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Letter in favor of House Bill 1161 concerning Public Health – Human Papillomavirus Vaccine – Information and Informed Consent (Christina's Law) to the Maryland Health and Government Operations Committee (HGO)

Dear Committee Members:

I am a pathologist certified by the American Board of Pathology in 1966. I have practiced diagnostic pathology, including pathologic diagnosis of cervical cancer since 1966 and molecular diagnosis of human papillomavirus (HPV) in Pap smear specimens since 2006. My research work also led to the discovery of HPV L1 gene DNA fragments in the Gardasil vaccines. A few representative publications on diagnostic HPV testing and its relation to Pap smear results as well as HPV L1 gene DNA fragments as Toll-like receptor 9 agonists in Gardasil vaccination are listed as follows:

1. Lee SH. From Pap Smear to HPV Vaccine: The Cervical Cancer Prevention Industry (book). New York: Nova Science Publishers, 2021. https://novapublishers.com/shop/from-pap-smears-to-hpv-vaccines-evolution-of-the-cervical-cancer-prevention-industry/
2. Lee SH. Toll-like receptor 9 agonists in HPV vaccine Gardasil9. International Journal of Vaccine Theory, Practice, and Research 2021; 1: 295-317.
3. Lee SH. Melting profiles may affect detection of residual HPV L1 gene DNA fragments in Gardasil®. Curr Med Chem. 2014;21:932-40.
4. Lee SH, Vigliotti JS, Vigliotti VS, Jones W. From Human Papillomavirus (HPV) Detection to Cervical Cancer Prevention in Clinical Practice. Cancers (Basel). 2014;6:2072-99.
5. Lee SH. Topological conformational changes of human papillomavirus (HPV) DNA bound to an insoluble aluminum salt—A study by low temperature PCR. Advances in Biological Chemistry 2013;3:76-85.
6. Lee SH. Detection of human papillomavirus L1 gene DNA fragments in postmortem blood and spleen after Gardasil® vaccination—A case report. Advances in Bioscience and Biotechnology 2012;3:1214-24.
7. Lee SH. Detection of human papillomavirus (HPV) L1 gene DNA possibly bound to particulate aluminum adjuvant in the HPV vaccine Gardasil. J Inorg Biochem. 2012;117:85-92
8. Lee SH. Guidelines for the use of molecular tests for the detection and genotyping of human papilloma virus from clinical specimens. Methods Mol Biol. 2012;903:65-101.

I was also the author of the expert report [**Exhibit 1**] for the petitioner in the case of Adan Gomez and Raquel Ayon vs. Secretary of Health and Human Services in the United States Court of

Federal Claims (No: 15-0160V). In this case, a healthy 14-year- old California boy died unexpectedly in sleep as a result of myocardial damage after receiving a second dose of Gardasil vaccination. https://www.leagle.com/decision/infdco20161018b29

Based on my experience and on unbiased information available in the public domain, I am writing in support of passing of House Bill 1161 for the following reasons.

1) The information disseminated by certain government agencies about the effectiveness of HPV vaccination in prevention of cancers is not based on facts. For example, the Vaccine Information Statement issued by the Centers for Disease Control and Prevention (CDC) claims "***HPV vaccine can prevent over 90% of cancers caused by HPV***" [**Exhibit 2**]. This claim is not supported by factual data.
   According to the testimony of Dr. Nancy C. Lee, former Associate Director for Science, National Center for Chronic Disease and Health Promotion, Centers for Disease Control and Prevention, Department of Health and Human Services before the SUBCOMMITTEE ON HEALTH AND ENVIRONMENT of the COMMITTEE ON COMMERCE, HOUSE OF REPRESENTATIVES, 106th United States Congress, cervical cancer occurs at an average age of 54 in the U.S. For a woman with cervical cancer precursor detected by Pap smear, her likelihood of survival is almost 100 percent with timely and appropriate treatment. When cervical cancer is detected at its earliest stage, the 5-year survival rate is more than 90 percent. The cervical cancer death rate declined 45 percent between the periods 1972-74 and 1992-94 and the overall incidence of the disease has decreased steadily from 14.2 per 100,000 in 1973 to 7.4 per 100,000 in 1995. This is largely attributed to the effectiveness of Pap smear screening for cervical cytology. "Cervical cancer is nearly 100 percent preventable" in the U.S., stated Dr. Nancy Lee [**Exhibit 3**] before HPV vaccines were introduced into the market in 2006.

