



April 25, 2014

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U.S. Department of Health and Human Services
200 Independence Avenue SW., Room 733G
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Attn: HHS Maternal Immunizations c/o Dr. Jennifer Gordon at Jennifer.Gordon@hhs.gov

Re: 79 FR 16797, Draft NVAC Maternal Immunization Working Group (MIWG) Recommendations on Maternal Immunizations

Dear Dr. Gellin,

The National Vaccine Information Center (NVIC), which is the oldest and largest charitable non-profit organization advocating for the prevention of vaccine injuries and deaths through public education and the inclusion of safety and informed consent protections in the U.S. vaccination system, submits this public comment to express our deep concern about draft recommendations of the National Vaccine Advisory Committee (NVAC) Maternal Immunization Working Group (MIWG).

Upon reviewing the draft recommendations, in general we note a lack of serious discussion and full acknowledgment by the MIWG of:

- The lack of pre-licensure clinical data on the safety and effectiveness of administering influenza and pertussis containing Tdap vaccines to pregnant women;
- The fact that ACIP recommendations direct obstetricians and other vaccine providers to engage in off-label use of influenza vaccines and pertussis containing Tdap vaccines when neither vaccine has been licensed by the FDA as safe and effective for routine use in pregnant women during any trimester;¹
- Published statements by vaccine researchers and federal agencies that pertussis containing vaccines are often failing to prevent infection and transmission of infection ² and that influenza vaccines have a low rate of effectiveness in adults and children; ³
- Published reports by the Institute of Medicine confirming gaps in vaccine safety science, including lack of scientific knowledge about the biological mechanisms of vaccine injury and death and lack of scientific knowledge about the different genetic, biological and environmental high risk factors that increase individual susceptibility to suffering vaccine complications; ^{4 5}
- The responsibility of public health officials to apply the precautionary and informed consent principles when recommending standing orders directing that all pregnant women be given influenza vaccines and pertussis containing Tdap vaccines during every pregnancy in any trimester.

With regard to each MIWG recommendation, our comments are:

1. ***Enhancing communications to address the safety and effectiveness of all currently recommended immunizations during pregnancy:*** In the absence of pre-licensure clinical trial data presented by vaccine manufacturers to the FDA to demonstrate that influenza vaccines and pertussis containing Tdap vaccines are safe and effective for routine use in all pregnant women in any trimester, this section inappropriately emphasizes creating

public communication strategies that reassure pregnant women and health care providers that vaccination during pregnancy has been proven safe and effective.

The MIWG report fails to establish a framework, such as the one used by the Institute of Medicine, for causality assessments when communicating known and unknown risks of vaccination during pregnancy. The report minimally acknowledges the limitations of epidemiological data for establishing individual risk for developing a poor health outcome following vaccination or for measuring small increases in vaccine risks within the general population.⁶ The report also does not discuss the extremely limited evidence base regarding scientific understanding of the biological mechanisms of vaccine injury and death in pregnant women and potential negative health impact on the developing fetus and newborn when vaccination during pregnancy stimulates an inflammatory response in a pregnant woman or her fetus that does not resolve and becomes chronic.⁷

While the report affirms the Food and Drug Administration's (FDA) regulatory role in assuring vaccines released for use by the public are safe and effective and admits that there are no "adequate and well controlled" pre-licensure studies supporting the safety or effectiveness of administering vaccines to pregnant women, the report recommendations about "enhancing communications" to pregnant women and vaccine providers do not fully or accurately communicate the theoretical benefits and unknown risks of vaccinating pregnant women. Instead, the report uses weak observational data as evidence for safety and effectiveness and promotes creation of communication strategies to convince doctors and other vaccine providers to strongly recommend influenza vaccines and pertussis containing Tdap vaccines to pregnant women so they will consent and get vaccinated.

This public communication strategy is disingenuous because it is based upon weak scientific evidence and lacks transparency. It violates both the informed consent and precautionary principles because not only does it fail to adequately disclose what is and is not known about the safety and effectiveness of vaccination during any trimester of pregnancy both to the pregnant woman and her unborn or newborn child, but it seeks to mask potential harm and failure to prevent infection and transmission of infection by overstating vaccine benefits and minimizing potential risks.

