



National Coalition of STD Directors

Statement of the
National Coalition of STD Directors
to the
Vaccines and Related Biological Products Advisory Committee
U.S. Food and Drug Administration
Safety and Efficacy of GARDASIL
May 18, 2006

The National Coalition of STD Directors represents the nation's directors of public health sexually transmitted disease prevention programs in states, large cities/counties and territories of the United States. We work to strengthen STD programs through multiple strategies, including increasing awareness of the social and medical impact of STDs. As a result, we know first hand the medical and social impact of HPV – including cervical cancer and genital warts.

Our programs run the nation's STD clinics. Every day our clinics treat people with genital warts caused by HPV. We know the pain and embarrassment our patients suffer. We also know that these patients may well have been exposed to other strains of HPV – those that cause cervical cancer. In short, our programs are on the frontlines of the STD epidemic.

Because HPV is so common, we believe that a vaccine is indeed the most effective strategy for controlling this ubiquitous infection. And, because we see the disproportionate burden of STDs in high risk, low income communities, we know that a vaccine is the most effective way to address the health disparities outcomes that accompany these infections.

We applaud the development of Gardasil. We were pleased to learn of the Food and Drug Administration's (FDA) plan to expedite consideration of this vaccine. We hope that the FDA will issue its decisions about approval by June 8 as originally indicated. The data from the clinical trials is exciting and promising and we see no reason why Gardasil would not be approved.

Many of our concerns do not fall within the jurisdiction of the FDA. We are concerned about the ability of public health program, which provide services to those with great need and few resources, to provide this very expensive vaccine. We are greatly concerned that our clinics will simply not have the resources

NCS D

1275 K Street, NW - Suite 1000
Washington, DC 20005-4006
202.842.4660
202.842.4542 (Fax)
info@ncsddc.org
www.ncsddc.org

Board of Directors

OFFICERS • *Chair*, Thomas Bertrand, *Massachusetts* • *Chair Elect*, Tim Lane, *Utah* • *Treasurer*, Raegan Camuso, *Pennsylvania*
Secretary, Julia Ashley, *Minnesota*
MEMBERS • Theresa Henry, *Virginia* • Heidi Jenkins, *Connecticut* • Peter Kerndt, *Los Angeles* • Laurie Kops, *Montana*
Pam Pitts, *Tennessee* • Charlie Rabins, *Illinois* • Karla Schmitt, *Florida* • Bruce Trigg, *New Mexico*
Ex-Officio, Gail Bolan, *California* • *Executive Director*, Donald J. Clark

necessary to provide vaccines. We are concerned that the providers in our system will not have the training needed to understand the promise and limitations of vaccines. We are aware that communicating about the vaccine may be challenging for our providers and understanding the vaccine benefits and limitations will be difficult for our patients. Targeted provider and public education efforts will be essential.

However, we have two concerns that we believe are critical safety issues within the jurisdiction of this committee.

- As an important safety consideration, we encourage the FDA to mandate, that health care providers advise women and girls of the importance of continued routine cervical cancer screening and appropriate follow-up. Continued screening will be essential for detection of the HPV types that cause cancers but are not included in the vaccine. In addition, since it is unclear how long vaccines will remain protective, it will be important for people to continue to be screened.
- We urge the FDA to mandate that providers make all consumers aware that the HPV vaccine will not provide protection against other STDs. Those receiving vaccines must protect themselves against HIV and other sexually transmitted infections. Requiring that those messages are provided by those administering vaccines is a critically important safety issue.

Across the country, STD programs are joining with immunization, cancer prevention, and women's health groups to prepare for vaccine implementation. These programs are working in coalition with public and non-profit organizations with which they have not worked in the past.

NCSA looks forward to working with its members to support widespread availability of GARDASIL and any future sexual health vaccines. Please let me know if our members can be helpful to this committee in anyway. For more information, please contact me directly. Thank you.

Donald J. Clark
Executive Director
National Coalition of STD Directors
1275 K Street, NW, Suite 1000
Washington, DC 20005