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MEDICAL BREAKTHROUGH: CERVICAL CANCER

Two at U of L help invent vaccine

Researchers aiming to save future generations

By **Laura Ungar**

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The Courier-Journal

A father's love for his daughters and a woman's love for her country led two Louisville researchers to a much-heralded medical breakthrough -- the world's first cervical cancer vaccine.

Dr. A. Bennett Jenson wanted to protect his three girls from the deadly disease. Shin-je Ghim wanted to help women in her native South Korea, where "so many" were dying.

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The two researchers at the University of Louisville's James Graham Brown Cancer Center now are waiting for the vaccine they helped invent to hit the market, around July. They also are working to create a cheaper version, using tobacco plants, and another vaccine to treat the disease -- with the



Dr. A. Bennett Jenson, left, and Shin-je Ghim of U of L's James Graham Brown Cancer Center began their work in 1989. (By Keith Williams, The Courier-Journal)

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- [Graphic: Human papillomavirus \(.jpg\)](#)
- [Graphic: Protecting against cervical cancer \(.jpg\)](#)

CERVICAL CANCER FACTS

- Cervical cancer begins in the lining of the cervix. Cells change to pre-cancerous and then to cancerous, which can take several years.
- The American Cancer Society predicts there will be 9,710 new cases of cervical cancer nationwide in 2006, and

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Louisville, who survived cervical cancer 1½ years ago, is pleased that future generations of women may not face the same threat.

"First thing on my mind was my granddaughters and great-granddaughters. This would be great if it were there for them," said Bastin, 64. "Whenever you have to hear the word 'cancer,' you have no idea what it does to you. It totally devastates you. With this vaccine, think of the people who would not have to hear the word I had to hear."

Despite its potential benefits, the vaccine has been the subject of controversy because it targets the sexually transmitted HPV, or human papillomavirus, which causes most cervical cancers. It is most effective when given before a girl becomes sexually active, or around 9 to 13 years old. Federal officials could vote next month on recommending universal use, although states would allow people to opt out.

Some people suggest the vaccine might give girls implicit permission to have sex. They say parents should decide whether their children are vaccinated, and keep in mind the risks associated with having sex too early.

"We're delighted with the medical breakthrough of the vaccine. But it's clear that just because a parent has purchased a new fire extinguisher for their home, that doesn't mean he should encourage his children to play with matches," said Kent Ostrander, executive director of the Family Foundation, a politically conservative nonprofit group based in Lexington.

Dr. Paige Hertweck, director of pediatric adolescent gynecology at U of L, said, "This is really not a moral issue.

"This is a cancer-preventing vaccine. That's what people need to think about," she said. "This is actually medical history in the making."

ultimate goal of wiping out cervical cancer.

"It's sort of a passion," said Jenson, who developed the vaccine with Ghim and another researcher at Georgetown University. "It's a disease that shouldn't be present and yet, it kills. It's the second-biggest cancer killer of women worldwide."

Anna Bastin of

3,700 women will die from the disease.

- Since 1955, the number of deaths has dropped significantly, mainly because of the Pap test.
- When treated early, cervical cancer often can be cured.

RISK FACTORS

- **HPV infection:** Human papillomavirus is passed from one person to another during sex. Having unprotected sex, especially at a young age, makes HPV infection more likely. Women with many sexual partners also have a greater chance of getting HPV.
- **Smoking:** Women who smoke are about twice as likely as those who don't to get cervical cancer.
- **HIV infection:** Having the virus that causes AIDS makes a woman's immune system less able to fight both the virus and early cancers.
- **Chlamydia:** A common sexually transmitted disease.
- **Diet:** A diet low in fruits and vegetables.
- **Weight:** Being overweight.
- **Birth control:** Long-term use of birth control pills -- five or more years.
- **Pregnancy:** Having many full-term pregnancies.
- **Low income:** Poor women often can't afford good health care, including Pap tests.
- **DES:** The hormone drug was used between 1940 and 1971 for women in danger of miscarriages. Their daughters have a slightly higher risk of cervical cancer.
- **Family history:** Studies suggest women whose mothers or sisters have had cervical cancer are more likely to get the disease.

PREVENTION TIPS

- Delay starting to have sex.
- Have few sexual partners and don't have sex with people who have had many partners.
- Quit smoking.
- Get a Pap test, which can detect HPV infection and pre-cancers. The test should be done every year with the regular Pap test, or every two years with the liquid-based Pap test.

Little initial interest

Jenson and Ghim -- along with Dr. Richard Schlegel, who is still at Georgetown -- began working on the vaccine in 1989, cutting a gene from the papillomavirus' DNA, infecting a cell and showing that the protein that developed mimicked the protein that exists in the virus.

This protein clumps together to create "papillomavirus-like particles," which are the basis of the vaccine and were developed by other scientists.

Jenson noted that he never doubted the value of his work, even though initially, "none of the drug companies were interested in what we were doing."

He said he thought of his daughters, in their late teens and early 20s at the time.

"This is one thing I wanted them to be protected from," he said.

Ghim said she thought about how cervical cancer has continued to exact a heavy toll in many other countries, even though deaths in the United States dropped significantly after 1955 because of Pap tests.

Merck & Co. and GlaxoSmithKline Inc. are working on separate versions of the vaccine. An advisory committee to the U.S. Food and Drug Administration last week unanimously endorsed Merck's version as safe and effective. Called Gardasil, it is expected to gain full federal approval in early June and hit the market two to four weeks later. GlaxoSmithKline's version is expected out next year.

Although Merck has not set a price, the vaccine is expected to cost \$300 to \$500 for three injections over six months -- which critics contend is too expensive. "It'll take time to see if the cost will go down and whether it will be used," said Bettie Steinberg, an HPV expert in Manhasset, N.Y., who has followed the vaccine development.

Still, she called the vaccine a "major breakthrough."

"Scientists work all their lives for something that can make a difference," she said. "When it really pays off like this, it's wonderful."

Georgetown spokeswoman Laura Cavender said any royalties that come from vaccine patents are shared with the inventors, although she wouldn't comment on this specific case.

And while U of L won't get money from Gardasil sales, spokeswoman Ellen de Graffenreid said the school is getting national attention. "When I expect it to get nuts is when the vaccine is finally approved," she said.

Treatment vaccine in works



Anna Bastin, 64, of Louisville survived cervical cancer a year and a half ago. It is the second-biggest cancer killer of women worldwide. (By Geoff Oliver Bugbee, Special to The C-J)

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The Louisville researchers' work is not completed, and they've received more than \$1 million for ongoing research from Kentucky, the federal government and the Brown Cancer Center.

Jenson, 66, and Ghim, 47, said they are about three years away from completing the second-generation preventive vaccine they are trying to grow by reproducing protein fragments in tobacco plants. They are working with a California researcher who will soon be moving to Kentucky Bioprocessing in Owensboro. It is expected to cost only \$6 to \$8 for three shots.

"There is a commitment to deliver this vaccine to the undeveloped countries because they need it most," Jenson said. "And it's an alternate use of tobacco plants. Instead of using them to make nicotine cigarettes that cause cancer, paradoxically, you use it for making a vaccine that protects women against cervical cancer."

Doctors warn that these vaccines won't negate the need for Pap tests, which can catch pre-cancer and early cancer. Bastin said a Pap test detected her cancer early. She had a radical hysterectomy but didn't need chemotherapy.

Jenson and Ghim said they hope that the treatment vaccine they are also developing -- with scientists in India -- someday helps cancer victims like Bastin.

"You think of retiring," said Jenson. "Then you think of everything that's still left to do."

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