Approved: March 6, 2007
Date

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

The meeting was called to order by Chairman Brenda Landwehr at 1:30 P.M. on February 7, 2007 in Room 526-S of the Capitol.

All members were present except:
Clark Shultz- excused
Tom Holland- excused

Committee staff present:
Norman Furse, Revisor's Office
Melissa Calderwood, Legislative Research
Mary Galligan, Legislative Research
Patti Magathan, Committee Assistant

Conferees appearing before the committee:
Mary Ann Caster- Cancer survivor
Dr. Henry W. Buck, OB-GYN
Dr. Alexandra Stewart, George Washington University Medical Center
Professor Jerry Slaughter, Kansas Medical Society
Chancellor Robert Hemenway, University of Kansas

Others Attending:
See Attached List.

Chair Landwehr announced that we would begin hearings on **HB2227** - Requiring female students enrolling in grade six to be inoculated against the human papilloma virus.

Proponent, **Representative Delia Garcia** stated that she had not been influenced by the entities that are being accused of influencing legislators to bring forth this policy. She brought this forth in the name of good policy in Kansas, emphasizing that she is a staunch supporter of health issues. We have the capability to prevent numerous occurrences of the second most common type of cancer in women. By the age of 50, over 80% of all women will have been infected with this virus. Following are organizations recommending the vaccine: Center for Disease Control, American Cancer society, American College of Obstetricians and Gynecologists, Society of Gynecological Oncologists. Representative Garcia has requested a revised fiscal note to adjust for uninsured and under-insured populations covered by another plan. She also pointed out that the cost to treat cervical cancer will be reduced with passage of this bill. (Attachment 1 & 2)

Proponent **Mary Ann Castor**, an eight-year cervical cancer survivor, described her symptoms, diagnosis, and treatment. Ms. Castor stated that cervical cancer doesn't end with surgery and she continues to be plagued with physical problems related to treatment. We have an opportunity to protect our daughters from the virus that causes cervical cancer before exposure. Our daughters deserve that chance.

Proponent **Dr. Henry W. Buck** provided the committee with a slide show of statistical information and pictures of diseased tissue. (Attachment 3) Dr. Buck stated that the most effective way to prevent disease is to avoid contact with someone who is infected. HPV vaccination is an evidence based recommendation based on reality. In addition to cervical cancer, the human papilloma virus also causes a high incidence of genital warts which would also be prevented by the vaccination. Congenital defects were found in five cases where a pregnant woman received the HPV vaccination within 30 days of delivery. This issue is being followed closely, and at this time it is not believed to be significant. The length of immunity is at least five years. This issue is being followed closely and it is unknown at this time if a booster might be required.

Alexandra Stewart, Assistant Research Professor from the Department of Health Policy, School of public Health and Health Services, The George Washington University Medical Center, testified from a neutral position. Her primary research area is U.S. vaccine policy, focusing on access issues for all populations. She discussed how school entry requirements impact our nation's health and how vaccines are financed through public and private payment systems. Vaccination laws have proven to be the most effective mechanism to vaccinate our children. Based on experience with other vaccinations, we can safely assume that a school

mandate requiring HPV immunization will achieve more widespread protection against cervical cancer than if Kansas relied on other policy reforms and parental education and persuasion. The existing structure for financing vaccines is designed to accommodate newly recommended vaccines. (Attachment 4)

Anita Jamison, proponent, told her story of symptoms, diagnosis, and treatment. She is a five-year survivor of cervical cancer. She stated that there is no reason not to vaccinate our children and asked the committee to please pass this bill.

Chair Landwehr announced that hearings on **HB2227** would be continued tomorrow, and opened hearings on **HCR 6006** - Resolution urging the governor and university of Kansas medical center to not enter any affiliation without legislative review.

Proponent **Jerry Slaughter** of the Kansas Medical Society stated that the Kansas Medical Society is a strong advocate and supporter of the University of Kansas School of Medicine and the school is most important to the ability of our state to train adequate numbers of physicians to meet the health care needs of the people of Kansas. He said that the proposed affiliation with St. Luke's Hospital, a Kansas city, Missouri-based medical care facility raises issues that should be given careful consideration.Any action by K.U.M.C. that could potentially weaken the university hospital must be critically evaluated. It has also been reported that neither the leadership of the hospital northe medical staff leadership has had meaningful participation in the affiliation discussions that KU has conducted with St. Luke's officials. (Attachment 5)

Opponent Chancellor **Robert Hemenway**, University of Kansas, informed the committee that it was recently announced that the medical center has entered into separate letters of intent with Saint Luke's Hospital and the University of Kansas Hospital to pursue broader affiliations with each institution. He said that an academic medical center consists of two basic elements: a medical school and its primary hospital. The medical school is where the research and teaching take place. Further research and teaching by the medical faculty and the delivery of cures take place at the hospital. As important as the relationship is between a medical school and its primary hospital, the best academic medical centers must expose their students to many types of patients, procedures and styles of care in order to produce the very best physicians. This requires that a medical school affiliate with more than one hospital. A single hospital cannot sustain the requirements of a large and growing medical school. We currently have multiple affiliates, including the two largest hospitals in Kansas, both in Wichita. In Kansas City, we have decided to affiliate with additional hospitals to train more doctors and better educate them. K.U. has applied for National Cancer Institute's Designated Cancer Center, which will not be attainable without additional affiliations. In addition, the affiliation will ultimately make it possible for us to train an additional 100 doctors a year at an annual cost in excess of $10 million, which will be paid to the KU Medical Center entirely by these new hospital partners. In addition, other benefits of the affiliations include a broad-based group of corporations and private donors which has pledged $150 million new dollars to support the expanded research and education vision of our medical center in partnership with other life sciences institutions. The positive economic impact of such growth would be impressive as well.

Dr. Hemenway stated that they will not support partnerships or affiliations detrimental to the future of the K.U. Hospital or it's patients, nor that transfer Kansas taxpayer dollars to directly benefit Missouri-located institutions. We will only support affiliations which advance the vision of creating and sustaining new levels of excellence. We will keep the Kansas board of Regents and the Kansas Legislature fully briefed on these affiliation discussions as we move forward. Adoption of a resolution such as this would require significant new administrative processes in order to comply with its intent. The restrictions imposed by it could easily prevent many promising and productive agreements from going forward. An academic medical center has in place hundreds of affiliations. Lives are saved every day because affiliations have been arranged. (Attachment 6)

Chair Landwehr announced that due to time constraints we would continue the hearings on **HCR 6006** tomorrow at 1:30. Meeting was adjourned at 3:30P.M.

HOUSE HEALTH AND HUMAN SERVICES
COMMITTEE GUEST LIST

DATE: February 8 , 2007

NAME	REPRESENTING
Gary Smith	CWA of KS
M. HARTZ	UCHS
Alexandra Stewart	George Wash U.
Amy Jordan Wooden	KUMC
Dorothy Hughes	KUMC
DAN MORIN	KS Medical Society
Jennifer Cox	Southwestern Nursing
[illegible]	SCANS / Southwestern
Jeff Bo. Ho. by	Merck
Monica Mayer	MVD
Suzanne Wikle	Kansas Action for Children
H.W. BUCK	KU
Phillip A. Inverso	PAT Hughes & Co.
Melissa JONES	Nat. Cervical Cancer Coalition
ROGER MARTIN	KANSAS ACTION FOR CHILDREN
BEATRICE SWOOPES	KS CATHOLIC CONF.
JERRY SCHLICHTER	Kans
ALLISON PETERSON	KMS
Barbara Belcher	Merck
[illegible]	Chiavelli
Adrienne Strecker	Sen. Lee
Jana Mackey	ICS NOW
[illegible]	Planned Parenthood
Patrick Woods	Gov. Office
Candice Rukes	Teen Pregnancy Prevention Program
Tamara Peck	Rep. Peck
Kathy Beavers	Rep. Wilk
[illegible]	Sister of Cancer Survivor
Marie Nelson	Kansas Masonic Foundation, Inc.

