Good afternoon. My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center, the mission of which is to prevent vaccine injury and death through public education and to defend the informed consent ethic in U.S. vaccine policies and laws. We appreciate the opportunity to provide comment today.

First, I would like to clarify my previous comment on behalf of NVIC mentioned during the passage of the last meeting’s minutes. The statement that cervical cancer is highly treatable is based on fact and appears on the CDC’s website, as well as the Johns Hopkins website. However, in making this statement of fact, we don’t want to minimize the lives impacted and/or lost to cervical cancer. Our statement was made to request balance in policy decisions and messaging on HPV vaccine and the public’s right to access to accurate information when making vaccine decisions.

In that context, we offer comment on vaccine innovation, economic modeling and return on investment. Earlier a member asked how do we compete with the wheelchairs? – meaning the vaccine injured.

The law states, and I quote - The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines.

Thus, NVIC's answer would be don’t compete with the injured; show us the science and give us a choice. Provide transparency with the public when messaging on vaccines. Messaging must include that vaccination is not without risk, as demonstrated by science and the law. Vaccines, like many pharmaceutical products, carry the risk for injury and death; some that are known, and many that are not.

Findings by the Institute of Medicine’s over 25 years of reports demonstrate significant gaps in this understanding and results in over 90% of claims to the federal vaccine injury compensation program (VICP) being litigative risk claims. It is also widely acknowledged by research that vaccine adverse events are underreported and federally commissioned reports on the VICP indicate few are aware of the program’s existence.

Where is that messaging and transparency with the pubic? What is being done to assure that existing vaccines are providing optimal prevention of vaccine injury and death, given the acknowledged research gaps, underreporting of vaccine adverse events and lack of awareness that results in lack of compensation to the vaccine injured who have faithfully vaccinated?

Absent from NVAC conversations on vaccine innovation is discussion on the human right of autonomy and exercise of informed consent. People do not want to be treated like numbers and are not owned by the government. Utilitarianism should not be the foundation for public health law and policy, and law and policy cannot be made based solely on economic models that treat the vaccine injured as acceptable collateral damage for the greater good. The right and responsibility for making medical risk-taking decisions, such as vaccination, rightly belongs to the person taking the risk, not public health officials.

Finally, NVIC has long supported access to vaccines, as well as the critical need for an independent federal agency to monitor vaccine safety and oversee vaccine safety research. How will inherent conflicts of interests created by the public private partnership in vaccine innovation be addressed, given the lack of such an agency?

Thank you.
Good afternoon. My name is Theresa Wrangham and I am the Executive Director for the National Vaccine Information Center, the mission of which is to prevent vaccine injury and death through public education and to defend the informed consent ethic in U.S. vaccine policies and laws. We appreciate the opportunity to provide comment today.

Many thanks for the thoughtful presentations. Regarding self-administration of vaccine through micro-needle patches, we encourage the NVAC to begin discussions relating to how VIS distribution will be assured in accordance with federal law and what steps will be initiated with consumers to educate on vaccine reactions and injuries that may occur, how to report them, etc. given the lack of health care provider presence during administration may occur with use of this technology. We also encourage the NVAC to work with the ACCV on these issues.

Regarding NIS data and IIS systems, NVIC receives many complaints and concerns from the public regarding privacy, or lack thereof, being forced to participate in IIS systems, and the sharing of sensitive medical information that many in the public are not aware is being shared and used without specific consent. We also get specific complaints about the NIS phone calls and are aware that many do not want to participate due to privacy concerns.

We note that medical procedures, such as vaccination, use to be a private conversation with health care providers. With the advent of technology, privacy has eroded, often without consent of the person losing privacy. To my knowledge since monitoring this committee, the NVAC has never addressed privacy issues held by the public in this regard and NVIC encourages discussion on the preservation of privacy relating vaccine status, which is sensitive medical information, and policy consideration to make IIS systems opt in instead of opt out to uphold the right to privacy.

We also note that with regard to HPV prevention, data from ACIP’s February meeting indicates it may be decades before it is know if this vaccine impacts prevention, HPV infection resolves without complication in over 90 percent of infected individuals within two years, and that HPV associated cancers make up a small percentage of total cancer cases in the U.S. with some of the associated cancers having highly successful screening in place as well as being highly treatable. HPV also continues to be one of the most expensive vaccines in use in the U.S. today.

Thank you.