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Big Charity hospital's future discussed

WXVT-TV | 08.20.08

Associated Press

BATON ROUGE, La. (AP) - A team of architects and historic preservationists are weighing in on the future of Big Charity hospital in New Orleans.

The public hospital was flooded by Hurricane Katrina. State officials are planning to build a new replacement facility, rather than renovating Big Charity.

The Foundation for a Historical Louisiana wants to save the Art Deco landmark.

The organization hired a Philadelphia architecture firm to analyze whether the Big Charity building can be used as a hospital. The report from that analysis will be released to state officials Wednesday.

LSU officials, who run the state's public hospitals, say the Big Charity facility was outdated even before Katrina flooded it in 2005.

http://www.wxvt.com/Global/story.asp?S=8869546&nav=menu1344_2

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Bush to make 13th post-Katrina visit to New Orleans Wednesday

The Times-Picayune | 08.19.08

Jan Moller

BATON ROUGE -- President Bush plans to mark the upcoming three-year anniversary of Hurricane Katrina with a speech at Jackson Barracks Wednesday that will extol the progress made since he promised the federal government would stay "as long as it takes" to rebuild the Gulf Coast.

It will be the president's 13th visit to the New Orleans area since it was devastated by the storm on Aug. 29, 2005, and possibly the last before he turns over the White House to a successor on Jan. 20. He is scheduled to deliver his remarks at 2:20 p.m., after a morning address to the Veterans of Foreign Wars national convention in Orlando, Fla. He will have dinner in Gulfport, Miss., before returning to his ranch in Crawford, Texas.

Gov. Bobby Jindal is scheduled to meet the president at Louis Armstrong International Airport and accompany him on a tour of the barracks as well as at the speech.

Although the Bush administration's initial response to the storm was widely criticized and contributed to the president's plummeting public approval ratings, Bush plans to focus on the money and resources that the federal government has contributed to the recovery.

"The story of your recovery is impressive," according to an advance copy of Bush's speech made available late Tuesday. "And it is the same story we see playing out across the Gulf Coast. Homes, businesses and schools are being rebuilt. Levees are being repaired. Families and communities are being reconnected. And from Biloxi to Beaumont, hope is being restored."

But five months to the day before his successor will be sworn in, Bush still has several items of unfinished business in a region where many residents remain disappointed with the slow and uneven pace of the recovery.

U.S. Sen. Mary Landrieu, D-La., said Louisiana continues to get shortchanged on recovery dollars when measured against neighboring Mississippi.

"I hope that what he (Bush) hears is that the federal government has still not met its full obligation to Louisiana and to the metro area or southwest Louisiana," Landrieu said, adding that Mississippi received at least \$2 billion more than Louisiana in federal block-grant dollars when measured against the amount of damage.

Bush will focus instead on the \$126 billion he says the federal government has committed to the recovery so far, money that has helped rebuild homes, schools and upgrade the levees and floodwalls whose failure during Katrina put 80 percent of the city under water.

"There is still a lot of work to do before this city is fully recovered," according to the speech. "And for people who are still hurting and not yet back in their homes, a brighter day may seem impossible. Yet a brighter day is coming, and it is heralded by hopeful signs of progress."

The president also plans to tout his recent decision to let Louisiana pay back its \$1.8 billion share of the levee improvements over 30 years, instead of three. Jindal had warned that the shorter timetable would have required the state to postpone some coastal restoration projects.

Among the main items left on the president's agenda is health care, where his administration continues to negotiate with the state on several key issues.

Chief among them is the federal government's reimbursement for the damage done by the storm to Charity Hospital. The state, backed by several independent studies, says that the Art Deco building on Tulane Avenue was more than 50 percent damaged by the wind and flooding, which would mean the federal government owes the state for a "replacement value" pegged at \$492 million.

The Federal Emergency Management Agency has put the damage at a far more modest \$23 million.

A large settlement is critical to the state's ability to finance a proposed new teaching hospital downtown, which would anchor a burgeoning biosciences district and serve as the primary training ground for the state's next generation of doctors and nurses.

Without a large down payment from the federal government, some state officials doubt the hospital can be built, since the state would have to borrow most of the \$1.2 billion construction cost.

"It's absolutely critical, " Louisiana State University System President John Lombardi said last week.

The state also is negotiating with the U.S. Department of Health and Human Services on an overhaul of the Medicaid program, which would funnel thousands of low-income residents into managed-care networks as a way of reducing costs and encouraging preventive care.

Some state officials had been expecting an announcement as early as this week about the health-care initiative, dubbed Louisiana Health First, but the text of Bush's speech makes only passing reference to health care.

Also left undone is a supplemental spending bill, which includes money for continued hurricane relief, that awaits action on Capitol Hill when Congress returns from its August recess.

http://www.nola.com/news/index.ssf/2008/08/bush_to_make_13th_postkatrina.html

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Vets deserve top-notch health care

The Times-Picayune | 08.20.08

Claude Brickell

Re: "VA brass keep options open on site of hospital," Page 1, Aug. 16.

Residents of the neighborhood on the edge of the Central Business District who stand to lose their homes to a new VA Medical Center have a right to be unhappy.

However, as veteran and a person new to New Orleans, I have experienced VA medical centers in Los Angeles and Little Rock, Ark., both of which benefit from adjacent university medical centers. I can testify to the overwhelmingly high level of care veterans receive there.

The senior doctors are the foremost in the country, and the new interns are bright, enthusiastic and extremely well-trained. New Orleans veterans deserve the same.

The American public for the most part takes our military service for granted. Less than 1 percent of us are willing to put our lives on the line to ensure the rest of Americans live in a free and just society. Is it too much to ask that a few residents of this city relocate, with due compensation, to ensure New Orleans veterans receive the expert care they have earned?

One solution might be for the city to move the existing historical homes. This could give the displaced residents a much improved location.

Claude Brickell

New Orleans

<http://www.nola.com/news/t-p/letterstoeditor/index.ssf?/base/news-12/1219209786111820.xml&coll=1>

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Latino named new police sergeant at Bogalusa hospital

The Daily News | 08.18.08

By Jacob Brooks

The LSU Bogalusa Medical Center has a new police sergeant.