HOUSE HEALTH AND HUMAN SERVICES
COMMITTEE GUEST LIST

DATE: February , 2007

NAME	REPRESENTING
Sarah Green	KHI News Service
Janet Neff	Ks Dept Hea Hlth & Env.
Sherry Haworth	Cancer Survivor/Rep. Garcia
Carrie Shapton	Partnership for Children
Barbara Hollingsworth	The Topeka Capital-Journal
Sara Natividad	Rep. Delia Garcia
John Breiner	Rep. Ward
BRENDA WALKER	KDHE
Shu Faust	KDHE
MARK DESETTI	KNEA
Sarah Howell	YWCA TPP
Luke Thompson	KHPA
Cynthia Smith	SCL Health System

Testimony

HB 2227: An Act concerning certification of receipt of certain tests or inoculations prior to admission and attendance at school, concerning the human papillomavirus (HPV) vaccine
Presented to the House Health and Human Services Committee

February 7, 2007

Good Afternoon. Chairwoman Landwehr and members of the House Health and Human Services Committee, thank you for the opportunity to conduct this bill hearing today so we may be informed on all sides of this very important issue in regards to women's health in Kansas. I am testifying in favor of H.B. 2227.

I am a staunch supporter of health issues, especially health access and women's health issues, which is why I love serving on this committee. I come from a family of five daughters, with two nieces and a nephew; not to mention the many aunts and uncles, and cousins who are mostly women. I am a college professor, and alumni of a sorority whose philanthropy is cancer awareness. This issue of HPV affects both women & men. I have followed this issue for a while now. This virus has affected my college students I work with, family members, my constituents, some of our fellow colleagues, and yes even some in this room. I have had many persons, including state employees, approach me in this Capitol building thanking me for bringing this to the forefront. As you may or may not know, I was not influenced by the entities that are being accused of influencing legislators to bring forth this sound policy. I brought this forth in the name of the good policy in Kansas.

The bottom line in this bill is that we have the capability to prevent numerous occurrences of the 2nd most common type of cancer in women. We should embrace this medical victory in order to ensure that our girls benefit fully from this scientific advancement. This vaccine will prevent many cases of cervical cancer in the future. As always, state law continues to ensure the rights of parents to object to the vaccine for religious or philosophical differences. Parents are allowed to opt out through a simple process, just as they may for any other required vaccination. In addition, more people will know about the vaccine and its benefits, increasing the rates of immunization. HPV causes virtually all cases of cervical cancer. By the age of 50, over 80% of all women

Representative Delia Garcia

House Health and Human Services
DATE: 2-7-07
ATTACHMENT 1-1

will have been infected with this virus. Requiring it is important because it will now be covered by health insurance companies and Medicaid. I wanted to introduce this sound policy for the sake of our Kansas women. I was glad to be joined by some of my colleagues, both Republican and Democrat, both conservative and not so conservative, both men and women.

I did want to add that the FDA (Federal Drug Administration) approved the vaccine, and the following organizations recommend it:

- CDC (Center for Disease Control)
- American Cancer Society
- American Academy of Pediatrics
- American College of Obstetricians and Gynecologists
- Society of Gynecological Oncologists

I have welcomed the negotiation to implement this vaccine program in 2009-2010 as opposed to this year, which I believe will alleviate most concerns on costs. On the topic of costs, I wanted to address the high fiscal note on HB 2227. I would request that we have a Revised Fiscal Note. On page 2, #3, the last sentence regarding the 7,448 females (40%) "might have private insurance, no insurance, or are under-insured." Approximately 30% of these girls are insured, therefore, this fiscal note may be artificially inflated. I am requesting the Revised Fiscal Note to take out the insured population, since we have the First Dollar Vaccine Coverage that covers this, therefore 30% of the insured young girls should be pulled out of the Fiscal Note. The Kansas General Fund does <u>not</u> pay for the insured girls, it pays for the underinsured. In regards to costs related, it has cost $1.7 billion for cervical cancer treatment, and this bill would help reduce those costs tremendously.

This human papillomavirus (HPV) is a virus that is preventable and vaccinating against it is no different that getting shots for Hepatitus B or Tetnus, which are now mandated/ required in all schools. The vaccine has met all of the benchmarks for safety and efficacy. We have a cancer that can be avoided.

I look forward to working this bill with you Chairwoman Landwehr and fellow committee members. If there are no questions for me now, I'd like to introduce one of the conferees.

Respectfully,

Delia Garcia

Rep. Delia Garcia
103rd District

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Moves to Vaccinate Girls For Cervical Cancer Draw Fire

As Merck Lobbies States To Require Shots, Some Fret Over Side Effects, Morals

By JOHN CARREYROU
February 7, 2007; Page D1

Bills being drafted in some 20 U.S. states that would make a cervical-cancer vaccine mandatory for preteen girls are sparking a backlash among parents and consumer advocates.

The bills coincide with an aggressive lobbying campaign by Merck & Co., the maker of the only such vaccine on the market. Called Gardasil, the three-shot regimen provides protection against the human papillomavirus, a sexually transmitted virus that is responsible for the majority of cases of cervical cancer.

If the state bills become law, they would guarantee the Whitehouse Station, N.J., drug maker billions of dollars in annual revenue from the vaccine.

POINTS OF CONTENTION

Concerns over mandating shots:

- Some parents say a vaccine for HPV, the sexually transmitted disease that can cause cervical cancer, effectively condones premarital sex.
- Long-term efficacy and risk of side effects are unclear. There have been 82 reports of adverse events associated with the vaccine.
- Gardasil is typically covered by insurance, but is costlier than many other common vaccines.

Proposed legislation varies from state to state, but the bills generally would require girls to show proof that they have received the inoculation in order to enter school. A number of immunizations -- including those for measles, chicken pox and polio -- are mandatory for U.S. schoolchildren because they block highly contagious diseases that can be spread easily in a group setting. But HPV is different because it is transmitted sexually. At $360 for the three shots, Gardasil is also costlier than many vaccines (a measles-mumps-rubella shot costs about $42.85 per dose, for instance), though it is generally covered by insurance.

Conservative Christian groups have long voiced opposition to the vaccine, saying it would conflict with their message of abstinence because it would, in effect, condone premarital sex. However, concern has spread beyond the religious right as momentum has grown for making inoculation mandatory. A growing number of parents are worried about exposing their

children to the unforeseen side effects of a new vaccine to protect them from a disease that is no longer very common in the U.S. and often doesn't develop until much later in life.

Tina Walker, the mother of an 11-year-old girl in Flower Mound, Texas, says she would prefer to wait until the vaccine has been on the market for several years before subjecting her child to it. "We are the guinea pigs here," she says.

Last week, Texas Gov. Rick Perry issued an executive order mandating that the vaccine be administered to all girls entering the 6th grade in the state as of September 2008. The Texas executive order, which includes an opt-out clause for religious or other "reasons of conscience," enabled the governor to bypass what would have likely been a heated debate in the Texas Legislature.

Many of the state bills contain opt-out clauses, but a few don't. The bill pending in Florida would bar students ages 11 or 12 from being admitted to public or private school in the state unless they can provide proof that they have been vaccinated or that their parents opted them out after receiving information about cervical cancer and the vaccine.

State by State

States that are considering making HPV vaccination mandatory for pre-teen girls, or have already mandated it:

- California
- Colorado
- Connecticut
- District of Columbia
- Florida
- Hawaii
- Illinois
- Indiana
- Kansas
- Kentucky
- Maine
- Michigan
- Minnesota
- Mississippi
- New Jersey
- New Mexico
- Oklahoma
- South Carolina
- Texas*
- Virginia

*Executive order enacted.

Sources: Merck; the National Conference of State Legislatures; Women in Government

Merck says cervical cancer is the second-leading cancer among women around the world, but the disease's prevalence is actually low in the U.S. The American Cancer Society estimates that 11,150 women will be diagnosed with cervical cancer and 3,670 will die from it in the U.S. this year. That's equivalent to 0.77% of cancers diagnosed in the U.S. and 0.65% of U.S. cancer deaths each year. By comparison, the society estimates that 178,480 American women will get diagnosed with breast cancer in 2007 and 40,460 will die from it.

Adding to some parents' concern, 82 adverse events among both teens and adult women have been reported since Gardasil became available last June. Many involve common immune-system responses to vaccines, such as nausea, fever or rashes.

TODAY'S MOST POPULAR

1. Beijing Gets Rid of Bad Translations
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3. Kodak's Printer Strategy: Cheaper Cartridges
4. Steve Jobs Raises Pressure on Music Firms
5. Should Bond Investors Watch the Thin Ice?

