

# South Carolina's Proposed Legislation: Cervical Cancer Prevention Act

Amanda J. Reich

South Carolina is currently among several states considering controversial legislation to require a cervical cancer vaccine for girls entering seventh grade. The "Cervical Cancer Prevention Act", H. 3136, seeks to amend South Carolina law by adding Section 44-29-187, South Carolina Code of Laws, which would require girls, beginning in school year 2009-2010, to receive the vaccine series unless they qualify for standard vaccine exemptions. South Carolina policymakers are faced with balancing a landmark achievement in public health, approval of the first vaccine developed specifically to prevent cancer, with the rights, values, and autonomy of South Carolina citizens.

## *Human Papillomavirus and Cervical Cancer*

Much of the debate surrounding the mandate of this vaccine stems from the fact that it targets genital human papillomavirus (HPV), a sexually transmitted illness. HPV infections cause cervical cancer and precervical cancer diseases (up to 80% of patients with these illnesses show evidence of HPV infection).<sup>1</sup> In the United States, an estimated 6.2 million people are infected every year, and the highest risk groups are comprised of young people.<sup>2</sup> Forty-eight percent of all sexually transmitted diseases (STDs) diagnosed in 2000 were among fifteen to twenty-four-year-olds. Three STDs accounted for 88% of the diagnoses, and these diseases were HPV, trichomoniasis, and chlamydia. HPV is the single most common STD, and is readily transmitted through sexual partners. In addition to cervical cancer, HPV is also associated with development of vaginal and vulvar cancers and precancerous lesions, anal cancer, and genital warts.<sup>3</sup>

HPVs are actually a group of over 100 viruses, approximately 30 of which can be passed from one person to another via sexual contact. Most HPVs occur without any symptoms and resolve spontaneously. Others, however, may persist for years and some of these persistent strains may cause cell abnormalities, including cervical cancer.<sup>4</sup> Risk factors that increase a woman's chance of contracting cervical cancer include multiple sexual partners, cigarette smoking, and failure to participate in cervical cancer screening. Although there is no cure, cervical cancer is treatable and women have a better prognosis when a diagnosis is made early.<sup>5</sup>

Infection with a high-risk strain of HPV is necessary for development of cervical cancer. In 2003, cervical cancer incidence in the United States was 8.1 per 100,000 women, with approximately 11,820 new cases reported.<sup>6</sup> Cervical cancer is particularly relevant to South Carolina. According to the Kaiser Family Foundation, South Carolina's incidence rate for cervical cancer, at 8.2 per 100,000 women, is higher than the national average.<sup>7</sup> The incidence rate reflects all new diagnoses of cervical cancer for the year 2003. According to South Carolina's Department of Health and Environmental Control (DHEC), approximately 200 new cases of cervical cancer are diagnosed annually, and 55 South Carolina women died of the disease in 2004. The agency also estimates that \$25 million is spent annually to treat HPV-related conditions in the state.

The National Breast and Cervical Cancer Early Detection Program seeks to provide screening services for low-income, uninsured, and underinsured women. In South Carolina, the program provided 30,430 Pap tests (where a sample of cells is collected from the cervix to check for abnormalities) between 2001 and 2005. Of these, 222 detected cervical cancer or cancer precursor lesions.<sup>8</sup> A significant disparity exists among the population of women diagnosed with cervical cancer. The incidence for black women is approximately 1.5 times higher than for white women, and death rates among blacks are twice as high as for whites. Hispanic women also bear a higher burden of the disease.<sup>9</sup> These differences are attributed, in part, to limited access to healthcare and cervical cancer screening.<sup>10</sup> South Carolina has one of the highest rates of uninsured women in the nation, and the numbers are substantially worse for low-income women in the state.<sup>11</sup> It is asserted by many that “ethical” policymaking would ensure that these differences are not compounded by differential access to immunizations. Many of the same barriers to healthcare and screening would likely also exist in vaccine coverage.

