Vaccination during Pregnancy: Is it Safe?
By Barbara Loe Fisher – November 10, 2013

It was 1977 when I found out I was going to become a Mom. I instinctively knew I needed to be careful while I was pregnant, especially during the first two trimesters when the major organ systems of the fetus develop at a rapid rate. In the 1960’s there had been a lot of publicity about babies dying or being born without arms or legs because women had taken a drug (Thalidomide) for morning sickness in the first or second trimester of pregnancy[1] and I wanted to make sure I did everything I could to protect my health and the health of my baby before and after he was born.

Mothers to be in my generation were told to take extra vitamins and eat nutritious food but, most of all, to avoid anything that could harm the developing fetus like alcohol, cigarette smoke, medications, radiation, household cleaning products and other toxic exposures. Some of us were aware of the risks of heavy anesthesia during delivery and signed up for Lamaze classes to prepare for a drug-free birth, which many obstetricians discouraged, and we chose to breastfeed, even though a lot of pediatricians were pushing formula and bottles back then.

Today, pregnant women face a different set of difficult questions and choices about keeping themselves and their babies healthy. Among them are whether or not to get vaccinations during pregnancy that public health officials, obstetricians and pediatricians say will protect pregnant women and their newborns from getting sick with influenza and B. pertussis whooping cough.

Toxic Exposures & Assumption of Safety – Is it a Good Idea?

Although since the 1970’s public health officials have recommended influenza vaccinations for pregnant women in the second or third trimester,[2] relatively few obstetricians promoted the vaccine until the past decade when, in 2006, the Centers for Disease Control (CDC) strengthened recommendations that all pregnant women, healthy or not, should get a flu shot in any trimester.[3]

Then, in 2011, a pertussis containing Tdap shot was recommended for all pregnant women, preferably after 20 weeks gestation.[4] Both current vaccine recommendations are[5, 6, 7] endorsed by the American College of Obstetricians and Gynecologists (ACOG),[8, 9] the American Academy of Pediatrics (AAP) and other medical trade associations.[10, 11]

With these recommendations, the time-honored rule of avoiding any potential toxic exposure that might interfere with the normal development of the fetus has been suspended and replaced with an assumption that vaccination during pregnancy is safe. But what is the scientific evidence documenting that this assumption is a well-informed one?

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 quickly answer that question.

**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 biologicals,[15] 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 genotoxic[19] 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 unvaccinated women[35] 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 lawsuits[40] but it is unclear whether vaccine injuries sustained by an unborn child in the womb will qualify for federal vaccine injury compensation.[41]
Rush to Vaccinate: Policy Preceding Science

In addition to lack of credible scientific evidence to demonstrate safety,[42, 43] there is not enough credible epidemiological and biological mechanism evidence to demonstrate it is effective or necessary[44, 45, 46, 47] for every pregnant woman to get an influenza and Tdap shot during every pregnancy. The rush to vaccinate pregnant women and reach into the womb to try to passively vaccinate the developing fetus[48, 49] is a clear case of policy preceding science.

An experimental genetically engineered nanoparticle vaccine for respiratory syncytial virus (RSV) and another one for Group B Streptococcus are in advanced clinical trials and reportedly likely will be exclusively recommended for pregnant women after they are licensed.[50] With new vaccines on the horizon that will target pregnant women, it is critically important that more bad vaccine policy does not precede good vaccine science.

Pregnant women today need to take a long, hard look at the well-advertised but theoretical benefits and unknown risks of getting vaccinated during pregnancy before making a vaccine decision. It is especially important when there are so many warning signs that America's highly vaccinated child and adult population in the 21st century is not very healthy.

Maternal and infant mortality statistics are a classic measure of a nation's public health status and, in this country, here are red flags that cannot be ignored any longer.

Maternal and Infant Mortality Rates High in America

How many young couples of childbearing age know that women getting pregnant and delivering babies in America today have more than twice the risk of dying during pregnancy, childbirth or after giving birth than they did three decades ago?[51, 52] Women having babies are dying of heart failure, high blood pressure and stroke, infection of the blood, diabetes and blood clots in greater numbers because the maternal death rate in America has been climbing since 1987.[53]

We now rank a dismal number 50 in maternal mortality in the world, which is worse than that of most European countries and some countries in Asia and the Middle East.[54]

Equally shocking is the fact that the U.S. now has the highest first day infant death rate of all industrialized countries[55] and ranks number 31 among nations in infant mortality.[56] Preterm birth rates have increased 36% since the early 1980's[57] and 6 out of every 1,000 babies born alive in America die before their first birthday.[58]

Birth defects, chromosomal damage, premature birth, low birth weight and sudden infant death syndrome are the leading causes of death for about 23,000 newborn infants every year,[59] with half of those deaths occurring on the first day of life. A baby born in America is twice as likely to die within the first 24 hours as babies born in the European Union.[60]

Why is Health in the U.S. on Such a Steep Decline?