MORE

COMPANIES

Dow Jones, Reuters

Merck Co. Inc. (MRK)	
PRICE	44.42
CHANGE	-0.22
	12:12a.m.
GlaxoSmithKline PLC ADS (GSK)	
PRICE	55.26
CHANGE	-0.30
	12:11a.m.

2-2

But a number of patients suffered syncopes, or fainting spells.

Richard Haupt, Merck's executive director of medical affairs, says the syncopes are caused by patients' anxiety at having a needle stuck in their arm and not due to any neuro-immune reaction to the vaccine. Mr. Haupt adds that the number of adverse events is small compared with the hundreds of thousands of doses of the vaccine administered so far in the U.S.

However, with any newly approved drug or vaccine, side effects often don't become apparent until a regimen has been on the market for a while, leading some patient and consumer advocates to urge states to hold off on requiring vaccination until Gardasil's safety is more clearly established.

Of the more than 25,000 patients who participated in clinical trials of Gardasil, only 1,184 were preteen girls. "That's a thin base of testing upon which to make a vaccine mandatory," says Barbara Loe Fisher, co-founder of the National Vaccine Information Center, an advocacy group that lobbies for safer vaccines.

Gardasil is approved for females ages 9 to 26, and the three-dose regimen is the same for all age groups. The vaccine protects against four strains of HPV that cause 70% of cervical cancer cases. So it would not eliminate the need for vaccinated women to have regular Pap smears to detect cancerous cells caused by other HPV strains. HPV is also the virus that causes genital warts.

Merck acknowledges that it doesn't know yet whether an initial vaccination will offer lifetime protection or whether patients will need booster shots. So far, the company has shown only that the vaccine lasts five years.

Merck started lobbying state legislatures to pass laws requiring vaccination last year after the Centers for Disease Control and Prevention's Committee on Immunization Practices recommended that all girls get the vaccine when they turn 11 or 12. Another HPV vaccine, called Cervarix, is in development from GlaxoSmithKline PLC, but so far Gardasil is the only regimen on the market.

As part of its lobbying campaign, Merck has been funding Women in Government, a Washington, D.C.-based advocacy group made up of female state lawmakers. An executive from Merck's vaccine division, Deborah Alfano, sat on Women in Government's business council last year, and many of the bills across the country have been introduced by members of the group.

Merck declined to say how much money it has funneled into its lobbying campaign, or contributed to Women in Government. A spokeswoman for Women in Government, Tracy Morris, declined to say how much it had received from Merck. In Texas, one of Merck's lobbyists is Gov. Perry's former chief of staff, and Merck's political action committee contributed $6,000 to the governor's re-election campaign.

"Parents should be concerned that the only company that makes this vaccine is pushing behind the scenes for mandatory laws," says Maryann Napoli, associate director for the Center for Medical Consumers, a consumer group based in New York.

At a Merrill Lynch conference yesterday, Margaret McGlynn, the president of Merck's vaccine division, acknowledged the company's aggressive lobbying campaign but said, "States decide what works for them." She added that she had her own daughter vaccinated with Gardasil and "immunizing females against cervical cancer is absolutely the right thing to do."

2-3

Mandatory vaccination across the U.S. would make Gardasil an automatic blockbuster for Merck at a time when the patents on some of its bestselling drugs are expiring and it's desperate to replace their revenue streams. Gardasil's sales in 2006 were $235 million.

Cervical cancer is a much bigger problem in the developing world, which accounts for more than 80% of cases of the disease. Merck says it's committed to bringing the vaccine to developing countries, but for now its availability is limited there to a few studies and demonstration programs.

Write to John Carreyrou at john.carreyrou@wsj.com

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FOCUS ON

HUMAN PAPILLOMAVIRUS

Kansas Legislature

2007

Henry W. Buck, M.D.

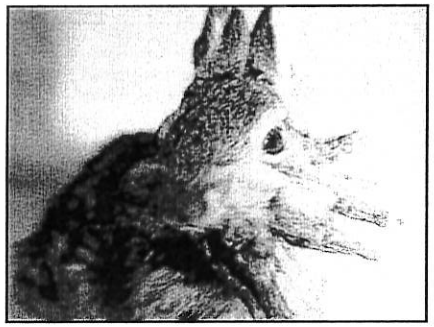
Lawrence

Curriculum Vita

- Graduate of K.U. and K.U. Medical School
- Univ. of Oklahoma Hospitals – intern, 1 yr. surg.
- K.U.M.C – residency in OB-Gyn
- U.S. Air Force – 2 years
- Private Practice OB-Gyn - 20 years in Lawrence
- Head Gynecology Watkins Health Center - 18 yrs.
- Chair of HPV & Other STDs Task Force of the American College Health Assn. - 14 years
- Principal Investigator K.U. site for initial clinical study of HPV vaccine

Disclosures

- Merck Speakers Bureau
- Merck OB-Gyn Advisory Board
- 3M/Graceway Pharmaceuticals Speakers Bureau
- Digene (HPV DNA test) Speakers Bureau
- SurePath (liquid Pap smears) Speakers Bureau



The Ideal

Universal abstinence* until marriage or at least long-term commitment.

*Abstinence defined as no hand-genital or genital-genital contact of any kind.

Abstinence

- The most effective way to prevent infectious diseases is to avoid contact with someone who has one.
- With Sexually Transmitted Infections (Disease), this is known as Abstinence.
- This is not based on morality or on religion. It is simply evidence based medicine

Reality

Virtually all available information demonstrates sexual behavior to be far from ideal.

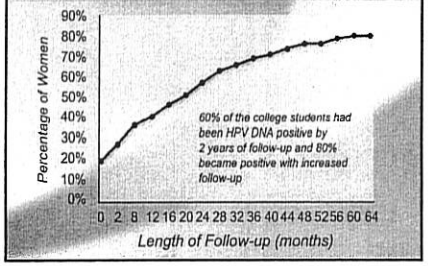
Some societies come close.

Some tend to have abstinence of females, but not males.

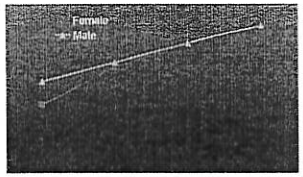
To be responsible as a society , we must deal with reality.

Risk of Acquiring HPV After First Intercourse in Female Adolescents

Development of HPV DNA Positivity



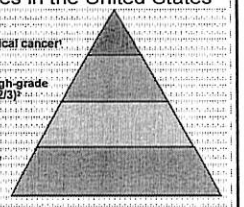
Percentage of US High School Students Who Have Had Sexual Intercourse[1]



In addition, 7.4% of US adolescents reported sexual debut before 13 years of age. By Grade 12, 29.3% of US adolescents reported ≥4 lifetime sexual partners.

GARDASIL® (Quadrivalent Human Papillomavirus [HPV Types 6, 11, 16, 18] Recombinant Vaccine)

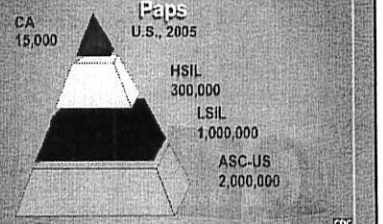
Estimated Annual Burden of HPV-Related Diagnoses in the United States



- 9,710 new cases of cervical cancer[1]
- 330,000 new cases of high-grade cervical dysplasia (CIN 2/3)[2]
- 1 million new cases of genital warts[3]
- 1.4 million new cases of low-grade cervical dysplasia (CIN 1)[2]

1. American Cancer Society. Cancer Facts and Figures 2006. Atlanta, GA: American Cancer Society; 2006:4. 2. Schiffman M, Solomon D. Findings to date from the ASCUS-LSIL Triage Study (ALTS). *Arch Pathol Lab Med*. 2003;127:946–949.
3. Fleischer AB, Parnish CA, Glenn BL, Feldman SR. Condylomata acuminata (genital warts): Patient demographics and treating physicians. *Sex Transm Dis*. 2001;28:643–647.

