



The public radio show about law and American life

# Justice Talking Radio Transcript

**The HPV Vaccine: Should States Mandate Its Use?—Air Date: 7/2/07**

*Nearly half of the states are now considering laws that would require girls entering sixth grade to be vaccinated against the cervical cancer-causing human papillomavirus (HPV). The move raises important questions about the best way to encourage the use of a vaccine that has the potential of reducing cervical cancer. Will immunizing girls lead to more premarital sex as some parents and conservative groups fear? Should the vaccine's manufacturer who has a financial stake in widespread use of the vaccine be pushing mandates? Join us on this edition of Justice Talking as we take a detailed look at how the law affects health policy and whether mandating this vaccine is the best approach.*

*This transcript is being provided free of charge for educational purposes. The views expressed herein are those solely of the guests and do not reflect those of the Annenberg Public Policy Center or NPR. Although every effort is made to make a verbatim rendering of the program, this transcript may vary slightly from the audio version and may contain minor grammatical or spelling errors. For permission to reprint, please contact Laura Sider at the University of Pennsylvania's Annenberg Public Policy Center, (215) 573-8919.*

MARGOT ADLER: This is Justice Talking, from the University of Pennsylvania's Annenberg Public Policy Center. I'm Margot Adler. Not a lot of people know about HPV, or human papillomavirus. This is surprising since it's the most common sexually transmitted disease in the world. In fact, most women have had it. There are 40 strains of the virus, some of which cause genital warts. Many people don't even know they have it because they don't have any symptoms and it often goes away on its own. But this STD can also have serious health effects. Some strains of the virus can lead to cervical cancer.

There's a new vaccine which protects against some of these cancer-causing strains. Routine vaccination is recommended for girls, ages 11-12, with catch-up vaccines for girls and women 13 to 26 years old. It takes a series of three shots over a six-month period to get vaccinated. So far it's only approved for use in women and girls. Later in the show, the debate over whether states should mandate that girls get this vaccine, and we'll hear about an international health organization that is trying to distribute the vaccine to women in the developing world.

But first, to help us understand more about HPV and the vaccine is Cosette Wheeler. She is a professor at the University of New Mexico Health Sciences Center. She's been studying the link between HPV and cervical cancer for 20 years. Welcome to Justice Talking.

COSETTE WHEELER: Thank you for having me.

MARGOT ADLER: How many people are infected with the virus? For a disease so many people have very few people know about it.

COSETTE WHEELER: These viruses are extremely common and they're very easily transmitted. In the United States it's been estimated, for example, that 10 million men and women each are infected with papillomavirus at any one time. And if I walk in to a routine pap-test clinic for women 40 years and under, as an example, about 40 percent of women are infected with at least one if not more of these papillomaviruses. So they are extremely common and people don't even know that they exist because most people are not symptomatic.

MARGOT ADLER: But when you get a pap test the only ones that you find out about are the ones that would have a relationship to cervical cancer. So in other words, I could go in to a doctor, have a pap test, and in fact could have some forms of HPV that they could detect, but I wouldn't even know about that when I got my results?

COSETTE WHEELER: What happens with papillomaviruses, of the 40 different types that infect the human genital tract, about 20 of those--or about half--are associated with invasive cervical cancer.

MARGOT ADLER: Is the only way you can get cervical cancer by having an HPV?

COSETTE WHEELER: Yes. There's a small number of non-HPV cancers, .3 percent, but 99.7 percent--so nearly 100 percent--of invasive cervical cancer is caused by one of the 20 different HPV types I mentioned.

MARGOT ADLER: Tell me about the rates of cervical cancer. How many people are getting cancer? And how many are dying from it in this country?

COSETTE WHEELER: In this country right now the newest figures are somewhere under 12,000 women per year are getting diagnosed with invasive cervical cancer and of those women about a quarter are dying from the disease.

MARGOT ADLER: What do we know about the people in this country who are dying from it?

COSETTE WHEELER: What we know is generally there are a lot of disparities seen in the women who are dying from invasive cervical cancer. In order to die from invasive cervical cancer you are at a greater risk for that scenario if you come with extensive disease. That means you don't go to the doctor. It means you don't get pap tests. And it means that the people at risk for that are lower-income women, women who live in rural communities, immigrants who do not

have access to good health care. There's a variety of reasons. But at the same time it includes women who have health insurance but just don't go to the doctor.

MARGOT ADLER: Let's talk about this new vaccine. How long has there been a vaccine? And how does it work?

COSETTE WHEELER: The first licensed and only currently licensed HPV vaccine is the quadrivalent HPV vaccine that was approved by the U.S. FDA in May of 2006.

MARGOT ADLER: And that's Gardasil, right?

COSETTE WHEELER: That's Gardasil.

MARGOT ADLER: Gardasil by Merck?