### *The Vaccine*

The pharmaceutical company Merck and Co., Inc. developed the first HPV vaccine (Gardasil), which was approved by the Advisory Committee on Immunization Practices as safe and effective in June 2006. Another company, GlaxoSmithKline, is expected to gain approval of its vaccine, Cervarix, in 2007. Clinical trials have demonstrated that both vaccines are safe and effective and can prevent up to 70% of cervical cancers in women.<sup>12</sup> Both vaccines target specific strains of HPV, and are not 100% effective in preventing all cervical cancers. Models suggest that vaccination of an entire cohort of twelve-year-old females could reduce the lifetime risk of cervical cancer by anywhere from 20%-66%.<sup>13</sup>

The Centers for Disease Control and Prevention recommends the vaccine for eleven to twelve year old girls, noting that it can be given to girls as young as nine.<sup>14</sup> The aim is to vaccinate girls before they become sexually active. Studies thus far have demonstrated that the vaccine provides immunity for up to five years, protection beyond that time frame has not yet been established. Research is ongoing to determine if a booster will be necessary in the future.<sup>15</sup> Three doses are required to complete the vaccine course, at a total cost of \$360 for the series. According to Merck and Co, Inc.’s website, the second vaccine should be administered two months after the first, and the final injection six months after the first.<sup>16</sup> Gardasil is an intramuscular injection. Minimal rates of adverse reactions in clinical trials included pain, swelling, erythema (redness of the skin), fever, nausea, pruritus (itching), and dizziness.

Research indicates that the vaccine is highly effective when used as prescribed, including completion of the three-vaccine series with no protocol violations.<sup>17</sup> It is important to emphasize this caveat; while the vaccine is highly effective at preventing HPV when used as directed, physician and patient compliance is necessary. In order to provide immunity, individuals must commit to the provision of three separate injections.

### *Policy Implications*

Important considerations for South Carolina policymakers include three primary concerns of the bill's opponents. The first is that mandating the vaccine will usurp parental authority; the second issue is the cost of the vaccine, which some deem as prohibitive; and finally, the fear that mandating a vaccine for a sexually transmitted illness will encourage promiscuity. Ethical leadership on this decision should reflect an understanding of the science and an appreciation for constituent concern.

What makes this vaccine unique from others is that it prevents a virus primarily spread via sexual contact, rather than by air or casual contact. Richard Zimmerman<sup>18</sup> (2006) argues in his ethical analysis of the HPV vaccine that this difference trumps any analogies one might make between this vaccine and previously mandated childhood immunizations. In a recent position statement, *Focus on the Family*<sup>19</sup> indicates that while in support of the vaccine itself, the group is opposed to mandatory vaccination and expects such decisions to be made by the parent. It is suggested generally that the political environment in South Carolina demands that the matter of personal choice be recognized. One policy option is to issue guidelines on vaccine recommendations. At the same time, one must consider the utility of issuing recommendations as opposed to mandates in regards to the vaccine. Rates of immunizations completed on a voluntary basis have historically been low. For example, a 1999 study in the *Journal of the American Medical Association* highlighted that while the U.S. Public Health Service objective was to vaccinate 60% of elderly and immune-compromised patients for the pneumococcal (flu) virus, only 37% were vaccinated. The study also found, however, that immunization rates were substantially increased with the inclusion of a simple, low-cost, low-literacy patient education tool.<sup>20</sup> Similar issues with voluntary prevention measures have been demonstrated in a lack of cervical cancer screening. Despite national recommendations for Pap tests, half of all women who develop the disease have never been screened for cervical cancer, and another 10% were not screened for five years preceding their diagnosis.<sup>21</sup> The highest risk groups, low income women, are also the least likely to have been screened.