Estimated Annual Abnormal Paps U.S., 2005

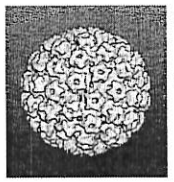


Impact of Cervical Cancer

- United States:
  - Annual incidence: ~10,000
  - ~10 women die each day of cervical cancer
- Worldwide:
  - Annual incidence: ~500,000
  - Second most common cause of cancer death in women
  - ~240,000 deaths each year

HPV

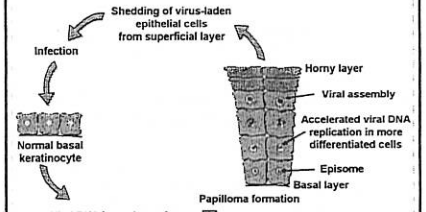
Nonenveloped double-stranded DNA virus[1]



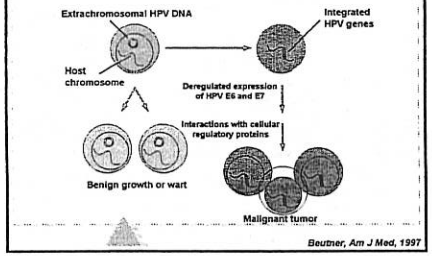
- **>100** types identified[2]
- **30–40** anogenital[2,3]

1. Howley PM. In: Fields BN, Knipe DM, Howley PM, eds. Philadelphia, Pa: Lippincott-Raven; 1996:2045–2076.
2. Schiffman M, Castle PE. *Arch Pathol Lab Med*. 2003;127:930–934. 3. Wiley DJ, Douglas J, Beutner K, et al. *Clin Infect Dis*. 2002;35(suppl 2):S210–S224. 4. Muñoz N, Bosch FX, de Sanjosé S, et al. *N Engl J Med*. 2003;348:518–527.

HPV Infection

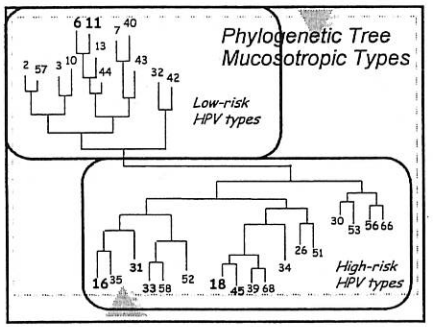


HPV Malignant Transformation



Beutner, Am J Med, 1997

Phylogenetic Tree Mucosotropic Types



Common HPV Types Associated With Benign and Malignant Disease

	HPV Types	Manifestations
Low-Risk	HPV 6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81	Benign low-grade cervical changes Condylomata acuminata (Genital warts)
High-Risk	HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, 82	Low-grade cervical changes High-grade cervical changes Cervical cancer Anogenital and other cancers

Cox. *Baillière's Clin Obstet Gynaecol*. 1995;9:1.
Muñoz et al. *N Engl J Med*. 2003;348:518.

Transmission of Genital HPV Infection

- **Sexual contact**
- Perinatal
- Other means
  - Fomites, including sex toys
  - **digital**

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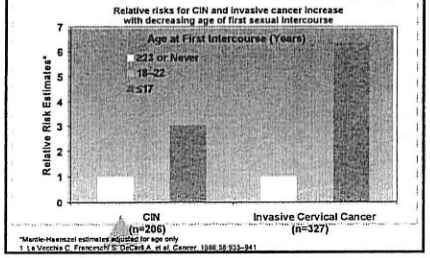
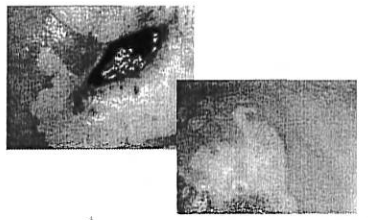
Risk of Cervical Lesions and Cancer in Women Exposed to HPV at a Young Age[1]



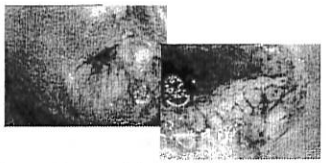
*Mantel-Haenszel estimates adjusted for age only

1. La Vecchia C, Franceschi S, DeCeti A, et al. Cancer. 1986;58:933–941.

Management of Women With CIN 1

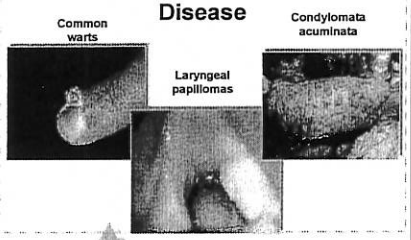


Management of Women with CIN 2 or 3



Except for special circumstances CIN 2 & 3 are both actively managed by either Excision (LEEP) or by Ablation (cryo)

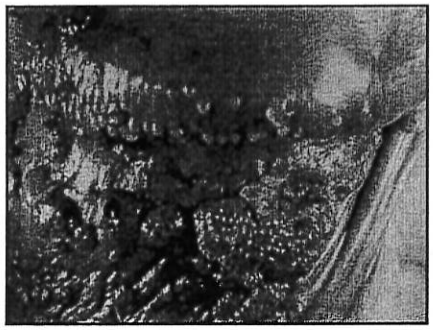
Benign HPV-Associated Disease

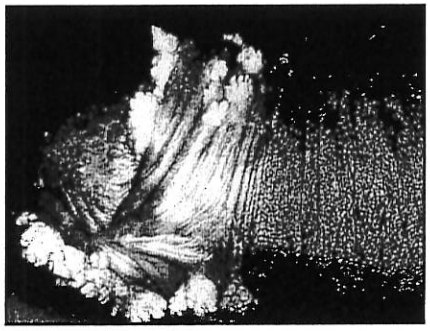


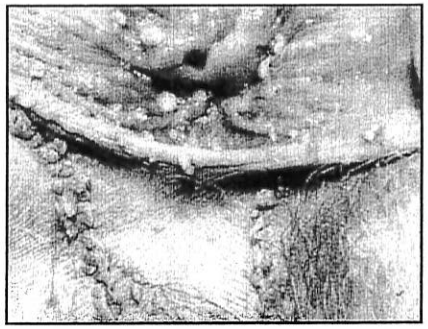
HPV and Anogenital Warts

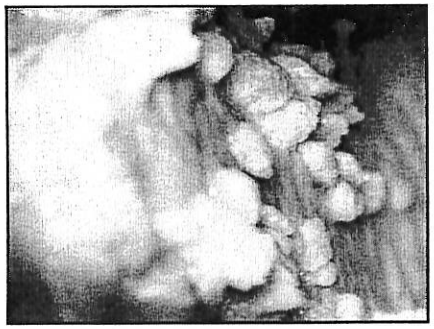
- HPV 6 and 11 responsible for >90% of anogenital warts[1]
- Infectivity >75%[2]
- Up to 30% spontaneously regress within 4 months.[3]
- Treatment can be painful and embarrassing.[4]
- Topical and surgical therapies are available for genital warts.[5]
- Recurrence rates vary greatly.[5]

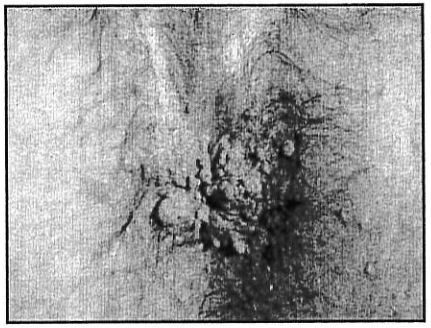
1. Jansen KU, Shaw AR. *Annu Rev Med*. 2004;55:319–331. 2. Soper DE. In: Berek JS, ed. *Novak's Gynecology*. 13th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2002:453–470. 3. Lacey CJN. *J Clin Virol*. 2003;32(suppl):S82–89. 4. Maw RD, Reitano M, Roy M. *Int J STD AIDS*. 1998;9:571–578. 5. Kodner CM, Nasraty S. *Am Fam Physician*. 2004;70:2335–2342.

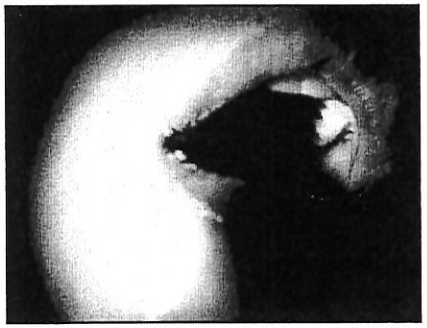








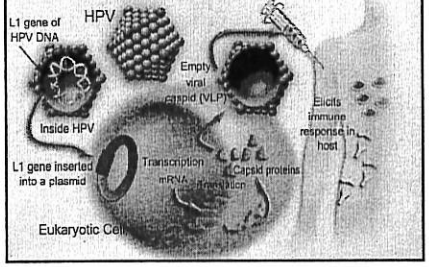




GARDASIL®: The First Cervical Cancer Vaccine in the United States

- Quadrivalent human papillomavirus 6/11/16/18 L1 virus-like particle (VLP) vaccine
- VLPs are produced in *Saccharomyces cerevisiae*
  - The L1 proteins self-assemble into VLPs.
  - Purified VLPs are adsorbed on aluminum-containing adjuvant.
  - The adjuvant is amorphous aluminum hydroxyphosphate sulfate (225 µg per dose)
- Each 0.5-mL dose contains HPV Types 6/11/16/18 (20/40/40/20 µg L1 protein, respectively).

