drug Administration (FDA) and Centers for Disease Control (CDC) to determine if a vaccine is safe.

FACT: Drug companies did not test the safety and effectiveness of giving influenza or Tdap vaccine to pregnant women before the vaccines were licensed in the U.S.^{12 13} and there is almost no data on inflammatory or other biological responses to these vaccines that could affect pregnancy and birth outcomes.¹⁴

FACT: The Food and Drug Administration (FDA) lists influenza and Tdap vaccines as either Pregnancy Category B or C biologicals¹⁵ which means that adequate testing has not been done in humans to demonstrate safety for pregnant women and it is not known whether the vaccines can cause fetal harm or affect reproduction capacity. The manufacturers of influenza and Tdap vaccines state that human toxicity and fertility studies are inadequate and warn that the influenza and Tdap vaccines should “be given to a pregnant woman only if clearly needed.”^{16 17 18}

FACT: There are ingredients in influenza and pertussis containing Tdap vaccines that have not been fully evaluated for potential genotoxic¹⁹ or other adverse effects on the human fetus developing in the womb that may negatively affect health after birth, including aluminum adjuvants, mercury containing (Thimerosal) preservatives and many more bioactive and potentially toxic ingredients.^{20 21 22 23 24 25 26 27 28 29}

FACT: There are serious problems with outdated testing procedures for determining the potency and toxicity of pertussis vaccines and some scientists are calling for limits to be established for specific toxin content of pertussis-containing vaccines.³⁰

FACT: There are no published biological mechanism studies that assess pre-vaccination health status and measure changes in brain and immune function and chromosomal integrity after vaccination of pregnant women or their babies developing in the womb.³¹

FACT: Since licensure of influenza and Tdap vaccines in the U.S., there have been no well designed prospective case controlled studies comparing the health outcomes of large groups of women who get influenza and pertussis containing Tdap vaccines during pregnancy either separately or simultaneously compared to those who do not get the vaccines, and no similar health outcome

comparisons of their newborns at birth or in the first year of life have been conducted. Safety and effectiveness evaluations that have been conducted are either small,³² retrospective,³³ 34 compare vaccinated women to vaccinated women³⁵ or have been performed by drug company or government health officials using unpublished data.³⁶

FACT: The FDA has licensed Tdap vaccines to be given once as a single dose pertussis booster shot to individuals over 10 or 11 years old. The CDC's recommendation that doctors give every pregnant woman a Tdap vaccination during every pregnancy - regardless of whether a woman has already received one dose of Tdap - is an off-label use of the vaccine.³⁷

FACT: Injuries and deaths from pertussis-containing vaccines are the most compensated claims in the federal Vaccine Injury Compensation Program (VICP) and influenza vaccine injuries and deaths are the second most compensated claim.³⁸

FACT: A 2013 published study evaluating reports of acute disseminated encephalomyelitis (ADEM) following vaccination in the U. S. Vaccine Adverse Events Reporting System (VAERS) and in a European vaccine reaction reporting system found that seasonal influenza vaccine was the most frequently suspected cause of brain inflammation after 18 years old, representing 32 percent of the total cases reported, and pertussis containing DTaP was among the vaccines most frequently associated with brain inflammation in children between birth and age five.³⁹

FACT: When a pregnant woman is harmed by an influenza or Tdap vaccine, drug companies selling the vaccines in the U.S., doctors and other vaccine providers are shielded from vaccine injury lawsuits⁴⁰ but it is unclear whether vaccine injuries sustained by an unborn child in the womb will qualify for federal vaccine injury compensation.⁴¹

<http://www.nvic.org/NVIC-Vaccine-News/November-2013/Vaccination-During-Pregnancy--Is-It-Safe-.aspx>

Vaccines are not routinely tested on pregnant women. In 1976, the FDA issued guidelines to vaccine manufacturers stating that pregnant women should be excluded from research.

Has TDaP been proven safe during pregnancy?

The TDaP vaccine is being offered to every pregnant woman, with each pregnancy, despite a dearth of safety testing.

The FDA currently classifies the Tdap as a Class C formulation.

Category C medications lack adequate and well-controlled studies in humans but have been associated with an adverse effect on the fetus in animal reproduction studies.

<https://www.focusforhealth.org/tdap-vaccine-during-pregnancy-a-difficult-decision-for-any-mom/> <https://www.voxer.com/v/7995f61b91>