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Marketing HPV Vaccine

Implications for Adolescent Health and Medical Professionalism

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IN PROMOTING ADOLESCENT HEALTH, immunization is frequently a cost-effective intervention, advancing “not only the functioning and opportunities of adolescents themselves, but also the quality of their adult lives.”¹ Gardasil, Merck’s new vaccine against 4 types of human papillomavirus (HPV), might achieve these goals. Used properly, it might benefit adolescent health and public health. Nevertheless, critical and unresolved questions remain and are addressed in this article. What are the consequences of this manufacturer’s decision to market its HPV vaccine primarily as an anticancer vaccine? Is the vaccine being targeted to adolescents at greatest risk and who stand to benefit most? Did professional medical associations (PMAs) that received funding from the company provide members with unbiased educational materials and balanced recommendations? Did the PMAs ensure that marketing strategies did not compromise clinical recommendations? In all, was the design and implementation of vaccine policy for adolescents consistent with scientific knowledge?

Brief History

This HPV vaccine was approved by the US Food and Drug Administration in

See also pp 750 and 795.

The new vaccine against 4 types of human papillomavirus (HPV), Gardasil, like other immunizations appears to be a cost-effective intervention with the potential to enhance both adolescent health and the quality of their adult lives. However, the messages and the methods by which the vaccine was marketed present important challenges to physician practice and medical professionalism. By making the vaccine’s target disease cervical cancer, the sexual transmission of HPV was minimized, the threat of cervical cancer to adolescents was maximized, and the subpopulations most at risk practically ignored. The vaccine manufacturer also provided educational grants to professional medical associations (PMAs) concerned with adolescent and women’s health and oncology. The funding encouraged many PMAs to create educational programs and product-specific speakers’ bureaus to promote vaccine use. However, much of the material did not address the full complexity of the issues surrounding the vaccine and did not provide balanced recommendations on risks and benefits. As important and appropriate as it is for PMAs to advocate for vaccination as a public good, their recommendations must be consistent with appropriate and cost-effective use.

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2006,² and worldwide sales in 2008 were \$1.4 billion.³ In the United States, 25% of girls aged 13 to 17 years have received at least 1 of 3 recommended doses.⁴ To achieve this penetration, the marketing of this vaccine broke with traditional practices. Heretofore, vaccines had been identified by the disease they were preventing (measles, mumps) or by their creators (Salk or Sabin). This HPV vaccine followed a different model. It was identified by a trade name, Gardasil, and promoted primarily to “guard” not against HPV viruses or sexually transmitted diseases but against cervical cancer.⁵ The marketing campaign that followed, accord-

ing to Merck’s chief executive officer, proceeded “flawlessly.”⁶ In 2006, Gardasil was named the pharmaceutical “brand of the year” for building “a market out of thin air.”⁶

Marketing this HPV vaccine as an anticancer vaccine appears to have enabled its manufacturer to circumvent possible parental and public unease with an antidote to sexually

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transmitted diseases. But in doing so, the company bypassed public health officials who would have spearheaded a risk-sensitive vaccination campaign.⁷ So too, this manufacturer understandably wanted as many adolescents as possible to be vaccinated. But the pursuit of this goal was neither cost-effective nor equitable.⁸ It meant rather than concentrating on populations in geographic areas with excess cervical cancer mortality, including African Americans in the South, Latinos along the Texas-Mexico border, and whites in Appalachia,⁹ the marketing campaign posited that every girl was at equal risk: "Your daughter could become 1 less life affected by cervical cancer."¹⁰

Recognizing that physicians' recommendations would be important to promote vaccine acceptance by families, and that, in turn, physicians' recommendations reflect endorsements by PMAs, Merck awarded sizable educational grants to PMAs in adolescent and women's health and oncology. The funding encouraged many PMAs to undertake or intensify vaccination activities.