COSETTE WHEELER: Correct. The quadrivalent vaccine targets four HPV types. Two of them are HPV 6 and 11. Those two HPV types, that are genital HPVs, don't cause invasive cervical cancer. They cause genital warts. And then HPV 16 and 18, the other two components of the vaccine, target the two main types worldwide that cause invasive cervical cancer. And they represent approximately 65 to 75 percent of all the invasive cancers in the world.

MARGOT ADLER: So it doesn't protect against all cervical cancer, as you said. This 35 to 25 percent are excluded from it.

COSETTE WHEELER: Yes, and that's actually the most important fact that people need to know about the current HPV vaccine. Gardasil--and I have to say that we all need to be aware also that there is a second HPV vaccine that has been submitted to the Food and Drug Administration for approval called Cervarix. Cervarix only contains two antigens, or targets, in the vaccine. But those two are the same components as Gardasil that are targeting invasive cervical cancer, HPV 16 and 18 prevention.

MARGOT ADLER: So this vaccine, which is GlaxoSmithKline's vaccine, basically targets cervical cancer but not genital warts?

COSETTE WHEELER: That's correct. But if you already are infected with the vaccine types that are prevented just in the case of Gardasil, four of the 40, or in the case of Cervarix, two of the 40, what happens is nothing. We don't really have any evidence that these vaccines help people who are currently infected. And we don't have any evidence that if you've been exposed in the past to those viral types that you gain any benefit. There may be some, but we don't know that.

MARGOT ADLER: So if you've already been infected, let's say, with 16, one of the ones that causes cervical cancer, does it make sense to still get vaccinated because you would be protected by 18, the other one that protects against cervical cancer?

COSETTE WHEELER: The problem with what you just said is that we don't know what we've been infected with in the past. The other component is there are no tests currently that provide that information. And even if there were, because a woman has no idea if she was exposed in the past, because there's no test for past exposure, getting a test now if it was available that said, oh, you don't have either one of these, would not be useful. But your point is well taken, which is that there is the possibility that if women were exposed to only one of the HPV vaccine types previously or currently that they may gain some benefit against the other infections. We just can't quantify that.

MARGOT ADLER: So are you worried that women will stop getting pap tests if they've been vaccinated?

COSETTE WHEELER: It's very possible. People use any excuse, including me, to not go to the doctor. It'll go away. I feel fine. I got that vaccine; I don't really need to go get one of those pap tests.

MARGOT ADLER: You told us that we can be tested for HPV. Why aren't we, and normally, and will such a test replace pap tests in the future?

COSETTE WHEELER: I and others certainly hope so. The reason that we have pap tests is obviously it's worked and it reduced the incidence of invasive cervical cancer in the United States and in other countries that have good pap programs by 80 percent. The reason we don't test for HPV in younger women routinely is that one in two people are infected, right? So what good would that do? And the truth is most people get rid of the viruses on their own. Very few get pre-cancerous lesions and have a problem.

MARGOT ADLER: Most women get pap tests as you said as part of their annual health exam. But do most women know the relationship between the pap test and HPV?

COSETTE WHEELER: Not in my experience, which is one great thing for, I hope, for anyone listening, is that it's almost amazing to me: I've been studying these viruses in populations for a long time and I would go into exam rooms to talk to patients that we would be asking to participate in research studies and ask them if they knew why they're getting a pap test. And the most common responses would be: Well, that's for my annual cancer screening. And then you could ask them: Well, do you know why we look for cancer that way? And they would say: Well, not really, I just do what they tell me to do. And the truth is that we don't tell women the reason you get a pap test, the main and nearly only reason, is that we are looking for changes in your cells that are caused by common viruses that infect everyone, cause usually no problem, but in some women they do cause abnormalities and they are called human papillomaviruses. And you should not be freaked out that people have these common infections. They are sexually transmitted, but they're like bacteria on our skin. Everybody who is sexually active is exposed.

MARGOT ADLER: Cosette Wheeler is a professor at the University of New Mexico Health Sciences Center who studies HPV and cervical cancer. Thank you for talking with me today.

COSETTE WHEELER: Thank you.

MARGOT ADLER: To learn more about the human papillomavirus and the new vaccine, go to our website, [justicetalking.org](http://justicetalking.org).

\*\*\*\*\*

MARGOT ADLER: Coming up on Justice Talking, given how widespread HPV infection is, should states require that 12-year-old girls get inoculated? Many states are considering just such a move, which has some parental rights advocates up in arms.

UNIDENTIFIED FEMALE: You know, we certainly recognize that HPV infection can result from sexual abuse or assault or that a person may marry someone still carrying the virus. So, you know, these are strong reasons why even someone practicing abstinence and fidelity may benefit from HPV vaccines. But again, we don't feel that that overrides parental rights to make a decision about their child's health in this case.

UNIDENTIFIED FEMALE: Parental rights arguments have really been the red herring that far right groups have used to distract parents, framing this as a parental rights and choice issue...

