CASE 11

Should HPV Vaccine Be Required for School Entry?

ALEXANDRA M. STEWART AND MARISA A. COX

The Pattersons pulled into the visitor parking lot of the State House. "Wow, look at the size of the crowd! What are all these people doing here?" Mrs. Patterson wondered.

As she put on her glasses to read the signs they carried, the crowd approached the car and began chanting, "My daughter, my choice! My daughter, my choice!"

"Let's just turn around and go home . . ." Mr. Patterson's voice trailed off.

"Absolutely not! We've already talked about this. We've already agreed. We must participate. We have to tell our story!" Mrs. Patterson insisted.

With that they pulled into the last available parking space, exited their car and slowly began to wade through the thick crowd. The state police had erected barricades around the main entrance, but it was useless; most of those gathered had broken through. After passing through security, the Pattersons made their way to a large, crowded room. Some people were sitting quietly alone, while others talked excitedly in groups, and still others waved the same signs as those seen outside. The crisp morning air was frigid, but it was warm inside, and the Pattersons found two seats in the back. They sat down to wait for events to unfold.

Meanwhile, shielded from the audience by a partition, Senator Angela Jenson watched the gathering crowd. As a senior member of the committee, the senator was not a stranger to large, opinionated groups. It seemed that everyone was always trying to lobby her about one thing or the other. As she scrutinized the audience, she got the sense that today was going to be different. Her staff had received more calls from constituents regarding this topic than any other and the media attention was overwhelming. Nevertheless, she was surprised by the turnout for this hearing, and the growing groups of protesters and media representatives gathering in front of the tall windows. She knew that in order to ensure that things would not get out of hand she would have to set firm ground rules for conducting the session and anticipate possible outbursts from an emotional audience. She approached the podium to call the hearing to order. The audience fell silent; the chanting from the protesters outside drifted into the room.

"Good morning and welcome to the Committee on Health and Human Services' first legislative session of 2006–2007. I am Senator Angela Jenson, chair of the committee. Our first order of business is to decide whether we should require girls entering the sixth grade to be vaccinated with the new human papillomavirus vaccine—HPV vaccine for short. The purpose of today's hearing is to learn from the invited witnesses who will educate the committee regarding several issues surrounding the vaccine. Their testimony will help us make our decision. We have a full roster of witnesses today: a healthcare provider, a vaccine policy expert, and members of the public. Each witness will have 5 minutes to deliver his or her presentation. Following each presentation, we ask the witness to remain standing for any questions.

"I apologize if anyone had a hard time getting in, but there has been unprecedented interest in the subject of today's hearing. In fact, I understand that many state legislatures are considering the same question at this very moment.[i] Finally, let me say that the committee recognizes that this is

[i] The legislatures included those in California, Colorado, Connecticut, the District of Columbia, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New Mexico, New York, Ohio, Oklahoma, South Carolina, Texas, Vermont, Virginia, West Virginia, and Wisconsin.

an intensely emotional topic involving our children. However, the committee and I request that all audience members refrain from displaying any banners or signs. Of course, verbal outbursts or other disruptions of any kind will not be permitted. Anyone who does not follow these instructions will be removed. The meeting is now called to order.

"Our first witness is Dr. Michael Jenner, a pediatrician who practices at Metropolitan Hospital."

WITNESS 1

Dr. Jenner walked behind the podium. "Thank you, Ms. Chairperson and committee, for allowing me to discuss how children can benefit from one of the greatest achievements of public health."

Although many in the crowd were unaware of it, Dr. Jenner was alluding to a Centers for Disease Control and Prevention list of 10 great public health achievements, which included vaccination.[1]

"I first must tell the committee that the history of vaccines and recommended immunizations is long and has been profoundly productive."

Dr. Jenner went on to explain that vaccines have saved more lives than any surgical technique or any medication ever invented, including antibiotics.[1] He reminded those in attendance that population-wide vaccination has eradicated smallpox across the globe, and the incidence of diphtheria, polio, congenital rubella syndrome, and influenza type b have decreased by almost 100% in the United States.[2] He added that large-scale immunization programs have reduced U.S. infant mortality rates from 20% a century ago to only 1% today.[3] Because of the contributions vaccines have made to human health throughout history, he noted, most governments have developed policies that support comprehensive population-wide immunization programs.[4]

"But what do all of these achievements in the science of immunization have to do with why we are here today? I have a brief presentation that I hope will help the committee to understand the importance of immunization against HPV and the consequences of rejecting a mandate for sixth-grade girls."

