



**Testimony of  
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**Statement on Bill 17-30  
HPV Vaccination and Reporting Act of 2007**

**Department of Health Fiscal Year 2010 Budget Hearing  
Committee on Health  
District of Columbia City Council**

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*Founded in 1871, Children's National Medical Center is a 283 bed not-for-profit academic medical center located at 111 Michigan Avenue, NW. The medical center's mission is to improve health outcomes for children regionally, nationally and internationally; to be a leader in creating innovative solutions to pediatric healthcare problems; and to excel in care, advocacy, research and education to meet the unique needs of children, adolescents and their families. Children's National is consistently ranked among the best pediatric hospitals in America by US News & World Report and has twice been named to The LeapFrog Group's Top Hospitals list for quality and safety.*

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Chairman Catania and members of the Committee, my name is Dr. Joseph Wright. I am a Professor of Pediatrics, Emergency Medicine and Health Policy on the faculty of the George Washington University Schools of Medicine and Public Health, and a Senior Vice President leading the Child Health Advocacy Institute at Children's National Medical Center. I have also recently been appointed a member of the Pediatric Advisory Committee of the federal Food and Drug Administration (FDA), although I am not testifying in that capacity this afternoon. Thank you for the opportunity to comment on the implementation of Bill 17-30, the Human Papillomavirus (HPV) Vaccination and Reporting Act of 2007.

Children's National has committed considerable time and thoughtful, informed, clinical debate to the issue of mandatory HPV vaccination. In 2007, our hospital's Committee on Advocacy and Public Policy (CAPP), a standing committee of our Board of Directors, spent months weighing the pros and cons of the issue. The Committee, which is comprised of hospital and community physicians, advocates, parents, child health policy experts and others, serves as the advisory body on issues of advocacy and public policy for Children's National and our entities.

After considering the complex ethical, medical and policy issues associated with mandating the HPV vaccine, the Committee on Advocacy and Public Policy recommended – and our Board of Directors approved – a hospital policy that endorses mandatory HPV vaccination with certain provisions: inclusion of a parental opt-out clause; guaranteed accessibility to the vaccine for vulnerable populations; and implementation of a public awareness campaign about the HPV virus, cervical cancer, and the vaccine.

The hospital's policy position also strongly states that compulsory vaccination should be accompanied by continuous and vigorous monitoring of vaccine administration safety and effectiveness data. Since FDA approval in June 2006 and passage of the District bill in April 2007, there have been several important studies published in the peer-reviewed scientific literature further evaluating HPV vaccine efficacy and post-market safety and effectiveness. I will commend the remainder of my time to briefly highlighting three recent analyses that summarize where the science is today.

- In May 2007, the New England Journal of Medicine published the results of two Phase 3 trials designed to evaluate vaccine efficacy in the prevention of, respectively, high grade cervical lesions, a cancer precursor, and anogenital disease caused by the human papillomavirus. The research was conducted by an international group of collaborating scientists collectively known as the FUTURE Investigators, the acronym standing for Females United to Unilaterally Reduce Endo/Ectocervical Disease. Both studies were randomized, placebo-controlled, double-blind trials involving thousands of subjects, the most rigorous methodology available, and conclude respectively...”In young women not previously infected with HPV, those in the vaccine group had a significantly lower occurrence of high grade cervical intraepithelial neoplasia related to HPV than those in the placebo group”.... “The vaccine significantly reduced the incidence of HPV-associated anogenital disease in young women”.
- Before I move from efficacy to safety and effectiveness, let me first define the Vaccine Adverse Event Reporting System, also known as VAERS. The VAERS, jointly monitored by the FDA and the Centers for Disease Control (CDC), is a very important component of the vaccine safety network through which post-immunization adverse events are reported. However, it is a passive surveillance system that is designed to detect trends or clusters, and cannot be used to determine causality. The Vaccine Safety Datalink, or VSD, program, on the other hand, is an ongoing, active surveillance system expressly designed to study patterns in the VAERS and determine if a vaccine is actually causing a side effect. The CDC and 8 large health care organizations are currently engaged in a Vaccine Safety Datalink analysis in which 500,000 doses of the HPV vaccine will be ultimately monitored. The study so far includes more than 375,000 doses administered to girls and women between the ages of 9 and 26 over a two year period.
- Since licensure, more than 23 million doses of the HPV vaccine have been distributed in the United States and the VAERS reports 11,916 incidents following vaccine administration. Six percent were classified as serious. In October 2008, data analysis of the VAERS and the VSD study was presented to the Advisory Committee on Immunization Practices of the CDC. It was determined that there is no clear evidence that any serious adverse events were attributable to the vaccine. A common pattern was not found and, on medical investigation, causes for the serious adverse events were conclusively explained by factors other than the vaccine. This information is detailed and publicly electronically available at the CDC website:  
< <http://www.cdc.gov/vaccinesafety/vaers/gardasil.htm> >
- In its April 2009 issue, the American Journal of Public Health, the academic journal of the American Public Health Association, published a meta-analysis of the issue from the standpoint of public health benefit and societal utility. Historical review of the similarities between today’s discussion and the discussion

surrounding implementation of the poliovirus vaccination program of the late 1950's was drawn. Parallels are also noted in the more recent addition to the immunization schedule of Hepatitis B, quite similar to HPV, in that it both involves a requirement of close, intimate contact for transmission and the administration of a series of three shots to confer protection. The bottom line conclusion from a public health perspective is that the immunization of many reduces and/or eliminates harm to the few. This is the nature of public health vaccination programs and justification for implementation of the program in the District of Columbia.

Children's National is aware of the concerns regarding compulsory HPV vaccination and, through our clinical practices, has worked to address parents' concerns and provide them with information about human papillomavirus, its link to cervical cancer and the safety and efficacy of the vaccine. To date, 1725 HPV vaccines have been safely administered at the Adolescent Health Center on our main Michigan Avenue campus since January of 2007.

While we continue to closely monitor the effect of the vaccine on our patients as well as the aforementioned national safety studies, we stand by our institutional position of supporting compulsory vaccination. In the end, we believe that this is an urgent public health concern and that proactive steps such as a vaccine mandate will decrease the incidence of HPV and ultimately cervical cancer rates in the District of Columbia.