HPV L1 Virus-Like-Particle (VLP) Vaccine Synthesis



Licensed & Candidate Prophylactic HPV Vaccines

Vaccine/ Manufacturer	HPV Types	Schedule	Adjuvant	Target Groups
Quadrivalent Merck	6/11/16/18	0,2,6 mos	Alum	Females & Males
Bivalent GSK	16/18	0,1,6 mos	Alum and MPL (AS04)	Females

Merck only one now available

Prophylactic Efficacy: GARDASIL® Was 100% Efficacious Against HPV 16- and 18-related CIN 2/3 or AIS

Population	n	GARDASIL Cases	n	Placebo Cases	Efficacy	95% CI
Protocol 005*	755	0	750	12		85.1–100
Protocol 007	231	0	230	1		-3734.9–100
FUTURE I	2,200	0	2,222	19		78.5–100
FUTURE II	5,301	0	5,258	21		80.9–100
Combined protocols	**8,487**	**0**	**8,460**	**53**	**100%**	**92.9–100**

*Evaluated only the HPV 16 L1 VLP component of GARDASIL.
†P-values were computed for the prespecified primary hypothesis tests: All p-values were <0.001, supporting the following conclusions: efficacy against HPV 16/18-related CIN 2/3 is >0% (FUTURE II); and efficacy against HPV 16/18-related CIN 2/3 is >25% (combined protocols).

Prophylactic Efficacy: GARDASIL® Was Efficacious Against HPV 6-, 11-, 16-, and 18-related CIN (CIN 1, CIN 2/3) or AIS

Population	n	GARDASIL Cases	n	Placebo Cases	Efficacy	95% CI
Protocol 007	235	0	233	3		-137.8–100
FUTURE I	2,240	0	2,258	37		89.5–100
FUTURE II	5,383	4	5,370	43		74.4–97.6
Combined protocols	**7,858**	**4**	**7,861**	**83**	**95.2%**	**87.2–98.7**

*P-values were computed for the prespecified primary hypothesis tests. All p-values were <0.001, supporting the following conclusions: efficacy against HPV 6/11/16/18-related CIN is >20% (FUTURE

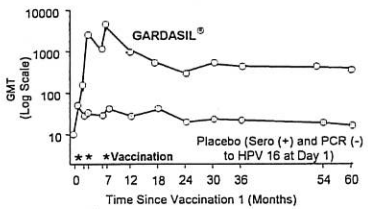
Prophylactic Efficacy: GARDASIL® Was Efficacious Against HPV 6-, 11-, 16-, and 18-related Genital Warts

Population	n	GARDASIL Cases	n	Placebo Cases	Efficacy	95% CI
Protocol 007	235	0	233	3		-139.5–100
FUTURE I	2,281	0	2,279	29		86.4–100
FUTURE II	5,401	1	5,387	59		90.2–100
Combined protocols	**7,897**	**1**	**7,899**	**91**	**98.9%**	**93.7–100**

- The efficacy of GARDASIL against HPV 6-, 11-, 16-, and 18-related VIN 1 or VaIN 1 was 100%.

Anti-HPV 16 Levels Through 5 Years

Protocol 007



Merck, unpublished data. Presented at ACIP meeting, June 2006

All-Cause Common Systemic Adverse Experiences*

Adverse Experience (1 to 15 days postvaccination)	GARDASIL® (N = 5,088) %	Placebo (N = 3,700) %
Pyrexia	13.0	11.2
Nausea	6.7	6.6
Nasopharyngitis	6.4	6.4
Dizziness	4.0	3.7
Diarrhea	3.6	3.5
Vomiting	2.4	1.9
Myalgia	2.0	2.0
Cough	2.0	1.5
Toothache	1.5	1.4
Upper respiratory tract infection	1.5	1.5
Malaise	1.4	1.2
Arthralgia	1.2	0.9
Insomnia	1.2	0.9
Nasal congestion	1.1	0.9

*Greater than or equal to 1% frequency and greater than or equal to the incidence in the placebo group.

All-Cause Serious Adverse Experiences*

Adverse Experience (1 to 15 days postvaccination)	GARDASIL® %	Placebo %
Headache	0.03	0.02
Gastroenteritis	0.03	0.01
Appendicitis	0.02	0.01
Pelvic inflammatory disease	0.02	0.01

One case of bronchospasm and 2 cases of asthma were reported as serious adverse experiences that occurred during Days 1–15 of any vaccination visit.

*Most frequently reported.

All-Cause Related Mortality

Cause of Death	GARDASIL® N	Placebo N
Motor vehicle accident	4	3
Overdose/suicide	1	2
Pulmonary embolus/DVT	1	1
Sepsis	2	0
Pancreatic cancer	1	0
Arrhythmia	1	0
Asphyxia	0	1

The events reported were consistent with events expected in healthy adolescent and adult populations.

DVT = deep vein thrombosis

New Medical Conditions After Enrollment*

	GARDASIL® (N = 11,813)	Placebo (N = 9,701)
Potential Autoimmune Disorder	3 (0.025%)	1 (0.010%)
Specific Terms		
Juvenile arthritis	1	0
Rheumatoid arthritis	2	0
Systemic lupus erythematosus	0	1
Other Terms	6 (0.051%)	2 (0.021%)
Arthritis	5	2
Reactive Arthritis	1	0

N = Number of subjects enrolled

*Potentially indicative of a systemic immune disorder.

GARDASIL® (Quadrivalent Human Papillomavirus [HPV Types 6, 11, 16, 18] Recombinant Vaccine)

Summary of Pregnancies in the Phase III Program for GARDASIL®1

	GARDASIL (n=10,418)	Placebo (n=9,120)
Subjects with pregnancies	1,115	1,151
Number of pregnancies	1,244	1,272
Pregnancies with unknown outcomes/Ongoing pregnancies	258	263
Pregnancies with known outcomes	996	1,018
Live births (% of pregnancies with known outcomes)	621 (62)	611 (60)
Fetal loss (% of pregnancies with known outcomes)	375 (38)	407 (40)

n = Number of subjects who received 1, 2, or 3 doses of only the clinical material in the given column.
The GARDASIL group included more 9- to 15-year-olds than the placebo group.
1. Data on file, MSD

GARDASIL® (Quadrivalent Human Papillomavirus [HPV Types 6, 11, 16, 18] Recombinant Vaccine)

Summary of Known Pregnancy Outcomes in the Phase III Program for GARDASIL®1

	GARDASIL	Placebo
Pregnancies with Known Outcomes/EOP Within 30 Days of Vaccination	112	115
Spontaneous loss	21 (18.8%)	26 (22.6%)
Elective termination	21 (18.8%)	23 (20.4%)
Live birth	70 (62.5%)	66 (57.4%)
Pregnancies with Known Outcomes/EOP Beyond 30 Days of Vaccination	879	898
Spontaneous loss	236 (26.8%)	237 (26.4%)
Elective termination	93 (10.6%)	117 (13.0%)
Live birth	549 (62.5%)	544 (60.6%)

Estimated EOP could not be precisely ascertained in 10 women.
EOP = Onset of pregnancy.
1. Data on file, MSD

GARDASIL® (Quadrivalent Human Papillomavirus [HPV Types 6, 11, 16, 18] Recombinant Vaccine)

Pregnancy Outcomes: Congenital Anomalies1

Results	GARDASIL® Cases	Placebo Cases
Congenital Anomalies*	15	16
Estimated onset of pregnancy ≤30 days of vaccination	5*	0
Estimated onset of pregnancy >30 days following vaccination	10	16

The types of anomalies observed were consistent (regardless of when pregnancy occurred in relation to vaccination) with those generally observed in pregnancies in women aged 16 to 26 years.

*Congenital anomalies included pyloric stenosis, congenital megacolon, congenital hydronephrosis, hip dysplasia, and club foot.