MARGOT ADLER: Stay with us.

\*\*\*\*\*

MARGOT ADLER: This is Justice Talking, the public radio show about law and American life. I'm Margot Adler. A year ago the Food and Drug Administration approved Gardasil, a vaccine for girls and women nine to 26 years old. The vaccine protects against HPV or human papillomavirus, which is the most commonly sexually transmitted disease in the world and is the cause of cervical cancer. While the vaccine doesn't protect against all strains of HPV, it does inoculate against two strains that cause 70 percent of cervical cancers. Over 30 states have considered or are considering legislation mandating that girls in middle school get the vaccine. But when there is talk of requiring a vaccine for an STD for adolescent girls, controversy follows.

Here to talk with me about state mandates for the HPV vaccine are Moira Gaul and Julie Kay. Moira Gaul is the director of women's and reproductive health at the Family Research Council, a Christian, conservative group devoted to issues of family and faith. Julie Kay is an attorney for the Sexuality and Family Rights Program at Legal Momentum, a feminist law and public policy organization focusing on women's issues. Welcome both of you to Justice Talking.

JULIE KAY: Thank you.

MOIRA GAUL: Thank you.

MARGOT ADLER: Moira, let's jump right in. What's the problem with mandating this vaccine?

MOIRA GAUL: Well, what the Family Research Council believes is that there at base is just not sufficient public health justification for mandating the vaccine. And in this case it would then infringe upon the rights of parents to make decisions regarding their children's medical care.

MARGOT ADLER: Julie, why do you believe the vaccine should be mandated?

JULIE KAY: We think that there is a real public health justification because the virus is so widespread and because the vaccine is so effective, and that if vaccination is not made mandatory we'll have far lower participation rates, which in turns means a less effective fight against HPV and cervical cancer. And that particularly women of color and women in poverty are going to be the ones who get left behind, because they won't have the vaccine paid for and they won't be getting the public education efforts that come along with mandatory vaccination.

MARGOT ADLER: Moira, don't states have to include an opt-out provision for parents which allows them to say they don't want their children vaccinated? It could be for religious reasons, for philosophical reasons, or safety concerns. Even if a state mandates a vaccine, don't parents still have the choice not to vaccinate their children?

MOIRA GAUL: I think you're right. Most states permit religious and/or philosophical exemptions to vaccine mandates in addition to exemptions for medical contraindications. But, you know, we strongly feel that the opt-out policy could potentially mislead parents to believe that immunization with this particular vaccine, Gardasil, is necessary to protect their child's health while in the school setting. And in this sense it could be coercive and again violate their rights. We, in contrast, support an opt-in policy which would allow parents to make the decision themselves concerning their child's level of risk and whether or not to vaccinate. You know, we've been very much in support of the federal Vaccines for Children program picking up this particular vaccine so that it would increase coverage and thereby increase access to all individuals who would desire to have the vaccine.

MARGOT ADLER: Julie, in New Hampshire all child vaccinations are voluntary. And as the Washington Post reports, the state still has one of the highest rates of child immunization in the nation. So just because they don't have to vaccinate by law, it would seem that a lot of parents would still go ahead and get the HPV vaccine for their daughters.

JULIE KAY: Well, I think--I'm not certain of what the ins and outs of the New Hampshire situation are, but what we've seen a great deal of in this country is that when vaccination is not mandatory it's just not widespread. And in fact we're seeing that already with the HPV vaccine, that although the federal Vaccines for Children program does cover the vaccine, there are a lot of people who are getting left behind, either by private insurers who are failing to provide adequate coverage or those who are not insured. And the gap really exists between those who will receive coverage and not, already. And we're fearful that this is going to continue if the vaccine is not mandatory.

MARGOT ADLER: Let's talk a little bit about that gap. Moira, I've heard that most women who die of cervical cancer in the U.S. are poor. They live in rural areas. So wouldn't a mandate be the best way to reach the women who are most at risk, those who don't have regular medical

care, don't get pap tests, who might not otherwise hear about the vaccine unless it was mandated?

MOIRA GAUL: Well, I'd just like to clarify that federally financed Vaccines for Children program covers all ACIP, Advisory Committee Immunization Practices from the CDC-recommended vaccinations for children 19 and under who are either on Medicaid, Medicaid eligible, uninsured, or under insured, or American Indian and Alaskan natives.

MARGOT ADLER: So you're saying that this vaccine, since they do recommend the HPV vaccine, that it would be available for free for all poor women in the United States?

MOIRA GAUL: For underserved children, 19 and under.

MARGOT ADLER: And Julie, how would you answer that?

JULIE KAY: Well, I think there are still people who fall into the gap who are not getting coverage either because private insurers are not paying pediatricians enough to cover the vaccine--it's an expensive vaccine; also the mandatory provisions act as sort of a gatekeeper to make sure that parents who are basically quite busy these days and needle-reluctant girls are likely to complete vaccination, that they will actually make the three visits within the six-month period and get vaccinated, that the mandatory provision really moves that process along and also insures that insurance coverage is provided more widely than what the federal Vaccines for Children program is able to do.