The HPV Vaccine

Three decades of research and clinical trials led to the HPV vaccine. Investigators first linked HPV infections to cellular changes in the cervix and HPV-16 to pathogenesis of cervical cancer.^{11,12} Other HPV types were then identified to have a causative role in cervical and anogenital cancers.¹³ Using these findings, Merck developed and tested an HPV-16 vaccine; as reported in 2002, women receiving this vaccine were free of persistent infection for the duration of the 17-month study. Because of "ethical and scientific" concerns,⁵ investigators did not make cervical cancer their end point, substituting, as a "reasonable surrogate,"⁵ persistent HPV infection. Still, they concluded that "[i]mmunizing HPV-16-negative women may reduce their risk of cervical cancer."⁵

The manufacturer next designed a vaccine against 4 types of HPV: 16 and

18, high-risk types, and 6 and 11, which have been linked to genital warts.¹⁴ When tested on 12 167 females aged 15 to 26 years, the vaccine protected against persistent HPV infections in those without previous infection.¹⁵ "Widespread immunization of female children and adolescents," the publication concluded, "may result in a substantial decrease in HPV-16-related and HPV-18-related cervical disease, including cervical cancer."¹⁵

Accompanying editorials were more circumspect. The vaccine appeared most effective against the least dangerous cellular changes and not protective or therapeutic for women with prior infections. Although HPV-16 and HPV-18 were most frequently associated with cellular changes, "the contribution of non-vaccine HPV types . . . was sizeable."¹⁶ Another editorial suggested that "[t]he new treatment raises many scientific, medical, economic, and sociological questions."¹⁷

Differences of perspective have persisted. One article suggested that the vaccine was beneficial but strongly recommended against mandatory vaccination.¹⁸ Another commentator noted, "I do believe that Gardasil protects against HPV 16 and 18, but the effect it will have on cervical cancer rates in this country is another question entirely."¹⁹ A cost-effectiveness analysis estimated that the vaccine would be cost-effective only if administered to girls younger than 16 years and only if it eventually demonstrates efficacy for longer than 5 years.²⁰ An accompanying editorial pointed out, "We still lack sufficient evidence of an effective vaccine against cervical cancer."²¹ No data were available to establish the duration of efficacy, possible adverse effects on natural immunity, whether vaccinated women will forgo Papanicolaou tests, and whether after suppressing HPV-16 and HPV-18, "other strains may emerge as significant oncogenic serotypes."²¹ Accordingly, the editorial concluded, "With so many essential questions still unanswered, there is good reason to be cautious about in-

roducing large-scale vaccination programs."²¹

Experience With Hepatitis B Vaccine

Merck's prior experience with its hepatitis B virus (HBV) vaccine helped frame its strategy for this HPV vaccine. Both the company and federal agencies initially targeted the HBV vaccine for a limited market. The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), which issues vaccine guidelines, defined the target population for HBV vaccine narrowly: health care workers who may have contact with blood and other bodily fluids, men who have sex with men, intravenous drug users, prisoners and staff in custodial institutions, and pregnant women in high-risk groups.^{22,23} The vaccine manufacturer did not suggest that because hepatitis B infections may lead to liver cirrhosis and liver cancer, the vaccine should be universal. Nor did it challenge the ACIP's presumption that most Americans were at low risk of contracting or dying from hepatitis B-related liver diseases, which in 1982 amounted to approximately 4000 cases. Although 800 individuals died annually from hepatitis B-related liver cancer, the vaccine manufacturer did not promote the vaccine as an anticancer product.²²

The HBV vaccine was not initially used by high-risk groups, and hepatitis B rates did not decline.²⁴ One reason was an absence of government reimbursement programs; as one analyst explained, "services for junkies and gay men were not a popular line item."²⁵ The ACIP, disappointed by the results, in 1991 proposed universal infant vaccination,²⁶ "before the humans who carried it had a chance to make the behavioral choices that spread it."²⁵ The American Academy of Pediatrics and the American Academy of Family Physicians endorsed the recommendation.²⁷

Nevertheless, use of the HBV vaccine lagged. A 1992 Merck-funded study reported that two-thirds of pe-

diatricians and one-third of family physicians thought universal vaccination desirable; however, only half the pediatricians and one-quarter of family physicians made HBV vaccination standard practice.²⁷ Solo practitioners were unwilling to stock the vaccine or await insurance company reimbursement, and many parents objected to adding another injection to the immunization schedule.²⁷

In 1994, to reduce the number of unvaccinated children, Congress enacted the Vaccines for Children Program, covering uninsured and Medicaid-eligible children. Administered by the CDC, the program purchases ACIP-recommended vaccines and supplies them to state and local health departments, who in turn distribute the vaccines to participating clinicians.²⁸ Once funding was available and universal vaccination recommended, use of the HBV vaccine soared. By 2002, 90% of children younger than 3 years had received it.²⁹

Role of Professional Medical Associations

The manufacturer's marketing strategy for this HPV vaccine sought to overcome the obstacles that its HBV vaccine had encountered: avoid limiting the vaccine to high-risk populations, promote it for all women, and secure government reimbursement and mandates. To these ends, Merck funded established PMAs including the American College of Obstetricians and Gynecologists and smaller groups, including the American Society for Colposcopy and Cervical Pathology (ASCCP), the Society of Gynecologic Oncologists (SGO), and the American College Health Association (ACHA).

