Approved: March 6, 2007
Date

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

The meeting was called to order by Chair Brenda Landwehr at 1:30 P.M. on February 8, 2007 in Room 526-S of the Capitol.

All members were present.

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:
Representative Tim Owens
Dr. Howard Rodenberg, Kansas Department Health and Environment
Susan Wikle, Kansas Action for Children
Mark Desetti, Kansas National Education Association
Judy Smith, Concerned Women of America
Beatrice Swoops, Kansas Catholic Foundation
Dr. Barbara Atkinson, University of Kansas Medical Center
Dr. Roy Jenson, University of Kansas Medical Center

Others Attending:
See Attached List.

Chair Landwehr re-opened hearings on **HB2227**- Requiring female students enrolling in grade six to be inoculated against the human papilloma virus. (H.P.V.)

Testifying in opposition was **Representative Tim Owens** who questioned the cost of implementing this program. Private physicians would have to maintain an inventory of the vaccine at expense to them complicated by the shelf life of the vaccine and no replacement program from the supplier or the federal government.

Proponent **Dr. Howard Rodenberg**, Kansas Department of Health and Environment, (K.D.H.E.) provided statistics regarding incidence of H.P.V. infection and cervical cancer deaths in Kansas. Dr. Rodenberg pointed out that by preventing infection with H.P.V., this agent represents the first vaccine we've ever had against cancer. Preventing both acute infections and long-term chronic disease are key goals of public health, and the vaccine is a significant advance in our capability to improve life and health. (Attachment 1)

Due to some operational concerns, K.D.H.E. recommends that this bill begin with the 2009 school year for several reasons. First is that concerns regarding the vaccine might be addressed, and second, the approaching availability of a second supplier drug could change pricing. In addition, a delay would insure that federal funds are available to allow all Kansas children who need the vaccine to receive it without "out-of-pocket" costs.

Dr. Rodenberg concluded by stating that this bill raises issues about sexual behavior in teens. The HPV vaccine is not a ticket to risk-free sexual behavior; it does not prevent HIV, AIDS or other sexually transmitted diseases. It does , however, allow us to protect our children in a way we've never had available to us before; and keeping our children safe is what most parents care most deeply about.

Suzanne Wikle, of Kansas Action for Children, testified as a proponent of **HB 2227** stating that her organization's interest in this issue is to support public policy that is in the best interest of Kansas Children. She stated that the H.P.V. vaccine is prevention at its best. She added that mandating the vaccine will reduce health disparities, that parental awareness will increase the likelihood of vaccination, and that vaccinating early makes sense. (Attachment 2)

MINUTES OF THE House Health and Human Services Committee at 1:30 P.M. on February 8, 2007 in Room 526-S of the Capitol.

Proponent **Mark Desetti**, of Kansas National Education Association, stated that **HB2227** is an appropriate measure designed to protect the health of girls and women. Mandating a vaccine is not without precedent. Polio, Tuberculosis, Hepatitis B, and Meningitis are examples. They support this bill because it would make the vaccination available to families who could not otherwise afford it. (Attachment 3)

Opponent **Judy Smith** of Concerned Women of America stated that they are not opposed to the vaccine but are opposed to a mandate. She cited some issues, including parental rights, long term support of the vaccine, expense, lack of long term data, and the fact that this vaccine doesn't eliminate 100 percent of the of types of H.P.V. virus. (Attachment 4)

Beatrice Swoops, Kansas Catholic Conference, testified in opposition to **HB2227**. She stated that the vaccine availability is a wonderful medical breakthrough, but she doesn't support a mandate for vaccination of 6th grade girls. Some concerns are the drug's duration of protection, the degree of protection, and the array of side effects it may cause. She also pointed out that typical vaccinations are meant to guard against illnesses which are transmitted by casual contact and to which a school child might acquire at school. H.P.V. is spread by sexual contact and a school child is not likely to be exposed to this disease at school. (Attachment 5)

The following supplied written testimony to the committee:
Marla Patrick, Proponent (Attachment 6)
Representative Jo Ann Pottorff, Proponent, (Attachment 7)
Kansas Association of School Boards, Neutral (Attachment 8)
American Cancer Society, Neutral (Attachment 9)
Right To Life of Kansas, Inc. Opponent (Attachment 10)
Sharon Smith, Opponent (Attachment 11)

Chair Landwehr closed hearings on **HB2227** and re-opened hearings on **HCR6006** - Resolution urging the Governor and University of Kansas Medical Center to not enter any affiliation without legislative review.

Dr. Barbara Atkinson of the University of Kansas Medical Center stated that she and Dr. Roy Jenson were there to answer questions left from Chancellor Hemenway's testimony yesterday. She presented a letter prepared by a KUMC student which addressed two of the questions that had been raised. (Attachment 12)

Written testimony was provided by:
The University of Kansas Hospital, Opposed (Attachment 13)
Kansas Board of Regents, Opposed (Attachment 14)
University of Kansas School of Medicine, Wichita - Opposed (Attachment 15)
Kansas Masonic Foundation, Opposed (Attachment 16)
Kansas Academy of Family Physicians, Neutral (Attachment 17)
Letter of Intent between K.U.M.C .and S.L.H .Attachment (Attachment 18)
Letter of Intent between K.U.M.C .and K.U.H. Attachment (Attachment 19)
Legislative Budget Committee Conclusion and Recommendations K.U.M.C, K.U. Hospital and Missouri-Based Hospitals (Attachment 20)

Following Questions and Answers, Chair Landwehr closed hearings on HCR 6006.

Chair Landwehr announced that we would not be working **HB 2098** today since some committee members had to leave. Meeting was adjourned. Next meeting will be Monday, Feb. 12.

Unless specifically noted, the individual remarks recorded herein have not been transcribed verbatim. Individual remarks as reported herein have not been submitted to the individuals appearing before the committee for editing or corrections.

HOUSE HEALTH AND HUMAN SERVICES COMMITTEE GUEST LIST

DATE: February 8, 2007

NAME	REPRESENTING
Jennifer Hurt	SCNS
Roy Jensen	KU
Barbara Atkinson	KU
Nancy Lindberg	KS Masonic Foundation
Mark [illegible]	KS Masonic Foundation
Sue Hamm	Pharmacy Intern
Matt Reaves	Rep Don Hill
Judy Smith	CWA of KS
Beatrice Swoopes	KS Catholic Conference
Jeanne Gawdun	KFL
[illegible]	LGR
Denny Koch	[illegible]
Barbara Belcher	Merck
Monica Mayer	MVD
Suzanne Wikle	Kansas Action for Children
Roger Martin	" " " "
Amy R. Scott	Baker SON
[illegible]	Baker University School of Nursing
Candice Rukes	Teen Pregnancy Prevention Program
Lindsey Douglas	Hein Law Firm
Shirley Palmer	State Rep.
Mark Desetti	KNEA
Bill Brady	KELC
Dan Morin	Kansas Medical Society
Allison Peterson	Kansas Medical Society
Dorothy Hughes	KU
John Peterson	Capitol Strategies
Patrice O'Hara	KDHE
[illegible]	KESTAR

HOUSE HEALTH AND HUMAN SERVICES COMMITTEE GUEST LIST

DATE: February 8, 2007

NAME	REPRESENTING
Ron Gaches	KDHA
John Breiner	Rep. Ward

KANSAS

DEPARTMENT OF HEALTH
AND ENVIRONMENT
Division of Health

Kathleen Sebelius, Governor
Roderick L. Bremby, Secretary

www.kdheks.gov

Testimony on House Bill 2227

Vaccination Against Human Papilloma Virus Before Attendance at Schools

House Committee on Health and Human Services

Howard Rodenberg MD MPH
Director, Division of Health
Kansas Department of Health and Environment

Chairperson Landwehr and Members of the Committee, I am Dr. Howard Rodenberg. I serve as Director of the Division of Health at the Kansas Department of Health and Environment and as State Health Officer. I appreciate this opportunity to support HB 2227, which would expand the list of mandatory vaccinations to include immunizing each female entering sixth grade against the human papilloma virus (HPV).

HPV has been identified as the causative agent in over 99% of cases of cancer of the cervix. HPV is spread through sexual contact, and acute infection is often without symptoms, transient, and resolve without treatment. However, in some individuals, HPV infections result in genital warts, Pap test abnormalities, or, rarely, cervical cancer. There is no way to determine who is at greater risk of developing cancer following an initial infection, and the development of cancer may occur months to years after the initial case. More than 6 million people in this country become infected with HPV every year, and nearly 10,000 women are diagnosed with cervical cancer. In Kansas about 100 cases of invasive cervical cancer are diagnosed with 34 deaths per year due to cervical cancer.

In June 2006 the Food and Drug Administration licensed a vaccine against human papillomavirus (HPV). The development of Gardasil protects against four strains of HPV, including the two strains that cause most cases of cervical cancer. The full immunization series consists of 3 vaccines given over a six month period. (A second company is developing a single-dose regimen as well). By preventing infection with HPV, this agent represents the first vaccine we've ever had against cancer. Preventing both acute infections and long-term chronic disease are key goals of public health, and the vaccine is a significant advance in our capability to improve life and health. As noted, every year in Kansas 100 cases of invasive cervical cancer are diagnosed, and 34 women die. It is expected that the vaccine would reduce the number of deaths by 50 to70%, thus saving 17 to 20 Kansas lives per year. It would also presumably reduce the number of invasive cervical cancers diagnosed, which would mean 50-70 fewer cases in Kansas each year.

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The length of vaccine protection (immunity) is usually not known when a vaccine is first introduced. So far, studies have followed women for five years and found that women are still protected. More research is being done to find out how long protection will last, and if a booster vaccine is needed years later.

While we are in support of this bill, there are a few operational concerns that may be resolved with some slight changes in language (Attachment 1).

KDHE recommends that this bill begin with the 2009 school year. There are several reasons for this request. It is known that another company has a similar vaccine in the pipeline for approval; the delay may allow for a competitive product to be placed in the market and this may affect pricing due to competition and economies of scale. In addition, concerns regarding the acceptability of the vaccine that have been expressed may have time to be addressed. Further, that delay will give our health care infrastructures some time to adapt to changes that are relatively unprecedented regarding adolescent vaccinations.

A delay would also help to insure that federal funds are available to allow all Kansas children who need the vaccine to receive it without "out-of-pocket" costs.

The federal contract price of the present HPV vaccine is $96.00 per dose ($288.00 for the series). Market price is currently $120.00 per dose ($360.00 for the series). These costs are for the vaccine only and do not cover administration costs. KDHE further estimates that each year, there would be approximately 18, 620 females entering the 6th grade. Of that cohort, 11,172 females (60%) may be eligible for vaccine through the VFC program. That would leave 7,448 females (40%) that may have private insurance, no insurance or are under-insured.

If all of the females that are in the VFC program entering sixth grade participate, it would cost the Immunization Program $3.2 million in VFC expenditures. Some girls would be eligible for the federal 317 vaccine program (for under-insured children), and the remainder would be covered by insurance or other private payers. It should be noted that in discussion with representatives of the insurance industry, I have been assured that virtually all private insurers in Kansas cover a vaccine once it is recommended by the Advisory Council on Immunization Practices (ACIP). The HPV vaccine obtained this endorsement earlier this year.

It is unclear how many would be covered by federal programs and how many through insurance or private payers, but the expected cost to insurance and other private payers would be about $2.7 million. The estimated total cost of the vaccine per year in Kansas is $5.9 million if every eligible girl is fully immunized. That estimate does not include administration costs.

VFC funding is not assured for HPV vaccine, but historically the VFC program has funded recommended and required vaccines. Congress appropriates the funding for the VFC program; appropriations for federal fiscal year 2007 and 2008 have already been made. The VFC program does not dictate to each state how the available funding is to be used, but it is likely that there would be a federal shortfall until at least fiscal year 2009 if HPV vaccine were mandated before 2009. Doing so would eliminate the need to request State General Funds to fund the vaccination program until anticipated federal funding in FY 2009.
There are cost savings to be had through administration of the HPV vaccine. An estimated "average cost" for treating a case of cervical cancer is $31,400 per case. That estimate averages

the costs from those that can be treated effectively with colposcopy and those for whom more aggressive treatment, including surgery and adjuvant therapies, are needed. In Kansas, that would be $3.14 million per year. We do not have cost estimates for years of productive life lost from cervical cancer, nor an estimate of costs of fatalities.

We would also suggest streamlining the roles of both KDHE and schools in disseminating information to parents about the HPV vaccine. KDHE will serve as a resource for educational materials, while schools will control the dissemination of the information in the manner best suited for their community. The cost of developing and disseminating information to parents through the schools is estimated at $3 per child, or about $54,000 per year.

The Kansas Department of Health & Environment (KDHE) supports the concept of vaccinating females to prevent cervical cancer, and hopes that our suggestions do not imply we are any less enthusiastic about the prospect of vaccinating our children against cancer. This is a great advance for health, and we would be failing in our responsibilities if we did not advocate for its adoption.

Finally, it needs to be said up front that this bill will raise issues about sexual behavior in teens. The HPV vaccine is not a ticket to risk-free sexual behavior; it does not prevent HIV, AIDS, or other sexually transmitted diseases. It does, however, allow us to protect our children in a way we've never had available to us before; and keeping our children safe is what most parents care most deeply about.

I hope that the information I've provided within this testimony will help the Committee make the best decision possible for the citizens of Kansas.

Thank you, and I'll be happy to answer any questions you might have.

ATTACHMENT I

RECOMMENDED CHANGES TO CURRENT LANGUAGE, HB 2227

(Changing line 28 of page one of the current version). Beginning with the 2009 school year each female student enrolling in grade six, or transferring into a Kansas school after grade six, shall present to the appropriate school board certification from a physician or local health department that the female student has received inoculation to fully immunize such female against the human papilloma virus.

Page 2, line 15, (e) 1 to read, The secretary shall furnish to each school district information relating to the connection between human papilloma virus and cervical cancer. (Removing unused language).

Line 21 page 2 to read, Each school district, shall provide the information required by this subsection to its students and their parents by a method determined to be effective in bringing the information to the attention of the parents and guardians of each female student.

Line 27 (f) (1) removed in its entirety.

Line 1 page 3 strike through until "the appropriate office of the department of health and environment."

Line 3 page 3 (3) strike through in its entirety.

KD HE

Session of 2007

HOUSE BILL No. 2227

By Representatives Garcia, Hill, Ballard, Burroughs, Carlin, Colloton, Crow, Faust-Goudeau, Feuerborn, Flaharty, Flora, Goyle, Hawk, Henderson, Horst, Huntington, Kuether, Loganbill, McCray-Miller, McLachlan, Menghini, Judy Morrison, Neighbor, Owens, Palmer, Pauls, Pottorff, Rardin, Ruiz, Sawyer, Storm, Svaty, Swanson, Trimmer, Williams, Winn and K. Wolf

1-25

AN ACT concerning certification of receipt of certain tests or inoculations prior to admission and attendance at school; amending K.S.A. 72-5209 and repealing the existing section.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 72-5209 is hereby amended to read as follows: 72-5209. (a) In each school year, every pupil enrolling or enrolled in any school for the first time in this state, and each child enrolling or enrolled for the first time in a preschool or day care program operated by a school, and such other pupils as may be designated by the secretary, prior to admission to and attendance at school, shall present to the appropriate school board certification from a physician or local health department that the pupil has received such tests and inoculations as are deemed necessary by the secretary by such means as are approved by the secretary *and, in addition, ~~for~~ each female student enrolling in grade six, shall present to the appropriate school board certification from a physician or local health department that the female student has received inoculation to fully immunize such female against the human papilloma virus*. Pupils who have not completed the required inoculations may enroll or remain enrolled while completing the required inoculations if a physician or local health department certifies that the pupil has received the most recent appropriate inoculations in all required series. Failure to timely complete all required series shall be deemed non-compliance.

(b) As an alternative to the certification required under subsection (a), a pupil shall present:

(1) An annual written statement signed by a licensed physician stating the physical condition of the child to be such that the tests or inoculations would seriously endanger the life or health of the child, or

(2) a written statement signed by one parent or guardian that the child is an adherent of a religious denomination whose religious teachings

beginning with the 2009 school year

or transferring into a Kansas school after grade six

are opposed to such tests or inoculations. ~~*With respect to immunization against human papilloma virus, the written statement shall contain a statement indicating that the parent or guardian received the information under subsection (e) on the connection between human papilloma virus and cervical cancer.*~~

(c) On or before May 15 of each school year, the school board of every school affected by this act shall notify the parents or guardians of all known pupils who are enrolled or who will be enrolling in the school of the provisions this act and any policy regarding the implementation of the provisions of this act adopted by the school board.