1. Data on file, MSD.

Dosage and Administration of GARDASIL®

GARDASIL should be administered intramuscularly as 3 separate 0.5-mL doses according to the following schedule:

- First dose: at elected date
- Second dose: 2 months after the first dose
- Third dose: 6 months after the first dose

Indications and Usage for GARDASIL®

GARDASIL is a vaccine indicated in girls and women 9 to 26 years of age for the prevention of the following diseases caused by HPV types 6, 11, 16, and 18:

- Cervical cancer
- Genital warts (condyloma acuminata)

& the following precancerous or dysplastic lesions:

- Cervical AIS
- CIN grades 2 and 3
- VIN grades 2 and 3
- VaIN grades 2 and 3
- CIN grade 1

GARDASIL® [Quadrivalent Human Papillomavirus (HPV Types 6, 11, 16, 18) Recombinant Vaccine]

Why Early Vaccination?

- Important to reach younger adolescents *prior to exposure*
- Adolescent females may have *increased susceptibility to HPV infection*[1-3]
- *Timing opportunity*: young children (9 to 12 years old) have more frequent contact with health care provider pediatrician) than older adolescents (>13 years old)[4]
- *Adolescents are sexually active*[5]
  - Nationwide, 7.4% of the students had sexual intercourse for the first time before age 13 years.
  - Overall, the prevalence of female students having sexual intercourse before age 13 years was 4.2%.[5]

1. Kahn JA. *Curr Opin Pediatr*. 2001;13:303–309. 2. Rapet KM, Kahn JA, *Curr Women Health Rep*. 2002;2:468–475. 3. ACOG Committee on Adolescent Health Care. Obstet Gynecol. 2004;104:891–898. 4. Dietz WH, Phelps-Tanguma CA, Averhoff F, et al. *J Am Board Fam Pract*. 2005;18:13–19. 5. Grunbaum JA, Kann L, Kinchen S, et al. *MMWR*. 2004;53(SS-2):1–96.

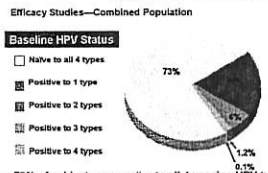
Why "Catch-Up" Vaccination?

- It is *not too late* to vaccinate older adolescents and young adult females.
  - Likelihood of exposure to multiple vaccine types is still low.
  - Those positive to 1 or more vaccine HPV types can still benefit from disease caused by the other vaccine types.
- *All* appropriate females *aged 9-26* should be considered vaccine candidates.
- *Timing opportunity*: office visits for Pap screening and/or oral contraceptives offer opportunity for counseling about vaccination.
- *Most* young women *can still benefit* from vaccination.

GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine]

Subjects Exposed to Any Vaccine HPV Type at Enrollment

Efficacy Studies—Combined Population



93% of subjects were naive to ≥3 vaccine HPV types (6, 11, 16, or 18) at enrollment.

27% of subjects had evidence of prior exposure to or ongoing infection with at least 1 of the 4 vaccine HPV types.

- 73% of subjects were naive to all 4 vaccine HPV types.
- Among subjects who were positive to a vaccine HPV type, most were positive to only 1 type.
- Exclusion criteria: 6 or more sexual partners

Data available on request from Merck & Co., Inc., Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package 20651717(4)-GRD.

Routine Vaccination Provisional Recommendation

- ACIP recommends routine vaccination of females 11-12 years of age with three doses of quadrivalent HPV vaccine
- The vaccination series can be started as young as 9 years of age

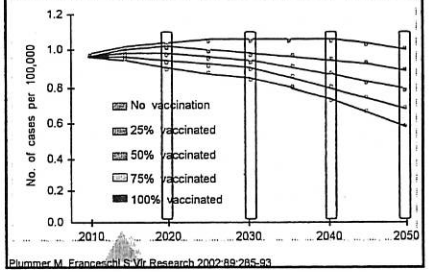
Summary for GARDASIL®

- Candidates: Females age 9 to 26
- Older: Studies up to age 48 – not yet FDA approved
- Previous disease or HPV DNA positivity: Give – will protect against other HPV types in the vaccine

Summary for GARDASIL®

- Males: Being studied – not yet FDA approved
- Pregnancy: Not studied, not FDA approved – report to Registry: (800) 986-8999
- Therapeutic: No, only prophylactic

Projected number of cervical cancer cases in developed countries, as a function of percent of population immunized



Plummer M, Franceschi S. Vir Research 2002;89:285-93

Currently Required in Kansas

Diphtheria	***Measles***
Tetanus	***Mumps***
Pertussis	***Rubella***
Polio	***Varicella***

Currently Required in Kansas

Diphtheria	*Measles*
Tetanus	*Mumps*
Pertussis	*Rubella*
Polio	*Varicella*

Hepatitis B

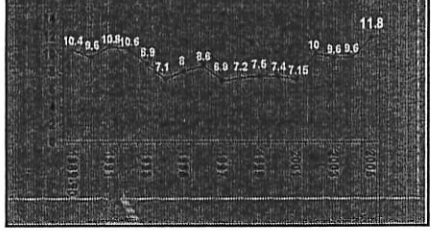
Encouraging Sexual Activity?

- 174 studies with 116,735 participants: sexual risk reduction interventions do not inadvertently increase the overall frequency of sexual behavior. *Smoak, et al*
- Knowledge of HPV as an STD is extremely limited among adolescents limiting the potential number who could be encouraged to become sexually active. *Am Ca Soc*
- There is simply no data to support this concern.

Results of Education

- Education and availability of emergency contraception: no change in sexual behavior. *Raine et al*
- Intensive education in college setting has failed to result in lowered Pap smear rate. *ACHA*
- Possible effects of education are reduced by use of alcohol. *ACHA*

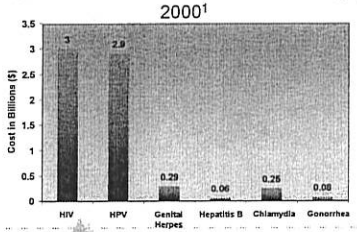
Abnormal Pap Potential in College Health ACHA Pap Smear Surveys



Focus on the Family (Dobson)

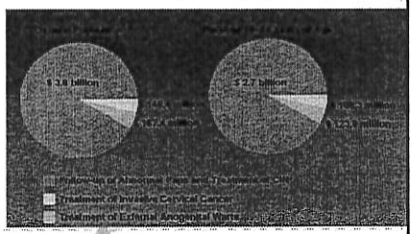
- Not having sex is the only choice that offers full protection against STIs and pregnancy.
- In addition to not having sex, some people choose to add the protection of this shot because we can't always predict what will happen in the future and how we might be unexpectedly exposed to this virus.
- HPV infection can result from non-consensual sex, including sexual assault and date rape.
- Young people may marry someone who is infected with the virus thus putting themselves at risk for infection.

Estimated Direct Medical Costs of HPV and Other STIs in Persons 15–24 Years of Age, 2000[1]



1. Chesson HW, Blandford JM, Gift TL, Tao G, Irwin KL. *Perspect Sex Reprod Health.* 2004;36:11–19.

Estimated Total Cost of HPV Infection in the United States, 2000[1]



1. Chesson HW, Blandford JM, Gift TL, Tao G, Irwin KL. *Perspect Sex Reprod Health.* 2004;36:11–19.

Cost

- Considering the huge economic and emotional costs of HPV caused diseases, it is believed that vaccination should be cost-effective. Data currently not complete, with many variables.
- This vaccine is the most expensive ever developed by Merck.

Funding for Vaccines

- Private Insurance
- Vaccines for Children Program (VFC)
- Section 317 Grant Program
  - State monies for uninsured
- Merck Vaccine Patient Assistance Program
  - http://www.merck.com/merckhelps/vaccines/home.html

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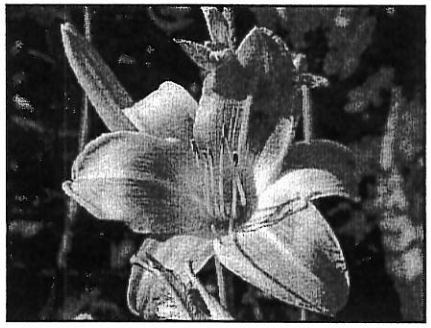

THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER
WASHINGTON DC

SCHOOL OF PUBLIC H TH
& HEALTH SE ES

DEPARTMENT OF HEALTH POLICY
CENTER FOR HEALTH SERVICES RESEARCH
& POLICY

Testimony on House Bill 2227
February 7, 2007

Chairwoman Landwehr and members of the House Health and Human Services Committee, thank you for the opportunity to testify regarding H.B. 2227. My name is Alexandra Stewart, and I am an Assistant Research Professor from the Department of Health Policy, School of Public Health and Health Services, The George Washington University Medical Center, in Washington, DC. I am here today because my primary research area is U.S. vaccine policy, focusing on access issues for all populations.

