

## **A missed shot: The failure of HPV vaccination state requirements**

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In an article appearing in the current issue of *Clinical Pharmacology & Therapeutics*, experts from the University of Pennsylvania Center for Bioethics and Johns Hopkins Berman Institute of Bioethics review the controversy surrounding the human papillomavirus (HPV) vaccine debate, and its effects on ethical and public health issues.

“The arrival of Gardasil® was a major achievement for cervical cancer prevention efforts worldwide,” says Jason Schwartz, MBE, Researcher, Penn’s Center for Bioethics and Department of History & Sociology of Science, and lead author. “Much of the initial enthusiasm for the vaccine was lost amid the controversy surrounding state proposals that would require teenage girls to be vaccinated in order to attend school. The events of the past year reveal important lessons regarding ways to introduce new vaccines successfully and in an ethically responsible manner.”

In the months leading up to the June 2006 approval of Gardasil®, there was unprecedented media coverage and support from even socially-conservative groups. However, this support for the vaccine began to slow in September 2006 following the introduction of a bill in the Michigan state legislature that would require the vaccination of girls attending public schools. Additional states also were quick to propose similar legislation. In response to the legislation, numerous groups expressed their opposition by arguing that it was either too soon to consider an HPV requirement, or that the sexual transmission of the virus did not warrant requiring the vaccine in schools.

The opposition grew when the governor of Texas issued an executive order requiring HPV vaccination for all girls entering the sixth grade. Critics of state HPV requirements called attention to how these policies violated obligations to respect parental autonomy. However, many critics often overlooked opt-out provisions, implying that the proposals made vaccination compulsory.

The authors note that, "Quite apart from whether it was prudent public health policy to implement state requirements for HPV vaccination so soon after the vaccine's licensure, these attacks on the state initiatives may have exacted a very real ethical price in terms of the public's understanding of the justifications for state vaccination requirements generally, as well as the public's understanding of the merits of the HPV vaccine itself." Additionally, they suggest that issues of price gouging, corporate profits, and political motives, may have also added to the opposition.

In order to move forward with cervical cancer prevention efforts, the authors suggest that attention be focused on assessing the long-term safety of the vaccine, while implementing effective patient and provider educational programs about HPV and the HPV vaccine, as this is the model that other successful vaccination programs have followed. "With a second HPV vaccine expected to be approved in early 2008, it is vital to understand the strategies that are most likely to lead to the long-term success of this remarkable weapon against cervical cancer," says Schwartz.

The authors also discuss the importance of designing and implementing HPV vaccination programs in developing countries. "Cervical cancer is a worldwide concern, but its impact is particularly severe in the developing world," says Schwartz. "It would be tragic if the negative attention created by the debate over HPV vaccine 'mandates' in the U.S. hamper efforts to make the vaccine available to those internationally who could

benefit most from it."

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