American Society for Colposcopy and Cervical Pathology. One recipient of this funding was the ASCCP, a society whose members perform colposcopies, removing and analyzing cervical tissue from patients with abnormal Papanicolaou test results.³⁰ Funding colposcopists to promote an HPV vaccine may seem unusual, because these clinicians have little occasion to rec-

ommend or deliver immunization. Moreover, should the vaccine become standard, the number of cervical lesions requiring analysis would likely decrease. Nevertheless, ASCCP leaders perceived vaccine promotion as an opportunity to turn a potential financial liability into an asset. They urged members to educate colleagues, legislators, and the public about the new anticancer vaccine. As one ASCCP president, a Merck consultant and speaker's bureau member,³¹ explained, "2006 will also bring the dawn of the new age of HPV vaccines," requiring "a whole new group of practitioners to educate about HPV and cervical disease."³² The ASCCP's members, he pointed out, should move beyond diagnosis to prevention through "education and the newest weapon in our arsenal, vaccination."³³ This HPV vaccine provided the society with a new mission. "Rather than sinking off into the sunset, our society is newly energized . . . We are on the rise!"³²

With funding from the HPV vaccine manufacturer, the ASCCP created an "Educate the Educators" program, training members to promote vaccine use, especially in "smaller and mid-sized communities that lack clinicians who have expertise in this area." At the day-long program, participants received a Speaker Lecture Kit, "HPV and the New HPV Vaccines Program," and a disc containing 173 slides.¹⁰ The kit's Overview states that "ASCCP trainers will . . . discuss the key points that each slide is designed to address. You also will receive training on how to give an effective presentation. By the end of the training you should feel comfortable with the material and able to give Local Education Programs in your own community."¹⁰

The ASCCP also established a product-specific Speaker Support Center with a registry of members who completed the course and where they had lectured. The manifest purpose was to assist "in finding venues for additional programs."¹⁰ But another function may have been to show the company the value of its investment. Although the ASCCP did not provide

continuing medical education (CME) credit, as stated in the Overview it arranged opportunities for CME-accredited courses through "grand rounds, in-service opportunities, patient education forums, risk management and quality improvement meetings, and professional association/society meetings."¹⁰ The ASCCP would maintain the Speaker Support Center, which would in turn maintain a registry of educators to be shared with "industry sponsors, hospitals, medical associations, and other who can facilitate local speaking engagements."¹⁰ By July 2007, participants had lectured to more than 11 000 health care professionals, as stated by the Friends of the ASCCP.¹⁰ "These trained speakers are helping doctors and advanced practice clinicians in every state better understand HPV and the value of the new vaccines and tests coming to market."¹⁰

The Speaker Lecture Kit, part technical, part public relations, is divided into 9 modules that enable speakers to "customize . . . talks for specific groups," (as stated in the notes to slide 1¹⁰) including pediatricians and gynecologists. The notes accompanying the overview slide (slide 42¹⁰) for module 4, which discuss the natural history of HPV infections, state that "[i]t is important to understand the natural history of infection in order to understand who to target for vaccination and to be able to talk to both patients and parents about the need for vaccination."

The notes accompanying the introductory slide (slide 2¹⁰) of module 1, "The Impact of Vaccines on Global Health," explain that the slides in this section are for lay audiences and physicians who "do not deal with vaccines on a daily basis." Diphtheria in 1900, notes slide 3, killed more Americans than cancer, with an average of 3 cases per year in the United States in the 1990s. Polio is another "excellent example" of vaccine effectiveness. According to the slide, in 1954, 18 000 cases of paralytic polio had occurred in the United States. In 2005, the disease was eradicated in the United States (slide 4).¹⁰

The slides then shift to cervical cancer. Medical and lay audiences should be told that as important as vaccines were to infectious diseases, the HPV vaccine was to cervical cancer. The notes accompanying the module on the "Conventional Pap Test" describe it as a "dominating technology," and then observe, "HPV vaccines appear to be another 'dominating technology'" (slide 16).¹⁰ Cervical cancer screening is described as "secondary prevention," identifying a precursor lesion; the HPV vaccine is primary prevention that would "eliminate the cause of cervical cancer" (notes, slide 13).¹⁰ The notes accompanying slide 68 acknowledge that in the United States, "only 4,400 women died of this disease" but also add, "Each day 13 women die of this disease in the U.S."¹⁰ According to slide 65,¹⁰ worldwide, cervical cancer is the second leading cause of cancer death in women, with 233 000 deaths in 2000.