I am pleased to participate in the 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.

It has long been recognized that the 10th 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 have withstood challenges in state and federal courts. The laws outline which immunizations are required and also allow some children to be excused from the requirements for one of 3 reasons:

1. Exemption may be granted for medical reasons (50 states),
2. Exemption may be granted for religious reasons (48 states, including Kansas),
3. Exemption may be granted because of the parent's personally held beliefs. (20 states, Kansas has not adopted this exemption)

Despite the availability of exemptions, over 95% of all school-age children ultimately receive mandated immunizations. The laws have proven to be the most effective mechanism ever devised to vaccinate our children. School vaccine mandates have 4 primary outcomes:

1. School vaccine mandates have increased the use of all recommended vaccines.

2. School vaccine mandates reduce incidence of disease for vaccine preventable diseases. Diseases that were once common have all but disappeared.

3. School vaccine mandates reduce disparities in vaccine coverage. Children who live in low-income families or have been unable to establish a medical home receive vaccinations because of school requirements.

4. School vaccine mandates increase available public funding for vaccines.

Thus, as a policy decision, we can safely assume that a school mandate requiring HPV immunization will achieve more widespread protection against cervical cancer than if Kansas relied on other policy reforms such as parental education and persuasion.

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The existing structure for financing vaccines is designed to accommodate newly recommended vaccines. HPV vaccine will be distributed through this mechanism and has already been implemented as follows:

A. PUBLIC FUNDING STREAMS FOR VACCINES:

Medicaid/State Children's Health Insurance Program (SCHIP):

- Mandatory benefit for all enrollees under age 21,
- American Indian, Alaska Native teens under 18,
- Optional benefit for all enrollees over age 21. In Kansas, this population is not covered for HPV, according to 12/06 Provider Manual. (other vaccines are covered)

Vaccines for Children Program (VFC):

- For children through age 18, HPV coverage is available at no cost to patient or provider
  - Uninsured
  - Have private insurance that does not provide coverage for HPV vaccine

Federally-qualified health centers and rural health clinics:

- Charge for services on a sliding scale.

B. PRIVATE FUNDING STREAMS FOR VACCINES:

Employer-based or individually purchased medical insurance:

- Many insurers will reimburse enrollees and providers for the cost of HPV vaccine according to current payment standards regarding cost sharing.
- A CPT code has already been established and is currently operating: 90649

As Kansas reviews the issues surrounding an HPV vaccine mandate, I hope my comments have informed this discussion. I will be happy to stand for any questions. Thank you.

KANSAS MEDICAL SOCIETY
KMS

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Statement of the Kansas Medical Society
on the
University of Kansas School of Medicine
Plans for Research & Education Partnerships
to Advance the Life Sciences

January 24, 2007

The Kansas Medical Society has been a strong advocate for, and supporter of, the University of Kansas School of Medicine since its inception. Even though the school of medicine operates through two campus locations, Kansas City and Wichita, it is still one medical school. And as Kansas' only medical school, no institution is more important to the ability of our state to train adequate numbers of physicians to meet the health care needs of the people of Kansas. KMS believes that the primary mission of the medical school, as a state taxpayer-supported institution, is to train high quality physicians, many of whom it is hoped will practice medicine in our state. KMS also understands that to achieve and maintain excellence in today's competitive academic and research worlds, the medical school must have the vision and the resources to give it the best opportunity to succeed.

It is clear that the discussions and plans which have been advanced to move KU aggressively forward in the area of life sciences research represent an opportunity that is unique, and which could produce substantial benefits to the medical center, the region, and to the state. The catalyst for these plans was a 2005 report sponsored by the Greater Kansas City Community Foundation. This report was intended to stimulate Kansas City-area educational, philanthropic, business, health care, and research institutions to collaborate on a strategy to drive the region's economic and intellectual prosperity, and to invigorate the urban core.

KU plans to make an institutional commitment of the highest priority to position the entire academic medical center complex as a national leader in life sciences research. While research is certainly a core attribute of any academic medical center, as a taxpayer-supported institution, KU has a responsibility to assure the state that this intensified focus on research will not overwhelm nor replace its other public purposes. There are several important issues including the overall mission of the medical center complex, the benefits to the state, and the impact on the medical center's clinical enterprise that should be carefully considered before any formal restructuring or affiliations are completed.

House Health and Human Services
DATE: 2-7-07

ATTACHMENT 5-1

As part of the overall plan KU intends to embark on a ten-year strategy to build its research capacity - adding 100 researchers, doubling its PhD training programs, and spending an estimated $645 million on physical and human resources, the bulk of it dedicated to research. How will this pronounced shift toward biomedical research and development impact the medical school's core mission of training physicians and other health care professionals for the entire state? Will preference and emphasis on the hiring of faculty favor researchers over teachers? Will the enhanced research orientation tend to drive students towards careers in academic research in greater Kansas City versus clinical practice in communities throughout the state? How will this emphasis on biomedical research affect the other essential teaching and clinical departments at KU? Will they also receive increased support for faculty and facilities to move their departments along the same trajectory? Will the Wichita branch of the medical school, which many believe is already in need of increased state support, be helped or hurt by these plans?

As a part of its plan to become a leader in life sciences research, KU has announced a proposed affiliation with St. Luke's Hospital, a Kansas City, Missouri-based medical care facility that is a direct competitor of the University of Kansas Hospital. KU officials have not yet made it clear why an affiliation with St. Luke's, or any other hospital for that matter, is essential to KU's plans to participate in the greater Kansas City life sciences effort. Whatever the reasons, the proposed affiliation with St. Luke's, in particular, raises some issues that should also be given very careful consideration.

The KU Hospital has been, and remains today, a critical component to the success of the KU academic medical center complex. The university hospital exists to support the teaching, clinical, and research activities of the University of Kansas Medical Center and its health sciences schools, to provide for the education and training of health care professionals, to provide patient care and specialized services not widely available elsewhere in the state. In addition, true to its mission, the KU Hospital and its medical staff provide substantial amounts of uncompensated care and care to Medicaid patients. It cannot be denied that the university hospital's affiliation with KU is a very valuable tie that differentiates that hospital from other hospitals in the region. In market terms, it undoubtedly gives the university hospital a competitive advantage that may be coveted by area hospitals. Any action by KU that could potentially weaken the university hospital – which, although operated as an independent authority, is still property of the state of Kansas – must be critically evaluated. It has been reported that the KU Hospital, and many of its clinical staff, are very concerned that the affiliation with St. Luke's could dilute the KU brand, and harm the university hospital's ability to compete in the region. How will this affiliation affect the ability of the university hospital to attract and retain clinical staff in order for it to continue to be a leader in improved quality, service to patients, and financial performance?

It has also been reported that neither the leadership of the hospital, nor the medical staff leadership, has had meaningful participation in the affiliation discussions that KU has conducted with St. Luke's officials. At a minimum, that could damage the spirit of trust and teamwork which has been so important in the hospital's ascending reputation as a well-run, high-quality institution. Given the history of the two hospitals and their very different cultures, a hurried or

forced collaboration is a recipe for divisiveness and discontent, as they will continue to compete for patients, clinical faculty, research funding, and academic recognition.

The Kansas Medical Society supports KU's desire to continue to expand its commitment to the life sciences research development effort in the greater Kansas City area. However, those plans should not diminish the medical school's capacity, commitment, and focus, on training physicians for our state, nor should they harm the university hospital or the clinical enterprise of the university medical center. If the plans and proposed affiliations are sound and consistent with the mission of the medical school, and if they produce benefits for the entire state, a more transparent, inclusive and deliberate discussion will help build support for the program. KU currently receives over $100 million of state-funded taxpayer support annually, and that number is likely to increase as the life sciences effort matures. The implications for the future of the entire University of Kansas Medical Center, including the faculty and the university hospital, for medical education and producing physicians for our state, and for the implications on state tax support, require that the plans for research and clinical affiliations be clearly articulated and carefully considered before any commitments or affiliations are formalized.