Dr. Jenner nodded to someone near the light switch, and the lights dimmed as Dr. Jenner began clicking through his slide show.

The first slide explained that HPV is the most common sexually transmitted infection in the United States; it included the following statistics. Over 20 million individuals are infected. Half of these individuals are young adults between the ages of 15 and 24, and 6.2 million additional persons will become newly infected this year. Of these newly infected individuals, 4.2 million will be between the ages of 15 and 24. The infection usually develops shortly after the onset of sexual activity. More than 80% of all sexually active women will have acquired genital HPV infection by age 50 years.[5]

"These figures should illustrate just how relevant this threat is to our daughters," Dr. Jenner said.

He clicked to go to the next slide.

"Slide No. 2 shows us that there are over 100 strains of HPV, and that two types, 16 and 18, are associated with 70% of cervical cancer cases in the United States."[ii]

Slide No. 2 also showed that an estimated 11,150 women are diagnosed with cervical cancer and 3,700 die of it each year.[6] Additionally, HPV strains 6 and 11 cause 90% of genital warts, recurrent respiratory papillomatosis,[iii] and low-grade cervical abnormalities.[5]

"I know that some of you are thinking that HPV will never affect your daughter, because she is not sexually active and will refrain from sexual activity until marriage, and her husband will do the same. Some of you are even thinking that I have no right to tell you how to raise your families, and that the government certainly has no right to force parents to submit their children for any particular medical treatment. But, I ask you to reconsider.

"As the next slide shows, the age of sexual debut will vary, and there are alternative methods that can reduce the rate of infection, including abstinence, monogamy, limitation of the number of sex partners, and consistent and correct use of condoms."

Dr. Jenner used his laser pointer to emphasize two key points: that no single HPV prevention method is 100% effective;[7] and that research about the average age of sexual debut in the United States indicated that children as young as 11 could benefit from the vaccine.[8]

"This is why receiving three doses of the recently recommended vaccine, Gardasil, produced by Merck and Co., Inc., is so important. Further, the vaccine is most effective if administered *before* exposure to the virus."

Dr. Jenner's next slide indicated that the human papillomavirus vaccine (Gardasil) will protect against HPV strains 6, 11, 16, and 18. The vaccine is almost 100% effective and the protection it offers will last for at least 5 years.[5] The

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[ii] Strains 16 and 18 also cause cervical abnormalities, anal and anogenital cancers, and are present in approximately one third of head and neck cancers. Approximately 35,000 head and neck cancers occur each year in the United States, accounting for 5% of all cancer; they are more common in men. Incidence of vulvar cancer is rising among young American women. HPV 16 and 18 are involved in approximately 70% of vulvar and vaginal cancers. *See generally*, American Cancer Society.

[iii] Approximately 20,000 cases of recurrent respiratory papillomatosis develop per year in the United States. It affects males and females. It is a rare, debilitating, and recurrent disease that causes obstructive papillomas (noncancerous tumors or warts) to grow in the respiratory tract. It is most common in juveniles and is believed to be maternally transmitted during birth. The median number of surgeries to remove the growths and maintain an open airway is 13, with a range of 2 to 179. *See MMWR*, 2007:56(No. RR-2) at 7.

Food and Drug Administration approved Gardasil for sale in the United States in June 2006. Dr. Jenner asserted that it is safe and effective, and is recommended by the Advisory Committee on Immunization Practices (see Box 11-1).

"ACIP has recommended the HPV vaccine for girls and women ages 9 through 26."

The next slide indicated the recommendations:

1. Girls ages 9 and 10 may be vaccinated at the discretion of their parents or guardians and physician.
2. Girls ages 11 or 12 are to be routinely vaccinated.
3. Females ages 13 through 26 should be vaccinated as a catch-up if they have not already received the vaccine.[9]

"As you can see from the recommendations, sixth-grade girls typically fall in the 11- or 12-year-old age category and should receive the vaccine as part of their routine pediatric visits.