Robert E. Latino, a former assistant chief with the Bogalusa Police Department will now provide security for LSU BMC's main campus on Plaza Drive, as well as the outpatient clinic on Memphis Street, the Thomas clinic on state Highway 438 and the eye and pediatric clinic on Willis Avenue and the Family Practice Unit on Avenue F.

LSU BMC CEO Kurt Scott announced the Latino's new position last week.

Latino served with BPD for 28 years and four years with Washington Parish Sheriff's Office.

"He served in the U.S. Navy for four years and is married to the former Linda Owens and they have three grown children, Allen Kellar, Niki Watson, and Lindsey Mitchell, plus eight grandchildren," according a statement from LSU BMC.

Latino is also associated with several local organizations and most recently was chairman of the American Legion's annual Independence Day parade in Bogalusa.

<http://www.gobogalusa.com/articles/2008/08/18/news/doc48a9e41b53d08430644574.txt>

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Bogalusa woman to begin costly globulin treatment

The Daily News | 08.18.08

BY MARCELLE HANEMANN

A woman who worked for more than three decades at the Bogalusa Medical Center is sick now herself, and she could use some help from the community she served as long as she was able.

Diane Stewart, 57, a former respiratory therapist and department head at the hospital, suffers from myasthenia gravis, lupis and scleroderma. Since at least 1991 her life has been a series of maladies, surgeries and other hospitalizations.

Stewart has had Legionnaire's Disease, a brain aneurism, double pneumonia, two collapsed lungs and an unknown respiratory problem that hospitalized and almost killed her last year. She has eye, ear and leg problems. Her maladies are too numerous to list. Even Stewart has trouble remembering them all.

When she first started getting sick, she would go back to work between stays in the hospital.

"I remember one time I was charting (patients) with oxygen on myself," she said.

Stewart said she enjoyed her work, but became too ill to continue.

"I'm a person who pays my bills," she said. "I worked all my life for the insurance. I worked all my life just to get sick like this."

Stewart "finally got on disability" in 2005, after more than a decade of medical problems.

"I never really wanted to, but I had to," she said. "Then when I got disabled, I didn't have Medicare. I got that last September."

Now Stewart said she needs nasal reconstruction surgery. But she needs Intravenous Immune Globulin (IVIG) treatment first.

"I've been putting this off," said Stewart. "I wasn't going to have it. It can cause blood clots. But my doctor in Baton Rouge said, 'You can't have surgery until you get this done or you will die.' I'm scared to death."

The procedure, which introduces donor blood serum antibodies, is also costly, and Medicare doesn't cover everything, she said.

"It costs more than \$10,000 per (IV)," said Stewart. "I'm told it will take three to five bags to start, and that's just the medicine."

She hopes that the community will help her out. She started the treatment Friday.

An account has been set up in her name at Capital One bank. For additional information, call 732-3633.

<http://www.gobogalusa.com/articles/2008/08/18/news/doc48a9e3b620081324577853.txt>

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EDITORIAL: Rescue us from FEMA The Times-Picayune | 08.20.08

The Federal Emergency Management Agency is supposed to help communities deal with disaster, but it seems bent on making recovery more difficult for greater New Orleans and other coastal communities.

Local governments, schools or hospitals that got aid after Hurricane Katrina or other storms will get substantially less help from the agency in a future disaster, according to a May 29 FEMA memo.

If FEMA paid an insurance deductible in the past, it will deduct that amount from disaster aid in the future. Given the exorbitant deductibles post-Katrina, the burden eventually could be too much for some institutions to survive.

To make matters worse, FEMA didn't discuss the policy or its ramifications beforehand and didn't announce it publicly. So, in the midst of hurricane season, this community and hundreds of others from Texas to Maine find themselves more vulnerable than they should be.

That is shameful, and President Bush ought to put a halt to the policy.

FEMA, which took the same stance last summer before revoking the policy, says it is simply trying to ensure that federal taxpayers are protected from multiple claims. That sounds reasonable, but the effects could be disastrous for coastal communities.

In the post-Katrina insurance market, local governments and nonprofits are facing dramatic increases in deductibles, which could mean that in another disaster they would have to pay for tens of millions of dollars worth of damage before being eligible for FEMA aid.

The rule, FEMA says, is not new. It's merely a reiteration of a longstanding policy, agency officials say.

That is difficult to swallow, though. FEMA hadn't described its policy that way in the past. "We probably weren't as articulate in explaining this in previous versions of the fact sheet," an agency spokesman said last week.

Articulate? FEMA didn't bother to try to explain the policy at all. The agency didn't hold public discussions and didn't immediately post the memo on its own Web site.

How were groups that will be affected by the policy supposed to know that it existed? When a hurricane hit, and they started trying to get recovery aid?

If allowed to stand, FEMA's deductible policy will have serious implications not only in this region, but across the nation. After Tropical Storm Fay this week, communities that were damaged by a previous storm could find themselves in a financial bind under this policy.

Applying the policy in New Orleans would be especially offensive since the vast majority of the damage here was caused by the failure of federally built levees during Katrina.

President Bush describes New Orleans as "one of America's most beloved cities" in remarks prepared for his visit here today. "Together, we are working to make sure that New Orleans comes back -- even stronger, safer and more vibrant than it was before the storm."

Those are heart-warming sentiments, and the president has demonstrated his sincerity. He can help again by rescuing us from FEMA.

<http://www.nola.com/news/t-p/editorials/index.ssf?/base/news-5/1219209662111820.xml&coll=1>

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Stem cell advance may help transfusion supplies

The Times-Picayune | 08.19.08

By MALCOLM RITTER

The Associated Press

NEW YORK (AP) — Scientists say they've found an efficient way to make red blood cells from human embryonic stem cells, a possible step toward making transfusion supplies in the laboratory. The promise of a virtually limitless supply is tantalizing because of blood donor shortages and disappointments in creating blood substitutes.

Red blood cells are a key component of blood because they carry oxygen throughout the body.

Experts called the new work an advance, but cautioned that major questions had yet to be answered.

The research, published online Tuesday by the journal *Blood*, was reported by scientists at Advanced Cell Technology in Worcester, Mass., the University of Illinois at Chicago and the Mayo Clinic in Rochester, Minn.

