ICWA calls for WA State to Restore Fully Informed Consent

On September 13, 2017, the CDC posted a new web page – Flu Vaccination & Possible Safety Signal – in response to their own study that showed the overall risk of SAB (spontaneous abortion/miscarriage) was twice as high for women who had received the flu vaccine during pregnancy in the 28 days following vaccination compared to those who had not and 7.7 times as high if the woman had received an H1N1-containing vaccine in the previous season. This was a small case-control study that took place over two flu seasons. It was not designed to estimate the risk of miscarriage following vaccination during pregnancy, but the CDC acknowledges the results to be a red flag and are calling it a "possible safety signal." Their page states:

> "CDC and its Advisory Committee on Immunization Practices (ACIP) are aware of these data, which were first presented to ACIP at a public meeting in June 2015. At this time, CDC and ACIP have not changed the recommendation for influenza vaccination of pregnant women."

They also state:

> "There is an ongoing investigation to study this issue further among women who were pregnant and eligible to receive flu vaccine during the 2012-13 through 2014-15 flu seasons. Results are anticipated in late 2018 or 2019."

News of this "safety signal" means that for the past two years the ACIP continued to recommend that pregnant women get a flu vaccine even in the first trimester, *knowing* that it potentially put their unborn children at risk, in order to continue gathering data—without *informing* them about the safety signal.

This denial of fully informed consent for pregnant women did not begin in 2015. It began in 2004, when the CDC first recommended flu vaccination during pregnancy despite the fact the FDA had not, and still has not, licensed any vaccine for use during pregnancy for protection of the infant because the appropriate safety studies had not and have not yet been done.

The CDC decided that the pregnant women of the United States would be unknowing participants in large-scale unregulated experiments.

All pregnant women are pressured to get vaccinated—yet the majority of pregnancies are not tracked for adverse events and data on outcomes is not gathered. The full impact of maternal vaccination, from fetal demise to neurological and developmental impairment, is not known.

The pregnant women who lost their babies in the retrospective studies the CDC cites were not told they were test subjects. They, along with many others, were falsely told by their

doctors—who were falsely told by the CDC, whom they trust to guide them—that influenza and Tdap vaccines are safe during pregnancy. Pregnant women are not told that the recommendations are based on "perceived" rather than proven safety. And pregnant women are not told that in 2013, when the CDC began to recommend getting the Tdap vaccine in every pregnancy, that the ACIP "believed" the potential and as yet unknown risks of such repeated vaccinations would be worth taking. Perception and beliefs are not evidence of safety.

ACIP recommendations are unquestioningly followed by every state as well as county health agencies, yet these ACIP recommendations are not accompanied by updated data on safety signals, known risks, or known vaccine limitations.

Failure of the ACIP and CDC to communicate critical information about vaccination during pregnancy, and failure to inform the public and providers on many critical issues regarding *all* vaccination is a reckless abuse of power and a violation of the Nuremberg Code, medical informed consent, and the Federal Policy for the Protection of Human Subjects ('Common Rule').

The CDC and the ACIP cannot be trusted to provide recommendations grounded on the principles of informed consent.

Informed Consent with respect to vaccination has long been absent because of the passage of the 1986 National Childhood Vaccine Injury Act and subsequent amendments and legislation such as the 21st Century Cures Act, which added the vaccines administered to pregnant women and their fetuses to the 1986 Act umbrella. These pieces of legislation created a Regulatory Vacuum in which no one is responsible for providing full and accurate information to prospective vaccine recipients.

But no legislation or agency has the power to override the human right to fully informed medical consent.

We, the board and members of Informed Choice WA, on behalf of the people of Washington State, are demanding a return of fully informed medical consent.

To accomplish this we propose that the State:

I. Immediately cease recommending vaccination during pregnancy and inform the general public and all vaccine providers of these facts:

a. The FDA has not licensed ANY vaccines for use in pregnancy for protection of the infant.
b. The CDC has issued a statement about a "safety signal" found in their own study that showed an increased risk of pregnancy loss.
c. By agreeing to vaccination, pregnant women are taking part in an uncontrolled experiment.

II. Immediately establish an Independent Vaccine Safety Panel to review all CDC/ACIP recommendations and examine full scientific papers and full IOM reports that address vaccine safety. This Safety Panel will have the goal of establishing new flexible state guidelines capable of continually incorporating the latest science on vaccine risk, flaws, and limitations, including non-specific effects and unintended outcomes so that new policies truly protect public health as well as protect individual health. The members of this panel

will be mutually agreed upon by the State and ICWA and all meetings, agendas, and minutes will be open to the public, recorded, and available online.

III. Establish fully informed medical consent regulations with regard to all vaccination to include the original 10 items as specified by the 1986 Act prior to amendment.

IV. Eliminate conflict of interest: Vaccine quotas and awards, rewards, incentives, and disincentive/noncompliance programs designed to increase rates are in *direct conflict* with the implementation and maintenance of flexible vaccination policies that serve the best interest of the public and the individual patient. Such vaccination policies incorporate the latest science and respect the right to fully informed medical consent. The Vaccine Safety Panel shall nominate a Conflict of Interest Committee to investigate and eliminate all such programs and sources in Washington State.

V. Establish Education Requirements:

a. All vaccine providers must receive full education on all aspects of vaccination including but not limited to full risks, contraindications, vaccine ingredients, identifying adverse events, reporting adverse events, and known environmental and genetic factors that increase risk of adverse events.
b. Provide access to similar educational materials to the general public and health agencies and also provide alternative approaches to infection prevention, limiting transmission, and protecting vulnerable populations.

VI. Enforce Mandatory Adverse Events Reporting in WA State utilizing existing data collection systems. Require vaccine providers report as is required by law:

a. "The occurrence of any event set forth in the Vaccine Injury Table"
b. "The occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert."

In addition, WA State shall make mandatory "the report of clinically significant or unexpected events following vaccination" as is "strongly encouraged" by the CDC. Such after-market reporting is absolutely necessary in determining the full range of adverse events in real world situations.

VII. Explore alternative public health measures to vaccination that reflect up-to-date science on immunity and examine new technologies with an emphasis on non-invasive approaches such as Rapid Diagnosis Technology and Immune Health Education.

THE NUREMBERG CODE

The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.