(d) If a pupil transfers from one school to another, the school from which the pupil transfers shall forward with the pupil's transcript the certification or statement showing evidence of compliance with the requirements of this act to the school to which the pupil transfers.

shall furnish to

(e) (1) The secretary ~~*shall prescribe procedures by which*~~ *each school district* ~~*shall provide*~~ *information* ~~*to parents and guardians of female students*~~ *relating to the connection between human papilloma virus and cervical cancer.* ~~*The procedures must ensure that the information is reasonably likely to come to the attention of the parents or guardians of each female student.*~~

Each

shall

(2) ~~*A*~~ *A school district,* ~~*with the written consent of the secretary, may*~~ *provide the information required by this subsection to its students and their parents by a method* ~~*different from the method prescribed by the secretary under subsection (a) if the agency determines that the method would*~~ *be effective in bringing the information to the attention of the parents and guardians of each female student.*

determined to

~~*(f) (1) The secretary shall collect and disseminate information to parents, conservators and guardians of female children relating to the connection between human papilloma virus and cervical cancer. The secretary shall prescribe the form and content of the information.*~~

(2) The information on the connection between human papilloma virus and cervical cancer must cover:

(A) The risk factors for developing cervical cancer, the symptoms of the disease, how it may be diagnosed and its possible consequences if untreated;

(B) the connection between human papilloma virus and cervical cancer, how human papilloma virus is transmitted, how transmission may be prevented and the relative risk of contracting human papilloma virus for primary and secondary school students;

(C) the availability and effectiveness of vaccination against human papilloma virus and a brief description of the possible side effects of vaccination; and

(D) sources of additional information regarding the disease, including

~~*any appropriate office of a school district and*~~ *the appropriate office of the department of health and environment.*

~~*(3) The department shall increase coordination among public and private local, regional and statewide entities that have an interest in providing information on the human papilloma virus vaccine.*~~

Sec. 2. K.S.A. 72-5209 is hereby repealed.

Sec. 3. This act shall take effect and be in force from and after its publication in the statute book.

KANSAS ACTION FOR CHILDREN
Making a difference for Kansas children.

Kansas Action for Children Inc.
720 SW Jackson | Suite 201
Topeka, KS 66603

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Celebrating 25 years
of child advocacy

To: Health and Human Services
From: Suzanne Wikle, Kansas Action for Children
Re: HB 2227

Good afternoon, Madam Chair and members of the committee. My name is Suzanne Wikle and I am the Director of Health Policy for Kansas Action for Children. I appreciate the opportunity to speak today in support of HB 2227.

The HPV vaccine is prevention at its best. Prevention is often emphasized as a fundamental aspect of healthcare that is essential for reducing the risk of developing chronic medical conditions. Avoiding disease and illness through preventative practice, whether it be a healthy diet and regular exercise that prevent heart disease or an immunization that prevents cancer, saves individuals from pain and suffering, financial hardships, and even premature death. With the development of a vaccine for human papilloma virus (HPV) we have the opportunity to prevent 70% of cervical cancer among the next generation of women. This is an instance where we know that prevention will work; this vaccine will drastically reduce the rate of cervical cancer. The acting Director of the National Cancer Institute says about Gardasil, "This vaccine opens a new era in cancer prevention. It has the potential the save women's lives."
(http://www.cancer.gov/newscenter/pressreleases/HPVStatement)

Mandating the vaccine will reduce health disparities. We know that there are disparities in access to health care. By mandating this vaccine for school entry it is more likely that every girl will have access to the vaccine, regardless of insurance or family financial status. Particularly vulnerable girls, those that are least likely to have health insurance now or in the future, will especially benefit from this vaccine if they are unable to access routine medical examinations every year. Without the school mandate and ensuring access to the vaccine, cervical cancer has the potential to become an indicator of health disparity.

Parental awareness will increase the likelihood of vaccination. Requiring this vaccine will also prove to be a mechanism by which parents will become informed about the benefits of the vaccine and the risks of cervical cancer. Without requiring the vaccine, too many parents and girls will be unaware of its value.

Vaccinating early makes sense. It is important for girls to receive the vaccine before they are at risk for contracting HPV. Optimally, girls will receive this vaccine when they are eleven or twelve years of age, a time when they will also be receiving other routine vaccinations. Targeting girls at this age ensures that they will receive the vaccine before engaging in sexual behaviors. Whether that is five, ten, or fifteen years later, they will have prevention against cervical cancer.

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ATTACHMENT 2

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KANSAS NATIONAL EDUCATION ASSOCIATION / 715 SW 10TH AVENUE / TOPEKA, KANSAS 66612-1686

Mark Desetti, Testimony
House Health and Human Services Committee
February 7, 2007

House Bill 2227

Madame Chair, members of the Committee, thank you for the opportunity to appear before you today to share our thoughts on **House Bill 2227**.

KNEA believes that HB 2227 is an appropriate measure designed to protect the health of girls and women. Cervical cancer is a serious threat to women and, now that a vaccine is available which can prevent this terrible disease, it is right that the Legislature should act to protect our girls.

This move is not without precedent. Many of us in this room can remember mass polio vaccinations in our schools – first with shots and later with sugar cubes. More recently we have required a Hepatitis B vaccination for elementary school children and a Meningitis vaccination for college students. My own children received the Hepatitis vaccination here in Kansas and one received his Meningitis vaccination on the K-State campus. As a parent I am glad to have the help of Kansas and our schools in the protection of my children's health.

The one issue with the HPV vaccination is cost. This is a series of three shots and is costly for families. We assume this action will make the vaccination available to all Kansas girls regardless of income or insurance. We believe it is appropriate for the state to make the vaccination available to families who could otherwise not afford it.

The bill allows for those who cannot take the vaccination for medical or religious reasons to opt out.

We urge the committee to pass HB 2227 favorably.

House Health and Human Services

DATE: 2-8-07

Attachment 3-1

Telephone: (785) 232-8271 FAX: (785) 232-6012 Web Page: www.knea.org

FDA News

FOR IMMEDIATE RELEASE
P06-77
June 8, 2006

Media Inquiries:
Julie Zawisza, 301-827-6242
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888-INFO-FDA

FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus

Rapid Approval Marks Major Advancement in Public Health

The Food and Drug Administration (FDA) today announced the approval of Gardasil, the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18. The vaccine is approved for use in females 9-26 years of age. Gardasil was evaluated and approved in six months under FDA's priority review process--a process for products with potential to provide significant health benefits.

"Today is an important day for public health and for women's health, and for our continued fight against serious life-threatening diseases like cervical cancer," said Alex Azar, Deputy Secretary, U.S. Department of Health and Human Services (HHS). "HHS is committed to advancing critical health measures such as the development of new and promising vaccines to protect and advance the health of all Americans."

HPV is the most common sexually-transmitted infection in the United States. The Centers for Disease Control and Prevention estimates that about 6.2 million Americans become infected with genital HPV each year and that over half of all sexually active men and women become infected at some time in their lives. On average, there are 9,710 new cases of cervical cancer and 3,700 deaths attributed to it in the United States each year. Worldwide, cervical cancer is the second most common cancer in women; and is estimated to cause over 470,000 new cases and 233,000 deaths each year.

For most women, the body's own defense system will clear the virus and infected women do not develop related health problems. However, some HPV types can cause abnormal cells on the lining of the cervix that years later can turn into cancer. Other HPV types can cause genital warts. The vaccine is effective against HPV types 16 and 18, which cause approximately 70 percent of cervical cancers and against HPV types 6 and 11, which cause approximately 90 percent of genital warts.

"This vaccine is a significant advance in the protection of women's health in that it strikes at the infections that are the root cause of many cervical cancers," said Andrew C. von Eschenbach, MD, Acting Commissioner of Food and Drugs. "The development of this vaccine is a product of extraordinary work by scientists as well as by FDA's review teams to help facilitate the development of very novel vaccines to address unmet medical needs. This work has resulted in the approval of a number of new products recently, including Gardasil, which address significant public health needs."

Gardasil is a recombinant vaccine (contains no live virus) that is given as three injections over a six-month period. Immunization with Gardasil is expected to prevent most cases of

(5)

cervical cancer due to HPV types included in the vaccine. However, females are not protected if they have been infected with that HPV type(s) prior to vaccination, indicating the importance of immunization before potential exposure to the virus. Also, Gardasil does not protect against less common HPV types not included in the vaccine, thus routine and regular pap screening remain critically important to detect precancerous changes in the cervix to allow treatment before cervical cancer develops.

"This is the first vaccine licensed specifically to prevent cervical cancer. Its rapid approval underscores FDA's commitment to help make safe and effective vaccines available as quickly as possible. Not only have vaccines dramatically reduced the toll of diseases in infants and children, like polio and measles, but they are playing an increasing role protecting and improving the lives of adolescents and adults," said Jesse Goodman, MD, MPH, Director of FDA's Center for Biologics Evaluation and Research.

Four studies, one in the United States and three multinational, were conducted in 21,000 women to show how well Gardasil worked in women between the ages of 16 and 26 by giving them either the vaccine or placebo. The results showed that in women who had not already been infected, Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed. While the study period was not long enough for cervical cancer to develop, the prevention of these cervical precancerous lesions is believed highly likely to result in the prevention of those cancers.

The studies also evaluated whether the vaccine can protect women already infected with some HPV types included in the vaccine from developing diseases related to those viruses. The results show that the vaccine is only effective when given prior to infection.

Two studies were also performed to measure the immune response to the vaccine among younger females aged 9-15 years. Their immune response was as good as that found in 16-26 year olds, indicating that the vaccine should have similar effectiveness when used in the 9-15 year age group.

The safety of the vaccine was evaluated in approximately 11,000 individuals. Most adverse experiences in study participants who received Gardasil included mild or moderate local reactions, such as pain or tenderness at the site of injection.

The manufacturer has agreed to conduct several studies following licensure, including additional studies to further evaluate general safety and long-term effectiveness. The manufacturer will also monitor the pregnancy outcomes of women who receive Gardasil while unknowingly pregnant. Also, the manufacturer has an ongoing study to evaluate the safety and effectiveness of Gardasil in males.

Gardasil is manufactured by Merck & Co., Inc., of Whitehouse Station, NJ.

For more information, see:

- http://www.fda.gov/cber/products/hpvmer060806.htm
- http://www.fda.gov/womens/getthefacts/hpv.html

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February 7, 2007

Testimony against **HB 2227** mandating HPV vaccination:

Chairman Landwehr and members of the House Health and Human Services Committee:

My name is Judy Smith. I am State Director for Concerned Women for America of Kansas. I am a registered pharmacist (Indiana) and am testifying against **mandating** girls entering sixth grade receiving the series of HPV vaccinations (**HB 2227**). CWA of Kansas is in favor of any vaccine or therapy that reduces or eliminates disease and suffering. We do not, however, believe mandating this vaccination is the best possible course of action by the State of Kansas for the following reasons:

- This vaccine only eliminates the danger from four of the more than 100 types of HPV virus. The types causing cervical cancer that are covered by the vaccine are responsible for 70 percent of the cases of cervical cancer in women, yet the vaccine does not protect against the types causing the other 30 percent of cervical cancers. We believe that parents and women will feel a false sense of security after vaccination. Even though they are told that they must still get Pap smears, it has been my experience that patients only hear what they want to hear. They will hear "protection against cervical cancer," not that it is only 70 percent protection.
- Medical protocol has always allowed patients the right to refuse treatment. Mandating this vaccine will take away parent's rights to review the risks and benefits of their daughters receiving the vaccine. There is a medical exception in the bill; however, many parents will not understand the full import of the issue and will not be able to give fully informed consent or refusal. The opt-out clause should be an opt-in accompanied by full disclosure of the risks and benefits to those receiving the vaccine. This can be done in the privacy of the doctor's office with parents making the decision that is best for their child without the state of Kansas interfering in that medical decision. Many children have auto-immune responses to outside immunogenic stimulation. A parent knows their own child and their specific problems. The state of Kansas could send out detailed information about the vaccine to all parents, encouraging vaccination, but the state should not mandate introducing yet another antigen into an already-crowded vaccine regimen.
- This vaccine has only been approved for nine months. There are no long-term studies on safety and efficacy over time. Neither Merck nor the FDA reveals in public documents how many 9-15 year-old girls were tested in the safety study. To mandate before long-term effects can be studied would be premature.
- Other recent vaccines have been highly marketed and encouraged by their manufacturers. In the case of the rotavirus vaccine for infants, the vaccine had to be recalled because of deaths and severe reactions. Are we ready to say with a certainty that this vaccine is completely safe for all children? Shouldn't parents make that decision based on all the facts?
- Many have said that the vaccine would only be optimally effective for five years. Mandating vaccination at 12 years could possibly result in lessened efficacy at 16 or 17 years, a time when sexual activity is more prevalent. How would the state ensure that all of these children get the booster shot that would maximize their protection?
- The regiment is VERY expensive ($360 for the three-shot series not counting office calls). How would families pay if they were uninsured or if their insurance company did not cover vaccines? Would the state end up paying Merck a subsidy? In fact, Merck, the company marketing Gardasil, is spending large amounts of money to lobby state legislatures and spending an undisclosed

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amount to persuade Women in Government, an advocacy group made up of female state legislators, to mandate the vaccine to sixth-grade girls.

- In addition, we are concerned that the state mandating a vaccine against a disease that is not air-borne but primarily sexually transmitted would send a message to our children that we are assuming they will be sexually active.

We applaud any medical advance that saves lives, prevents misery and enhances a healthy body. However, in light of the reasons listed above we do not agree with making this vaccine **mandatory** for all girls entering sixth grade. We believe in patent education. We would rather see the state spend its time educating parents about all the risks and benefits of this vaccine so they can make the proper informed choice for their children. Patient's rights have always included a right to refuse. The state should not force parents to use a religious or medical exception to opt their children out of this medical decision.

Judy Smith
State Director
Concerned Women for America of Kansas

Statement from Concerned Women for America's national office:

"Concerned Women for America does not object to the new vaccine that protects against certain strains of the human papillomavirus or HPV, a sexually transmitted disease that can cause cervical cancer in women. Proponents of this vaccine, however, wrongly wish to compel every young girl for 9-11 years old to be vaccinated before she attends school. Concerned Women for America is committed to support, protect, and advocate the God-given right of parents to direct the upbringing and education of their children. Parents know what is best for their daughters and if given the information about this disease will make the best decision for the health of their child. Therefore, we urge lawmakers to resist mandating this vaccine."

CWA of Kansas
PO Box 11233
Shawnee Mission, KS 66207
913-491-1380

House Health & Human Services
February 7, 2007

6301 ANTIOCH • MERRIAM, KANSAS 66202 • PHONE/FAX 913-722-6633 • WWW.KSCATHCONF.ORG

TESTIMONY IN OPPOSITION TO H.B. 2227

Madame Chair and Members of the Committee:

Thank you for the opportunity to testify in opposition to H.B. 2227, the proposed legislation concerning the HPV vaccine. My name is Beatrice Swoopes, the Associate Director of the Kansas Catholic Conference, the public policy office for the Catholic Church in Kansas.

The U.S. Food and Drug Administration (FDA) recently approved Gardasil, a vaccine that protects against two strains of Human Papilloma Virus (HPV) responsible for 70% of cervical cancer. This is a wonderful medical breakthrough since cervical cancer is still a major health problem for women. It is the 2nd most common cancer worldwide, and the 11th most common cancer in American women. Mandating the drug be given to girls as they enter 6th Grade presents concerns.

As beneficial as all this might be there are still some questions about the drugs duration of protection, the degree of protection, and the array of side effects it may cause. These questions still remain for researchers. Prelicensure studies were limited and produced short term data results. The American College of Pediatricians suggests that until further research is completed, "HPV vaccine recipients should be fully informed as to the current limits of knowledge regarding the vaccine's potency and duration of protection."

Another point the American College of Pediatricians makes is that "Parents and adolescents should also be reminded that 30% of cervical cancers are not caused by HPV strains included in the current HPV vaccines. They should also understand that this vaccine offers no protection against other forms of sexually transmitted diseases."

Another objection to administering the drug by mandate is more basic. The rationale for universal vaccinations for school children is the public good, in general, and some attendant assumption that school children will typically and easily be exposing each other to certain kinds of illnesses (chicken pox, measles, mumps, etc.) without regard to the behavior in which the children are engaged. This vaccination is for a disease spread only by engaging in a particular kind of behavior, and indeed a kind of behavior not particularly well-suited for school. Thus, the typical child is not really exposed to this disease at school, and may never engage in the behavior that will expose her to it at all. The assumption of the burden (vaccines are always burdens in at

MOST REVEREND RONALD M. GILMORE, S.T.L., D.D.
DIOCESE OF DODGE CITY

MOST REVEREND MICHAEL O. JACKELS, S.T.D.
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MOST REVEREND EUGENE J. GERBER, S.T.L., D.D.
BISHOP EMERITUS - DIOCESE OF WICHITA

MOST REVEREND JOSEPH F. NAUMANN, D.D.
Chairman of Board
ARCHDIOCESE OF KANSAS CITY IN KANSAS

MICHAEL P. FARMER
Executive Director

MOST REVEREND GEORGE K. FITZSIMONS, D.D.
BISHOP EMERITUS - DIOCESE OF SALINA

MOST REVEREND PAUL S. COAKLEY, S.T.L., D.D.
DIOCESE OF SALINA

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least two ways: they are impositions on human freedom and they also expose the recipient to certain risks), then, on the typical child (and her parents and their beliefs), seems excessive and thus unjustified prudentially. Good government must always balance the demands it makes on the citizenry against the public good. It would be a failure of good governance to mandate this burden. Recommending the vaccine seems much more advisable.