While this paper is not designed to present an exhaustive cost-benefit analysis, it is worth emphasizing that the cost of immunizing the population obviously increases as more vaccines are required. Insurance companies vary in coverage rates, although most large plans will cover the cost of required vaccines after a short lag time.<sup>22</sup> One must keep in mind that at this point, required vaccination for HPV would not negate the need for screening exams. The cost of this burden is shared by the federally funded National Breast and Cervical Cancer Early Detection Program. Additional federal assistance comes in the form of the Vaccines for Children Program, which provides free vaccinations to children and adolescents under the age of nineteen, who are either uninsured, Medicaid-eligible, American Indian, or Alaskan Native.<sup>23</sup> The CDC has indicated that the HPV vaccine will be covered for eligible populations under this program. Methods to reduce barriers to vaccine access must be considered with any

legislative action, as minority and low-income women bear a disproportionate burden of cervical cancer diagnoses and mortality.

There has been some concern that the introduction of the vaccine could interfere with the efficacy of the highly successful Pap smear screening program.<sup>24</sup> Pap smears are responsible for a substantial reduction in cervical cancer mortality rates, and will remain a necessary component of preventive care in tandem with the vaccine. Some health professionals fear adolescents or their parents will gain a false sense of security once vaccinated, and fail to continue regular cervical cancer screenings. Appropriate vaccine introduction should include an awareness or educational component to ensure continued screening. This effort will, of course, represent an additional cost to the state.

Informing children about the purpose of the vaccine and initiating a conversation regarding sexual activity has been cited by some critics as potentially undermining abstinence education. Additionally, some parents feel that such discussions should be presented on their own terms and within their own timeframes, and the vaccine may conflict with parental decision-making. The Bill and Melinda Gates Foundation has announced an allocation of \$27.7 million in funding to research appropriate methods to introduce the vaccine.<sup>25</sup> The grant was also initiated in part due to similar concerns related to introduction of an HIV vaccine which might someday be available. The assumption is that advances in medical technology will continue to demand that these issues be confronted. Regardless of the approach, the fact is that current rates of adolescent sexual behavior must for all intents and purposes be recognized. According to the Youth Risk Behavior Surveillance System, a representative survey of students in ninth through twelfth grades, 49.7% of female students in South Carolina had engaged in sexual intercourse in 2005.<sup>26</sup>

If the bill is passed as written, without an amendment to allow for parents to opt out of the immunization requirement, current exemptions for vaccines would apply. According to DHEC, the only allowable exemptions are for medical and religious reasons. A religious exemption may be granted to any student whose parent, guardian, or person *in loco parentis* signs the appropriate section of the exemption stating they are members of a recognized religious denomination in which the tenets and practices of the religious denomination conflict with immunizations.<sup>27</sup> Policy options currently under consideration include allowing parents the option of excluding their child from participating in the vaccination. One paper that studied the costs and benefits of an HPV vaccine proposed school-based, as opposed to clinic-based, vaccinations. This method would take advantage of existing infrastructure and reduce some compliance issues among adolescents.<sup>28</sup> While school-based vaccinations would likely promote efficiency in delivery, this approach could also potentially exacerbate issues related to parental autonomy. While making the immunization more accessible and controlled, it would also make it much more difficult to avoid.

Any option considered by policymakers should weigh both the ethical ramifications of requiring a vaccine despite parental and social sensitivity against the potential outcomes of failing to ensure maximum effort towards protecting the health of our citizens. In

weighing these options, a responsible decision will include safeguards to enhance accessibility for all populations; in particular, barriers to low-income and at-risk populations should be eliminated. Additionally, appropriate education is necessary to promote health literacy and increased rates of completed vaccine cycles and continued preventive screening.

### Update

As of April 19, 2007, H.3136 has failed to pass the South Carolina House of Representatives after a tabling motion by its sponsor Rep. Joan Brady. According to newspaper accounts the bill failed due to its sexual context. “It’s a cancer caused by sex; people don’t like that.”<sup>29</sup>

Since the Centers for Disease Control and Prevention have recommended its widespread use and DHEC will continue its evaluation of the vaccine, it is hoped that the use of the vaccine will eventually receive policy approval in South Carolina.

Additionally, the failing amendment or tabling votes to the legislation were close (49-41 and 56-48) during House debate, which is “promising” according to the bill’s supporters. Further, more education and outreach on the cancer vaccine may override future objections to the bill.

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### Endnotes

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