The researchers said the cells they made behaved like natural red blood cells in lab tests, and that their process could be used in large-scale production. The results suggest that embryonic stem cells could someday supply type O-negative "universal donor" red cells for transfusion, they wrote.

Mohandas Narla, director of the Lindsley F. Kimball Research Institute at the New York Blood Center, called the results "a very good start."

Now it will be important to show that the complex lab process really can pump out red cells on a large scale, and that the cells will survive long enough in the human body to be useful, he said. Natural red cells circulate for an average of 120 days.

<http://www.nola.com/newsflash/index.ssf?/base/national-9/1219171145311190.xml&storylist=health>

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Study: Adult obesity climbs in 37 states
AHA News | 08.19.08

Adult obesity rates increased in 37 states last year, according to a report released today by Trust for America's Health and the Robert Wood Johnson Foundation. More than one in four adults were obese in 28 states, up from 19 states in 2006, based on a three-year average of data from the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance Survey.

The report calls for a national strategy to combat obesity that includes investing in community-based disease-prevention programs, encouraging workplace wellness programs, and requiring insurers to cover obesity-prevention services.

"We must work together, governments, schools and communities, to improve nutrition and increase physical activity for all ages," said RWJF President and CEO Risa Lavizzo-Mourey, M.D.

"We must ensure that strong policies are implemented and enforced in every state, not only to help reverse existing obesity rates, but to prevent obesity among our nation's children – and generations to come."

http://www.ahanews.com/ahanews_app/jsp/display.jsp?dcrpath=AHANEWS/AHANewsNowArticle/data/ann_080819_obesity&domain=AHANEWS

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Hospital death rates unveiled

USA TODAY | 08.20.08

By Steve Sternberg and Anthony DeBarros, USA TODAY



By Bradley C. Bower for USA TODAY

Physician Nainesh Patel observes the status of a patient's arteries and heart on a computer screen at Lehigh Valley Hospital in Allentown, Pa. It's one of the top hospitals in the country, according to a new government analysis obtained by USA TODAY.

Motorists heading through the Lehigh Valley from Allentown, Pa., earlier this year passed two giant billboards proclaiming: "Fast Heart Attack Care Saved My Husband's Life."

What the billboards didn't say was just how fast. It took 24 minutes for Richard Silverman's doctors at Lehigh Valley Hospital to clear a 100% blockage from his heart's most vital artery. That's a third of the 90-minute goal that hospitals strive for.

"Maybe five minutes more and I'd be gone," Silverman, 63, co-owner of Pro-dent, a dental laboratory in Allentown, says his doctor told him.

Doctors at Lehigh Valley are proud of their speed. It's one reason the hospital boasts the lowest heart attack death rate in the country, 11.6%, in a new government analysis obtained by USA TODAY. Among those at the other end of the spectrum is Virginia's Danville Regional Medical Center with death rates for heart attack of 19.6% and for heart failure of 15.5%.

Until today, hospital death rates were closely guarded secrets, discussed in board rooms but beyond the reach of patients whose lives are on the line. That changed this morning when USA TODAY posted on its website the government's best estimates of heart attack, heart failure and pneumonia death rates for every U.S. hospital for two years.

Now anyone with access to a computer can directly compare a local hospital with the one across town to see how it stacks up against the biggest medical institutions nationwide.

Death rates from heart attack, heart failure and pneumonia are widely viewed as yardsticks of a hospital's overall performance.

"We're in an era of change at last," says Donald Berwick, president and CEO of the Institute for Healthcare Improvement, a non-profit in Cambridge, Mass., that works with hospitals to improve care and eliminate errors.

Compare hospitals

Last year, the U.S. Centers for Medicare and Medicaid Services (CMS) released a broad comparison of death rates for heart attacks and heart failure, noting how hospitals compared with the national average — better, worse or no different — without releasing the death rates themselves.

This year the agency decided to disclose them to consumers.

The agency shared the information in advance with USA TODAY to reach the widest possible audience. The agency also posted its new mortality estimates on a government website (hospitalcompare.hhs.gov), along with more than two dozen other measures of how well hospitals meet patients' needs.

Among them are statistics on what percentage of a hospital's patients get appropriate care for a variety of ailments, including childhood asthma, and 10 measures of patient satisfaction with the hospital experience.

All three types of measurements give hospitals ways to assess — and improve — their quality of care, but many health officials regard the number of patients who die in the hospital or soon after discharge as the ultimate measure of performance.

"That's why we think this is so meaningful," says Barry Straube, the chief medical officer of CMS.

Knowing a hospital's death rates also gives consumers more power to influence the quality of their medical care, says Lisa Iezzoni, associate director of the Massachusetts General Hospital Institute for Health Policy.

"What the mortality rate does is give you an entree to talk to your doctor and say, 'Look, is this hospital stay going to kill me?'"

That's not an easy question to answer with any certainty.

By trying, officials knew they were courting trouble with the hospital industry, Iezzoni says. An earlier effort by Medicare to report on hospital death rates faltered in the early '90s.

The agency wilted under relentless criticism that its so-called death list didn't give adequate weight to a hospital's mix of patients, including how sick, poor and old they were.

This time, the architects of the new analysis took a different approach. They tallied death rates for common life-threatening conditions, not the hospitals' overall mortality rates. And they chose a strict statistical formula that allows them to say with 95% confidence that a hospital's death rates fall within a certain range.

For Lehigh Valley, the range was 9.3% to 14.4%, with 11.6% representing the best estimate of the heart attack death rate.

But there's a rub, experts say. Using this method of analysis, only a handful of hospitals stand out as better or worse than the national average.

"There's great conservatism in calling people better or worse," says Yale cardiologist Harlan Krumholz, who helped develop the approach, adding that Medicare "got burned in the past."

Leah Binder, CEO of Leapfrog, a consortium of Intel, Boeing, Marriott and other corporations aiming to lower health costs to their employees by improving the quality of care, says employers want much more information than what the government is willing to provide.

"The problem with the CMS data is that most hospitals look average, which isn't what employers want. What they want is to compare hospitals." She says Leapfrog hopes to have its own rating system by this fall.