"You may have also heard this vaccine is very expensive and many families who want the vaccine have even decided that their budgets will be unable to stretch to cover it. Let me reassure you. Insurance coverage or alternate funding is available."

He clicked to the next slide.

"This slide describes the public and private programs that are available to help families afford the vaccine. Thus far, my patients who are covered by private health insurance have spotty coverage for the vaccine. This is not unusual, because insurers take a period of time before covering any newly recommended vaccines and I expect that those of you who are privately insured will see the coverage catching up soon."

Dr. Jenner added that Medicaid covers all vaccines as soon as they are recommended.[10] He further explained that those who do not have health insurance coverage of any type would be eligible for vaccines free of charge through a federal program called the Vaccines for Children program (VFC). The VFC program purchases almost half of the vaccines administered in the United States and distributes them to eligible providers.[11]

"I am a registered VFC provider," he said. "Thus, all of my eligible patients will receive all three doses of the vaccine free of charge."

He described another federal program, called the 317 program, that may provide free or reduced vaccines to children,[12] and he added that, depending on their budgets, state and local programs might provide the vaccine to children who do not qualify for 317 or VFC.

As the lights came back on, Dr. Jenner concluded his speech. "I appreciate the opportunity you have given me to speak with you this morning and look forward to working with my patients and their families to ensure that HPV does not affect them in the future. I will stand for any questions."

Senator Jenson responded, "Thank you Dr. Jenner. Are there any questions or brief comments?"

A gentleman sitting in the middle of the room stood and asked, "Dr. Jenner, my son is about to start sixth grade. If preventing HPV is such an important part of health care, why is the vaccine only for girls?"

Dr. Jenner commented that many others had asked him the same question, and explained that the vaccine is recommended for females only because no boys or men were included in the clinical trials or tests that studied the vaccine.[13] But further research that focuses on males was under way.[iv,5]

"When the trials are concluded, and if they show that the vaccine is safe and effective for boys, I expect that a recommendation for males will be forthcoming. By the way, this is anecdotal evidence, but some of my colleagues have already administered the vaccine to their sons. I anticipate that use in both boys and girls will be common once the studies are completed and a recommendation is made. Until then, please remember that males can contract and pass the infection and also experience adverse health effects of their own if they become infected. That is why the same discussions

BOX 11-1 The Advisory Committee on Immunization Practices

The Advisory Committee on Immunization Practices (ACIP) is made up of experts in fields associated with immunization who have been selected by the secretary of the U.S. Department of Health and Human Services. The committee's only job is to provide advice and guidance to the secretary, the assistant secretary for health, and the Centers for Disease Control and Prevention. ACIP drafts and issues written recommendations for the routine administration of vaccines to children and adults in the civilian population. The recommendations are based on research that identifies the appropriate age, dosage, precautions, and contraindications for each vaccine.[6] A contraindication is a condition that makes administering the immunization inadvisable.[7]

[iv] On October 21, 2009, ACIP issued recommendations for the permissive use of Gardasil in males aged 9 through 26 to reduce the likelihood of acquiring genital warts. However, ACIP did not recommend the vaccine for routine use in males.

that are taking place with and about our daughters must also include our sons."

A woman in the front of the room stood and asked, "If my daughter is not sexually active, why must she receive the vaccine now? I would prefer that she wait and make the decision for herself when she becomes an adult."

"Another excellent question. The simple answer is that the vaccine will not be as effective because most adults will already have been exposed to at least one strain of the virus. As a result, the recommendation is for 11- and 12-year-old girls. The virus is transmitted via sexual contact. Remember, the age of sexual debut varies for each individual, and it is best to administer the vaccine earlier rather than later in order to provide protection before exposure. You can think about it like any other vaccine. We do not always know when we will be exposed to a disease, but we are vaccinated to ensure that we are protected *just in case* we are exposed. This does not mean that the exposure will occur, only that we are protected. For example, we routinely receive immunizations for tetanus but never really expect to step on a rusty nail. The HPV vaccine is no different. Prevention is always better than treatment. The goal is to vaccinate girls so that they will not have to endure the medical interventions required to treat cervical cancer and other HPV-related diseases. Thank you for your question."