Another point that I think is very important is that when vaccination is made mandatory, girls are likely to get vaccinated earlier, when it's most effective. And I think that's why you're looking at vaccinating girls going into the 6th grade, because once they are exposed to HPV, the vaccine is no longer effective for those strands. So it is really important that girls get vaccinated well before their possible first exposure to the vaccine through sexual contact.

MARGOT ADLER: Am I right that both of you really agree on most things except the question of whether this vaccine should have an "opt in" or an "opt out" policy? Julie?

JULIE KAY: Parental rights arguments have really been the red herring that far right groups have used to distract parents, framing this as a parental rights and choice issue when there are opt-out provisions in 48 states on the basis of religious objections, there are 18 states that have opt-out provisions for conscientious objections. And these groups were really chastised when they initially opposed the vaccine. They were arguing that safer sex promotes promiscuity or that the vaccine was unnecessary because of "abstinence only." And I think that they have seen such backlash to that argument that they're really now rephrasing it as parental rights. This has been a discussion that's been going on for a number of years as the vaccine was being developed. And I think there isn't an underlying opposition to vaccination itself because of its affects on the abstinence-only ideas and promotion.

MARGOT ADLER: I want to give Moira a chance to reply now. My own sense is that different conservative groups have very different takes, and that the Family Research Council has had a very different take on this than some other conservative groups. Moira?

MOIRA GAUL: Well, I would like to point out that the vaccine community in general has not advocated for mandatory immunization with this particular vaccine. And there has certainly been concern from a large part of the medical community. They've either directly opposed or cautioned towards mandatory vaccination, and this includes members of the CDC Advisory Committee on Immunization Practices and their members. There has not been consensus in either the medical or vaccine community about supporting mandatory immunization at this point.

MARGOT ADLER: Moira, we already vaccinate against chicken pox, measles, and in the vast majority of states, children are vaccinated against Hepatitis B, which can be sexually transmitted. Ultimately, what makes this vaccine any different from any of the other vaccines children currently receive?

MOIRA GAUL: You know, what sets this vaccine apart and really puts it in its own category is that there's only one route of transmission for infection, and that is that it is a sexually transmitted infection, unlike Hepatitis B and other vaccines that children receive for the school setting.

JULIE KAY: I think it's a real disservice to minimize the public health concerns that are involved with HPV. Right now young people ages 15 to 24 comprise almost half of more than six million Americans who will become infected with HPV this year. Eighty percent of women have been exposed to this virus by the time they're age 50. So I think to say that we can wait and see is really not recognizing the seriousness of this virus. And part of that I think comes from the fact that it is a sexually transmitted disease and there is a stigma. I think that if we had discovered a vaccine against skin cancer we wouldn't be having this conversation now. But that because there has been such a belittling of HPV, because it's a virus that's portrayed as not so contagious because it's spread by sexual contact rather than through a sneeze or an airborne method, people have said we don't need it. We don't need to give it to young girls. They're not having sex anyway. And we know that that's wrong. We know that 15 to 24-year-olds are really overwhelmingly impacted by the spread of this virus.

MARGOT ADLER: Moira, you know we're talking mostly about 12-year-old girls. How much do they actually ask about medical care? When a kid gets a shot for measles, mumps, or rubella, they usually don't even know anything more than it's a shot and it hurts. Isn't it the same for the HPV vaccine?

MOIRA GAUL: Well, what we would support is that medically accurate information about the vaccine should be made available to both youth and parents upon vaccine administration, and this would include such information: that cervical cancer causing strains of HPV are sexually transmitted; that the vaccine will not prevent infection with other strains of HPV, of which there are many; and that the vaccine will not prevent infection with other types of STDs. So we feel medically accurate information should be made available to both youth and parents. And then

the parents might, um, request that healthcare providers clearly communicate risks associated with adolescent sexual activity.

JULIE KAY: One of the positive aspects of this vaccine being developed and the public debate that's happened around it is that I think that most women don't know what they get when they've gotten HPV, when they've been diagnosed with it. There's been a real need for public education on HPV and on sexual health generally. And we've started hearing from a lot of women since we've been working on this issue who have told us about their experience of going through having a diagnosis that they have HPV. They've had to get cervical warts removed. They've had complications and difficulties with that. And obviously it can lead to cervical cancer. There's a real shortage of information about the disease and there are a lot of women who are not getting annual pap smears and adequate reproductive health care. And we think that the vaccination, the mandatory vaccination will bring the kind of education and will bring this discussion to the forefront more and will inform parents better through that very process.

