



# **HPV Vaccine Legislation - Virginia's Experience in 2007**

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**Presentation to ASTHO Senior Deputies  
Joe Hilbert – Executive Advisor  
Virginia Department of Health**



# Human Papillomavirus (HPV)

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- **Causes virtually all cases of cervical cancer**
- **Nearly 10,000 women in U.S. diagnosed with cervical cancer each year, 3,700 die annually**
- **HPV Prevalence – 20 million cases in U.S.**
- **HPV Incidence – 6.2 million cases per year in U.S.**

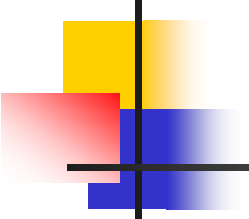


# Governor's Task Force on Cervical Cancer Task Force

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- Executive Directive 5 (January 2005)
- Focus on early detection, public awareness, achievement of HP2010 goals, reducing incidence, and development of policy recommendations to Governor and General Assembly
- Recommendation 5: Once the HPV vaccine receives FDA approval, follow the ACIP guidelines and if necessary allocate funding. VDH should report to Joint Commission on Health Care by December 2007
- Task Force Report released November 1, 2005

# Development of HPV Vaccine

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- February 2005 - Merck announces \$40 million investment to renovate manufacturing plant in Rockingham County, Virginia to manufacture Gardasil
  - June 2006 - FDA licenses Gardasil, manufactured by Merck
  - June 2006 - ACIP recommends administering vaccine to girls between 11 – 12 years of age, before they become sexually active



# Policy Developments in Late 2006

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- Merck looked to build market share prior to competitors gaining FDA approval for their own HPV vaccine (GlaxoSmithKline – Cervix)
- VDH requested and received additional funding to purchase HPV vaccine for its patients.
- Merck focused efforts on state legislatures to develop various public policy approaches to promote and/or mandate HPV vaccination
- VDH received word that legislation that would mandate HPV vaccine as a condition of school entry was being discussed/considered.



# VDH Assessment of Potential Legislation

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- Premature to mandate HPV for school attendance. With every new vaccine there have been vaccine shortages in the first year or so. This leads to waivers, etc.
- HPV vaccine is very costly. If it is mandated VDH would be required to administer free to everyone.
- Because of its high cost, private physicians not willing at this time to tie up their funds in expensive inventories. So if it is required and is free at VDH, there would probably more demand than anticipated in the VDH budget amendment request, which was developed with the assumption that there would not be a mandate
- Allowing a new category of opting out for this vaccine could create a loophole for anti-immunization groups to use for other childhood vaccines. Currently, the only opt outs are for medical reasons or if the administration of immunizing agents conflicts with religious tenets or practices.



# 2007 Virginia Legislation

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## HB2035 (as introduced)

- **Established mandate for school entry – 3 doses with first dose on or after 11<sup>th</sup> birthday**
- **Opt out provision – Parent could decline vaccination for child, on a form prescribed by Board of Health, after having reviewed materials prescribed by Board of Health concerning link between HPV and cervical cancer**
- **Effective Date – September 1, 2008**



# HB2035 Was Amended in Committee

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- **First dose required prior to entry in sixth grade (in response to VDH suggestion)**
- **Removed opt out provision (in response to VDH concerns)**
- **Changed effective date to October 1, 2008 (in response to estimated fiscal impact, this had effect of moving fiscal impact to the next budget biennium)**



# **HB2035 Was Further Amended on the House Floor**

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- **Reinserted opt-out provision (in response to concerns by conservative legislators)**
- **House Vote: 80-17; Senate Vote 40-0**



# Governor's Review of the Bill

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- VDH Recommended a Veto
- Governor proposed an amendment to the bill
- *Because the human papillomavirus is not communicable in a school setting, a parent or guardian, at the parent or guardian's sole discretion, may elect for their child not to receive the human papillomavirus vaccine, after having reviewed materials describing the link between the human papillomavirus and cervical cancer approved for such use by the Board.*
- General Assembly agreed to the Amendment
- Governor Signed the Bill on April 11.



# Dynamics Affecting this Legislation

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- **Powerful Patron - Chair of House Health Committee, Chair of Joint Commission on Health Care, and Chair of House Appropriations Subcommittee on Health and Human Resources**
- **Strong lobbying by Merck**
- **VDH was most concerned about the opt out provision, less concerned about the mandate**
- **Lack of official Administration position on the bill until fairly late, when it became "No Position"**
- **Short legislative session (45 days) prevented opposition that emerged to this type of legislation in other states from becoming effective in Virginia.**



# Questions??

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