After a pause during which no one else stood or raised a hand, Senator Jenson approached the podium. "As there are no further questions, our next witness is Ms. Angela P. Vincent, a professor from State University."

WITNESS 2

Ms. Vincent took her place and greeted those in attendance. "Good morning Chairwoman Jenson and committee members. I am pleased to participate in this important discussion regarding whether to require HPV vaccine for school entry. This debate will provide the committee the opportunity to consider the scientific, legal, ethical, and financial issues surrounding compulsory vaccination. I will discuss how school entry requirements impact our nation's health and how vaccines are financed through public and private payment systems.

"One of the first questions I am asked, no matter the audience, is 'how is it possible that the government can force me to submit my child to unwanted medical treatment?' In fact, mandating immunizations is deeply embedded in the United States legal system. The Tenth Amendment of the Constitution grants states the right to pass laws that require the vaccination of children for school entry, and all states have done so. The validity of these laws has withstood multiple challenges in state and federal courts."

Ms. Vincent then explained that the laws outline the specific immunizations that are required and also allow children to be excused from the requirements for one of the following three reasons:

1. Exemption may be granted for medical reasons in all 50 states.
2. Exemption may be granted for religious reasons in 48 states.
3. Exemption may be granted because of the parent's personal beliefs in 20 states.[14]

However, despite the availability of exemptions, over 95% of all school-age children ultimately receive mandated immunizations.[15] For example, in 2006, an estimated 23% of children aged 19–35 months had not received all the recommended immunizations. By age 5 years, 95% of children were up to date. The increase in coverage rates is directly associated with school immunization requirements. The laws have proven to be the most effective mechanism ever devised to vaccinate children.[15]

"Because of these mandates," Ms. Vincent continued, "the use of all recommended vaccines has increased, the incidence of vaccine-preventable diseases has decreased, and diseases that were once common have all but disappeared. Disparities in vaccine coverage have been dramatically reduced. Children who have low-income families or whose families have been unable to establish a medical home receive vaccinations because of school requirements. Finally, the laws increase public funding for vaccines.

"Based on the facts, we can safely assume that a state law requiring HPV immunization is a good public policy decision because it will achieve more widespread protection against cervical cancer than if we were to rely on other policy reforms such as parental education and persuasion.

"It is essential that every community vaccinates enough of its citizens to achieve herd immunity, which is the resistance to a disease that develops in the community when a sufficient number of individuals are vaccinated."[v]

Ms. Vincent stressed that in order to ensure that immunization rates remain high, public and private stakeholders including government, academia, vaccine manufacturers, healthcare providers and consumers must continue to work together.[15]

"The existing framework for financing vaccines is designed to accommodate newly recommended vaccines. HPV vaccine will be distributed through this mechanism, which has already been implemented. The public funding streams for vaccines include Medicaid and the State Children's Health Insurance Program. These programs are intended for children who live in families with low income," Ms. Vincent said.

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[v] Herd immunity protects those few individuals who are unable to receive vaccinations due to age or health status. Each vaccine-preventable disease requires a different percentage of coverage before herd immunity is achieved; this necessary coverage ranges from 75% for mumps to 94% for pertussis.

She reiterated what Dr. Jenner indicated, that the VFC program provides free vaccines to children through age 18 who are Medicaid eligible, uninsured, or who have private insurance that does not provide coverage for the HPV vaccine, or who are Native American or Alaska Native.[16] Also, federally qualified health centers and rural health clinics may charge for vaccines on a sliding scale.

Ms. Vincent went on, "The private funding streams for vaccines include employer-based or individually purchased medical insurance. Many insurers will reimburse enrollees and providers for the cost of HPV vaccine according to their current cost-sharing and payment standards. Every healthcare service is assigned a current procedural terminology code that determines the amount of reimbursement a provider will receive from an insurer. A current procedural terminology code has already been established for HPV vaccine, an indication that it is already considered standard medical practice.

"As the committee reviews the many questions surrounding an HPV vaccine mandate, I hope my comments have informed this discussion. I will be happy to answer any questions. Thank you."

Senator Clark raised his hand with a question. "Thank you Professor Vincent. Can you tell me how much the vaccine will cost? I understand that it is the most expensive vaccine to date. I am concerned a school entry requirement will break the state's budget and that families will not be able to pay for a mandatory vaccine."