The fundamental commitments of Catholic health care, respect for life and human dignity, acting on behalf of the common good, prudent stewardship of resources, and justice give validity to providing the HPV vaccine to patients, but only at their request, and at an age appropriate to the need.

The American College of Pediatricians is "opposed to any legislation which would require HPV vaccination for school attendance" as required by this bill. This vaccine prevents a disease which is exclusively sexually transmitted; mandating it as early as this bill suggests, places the medical provider in an ethical dilemma.

For these reasons the Kansas Catholic Conferences urges your rejection of H.B. 2227 for passage.

Respectfully submitted,

Beatrice Swoopes
Associate Director

Marla Patrick
1542 Svensk Rd
Lindsborg, KS 67456

February 7th, 2007

House Health and Human Services Committee
Kansas State Capitol
300 SW 10th St
Topeka, KS 66612

Dear Chairwoman Landwehr and members of the House Health and Human Services Committee:

I am here today to ask you to add the Human Papilloma Virus vaccination to the state health department's list of required immunizations for 6th grade girls. This vaccine can prevent disease from two types of HPV that are responsible for about 70% of all cervical cancers. Currently, due to the lack of awareness about the vaccination resulting in the lack of availability, and the cost involved, I have, to date, been unable to obtain the vaccination for my 13 year old daughter in our rural town.

If such a vaccination had been offered 20 years ago, maybe I could have been one of the seven out of ten women who are spared a diagnosis of pre-cancerous cervical cells. I could have been spared the solution, which was a total hysterectomy at the age of 23. Along with the expense, and the hysterectomy itself, I could have been spared having my choice to conceive a second child taken away from me.

It's extremely important to me that my daughter receives this vaccination. It seems though, that no matter how hard I try, I am unable to obtain this vaccination for my daughter and her future. Part of a mother's required duties it seems, is the worrying portion of raising children. With my diagnosis of pre-cancerous cells, I worry that my daughter could also be denied the choice of having a family. When I realized that she could receive a vaccination that could save her reproductive health from a future cancer diagnosis, I was given one less thing to worry about. But I quickly found out that due to a lack of awareness, lack of availability, and the high cost, that my relief has been premature.

Upon hearing about the HPV vaccine, I immediately contacted our family physician, who is located at our one and only clinic-a rural health clinic, and asked him about getting my daughter the HPV vaccination. The doctor wasn't even aware of the vaccination. He promised to look into it and talk to me more at length about it when I returned to the clinic. I returned two weeks later, and he stated that he was "unsure" if they would get the vaccine. When pressed as to why, he simply stated that it was "probably a demand thing".

I asked who I would need to speak with in order for them to feel the demand was there. He stated, "Honestly, it probably wouldn't do any good". My daughter's reproductive health rests on whether or not enough people know about the vaccine and feel too that it would be best for their daughters to get one, too? I find it absurd that my daughter's reproductive future has come down to what is "popular". That is what it comes down to *in their own words*.

Needless to say, the next time I was in the clinic, I brought it up again, speaking with one of the nurses, and making it known how upset I was that none of the clinics I had called are currently carrying it, and most can't tell me when or if they will have it in the future. The nurse stated that maybe it was a "bottom dollar" issue. That if they order it, with the cost that it is, if they don't use it,

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they will lose money. I understand their need to watch the "bottom dollar", but how do you put a price on my daughter's reproductive health?

Worse, as I said before, this is our only clinic in town. The next nearest clinic is a county health department and it's over 15 miles away. I've called them too. They also stated they "might" get it. To add insult to injury, our health insurance provider told me they wouldn't pay for it anyway. My daughter's future reproductive health is essentially being put on hold.

I also think about all the other girls in my daughter's class; those whose mothers didn't know what I was talking about when I brought up the HPV vaccine. How can people "demand" something if they aren't aware it exists? Of the approximately 15 women that I have mentioned the HPV vaccination to, only ONE knew what it is. After being told about the vaccination, every single one of the mothers expressed it as something they would want their daughter to have.

I also think about those parents who are without transportation and cannot easily travel 15 miles to the next nearest clinic that *might* get the vaccine - those who have no choice but to rely on the local clinic. I think about those who can't afford the shot itself with its hefty price tag. If I can find a clinic that actually gets it, I will be able to manage the 360.00 for the price of the shot, and will find the time to make the trek to another town for my daughter to get it. But what about the others for whom these aren't realistic options?

All of this is why I believe it so important to make this one of the required vaccinations. If it is added to the list of required vaccinations, as always happens, public awareness will follow. The clinics will begin to keep it in stock, and insurance companies will begin covering it.

Making this a required vaccination will ultimately protect the reproductive health of countless young girls like my daughter. The decision you make in regards to this vaccination means so much more than whether or not the HPV vaccine will be added to the list of required vaccinations. Your decision will in effect decide whether or not seven out of every ten girls exposed to HPV will have to face being told, "you have cervical cancer" as a result of that exposure. It means that you will ensure that seven out of ten girls won't be financially ruined by the expense of battling cancer. It means seven out of ten girls will still be able to make the decision of whether or not to have children. Seven out of every ten girls will be given a better future due to the actions of this board. Please add the HPV vaccination to the list of required vaccinations. This is a chance for the Legislature to do something proactive for the well being of not only my daughter, but many other daughters, too. They all deserve the chance to be one of those seven.

Thank you for your time.

Respectfully,

Marla Patrick

STATE OF KANSAS

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REPRESENTATIVE, EIGHTY-THIRD DISTRICT
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TOPEKA

HOUSE OF REPRESENTATIVES

COMMITTEE ASSIGNMENTS

Member
APPROPRIATIONS
GENERAL GOVERNMENT BUDGET
ELECTIONS AND GOVERNMENTAL ORGANIZATION
JOINT COMMITTEE ON STATE BUILDING CONSTRUCTION

February 7, 2007

Testimony on HB 2227

House Committee on Health and Human Services

Thank you Madame Chair for allowing me the opportunity to present this testimony to the committee. I am in support of **HB 2227** as I feel it is an issue of great importance to women today.

Human papilloma virus (HPV) is accountable for 99% of cervical cancer cases. Every year in the United States over10,000 women are diagnosed with cervical cancer. Another 3,700 women lose their lives every year fighting this disease. Cervical cancer remains the second leading cancer killer of women worldwide.

In 2006, the FDA approved a preventative vaccine for girls and women aged 9 to 26. This vaccination was unanimously recommended to be routinely given to 11 and 12-year old girls. The vaccination is also suggested for use by all other FDA-approved age groups. This vaccine against HPV corresponds with other inoculations routinely administered at age 11 and 12, including a booster for tetanus, diphtheria and whooping cough.

This vaccination will greatly decrease the prevalence of this cancer among women as it protects them from contracting HPV. I urge you to support this bill and protect our female population from one of many cancers.

Representative Jo Ann Pottorff
District 83

House Health and Human Services
DATE: 2-8-07

ATTACHMENT 7

KANSAS ASSOCIATION OF SCHOOL BOARDS

1420 SW Arrowhead Road • Topeka, Kansas 66604-4024
785-273-3600

Testimony on **HB 2227**
before the
Health and Human Services Committee

by

Donna L. Whiteman, Assistant Executive Director/Legal Services
Kansas Association of School Boards

February 7, 2007

Madam Chair and Members of the Committee

Thank you for the opportunity to provide information on H.B. 2227 and how it will affect the 296 public schools across the state.

Under current law, the board of education of every school district must notify parents that enrolling students must have a certificate from a physician or local health department stating the pupil has received the required tests and inoculations.

H.B. 2227 will require schools to also monitor whether all female students enrolling in 6th grade have a certificate from a physician or local health department indicating the student has received the inoculation to immunize them against the human pappilloma virus.

Concerns about H.B. 2227 as written are:

- Section (e)(1) – requires the Secretary of Health and Environment to *"prescribe procedures by which each school district shall provide information to parents and guardians of female students relating to the connection between human papilloma virus and cervical cancer. The procedures must ensure the information is reasonably likely to come to the attention of the parents or guardians of each female student."*

- To ensure this notice is accomplished in the most cost effective way, KASB suggests allowing school districts to distribute this information at enrollment. Distributing this information at enrollment when parents are present would be both cost effective and the most effective way to reach parents.

- The committee may also want to look at whether it wants K.S.A. 72-5211a to apply to this new inoculation requirements. K.S.A. 72-5211a states that a school district may exclude from school attendance any pupil who has not complied with the inoculation requirements of K.S.A. 72-5209 and further states, **"A pupil shall be subject to exclusion from school attendance until such time as the pupil shall have complied with the requirements of K.S.A. 72-5209."**

Thank you for the opportunity to present testimony on this bill.

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Testimony for the House Health and Human Services
Lisa Benlon, Leg/Government Relations Director
American Cancer Society
Re: **HB 2227**
February 7, 2007

Chairman Landwehr and Committee Members,

Thank you for the opportunity to testify as a neutral conferee on HB2227.

The American Cancer Society is the nationwide community-based voluntary health organization dedicated to elimination cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy, and service.

The American Cancer Society acknowledges the HPV vaccine is an extraordinary biomedical advance and holds remarkable potential for preventing the most common kinds of cervical cancer. The Society supports the widest possible use, availability and coverage in accordance with the vaccine administration guidelines of this newly available vaccine. It is important to understand that Pap tests must continue even for those who have received the HPV vaccination series. The vaccine does not cover all the types of HPV viruses that lead to cervical cancer.

We would hope that all young women take advantage of protecting themselves from cervical cancer by becoming inoculated.

However, as yet, the American Cancer Society has no position on whether the vaccine should be mandated for all girls about to enter the sixth grade.

I would be happy to stand for questions.

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ATTACHMENT 9

RIGHT TO LIFE OF KANSAS, INC.

214 S.W. 6th St., Suite 208, Topeka, KS 66603-3719 - Phone: 913-233-8601

Testimony Concerning House Bill 2227
Before the House Health and Human Services Committee
February 7, 2007

Chairperson Landwehr and members of the committee,

While we fully recognize the need for children to be vaccinated against certain communicable diseases prior to admission to entering school we must oppose House Bill 2227.

Because the human papillomavirus is not transmitted through casual contact and can only be transmitted through sexual intercourse with a person infected with HPV there is no justification for mandating the vaccine as a condition of public school attendance. We believe that parents are to be the primary educator and decision maker regarding their child's well being and physical health and such a mandate intrudes on those very parental duties and rights. "Remember that the culture of death is not a benign dictator: it becomes a tyrant as soon as it is able to enforce it's will." (Euteneuer, Rev. Thomas: The Dictatorship of Choice.) (See attached article).

We also believe this vaccine needs further testing to see if it is indeed safe to be given to anyone, especially little girls. An article in the Washington Times last Saturday revealed there have been reports in as many as 20 states that indicate that there are in fact many side effects from the vaccine and some of them are very serious. The side effects include severe headaches, dizziness, temporary loss of vision and seizures. (See attached news account)

Chairperson Landwehr and members of the committee we respectfully ask that you vote against House Bill 2227.

Prepared by Laura Malleck, Lobbyist
Right To Life of Kansas, Inc.

AMERICAN LIFE LEAGUE, INC.

Affiliated with American Life League

House Health and Human Services

DATE: 2-8-07

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The Dictatorship of Choice

Merck's lucrative HPV vaccine is now being proposed as mandatory by twelve states for girls 11 years old and above. Yes, the word is mandatory. Remember that the culture of death is not a benign dictator: it becomes a tyrant as soon as it is able to enforce its will. Cynically, the whole premise of the culture of death is "freedom of choice," but if Merck and the CDC have their way soon we will be bulldozing chemicals into little girls' bodies for no other reason than that their parents' generation has deprived them of a choice. Those who say that they don't want to force their morality on others are now having others' immorality forced upon them.

I have written before that this is not an innocuous little program to protect girls from disease. It is the newest program of fear-mongering that manipulates baby-boomer and Gen X mothers to "protect" their pre-adolescent kids from what they themselves know to be the ravages of the culture of sexual promiscuity. It leaves virtually no room for the moral approach of chastity before and during marriage and in fact denigrates that approach as unrealistic. While there are many reasons
why this vaccine should be opposed and rejected, I object most strongly to its capacity to degrade human and sexual relations under the guise of real-world protection.

How is a mother to explain this intrusion to her child? She may tell her girl that the chicken pox vaccine is necessary because even casual contact with other kids may infect her. But if the daughter asks the mother why she needs to get three shots for the HPV vaccine, mom would have to explain it in some disingenuous or crude way: "Well, honey, you
may someday have sex with someone who has this disease, and you have to be safe." The reactions from the child may range from embarrassment to shock to horror. If mother says, "Your future husband may have this disease... ," she will also have to explain why the girl would even want to marry someone with a disease and whether or not Daddy had that
disease when she married him. Any way you slice it this shot is degrading to kids' relationships with their parents, their purity, and the sense of wonder that they should have toward the beauty of human sexuality.

And that's the point. The culture of death, like every despotic regime, enters into God's realm with haughty pretense and sullies it. It eventually establishes itself inside the temple as its own authority and mandates a new law contrary to both spirit and nature. Last time I checked, the Scriptures still say that our bodies are temples of the Holy Spirit (1 Cor 6:9), but the CDC is rapidly squatting on another's property and soon will claim total ownership of the temple if these HPV
vaccine "mandates" are any way indicative of the future.

If parents want to assure that God's plan of sexual purity will set the agenda for their kids' future marriages and families, now is the time to change their culture. The only real response to these intrusions of the culture of death is to reject them and all their works and all their empty promises. We have to get and keep the tainted culture out of us and stop pretending that it is the "real world." Pre-adolescent girls getting expensive shots to protect them from sexually transmitted
diseases is not "real," it's perverse. Creating a culture of life and purity will in no way be without its sacrifices - even heroic ones - but if our children's and family's integrity is not worth the sacrifice, what is?

One final question that has been asked by many and needs a clear answer: Would it be immoral for someone to take or administer this vaccine? No. The HPV vaccine is not made from aborted fetal cell lines and is not in itself an immoral substance. The Church is not in the business of manipulating consciences to make a point about the culture of death. The Church's point is that the real manipulators are sitting in the CDC and state legislatures and school boards, and we should insist upon our freedom from their unwarranted intrusions into God's temple.

Sincerely Yours in Christ,

Rev. Thomas J. Euteneuer
President, Human Life International

Subj: **Vaccine center issues warning on Gardasil - HPV vaccine**
Date: 2/5/2007 8:44:28 A.M. Central America Standard Ti
From: ltignor@all.org
To: ltignor@all.org

http://www.washtimes.com/functions/print.php?StoryID=20070202-100152-9747r

The Washington Times
www.washingtontimes.com

Vaccine center issues warning

By Gregory Lopes
THE WASHINGTON TIMES
Published February 3, 2007

The National Vaccine Information Center yesterday warned state officials to investigate the safety of a breakthrough cancer vaccine as Texas became the first state to make the vaccine mandatory for school-age girls.

Negative side effects of Gardasil, a new Merck vaccine to prevent the sexually transmitted virus that causes cervical cancer, are being reported in the District of Columbia and 20 states, including Virginia. **The reactions range from loss of consciousness to seizures.**

"Young girls are experiencing **severe headaches, dizziness, temporary loss of vision** and some girls have lost consciousness during what appear to be seizures," said Vicky Debold, health policy analyst for the National Vaccine Information Center, a nonprofit watchdog organization that was created in the early 1980s to prevent vaccine injuries.

Following federal approval of the vaccine in July 2006, a storm of legislation was introduced across the nation that would make the vaccine mandatory in schools. The District and Virginia are part of a group of at least 17 states considering such legislation. A measure had been introduced in Maryland, but it was shelved last week over concerns about the mandatory language in the bill.

Yesterday, Texas Gov. Rick Perry signed an order making Texas the first state to require the vaccine. Girls ages 11 and 12 would receive the human papillomavirus (HPV) vaccine before entering the sixth grade starting in September 2008.

The American Cancer Society estimates there were 9,710 new cases of cervical cancer in the United States in 2006. The District's cancer control center estimates a total of cervical cancer cases in the city last year, and the American Cancer Society estimates that last year Maryland and Virginia each had 210 cases of cervical center.

Merck began marketing Gardasil last year after the Food and Drug Administration approved it for females ages 9 to 26. The vaccine is the first of its kind to build immunity against two strains of HPV, which lead to 70 percent of cervical cancer cases in the United States.

The vaccine is not effective in men, who can get cancer from other strains of HPV.

Its side effects were reported to the Vaccine Adverse Event Reporting System, a federal reporting system for consumers to notify federal regulators of bad reactions to medications. The adverse events began being reported in July 2006, when an advisory panel to the Centers for Disease Control and Prevention recommended girls ages 11 and 12 receive the series of shots.

The types of side effects reported are not cause for alarm, according to the American Cancer Society.

"We have not been informed of an instance that would call into question the overall safety of the vaccine," said Debbie Saslow, director of breast and cervical cancer control at the American Cancer Society, adding that about 70 similar events had been known in October 2006.