The Speaker Lecture Kit presents "results to date" and includes unpublished data from the manufacturer. The module called "The Potential Impact of HPV Vaccines" reflects the HBV experience. "Some clinicians involved in the U.S. cervical cancer screening program have questioned the need for HPV vaccination in the U.S." (notes, slide 113).¹⁰ Was it cost-effective? The answer: other vaccines exist for relatively unusual diseases (rotavirus, meningococcal disease) and many newer vaccines are "not inexpensive" either, according to the notes to slide 119.¹⁰ Although no cost estimate is provided for this HPV vaccine, it notes that the meningococcal vaccine costs \$82 for 1 dose. Notably, this HPV vaccine would eventually cost \$360 for the required 3 doses.³⁴

The Speaker Lecture Kit encourages speakers and their audiences to help in "convincing states and federal agencies to pay for the vaccine, convincing insurance to pay for it [and] encouraging state mandates for use" (slide 131).¹⁰ "All of us who are involved with cervical disease are going to need [to] work at the state and local levels to assure that the HPV vaccines are funded" (notes, slide 128).¹⁰

The Speaker Lecture Kit also contains suggestions on how to best educate the public. For example, older women may not think they are at risk, but changing ages and patterns of marriage increase their vulnerability. "Today, over half of all women marrying in the U.S. are 30 years or older and less than 25% of those marrying are under the age of 25 years. Many of these unmarried . . . women are obviously having multiple partners and their partners are having multiple partners therefore placing them at risk for acquiring new HPV infections" (notes, slide 162).¹⁰ Moreover, parents do not realize how many young children are sexually active. "Some parents believe that vaccination can wait until later. Many parents don't realize that many children in middle school are already sexually active" (notes, slide 142).¹⁰ Finally, since parents might be uncomfortable discussing a vaccination for a sexually transmitted disease, "downplay the sexually transmitted infection (STI) issues surrounding HPV" (notes, slide 154).¹⁰

Although some slides in this Speaker Lecture Kit note the uneven distribution of cervical cancer rates, the material does not call attention to the particular needs of those most at risk. Instead, the final slides propose that women older than 26 years might ask for the vaccine despite prior HPV exposure. In such cases, the physician is instructed not to minimize efficacy but to tell the patient that she might not have been exposed to HPV-16 and HPV-18. "It is reasonable to question whether we should deny safe and highly effective vaccine to older sexually active women" (notes, slide 157).¹⁰

Society of Gynecologic Oncologists. Another group funded by this HPV vaccine manufacturer was the SGO. Founded in 1968, the SGO is a subspecialty organization of obstetricians and gynecologists who treat cancers of the reproductive tract.³⁵ Like other PMAs, the SGO promotes its members' interests. For example, it formulated guidelines for patient referrals so that Medicare would reimburse the subspecialty

at a higher rate.³⁶ It also sought to improve medical training and increase research funding, particularly for early detection of ovarian cancer.³⁷

These efforts notwithstanding, the SGO was concerned about its future as a subspecialty. The 2001 presidential address³⁸ argued that the current tools of surgery, radiation, and chemotherapy "will look like crude and barbaric relics of a less sophisticated past. We cannot slash, burn, and poison our way into the future." The development of innovative treatment strategies will mean that "we will witness the transformation of our specialty from a surgically based to a medically based discipline."³⁸ One case in point: HPV vaccine in preventing cervical cancer.³⁸

Determined to increase industry funding, the SGO in 2006 established what was in effect an HPV vaccine speakers' bureau.³⁹ Funded by Merck, along with GlaxoSmithKline, Cytoc, and Myriad, the Physician Education Awareness Campaign was overseen by an "education resource" panel.^{39,40} Panel members, some with financial ties to Merck, composed the curriculum and, initially, delivered the talks (34 speakers in 16 states).^{41,42} The intended audiences were physicians and other health care professionals.⁴⁰