"There is no single answer to that question," Ms. Vincent began. "The price of the vaccine is dependent on the purchaser. Many people have heard that each dose costs $120, making the three-dose series a whopping $360. However, that price is reserved for only those few individuals who will purchase the vaccine privately, without health insurance or access to government support. As Dr. Jenner and I explained, most Americans do not pay the full retail price for vaccines out of pocket.

"If the purchaser has private insurance, the vaccine will be subject to the plan's usual cost-sharing arrangements. If the purchaser is a Medicaid or SCHIP beneficiary, has private insurance that does not cover the vaccine, or is Native American or Alaskan Native, the vaccine will be free through the Vaccines for Children program.[16] Let me remind you that since VFC vaccines are financed by the federal government, there is no fiscal impact on the state.

"If our Department of Health wishes to purchase vaccines for those who do not otherwise qualify for different programs, the department may take advantage of a predetermined federal discount rate. The purchase, of course, will be made with state funds. So you can see that very few individuals will pay full retail price, and the state will never pay full price."

"Thank you Professor Vincent, I think I understand now," Senator Clark commented.

Senator Jenson stood and said, "Thank you, Professor Vincent, for your helpful testimony today. If there are no further questions, I now recognize the next witness, Mrs. Elizabeth Ellsworth."

WITNESS 3

Mrs. Ellsworth spoke loudly and clearly. "Thank you for allowing me to voice my absolute outrage over this unacceptable and inappropriate intrusion of my family values. I do not believe that the government should be able to interfere with my rights, as a parent, to make medical decisions for my children! Forced vaccination is un-American enough, but now you tell me that my 11-year-old daughter is going to contract a sexual disease while sitting in her classroom! It's just too much! HPV is not spread by casual contact; there is no reason to require vaccination for school attendance.

"I am afraid that if my daughter receives this vaccine, that she will think that she is protected from all diseases and that it is a green light for her to have sex! I believe that the school system should work *with* families to deliver the same message to our children about early and inappropriate sexual activity. And that message should be abstinence only! We should support the federal programs that teach abstinence until marriage as the sole strategy for preventing early sexual activity and sexually transmitted infections among adolescents. Indiscriminate administration of the HPV vaccine to young children does not do that. I hope that the committee rejects the attempt to displace my authority over my children and to legislate family values. In order to protect our way of life, every member of this committee must vote against this bill. If this measure is adopted, I will certainly not be voting to reelect any member of the committee come the next election."

An agitated audience member rose and exclaimed, "Girls deserve protection! We all believe our daughters are not sexually active, but the truth of the matter is that they engage in sex very frequently! If there were a vaccine for a predominantly male cancer, there would be no debate . . . we would readily accept a mandate. We want to save our children, and there is no point in making this a political debate, it is a life or death situation, and I believe we owe it to our daughters to protect them!"

Hoping to calm the crowd, Senator Jenson returned to the microphone, saying, "Mrs. Ellsworth, thank you for your comments." As security guards swiftly escorted the heckler from the room, Senator Jenson asked for questions.

A woman stood and asked, "If this measure is implemented, will the school distribute any information about it to our girls? I am concerned that any information given to our children may be too graphic and explain more than they are equipped to handle at this age."

Senator Jenson once again approached the podium. "Thank you for the question. I can assure you that we have

no plans to distribute any additional material to the students. I anticipate that parents will receive an explanation of the requirement as well as information regarding HPV infection, the vaccine, the connection between HPV and cervical cancer, and how the requirement can be satisfied. The materials will be approved by both federal health authorities and each school district. You may also wish to call our curriculum coordinator to request a copy of the sexual education materials that will be used in health classes this year."

Senator Jenson introduced the fourth witness, Mr. Jason Samuels.

WITNESS 4

"Thank you, Senator Jenson and the committee. I have two children, a boy, 8 years old and a girl, 14. I am here to warn the committee about the dangers and certain harm that will result if this vaccine is required for our daughters. I have information that the government is keeping from the public. Did you know that the Food and Drug Administration approved Gardasil on an expedited basis?"