Honest communication by federal health agencies requires that pregnant women and their health care providers have access to information related to the scope of all risks or harm - both known and unknown - as well as any benefits associated with the use of vaccines during pregnancy. While the report puts forward observational data supporting benefits of vaccination during pregnancy, risk information should include information on:

- lack of credible scientific evidence to demonstrate safety,^{8 9}
- lack of credible epidemiological and biological mechanism evidence to demonstrate influenza vaccines and pertussis containing Tdap vaccines are *effective* or *necessary*^{10 11 12 13 14} for *every* pregnant woman in any trimester during *every* pregnancy;
- research deficits, such as limited biological mechanism research and gaps in vaccine safety science repeatedly acknowledged in reports published by the Institute of Medicine over the past 25 years;^{15 16}
- lack of 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;¹⁷
- lack of prospective, placebo controlled pre-licensure trials conducted by drug companies evaluating safety and effectiveness of giving influenza vaccine or pertussis containing Tdap vaccine to pregnant women before the vaccines were licensed in the U.S.^{18 19}
- lack of data on inflammatory or other biological responses to influenza vaccines and pertussis containing Tdap vaccines that could affect pregnancy and birth outcomes.²⁰
- Food and Drug Administration (FDA) listing of influenza vaccines and Tdap vaccines as either Pregnancy Category B or C biologicals,²¹ 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.
- manufacturer product inserts which state that for influenza vaccines and pertussis containing Tdap vaccines human toxicity and fertility studies are inadequate and that both vaccines should "be given to a pregnant woman only if clearly needed."^{22 23 24}
- lack of well designed prospective case controlled studies comparing the health outcomes of large groups of women who get influenza vaccines and pertussis containing Tdap vaccines during pregnancy either separately or simultaneously compared to those who do not get the vaccines, as well as no similar health outcome comparisons of their newborns at birth or in the first year of life post licensure of use in U.S. and use of unpublished safety and effectiveness evaluations conducted, that are small,²⁵ retrospective,^{26 27} comparing vaccinated women to unvaccinated women²⁸ and performed by drug company or government health officials;²⁹

- incomplete evaluation of ingredients in influenza vaccines and pertussis containing Tdap vaccines for potential genotoxic³⁰ 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;^{31 32 33 34 35 36 37 38 39 40}
- significant problems with outdated testing procedures for determining the potency and toxicity of pertussis containing vaccines that have prompted some scientists to call for limits to be established for specific toxin content of pertussis-containing vaccines;⁴¹
- 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.⁴²
- admission by the CDC that federal health officials do “not know exactly how many people die from seasonal flu each year”⁴³ and that influenza vaccine is at best **less than 70 percent effective** in preventing influenza,⁴⁴ and influenza studies are poorly designed and have failed to demonstrate that influenza vaccine is effective or safe;^{45 46}
- findings from 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 revealing that seasonal influenza vaccine is the most frequently suspected cause of brain inflammation after 18 years old, representing 32 percent of the total cases reported, and that pertussis containing DTaP was among the vaccines most frequently associated with brain inflammation in children between birth and age five.⁴⁷

The scope of vaccine risk information listed above should also be included in all federal health agency public communication strategies related to the introduction of future vaccines recommended for use in pregnancy, such as RSV and Group B Streptococcus vaccines currently in clinical trials that will target pregnant women.

The MIWG should also recommend that CDC create new Vaccine Information Statements (VIS) specific to vaccine use in pregnancy to assure that this special population receives accurate and complete vaccine benefit and risk information.

Post-marketing vaccine safety surveillance platforms, such as VSD, VAERS, PRISM and VAMPSS, which are epidemiological platforms that have been created by federal health officials to monitor vaccine safety have serious shortcomings in terms of quality of data, transparency and public access.

Additionally, the MIWG draft recommendations should contain suggestions for ways to improve vaccine provider compliance with requirements to report vaccine complications to the congressionally mandated Vaccine Adverse Events Reporting System (VAERS). NVAC recommendations should encourage increased and more accurate reporting by physicians and all vaccine providers of adverse health outcomes following vaccination to federal health agencies, especially when pregnant women are vaccinated.

The MIWG report contains errors in its representation of the legal requirements of vaccine providers to report to VAERS and should be corrected to reflect these legal requirements as follows:⁴⁸

- the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
- the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
- such other matters as the Secretary may by regulation require.

2. **Maximizing obstetric provider recommendation and administration of recommended maternal immunizations:**

NVIC strongly opposes many of these recommendations, which use language advocating that obstetricians “routinize” maternal vaccination. It is inappropriate to “routinize” vaccination during pregnancy when there is (1) a lack of knowledge about the biological mechanisms of vaccine injury and death in pregnant women and the developing fetus ; (2) no pre-licensure data from case controlled, prospective clinical trials of Tdap and influenza vaccines to confirm safety and effectiveness of giving these vaccines to women during every pregnancy in any trimester and (3) over reliance on retrospective epidemiological data often using closed databases to assure obstetricians that vaccination during pregnancy is safe and effective.

