

## **Catholic Medical Association Position Paper on HPV Immunization**

On June 8, 2006, the U.S. Food and Drug Administration (FDA) approved Gardasil<sup>®</sup> (Merck), a vaccine against human papillomavirus (HPV) types 6, 11, 16, and 18, for use in girls and women 9–26 years of age. On June 29, 2006, the Advisory Committee on Immunization Practices recommended routine vaccination of girls at 11–12 years of age, with catch-up vaccination of girls and women 13–26 years of age.<sup>1</sup> Many parents have asked whether this vaccine is morally licit and whether this recommendation for broad use is warranted. In addition, some public health agencies and legislatures are considering whether immunization for HPV should be made mandatory for school attendance. This statement outlines the Catholic Medical Association's position on these issues regarding HPV vaccine.

### **Significance of Addressing HPV**

HPV causes genital warts and anogenital cancers, including cervical cancer.<sup>2</sup> More than 40 HPV types can infect the genital tract, but about 70% of cervical cancers are caused by types 16 and 18,<sup>3,4</sup> and about 90% of genital warts are caused by types 6 and 11.<sup>5</sup> Each year in the U.S., an estimated 6.2 million persons acquire new HPV infections annually; 9,710 new cases of cervical cancer are diagnosed; and the disease kills about 3,700 women.<sup>6,7</sup> The number of lifetime sexual partners is the most important risk factor for genital HPV infection.<sup>8</sup> In a study among college women, HPV infection rose to 40% within two years after commencement of sexual activity.<sup>9</sup> Condoms provide, at best, marginal protection against HPV.<sup>10,11</sup>

### **The HPV Vaccine**

A multicenter, randomized, double-blind trial enrolled 552 women 16–23 years of age in the United States, Scandinavia, and Brazil, who were given 3 doses of vaccine or placebo over 6 months. Over the 36-month study period, the vaccine demonstrated 89% efficacy against persistent infection and 100% efficacy against disease (warts, neoplasia, or cancer) caused by the 4 HPV types contained in the vaccine.<sup>12</sup> Data submitted to the FDA (and summarized in the manufacturer's prescribing information) demonstrated similar efficacies in larger cohorts of women and that the vaccine produced anti-HPV antibody titers in girls 9–15 years of age that were non-inferior to those produced in women 16–26 years of age.<sup>13</sup> The duration of efficacy of the vaccine is not yet known; booster injections may be required for sustained immunity. Testing in males is underway.

The HPV vaccine appears to be safe. Like other injected vaccines, HPV vaccine causes pain, swelling, and erythema at the injection site.<sup>13,14</sup> Fever was reported in 10.3% of Gardasil<sup>®</sup> recipients, compared to 8.6% of placebo recipients.<sup>13</sup> No serious adverse events were attributed to Gardasil<sup>®</sup>.

The 3-dose Gardasil<sup>®</sup> vaccine series costs about \$350. Cost-effectiveness models have estimated about that, overall, a program of universal vaccination of adolescent girls will cost \$23,000–\$45,000 per quality-adjusted life year saved.<sup>15-17</sup> These cost-benefit ratios fall within the range generally deemed acceptable for preventive medicine.

## Does the CMA Support Use of the HPV Vaccine?

*The CMA supports widespread use of Gardasil<sup>®</sup> for girls and women in the age range for which the vaccine has been recommended by the ACIP, because it is effective, safe, and ethical to use, provided certain conditions are met.*

### 1. Is Use of the HPV Vaccine Ethical?

There is no ethical objection to the HPV vaccine either as a strategy against disease or in its production. Patients and parents must have the opportunity to give informed consent to its administration.

#### *Ethics*

- The fact that HPV is spread primarily by sexual contact does not render vaccination against it unethical. Healing and preventing diseases, no matter what their source, are acts of mercy and a moral good. Prevention of HPV infection is distinct from, and should not be construed as encouraging, the behavior by which HPV is spread.

#### *Production*

- Gardasil<sup>®</sup> is composed of recombinant type-specific capsid proteins that are expressed in yeast and that aggregate spontaneously into virus-like particles. Its production does not involve cell lines derived from tissues of intentionally aborted babies as do other common vaccines such as those against hepatitis A, (some) rabies, rubella, varicella, and zoster.