Gardasil was approved after only 6 months of review.[17]

"This process is highly unusual—what's the rush? I think that the government favors big business over the health and safety of our children. Did you know that Merck—the company that makes Gardasil—produced Vioxx®, the drug that is responsible for several heart attacks and deaths? Merck wants Gardasil to be mandated because they want to recover profits that were lost to several Vioxx® lawsuits. Additionally, there are recent reports that three girls died shortly after taking Gardasil. How many more deaths are we going to allow while supporting drug manufacturers? I do not want my daughter to be a subject in a mass government experiment. Trying to force Gardasil on us is just like the abuse that African American men suffered during the Tuskegee experiments. Did the government ever apologize? Did the government ever compensate their families for their loss?

"In closing, I want the committee to stand for *our* children and *not* the drug companies. My daughter, my choice!"

Senator Jenson rose, looked hesitantly into the audience, and asked for questions. A woman sitting near the front of the room rose. "I have a daughter about the same age as yours. You speak of several deaths that may have been associated with the vaccine. What about the young women who die of cervical cancer each year?"

Mr. Samuels looked at the woman and replied "I feel sad for the families who have lost loved ones to cervical cancer, but with proper screening, these tragedies can be prevented. I am more uncomfortable exposing my healthy daughter to a medical intervention when effective, tested, and long-term detection and treatment methods are already in place. I hope that you will not put your healthy daughter in harm's way when all you have to do is ensure that she gets all appropriate screenings."

A man stood and said, "Mr. Samuels indicated that the vaccine may be dangerous and he seemed to say that the government can't be counted on to compensate victims for their pain. I don't understand why we're even talking about compensation. Shouldn't we be talking about avoiding harm? If the vaccine isn't required, we don't have to worry about risk and compensation."

Senator Jenson approached the podium. "Thank you for your comments. Perhaps Professor Vincent can help us understand how the government addresses vaccine injuries. Professor Vincent?"

Professor Vincent returned to the podium. "Thank you Senator Jenson. While in a perfect world, vaccines would never cause harm to those who receive them; unfortunately, this is not a perfect world. We must realize that all medical interventions come with some amount of risk. The U.S. government acknowledges this fact and has established a program called the Vaccine Injury Compensation Program—VICP. The VICP provides a system—the vaccine court—for individuals who have been injured by vaccines to receive compensation."

Box 11-2 describes the VICP and vaccine court.

"The vaccine court program is funded through a tax on each dose of vaccine administered. While some of you might think that this system is just another mechanism to shield manufacturers, it is important to remember that vaccines are vital to public health, are costly to develop and manufacture, and that the government buys most of the doses administered in the United States at a lower, negotiated rate. If manufac-

BOX 11-2 The Vaccine Injury Compensation Program and the Vaccine Court

The Vaccine Injury Compensation Program's vaccine court is an alternative to the traditional legal system. Persons who believe that they have been injured by a vaccination file claims before the U.S. Court of Federal Claims, instead of a state court. The claims are heard by a special master instead of a judge. Claims may be filed if the injury has lasted for more than 6 months after the administration of the vaccine or resulted in a hospital stay and surgery or resulted in death.[18] Injured parties may be represented by a lawyer, but this is not [illegible][19]

turers were to be exposed to the high cost of litigation from various lawsuits in different state courts, there would be little incentive to remain in the market and we would all suffer the consequences of reduced supply, lack of innovation, and an increase in cases of vaccine-preventable diseases.

"Claims for injuries associated with the HPV vaccine may be brought to the VICP. While this is not directly related to a decision to mandate the vaccine, the committee should note that the VICP provides another safeguard to ensure that the vaccine is administered responsibly. Thank you for this important question."

Senator Jenson said, "Thank you Mr. Samuels and Professor Vincent. We appreciate your taking the time to come here today and will consider your comments as we deliberate. If there are no further questions, our next witness is Ms. Roberta Espinoza."

WITNESS 5

Ms. Espinoza made her way to the podium and began. "Thank you for the opportunity to speak with you this afternoon. I have two daughters, one who will be starting sixth grade at Parkland Middle School in the fall. When I heard that there was a shot to prevent my girls from developing cancer, I couldn't help but think how times have changed, how medical science has advanced, and how promising the future looks for my kids. When I was growing up, we didn't know much about cancer, and there was limited opportunity to prevent it. This is why I am so excited about Gardasil. We now have the means to protect our children from developing cervical cancer. I did some research on my own about HPV infection and the numbers of people who are infected, how it is spread, Gardasil and its connection to cervical cancer, and the importance of early preventive measures. I believe that Gardasil is a very good thing and that girls should be vaccinated.