Likewise, the CDC will not alter its approval of the vaccine despite the number of adverse events revealed through the reporting system.

"A report to the Vaccine Adverse Event Reporting System does not necessarily mean the adverse event was serious or that it was caused by the vaccine," said CDC spokesman Curtis Allen. "This vaccine has been tested around the world and has been found to be safe and effective."

Merck is heavily promoting the vaccine through its salespeople imploring doctors to provide it and running TV ads urging young women to get vaccinated so there will be "One Less" cancer patient.

But physicians disagree with public health officials over whether Gardasil is the panacea for cancer. Clayton Young, an obstetrician/gynecologist in Texas, objects to Merck's claim that Gardasil will prevent cervical cancer.

"There is no proof Gardasil will stop cervical cancer," he said. "They haven't been studying it long enough to make that claim."

Merck spokesman Chris Loder said the vaccine is effective for five years and the Whitehouse Station, N.J., drug maker is not sure how long afterward the vaccine will work. Critics point out that an additional booster shot may be necessary.

Advocates for a mandatory vaccine say that although the vaccine does not prevent all causes of cervical cancer, Gardasil is an effective vaccine against the most prevalent cause and therefore is a correct public health measure.

Gardasil is delivered in three separate injections that cost $120 to $150 per injection. Blue Cross Blue Shield, an omnipresent health insurer in the Mid-Atlantic region, covers the vaccine for girls in the federally recommended age groups.

Merck revenue from Gardasil reached $155 million for the fourth quarter of 2006 and $255 million for the entire year.

To the members of the Health & Human Services Committee:

I wish to urge you to kill House Bill 2227, a bill which seeks to require parents to vaccinate their daughters with a vaccine that purports to give them immunity to the human papilloma virus (hpv) & thus prevent them from getting cervical cancer later in life. It is my understanding that the only vaccine against hpv that is FDA approved as of this date is Gardasil, which is put out by Merck so that is whose deception I will focus on.

Merck is marketing this as a vaccine that will keep you from contracting cervical cancer. Although hpv is believed to be involved in this cancer it is not always present in cervical cancer tumors & therefore they cannot truthfully say it will prevent you from getting cervical cancer.

Merck's trial methodology for this vaccine is bogus. their test group was too small, the period too short & their group of test subjects were of the age group that there is a very low incidence of cervical cancer. Their claim of the vaccine being 100% effective is actually can also be interpreted to be 0% effective.

The statistics I read said that there are 10,500 new cases of cervical cancer per year & Merck says for the vaccine to work it must be given before a girl becomes sexually active. The statistics in the material from vaclib.org that in order to prevent 1 case of cervical cancer you are wanting to require 190, 9 year old girls to take a questionably "tested" vaccine, at a cost of $360 (a 3 shot regimen @ $120. a shot presently) for a cancer that primarily shows up in the 40-55 age group. If you all remember the scam of the hepatitis B vaccine, hep B is a disease primarily in sexually promiscuous people & IV drug users yet the health department is scamming the parents into giving this to their newborns & then telling them they need to get a booster every 7 years. And with the prevalence of the chickenpox vaccine there is a higher incidence of shingles. This vaccine is not necessary, is not tested satisfactorily & it is time the State of Kansas stopped scamming parents into thinking they need to give

their children all these vaccinations. Because of lazy, incompetent people sitting on the board that recommends new vaccines the children that primarily got their childhood vaccines in the 1990's & for a few years after that got an overload of mercury & that is likely a big part of the behavioral problems you see in that age group. Those vaccine companies knew mercury was a problem but would not take it out until forced to & it is still not out of all of them. Vaccines are implicated in the increase in allergies, asthma, auto-immune diseases & cancer. And vaccine manufacturers have been able to bribe Congress into giving them immunity from liability if someone is injured from their vaccine so there is no incentive for them to make sure they are safe.

Merck is spending big bucks in every state legislature to get this vaccine on the schedule, there is no downside for them, they are not responsible. As we have seen so many times recently drugs that were approved by the FDA but later recalled because of deaths & serious injury, that is because the drug companies do grossly inadequate testing & the FDA is just a rubber stamp for the drug companies. Please take the time to read the material accompanying this letter.

Sharon Smith
316-742-9907

Sharon Smith

Vaccination Liberation - Information			
Legal:	**Science:**	**Misc:**	**Searches:**
Exemptions State_Chapter/ Resource_Contacts Avoid_Vaccinations Activism LegalNews	Introduction Basic_Facts Package Inserts Ingredients of Vaccines Q_and_A Artificially Sweetened Times	Membership Books Videos Tapes 100+ Anti-Vax links Vax_Cartoons Breaking News Planned_Events	KeyWord_Index Index/Link_Pages Search_Our_Site Home_Page Index_Page Smallpox Alert!

Introduction | Adverse Effects | Do Vaccines cause Cancer? | More_Cancer_Info | Conclusions | Effective? | Ingredients | Gardasil_News | Placebo? | Treatment | Trial-Quality | Cervical | Statistics | More_Info_Links

Gardasil® HPV vaccine: Cancer cause or Cancer preventive?

Updated June 9, 2006

Introduction:

Gardasil was licensed by the FDA on June 8, 2006 as a vaccine against human papillomavirus (HPV), the virus associated with cervical* cancer. Great success in trials is claimed. We expect the reality to be much more sobering than the hype. Indeed, vaccines have been associated with an increase in cancer for 150 years. And this trend has never ended as Polio vaccines and even the flu vaccine have been implicated as cancer causing. It is best to live a healthy lifestyle and keep toxic compounds, which all vaccines contain, out of your body.

Important Facts:

- Most women do not experience any symptoms from contact with human papillomavirus. **Immunity is natural** and it's believed that the immune

system clears the virus quickly.

Risk Factors:

- "**Diet**: Women with diets low in fruits and vegetables may be at increased risk for cervical cancer. Also overweight women are more likely to develop this cancer." Source: www.cancer.org
- Use of oral contraceptives.
- Smoking.
- Other exposure to **toxic compounds** in the food, air and water. We expect that the vaccine itself will be a contributor to cancer. See our section on cancer.

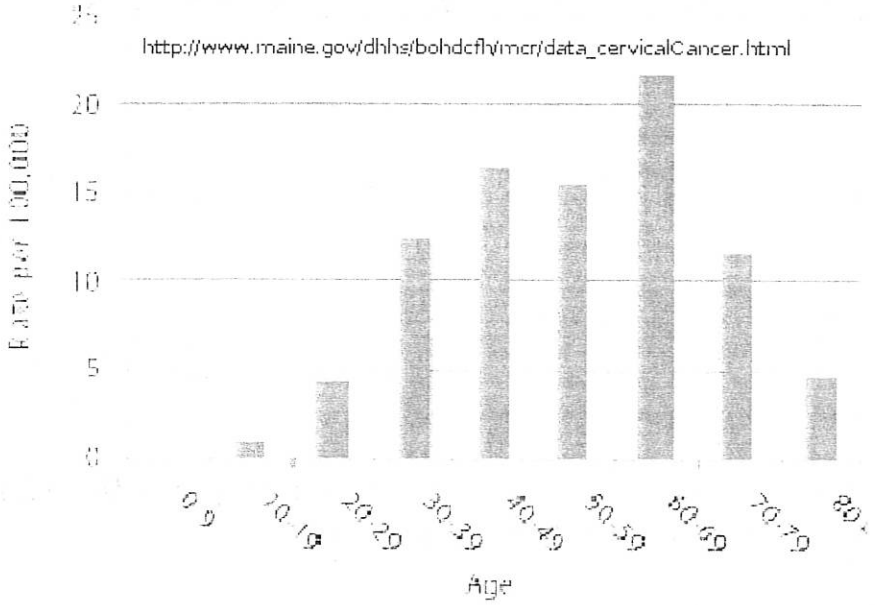
Cost Effective?

IF the vaccine works, (Highly Unlikely),
And **IF** it prevents all cervical cancer, (Impossible),
and **IF** the year 2004 rate of 10,500 new cervical cancer cases per year remained constant, (rather than dropping on its own, which in fact it has been doing...)
then 190 girls [or more] must be vaccinated at a cost of $300 x 190 to $500 x 190 = $57,000 - $95,000 per each case of cancer prevented. Add this cost to the cost of treating the other diseases **caused** by this vaccine and you will readily appreciate why we urge you to strive for immunity through diet and other lifestyle factors. In addition, the concept of vaccinating **190 nine year old girls** to prevent one case of disease **31 years later in the 40 to 55 age group** seems like a story which should begin, "*Once upon a time, the wagon of the snake oil salesman was seen approaching ...*" . See our statistics section.

What was the quality of the vaccine trial methodology?

Source of graph: http://www.maine.gov/dhhs/bohdcfh/mcr/data_cervicalCancer.html

Maine Age-Specific Incidence Rates - Cervical Cancer, 1997-1998



USA

Cervical cancer rates have been dropping for several years.The cervical cancer death rate declined 45 percent between the periods 1972-74 and 1992-94 and the overall incidence of the disease has decreased steadily from 14.2 per 100,000 in 1973 to 7.4 per 100,000 in 1995. Source: http://www.hhs.gov/asl/testify/t990316b.html

Much the same is true in Canada.

Note: In the above graph that 9 year old girls are not shown to have cervical cancer, 10-19 year old girls are expected to have 1 cervical cancer case per year per 100,000. In the 20-29 year old women less than 5 cases are expected per 100,000 women. Merck "tested" the vaccine in 9 to 26 year old women. In 100,000 women in the 9-26 year old age group one would expect about 3-4 cervical cancer cases per year (depending upon the age distribution).

In 4 years that would equate to 12 to 16 cases in 100,000 and if the trial contained only one-tenth as many subjects (10,000), that would translate to 1 to 2 cases. The average followup was 2.4 years for 20,541 subjects with an expected number of cervical cancer cases totaling one to three. Thus Merck's trial contained too few subjects for too short a period of time of followup for evaluating cervical cancer incidence . In the table below you can