MOIRA GAUL: You know, I think that the CDC has definitely made it clear that the single most important factor associated with invasive cervical cancer is the fact that women have never or rarely been screened for cervical cancer. So I would agree with that point. What has been a point of concern has been the messaging with distribution of the vaccine. We hear some, even some legislators that have introduced bills, have stated that it has the potential to eradicate cervical cancer. And that's just absolutely false information. So it's very worrying to hear that, because that, in a sense, would encourage women not to have their annual pap test. So--

JULIE KAY: Well, we definitely need better education around this issue and more money for reproductive healthcare, generally from Title X to genuine sexuality education. But certainly the number-one indication of cervical cancer is the HPV virus itself. Yes, you can screen afterwards, but if we now have a vaccine where we can stop women from getting the virus, then that should be our first line of defense.

MARGOT ADLER: Julie, I've heard that some public health groups are concerned about the speed at which the vaccine has been introduced to the market. Even groups who support mandates in theory say let's wait and actually see if this vaccine has any side-effects before we require it. Others say that Merck has been too heavily involved, lobbying for the mandates. And, you know, there's a joke going around that HPV actually stands for "help pay for Vioxx" and the lawsuits that came out of it. Aren't these valid concerns?

JULIE KAY: I think there are some valid concerns about the drug company's inappropriate lobbying early on. And certainly as a women's rights organization and an organization that's very concerned with women's health, we have some real suspicion when drugs come out that affect women's reproductive health. But I don't think that the early lobbying by the vaccine's maker should obscure the fact that mandatory vaccination itself remains innocent and it's imperative. And we are facing a real public health crisis with the spread of HPV and the number of adolescents and young women who are getting it. Yeah, unfortunately that's the way drugs are developed in this country. It's very much private-market generated. However we may look down on the drug company's activities and their profit motive, they have developed a vaccine that is excellent for women's health. And I'm not sure how much to go into what they did where,

but we certainly don't want to lose the positive aspects and throw out the good vaccine with the bad bathwater.

MARGOT ADLER: Would you or have you vaccinated your own daughters with Gardasil? I'll start with you, Moira.

MOIRA GAUL: Well, I actually, I don't have a daughter so I'm not able to answer that question.

JULIE KAY: Can Moira answer whether her boss, Tony Perkins, is going to vaccinate or not? I know he had come out saying that he would not inoculate his own daughter.

MOIRA GAUL: What we have definitely said is some parents who conclude that their daughter is at low risk for contracting HPV virus, or HPV infection, may decide to allow her to make the decision for herself at 18. And we certainly stand by that.

MARGOT ADLER: And, Julie, um, what about you?

JULIE KAY: I think I just also want to add that what we haven't really addressed is that not all sex is consensual, unfortunately. And so it's not always a young woman's choice or not of whether to engage in sexual activity and I think that's important to always keep in mind.

MOIRA GAUL: And, you know, we certainly brought that point to light in our statement that I delivered to the CDC committee last February in 2006. You know, we certainly recognize that HPV infection can result from sexual abuse or assault or that a person may marry someone still carrying the virus. So, you know, these are strong reasons why even someone practicing abstinence and fidelity may benefit from HPV vaccines. But again we don't feel that that overrides parental rights to make a decision about their child's health in this case.

MARGOT ADLER: Moira Gaul is the director of women's and reproductive health at the Family Research Council. Julie Kay is an attorney for the Sexuality and Family Rights Program at Legal Momentum. Thank you both for coming on our show.

JULIE KAY: Thank you.

MOIRA GAUL: Thank you very much.

\*\*\*\*\*

MARGOT ADLER: Coming up on Justice Talking, Maine is one of the states where some legislators want to make the HPV vaccine mandatory. We hear from some teenage girls there. They'll tell us what they know about the vaccine. And Merck has spent almost a billion dollars advertising Gardasil.

UNIDENTIFIED FEMALE: Each year in the U.S. thousands of women learn they have cervical cancer. I could be one less.

UNIDENTIFIED FEMALE: One less statistic. One less.

UNIDENTIFIED FEMALE: Because now there's Gardasil, the only vaccine--

MARGOT ADLER: We'll talk about Merck, the business of marketing, and the role the pharmaceutical company played in lobbying states to mandate the vaccine.

UNIDENTIFIED MALE: It involves everything that could possibly be controversial in America. It involves cancer. It involves a sexually transmitted disease. And it involves virgin, underage girls. And it involves government mandates in which these girls will be injected with something. You know, that's just a bomb waiting to go off for most companies in the marketing business.

MARGOT ADLER: Stay with us.

\*\*\*\*\*

MARGOT ADLER: This is Justice Talking, where we make the connection between law and American life. I'm Margot Adler. We're talking today about the new HPV vaccine which promises to protect against four strains of the human papillomavirus, two of which can cause cervical cancer. HPV is the number-one sexually transmitted infection in the world. Later in the show we'll hear about international efforts to distribute this vaccine to women in the developing world. One of the major challenges in spreading the word about this new vaccine, which is meant for girls as young as 9 and women up to 26 years old, is that so few people even know what HPV is, how you get it, or its connection with cancer. From Maine, Johanna Greenberg polled her friends to find out what they knew.