Berwick, of the institute, has studied the "death list" controversy. He says all the politics around measurement add up to an effort to protect hospitals against false alarms.

"It's protect the hospital or protect the patient," he says. "You can't have it both ways."

The new formula, developed by teams led by Krumholz and Harvard's Sharon-Lise Normand, captures all deaths among 35 million Medicare beneficiaries that occurred within 30 days of the patients' hospital admission.

They also factored in the hospital's patient mix and how many deaths might be expected in a hospital with that population. By tracking deaths from all causes, Krumholz says, the agency was less likely to miss a death related to hospital quality.

Including deaths that occurred within 30 days after admission made it tougher for a hospital to game the system by shipping risky cases somewhere else.

John Rumsfeld of the Denver VA Medical Center helped evaluate the approach for the non-profit National Quality Forum. He says the method makes it hard for hospitals to complain they've been misjudged.

"When your numbers aren't what you like them to be, it's not because you didn't have the same patients as the hospital across the street," Rumsfeld says. "It's because you didn't do as well as you could with the hand you were dealt."

With all its imperfections, Berwick says it is a useful tool.

"This is turning the lights on for providers of care, as well," he says. "Doctors and hospitals can't decide to do better unless they know how they're doing."

Teamwork

For the doctors at Lehigh Valley, the new analysis confirms what virtually everyone knew. "We have a culture of excellence," says Michael Rossi, chief of cardiology.

The hospital decided to treat heart attack patients by clearing their arteries with a balloon long before it became the gold standard. The hospital's chief quality officer, Anthony Ardire, says he routinely briefs board members on infection rates, pressure ulcers and scores of other benchmarks of patient care.

"If we fall back a bit, or if we're not making progress," Ardire says, "they want to know what we're going to do about it."

The key to the hospital's success is teamwork, a willingness to accept criticism and attention to every detail, he says. "There's no one thing that determines whether you save a life."

Consider the Silverman case. Just a day earlier, the hospital had given paramedics the power to diagnose heart attacks in the ambulance using an electrocardiogram. Doctors in the emergency room confirmed the diagnosis and rushed Silverman upstairs for angioplasty. What they hadn't counted on was the wait at the elevator doors.

"We learned that if we lock down our elevators when we know a patient's coming, we can save three or four minutes," says Nainesh Patel, the doctor who cleared Silverman's artery.

At Cedars-Sinai Medical Center in Los Angeles, patients with pneumonia are similarly fast-tracked to treatment. A triage nurse sends those with symptoms for a chest X-ray without waiting for a doctor. Those who are positive are quickly placed on antibiotics, says James Loftus, co-chair of emergency medical care. The result is a death rate of 7.5%, one of the lowest in the USA.

Adapting

Sometimes even hospitals known for their excellence discover problems, including Baylor Health Care system, winner of this year's National Quality Health Care Award.

When last summer's CMS report came out, one of the 11 hospitals in the Dallas-based system, Baylor All-Saints Medical Center in Fort Worth, was found to have a heart failure death rate of 14.6%, higher than the 11.1% average.

What leapt out of a review of the patients' records was that just 10 of 31 deaths occurred in the hospital, suggesting that some deaths were due to follow-up care by local doctors and nursing homes, says Paul Convery, Baylor's chief medical officer. "This was a signal that we have to be responsible for patients after they've left our halls."

Finally, there are 115 hospitals, such as Danville (Va.) Regional, that have been singled out for having higher death rates than the national average. Danville last year ranked higher than the national average in both heart attack and heart failure. In the new report, Danville has improved. Although its heart attack death rate is still high, it now falls within the average range.

Michael Moore, the hospital's chief of medical education, says the numbers don't account for the poverty and lack of education pervasive in southern Virginia. Patients with heart attacks don't seek care quickly enough, he says, while those with heart failure don't follow doctors' orders.

"We take these reports very seriously," he says. "We continue to work to try to improve."

But Ardire of Lehigh Valley says the challenge is to provide top-notch care no matter who your patients are. "We have those patients here, too," he says.

http://www.usatoday.com/news/health/2008-08-20-hospital-death-rates_N.htm?loc=interstitialskip

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What's in Their Wallets?

Gambit Weekly | 08.20.08

By David Winkler-Schmit

Five months without getting paid was all In This Together (ITT), a local HIV/AIDS agency, could afford. Michael Hickerson, ITT's executive director, and his partner, Dave Munroe, ITT's board chair, say they were keeping ITT afloat and serving 225 clients by taking out a cash advance on a personal credit card. After spending \$120,000 for services since March, the two men decided in late July that ITT could no longer provide HIV/AIDS services to its clients.

"At this point, we're not fighting to get these programs back," Hickerson says. "Our clients have been transitioned; our staff is gone. What we want is the system, the process, corrected."

Local HIV/AIDS agencies say they take the same risk every year. Even though the fiscal year for funding the services they provide begins in March, it takes at least three months for City Hall to execute contracts and begin reimbursing them. Meanwhile, the agencies continue to offer a variety of critical services — medication, primary medical care, food delivery, transportation and housing assistance — without a guarantee of reimbursement from the city.

It's now August, and the city still hasn't completed the contracting process. ITT has closed its doors, and another agency says it is in "critical condition."

Fran Lawless, director of the Mayor's Office of Health Policy and AIDS Funding (MOHP), which disperses the federal funds annually, says her hands are tied. Because of the city's new contract review policy, Lawless says, all professional contracts take longer to execute. "I couldn't give [Hickerson] his money any quicker," she adds. "The mayor didn't sign those [award] letters until June 23."

The award letter to which Lawless refers does not mean ITT or similar programs will get city contracts (and funds). The city's chief administrative officer, Brenda Hatfield, followed up the June 23 award announcement with another letter stating that "the selection only prompts a negotiation and does not guarantee a city contract." The letter also warns ITT and eight other agencies, "You should begin no work until all parties execute the contract."

Following Hatfield's advice would have forced all the agencies to stop providing services as of February 29 — five months ago. They didn't. Instead, more than 4,000 people living with HIV/AIDS in the New Orleans area continued to get assistance. But how much longer can the agencies survive without funding?