The SGO teaching materials omitted cautionary qualifications. The frequently asked questions section, for example, opened with "Why is this vaccine important?" The answer repeated the manufacturer's explanation: "This is the first vaccine directed against a cancer."⁴³ On rates of cervical cancer, the answer first noted the worldwide incidence and then declared that the disease "often affects younger women, taking the lives of mothers or making motherhood an impossible dream for others."⁴³ It did not include data on disparities in cervical cancer incidence and outcomes. This section also failed to include questions such as "Do I still need Papanicolaou tests?" "How long will efficacy last?" "How long has the vaccine been used?" and "Might risks outweigh benefits?"

The SGO next made the slide set available to all members, solicited them as speakers, and alerted them to Merck's stipulations. "They will be required to report to SGO where and when they have made presentations. This particular caveat is important as it is part of the sponsorship agreement SGO has reached with Merck for their support of the educational program."¹⁰ The SGO also began planning its next campaign, a "consumer-driven outreach initiative."¹⁰

American College Health Association. The ACHA was founded in 1920 and defines itself as "the principal advocate and leadership organization for college and university health."⁴⁴ Its members deliver student health care, including vaccinations.⁴⁴ It, too, wanted to be "proactive in developing corporate, federal, or foundation grant opportunities."⁴⁵

With funding from this vaccine manufacturer, the ACHA created an HPV Vaccine Toolkit for clinicians, including talking points, sample e-mail messages to students and parents, sample press releases, and public service announcements.⁴⁶ If a female student responded "no" when asked if she was sexually active, clinicians were supposed to explain that the HPV vaccine is most effective for her.⁴⁶ If she was sexually active, clinicians were instructed to say that she probably had not been infected with all 4 viruses.⁴⁶

A sample letter/e-mail to students announced a new vaccine "that protects against HPV—and it could help save your life."⁴⁶ It listed college students' everyday worries—dates, examinations, roommates—and declared, "Well now there's something you don't have to worry about anymore. And this worry is a big one. Why worry about cervical cancer?"⁴⁶ Sample public service announcements reiterated the message: "Hey ladies. You worry about tests. . . . You worry about your next date. Well now there's something you don't have to worry about any more—and it could help save your life."⁴⁶ Sample letters to parents included the following: "Will she

get good grades? Will she call home often? The last thing you want her to worry about is cervical cancer. . . . Encourage your daughter to 'Be Smarter and Get Vaccinated' at the Student Health Service—it could help save her life."⁴⁶ In none of these cases was Merck funding mentioned.

In November 2006, the ACHA featured a company-funded webcast, "HPV Vaccine Update."⁴⁷ Some 350 members viewed the webcast and 120 received CME credit for it.⁴⁸ Five of the 11 webcast presenters and program committee members had received expense reimbursement from the company, had participated in its speaker's bureau, or both.⁴⁷ The ACHA, however, only asked that the relationships be disclosed. "It remains for the participants to determine whether the faculty's outside interests may reflect a possible bias."⁴⁷

Conclusion

As marketing of this HPV vaccine demonstrates, pharmaceutical company campaigns can undercut the most cost-effective and appropriate use of new agents to the detriment of adolescent health. By making this vaccine's target disease cervical cancer, the sexual transmission of HPV was minimized, the threat of cervical cancer to all adolescents maximized, and the subpopulations most at risk practically ignored.

That these arguments were delivered by PMAs is cause for concern. Professional medical associations are obligated to provide members with evidence-based data so they can present relevant risks and benefits to their patients. To this end, PMAs must become more transparent about their relationships with industry, disclosing both the precise funding and technical assistance they have received to develop and disseminate the promotional products.⁴⁹ Under no circumstances should PMAs administer product-specific speakers' bureaus, nor should they accept funding that requires them to report activity to the donor. It is important for PMAs to

advocate for vaccination as a public good, but recommendations must be consistent with appropriate and cost-effective use. In no other way will adolescents' or anyone else's health and quality of life be enhanced.

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Study concept and design: S. Rothman, D. Rothman.

Acquisition of data: S. Rothman.

Analysis and interpretation of data: S. Rothman, D. Rothman.

Drafting of the manuscript: S. Rothman, D. Rothman.

Critical revision of the manuscript for important intellectual content: S. Rothman, D. Rothman.

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