JOHANNA GREENBERG: The first time I heard about the human papillomavirus, or HPV, was just about six months ago when my mom brought it up. After that I decided to talk to my peers to find out what they knew about the new vaccine, Gardasil. It prevents certain strands of HPV which can cause cancer. Do you know what the HPV vaccine is?

UNIDENTIFIED FEMALE: Um, I know it's a shot that you get to prevent the HPV virus.

UNIDENTIFIED FEMALE: Um, my mom has asked me about it a few times but I've never really known what to say because I don't know a lot about it.

JOHANNA GREENBERG: Have you heard about the HPV vaccine before?

UNIDENTIFIED FEMALE: No. Well, only really this year, like with the commercials on TV.

JOHANNA GREENBERG: Here's the TV commercial from Merck, the maker of the vaccine.

UNIDENTIFIED FEMALE: One less. Because now there's Gardasil, the only vaccine that may help protect you from the four types of human papillomavirus that may cause 70 percent of cervical cancer.

UNIDENTIFIED FEMALE: I want to be one less woman who will battle cervical cancer. One less.

JOHANNA GREENBERG: Some of my friends have received the vaccine but didn't really know anything beyond that. So have you received the HPV vaccine?

UNIDENTIFIED FEMALE: Yes, I have.

JOHANNA GREENBERG: And why did you receive it?

UNIDENTIFIED FEMALE: Because my mom told me to.

UNIDENTIFIED FEMALE: Yes, I've gotten two out of three of the shots. I'd only heard of it maybe a couple of months before I received it, and only because of the publicity that surrounded it.

JOHANNA GREENBERG: Shortly after my 18th birthday, my mom, Gretchen Greenberg, told me that she wanted me to get the vaccine.

GRETCHEN GREENBERG: It was a vaccine like any other vaccine. I'd want you to get a measles, mumps, and rubella vaccine. And I'd want you to get another vaccine to protect you from another potential disease.

JOHANNA GREENBERG: So I made the appointments to get the three shots from my doctor.

UNIDENTIFIED FEMALE: There's just a fine little needle and take a nice deep breath. There's a little poke. And it's going in. I'm sorry if it stings a little bit. I'll just pat that and hold on a minute and I'll put a little band-aid on there.

JOHANNA GREENBERG: Okay. My friend, 17-year-old Hannah Johnson, hasn't received the vaccine yet. However, her mother approached her about getting it.

UNIDENTIFIED FEMALE: Have you thought about it?

HANNAH JOHNSON: Um, no, not really.

JOHANNA GREENBERG: But not all parents are as supportive of the HPV vaccine for their daughters as Hannah's and mine. Because HPV is a sexually transmitted infection, some parents are uncomfortable about the vaccine because they feel like giving this vaccine to their young daughters might send the girls the message that it's okay to have sex. Hannah Johnson's mother wondered about this too.

UNIDENTIFIED FEMALE: Do you feel that if you had a vaccine or got the HPV vaccine it would make you, um, I guess, want to be sexually active?

JOHANNA GREENBERG: Hannah says no.

HANNAH JOHNSON: Well, like, if I'm a 13-year-old girl and I'm sitting at my doctor's office and they come in and they give me a vaccination and I'm like, what's this for? And they say HPV, and they explain it to me, I'm not going to be like, oh this is my ticket for sexual freedom. Like, that would never cross my mind: Now I can go have sex with whoever I want because my cervix is protected. [LAUGHS] But like, I just, I would never think of it like that.

JOHANNA GREENBERG: Regardless of what parents and girls may think of the vaccine, here in Maine some state legislators want to require it for girls entering 6th grade. But so far efforts to enact this mandate have been unsuccessful. For Justice Talking, I'm Johanna Greenberg.

\*\*\*\*\*

MARGOT ADLER: Many people have seen the television ads for the HPV vaccine, Gardasil, ads which encourage young women to become "one less" woman affected by cervical cancer. These television spots are just one part of a massive advertising campaign led by the vaccine's manufacturer Merck, which spent nearly one billion dollars trying to get the word out about Gardasil. In the process the pharmaceutical company has also stirred up a bit of controversy around its aggressive lobbying tactics and its involvement in the push for state mandates.

Jim Edwards is a reporter who covers the pharmaceutical industry for Brandweek Magazine. He has closely followed the Merck Gardasil story. Jim, welcome to Justice Talking.

JIM EDWARDS: Thank you for having me.

MARGOT ADLER: You've reported on marketing campaigns for other pharmaceuticals. What surprised you most about how Merck is marketing this particular product, Gardasil?

