National Vaccine Information Center

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

Captain Angela Shen, DFO
National Vaccine Program Office
U.S. Department of Health and Human Services
Room 715H, Hubert H. Humphrey Building,
200 Independence Avenue SW,
Washington, DC 20201.
email *nvac@hhs.gov*.

Re: 83 FR 25020, Solicitation of Written Comments on the Human Papillomavirus Vaccination Implementation Work Group Draft Report and Draft Recommendations for Consideration by the National Vaccine Advisory Committee

Dear Capt. Shen,

The National Vaccine Information Center (NVIC), which was founded by parents of vaccine injured children in 1982, 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 U.S. vaccine policies and laws. We submit this public comment to respectfully express our on-going deep concern regarding the lack of attention to vaccine safety and informed consent protections in recommendations made by the National Vaccine Advisory Committee (NVAC), in this case, the HPV Working Group.

The HPV Vaccination Work Group Draft Report and Recommendations appears to have been rushed to public comment. The public was given only 15 days to respond and public comments were limited to three pages. This very short notice has hampered the public's ability to comment and there has been a lack transparency in that comments received on the *Federal Register* have been blocked from public view. Stakeholder engagement on the draft report and recommendations also appears to have been limited to those in agreement with the federal HPV vaccination schedule with no representation of parent organization stakeholders concerned about vaccine safety and informed consent issues.

NVAC was established by Congress under the National Childhood Vaccine Injury Act of 1986 and NVIC co-founders were responsible for securing vaccine safety informing, recording, reporting and research provisions in the Act. The NVAC Charter emphasizes the equal duty of NVAC to optimally prevent vaccine adverse reactions: *"The Secretary of Health and Human Services is mandated under Section 2101 of the PHS Act (42 U.S.C. Section 300aa-1) to establish a National Vaccine Program (NVP) to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines".* Additionally, the NVAC Charter specifies that among the 15 individuals appointed to serve as NVAC voting members are individuals representing "parent organizations concerned with immunizations."

NVIC is a federally recognized parent organization stakeholder with historic standing. In 1988, an NVIC co-founder was appointed as a voting member on the first NVAC. Since then, NVIC has nominated several parents, who have subsequently been appointed to the NVAC, as well as provided public comment during meetings and participated in NVAC workgroups and public engagement projects. However, in recent years, parents from organizations expressing concerns about vaccine safety issues have been excluded from NVAC activities.

To fulfill the NVAC Charter and mission, DHHS should take steps to increase transparency with the public on comments received, improve public outreach, allow longer public comment periods, and broaden the diversity of stakeholders and workgroup participants to include vaccine consumer perspectives, which may differ from industry, medical trade organizations and federal agencies responsible for vaccine research, development, regulation, policymaking and promotion.

CDC Data on HPV, HPV Related Cancers and HPV Vaccine

According to the Centers for Disease Control and Prevention (CDC), there are over 200 identified HPV types with two types (16 and 18) associated with the majority of HPV-associated cancers (cervical, oropharyngeal). More than 90 percent of HPV infections, including high risk types, clear within six months to two years without sequelae.[1]

The current two and three dose HPV 9-valent vaccine series is the most expensive of the federally recommended vaccine schedules. HPV vaccine costs are between $336 and $613 per person, depending on age and timing.[2] [3] Using 2014 population data as a zero point to produce a simple cost estimate, to vaccinate all Americans according to CDC recommendations would cost between $5.5 to $32.2 billion. It would cost between $1.3 to $1.7 billion annually thereafter to vaccinate incoming children 11 years of age, assuming population and pricing remains stable.[4] [5] These estimates do not include costs associated with vaccine adverse events, which are historically underreported. During the February 2018 meeting of the Advisory Committee on Immunization Practices (ACIP), CDC's trend data presentation included the statement that "it may take decades to see population-level impact" from this very expensive vaccine."[6]

Recommending a one-size-fits-all HPV vaccination policy for children and adults is a heavy financial burden to ask of the American people, given that there are other behavior based disease prevention strategies, which are as effective and far less costly, including regular pap smears, use of condoms, limiting numbers of sex partners, and abstinence.[7]

According to the CDC, there were 42,394 new HPV related cancer cases reported in 2014, which represents less than three percent of all cancers diagnosed in the U.S. and one one hundredth of a percent (.0001) of the U.S. population.[8] [9] The CDC estimates that 79 percent of those cases, or 33,491 cases, were a match to HPV strains contained in the 9-valent vaccine.[10] In 2012, the CDC reported that between 2004 and 2008, there were approximately 26,000 new cancers attributable to HPV reported annually.[11] Therefore, 2014 data reveal an increase in annually reported new HPV associated cancers since HPV vaccines were licensed in 2006. Some have suggested the rise in oropharyngeal cancers among U.S. is due to changes in sexual behavior in birth cohorts who participated in the sexual revolution.[12]