#### *Informed Consent*

- Generally accepted principles of informed consent include *disclosure* (of benefits, risks, and alternatives), *understanding* and *voluntariness*. (Regarding voluntariness, see the discussion of mandates for the HPV vaccine, below.) In addition to the basic facts summarized in the manufacturer's prescribing information, physicians should ensure that patients and parents understand that:
  - Although Gardasil<sup>®</sup> covers HPV 16 and 18, which account for 70% of cervical cancers, 11 other high risk strains of HPV exist that cause cancer;
  - The duration of efficacy of the vaccine is not yet known. Booster injections may be required for sustained immunity;
  - There are effective alternatives for preventing cervical cancer. For example, as a result of routine Pap smears over the past 50 years, the age-adjusted incidence of cervical cancer in U.S. women declined from 14.8/100,000 in 1975 to 7.1/100,000 in 2003; and during that time, the age-adjusted mortality from cervical cancer declined from 5.6/100,000 to 2.5/100,000.<sup>18</sup>

## 2. Should the HPV Vaccine Be Mandated?

Public health officials and legislators across the country are discussing whether the HPV vaccine should be required for attendance at school by girls  $\geq 9$  years of age. Indeed, in some areas, public officials have been faced with intense lobbying efforts to mandate the use of this vaccine. *The CMA opposes mandating the use of HPV vaccine, as well as direct or indirect efforts to pressure parents or minors to accept it.*

- HPV vaccine is a medical treatment, and under natural<sup>19,20</sup> and civil law, it is parents who have the primary authority and responsibility to raise their children and to approve medical treatments for them. Addressing the issue of sexually transmitted infections (STIs) is a part of parents' indispensable task of teaching their children about sex and forming them in chastity. Using mandates or other pressure (such as threatening to exclude children from attending school) violates parental rights and undermines parents' authority.
- While Gardasil<sup>®</sup> appears to be safe, effective, and ethical, there is always risk, however small, with any vaccine. Moreover, there are valid alternatives for avoiding or monitoring for HPV infection.
- To justify withholding educational opportunity from students whose parents believe that vaccination is not in the students' best interest, at least the following conditions should be met:
  1. The disease is potentially serious;
  2. Non-vaccinated students would pose a substantial risk to others were they allowed to attend school;
  3. The vaccine that prevents it is safe and effective;
  4. The vaccine meets reasonable standards for cost-effectiveness; and
  5. The vaccine is provided to students who cannot afford it.

Criterion #2 is not met by HPV infection. We presume that genital HPV infection is not transmitted while students are in school, and excluding non-vaccinated students from school would not prevent extramural transmission.

- Given the importance of parental involvement for raising children, and particularly in forming their children in chastity, it would be counterproductive to override their ethical objections and negate their authority on this issue.

## 3. How Can HPV Immunization Programs Best Serve the Health of Patients and Society?

*Physicians should take advantage of questions about or requests for HPV vaccination to address broader adolescent health issues. Campaigns for widespread immunization against HPV should not undermine efforts to reduce non-marital sexual activity and to promote chastity.*

A visit to the clinic for vaccination against HPV infection, as well as tetanus, diphtheria, pertussis, and meningococcal disease, presents an opportunity for the physician to discuss the broader range of health issues faced by adolescents. Such issues include the benefits of healthy eating and regular exercise, as well as the risks posed by drug and alcohol use, driving while intoxicated, and extramarital sexual activity. To the greatest extent possible, physicians should respect and support parents, who have the primary responsibility for protecting and raising their children, and assist them in this task.

At the same time, support for Gardasil<sup>®</sup> and future vaccines against STIs should not undermine efforts by physicians, parents and society to promote chastity because

- Neither Gardasil<sup>®</sup> nor other vaccines can address the many other harmful STIs that are prevalent at high levels;<sup>21</sup>
- There are significant, harmful, non-infectious sequelae of premarital sexual activity that cannot be prevented by any vaccines, including increased risks for depression,<sup>22</sup> suicidal ideation,<sup>23</sup> and future divorce,<sup>24</sup> and
- Premarital sexual activity is often only one instance of a spectrum of related risky behaviors (including tobacco, alcohol and substance abuse) that must be addressed consistently for the sake of teenagers' health.<sup>25</sup>

An explosion in the number and severity of STIs has been one result of the breakdown in sexual morality over the last 40 years. Gardasil<sup>®</sup> can help to address *one* consequence of the spread of HPV, i.e., cervical cancer. At the same time, to best promote the health and happiness of adolescents, physicians, parents and social institutions should redouble their efforts to promote chastity. Consistent messages about and support for this virtue will not only help to reduce disease, but will help individuals, couples, and marriages to flourish.

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