Testimony Before the House Committee on Health and Human Services

Wednesday, February 7, 2007
House Resolution 6006
by
Robert Hemenway
Chancellor, University of Kansas

Chairman Landwehr and members of the committee:

I am pleased to have this opportunity to appear before you and share with you some exciting developments at the University of Kansas Medical Center. It was recently announced that the medical center has entered into separate letters of intent with Saint Luke's Hospital and the University of Kansas Hospital to pursue broader affiliations with each institution. The parties are now working on the details of these new partnerships and I am hopeful that the major issues involved will be resolved in the next several weeks.

I appear before you today as the Chancellor of the University and as Vice Chairman of the Board of the University of Kansas Hospital Authority.

Much like my appearance before the Joint Committee on Legislative Budget in December, my purpose today is to provide you with an update on why the University of Kansas is pursuing these affiliations and why such partnerships are good for Kansas. I will also address why House Resolution 6006 is unnecessary and may, if enacted, have some fairly significant and costly, unintended consequences to our state. Most important, I want to leave plenty of time to respond to your questions.

The University of Kansas Medical Center exists to educate and train health professionals and scientists, people who are committed to discovering cures for diseases that afflict us, and delivering those cures to the people of Kansas and the region.

An academic medical center consists of two basic elements: a medical school and its primary hospital. The medical school is where the research and the teaching take place; further research and teaching by the medical faculty and the delivery of cures take place at the hospital. The quality of an

academic medical center is determined by the quality of its medical school, its allied health and nursing schools, and its hospital and the extent to which all focus on discovery and delivery of cures.

In the last few years The University of Kansas Hospital has become financially and administratively sound. The creation of a KU Hospital Authority Board and restructuring of the hospital in 1998 put into place an administrative team that has carefully managed the hospital. The KU Hospital has gone from a place with serious problems to a financially successful hospital with a proud record of superb care.

Unlike community and for-profit hospitals, an academic medical center hospital must re-invest its profits into the medical school and its faculty to promote the basic research and teaching that give rise to the discovery of cures. Kansas state statute requires this re-investment. In every academic medical center there is a tension in striking the right balance between meeting the financial needs of the hospital and investing in the medical school. The best administrators and the best hospital boards understand this and find that right balance.

As important as the relationship is between a medical school and its primary hospital, the best academic medical centers must expose their students to many types of patients, procedures and styles of care in order to produce the very best physicians. This requires that a medical school affiliate with more than one hospital. A single hospital cannot sustain the requirements of a large and growing medical school.

In fact, a majority of the top 25 academic medical centers in the U.S. have multiple major hospital affiliations. This is the norm rather than the exception.

We currently have multiple affiliates, including the two largest hospitals in Kansas - Wichita's Via Christi Regional Center and Wesley Medical Center. In Kansas City, we have decided to affiliate with additional hospitals to train more doctors and better educate them. Broad affiliation also is necessary if the KU Medical Center is to achieve its goal of becoming a National Cancer Institute-designated cancer center - the gold standard for cancer care. Expanding our research effort to seek cures for cancer is KU's No. 1 goal. We are far less likely to attain our cancer center goal without these affiliations.

The Director of the KU Cancer Center, Dr. Roy Jensen, has confirmed that our university's quest for National Cancer Institute designation for our cancer center will be aided by greater collaborations with hospitals in our region. In fact, obtaining such a designation may be impossible without such partnerships.

KU's application for NCI designation requires significant levels of collaboration among health care institutions.

In order to achieve NCI designation as a comprehensive cancer center, KU will have to enlist the support and partnership of our region's leading health care providers. Obviously, the KU Hospital Authority will lead the way, but to be successful we must also have the major hospitals in Kansas City, Wichita, and in the region behind our application. These hospitals could choose to affiliate with other cancer centers, such as the one in St. Louis, and in doing so would significantly compromise our region's ability to obtain NCI status at our state's academic medical center.

The affiliation with these partners will ultimately make it possible for us to train an additional 100 doctors a year at an annual cost in excess of $10 million, which will be paid to the KU Medical Center entirely by these new hospital partners. As the state's only medical school, we are eager to train 100 additional doctors every year. Since more than half of all practicing physicians in Kansas are graduates of our medical school or residency programs, we are confident that this affiliation will make more doctors available to serve Kansas communities.

In addition to other benefits, these broader affiliations are supported by a broad-based group of corporations and private donors that has pledged $150 million new dollars to support the expanded research and education vision of our medical center in partnership with other life sciences institutions. This is a staggering level of private investment in our state's academic medical center and one that is necessary for us to achieve our goal of obtaining top 50 status in National Institutes of Health funding.

The positive economic impact of such growth would be impressive as well. Take for example the University of Iowa, which ranks 30th overall in National Institutes of Health funding: they contribute $4.1 billion in total state business volume impact, based on a study released just last month.

KU, by comparison, ranks 81st in NIH funding and contributes $1.3 billion in total state business volume impact—an impressive contribution, but you can easily see how moving up in the rankings could provide a significant economic windfall for our state.

Medical research and education are expensive and complicated. But the fundamental purpose of KUMC is simple: making the people of Kansas and the United States healthier. The superb doctors and researchers at the KU Medical Center, KU Hospital, Saint Luke's, Children's Mercy Hospital, the Veterans Administration Hospitals in Kansas City, Leavenworth, Topeka and Wichita, as well as our medical faculty and partner hospitals in Wichita, Salina, and Topeka, are part of a vibrant network of talent focused on this fundamental purpose.

As we work to finalize definitive agreements, let me reassure you, as I did the Legislative Budget Committee, of the issues that are **not** on the table:

- We will not support any partnerships or affiliations detrimental to the future of the KU Hospital or the patients it serves.

- We will not support affiliations that transfer Kansas taxpayer dollars to directly benefit Missouri-located institutions.

- We will only support affiliations which, in accordance with national graduate medical education guidelines, provide KU Hospital with an appropriate number of resident physicians.

- We will not support any affiliation that would compromise our commitment to train doctors for Kansas or to serve indigent Kansans.

- These affiliations are not being pursued to provide KU-based researchers with access to Missouri-based locations for the purpose of conducting stem cell research. In fact, St. Luke's hospital does not do stem cell research.

- We will only support affiliations which advance the vision of creating and sustaining new levels of excellence in the KU School of Medicine—and thereby contribute to improving the health of our state and region.

We believe in responsible, ethical medical research that is recognized by the National Institutes of Health, and that gives patients access to cures that save lives.

We will keep the Kansas Board of Regents and the Kansas Legislature fully briefed on these affiliation discussions as we move forward—and at all times we welcome your feedback and look forward to addressing your concerns.

Finally, I would urge caution in adopting a resolution such as this. Its wording would require significant new administrative processes in order to comply with its intent, and the restrictions imposed by it could easily prevent many promising and productive agreements from going forward. The language of the resolution would prevent the KU Hospital and the KU Medical Center, including our campus in Wichita, from entering into any commitment for any affiliation with other hospitals, institutions or entities without legislative approval.

While we always welcome the opportunity to respond to any concern you may have about the University of Kansas, we believe that an effective and sound system of oversight already exists. The Medical School, Nursing School, and Allied Health Professions must follow national accreditation guidelines in all of its programs, and accreditors periodically review these programs. The University of Kansas Hospital is governed by an authority board appointed by the governor and approved by the Senate. The University of Kansas is governed by a Board of Regents appointed by the governor and confirmed by the legislature. These entities are bound by state law to pursue and achieve a specific mission to benefit the state and its citizens. We believe that the appropriate levels of oversight already exist and that this resolution is therefore simply not necessary in order to protect the interests of the state.

An academic medical center has literally hundreds of affiliations, ranging from agreements to place nurses in hospitals for practicum training, to agreements sharing life-saving medical equipment to transplant a baby's liver. Lives are saved every day because affiliations have been arranged. It would be counter-productive to make each of those transactions subject to legislative oversight.

Let me assure you the University of Kansas remains fully dedicated to discovering and delivering more cures to Kansans, creating better health, training more doctors, training better doctors, training other health care professionals, and contributing to the economic vitality of our state. The achievement of all of these goals is enhanced as a result of the affiliations currently being pursued.

Thank you for your consideration and attention. I would be pleased to respond to your questions.