The federal government allots funds annually for HIV/AIDS care and services for people in urban areas. The U.S. Department of Health and Human Services' Health Resources and Administration doles out the money through grant awards, which are given to eligible metropolitan areas that have the highest number of people living with HIV/AIDS. New Orleans, which has 4,144 people living with HIV/AIDS, is one of the areas funded by the Part A Ryan White HIV/AIDS Program, named in honor of the Indiana teenager whose struggle against AIDS and the discrimination surrounding it helped increase public education and awareness of HIV and AIDS.

On March 11, Health and Human Services Secretary Michael Leavitt announced \$550 million in federal grants for Part A of the Ryan White program, with New Orleans receiving just over \$7 million for primary care and support services. By that time, however, the city was just beginning to decide which agencies it would fund.

On January 31, Lawless' office solicited proposals from local providers. The deadline was February 21, a week before the Part A Ryan White 2008 fiscal year began. Under the city's new contract review policy, a selection review panel was to evaluate the proposals and choose recipient programs. In previous years, MOHP would review the proposals. Now, says Lawless, a new executive order slows down the process of awarding service contracts.

"The media wants transparency, City Council wants transparency, so you take it out of the hands of the department and you put it in the hands of an objective, neutral group of people to review the proposals,"

Lawless says. "Would you have time to review, say, 67 proposals that are 250-300 pages in length? It's hard to get people to do that kind of review."

According to Mayor's Executive Order CRN 08-01, which went into effect on April 4, all proposed professional service contracts are evaluated by a selection review panel that includes the city's CAO or deputy CAO, the requesting department's director, the Disadvantaged Business Enterprise Program Compliance Officer, and a community member.

While the city reviewed the proposals, local agencies such as Belle Reve, which offers assisted living for persons with AIDS, kept its operations going by borrowing money. Belle Reve's executive director, Vicki Weeks, says arranging for bank loans is something her organization has grown accustomed to, although borrowing money drives up operating costs.

"What it does — and it's not just that grant, but it's HOPWA (Housing Opportunities for People With AIDS), too, which started in January — it makes all organizations survive off a credit line," Weeks says. "They pay interest on the credit and have to fundraise to pay the interest because the interest can't be paid by a federal grant."

The city's Office of Recovery, Development and Administration oversees the HOPWA grants. HOPWA funding covers the calendar year, but, as is the case with the Ryan White funds, the city doesn't release the money until late in the year.

"Last year we got it in November," says Weeks. "So from January to November, we had to survive on a credit line — and that's a lot of money."

Weeks says that getting a line of credit is much harder for smaller agencies such as ITT. Belle Reve uses its buildings as collateral for loans, but ITT leases office space and doesn't own a major asset that can be used to secure a loan. So, to keep ITT open, Munroe and Hickerson did some fundraising, solicited donations and received money from other sources. When those resources couldn't cover all of ITT's bills, the couple took out a \$25,000 cash advance on their credit card.

It's because of people like Trenika Williams that Munroe and Hickerson were willing to put themselves in a financial bind. Williams learned she was HIV positive and pregnant in July 2007. At first, the 28-year-old single mother of two felt she had nowhere to turn. She tried contacting other agencies, but her phone calls weren't returned. She eventually registered with the NO/AIDS Task Force, but she felt she needed additional help.

"I needed someone to take me by the hand because I didn't know what I was doing," Williams says.

That someone was Hickerson. After hearing about ITT from a friend, Williams visited the agency's offices in February and was immediately taken with Hickerson's resourcefulness.

"If he couldn't do it himself, he sent me somewhere that could," Williams says. Williams transferred over to ITT, and until the agency closed, it gave Williams rental and utilities assistance. Williams now gets no financial help — and won't until she sees her new case manager at Leading Edge, an HIV outpatient clinic in Kenner. She says she still considers Hickerson a lifeline. "I could still call him because he gave me his personal phone number, and he told me to call him if I ever needed help."

For Hickerson, who is HIV positive, ITT is a reflection of himself. "I am this. I am these clients and that's why we provide these services," he says. Hickerson, a social worker and native New Orleanian, grew up poor and says he opened ITT in 2005 because he wanted to create an agency that would be culturally sensitive to the needs of economically disadvantaged African Americans living with HIV/AIDS. He says that 75 to 80 percent of his clients were African Americans, as was 90 percent of ITT's staff.

Hickerson adds that some of his clients were homeless and many have high medical and social needs. ITT's location on Canal Street was easily accessible to clients, and the agency could offer housing assistance through its HOPWA grant as well as medical case management services through Ryan White funds. For the fiscal year 2007-2008, ITT signed a contract with the city to provide \$213,516 worth of medical case management services. Hickerson says he wasn't happy with how long it took the city to execute the contract — ITT received its first Ryan White fund reimbursement in late September, nearly

seven months into its fiscal year. However, he says, ITT was bringing in clients that might have chosen to ignore their disease rather than go to other agencies, where they felt uncomfortable or misunderstood. "People have choices, and they chose [the ITT agency]," Hickerson says.

Hickerson and Munroe applied for \$304,615 in Ryan White funds for 2008-2009. Because the city's application guidelines now require agencies to offer medical case management, non-medical management, transportation and outreach services, ITT had to add outreach, non-medical case management and transportation to its menu of programs.

Hickerson and Munroe heard nothing from the city until June 23, when a letter arrived stating they had been awarded a total of \$149,863 in Ryan White funds. According to the letter, the funds were to be spent on non-medical case management (\$125,907) and outreach (\$23,956). They received nothing for medical case management.

The federal government instituted new rules and definitions this year regarding the distinction between medical case management and non-medical case management. Lawless says that agencies must interact with a patient's primary care provider to qualify for medical case management funds. She claims that ITT wasn't doing that. Munroe counters that ITT did try to contact clients' doctors, but because Lawless' office hasn't insisted that primary care providers interface with medical case manager providers like ITT, the required interaction has become a problem for many agencies.

"They're all struggling to establish lines of communication with these primary medical entities," Munroe says.

By that time, ITT's continued existence became a matter of time and money. "We didn't get enough money, and it didn't come soon enough," says Munroe.