see that only the first 2391 subjects had a 4 year followup.

```
Protocol Number Followup
#005      2391  4.0 years median        = 9564 person years followup.
#007       551  3.0 years median        = 1653 person years followup.
#013      5442  2.4 years median        =13,061 person years folowup.
#015     12,157 2.0 years median        =24,314 person years followup
                                Total   -----------
                                        48,592 person years of followup.
[48,492 is about half of 100,000 or expected cases total of about 1.5
for both sides of the trial !]
Total of 20,541 subjects 16 to 26 years of age at enrollment.
[Protocols 016 and 018 had an enrollment N = 1121 of
9- to 15-year-old Female Adolescents.]
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Note: The package insert mentions, "21,464 total subjects (9- to 26-year-old girls and women and 9- to 15- year-old boys)".

Conclusions:

* The trial procedure was inadequate. (Too Few people-years of Data.) [Above]
* The trial methodology was fraudulent. (Less than 10% of those in the "placebo" group got a true placebo)
* The trial conclusions are mis-stated: The effectiveness of the vaccine in preventing cervical cancer is said to be 100%. However, there were ZERO cases of cervical cancer in both the vaccinated and the unvaccinated groups. That is ZERO PERCENT effectiveness.
* The vaccine contains aluminum which can CAUSE cancer. The vaccine also contains Polysorbate 80 which has been linked to disturbance of reproductive abilities in rats.

Known or feared adverse effects of Gardasil

Source: http://www.pressofatlanticcity.com/news/newjersey/story/6364624p-6220794c.html

An FDA review of the results of studies on the vaccine found two important concerns, according to the documents released ahead of Thursday's meeting of the Vaccines and Related Biological Products advisory committee.

* The first is that the vaccine may lead to an increased number of cases of a cancer precursor among patients already infected by any of the four virus types at the time they receive the vaccine, and whose immune systems have not cleared the virus from their bodies.

* The second concern is that any advantage the vaccine provides in protecting against the four virus types could be offset by infection by any of the multiple other types of HPV that the vaccine does not cover, according to the FDA documents.

* FDA staff also asked that the committee examine **five cases where children with birth defects** were born to women who had received the vaccine around the time of conception.

Gardasil is given in three injections over six months and will cost $300-$500.

Gardasil

From the package insert

Claims for effectiveness in preventing cancer are based on indirect efficacy measurements. The number of subjects, the age of the subjects (9-26) and the duration of the trials was such that no cases of cancer were recorded in either the Placebo or Gardasil groups. **In other words, there is no proof that even one case of cervical cancer has been prevented to date by this vaccine.**

Placebo: Table 6 lists 3470 subjects receiving Aluminum-

Containing Placebo and only 320 containing Saline Placebo. [Note: Alumunum-Containing Placebo is **not** a Placebo and would bias the "safety" results.]

GARDASIL is not recommended for use in pregnant women. There were 15 cases of congenital anomaly in pregnancies that occurred in subjects who received GARDASIL and 16 cases of congenital anomaly in pregnancies that occurred in subjects who received placebo.

Further sub-analyses were conducted to evaluate pregnancies with estimated onset within 30 days or more than 30 days from administration of a dose of GARDASIL or placebo. For pregnancies with estimated onset within 30 days of vaccination, 5 cases of congenital anomaly were observed in the group that received GARDASIL compared to 0 cases of congenital anomaly in the group that received placebo. The congenital anomalies seen in pregnancies with estimated onset within 30 days of vaccination
included pyloric stenosis, congenital megacolon, congenital hydronephrosis, hip dysplasia and club foot. Conversely, in pregnancies with onset more than 30 days following vaccination, 10 cases of congenital anomaly were observed in the group that received GARDASIL compared with 16 cases of congenital anomaly in the group that received placebo. 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.

Overall, 17 and 9 infants of subjects who received GARDASIL or placebo, respectively (representing 3.4% and 1.8% of the total number of subjects who were breast-feeding during the period in which they received GARDASIL or placebo, respectively), experienced a serious adverse experience. None was judged by the investigator to be vaccine related.

In clinical studies, a higher number of breast-feeding infants (n = 6) whose mothers received GARDASIL had acute respiratory illnesses within 30 days post-vaccination of the mother as compared to infants (n = 2) whose mothers

Cervical Cancer and the HPV Vaccine

The Ministry of Health (MoH) announced on the 20th of July that the medicines regulatory authority, Medsafe, had approved the vaccine Gardasil® for girls as young as nine. The MoH has all but admitted that the licensing of the vaccine in New Zealand was rushed through. New Zealanders should be able to make an informed decision about this vaccine and not be coerced or frightened into think it is a "must-have" for themselves or their daughters without knowing more about the vaccine, what it can and can't do, whether or not HPV is the last word on the causes of cervical cancer and the actual risks of cervical cancer.

The following information is excerpted from the 3rd edition of *Investigate Before You Vaccinate: making an informed decision about vaccination in New Zealand*, due out in early September, 2006.

The developers of human papilloma virus vaccine are touting it as the first vaccine to prevent cancer, a moniker that was once attributed to the hepatitis B vaccine (and still is in some quarters[1]). Generally the medical community stopped calling the hepatitis B vaccine the first vaccine to prevent cancer when it was pointed out that there are plenty of other ways to get liver cancer besides hepatitis B infection, that being vaccinated against hepatitis B didn't stop vaccine recipients from getting liver cancer in some other way (these issues are worth keeping in mind as we consider the HPV vaccine).

So now we have a new vaccine that carries the "first vaccine against cancer" mantle.

Cervical Cancer

In New Zealand in 2000, 205 women were diagnosed with cervical cancer (a rate of 8.5 per 100,000 women) and 60 women died (a mortality rate of 2.5 per 100,000 women).[2] Between 1991 and 2000 the incidence of cervical cancer in new Zealand fell by 34.1% and the death rate by 45.7%. This fall in both morbidity and mortality can largely be attributed to the cervical cancer screening programme. Through the detection of abnormal cervical cells (using a pap smear) precancerous conditions can be detected and treated before the development of cervical cancer, thus reducing the incidence of, and mortality from cervical cancer.

The life time risk of cervical cancer is very low. Although there don't seem to be specific figures for New Zealand women, in the US, where cancer incidence is generally similar, the lifetime risk of developing cervical cancer is 0.75% or 1 in 133 women, and the lifetime risk of dying from cervical cancer is 0.25% or 1 in 400 women.[3]

While cervical cancer may be the second most common cancer in women in other parts of the world, that is certainly not the case in New Zealand, where it comes eighth behind breast, colorectal, skin (melanoma), lung, ovarian and uterine cancer and Non-Hodgkins lymphoma.[2]

It was long believed that cervical cancer was associated with sexual intercourse, because it is rare in women who have never had sex (e.g. celibate women such as nuns). Now it is the human papilloma virus (HPV) that is believed to be responsible, in part, for the development of cervical cancer. Dr Harry Haverkos from the US FDA Center for Drug Evaluation and Research writes that HPV play at least a major if not a necessary role in the development of cervical cancer.[4] He goes on to say that "many investigators acknowledge that HPV is not sufficient to induce cervical cancer" and one or more other factors are also likely in order to initiate the cancer:

> *"HPV can be found in a growing proportion of patients with cervical cancer, approaching 100%, but is not yet found in every patient with disease. Other factors, such as herpes simplex virus type 2 infections, cigarette smoking, vaginal douching, nutrition, and use of oral contraceptives, have been proposed as contributing factors."*

It is estimated that 75% of sexually active men and women have been exposed to HPV at some point in their lives. [3]

However, it is extremely important to note that some other factor is required to trigger the

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development of cervical cancer, and the medical community doesn't seem to know quite what that is. And when you consider that as many as 75% of women are exposed to HPV at some point in their lives, yet only 1% on them go on to develop cervical cancer, it is very, very clear the HPV infection alone is not the problem. HPV infection ***does not*** kill people!

But, of course, the vaccine manufacturers could see yet another captive market just waiting for yet another vaccine to save them from a cancer fate. It would clearly be easy to brush over the less than impressive incidence statistics with a public campaign of fear. After all, they already have a recipe that had been used so successfully with the flu vaccine.

The Human Papilloma Virus Vaccine

The human papilloma virus vaccine is based on 15 years of work by Professor Ian Frazer, who leads the Cancer and Immunology Research Centre at the University of Queensland.

Frazer and Dr Jian Zhou were trying to develop a treatment for women already infected with HPV, and in the process developed a "fake" virus – the virus coating without the pathogenic material inside – which then became the basis for the vaccine.

Of course, the theory for HPV vaccines is just like any other – inject a bit of the virus and trick the body into thinking it is under attack. The body produces antibodies to fight the virus and then retains a memory so that if it genuinely comes under attack from the real virus it knows what to do and rids the body of the virus before it comes to any harm. But it isn't that simple.

It is widely quoted that the human papilloma viruses comprise a group of some 80 to 100 viruses of which about 30 are believed to be linked to cervical cancer. Of these 30, HPV 16 and 18 are the ones that do most of the damage; although the figures vary from one paper to the next, HPV-16 is believed to be found in around 50% of cervical cancer cases and HPV-18 in another 20%. Which leaves another 30% of cancers that are associated with one of the other forms of the virus. Which is where the aim to prevent cancer through vaccination gets a little tricky.

Dr Thomas Broker addressed a 1999 workshop on 'Evolving Scientific And Regulatory Perspectives On Cell Substrates For Vaccine Development' held by the US FDA.[5] On the topic of HPV he said:

> *"We have found a brand new HPV type for every 10 people that we have looked at. Philodelius and Ethel Michelle Diveres and zur Hausen and Shamen in European study of tutanius papilloma viruses have found a new papilloma virus for just about every other person they have looked at when they use the combination of nested PCR and DNA sequencing. Robbie Burke's group, Jill Polefski's group, have very comparable experiences looking at anal papillomas or female genital tract. It is my contention right now that instead of 80 HPV genotypes or 150 that have been officially named, that there probably are millions of variants, virtually a continuum."*

Which presents somewhat of a problem if you want to develop a vaccine, as he went on to point out:

> *"Well the real problematic thing for any clinical management, either vaccination programs or small molecule drugs, is this absolutely exploding number of virus types."*

Despite this problem at least two pharmaceutical companies have since developed a vaccine: Merck & Co have developed Gardasil®, a quadrivalent vaccine for HPV 6, 11, 16 and 18; and Cervarix™, a bivalent vaccine for HPV 16 and 18 developed by GlaxoSmithKline.

And as HPV is a sexually transmitted virus it makes "good sense" to vaccinate women while they are still girls, before they become sexually active. In order to get them before all are sexually active it means vaccinating them when they are 11 or 12 years old. Which also makes good sense to the manufacturers and the pro-vaccine agencies because this is also at an age when girls are not yet old enough to take responsibility for themselves and are largely unaware of their rights to informed consent; an age at which vulnerable parents wanting to do the best for the children as they enter their teens, and face the awakening of their sexuality, still have the right to make such decisions. An age before young girls find their voice and learn that they can say no!

Merck's HPV vaccine

Gardasil® is the quadrivalent HPV vaccine developed by Merck & Co. It is a genetically modified, recombinant, quadrivalent vaccine containing virus-like protein particles from HPV types 6, 11, 16, and 18 inserted in to yeast cells.

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The vaccine also contains approximately 225 micrograms of aluminium as an adjuvant, 9.56 mg of sodium chloride and 0.78 mg of L-histidine.[6]

A number of clinical trials of the vaccine have been reported on in the medical literature since 2002. Efficacy was assessed in four Phase II and III trials involving 20,541 women aged 16 to 26 years with follow up for between two and four years.[6]

(Not only did Merck fund these trials, as would be expected, but in one of the Phase II trials ten of the authors were employed by Merck and the company has financial arrangements with several other authors.)

Gardasil® was submitted for regulatory approval in the latter part of 2005 and in May 2006 Merck & Co began it's campaign to have all children in the US vaccinated with it.[7] The US Census Bureau says there are 32 million pre-teens and adolescents in that country, a considerable market for the vaccine.

Unsurprisingly, on June 8, 2006, the FDA announced that it had approved Gardasil® for use in females aged nine to 26 years. The FDA emphasized "that the product does not protect women if they have already been infected with HPV" and said this "indicates the importance of immunization before potential exposure to the virus." However, they also admitted that the vaccine does not protect against less common strains of HPV that are also associated with cervical cancer and "routine Pap screening will therefore remain critical."

At the same time Merck & Co. announced that the vaccine would cost about US$120 per dose;[8] US$360 for the three doses required (approximately $600 in New Zealand currency at the June 2006 exchange rate).

Then on June 29, the ACIP recommended "the routine use of the human papilloma virus vaccine for girls (age) 11 to 12. The recommendations also include permissive use of the vaccine down to age nine and up to age 26."[9]

Gardasil® does have some competition in the form of GlaxoSmithKline's bivalent HPV vaccine Cervarix™, which has not yet been submitted to the US authorities for licensing, although GSK plan to file for approval in the US in late 2006, and filed for approval in Europe, Australia, parts of Asia and Latin America from March 2006.[10]

What's Wrong With This Picture

Both Merck and GSK claim very high efficacy for their HPV vaccines – between 90 and 100% effectiveness in preventing HPV infection and the development of precancerous lesions. So what is wrong with this picture?

If you dig a little deeper there are plenty of problems with this apparent wonder-vaccine, the "first vaccine to prevent cancer"!

Does HPV cause cervical cancer and will an HPV vaccine prevent cancer, or even reduce the incidence? The ability of these vaccines to achieve this remains to be seen, but it is difficult not to be more than a little skeptical, specially as there are doubts about the real role of HPV in the development of cervical cancer.

Merck has claimed that Gardasil® is 100% effective in preventing cervical cancer because none of the women in it's study group developed precancerous lesions on their cervix while 21 out of 5,258 women in the placebo group did (0.4%). Cervical cancer takes years to develop – it is rare in women under 35 and the risk increases with age. All this clinical trial proved is that it stopped women developing precancerous lesions over the 17 months of the study, not for the rest of their lives. At best this study suggests that the vaccine slows down the development of precancerous lesions.

A US Obstetrician Gynecologist, Dr Clayton Young, opposes the HPV vaccine and points out that:

> *"The vast majority of women clear or suppress the virus to levels not associated with CIN II or III* and for most women this occurs promptly. The duration of HPV positivity (which is directly related to the likelihood of developing a high grade lesion or cervical cancer) is shorter, and the likelihood of clearance is higher, in younger women.*
>
> *Therefore, vaccinating these children against HPV with a vaccine that is of unknown duration of efficacy will only postpone their exposure to an age which they are less likely clear the infection on their own and be subject to more severe disease. This would require an unknown number of boosters and is a setup for complacency in the older population that is a recipe for disaster. Furthermore, the likelihood for regression to a normal pap*

* Cervical Intraepithelial Neoplasia are cancer precursor lesions and are graded as I, II or III.

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from CIN II is 40%. This beats Gardasil's "best" reduction of CIN II-III of only 12%. In this case, "first do no harm" rules."

Dr Young goes on to discuss the efficacy of the vaccine in the age group for which it has been approved:

"The study of the vaccine in children and adolescents is limited to only measuring the development of antibodies to the HPV subtypes in the vaccine. There is absolutely no evidence that the vaccine prevents anything when administered at this young age. Merck expects you to extrapolate their adult data to the immune response in children. If they were really interested in vaccine efficacy in children, should it not be studied properly in children?"

We've already looked at Dr Thomas Broker's comments on the number of HPV viruses that may be circulating and the suggestion that constant mutation may up the number of viruses from about 100 into the thousands. However, another issue is that not all researchers in this area are convinced that HPV contributes in any way to cervical cancer.

Does HPV Really Cause Cervical Cancer?

In 1992 Drs Peter Duesberg and Jody Schwartz, molecular biologists at the University of California at Berkeley, questioned the increasingly popular idea that HPV plays a central role in cervical cancer.

They wrote that there is a "lack of consistent HPV DNA sequence and of consistent HPV gene expression in HPV DNA-positive tumors" in cervical cancer and pointed out that HPV is present in no more than 67% of age-matched women with cervical cancer, clearly demonstrating that cervical cancer can happen without HPV infection.[11]

This is a major "fly in the ointment" and one that seems to have been completely ignored by all those falling over themselves to add yet another vaccine to the schedule, including New Zealand's own IMAC who will discuss the HPV vaccine at their September 2006 Vision for Vaccines symposium.[12] IMAC also have a section on HPV vaccines and cervical cancer in their new 2006 *Immunisation Handbook* which indicates an intention that this vaccines should be added to the schedule in the near future.[12] The MoH has said that the vaccine will be considered in August 2006 for addition to the schedule when changes are next made in 2008.

Interestingly, Duesberg and Schwartz offer an alternative and entirely valid reason why HPV is associated with many cervical cancers saying:

"Since proliferating [cancer] cells would be more susceptible to infection than resting cells, the viruses would be just indicators, rather than causes of abnormal proliferation."[11]

But given our inherent and morbid fear of cancer, it is much easier to believe that we have found a cause and then a "cure", than to risk finding out we are no closer to knowing why some women get cervical cancer and why some don't, even though many lifestyle factors, particularly exposure to tobacco smoke (passive or active), are clearly also involved. And, of course, it is much more profitable for the pharmaceutical companies to have a vaccine mandated for children than for those same children to refuse to take up smoking.

Safety

When it comes to safety there are a number of concerns regarding Gardasil®. The Vaccines and Related Biological Products Advisory Committee, in their Background Document released immediately prior to their meeting that considered the licensing of Gardasil® states that they had two concerns that they identified during the efficacy review of Gardasil®:[13]

- that the vaccine may lead to an increased number of cases of a cancer precursor lesions among patients already infected by any of the four virus types at the time they receive the vaccine, and whose immune systems have not cleared the virus from their bodies. That is, that the vaccine may actually stimulate or trigger the development of precancerous lesions, if the recipient has already been exposed to those four HPV types.
- that any benefit offered by the vaccine is offset by a possible increase in precursor lesions or worse cases due to HPV types not contained in the vaccine.

In addition, during the clinical trials there were five cases of babies with congenital birth defects born to women who had had the vaccine within 30 days of becoming pregnant. There were no such birth defects in the placebo group of women who had become pregnant within 30 days of receiving the placebo.[13]

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The participants in the study were followed up for 14 days after receiving either the vaccine or the placebo. There were numerous adverse reactions to both Gardasil® and the placebo, which is hardly surprising as some of the placebos also contained aluminium which is known to cause both localised injection site and systemic adverse reactions.

The impact of aluminium on localised or injection site reactions was clear:

	Gardasil® (N = 5088) %	Aluminium Placebo (N = 3470) %	Saline Placebo (N = 320) %
Injection Site			
Pain	83.9	75.4	48.6
Swelling	25.4	15.8	7.3
Erythema	24.6	18.4	12.1
Pruritus	3.1	2.8	0.6

From the Gardasil® datasheet.[6]

The percentage of participants who received Gardasil® who experience both mild to moderate and severe injection site reactions increased with each of the subsequent two doses, while such reactions decreased in frequency with both placebos. Some 60% of the participants that received either the vaccine or the aluminium containing placebo reported systemic reactions such as headache, nausea, diarrhoea, vomiting, fatigue, abdominal pain, dizziness and myalgia.[6]

