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*****VIA EMAIL*****

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Re: 81 FR 58947, Solicitation of Written Comments on the Maternal Immunizations Working Group Phase II's Draft Report and Draft Recommendations for Overcoming Barriers and Identifying Opportunities for Developing Maternal Immunizations for Consideration by the National Vaccine Advisory Committee

Dear Dr. Bok,

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 on-going deep concern about recommendations of the National Vaccine Advisory Committee (NVAC) Maternal Immunization Working Group (MIWG). Our initial concerns relating to the MIWG's recommendations on maternal vaccines was delivered to the NVAC on April 25, 2014.

Upon reviewing the MIWG recommendations for overcoming barriers, NVIC continues to note a lack of serious discussion and full acknowledgment 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.
- The targeting of this population for vaccine innovation and new vaccine development for disease where benefit is not clearly established.

With regard to each MIWG recommendation, our comments are as follows:

1. Focus Area 1 - Ethical Issues: The main focus of this section appears to be the relaxing of how pregnant women are classified for the purposes of research. The report states that for ethical research purposes pregnant women are not a vulnerable population, but a scientifically complex population with the goal being to create a culture of inclusion for clinical research purposes.

However, the logic used to arrive at this new classification excludes the unborn child. Vulnerable populations are considered to be those that have a compromised ability to protect themselves and that are able to provide informed consent.⁶ While pregnant women have the capacity to protect themselves and provide informed consent, their unborn children do not and are a vulnerable population. The MIWG's report acknowledges that there is also little in the way of science to understand what adverse events may result from vaccines used during pregnancy where the unborn child is concerned, yet advocates for aggressive recruitment of pregnant women for this purpose. There is no accompanying statement relating to how informed consent in providing pregnant women with information on the lack of science will be discharged to assure that true informed consent has been obtained. In effect, pregnant women are being asked to subject their unborn child to unknown risk in the name of research and vaccine innovation without clear evidence to demonstrate that vaccines during pregnancy are necessary, safe and effective.

Additionally, while retrospective, observational studies are cited throughout the report, there is no statement on economic feasibility; information on numbers needed to treat (NNT) to prevent disease, mortality, hospitalization, etc.; and information on disease incidence, prevalence, mortality, or the frequency and severity of disease complications included in the discussion on maternal vaccination and/or innovation. This type of information is critical to informing policy-making and the wise use of resources as vaccine innovation is considered versus other possible treatments and interventions for diseases experienced by infants.

Stronger informed consent protection language is needed to assure that pregnant women electing to take part in research are fully informed of the risks, both known and unknown. 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,^{7 8}
- lack of credible epidemiological and biological mechanism evidence to demonstrate influenza vaccines and pertussis containing Tdap vaccines are *effective* or *necessary*^{9 10 11 12 13} 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;^{14 15}
- 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;¹⁶
- 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.^{17 18}
- lack of data on inflammatory or other biological responses to influenza vaccines and pertussis containing Tdap vaccines that could affect pregnancy and birth outcomes.¹⁹
- Food and Drug Administration (FDA) listing of influenza vaccines and Tdap vaccines as either Pregnancy Category B or C biologicals,²⁰ 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.”^{21 22 23}
- 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,²⁴ retrospective,^{25 26} comparing vaccinated women to unvaccinated women²⁷ and performed by drug company or government health officials;²⁸

- incomplete evaluation of ingredients in influenza vaccines and pertussis containing Tdap vaccines for potential genotoxic²⁹ 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;^{30 31 32 33 34 35 36 37 38 39}
- 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;⁴⁰
- 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.⁴¹
- admission by the CDC that federal health officials do “not know exactly how many people die from seasonal flu each year”⁴² and that influenza vaccine is at best **less than 70 percent effective** in preventing influenza,⁴³ and influenza studies are poorly designed and have failed to demonstrate that influenza vaccine is effective or safe;^{44 45}
- 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.⁴⁶

2. **Focus Area 2 – Policy Issues:** 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 focuses on how to lift product liability from vaccine manufacturers to increase the production of maternal vaccines.

Due to lack of enough credible scientific data regarding the safety and effectiveness of giving vaccines to pregnant women during pregnancy, NVIC 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 of safety and effectiveness for vaccines given to pregnant women should be maintained by federal health agencies. The best way to accomplish this 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.

3. **Focus Area 3 – Pre-Clinical and Clinical Research Issues:** While electronic health records (EHs) 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.

However, 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.

Where EHs are in use, NVIC 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.⁴⁷ The creation and utilization of EHs must be by consent of the individual via a voluntary opt-in mechanism to respect the expectation of privacy in the provider-patient relationship and the highly sensitive nature of this information. NVIC supports the right to the individual to determine what health information is shared with government and public health officials in surveillance efforts.

4. **Focus Area 4 – Provider Education & Support Issues:** With enactment of the Affordable Health Care Act, access to health care for Americans has rightfully become a priority. 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 above and support the consumer's right and ability to exercise informed consent to vaccination without sanction. 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.

Communications with professional societies to update professionals who care for pregnant women of changes in definitions that allow for their inclusion in clinical research is reasonable. Obstetricians and other vaccine providers should also be made aware of ACIP recommendations.

However, these communications should in no way undermine that obstetricians and other vaccine providers should be recognized and 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, and not solely based on public health policies and routine implementation of federal agency recommendations. As such, 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 and/or provider 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 the ACIP has recommended for use during pregnancy. However, NVIC strongly opposes adoption of any government performance measure gauging vaccine distribution by obstetricians or other vaccine providers as an incentive to pressure providers and pregnant women to conform to ACIP recommendations to meet federal health agency goals of achieving higher vaccine uptake among pregnant women.

Furthermore, 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 her unborn child, federal agency strategies to incorporate ACIP recommendations as a "standard of care" or "standing orders" to increase vaccine uptake interferes with the physician-patient informed consent dialogue that pregnant women expect and deserve when making important health care decisions for themselves and their unborn child.

In closing, for over three decades, NVIC has supported consumer access to risk and benefit information for diseases and vaccines and their right to make voluntary decisions to accept, delay or decline any vaccine without sanction. We strongly opposes a one-size-fits all approach to federal vaccine policy implementation 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.

NVIC appreciates the opportunity to provide the NVAC these comments and we respectfully reiterate that the MIWG's report as a whole would benefit from in the inclusion of stronger informed consent language to assure that that focus areas outlined in the report also conform to the healthcare professionals obligation to discharge informed consent duties with the public.

Respectfully submitted,

/s/ Barbara Loe Fisher
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