N'R Peace is another HIV/AIDS agency that caters primarily to African Americans. Demitre Blutchter, N'R Peace's executive director, says the agency focuses on that population because, although African Americans account for only 12 percent of the nation's population, more than 53 percent of new HIV cases are in the African-American community. Blutchter says the agency tries to locate and serve people who have been "lost to care," unaware of services available and how to get them. Some of his clients have been recently released from jail and are trying to return to care.

Blutchter's agency works with 145 clients but is running out of money. Blutchter isn't sure how much longer the agency can survive.

"Being a small, minority agency, it's been tough," Blutchter says. "I have depleted my line of credit and all small fundraising projects."

In the city's specifications for Ryan White funding, it encourages minority agencies like Blutchter's and Hickerson's to apply. Lawless cautions, however, that agencies should still have at least a year's worth of reserve funds for operating costs. "They really should, to operate," Lawless says. "Anybody would have a hard time, but realistically, within six months, we usually have the contracts executed, which is fairly quick considering other city contracts."

That's not how the federal government views it. David Bowman, a spokesperson for HRSA, writes in an email response that "the local award process must be done within a reasonable amount of time. The expectation is 120 days; however we have no control over delays at the local level." Later in the same email, he adds that the HRSA project officer has been in contact with the city about the delays.

Ralph Brisueno is the director of the Ryan White program for the City of Baltimore. Brisueno reports that his department is already planning for the next fiscal year of Ryan White funds. He says funding is a competitive process and the request for proposals goes out in November, so that as soon as the federal government announces funding totals, the award letters, which establish funding, are delivered to agencies. Brisueno says that Baltimore, like New Orleans, operates on a reimbursement system — work is completed before payment — so agencies received the first Ryan White-funded payment in April, one month into the fiscal year. When Brisueno was informed that New Orleans agencies still aren't under contract and haven't yet been paid for services, he was blunt in his assessment.

"That's a tragic situation, because it puts everyone in a bind."

Gambit Weekly contacted Part A Ryan White programs in Fort Lauderdale, Fla.; Norfolk, Va., and Miami. All reported that contracts were signed and are being funded.

Noel Twilbeck, executive director of NO/AIDS Task Force, says the funding delays also affect larger agencies like his because it creates a cash-flow burden: agencies have to continue paying bills for services while waiting for the city to reimburse them. Twilbeck knows the process could be better and he mentions other Ryan White cities, New York and Boston. As for the award letter not actually guaranteeing a contract, Twilbeck says that it's something that agencies are willing to risk because it means people continue to get the services they need.

"If we didn't, we couldn't offer primary care, case management, delivered meals, mental health, etc.," Twilbeck explains. "We would have to stop on February 28 (normally, the last day in the fiscal year). We do take a chance every year even with the award letter."

Lawless says she finds it "interesting" that Blutchter and Hickerson would tell a reporter about their financial difficulties, but they didn't inform her office. She suggests that the two agencies' financial problems might be of their own making and not because the city hasn't yet funded them.

"I can't tell an agency how to handle their finances," Lawless says. "But we have 12 other agencies that are in operation and if [Hickerson] can't sustain the needs of his clients, they can go elsewhere."

So why haven't other HIV/AIDS agencies publicly complained about the city's failure to pay out monies in a timely fashion? The answer could be a simple one: fear. Hickerson and Munroe say that the other agencies are afraid that if they speak out, they may be denied a contract, or given less. They point out that last year they alerted the National Minority AIDS Council about the city's inefficient funding process. The Washington D.C.-based council sent a letter to Mayor Nagin and then flew down to discuss the situation with city officials. Ravinia Cozier, NMAC's director of public policy and government relations, says that city officials didn't seem to understand the urgency of the crisis. After the meeting, NMAC sent a second letter outlying its concerns and recommendations.

The city never responded to the second letter, says Cozier.

Cozier adds that culturally sensitive minority agencies such as ITT play a vital role in serving those living with HIV/AIDS.

"People need to feel confident that the people who serve them will understand not just HIV/AIDS but the many complicated obstacles in their life, from poverty, education, housing, jobs, etc., and how this disease impacts all of those issues and others."

Although Lawless categorically denies Hickerson and Munroe's claims, there could be some truth to the accusation. An anonymous source from another local HIV/AIDS agency contacted Gambit Weekly regarding why ITT didn't receive adequate funding. The source didn't want to be identified for fear that MOHP would cut off the source's own city funding. The source was quite clear, however, on the question of whom ITT was serving before it ceased HIV/AIDS services and who was responsible for the closure.

"These are the poorest people of the poor. [The city] literally drove Michael out of business. He was working with people NO/AIDS didn't know how to work with."

http://www.bestofneworleans.com/dispatch/2008-08-19/cover_story.php

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Drug Makers' Push Leads to Cancer Vaccines' Fast Rise

The New York Times | 08.19.08

By ELISABETH ROSENTHAL



Caleb Kenna for The New York Times

A Merck advertisement for Gardasil, a cancer vaccine.

In two years, cervical cancer has gone from obscure killer confined mostly to poor nations to the West's disease of the moment.

Tens of millions of girls and young women have been vaccinated against the disease in the United States and Europe in the two years since two vaccines were given government approval in many countries and, often, recommended for universal use among females ages 11 to 26.

One of the vaccines, Gardasil, from Merck, is made available to the poorest girls in the country, up to age 18, at a potential cost to the United States government of more than \$1 billion; proposals to mandate the vaccine for girls in middle schools have been offered in 24 states, and one will take effect in Virginia this fall. Even the normally stingy British National Health Service will start giving the other vaccine — Cervarix, from GlaxoSmithKline — to all 12-year-old girls at school this September.

The lightning-fast transition from newly minted vaccine to must-have injection in the United States and Europe represents a triumph of what the manufacturers call education and their critics call marketing. The vaccines, which offer some protection against infection from sexually transmitted viruses, are far more expensive than earlier vaccines against other diseases — Gardasil's list price is \$360 for the three-dose series, and the total cost is typically \$400 to nearly \$1,000 with markup and office visits (and often only partially covered by health insurance).