Interestingly, the participants were followed up for auto-immune problems that may be related to the vaccine, a process that is very unusual for vaccine safety studies. Although the incidence of new medical problems were low in both groups over those four years there was a significant difference between the vaccine and placebo groups with three times the incidence of serious medical problems in the vaccine group. One case of juvenile arthritis, two of rheumatoid arthritis, five of arthritis and one of reactive arthritis were reported in the vaccine group.[6]

The reality is that until the vaccine is being used and adverse reaction reports start coming in, no-one has an accurate idea of how many adverse reactions there will be or how serious. If Gardasil® is administered together with other vaccines such as the adolescent DTaP it is going to be even harder to assess the overall impact of this vaccine on children's short and long term health.

Cost Benefit and Lasting Immunity

One big issue is the cost:benefit ratio, and at the moment it is not looking too good. Even if we ignore issues of whether or not HPV causes cervical cancer, this vaccine is very, very expensive. At the exchange rate at the time of writing, the three doses of Merck's Gardasil® will cost us $600 per 11 or 12 year old girl – approximately $16.5 million a year to vaccinate all eligible girls in New Zealand.*

Even if this vaccine works, and assuming for a moment that HPV definitely does cause cervical cancer, it won't wipe out cervical cancer. It contains only two of the viruses thought to be responsible for about 70% of cervical cancer. What about the other 30%? Even the "inventor" of the vaccine, Professor Ian Frazer, says this doesn't mean that pap smears and the cervical cancer screening programme can be consigned to the history books.[14] Women will still need to have regular smears, and as there is no other way of telling what HPV type a woman might have been infected with, all of them will need to be screened. On top of the cost of the vaccine!

In fact, one doctor expressed his concerns to the *Herald on Sunday* about possible complacency once a vaccine is introduced. The *Herald* reported that he "worries about the possibility a fix-it jab will make women think, incorrectly, that they no longer need to have regular pap smears. Another raises questions about whether, further down the track, the virus might mutate and fight back."[15]

The other point is that no-one knows how long any vaccine conferred immunity will last. It may not be long, perhaps five to ten years if many other vaccines are anything to go by. If your daughter is vaccinated at 11 then by the time she becomes sexually active, or at least soon after, her immunity may have waned to the point that she has no protection. The manufacturers and regulatory agencies have no idea at this stage how long any immunity will last. Will she know that? Will she have been told what else she can do to protect herself, or will she have been told "It's okay, you've been vaccinated, you're protected against HPV and cervical cancer."

And if boys are not vaccinated, there will be no chance of reducing the circulation of the virus in the community, those two strains of HPV – 16 and 18 – will still be out there, just waiting until your daughter's immunity wears off.

* Based on a birth rate of 55,000 per year, half of which are girls.

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One of the striking things about vaccination programmes is that, rather than admit that vaccines are not perfect, those who promote vaccines act like they will solve everyone's health problems. No one bothers to tell parents and their children what else they can do protect their children.

Other Options For Preventing Cervical Cancer

First, there is an alternative means of preventing, or at least reducing the risk of, contracting an HPV infection. A study published in the June 2006 issue of the *New England Journal of Medicine* found that the consistent use of condoms offered considerable protection against HPV.[16]

Dr Rachel Winer and colleagues found that women whose partners always wore a condom during sex were 70 percent less likely to become infected with HPV than those whose partners used protection less than five percent of the time. In addition, the study found that, at the end of the eight month study, in women reporting 100 percent condom use by their partners, no pre-cancerous cervical lesions were detected, whereas 14 such lesions were detected among women whose partners did not use condoms or used them less consistently.*

But of course condoms aren't the same lucrative 'golden goose' for pharmaceutical companies that a vaccine is. Despite that fact that condoms have other health benefits such as protecting against other sexually transmitted diseases and pregnancy, they simply are not as profitable as Gardasil® will be for Merck.

Clearly not every woman gets cervical cancer. In fact, more than 99% of women don't develop cervical cancer. So, why not? Don't look to the pharmaceutical companies, regulatory agencies and pro-vaccine organisations to tell you, but it is there in the medical literature all the same. Like many other chronic diseases dietary deficiencies are implicated as causal factors. Selenium is one of those deficiencies and inadequate selenium has a role in the development of cervical cancer.

Research published in 2003 concluded that selenium and zinc deficiency may be risk factors. The results of the study "showed that the tissue contents of zinc, selenium, and calcium were significantly lower and the copper and iron concentrations and copper/zinc ratio were significantly higher in cervical cancer tissue than that for paired nonlesion tissue." In addition the blood levels "of zinc, selenium, calcium, and iron were lower and copper and manganese levels and copper/zinc ratio were higher in patients with cervical cancer than in healthy subjects."[17]

Another study, also published in 2003, got the same results: that significantly lower selenium and zinc levels and higher copper/zinc ratios were found in both CIN [Cervical Intraepithelial Neoplasia] and cancer patients compared with the controls."[18]

In addition, a 1993 paper reported that among a cohort of 15,161 women, low serum levels of total carotenoids, alpha-carotene and beta-carotene were a significant risk factor for cervical cancer. Smoking was also strongly associated with cervical cancer in this study.[19]

VACCINATION AND INFORMED CONSENT

In New Zealand health professionals have a legal obligation to obtain informed consent before vaccinating a child or adult. Informed consent can only be provided by a patient or caregiver (parent) when the patient or caregiver has considered **all** the information pertaining to the risks and benefits of vaccination.

There is pressure on health professionals to provide only information that is sanctioned by the Ministry of Health. However, "official" information is incomplete and it is recognised by New Zealand consumer advocacy and health organisations that further information is necessary in order for people to be able to make an informed decision.

INVESTIGATE BEFORE YOU VACCINATE
MAKE AN INFORMED DECISION

The Immunisation Awareness Society is a voluntary society, funded by membership subscriptions and donations.

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* Participants were either virgins or had had their first sexual intercourse within two weeks of the study commencing.

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February 8, 2007

Madame Chairwoman and Members of the Committee,

My name is Adam Obley. I am a second-year medical student at the University of Kansas School of Medicine. I submit this testimony in opposition to HR 6006.

I understand that concerns have been raised about the potential effects of the proposed agreements on medical education. One concern is that expanding the research mission of the university will come at the expense of medical education. It has been my experience in the basic science classroom over the last two years that the best and brightest researchers are frequently the most engaging, enthusiastic, and effective teachers. Moreover, the increasing pace of discoveries in basic science and translational research demand that the next generation of physicians be trained to grasp and apply emerging technologies and techniques. In short, it is my belief that a robust research enterprise at KUMC will in fact significantly strengthen medical education.

Another concern that has been raised is that an increasing focus on research will lead to fewer students entering primary care specialties and practicing in underserved areas. I see no convincing evidence to support this assertion. Last year, KU School of Medicine was first in the nation in placing graduates in family medicine residency programs. Consistently, KU School of Medicine exceeds the national average in the number of graduates choosing primary care residencies. Furthermore, the notion that physician-researchers will not practice in primary care is patently false. Last year's Rainbow Award (the highest award presented by students to an excellent physician-mentor) winner was Dr. Daniel Dickerson. Dr. Dickerson has both a medical degree and a PhD in biochemistry from the KU School of Medicine. Far from secluding himself in the research lab, Dr. Dickerson practices family medicine in Eudora, Kansas.

Among my fellow medical students there is a palpable excitement that important progress for KUMC lies just over the horizon. We've come to medical school for different reasons and from diverse backgrounds, but I believe we are united in the belief that making KUMC a national leader in research, patient care, and medical education will serve us, the state of Kansas, and most importantly, our future patients well.

Thank you for your time and consideration.

Adam Obley, MS-2
University of Kansas School of Medicine

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ATTACHMENT 12

THE UNIVERSITY
OF KANSAS HOSPITAL
KUMED

Statement to the Committee on Health and Human Services
On House Resolution Number 6006
From Irene Cumming,
President and CEO,
The University of Kansas Hospital Authority

The University of Kansas Hospital Authority has been and remains fully supportive of the University of Kansas School of Medicine in its efforts to become a top tier medical school and in its efforts to achieve National Cancer Institute designation. We want our partner, the School of Medicine, to move forward as the area's life sciences leader. We understand that philanthropic funds have been pledged from across the greater Kansas City area which could benefit the School of Medicine. To demonstrate the Hospital Authority's support for the School of Medicine's efforts, a Letter of Intent was signed by the University of Kansas Hospital Authority and the University of Kansas last week. While there are a number of issues left to address before a final agreement can be reached, we are all hopeful they can be resolved, so that things will be brighter for the School of Medicine, the Hospital, the State, the region, our physicians and especially our patients.

Irene M. Cumming

House Health and Human Services
DATE: 2-8-07
ATTACHMENT 13

KANSAS BOARD OF REGENTS

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February 7, 2007

Representative Brenda Landwehr
Chairwoman
House Health & Human Services Committee
Statehouse, Room 115-S
Topeka, KS 66612

Representative Geraldine Flaharty
Ranking Member
House Health & Human Services Committee
Statehouse, Room 521-S
Topeka, KS 66612

Dear Chairwoman Landwehr and Ranking Member Flaharty:

On behalf of the Kansas Board of Regents, I write to you in opposition of HCR 6006, a resolution that proposes that the Governor, the University of Kansas (KU), the University of Kansas Medical Center (KUMC), and the University of Kansas Hospital Authority, not proceed with any affiliations for KUMC and the KU Hospital with other hospitals, institutions, and entities until the Legislature has had the opportunity to review them and participate in the consideration of the matters involved.

It is important to note that current statutes authorize the Board of Regents and any state educational institution, with the approval of the Board, to enter into contracts with any party or parties if the purpose of the contract is related to the operation or function of the Board or institution. In addition, Board policy authorizes the Regents institutions to enter contracts with any party if related to the operation, function, or mission of the institution. The Board believes that this framework appropriately allocates responsibility for making these types of decisions.

KU Chancellor Bob Hemenway and KUMC Executive Vice Chancellor Barbara Atkinson have kept the Board apprised of the affiliation discussions taking place at KUMC. In fact, during the Board's January meeting, Executive Vice Chancellor Atkinson provided us with a comprehensive briefing/update on these discussions. The Board has the utmost confidence in the leadership at KU and KUMC and knows that these institution's leaders will keep us informed as this important process continues – which is why I believe HCR 6006 is unnecessary.

Thank you for your consideration and for your continued commitment to ensuring a healthy future for all Kansans.

Sincerely,

Nelson Galle
Board Chairman

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ATTACHMENT 14

The University of Kansas
School of Medicine-Wichita

Office of the Dean

February 7, 2007

Dear Legislator:

Thank you for your interest in the University of Kansas Medical Center and the ongoing discussions between our School of Medicine and Kansas City area hospitals. We always welcome the opportunity to share our vision for the medical center and how we can better serve Kansans through the delivery of health care and discovery of cures.

As you know, I am the Dean of the School of Medicine in Wichita where approximately one-third of our third and fourth year medical students do their training. We also have a number of successful residency programs that are conducted with the two major hospitals in Wichita – Via Christi and Wesley Medical Center. We are proud of the fact that on average, 60 percent of the residents who graduate from our 12 residencies each year remain in Kansas to practice. In addition, 40 percent of our graduates last year entered a family medicine residency – a particular point of pride for us. These impressive statistics demonstrate just how committed the University of Kansas Medical Center is to providing physicians for Kansas. It is a mission we take very seriously and one we never forget.

But this is no time for complacency. In order to grow our research, education and clinical capacity, we must leverage our public investment with private dollars and expand our collaborations with multiple hospitals and research institutions – regardless of a state line. For instance, these new partnerships are critical to achieving our goal of a National Cancer Institute (NCI)-designated comprehensive cancer center. This is the University's number one priority and we remain grateful for the legislature's investment in this goal as well. Specifically for Wichita, we can and will play an integral role in our cancer mission through clinical trials. It will take a multitude of doctors and patients to facilitate these clinical trials and that means partnerships with Missouri institutions as well as with the Wichita campus and physicians throughout Kansas.

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Because I believe that multiple hospital affiliations hold enormous promise for the betterment of our School of Medicine, and ultimately for Kansans who are often treated by a KU-trained physician, I would like to register my opposition to House Resolution 6006. Legislative review of these proposed partnerships presents an enormous and unnecessary burden on us and will only hinder our ability to collaborate to find cures, improve health and train more and better doctors for Kansas.

Thank you for the opportunity to submit this letter for the record. I am sorry that I could not be present at today's hearing. I appreciate all that you do and look forward to our continued working relationship.

Sincerely,

S. Edwards Dismuke, MD, MSPH
Dean, KU School of Medicine - Wichita

February 7, 2007

Representative Brenda Landwehr
Chairperson, House Health and Human Services
State Capitol
300 SW 10th Avenue
Topeka, KS 66612

Re: House Resolution 6006

Dear Madam Chair and Members of the Committee:

The Kansas Masonic Foundation is the philanthropic arm of the 28,000 Masons in the state of Kansas. It was just forty-one years ago, in 1966, that The Kansas Masonic Foundation was formed for the purpose of expanding Masonic charity in the areas of scientific programs and education.

In 1974 the affiliation between the Kansas Masonic Foundation and the University of Kansas Medical Center cancer program began. That year, the Foundation made its first grant of $32,000 to help fund the Kansas Masonic Oncology Clinic. Over the next thirty years, that total of support to cancer research and education at KU Medical Center grew to more than $5 million dollars.

In November 2003, the Kansas Masonic Foundation pledged an additional $15 million dollars to support the KU Cancer Center in attaining National Cancer Institute (NCI) Designation. The attainment of NCI designation will place the KU Cancer Center and the Kansas Masonic Cancer Research Institute at the forefront of discovery for the treatment and prevention of cancer. It will help the Kansas Masonic Cancer Research Institute take its place among the leading cancer research and treatment centers such as a Mayo Clinic and M.D. Anderson. To date we have raised $9.6 million for the "Partnership for Life" Campaign.

I share this background with you so you can understand how important it is to Kansas Masons, their families and friends, that nothing happens to threaten the achievement of an NCI designation for the KU Cancer Center. Specifically, we do not think that House Resolution 6006 should be passed.

As an NCI designated Cancer Research Center, KU will need access to a multitude of doctors and patients to facilitate clinical trials. To that end, KU Medical Center has been working hard

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to establish the Midwest Cancer Alliance to forge relationships with hospitals and physicians through Kansas and the region.

We appreciate the support that the Kansas Legislature made last year in providing the $5 million funding and we hope that the funding will continue annually. But we also hope that the Legislature will allow the KU Medical Center to continue its collaboration among health care institutions which will be to the benefit of all cancer patients in the region, bringing the latest cancer therapies to them.

We do not believe that House Resolution 6006 should be passed. It would create an unnecessary burden on KU Medical Center and could jeopardize their achievement of an NCI designation.

Sincerely,

Mark E. Nelson

Mark Nelson
Executive Director
Kansas Masonic Foundation

Kansas Academy Of Family Physicians

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Caleb Bowers
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Carolyn N. Gaughan, CAE
Executive Director

The largest medical specialty group in Kansas.

Statement of the Kansas Academy of Family Physicians on Proposed Plans of the University of Kansas School of Medicine To Develop a Life Science Center

The Kansas Academy of Family Physicians enjoys a good working relationship with the University of Kansas School of Medicine. A majority of the family physicians in Kansas are alumni of the institution, and received the benefits of an outstanding University of Kansas School of Medicine education.

KAFP has observed with anticipation the exciting discussions about the proposed alignments of the University of Kansas School of Medicine and leading medical and scientific research institutions in the Greater Kansas City area. We are proud to think of the possibilities unfolding for our university, and its opportunity to become one of the country's top 20 life sciences centers.

However, as discussions have progressed, we have many unanswered questions. Primary among them is this: What will safeguard provisions for clinical training of family physicians for the State of Kansas? The Education Affiliation Objective was authored by the prestigious steering committee to establish aligned teaching affiliations among the leading institutions of Greater Kansas City. It states this lofty goal: to "elevate their respective educational missions and capabilities and to enhance the area's research platform through the enhancement of faculty recruitment and post-graduate support." However this objective and the stated concerns of the steering committee which were presented to the Kansas Medical Society Council on 1/20/07, fail to mention the most obvious and key mission: that of training physicians to provide health care for the citizens of Kansas. The goal of becoming a world-class research institution does not eliminate the School of Medicine's obligation to train enough family physicians to serve Kansans' needs. Efforts by faculty in both Departments of Family Medicine have been exceptional, and results have been much better than at other medical schools. But despite this many areas of Kansas are still health care shortage areas, with dramatic problems of access to medical care. More family physicians are needed. This is a significant concern for the current family physicians of Kansas, who provide the backbone of primary care in the state and wonder where their future partners will come from, as the aging population requires more care. The KAFP urges the School of Medicine to place as high a priority on training clinical physicians, and especially family physicians, to care for Kansans as it does on becoming a world-class research institution. Without enough family physicians, Kansans' access to high quality, primary care will be severely limited.

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Kansas Academy Of Family Physicians

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The largest medical specialty group in Kansas.

There has clearly been a special relationship between the University of Kansas Hospital and the University of Kansas School of Medicine. Their affiliation has cultivated an outstanding teaching environment for the future physicians of Kansas and at the same time demonstrated sustainable economic success. The University of Kansas Hospital has been clear and unwavering in its support of clinical training. The recent offers from the University of Kansas Hospital to significantly increase its support to the School of Medicine are a clear example of the value of this relationship.

KAFP fully supports the University of Kansas School of Medicine's efforts to develop a world class life science center and we also understand the need to develop supporting partnerships and affiliations in the greater Kansas City area. However, those efforts should never diminish the more fundamental mission of the University of Kansas School of Medicine to prepare and produce physicians for our state. This mission is of such importance that any future discussions or affiliations by KU should clearly state the protection of this essential mission.

Nearly $110 million of state support is annually awarded to the University of Kansas School of Medicine. KAFP believes that this state support funded by Kansas tax payers demands careful consideration of all future affiliations. The tax payers of Kansas expect and deserve an adequate supply of well-trained family physicians in exchange for this support. Legislators have already voiced serous questions about the proposed affiliations. We believe these questions should be answered in an open and transparent discussion involving all associated parties.