JIM EDWARDS: There's a couple of things have surprised me about it. The first is that Merck bothered to market a vaccine in the first place. The entire business model of the American pharmaceutical industry relies largely on treating the symptoms of diseases rather than actually curing them, because if you treat a disease's symptoms but you don't actually cure it, you can sell and re-sell that drug to the same patient over and over. The second thing has been how well Merck has tackled the disease category it's in. It involves everything that could possibly be controversial in America. It involves cancer. It involves a sexually transmitted disease. And it involves virgin, underage girls. And it involves government mandates in which these girls will be injected with something. You know, that's just a bomb waiting to go off for most companies in the marketing business. And Merck went at it. They've had their problems, but they've generally been successful in persuading people this is a good thing. So I'm almost surprised it wasn't more controversial, if you like.

MARGOT ADLER: Some people have said that Merck blew it because some of the biggest advocates for mandating the vaccine got money from Merck. What happened?

JIM EDWARDS: That was the most controversial part of this campaign. What Merck did was it became very concerned to get all 50 states in the United States to agree to make the Gardasil

vaccine a requirement for girls going to school. So they produced a quite intense lobbying campaign. Unfortunately, they were caught in Texas giving \$5,000 to the governor's election campaign on the same day that they met with the governor in which the governor decided that he would order this vaccine be given to all Texas schoolgirls. And of course that looked extremely suspicious. And the Texas Legislature later voted to reverse that.

MARGOT ADLER: Given what happened, where does Merck currently stand on the issue of mandating the vaccine?

JIM EDWARDS: Merck's obviously in favor of the vaccine being mandated. And it's been successful in persuading the FDA to recommend that the vaccine is one of the many vaccines that children receive. So Merck has been successful, if you like, in persuading the federal government that, yes, this vaccine should be mandated. And that's good news for Merck because it puts the emphasis on the states to get it done, basically.

MARGOT ADLER: But I gather they've also removed some of their arguments from their website and they're no longer actively lobbying for mandating this state by state.

JIM EDWARDS: Correct. After the fiasco in Texas the very existence of their lobbying campaign became extremely controversial and there was more news coverage of the lobbying campaign than there was of the benefits or otherwise of Gardasil itself. So Merck just said: You know what? We're going to end the whole thing. We won't do anymore lobbying. At this point, though, because they've got those decisions from the FDA, you could argue that they kind of don't have to do anymore lobbying.

MARGOT ADLER: Merck is facing a lot of distrust coming out of the Vioxx situation. That was an arthritis drug they marketed very heavily. The drug may have caused thousands of deaths before it was pulled from the market. Why should people trust Merck to do the right thing, especially when it comes to their 12-year-old daughters?

JIM EDWARDS: Well, that's a good question. Merck is hoping you will trust them because the difference between this drug and a drug like Vioxx is that, you know, Vioxx is a chemical. It's something that's made in a lab and when you introduce it into a human body it has various effects and side-effects. This is a vaccine, so it goes back to that long tradition of public health where vaccines have had a pretty good safety record. It goes back to the history of Jonas Salk and polio, if you like, where essentially--and it works by the same principle is my understanding--you introduce the virus in a weakened state. Your body learns to recognize that virus. And then if you ever encounter it in its virulent state, you are immune to it. So Merck is sort of leaning very heavily on the fact that this is a public health act, that they are not trying to promote it as a sort of--as if it were a commercial brand or profit maker. They see it very much as, you know, part of the fight against cancer and part of the fight for public health.

MARGOT ADLER: And it seems that you're saying that despite all the stuff that's happened, you think they're going to come out on top?

JIM EDWARDS: Oh yeah, don't write off Merck. [LAUGHS] Merck will come out on top. New things are always controversial, particularly in the area of sex, sexually transmitted diseases and the pharmaceutical industry. The drug business is always perennially controversial, but these guys are professionals; they knew it would be that way going in. And as long as there is no hideous side-effect or fatal or disastrous after-effect of this drug, we, the population, will come to accept it. There might be a time, you know, 50 years from now, when we'll look back and we'll go: Wow, people in America, you know, like one in three of us really had HPV? That's Merck's timeline for this. That's what they're looking at. So--and Merck has huge resources. I mean, you know, they make nearly \$400 million a quarter off this drug. So when you've got that kind of resources to work with, no, you should never write off Merck.

MARGOT ADLER: That was Jim Edwards, a reporter for Brandweek Magazine. You'll find a link to his blog on our website, [justicetalking.org](http://justicetalking.org).

\*\*\*\*\*

MARGOT ADLER: Merck has agreed to donate the vaccine to an international effort against cervical cancer. It's a program led by PATH, a nonprofit organization that works to improve the health of people around the world. Jackie Sherris is vice president of global programs at PATH and she's here to talk with me about the impact of cervical cancer in the developing world. Welcome to Justice Talking.

JACKIE SHERRIS: Thank you.