Award-winning advertising has promoted the vaccines. Before the film "Sex and the City," some moviegoers in the United States saw ads for Gardasil. On YouTube and in advertisements on popular shows like "Law and Order," a multiethnic cast of young professionals urges girls to become "one less statistic" by getting vaccinated.

The vaccine makers have also brought attention to cervical cancer by providing money for activities by patients' and women's groups, doctors and medical experts, lobbyists and political organizations interested in the disease, sometimes in ways that skirt disclosure requirements or obscure the companies' involvement.

Even critics of the marketing efforts recognize the benefits of the vaccines. Girls who get the shots are less likely to have Pap tests with worrisome results that would lead to further treatment, saving themselves anxiety and discomfort and, in those cases, saving money. When it occurs, cervical cancer is a dreadful disease; genital warts, partly prevented by the Merck vaccine, can be a painful nuisance. But some experts worry about the consequences of the rapid rollout of the new vaccines without more medical evidence about how best to deploy them. They say that because of the aggressive marketing, even parents of girls who are far from being sexually active may feel pressured into giving them a vaccine that is not yet needed and whose long-term impact is still unclear. Legislative efforts to require girls to have the vaccine only add to the pressure.

In the United States, hundreds of doctors have been recruited and trained to give talks about Gardasil — \$4,500 for a lecture — and some have made hundreds of thousands of dollars. Politicians have been lobbied and invited to receptions urging them to legislate against a global killer. And former state officials have been recruited to lobby their former colleagues.

"There was incredible pressure from industry and politics," said Dr. Jon Abramson, a professor of pediatrics at Wake Forest University who was chairman of the committee of the Centers for Disease Control and Prevention that recommended the vaccine for all girls once they reached 11 or 12.

"This big push is making people crazy — thinking they're bad moms if they don't get their kids vaccinated," said Dr. Abby Lippman, a professor at McGill University in Montreal and policy director of the Canadian Women's Health Network. Canada will spend \$300 million on a cervical cancer vaccine program.

Merck's vaccine was studied in clinical trials for five years, and Glaxo's for nearly six and a half, so it is not clear how long the protection will last. Some data from the clinical trials indicate immune molecules may wane after three to five years. If a 12-year-old is vaccinated, will she still be protected in college, when her risk of infection is higher? Or will a booster vaccine be necessary?

Some experts are concerned about possible side effects that become apparent only after a vaccine has been more widely tested over longer periods.

And why the sudden alarm in developed countries about cervical cancer, some experts ask. A major killer in the developing world, particularly Africa, where the vaccines are too expensive for use, cervical cancer is classified as very rare in the West because it is almost always preventable through regular Pap smears, which detect precancerous cells early enough for effective treatment. Indeed, because the vaccines prevent only 70 percent of cervical cancers, Pap smear screening must continue anyway.

"Merck lobbied every opinion leader, women's group, medical society, politicians, and went directly to the people — it created a sense of panic that says you have to have this vaccine now," said Dr. Diane Harper, a professor of medicine at Dartmouth Medical School. Dr. Harper was a principal investigator on the clinical trials of both Gardasil and Cervarix, and she spent 2006-7 on sabbatical at the World Health Organization developing plans for cervical cancer vaccine programs around the world.

"Because Merck was so aggressive, it went too fast," Dr. Harper said. "I would have liked to see it go much slower."

In receiving expedited consideration from the Food and Drug Administration, Gardasil took six months from application to approval and was recommended by the C.D.C. weeks later for universal use among girls. Most vaccines take three years to get that sort of endorsement, Dr. Harper said, and then 5 to 10 more for universal acceptance.

"In that time, you learn a lot about safety and side effects and how to use it," Dr. Harper said. "Those getting it early should be the ones who really want it and willing to accept the risk."

Dr. Richard Haupt, medical director at Merck, said the vaccine had not been rushed into use, saying that five years in clinical trials was normal before applying for licensing. He said Merck educated physicians, politicians and the public about the new vaccine to “accelerate and facilitate access.”

Spokesmen for Merck and Glaxo say all indications are that their vaccines are safe and effective, and there is no evidence that a booster shot will be needed. A Glaxo spokeswoman, Sarah Alspach, said its formulation produces a “stronger and longer-lasting immune response” than conventional vaccines.

“You can only study a vaccine for so long before you license and use it in a population where it has enormous value,” said Dr. Haupt at Merck. “Our hope and belief is that this is a remarkable vaccine that will have huge impact on women.”

But with their high price, the vaccines are straining national and state health budgets as well as family pocketbooks. These were the first vaccines approved for universal use in any age group that clearly cost the health system money rather than saved it, in contrast to less expensive shots, against measles and tetanus, for example, that pay for themselves by preventing costly diseases.

Health economists estimate that depending on how they are used, the two cervical cancer vaccines will cost society \$30,000 to \$70,000, or higher, for each year of life they save in developed countries — a cost commonly seen in treating people already suffering from deadly cancers. That number will be far higher if a booster is needed.

Looked at another way, countries that pay for the vaccines will have less money available for other health needs. “This kind of money could be better used to solve so many other problems in women’s health,” said Dr. Lippman at McGill. “Some of our provinces are running out of money to provide primary care. I’m not against vaccines, but in Canada and the U.S., women are not dying in the streets of cervical cancer.”

By contrast, if the vaccine were to become cheap enough to be used in the developing world, particularly Africa, it would revolutionize women’s health. Charities like the Global Alliance for Vaccine and Immunizations, backed by the Bill & Melinda Gates Foundation, are trying to devise a solution.

The vaccines offer partial protection against infection from human papillomavirus, or HPV, a common and generally benign sexually transmitted virus that can in rare cases cause cancer after years of silent infection. The Merck vaccine also prevents some genital warts that are caused by other strains of the virus.

In Britain, “this initiative was seen as a good use of resources that fits with the government’s health priorities and political priorities,” said Professor David Salisbury, who heads the Department of Health’s Vaccine and Immunization Committee.

But critics urge restraint. “There is no need to rush,” said Angela Raffle, a specialist in cervical cancer screening with the National Health Service in Britain, where 400 people die of the cancer each year. “If we do this quickly and badly, we could cause more deaths,” from side effects, for example, or from giving girls false security that they are protected for life and no longer need to be screened, Ms. Raffle said.