U.S. public health officials say there are "no clear" answers for why our maternal mortality rate is skyrocketing.[61] They don't know why so many of our babies are dying on the first day and within the first year of life, in stark contrast to many other nations where maternal and infant mortality rates are declining.

Public health officials also can't figure out why so many infants and children in America are plagued with brain and immune system problems. The unprecedented, unexplained chronic disease and
disability epidemic[62] has gotten worse in the past three decades – with 1 child in 6 now learning disabled;[63] 1 in 9 suffering with asthma;[64] 1 in 50 developing autism;[65] 1 in 400 becoming diabetic[66] and millions more suffering with severe food allergies,[67] inflammatory bowel disease[68] and other chronic illness.[69, 70]

The health of American adults has also deteriorated during the past three decades compared to other wealthy nations where health is improving[71] and our life expectancy is worse than many other countries as well.[72] The CDC says that today chronic diseases are the most common and costly causes of death and disability with about half of all adults living with at least one chronic illness.[73]

**U.S. Number One Market for Drugs & Vaccines**

What is not on the list of potential causes for this failing public health report card is lack of access to drugs and vaccines. With a population of 316 million people out of 7 billion people on the earth, the U.S. spends nearly $3 trillion dollars per year on health care[74] – more than any other nation in the world[75, 76] – and we consume 40 percent of all drugs sold globally.[77, 78, 79] In addition, America is the leading purchaser of vaccines in the world's $32 billion dollar vaccine market.[80, 81, 82]

Since 1981, 95 percent of all children entering kindergarten have received multiple doses of seven vaccines including pertussis and measles vaccines.[83] In 1991, the CDC recommended all infants get a hepatitis B shot at 12 hours old[84] and, by 2012, more than 70 percent of all newborns had received a hepatitis B shot at birth while between 80 and 90 percent of three year olds had gotten multiple doses of eleven vaccines.[85]

In a crusade to eliminate an expanding list of microbes, U.S. health officials currently direct pediatricians to give children 49 doses of 14 vaccines by age six starting on the day of birth with more than two dozen doses administered by an infant's first birthday.[86] More than two dozen additional vaccinations are recommended or mandated for teenagers and adults, including annual flu shots throughout life.[87]

**Has Mandated Use of More Vaccines Compromised America’s Health?**

Every state in the U.S. has laws requiring dozens of vaccinations for daycare and school attendance[88] in contrast to neighboring Mexico and Canada, which recommend but do not mandate vaccines (a provision in Canada's Constitution prohibits compulsory vaccination).[89]

Japan, New Zealand, Australia, Iceland and Norway recommend but do not legally require vaccines and 15 countries in the European Union, including United Kingdom, Germany, Spain, Greece, Denmark, Netherlands, Finland and Austria similarly recommend but do not mandate vaccines.[90]

All of these countries have lower infant mortality rates than the U.S. and do not recommend that infants under one year old get as many vaccines as American infants do.[91]

In fact, no other country legally requires[92] the numbers of vaccinations that the U.S. does for children to attend daycare and school or for adults to keep their jobs.[93]

It is no wonder that more Americans are asking questions about why our children need so many vaccines and why adults need to get a flu shot every year – even during pregnancy – when our population is already the most vaccinated in the world but far less healthy than other countries that do not mandate or recommend so many vaccines.
Ask for the Science

If you are pregnant and have other children, be aware that the American Academy of Pediatrics is urging pediatricians to vaccinate parents bringing their children in for sick or well baby visits, especially pregnant women.[94] If an obstetrician or pediatrician pressures you to get vaccinated while you are pregnant, ask the doctor to show you the science. If you conclude the vaccine’s benefits do not outweigh the risks for you and your baby but are threatened or sanctioned in any way for making an informed choice, you should find another doctor who will treat you with respect and honor your health care choices.

Go to NVIC.org to learn more and sign up for NVIC’s free online Advocacy Portal so you can work to protect the freedom to make voluntary vaccine decisions in your state.

It's your health, your family, your choice.