   HPV infection is highly prevalent among sexually active young Americans and generally produces no symptoms in the female patients. More than 90% of HPV infections are self-cleared with no residual health consequences on clinical follow-up. Only when the patient's immune system cannot clear the infection and the HPV infection becomes persistent, cervical carcinogenesis may take place in a small percentage of patients. And, it can take 10 to 20 years, or even longer, for HPV-infected cervical cells to develop into a cancerous tumor. [**Exhibit 4**] As a result, the approval for HPV vaccines to be marketed was based on short-term clinical trial studies, using self-reversible precancerous histological changes (CIN 2/3 or worse) as surrogate endpoints to evaluate the vaccine efficacy in "cancer prevention". [**Exhibit 5**] However, the CIN2/3 or worse lesions are not appropriate surrogate endpoints for cervical cancer because cervical intraepithelial neoplasia (CIN1, CIN2, and CIN3 lesions) represent a spectrum of disease. While low-grade, or CIN1 lesions, represent a chronic HPV infection, CIN2 and CIN3 lesions are unpredictable self-regressing precancerous cellular changes, not really cancer. [**Exhibit 6**] The CIN2 lesions diagnosed on a LEEP sample may not be a real disease state but a misclassification of biologic CIN 3 or CIN1 (HPV infection) that is independent of other clinical markers of precancer. [**Exhibit 7**]

In a recently published follow-up study, the age-adjusted incidence of distant stage cervical cancer in the U.S. in the year of 2018 was found to be 0.99/100 000 compared with 0.78/100 000 in 2001 (https://pubmed.ncbi.nlm.nih.gov/35981903/), indicating that the advanced stage invasive cervical cancer rate was increasing 12 years after the introduction of HPV vaccination in 2006.

2. HPV vaccination is associated with potential serious adverse events, including sudden unexpected cardiac deaths [**Exhibit 1**] and fatal myocarditis [**Exhibit 8**]*.

The healthcare providers who administer HPV vaccines should inform their clients of the potential benefits and risks of HPV vaccination for the vaccine recipients to make a proper informed decision.

Thank you for your consideration.

Sincerely,

Sin Hang Lee, MD, F.R.C.P.(C), FCAP
Director
Milford Molecular Diagnostics Laboratory Date submitted: March 10, 2023

*All component vaccines need potent adjuvants to enhance the immune response of the host to generate a high level of antibodies against the antigen. The HPV vaccine Cervarix uses 3-O-desacyl-4'-monophosphoryl lipid A, a TLR4 agonist, bound to aluminum hydroxide as the adjuvant, the HPV vaccine Gardasil uses HPV L1 gene DNA fragments, a TLR9 agonist, bound to amorphous aluminum hydroxyphosphate sulfate (AAHS), as the adjuvant, and the mRNA COVID-19 vaccines use ssRNA as TLR 7/8 agonists and phospholipids as TLR4 agonist in stabilized nanoparticles as the adjuvant (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7554980/). Activation of these toll-like receptors leads to strong and long-lasting adaptive immune responses through tumor necrosis factor-α (TNF-α), interferon-γ (IFN- γ) and other pro-inflammatory cytokines that are secreted by activated immune cells. However, TNF-α and IFN-γ may cause serious adverse reactions in certain genetically and physically predisposed individuals, including myocardial necrosis often reported as myocarditis and pericarditis in some recipients of mRNA COVID-19 vaccines.