In summary, the Kansas Academy of Family Physicians supports the development of a world class research institution involving University of Kansas Medical Center and the University of Kansas Hospital, provided that the more fundamental commitment to training the clinical physicians, and more specifically the family physicians, that Kansans need is recognized and clearly prioritized by all involved parties.

Sincerely,

Joe D. Davison, MD
Board Chair

The mission of the Kansas Academy of Family Physicians is to promote access to and excellence in health care for all Kansans through education and advocacy for family physicians and their patients.

17-2

Letter of Intent

Between KUMC and SLH

Whereas, the life sciences hold the key to better health and quality of life for all citizens, as well as the promise of sustainable growth in jobs and improved standards of living; and

Whereas, the State of Kansas and the greater metropolitan Kansas City area have the goal of creating one of the top 20 life sciences research centers in the United States; and

Whereas, it is in the best interests of the citizens of Kansas and Missouri that unity of effort in life sciences research and education be achieved across state lines: and

Whereas, a robust medical research and educational pipeline in the life sciences in the greater Kansas City area will lead directly to advances in medical treatment modalities, including preventive measures; and

Whereas, the collaboration and affiliation of area hospitals with research and educational institutions are essential elements of the life sciences effort; and

Whereas, Saint Luke's Hospital (SLH) and the University of Kansas Medical Center and School of Medicine (collectively, KUMC) desire to develop a relationship that supports the vision of the greater Kansas City community as a center for research and education in the life sciences; and

Whereas, realization of this vision, as articulated in the "Time to Get it Right" and "Time to Get Things Done" reports, requires KUMC to establish new affiliations for joint educational and research programs in order to achieve effective collaboration with multiple partners in the Kansas City Area Life Sciences Initiative; and

Whereas, SLH has the goal of becoming a major academic teaching and research hospital for KUMC; and

Whereas, KUMC seeks to expand the range of educational and research opportunities for its faculty, residents and students and to obtain access to community resources and funding in support of its efforts to move into the "top tier" of public medical centers and medical schools in the United States, while maintaining and improving its existing relationship with the Kansas University Hospital (KUH) as the primary academic clinical, teaching and research hospital of KUMC; and

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Whereas, it is in the best interests of the state of Kansas and the region to have a top rated School of Medicine that attracts and trains exceptional physicians committed to providing quality health care services and promoting health for the future of the region; and

Whereas, the parties desire to elevate the amount and quality of research conducted within each institution by collaborative arrangements aiding in the recruitment of new investigators, in the attraction of new projects in areas of mutual interest, and in the development of financial, laboratory, and other resources that will improve the capability of each institution to conduct research, report and publish results, improve grant opportunities, and ultimately lead to translation of research results into improved patient care, patents, and other intellectual property for commercial success; and

Whereas, contemporaneous with the execution of this Letter of Intent, SLH and KUMC acknowledge that KUH and KUMC are also executing a Letter of Intent regarding the life sciences initiative, which letters shall be read in harmony, and not conflict, with each other. Both letters of intent will form the basis for respective definitive agreements by and between SLH and KUMC and between KUH and KUMC.

Now, therefore, as a sign of the good faith intent of the parties, the undersigned hereby agree to the following non-binding statement of intent and purpose as the basis for future definitive agreements to be completed by March 31st, 2007:

1. KUMC and SLH will enter an education affiliation agreement that covers inter-institutional relationships in graduate medical education, undergraduate medical education, and the education of other health professionals, and a research affiliation agreement that will enable collaborative research efforts in various areas, including Cancer, Neurology, Nephrology, Endocrinology, and Cardiovascular Medicine.

2. All faculty appointments in the University of Kansas School of Medicine (School) will be determined by the Executive Dean of the KU School of Medicine ("Executive Dean"). The Executive Dean will grant faculty titles--either modified or unmodified -- as appropriate to members of the SLH medical staff based on academic qualifications and education/research/scholarly activity.

3. Medical Staff

   a. Limitations on SLH Recruitment of Physicians. KUMC's affiliation agreement with SLH will restrict SLH from:

      (1) Recruiting members of the KUH medical staff without the written concurrence of the KUH CEO and the KUMC EVC. As a penalty for violations of this provision, such physicians recruited to the SLH medical staff will not be eligible for a KUMC faculty appointment for a period of time to be determined in the Definitive Agreement.

      (2) Recruiting physicians outside the Greater Kansas City market with whom KUH is in active negotiations. As a penalty for violation of this

provision, such physicians recruited to the SLH medical staff will not be eligible for a KUMC faculty appointment for a period of time to be determined in the Definitive Agreement.

b. Limitations on KUH Recruitment of Physicians. KUMC's affiliation agreement with KUH will restrict KUH from:

(1) Recruiting members of the SLH medical staff without the written concurrence of the SLH CEO and the KUMC EVC.

(2) Recruiting physicians outside the Greater Kansas City market with whom SLH is in active negotiation.

(3) As a penalty for violations of provisions 3b(1) and 3b(2), such physicians recruited to the KUH medical staff will not be eligible for a KUMC faculty appointment for a period of time to be determined in the Definitive Agreement notwithstanding any existing agreement between KUH and KUMC. This provision is not to be interpreted as inconsistent with provisions of the Master Affiliation Agreement providing for a closed medical staff.

c. KUH Medical Staff Not Eligible for SLH Medical Staff Appointments. Physicians on the KUH medical staff will not have clinical privileges at SLH without permission from both the KUH and SLH CEOs. Physicians on the SLH medical staff will not have clinical privileges at KUH without permission from both the KUH and SLH CEOs.

4 Teaching, Residency and Fellow Programs

a. GMEC Executive Committee. KUMC will provide for the oversight of GME programs sponsored by KUMC in accordance with the accreditation standards of the Accreditation Council for Graduate Medical Education (ACGME). The KUMC GME committee structure will be modified to establish an Executive Committee of the existing Graduate Medical Education Committee (GMEC). The Executive Committee for GMEC shall include the Vice Dean for Medical Education as its chair. The other members of the Executive Committee will be the Associate Dean for Graduate Medical Education, and the Senior Associate Dean for Finance of the School and a senior officer from each of the other affiliated institutions (including KUH, SLH, the VA, and other major participating institutions and organizations). Responsibilities of the Executive Committee will include the identification and allocation of resources sufficient to develop, implement and sustain the operations of the residency programs in accord with the KUMC Resident and Fellow Program Sizing Master Plan.

b. KUMC Resident and Fellow Program Sizing Master Plan. By March 31, 2007, KUMC will, in consultation with its Program Directors, develop a KUMC Resident and Fellow Program Sizing Master Plan by program with each of its affiliated hospitals that meets educational, community and academic

programmatic expansion needs. This plan will be approved by the GMEC.

(1) As a subset of the overall KUMC Resident and Fellow Program Sizing Master Plan, KUMC and each affiliate hospital will develop that affiliate's Resident and Fellow Program Sizing Plan by program that defines educational, community, and academic programmatic expansion needs of KUMC and that affiliate. The KUMC Resident and Fellow Program Sizing Master Plan will establish baseline quality measures and future quality goals (to be mutually and reasonably determined in the Definitive Agreement), current and future size requirements (to be mutually and reasonably determined in the Definitive Agreement) and means of support funding to achieve such goals (to be mutually and reasonably determined in the Definitive Agreement).

(2) KUMC Residency and Fellowship Programs. In accordance with the institutional and program accreditation requirements of the AGME, the programs sponsored by KUMC will operate across all affiliated sites in an integrated fashion. All residents in a given program operated under the affiliation will rotate among the affiliates in a manner consistent with the educational opportunities at each affiliate and consistent with each program's needs and the capacity of each affiliate. The specific rotation schedule will be determined by the respective program director and associate or assistant program director based on the educational goals and objectives for the program. While it is not the intent of this agreement to reduce the size of the residency programs at KUH, considerations of ACGME accreditation may result in transient changes in program size. In any instance in which program quality or size fails to meet the benchmarks established in the KUMC Residency Size Master Plan, the particular program director shall, in consultation with the GMEC and the Executive Committee of the GMEC, develop and implement a work plan that will result in re-establishment of compliance with the KUMC Residency Program Sizing Master Plan. In any case, all the residency programs at KUMC-affiliated institutions will operate in accordance with all institutional and program accreditation requirements of the ACGME. Such details shall be specified in the Definitive Agreements.

(3) Student Rotation. The Executive Dean in consultation with the SoM Education Council, its subcommittees, and clerkship directors will determine placement of medical students.

5. Licensing and Branding

a. KUH Rights. KUH will be able to present itself to all audiences as the "Primary Academic Clinical, Teaching and Research Hospital of KUMC" and to market all

inpatient and outpatient services that it now offers (or in the future may offer) using the brands and trademarks it has been granted under the terms of the License Agreement dated October 1, 1998 between KUH and the University of Kansas ("License Agreement"). Notwithstanding the preceding, the use of phrase "Primary Academic Clinical, Teaching and Research Hospital of KUMC" by KUH will not be permitted until a Definitive Agreement is executed between KU and KUH. If any of the rights granted to SLH in 5(b) infringe on the License Agreement, KU and KUH will have all rights and remedies afforded to them for such infringement under the License Agreement.

b. SLH Rights.

(1) Saint Luke's Hospital of Kansas City—Plaza Location (SLH) shall be referred to, subject to resolution of compensating mechanisms, as either :

(i) "A Teaching and Research Hospital of the KUMC" based upon consummation of the KUMC and SLH Definitive Agreement;

or

(ii) " A Major Academic Teaching and Research Hospital of the KUMC" based upon consummation of the KUMC and SLH Definitive Agreement that includes:

a. Agreed to provisions for SLH unrestricted mission support of KUMC; and

(1) A detailed plan to achieve a Teaching Program of significant size in terms of number of students, residents and fellows (to be reasonably determined in the Definitive Agreement) within 6 months of plan completion;

or

(2) A detailed plan to achieve a Research Program of significant size (to be reasonably determined in the Definitive Agreement) within 6 months of plan completion.

or

(iii) "A Major Academic Teaching and Research Hospital of the KUMC" based upon achievement of:

a. Payment of SLH unrestricted mission support of KUMC as agreed.; and

will solicit and recommend collaborative research efforts in various areas.

11. KUMC will, in coordination with KUH and SLH and other affiliates, develop a joint strategy to communicate to the Kansas City funding community their collaborative projects and the general benefits of research, including appropriate measurement of success of the affiliations based upon collaborative projects or research programs, joint grants, discoveries, publications and intellectual property.

12. KUMC and SLH will coordinate with KUH as applicable and will coordinate with each other and all affiliated organizations to establish networks in order to develop appropriate research centers and institutes that can link to other world-class programs.

13. KUMC will make available to SLH research cores including, but not limited to, mass spectrometry, bioinformatics, biostatistics, and genomics. KUMC will provide research administration support to SLH for collaborative programs and research projects including assistance with pre- and post-award grant application development. The parties, within their resources and capabilities, will make available laboratory and other research space to facilitate the parties' collaborative research projects.

14 The parties will each pay the other party's appropriate direct and indirect costs attributable to collaborative projects conducted on the other party's premises based upon equitable consideration of expenses, revenues, and other factors.

15. The initial agreements for education and research will have a ten-year term, which will be subject to revision based on mutual agreement. Such agreements may be renewable upon mutual consent of the parties.

16. Multiple Agreements Among Parties. The parties envision potentially three final agreements. These agreements will proceed and be negotiated independently and may be signed on different dates, provided that such agreements do not conflict with the two letters of intent. KUMC, KUH and SLH may enter into a Definitive Agreement that will address issues, if any, of common importance and interest to KUH, KUMC and SLH. KUH and the KUMC will enter into a Hospital Affiliation Agreement ("KUH Affiliation Agreement"). KUMC and SLH will enter into a separate Affiliate Hospital Agreement ("SLH Affiliation Agreement"). These latter two agreements will address areas of importance and interest that will not be related to the issues in any three-party Definitive Agreement. The Parties agree, however, that nothing in such separate agreements will conflict with or undermine the terms of any Definitive Agreement that may be negotiated among the Parties. Because KUH is an instrumentality of the State of Kansas, and KUMC is an agency of the State of Kansas, all agreements, including the Definitive Agreement and the separate agreements, will be transparent and will fully disclose all terms of the Parties' relationships, consistent with the provisions of the Kansas Open Records Act.

17. Board Approval. This letter is subject to the approval of the board of directors of the St. Luke's Hospital. While the President and CEO of SLH may sign this non-binding letter of intent, such signature is without approval of the SLH board of directors.

In witness whereof, the undersigned have set their hands:

FOR:

The University of Kansas

St. Luke's Hospital

_____

_____

18-8

LETTER OF INTENT

BETWEEN KUMC AND KUH

FOR PURPOSES OF SUPPORTING A KUMC AFFILIATION WITH SLH

January 31, 2007

Whereas, the life sciences hold the key to better health and quality of life for all citizens, as well as the promise of sustainable growth in jobs and improved standards of living; and

Whereas, the State of Kansas and the greater metropolitan Kansas City area have the goal of creating one of the top 20 life sciences research centers in the United States; and

Whereas, a robust medical research and educational pipeline in the life sciences in the greater Kansas City area will lead directly to advances in medical treatment modalities, including preventive measures; and

Whereas, the collaboration and affiliation of area hospitals with research and educational institutions are essential elements of the life sciences effort; and

Whereas, the University of Kansas Medical Center and School of Medicine (together, KUMC) have determined to develop a relationship with Saint Luke's Hospital of Kansas City—Plaza Location (SLH) that supports the vision of the greater Kansas City community as a center for research and education in the life sciences; and

Whereas, realization of this vision, as articulated in the "Time to Get it Right" and "Time to Get Things Done" reports, requires KUMC to establish new affiliations for joint educational and research programs in order to achieve effective collaboration with multiple partners in the Kansas City Area Life Sciences Initiative; and

Whereas, KUMC seeks to expand the range of educational and research opportunities for its faculty, residents and students and to obtain access to community resources and funding in support of its efforts to move into the "top tier" of public medical centers and medical schools in the United States, while maintaining and improving its existing relationship with the University of Kansas Hospital Authority (KUH) as the "Primary Academic Clinical, Teaching and Research Hospital of KUMC"; and

Whereas, it is in the best interests of the state of Kansas and the region to have a top rated School of Medicine which builds on a close and historic relationship with a competitively strong, clinically excellent hospital to attract and train exceptional physicians committed to providing quality health care services and promoting health for the future of the State of Kansas and the region; and

Whereas, KUH has the statutory mission to facilitate and support the education, research, and public service activities of KUMC and its health sciences schools, to provide patient care and

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specialized services not widely available elsewhere in the state and to continue the historic tradition of care by the KUH to medically indigent citizens of Kansas; and

Whereas, the KUH, consistent with its statutory mission, supports KUMC's desire to enhance its affiliation with SLH in the interests of education and research; and

Whereas, the KUH has articulated concerns shared by KUMC, that an academic affiliation between KUMC and SLH may have the inadvertent and undesirable consequences of adversely affecting KUH's and KUMC's clinical enterprise; and

Whereas, there is an existing Master Affiliation Agreement between KUH and KUMC and an existing Licensing Agreement between KUH and KUMC; and

Whereas, contemporaneous with the execution of this Letter of Intent, KUH and KUMC acknowledge that KUMC and SLH are also executing a Letter of Intent regarding the life sciences initiative, which letters shall be read in harmony, and not conflict, with each other. Both letters of intent will form the basis for definitive agreements by and between KUMC and SLH and between KUMC and KUH.

Whereas, while the parties have reached substantial agreement on a number of issues as reflected in paragraphs 1 through 10 of this Letter of Intent, the parties have yet to reach resolution on six issues identified in this Letter of Intent. They are summarize at the conclusion of this document and are anticipated to be resolved between the parties in related agreements, including the definitive Affiliation Agreement, Financial Agreement, and the Master Affiliation Agreement.

Now, therefore, as a sign of the good faith intent of the parties, the undersigned hereby agree to the following non-binding statement of intent and purpose as the basis for future definitive agreements to be completed by March 31st, 2007:

1. KUH as Primary Academic Clinical, Teaching, and Research Hospital. KUH will continue to be the "Primary Teaching Hospital" of the SoM. While, under the current Master Affiliation Agreement between the parties, KUH may enter into agreements with other institutions for the use of the KUH and KUH facilities for graduate medical education, per the American Council on Graduate Medical Education, KUMC will remain the only sponsor of graduate medical education for which KUH is the primary teaching hospital. So long as the medical staff of KUH remains a closed staff, KUH will be the only hospital where the SoM's employed physicians will be allowed to be members of a Medical Staff unless approved by the KUH CEO, both provisions in accordance with the then current Master Affiliation Agreement. KUH will be designated the Primary Academic Clinical, Teaching and Research Hospital of KUMC upon execution of the Definitive Agreement (which will define the underlying criteria of such designation) between KUMC and KUH and which will be developed in conjunction with a corresponding Financial Agreement.

2. KUMC Research and Education Affiliation with SLH. KUMC will enter an affiliation agreement with SLH for the purposes of graduate medical education, undergraduate

medical education, and the education of other health professionals, and a research affiliation agreement with SLH for the purposes of enabling collaborative research efforts in various areas, including Cancer, Neurology, Nephrology, Endocrinology, and Cardiovascular Medicine. Notwithstanding the preceding sentence, this should not preclude development by KUMC or KUH of significant research efforts in these and other areas on the KUMC campus, consistent with the then current Research Affiliation Agreement. In addition, KUMC in partnership with KUH will develop a comprehensive cardiovascular research program on the KUMC/KUH campus. The affiliation agreements between KUMC and SLH will not encompass or include clinical program development, growth or management on any level.

3. Medical Staff

a. Limitations on SLH Recruitment of Physicians. KUMC's affiliation agreement with SLH will restrict SLH from:

(1) Recruiting members of the KUH medical staff without the written concurrence of the KUH CEO and the KUMC EVC. As a penalty for violations of this provision, such physicians recruited to the SLH medical staff will not be eligible for a KUMC faculty appointment for a period of time to be determined in the Definitive Agreement.

(2) Recruiting physicians outside the Greater Kansas City market with whom KUH is in active negotiations. As a penalty for violation of this provision, such physicians recruited to the SLH medical staff will not be eligible for a KUMC faculty appointment for a period of time to be determined in the Definitive Agreement.

b. Limitations on KUH Recruitment of Physicians. KUMC's affiliation agreement with KUH will restrict KUH from:

(1) Recruiting members of the SLH medical staff without the written concurrence of the SLH CEO and the KUMC EVC.

