



Statement
Bobbie S. Gostout, MD
Society of Gynecologic Oncologists

Vaccine and Related Products Advisory Committee Meeting
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I am Dr. Bobbie S. Gostout, associate professor, Division of Gynecologic Oncology, Mayo Clinic, Rochester, MN. I am here today representing the Society of Gynecologic Oncology (SGO).

The Society has received educational grants from Merck to support our Annual Meeting on Women's Cancer™. We do not receive any financial support from the vaccine division. My travel is being paid for by SGO.

I am here today to represent the physicians who treat women for whom prevention has failed. Gynecologic oncologists are obstetrician-gynecologists with an additional three to four years of training. We are trained in the comprehensive management of patients with female reproductive cancers, including both surgery and the administration of chemotherapy. Almost all practicing gynecologic oncologists are members of the Society of Gynecologic Oncologists.

It is especially important that you hear our perspective because you have an opportunity today to approve a vaccine that can reduce the incidence of cervical cancer and precursor lesions. Not since the introduction of the Papanicolaou (Pap) test over a half of century ago has such an opportunity existed.

Since the introduction of the Pap test, the incidence of cervical cancer in the United States has been dramatically reduced and the death rate has declined by 74%. Despite this important advance, each year over 10,000 women will learn that they have invasive cervical cancer and 3,700 women will die from a potentially preventable disease.

Let me put a human face on these statistics. This cancer disproportionately affects women during their childbearing years and childrearing years resulting in childless couples and, for those with advanced disease, leaving behind motherless children.

I see these women in my practice very day. One patient, _____ particularly exemplifies the human cost of this disease. After years of normal Pap tests, she was diagnosed with an invasive cervix cancer six months following the birth of her second child. She endured an initial surgery to diagnose the cause of her bleeding and a second surgery to treat the cancer. She required subsequent radiation therapy. Because of these procedures, she was away from her children and family more than she was with them. Over the next five years our eyes met in fear many times when a symptom or physical exam finding gave us reason to worry that the cancer was back. With each scare, I understood the unspoken plea in her eyes – “I can’t die now! My young family needs me!”

Now more than five years out from treatment, we are feeling confident that this patient will survive. Unfortunately, I could also tell you similar tales of others who did not. I caution you to not console yourself by telling yourself quietly that this cancer does not happen to women like your family members. I assure you that many of the patients that I see could easily be your sisters, cousins, aunts or nieces. This cancer affects real women- -women like you, your family members and me.

What is so heart wrenching for me to treat women like _____ is the knowledge that we are so close to being able to eliminate this cancer.

SGO urges you take the next step in this quest by today approving the **broadest possible application** of the vaccine in order to afford maximum protection to as many people as possible as early as possible.

On behalf of the Society of Gynecologic Oncologists, I thank you for this opportunity to provide a statement and appear before you today. Attached is a copy of the Society’s position statement on a cervical cancer vaccine.



February 17, 2006

**The Society of Gynecologic Oncologists
Statement on a Cervical Cancer Vaccine**

Cervical cancer affects more than 10,000 women and families each year in the US and hundreds of thousands worldwide. An estimated 3,700 women lost their lives to this potentially preventable disease in 2005. This cancer disproportionately affects women during their childbearing and childrearing years resulting in childless couples and, for those with advanced disease, leaving behind motherless children. Poor and underserved minority women are especially at risk due to inadequate access to basic preventative tests and lack of health knowledge concerning cancer prevention. In the 30 year "War on Cancer," prevention has often been cited as the loftiest goal with the greatest impact on the burden of disease. For cervical cancer, this goal is becoming a reality.

Research has identified the human papillomavirus (HPV) as the causative agent of most cervical cancers, with HPV 16 and 18 being the most common cancer causing types. Because persistent HPV infection is the leading cause of cervical cancer and its precursors, research has focused on ways to prevent HPV infection. The Society of Gynecologic Oncologists (SGO) is responding to important breakthrough research, which shows that cervical cancer can be prevented through vaccination.

Peer reviewed manuscripts are now available describing results from several large randomized clinical trials of prophylactic HPV vaccines. Both major trials show dramatic efficacy in preventing HPV 16 and 18 infections, as well as efficacy in preventing precancerous cervical lesions. Combined studies include more than 6,000 vaccinated children, adolescents and adults, all without serious adverse events.

While actual cancer events will not be measurable for several decades, HPV infection and the development of precancerous cervical lesions are appropriate surrogate biologic endpoints. Evidence shows that virus-like-particle (VLP)-based vaccines induce protective immunity to HPV 16 and 18 in 90-100% of vaccinated individuals thereby protecting individuals (or their partners) from the most feared consequence of persistent infection – cervical cancer.

The Society of Gynecologic Oncologists (SGO) endorses the concept of vaccination to prevent cervical cancer and encourages the responsible federal agencies to take action to review, approve and release vaccine(s) as early as possible following appropriate review. Furthermore, SGO encourages the broadest possible application of the vaccine in order to afford maximum protection to as many people as possible and as early as possible. Specifically, SGO supports the implementation of a program that includes vaccination of females and males, and endorses a catch-up program for young adults.