While obstetricians and other vaccine providers should be made aware of ACIP recommendations, they also should be trusted as health care professionals to exercise their best professional judgment in recommending vaccination to a

patient based on assessment of individual needs and risk factors, not solely based on public health policies and routine implementation of federal agency recommendations. Obstetricians and all vaccine providers should be required to continue to provide health care to pregnant women regardless of vaccination decisions that do not conform with ACIP recommendations. They should also be required to report all potential vaccine-related complications to VAERS rather than the vaccine manufacturer, including reporting development of brain and immune system dysfunction or death in the mother or fetus following vaccination during pregnancy.

NVIC supports the removal of barriers that prevent pregnant women and providers from having access to vaccines ACIP has recommended for use during pregnancy. However, NVIC strongly opposes adoption of any government performance measure gauging vaccine distribution by to be used by obstetricians or other vaccine providers as an incentive to pressure providers and pregnant women to conform to ACIP recommendations get vaccinated during pregnancy in order to meet federal health agency goals for achieving higher vaccine uptake among pregnant women. Because obstetricians and other vaccine providers cannot predict whether or not a vaccine they administer to a pregnant woman will protect and not harm her or the fetus, federal agency strategies to incorporate ACIP recommendations as a “standard of care” or “standing orders” to increase vaccine uptake interferes with the physician-patient dialogue that pregnant women expect and deserve when making important health care decisions for themselves and their unborn child.

NVIC strongly opposes this one-size-fits all approach to federal vaccine policy implementation in order to “increase workflow efficiencies” because it compromises the physician-patient relationship and the informed consent ethic, as well as sacrifices quality of health care for individuals who may be more susceptible to complications from vaccination.

- 3. *Focusing efforts to improve financing for immunization services during pregnancy and postpartum:*** We appreciate the MIWG’s recognition that the Affordable Health Care Act focuses on providing increased access to health care for Americans. NVIC supports access to health care, including preventive health care. However, we recognize the difference between *access* to health care and creation of institutional mechanisms which *compel* use of health care, including use of vaccines during pregnancy, without regard for individual genetic, biological and environmental risk factors or respect for deeply held values and beliefs.

While vaccine access presents logistical challenges that should be appropriately addressed by federal and state health agencies, we reiterate concerns outlined in comments for Recommendations 1 and 2 that providers and consumers must be able to exercise informed consent to vaccination. Lack of biological mechanism information and pre-licensure clinical trial data demonstrating that it is safe and effective to give pregnant women influenza and pertussis containing Tdap vaccines during every pregnancy is at odds with ACIP recommendations, especially when FDA has not licensed either vaccine for routine use during every pregnancy and during any trimester of pregnancy.

NVIC cannot support recommendations to improve vaccine financing for delivering vaccines to pregnant women in the absence of good safety and effectiveness data regarding vaccinating pregnant women during every pregnancy in any trimester.

- 4. *Supporting efforts to increase the use of electronic health records (EHRs) and Immunization Information Systems (IISs) among obstetrical care providers:*** While EHRs have the potential to facilitate provider understanding of a patient’s health history and medical care needs, we oppose their utilization as a mechanism to secure vaccine provider or vaccine recipient adherence to ACIP recommendations, especially with regard to vaccination of pregnant women for reasons already stated. Where EHRs are in use, however, we would encourage utilization to increase vaccine provider recording of adverse health outcomes following vaccination, including adverse health outcomes that occur after vaccination during pregnancy, to VAERS.⁴⁹

Vaccine provider failure to record adverse health outcomes following vaccination in the medical record or to report vaccine adverse events to VAERS can result in failure to properly identify, treat and acknowledge vaccine-related health problems appropriately, which often results in re-vaccination that leads to more severe injury. This is especially relevant to the ACIP recommendation that all pregnant women receive influenza and pertussis containing vaccines during every pregnancy because it is very important for vaccine adverse reaction data to be collected for women having more than one child.

- 5. *Recognizing and addressing current vaccine liability law barriers to optimize investigations and uptake of recommended and future vaccines during pregnancy:***

Due to lack of enough credible scientific data regarding the safety and effectiveness of giving vaccines to pregnant women during pregnancy, the National Vaccine Information Center does not support giving vaccine manufacturers or vaccine providers a civil liability shield under the federal vaccine injury compensation program when vaccines given during pregnancy harm a pregnant woman or her unborn or newborn baby. High standards for proof for safety and

effectiveness of vaccines given to pregnant women should be maintained by federal health agencies and the best way to do that is to hold vaccine manufacturers, vaccine providers and vaccine regulators and policymakers accountable in a civil court of law for maternal, fetal and newborn injuries and deaths that can be proven to be caused by vaccination during pregnancy.

Respectfully submitted,

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