(2) Recruiting physicians outside the Greater Kansas City market with whom SLH is in active negotiation.

(3) As a penalty for violations of provisions 3b(1) and 3b(2), such physicians recruited to the KUH medical staff will not be eligible for a KUMC faculty appointment for a period of time to be determined in the Definitive Agreement notwithstanding any existing agreement between KUH and KUMC. This provision is not to be interpreted as inconsistent with provisions of the Master Affiliation Agreement providing for a closed medical staff.

c. KUH Medical Staff Not Eligible for SLH Medical Staff Appointments. Physicians on the KUH medical staff will not have clinical privileges at SLH without permission from both the KUH and SLH CEOs.

d. Unmodified Faculty Appointments for KUH-Employed Physicians. KUMC

agrees that Promotions and Tenure Committee approved KUH employed physicians (e.g., Cardiology and Emergency Room) will be eligible for the same unmodified faculty appointments received by members of the SLH medical staff. KUMC will evaluate their appointment status using similar academic criteria as other affiliate track physicians including existing rights of appeal. But for existing agreements between KUH and KUMC, all faculty appointments in the School will be determined by the Executive Dean of the KU School of Medicine in accordance with all applicable bylaws, policies and procedures of the University, the Medical Center and Medical School. The Executive Dean retains the discretion to grant faculty titles--either modified or unmodified -- as appropriate to members of the KUH medical staff based on academic qualifications and education/research/scholarly activity, and the academic needs at the SoM .

e. KUH Physician Alignment.

(1) By March 31, 2007, KUH and KUMC, with support from the clinical chairs and KUPI, will develop a unified physician/KUH and KUMC alignment plan ("Alignment Plan") that commonly defines collective clinical objectives of KUH and KUMC/KUPI, KUH and KUMC/KUPI physician manpower needs, supporting physician and clinical management processes, structures and vehicles, and the preferred organizational model to support achievement of those ends, and KUMC academic needs. Any such Alignment Plan should include an acceptable method(s) of retaining and recruiting medical staff members and to address KUH's concern that it not be at a competitive disadvantage and to addresss situations where KUH identifies a clinical provider need at KUH that does not correspond with identified needs at the SoM.

(2) KUMC and KUH, with support from Clinical Chairs and KUPI, will quickly proceed with the development of a Joint Physician Recruitment Plan Infrastructure to first define the need for (i.e., Medical Staff Development Planning process) and then attract, recruit and retain leading clinicians and physician scientists.

f. KUMC financial support for physicians who conduct any clinical activity as a member of the SLH Medical Staff will be limited to providing support for teaching and research activity of clinical investigators. No such support will exceed the unrestricted mission support provided by SLH plus the community and philanthropic support given to KUMC and designated for use at SLH.

4. Teaching, Residency and Fellow Programs

a. GMEC Executive Committee. KUMC will provide for the oversight of GME programs sponsored by KUMC in accordance with the accreditation standards of the Accreditation Council for Graduate Medical Education (ACGME). The KUMC GME committee structure will be modified to establish an Executive Committee of the existing Graduate Medical Education Committee (GMEC). The Executive Committee for GMEC shall include the Vice Dean for Medical Education as its chair. The other members of the Executive Committee will be the Associate Dean for Graduate Medical Education, and

the Senior Associate Dean for Finance of the School and a senior officer from each of the other affiliated institutions (including KUH, SLH, the VA, and other major participating institutions and organizations). Responsibilities of the Executive Committee will include the identification and allocation of resources sufficient to develop, implement and sustain the operations of the residency programs in accord with the KUMC Resident and Fellow Program Sizing Plan.

b. Resident and Fellow Program Sizing Plan. By March 31, 2007, KUMC will, in consultation with its Program Directors, develop a Resident and Fellow Program Sizing Plan by department with each of its affiliated hospitals that meets educational, community and academic programmatic expansion needs. This plan will be approved by the GMEC.

(1) As a subset of the overall Resident and Fellow Program Sizing Plan, KUMC and KUH will develop a KUH Resident and Fellow Program Sizing Plan by program that defines educational, community, and academic programmatic expansion needs of KUMC and KUH. The KUH Resident and Fellow Program Sizing Plan will establish baseline quality measures and future quality goals (to be mutually and reasonably determined in the Definitive Agreement), current and future size requirements (to be mutually and reasonably determined in the Definitive Agreement) and means of support funding to achieve such goals (to be mutually and reasonably determined in the Definitive Agreement).

(2) KUH Residency and Fellowship Programs. In accordance with the institutional and program accreditation requirements of the AGME, the programs sponsored by KUMC will operate across all affiliated sites in an integrated fashion. All residents in a given program operated under the affiliation will rotate among the affiliates in a manner consistent with the educational opportunites at each affiliate and consistent with each program's needs and the capacity of each affiliate. The specific rotation schedule will be determined by the respective program director and associate or assistant program director based on the educational goals and objectives for the program. Each affiliate institution in consultation with the program director and the executive committee of the GMEC will develop a Resident Program Sizing Plan which the Executive Commmittee will aggregate into a KUMC Resident Program Size Master Plan. While it is not the intent of this agreement to reduce the size of the residency programs at KUH, considerations of ACGME accreditation may result in transient changes in program size. In any instance in which program quality or size fails to meet the benchmarks established in the KUMC Residency Size Master Plan, the particular program director shall, in consultation with the GMEC and the Executive Committee of the GMEC, develop and implement a work plan that will result in re-establishment of compliance with the KUMC Residency Program Sizing Master Plan. In any case, all the residency programs at KUMC-affiliated institutions will operate in accordance with all institutional and program accreditation requirements of the ACGME. Such details shall be specified in the Definitive Agreements.

(3) Student Rotation. The Executive Dean in consultation with the SoM Education Council, its subcommittees, and clerkship directors will determine placement of medical students.

c. Additional SLH Academic Affiliations. KUMC's affiliation agreements with SLH will provide that SLH shall retain its ability to continue existing affiliations with other universities, medical or professional schools for purposes of graduate medical education or to educate medical students and other health care professionals.

5. Licensing and Branding

a. KUH Rights. KUH will be able to present itself to all audiences as the "Primary Academic Clinical, Teaching and Research Hospital of KUMC" and to market all inpatient and outpatient services that it now offers (or in the future may offer) using the brands and trademarks it has been granted under the terms of the License Agreement dated October 1, 1998 between KUH and the University of Kansas ("License Agreement"). Notwithstanding the preceding, the use of phrase "Primary Academic Clinical, Teaching and Research Hospital of KUMC" by KUH will not be permitted until the Definitive Agreement is executed consistent with the provisions of section 1 above. If any of the rights granted to SLH in 5(b) infringe on the License Agreement, the parties will have all rights and remedies afforded to them for such infringement under the License Agreement.

b. SLH Rights.

(1) Saint Luke's Hospital of Kansas City—Plaza Location (SLH) shall be referred to, subject to resolution of the Compensating Mechanisms provisions 6(b) and (c), as either :

(i) "A Teaching and Research Hospital of the KUMC" based upon consummation of the KUMC and SLH Definitive Agreement;

or

(ii) "A Major Academic Teaching and Research Hospital of the KUMC" based upon consummation of the KUMC and SLH Definitive Agreement that includes:

(a) Agreed to provisions for SLH unrestricted mission support of KUMC (as detailed in 6(b)) equal to or greater than KUH unrestricted mission support; and

(1) A detailed plan to achieve a Teaching Program of significant size in terms of number of students, residents and fellows (to be reasonably determined in the Definitive Agreement) within 6 months of plan completion; ~~or~~or

(2) A detailed plan to achieve a Research Program

of significant size (to be reasonably determined in the Definitive Agreement) within 6 months of plan completion.

or

(iii) "A Major Academic Teaching and Research Hospital of the KUMC" based upon achievement of:

(a) Payment of SLH unrestricted mission support of KUMC (as detailed in 6(b)) equal to or greater than KUH unrestricted mission support; and

(1) Achievement of a Teaching Program of significant size in terms of number of students, residents and fellows (to be reasonably determined in the Definitive Agreement); ~~or~~ or

(2) Achievement of a Research Program of significant size (to be reasonably determined in the Definitive Agreement)

(iv) SLH shall not be permitted to refer to itself as "Primary" in relation to its affiliation with KUMC.

(2) SLH will not be able to use the branding rights granted in 5(b)(1) in relation to advertising any of its clinical programs and services – nor in any venues commonly seen, heard, or accessed by prospective and current patients. SLH may use the branding rights granted in 5(b)(1) and SLH affiliate and volunteer track physicians may refer to their appropriate faculty appointments on their letterhead, business cards, and in teaching and research communications (e.g., grant applications, academic presentations and the like). An appropriate mechanism shall be developed to resolve disputes among the parties, including SLH.

6. Financial

a. KUH Payment of Teaching and Research Costs. KUH will provide appropriate mission support that could include direct and indirect costs of teaching (excluding the current DME shortfall until it is corrected) and research (as applicable) and the provisions of incremental mission support.

b. SLH Payment of Teaching and Research Costs. KUMC's affiliation with SLH shall provide that SLH will provide appropriate mission support that could include direct and indirect costs of teaching and research (as applicable) and the provisions of incremental mission support (to be defined in the KUMC – SLH Definitive Agreement) so that KUH and State of Kansas support of KUMC does not result in subsidizing SLH - KUMC academic activity.

c. Compensating Mechanisms. It is agreed by KUMC and KUH that during a time period to be defined in the definitive agreement, if relative increases in the proportion of uncompensated care at KUH and decreases in proportion of uncompensated care at SLH occur (controlled for environmental changes, reimbursement changes, material changes in KUH operating environment, etc.) or relative decreases in overall patient volume at KUH and increases in patient volumes at SLH occur (controlled for environmental changes, reimbursement changes, material changes in KUH operating environment, etc.) so that KUH's financial performance is adversely impacted and/or causes KUH capital shortfalls, then provisions to be defined in the Definitive Agreement and whatever other supporting documentation is necessary will be established and enacted among KUH, KUMC, SLH and/or "community interests" as legally possible to compensate KUH and KUMC.

7. Research

a. Allocation and Location of Community Funded Research Assets. In those instances where community funds are to be used to acquire research assets that have a material clinical or teaching application, the geographically-contiguous, academically-integrated shared campus of KUH and KUMC will be considered first as the preferred location. Where any institution uses its own funds to acquire a research asset, this paragraph (a) will not apply.

b. Linkage With World-Class Programs. KUMC and KUH will coordinate with SLH as applicable and will coordinate with each other and all affiliated organizations to establish networks in order to develop appropriate research centers and institutes that can link to other world-class programs.

c. Joint Research Operations Committee. KU will establish a Joint Research Operations Committee (JROC) with equitable, proportionate representation from affiliated hospitals, including KUH and SLH. JROC will solicit and recommend collaborative research efforts in various areas.

d. Research Collaborations Among KUMC, KUH and SLH. KUMC will, in coordination with KUH and SLH and other affiliates, develop a joint strategy to communicate to the Kansas City funding community their collaborative projects and the general benefits of research, including appropriate measurement of success of the affiliations based upon collaborative projects or research programs, joint grants, discoveries, publications and intellectual property.

8. Definitive Agreements.

a. Multiple Agreements Among Parties. The parties envision potentially three final agreements. These agreements will proceed and be negotiated independently and may be signed on different dates, provided that such agreements do not conflict with the two letters of intent. KUMC, KUH and SLH may enter into a Definitive Agreement that will address issues, if any, of common importance and interest to KUH, KUMC and SLH. KUH and the KUMC will enter into a Hospital Affiliation Agreement ("KUH Affiliation

Agreement"). KUMC and SLH will enter into a separate Affiliate Hospital Agreement ("SLH Affiliation Agreement"). These latter two agreements will address areas of importance and interest that will not be related to the issues in any three-party Definitive Agreement. The Parties agree, however, that nothing in such separate agreements will conflict with or undermine the terms of any Definitive Agreement that may be negotiated among the Parties. Because KUH is an instrumentality of the State of Kansas, and KUMC is an agency of the State of Kansas, all agreements, including the Definitive Agreement and the separate agreements, will be transparent and will fully disclose all terms of the Parties' relationships, consistent with the provisions of the Kansas Open Records Act.

b. Breach of Agreements. Once the parties finalize the Definitive Agreement, KUH Affiliation Agreement and SLH Affiliation Agreement, mutual destinies are bound together and the potential withdrawal of any one party (KUMC, SLH, KUH) poses significant risks to the other parties. The Agreements will be for a term of ten (10) years and prevent withdrawal unless pursuant to mutal agreement and have strong provisions to mediate disputes. Notwithstanding, paragraphs 1 and 5(a) of this letter (as those paragraphs relate to the use of the term "Primary Academic Clinical, Teaching and Research Hospital" by KUH) will be renegotiated as part of the next Master Affiliation Agreement between KUH and KUMC.

c. Renegotiation of Agreements. KUMC will not renegotiate material elements (to be defined in the definitive agreement) of the SLH Affiliation Agreement with SLH without conducting a thorough risk mitigation process with KUH as part of the affiliation renegotiation. Furthermore, renegotiation of material elements of the SLH Affiliation Agreement (to be defined in the definitive agreement) that materially impact KUH (to be defined in the definitive agreement) will be cause for renegotiation of the KUH Affiliation Agreement and KUMC support agreement at KUH's discretion.

9. Remaining Issues.

a. Definition of KUH's status as the "Primary Academic Clinical, Teaching and Research Hospital" (paragraph 1);

b. Development of a KUMC-KUH Alignment Plan (paragraph 3(e));

c. Development of a KUMC-KUH Resident and Fellow Program Sizing Plan (paragraph 4(b));

d. Development of KUH-KUMC Financial Agreements (paragraph 6(a));

e. Development of Compensation Mechanisms for KUH-KUMC Financial Risks (paragraph 6(c));

f. Definition of Appropriate KUH Leadership Role in Achieving NCI Designation.

10. Board Approval. This letter is subject to the approval of the board of

directors of the University of Kansas Hospital Authority. While the President and CEO of KUH may sign this non-binding letter of intent, such signature is without approval of the KUH board of directors.

In witness whereof, the undersigned have set their hands:

FOR:

The University of Kansas	University of Kansas Hospital Authority
_____	_____

Legislative Budget Committee

KANSAS UNIVERSITY MEDICAL CENTER, KANSAS UNIVERSITY HOSPITAL AND MISSOURI-BASED HOSPITALS

CONCLUSIONS AND RECOMMENDATIONS

The Committee recommended continued dialogue between the University of Kansas School of Medicine and the University of Kansas Hospital, and that Kansas-based proposals for the Kansas City area be developed jointly by the University of Kansas School of Medicine and the University of Kansas Hospital.

Proposed Legislation: None.

BACKGROUND

The Legislative Coordinating Council tasked the Legislative Budget Committee with reviewing ongoing discussions of joint life sciences programs between Kansas University Medical Center, Kansas University Hospital, and Missouri-Based Health Systems.

COMMITTEE ACTIVITIES

During the December meeting of the Legislative Budget Committee, Robert Hemenway, Chancellor of the University of Kansas, addressed the issue of proposed collaboration between the University of Kansas School of Medicine and the University of Kansas Hospital. He gave a brief history of the relationship between the School of Medicine and the University of Kansas Hospital, which was split from the School of Medicine in 1998 when it was placed under the University of Kansas Hospital Authority by 1998 SB 373.

The Chancellor noted the success of the University of Kansas Hospital under the Authority. The Hospital has over 3,550 employees, 465 staffed beds, and 450 University of Kansas faculty physicians. In addition, the hospital has a new $77.0 million Center for Advanced Heart Care and the region's only level one trauma center and burn center. The Chancellor noted that the University of Kansas School of Medicine receives $30.0 million in annual support from the Hospital, for the most part from fees paid for services provided by the Medical Center to the Hospital. This level of support was not possible when the Hospital was first placed under the governance of the Authority.

The Chancellor noted that the Greater Kansas City Community Foundation and the Kauffman Foundation funded a study by a Blue Ribbon Task Force to assess higher education in the Kansas City area. The study, entitled "Time To Get It Right: A Strategy for Higher Education In Kansas City" concluded that the area had the potential to become a life sciences center in the country . He explained that discussions had started in June with region's life science leaders about how additional education and research partnerships might help the Kansas City area achieve this goal. He pointed out that leadership at the Hospital and Medical Center are committed to building for the future, which includes the School of Medicine becoming a top-tier research institution. Among the other goals he expressed for the future were the following:

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- The University of Kansas Hospital as a competitively strong, clinically excellent and accessible institution.

- A partnership between the two institutions that will enable the cancer center to achieve National Cancer Institute (NCI) designation.

- The main goal of the health of Kansans will not be compromised.

The Chancellor did make it clear that there are several things that will not occur as the Medical School and the Hospital strive to achieve these goals. The Medical School will not support:

- Partnerships or affiliations that would be detrimental to the future of the KU Hospital or the patients it serves;

- Affiliations that transfer Kansas taxpayer dollars to directly benefit Missouri-based institutions;

- Affiliations that reduce the number of resident physicians from the School of Medicine serving in the KU Hospital; or

- Affiliations that would compromise the School of Medicine's commitment to train doctors for Kansas or to serve indigent Kansans.

He noted that the School of Medicine is committed to support only affiliations which advance the vison of creating and sustaining new levels of excellence in the University of Kansas School of Medicine and thereby contributing to improving the health of the state and region. In addition, any affiliation proposal will be fully vetted and shared with the Hospital Authority board prior to adoption and that faculty will be consulted and informed about any proposal.

The Committee then heard testimony from former state Senator Dave Kerr, on behalf of the University of Kansas Hospital Authority. He first noted that the statutory mission of the University of Kansas Hospital is to operate a teaching hospital for the benefit of the University of Kansas Medical Center, to provide high quality patient care, and to provide a site for medical and biomedical research. He then provided details regarding the success of the Hospital since it was placed under the authority, including:

- Increased in-patient utilization;

- A shifting payer mix with more insured patients and fewer Medicaid and self-pay patients;

- Increased service to the indigent as evidenced by increased uncompensated care;

- Increased employee satisfaction;

- Reduced employee turnover; and

- Increased patient satisfaction.

Senator Kerr then noted the financial stability of the Hospital, pointing to the increase in the operating margin (the difference between revenues and expenditures) from $4.3 million in FY 1996 to $48.1 million in FY 2006. In addition, he noted the increased capital investment by the Hospital, which increased from $33.0 million in years 1993 through 1998 to $297.0 million in the years 2004 through 2007. This stability has allowed the Hospital to open a new $77.0 million Center for Advanced Heart Care in October of 2006 and invest $74.1 million in cancer research from 2000 to 2007, with the anticipated opening of an outpatient cancer center in the area in 2007.

Senator Kerr noted that investment in the University of Kansas has increased as well, growing from $6.9 million in FY 1999 to a budgeted $30.0 million in FY 2007. The

Hospital has proposed to provide an additional $400.0 million to the School of Medicine over the next 10 years to achieve the goals set forth by the Greater Kansas City Community Foundation Blue Ribbon Task Force report.

CONCLUSIONS AND RECOMMENDATIONS

The Committee recommended continued dialogue between the institutions, and that proposals from the Kansas side be developed jointly by the University of Kansas School of Medicine and the University of Kansas Hospital.