Since the fast track licensure of HPV vaccines in 2006, a total of 57,287 HPV vaccine adverse events have been reported to the federal vaccine adverse reporting system (VAERS) with 8,343 of those events classified as serious.[13] It is estimated that only one percent of vaccine reactions are reported to VAERS.[14] NVIC is not alone in expressing concern about the number and severity of HPV vaccine adverse events occurring in previously healthy girls.[15] [16] [17] [18] Other countries have responded by amending HPV vaccine policies or withdrawing recommendations for universal use.[19] [20]

We note that nowhere in the draft document is any attention paid to vaccine safety, no mention of the legal duty under the 1986 Vaccine Injury Act for vaccine administrators to inform or record and report vaccine adverse events. The national HPV vaccine promotion strategy recommended in this document fails to acknowledge the personal and family medical histories of individuals or respect for their values and conscientiously held beliefs, including religious beliefs.[21] This approach is a prescription for causing mistrust of doctors aggressively implementing one-size-fits-all federal vaccine policies that place a greater emphasis on meeting vaccine uptake goals than protecting the health of individuals susceptible to vaccine adverse responses or respecting freedom of conscience and personal values and beliefs.[22]

Policy Recommendations to Increase HPV Vaccine Uptake Not Well Founded

HPV infections are sexually transmitted and not acquired in a public setting. Despite more than a decade of HPV vaccine use, there are significant scientific knowledge gaps about the biological, genetic and environmental high risk factors causing chronic HPV infection leading to cancer, and there are similar knowledge gaps about the biological mechanisms and risk factors for brain and immune system dysfunction following HPV vaccination.[23] [24] Trend data indicating an increase in new HPV associated cancers since introduction of HPV vaccines, persistent reports of chronic illness and disability following HPV vaccinations, and the vaccine's prohibitive cost combine together to call into question the aggressive vaccine marketing strategy recommended in the NVAC draft report.

Following are comments related to specific draft recommendations:

- **Focus Area 1- Are there additional national organizations that might contribute to increasing HPV vaccination coverage:** This action item seeks only to engage those organizations that agree with a "no exceptions" approach to increasing HPV vaccination rates without an equal emphasis on safety and informed consent. The focus should shift to raising public awareness about the HPV vaccine's availability and ensuring that those considering vaccination receive full and accurate information about both the disease and the vaccine to facilitate educated and sanction-free vaccine decision making. Federal recommendations should refrain from incentivizing health care professionals to meet vaccination thresholds, as this interferes with the medical ethic of physicians putting the patient first.[25] [26]

- **Focus Area 2 – Is there general guidance for states that do not yet have coalitions?** Again, the sole purpose of this action item focuses on developing new marketing strategies to increase vaccine uptake without concern for preventing vaccine reactions and facilitating fully informed vaccine decision making. Protection of autonomy and

privacy are human rights. When making decisions about use of a pharmaceutical product that carries a risk of injury or death, Americans should not be subject to tracking, harassing reminder calls, and coercion so doctors can meet vaccine uptake quotas. Medical privacy and informed consent protections should be added to the draft document.

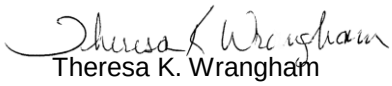
- **Focus Area 3 – How can state immunization programs and coalitions engage with health systems to work together on improving HPV vaccination coverage:** There are medical privacy issues raised by NVAC's call for strengthening use of electronic Immunization Information Systems (IIS) that track the vaccination status of citizens, as do electronic health records (EHR), in order to promote compliance with federal HPV vaccine policy recommendations. [27] The authoritarian tone of the draft recommendation dictates to health care professionals how to deliver care to their patients, and then holds them accountable for the voluntary decisions that patients make. It could easily be interpreted as an effort to strong-arm doctors and other vaccine administrators to, in turn, strong arm patients in order to meet vaccine uptake quotas. The IIS and EHR systems being developed to track the vaccination status of Americans should be done with full, informed consent on an "opt in" basis and not automatic inclusion of personal medical information on an "opt out" basis. Protection of medical privacy and voluntary informed consent in the federal operation of IIS and EHR systems is not served when doctors and the people are coerced into meeting vaccine uptake goals set by government.

- **Focus Area 4 – Please specify recommendations on how to meet the needs of providers in rural areas:** Technology recommendations, such as telemedicine or targeted use of social media, may assist in the delivery of information on the availability of an HPV vaccine to providers in rural areas. Support and outreach to all providers, including those in rural areas should prioritize vaccine safety and facilitation of informed decision making.

Given that it may take decades to fully evaluate and answer outstanding questions about HPV vaccine effectiveness and safety, NVIC recommends a more restrained NVAC recommendation prioritizing safety, affirming respect for the precautionary principle and the informed consent ethic, and encouraging shared decision making by vaccine providers and the people to foster relationships based on transparency, patient empowerment and trust.[28]

Sincerely,

Barbara Loe Fisher
Co-founder & President



Theresa K. Wrangham
Executive Director

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