



Statement of the  
American Social Health Association  
Before the

Vaccines and Related Biological Products Advisory Committee  
U.S. Food and Drug Administration  
Safety and Efficacy of GARDASIL  
May 18, 2006

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Good afternoon, I am Deborah Arrindell, Vice President of Health Policy for the American Social Health Association. I appreciate the opportunity to address the Committee on behalf of the American Social Health Association (ASHA). For 92 years, ASHA has sought to eliminate sexually transmitted infections (STIs) and their harmful consequences for individuals, families and communities. We have had an HPV and Cervical Cancer Resource Center since 1998. We talk to thousands of people each year about HPV through our contact centers that include a daily live chat room and an email response service that will answer approximately 4,000 emails about HPV and cervical cancer this year. ASHA provides accurate, accessible information and we are proud that our website is the number one ranked (non-governmental) Google site for information about HPV. We appreciate the opportunity to address the Committee on safety issues related to Gardasil.

The development of the vaccine Gardasil is an exciting and critically important advance in the tools available to prevent cervical cancer. We appreciate the Food and Drug Administration's (FDA) plan to expedite consideration of this vaccine and hope it will soon be widely available. We are confident that this committee will recommend approval of Gardasil when it is certain of its efficacy and safety as confirmed by the data from the clinical trials.

ASHA has first hand experience with the complexity of communicating about HPV and cervical cancer. Research shows that both patients and providers find HPV, with its variable clinical presentations, difficult to fully understand. We believe that communicating about the vaccine may be challenging for providers and understanding the complexities will be challenging for consumers. Targeted provider and public education efforts will be essential.

We believe it is imperative for consumers to be aware, that even with vaccination, comprehensive cervical cancer screening and follow-up programs must be continued. **The FDA should require that the package insert direct health care providers, administering the vaccine, to advise all female patients of the importance of routine cervical cancer screening and appropriate follow-up.**



As the Committee knows, Gardasil has proven over 99% effective against two types of HPV that cause 70% of cervical cancer. Continued screening will be essential for detection of the remaining 30% of cancers from high-risk HPV types not included in the vaccines.

Additionally, the vaccine does not protect against HPV infections that were acquired before vaccine administration. And, whether the vaccine provides multi-decade protection or efficacy decreases with time is unknown. This information must be communicated to consumers.

Finally, although outside the jurisdiction of this committee, it is important to acknowledge that approval of this vaccine in no way insures access for low income, and other at risk populations. The Department of Health and Human Services has noted that cervical cancer rates are sentinel markers for larger, systemic health care concerns that must be addressed by cancer control and other strategies. The access issues that are currently problematic in high risk and low resource populations will not be alleviated by vaccine availability alone. Access for those groups who bear the highest burden of cervical cancer must be a public health priority.

In summary, we urge the FDA to develop mechanisms to ensure that providers fully educate patients that Pap testing and HPV testing will continue to be essential. It will be decades before most cohorts of women will have received the vaccine. In addition, the vaccine does not protect against prior infection and the duration of protection is unknown.

We are excited about the prospect of rapid approval and availability of this vaccine. This vaccine will be an important step forward in the control of cervical cancer not only in this country but worldwide. But we urge policy makers to continue support for cervical cancer screening. Relaxing existing cervical cancer control efforts would be harmful.

The American Social Health Association will do everything our resources permit to support widespread availability and acceptability of cervical cancer vaccines. We appreciate FDA's commitment to providing accurate information regarding the benefits and limitations of the products it approves. We would welcome an opportunity to further discuss these HPV vaccine issues with members of the Committee or FDA staff. Thank you.