MARGOT ADLER: We've been talking about cervical cancer and the HPV vaccine. Here in the U.S. nearly 4,000 women die of cervical cancer each year. But internationally the situation is much worse. Tell us about that.

JACKIE SHERRIS: Yes. There are about half a million cervical cancer cases worldwide and about 270,000 deaths each year. And 85 percent of those occur in the developing world, with the highest incidence occurring in sub-Saharan Africa, Central and Southern America, and South Asia.

MARGOT ADLER: Give us a sense of how this kind of cancer compares with other kinds of cancer in the developing world.

JACKIE SHERRIS: Cervical cancer is in most parts of the developing world the number-one cancer killer among women. So it's a big problem. The good news for cervical cancer, however, is that it's preventable, which is not the case of many other cancers. Breast cancer, for instance, is also an important killer of women but is much more difficult to prevent because symptoms don't occur until late. With cervical cancer you can identify early pre-cancerous lesions and treat them and have almost 100 percent chance of preventing the disease. Furthermore, now we have the vaccine that prevents primary infection with the virus that causes cervical cancer. So there are a lot of opportunities to make a difference with this disease.

MARGOT ADLER: In the U.S. cervical cancer is, as you said, very treatable and it's clearly treatable internationally if it's caught early. Why is it killing so many women internationally?

JACKIE SHERRIS: Well, in the United States we as women have ready access to pap screening. And pap screening is a great approach. You take some cells from the cervix. If you see any abnormalities you evaluate it further. And then you treat whatever those abnormalities are and a woman doesn't develop cancer. And in the developing world those kinds of programs simply haven't been sustainable.

MARGOT ADLER: It sounds like an HPV vaccine would be even more relevant in other countries than it is here. Is it being used in other countries already?

JACKIE SHERRIS: Not in the developing world at this point. Some, there's some access in wealthier communities to the vaccine, but cervical cancer is a disease of poor women, and so making the vaccine available in the developing world is going to require large investments in broad public sector programs that can reach women who can't afford to purchase a vaccine themselves.

MARGOT ADLER: So what is PATH doing to address this health issue?

JACKIE SHERRIS: PATH has been involved in cervical cancer prevention for almost 15 years now. Just recently we've initiated a program looking at the HPV vaccine, and our focus is to go into four countries and demonstrate what it takes to get the HPV vaccine out to young girls and young adolescents and actually launch these programs. As you can imagine, in many developing country settings there aren't any regular health services that reach 10 to 14-year-old girls, for instance. So there are a lot of issues that need to be addressed.

MARGOT ADLER: In the United States there's been a big debate over mandating this vaccine. Some oppose it on religious grounds. Some people are anti-vaccine all together. Do these concerns come up in the countries that you'll be working in?

JACKIE SHERRIS: At this point, no. We're still early in the development of programs and there are, I think, more immediate issues that countries are worried about. Again, how do you actually get this vaccine out in three doses to an age group that doesn't have any access to services? How do you make sure the communities understand the vaccine and that there aren't socio-cultural barriers? What about the costs? How are we going to afford it? How are we going to integrate this vaccine into existing programs? I think those issues are of more concern at this point than, you know, are we going to mandate or are we not.

MARGOT ADLER: Given the huge healthcare concerns all over the developing world--I'm thinking of AIDS and TB, for example--where does HPV and cervical cancer fall on the priority list?

JACKIE SHERRIS: A great question. And that's an issue that is of concern to us because there certainly is the challenge in some settings that this disease, even though it does have a quite a high health burden--in Latin America, for instance, more women die of cervical cancer than die

from maternal mortality causes--there is often an undervaluing of women in the health system and particularly an undervaluing of the health of older women and the value of older women in societies. So we've spent quite a bit of time trying to raise awareness about the importance of women in their forties and fifties in their communities, particularly in Africa, where these women are often providing care and support for AIDS orphans and families who are suffering from AIDS. And we certainly don't want to be in a position where these women survive the AIDS epidemic, if you will, and then get cervical cancer and die from that. That said, in some countries where they are so overburdened with malaria and TB and AIDS, and cervical cancer is a lower health burden for them--because rates do vary across, across countries--they may decide to focus their efforts on other health problems in the short term and address HPV and cervical cancer as their research situation improves.

MARGOT ADLER: Jackie Sherris is vice president of global programs at PATH, an international nonprofit organization that works to improve health of people around the world. Thank you so much for coming on Justice Talking.

JACKIE SHERRIS: It's my pleasure. Thank you for having me.

MARGOT ADLER: To learn more about PATH's plan to distribute the HPV vaccine to women in India, Peru, Uganda, and Vietnam, go to our website, [justicetalking.org](http://justicetalking.org).

While there, post on our message boards, learn more about our guests, and sign up for our free podcasts. And check out our blog, where many of the nation's leading commentators give their views on law and American life. Thanks for listening. I hope you'll tune in next week. I'm Margot Adler.

\*\*\*\*\*