

# HPV Vaccine Marketing Practices Questioned

BY DIANA MAHONEY

Women at the highest risk for human papillomavirus infection were among the least likely to get the message that there is a vaccine that can protect them, editorialists said in a special communication published in JAMA.

Sheila M. Rothman, Ph.D., and David J. Rothman, Ph.D., of Columbia University, New York, contend that Merck & Co. promoted its quadrivalent human papillomavirus vaccine Gardasil as an anticancer agent, maximizing the threat of cervical cancer and minimizing the sexual transmission of the virus.

"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, the marketing campaign posited that every girl was at equal risk," Dr. Rothman and Dr. Rothman wrote (JAMA 2009;302:781-6).

Further, Merck's marketing strategy included awarding "sizeable educational grants" to professional medical associations in adolescent and women's health and oncology to encourage these organizations to undertake or intensify vaccination activities, according to the authors.

In an interview, Pamela Eisele, a spokeswoman for Merck, denied the claims. "We did not require any reporting or review of any materials developed," Ms. Eisele said. "Merck provides independent grant support to professional medical as-

sociations that develop and distribute their own educational information about HPV and cervical cancer to broad audiences. Merck did not have any input or influence over the content of the materials those organizations developed."

"We value our relationships with these groups and conduct our interactions with strict adherence to the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals," said Ms. Eisele. In addition, "Merck closely follows the standards for commercial support of continuing medical education established by the Accreditation Council for Continuing Medical Education."

Dr. Rothman and Dr. Rothman charged that the role of several professional medical associations in the marketing of the HPV vaccine "is cause for concern."

Professional medical associations "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."

One recipient of Merck funding, the American Society for Colposcopy and Cervical Pathology (ASCCP), used the grant money to create a day-long program to educate its members on vaccine use. Further, the society developed a Gardasil-specific speaker support center that included a registry of members who completed the educational program and a database of when and where they presented, Dr.

Rothman and Dr. Rothman said. The society also "arranged opportunities for CME-accredited courses" through various venues.

Attendees of the ASCCP educational program receive a Speaker Lecture Kit of nearly 200 slides with information on cervical cancer risk for medical and lay audiences as well as strategies for convincing government agencies to mandate HPV vaccination and for convincing insurers to pay for the vaccine, the editorialists noted. One of the slides recommended downplaying the fact that HPV is a sexually transmitted infection to minimize parental discomfort, according to Dr. Rothman and Dr. Rothman.

The ASCCP's member clinicians "have little occasion to recommend or deliver immunization," and could potentially see a negative economic benefit from a successful vaccination effort, yet "ASCCP leaders perceived vaccine promotion as an opportunity to turn a potential financial liability into an asset," and to re-energize its society, according to Dr. Rothman and Dr. Rothman.

"That is not the case," Dr. L. Stewart Massad, chair of the ASCCP's Practice and Ethics committees, said in an interview. "We have long recognized that the current [cervical cancer] prevention system is flawed. Although prevention based on Pap testing, colposcopy, and destruction of precursors is effective, it is expensive, intrusive, in-

sensitive, and nonspecific, and it results in the overtreatment of thousands of women each year."

Given the potential for conflicts of interest associated with an industry-supported educational program, "we set up internal systems to evaluate the materials for bias, and I reviewed all of the materials independently," Dr. Massad said,

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noting that he accepts no financial support or grant money.

Merck also gave grant money to the Society of Gynecologic Oncologists (SGO).

Dr. Rothman and Dr. Rothman wrote that the SGO was concerned about its future as a subspecialty and perceived the HPV marketing opportunity as a way to springboard its transformation from a surgically based to a medically based discipline. The organization used the funding from Merck and other companies to create a physician education campaign, which was overseen by a resource panel that included some members with financial ties to Merck.

The materials created by the SGO panel "omitted cautionary qualifications," according to Dr. Rothman and Dr. Rothman. Further, the materials "did not include data on disparities in

cervical cancer incidence and outcomes," nor did it include questions about the vaccine's history and efficacy, whether the risks outweigh the benefits, or a discussion of the continued need for Pap tests.

Additionally, as part of the sponsorship agreement with Merck, society members who used the teaching materials were required to report to the society where and when they presented the material, Dr. Rothman and Dr. Rothman said.

The American College of Obstetricians and Gynecologists also received grant money for HPV vaccine education.

In an interview, Dr. Hal C. Lawrence III, vice president of practice activities for ACOG, emphasized that the college "thoroughly reviewed the evidence before making any recommendations about the HPV vaccine."

"We wouldn't make any recommendations if we didn't feel strongly about the importance of the vaccine, both in the prevention of cervical cancer but also in other HPV illnesses," he said. "Although the incidence of cervical cancer has diminished dramatically, the incidence of venereal warts, condyloma, and abnormal Pap tests is still significant."

Dr. Rothman and Dr. Rothman concluded that professional medical associations should refrain from promoting product-specific speakers bureaus and refuse funding that requires reporting activity to the donor.

Neither reported having relevant financial disclosures. ■

## Surgeons Hope to Dispel Myths

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of the organization is a real plus, agreed Dr. Charles E. Miller, a past president of the AAGL (formerly the American Association of Gynecologic Laparoscopists), who is not a member of the group.

Most of the time, the sharing of best practices across surgical specialties is something that only happens in the hallway when there's time to find out what a colleague has been doing. That's one of the major reasons why certain techniques will become prevalent in one specialty and lag behind in another, said Dr. Miller, who is also the director of minimally invasive gynecologic surgery at Lutheran General Hospital in Park Ridge, Ill.

Dr. Miller, who advocates increased training as well as recognition for mini-

mally invasive gynecologic surgeons, said he has high hopes for the Memphis Robotic Surgery Society. While the adoption of laparoscopic surgery has been slow in gynecology, Dr. Miller said he is seeing real enthusiasm for the use of robotic techniques, even among physicians who shied away from adopting other minimally invasive techniques. Many surgeons feel comfortable with the new robotic technology, he said, which offers sharp images, well-articulated instrumentation, and a console that they can become facile with quickly.

The goal of the members of the new Memphis Robotic Surgery Society is to create an environment where patients can get the minimally invasive approach that is appropriate for them, Dr. Stanford said. But since robotic surgery is still a

young and evolving field, there isn't clear agreement about who the appropriate patients are. In gynecology, robotic devices are being used for minimally invasive procedures for fibroids, endometriosis, and difficult hysterectomies, he said.

"We want to be able to give patients an option to get minimally invasive surgery," said Dr. Stanford, who runs a fellowship program in minimally invasive gynecologic surgery at the University of Tennessee. "We want to do it the right way."

Another aim of the society is to dispel myths and show the benefits of robotic procedures, said Dr. Todd Tillmanns, president of the group and a gynecologic oncologist at the West Clinic in Memphis. As someone who focuses on robotic surgery, Dr. Tillmanns said he hears a lot of myths—for example, that robotic procedures can't be performed on obese patients or on patients with pri-

or surgeries. Studies have shown that those statements aren't true, he said, and that in fact the techniques have many advantages for patients.

In gynecology, patients experience significantly less blood loss, less pain, and return to their normal activities in about a fifth of the time it would take them if they had undergone a traditional open procedure, Dr. Tillmanns said. He added that he wants to get that message out to patients and physicians and that the new society can help do that through prospective data collection.

The society is beginning to collect data on surgeries to help the physicians look across specialties at patient outcomes, positioning, port placement, anesthesia issues, and other data points that could help make the surgeries more effective over time. They hope to be able to pool and share their data with other groups. "The spirit of it is to be collaborative," Dr. Stanford said. ■