"I understand that some parents may believe that allowing young girls to be vaccinated may send a different message about their personal conduct than what we teach them at home. I understand that some may be worried that any deviation from an abstinence-only message will encourage early sexual activity. But I also understand that if my daughters do not receive the vaccine, I am putting them at risk unnecessarily. As their mother, my job is to protect my children from all potential threats. I am not willing to take the chance that they could develop cervical cancer simply because I am uncomfortable talking to them about their bodies. I owe them more than that."

Ms. Espinoza took aim at abstinence-only programs. She asserted that the programs have failed and that research evaluations by Congress have showed that abstinence-only education makes no difference at all.[7]

"They do not prevent early sexual conduct," she said. "I learned that students involved in these programs have the same rates of sexually transmitted infections and unintended pregnancies as anybody else. While the abstinence message may reflect the values and aspirations of many parents, clearly, it is not a reality for millions of teenagers.

"I also understand that some of you may still be concerned that if we begin to teach our children about safe sex, that they will think that it is okay to start having sex at a young age. However, I have done some research on the topic."

While doing her research Ms. Espinoza discovered that studies show the following:

1. Adolescents did not change reported rates of sexual activity or increase the frequency of unprotected intercourse when they were educated about the availability of emergency contraception.
2. The percentage of adolescents who had ever had sex did not change when condoms were available or in schools with condom availability programs.[7]

"In light of this evidence, I do not think that introducing HPV vaccine to our girls will encourage early sexual activity.

"If it were up to me, I would add HPV vaccine to the required list of vaccines. I want my daughters to be vaccinated. I want all girls to be vaccinated early. I want my children to receive comprehensive sexual education that includes a full discussion of ways to protect themselves from all the negative consequences of unprotected sex. I want you to have the courage to take advantage of the opportunities for a healthy future that the vaccine promises. I thank you, Senator Jenson, and I thank the committee."

Once again, Senator Jenson rose and asked for questions. A woman seated in the back of the room rose and asked: "I thought that at the very least, as an American citizen, I had the right to make decisions about my family's religious and moral upbringing. The school has no place teaching my children about sex when I have chosen an abstinence-only message for them. That is what our religion requires. Mandating this vaccine will force the issues upon us and result in conversations that should not be had with children, especially at school. School is a place for reading, writing and arithmetic, not sex education. This committee has no right to violate my religious beliefs. How can I stop the school from dictating how I raise my family?"

Senator Jenson asked, "May I take this question Ms. Espinoza?"

Ms. Espinoza nodded, and Senator Jenson reminded the crowd that many school mandates include three types of exemptions, including those for medical contraindications[vi,20] and those for religious and philosophical beliefs.

[vi] Contraindication—A characteristic or attribute of an individual that may be temporary or permanent that prohibits the administration of a drug, vaccine, or other therapeutic intervention.

"I can assure you that any requirement will include, at a minimum, an exemption for medical contraindication. The committee will also consider additional exemptions to accommodate philosophical and religious beliefs. I can assure you further, that your comments will be considered and that we will have the conversations necessary to ensure that we have balanced the interests of religious expression with our obligation to protect the public's health. Thank you for your thoughtful comments.

"Our final witness is Mrs. Emily Patterson."

WITNESS 6

It was finally Mrs. Patterson's turn. She slowly made her way through the aisle to the podium. After she adjusted the microphone, she reached into her tote bag and pulled out an 8 × 10 picture of an attractive young woman in a silver frame. She took a deep breath and looked around the room.

"Good afternoon, Senator Jenson, committee members and guests. I am grateful to be able to talk with you all today. I'd like to introduce you to Tracy. Isn't she lovely? We always thought so. She loved to swim and bake. In early 2001, she began having stomach pains and unusual bleeding that went on for several months.[21] She never said anything to me or her father about it. She finally went to a doctor when her pain was so severe, she could not stand up. When her cervical cancer was diagnosed, it was already at stage IIB."

After diagnosis, cancer is identified by stages from zero to IV.[vii,22] Mrs. Patterson told the crowd that her daughter was 25 years old when she was diagnosed, which is younger than the usual victim.[viii,23]

"She did not visit a doctor earlier because she was trying to save money. You see, Tracy's job provided health insurance, but she always said that because she was just beginning her career straight out of college, she could not afford the premiums for something that she never used. After paying her student loans, rent, and buying fancy coffee, there was nothing left, so she took a chance. She missed her recommended Pap exams that most likely would have detected the disease early enough to save her life. What's the harm? She had always been so healthy and so athletic. We didn't press her. We should have.

"During the next 2 years, my daughter Tracy was forced to move back in with us and suffered through multiple rounds of brutal internal and external radiation, chemotherapy, surgeries, hair loss, weight loss, and unrelenting nausea, pain, and fatigue. Her uterus, cervix, most of her vagina, ovaries, fallopian tubes, colon, and rectum were removed. Then she tried experimental treatments at the National Institutes of Health outside Washington, DC. Through it all, we never gave up. We thought we were lucky because we could afford the expensive care.

"Tracy knew she would heal. Her hair would grow back, she would adopt children, her scars would be hidden, she would find another job, and she would rebuild everything. Tracy wanted to live. Of course, the end came too soon, and Tracy died when the cancer spread throughout her body. She was 27. Our only child is buried next to her grandparents and we visit her often.

"Tracy's father is with me today. We implore the committee to make the HPV vaccine a requirement for girls going to school. I have carefully listened to the other witnesses' concerns as they have been expressed here today."

Mrs. Patterson asserted that more than 4,000 women like Tracy would die that year.[24]

"Each one will be someone's daughter, someone's mother, someone's sister, someone's friend. And you will miss them. Isn't prevention better than all the latest treatments? Your honors, I believe that I have gone past my allotted time to speak, but don't you think our children are worth it?"

The room was silent as Mrs. Patterson placed Tracy's picture back in her tote bag. As she turned, Mr. Patterson was there to help her back through the room, through the chanting crowd outside, through the parking lot, and back to their car.

CONCLUSION

As the Pattersons made their way out, Senator Jenson gathered herself and approached the microphone, "Mrs. Patterson, I'm sure I speak not only for myself, but for the entire committee and our guests, when I thank you most sincerely for your moving testimony. We thank all the witnesses for their contributions today and of course our audience for their patience and cooperation. We will consider all comments carefully and intend to make our decision with the best interests of our children in mind."

About the Authors

Alexandra M. Stewart, JD, is an assistant professor in the Department of Health Policy at The George Washington University School of Public Health and Health Services. Professor Stewart has over 10 years' experience examining how state and federal laws impact U.S. vaccine policy and practice. She has completed analyses of the 2010 health reform initiatives to determine how changes will impact all areas of immuni-

[vii] Stage IIB = The cancer has spread beyond the cervix to the upper two thirds of the vagina and to the tissues around the uterus.

[viii] From 2002 to 2006, the average age of a woman diagnosed with cervical cancer was 48. Very few cervical cancer diagnoses (0.2%) are in women under age 20; 14.9% occur between ages 20 and 34; 26.2% between ages 35 and 44; 23.5% between ages 45 and 54; 15.8% between ages 55 and 64; 10.4% between ages 65 and 74; 6.6% between ages 75 and 84; and 2.5% ages 85 and over.[23]

zation policy, as well as how other laws influence immunization access. She directs Epidemiology of U.S. Immunization Law, a Centers for Disease Control and Prevention-supported initiative that conducts research and provides technical assistance to improve standards for immunization coverage and performance in children and adults. This project produced the largest single legal analysis of immunization policy ever undertaken and contributed to the development of essential tools for public health practice and policy. It has explored access to immunizations under Medicaid, the federal employee health benefit programs, and state insurance law, produced reports detailing immunization requirements for staff and residents of long-term care facilities, and reviewed state laws as they relate to the use of standing orders to deliver immunization services. Professor Stewart is also lead instructor of a graduate level course focusing on U.S. vaccine policy. She earned her law degree from The George Washington University Law School.

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