The Campaigns

Stephanie Levi decided to give her two daughters the vaccine in late 2006 after receiving a newsletter from their physician. “When you get a letter saying this is what you need to do to protect your girls, of course you do it,” she said, adding that she was curious because she had not realized cervical cancer was a problem.

That week, she noticed articles and advertisements for the vaccine. “I remember thinking I had better do this quickly,” said Ms. Levi who lived in New York then and now lives in Rome.

It is not hard to hear about Gardasil.

In television advertisements, a cast of hip people in their 20s — artists, writers and professionals — describe why they got the shots, in the language of liberation, such as, “I chose to get vaccinated

because my dreams don't include cervical cancer." The advertisements direct viewers to gardasil.com, which includes patients' stories, buddy icons and downloads for holding an event at sororities.

Girls of any age who have had one dose of the vaccine can ask for text-message "reminders" from Merck to get the next two shots. The offers come with another reminder: "I understand that the information I provide will be used by Merck or those working on behalf of Merck for market research purposes."

For such efforts, Merck last May swept the 2008 Pharmaceutical Advertising and Marketing Excellence awards, and Gardasil was named Brand of the Year by Pharma Executive Magazine.

The marketing helped make Gardasil one of Merck's best sellers, with a projected sales of \$1.4 billion to \$1.6 billion outside Europe this year, and more from sales in Europe, where Merck sells the vaccine through a joint venture with Sanofi Aventis.

Aggressive pharmaceutical advertising is nothing new, but the campaign was a revolution for a vaccine. Vaccines were traditionally the orphans of the pharmaceutical world because they were cheap and not particularly profitable. But the two for cervical cancer are the latest in a wave of high-priced vaccines that have come to market since 2001, opening a lucrative new field.

Co-opting Doctors and Nurses

Girls and their families are by no means the only marketing target.

In 2006, hundreds of doctors and nurses were signed up as unofficial spokesmen for Gardasil, trained by Merck, provided with a multimedia presentation and paid \$4,500 for each 50-minute talk, delivered over Merck-sponsored meals. Many were paid for attending Merck "advisory board" meetings to discuss the shots.

Merck said it provided assistance to speakers "to make sure they are providing accurate information in accordance with F.D.A.-approved labeling and to make sure dissemination of information is always appropriate," said Amy Rose, a company spokeswoman.

Promotion and marketing for Cervarix, Glaxo's version of the vaccine, has been far less visible, in part because it has not been approved yet for use in the United States, and because consumer advertising of medicines is prohibited in much of Europe. Outstanding data from final clinical trials will probably be submitted to American drug regulators early next year, the company said.

There has also been a proliferation of cervical cancer awareness conferences and campaigns, sponsored by a host of new or newly energized scientific and patient groups financed with the help of Merck and Glaxo. In some cases the financial support has been indirect, so patients are unaware that expert advice has been at last partly paid for by the vaccine makers.

Gregory A. Poland, a vaccine expert at the Mayo Clinic, was a nonvoting member on the C.D.C. panel that recommended Gardasil in 2006 and has publicly defended the panel's decision. Records show he received at least \$27,420 in expenses and consulting fees from Merck from 1999 to 2007. Both the C.D.C. and Dr. Michael Camilleri, chairman of the Mayo Clinic Conflict of Interest Review Board, speaking on Dr. Poland's behalf, said the payments complied with institutional requirements.

To encourage vaccination on campus, Merck provided the American College Health Association with an unrestricted grant to train its officers to speak about the new vaccine and to create kits to discuss cervical cancer and promote the vaccine for college health services. The association now recommends the shot for all female college-age students, even though many in that group already have HPV, rendering the vaccine less useful.

Dr. James Turner, president-elect of the association, said it accepted Merck's grant to undertake the campaign because "HPV is a very important health issue for college students," adding that his group was "a very small organization, and we don't have funds."

Small charities have also benefited from Merck's contributions.

At the second annual patient conference of the National Cervical Cancer Coalition, planned for Los Angeles this October, four of the seven scheduled speakers have received money for research or consulting from Merck, Glaxo or other companies involved in HPV screening or detection, though the conference organizers do not mention that. The coalition, which supports widespread use of the cervical cancer vaccines, is headed by a businessman, Alan Kaye, who owns a pathology lab that performs Pap smears and HPV tests, among other services. "We are a poor nonprofit, and I've been working on this issue for years," said Mr. Kaye, who hopes to receive grants from the drug makers to help pay for the conference.

Persuading the Governments

In country after country, Merck and Glaxo also appealed to politicians. Vaccines, unlike antibiotics, tend to be recommended or mandated by governments. "We support policy leaders and try to educate legislators," Dr. Haupt said.

In the United States, 41 states have passed or begun considering legislation on cervical cancer, according to the National Conference of State Legislatures, and 24 have considered proposals to mandate the vaccine for girls, generally in middle school.

Many bills, like ones passed in Colorado, New Jersey and New York, allocate more money for HPV and cervical cancer education or to promote the vaccine. Others, like proposals in Iowa and Louisiana, require insurers to cover it.

The only state to pass a bill requiring the vaccine for school entry is Virginia; it takes effect in October, after school begins, so will first apply in 2009.

Merck has a growing economic interest in Virginia. In December 2006, Merck announced it would invest \$57 million to expand its Elkton, Va., plant to make Gardasil, helped by a \$700,000 grant from a state economic development agency that is part of the executive branch. Two months later, Gov. Tim Kaine, who has been mentioned as a possible Democratic vice presidential candidate, signed legislation requiring Gardasil for schoolgirls. Four months after that, Merck pledged to invest \$193 million more in the plant to make drugs and vaccines, helped by a state grant of \$1.5 million.

Delacey Skinner, a spokeswoman for the governor, said the state's vaccination program included an unusually broad freedom to decline the shot. To exempt children from other vaccines, parents must provide a medical reason; for Gardasil, they do not. "It is a very easy step that we can take to prevent a sometimes deadly but certainly serious form of cancer," Ms. Skinner said.

"Without hesitation or question," she added, the decisions about the plant and about the mandate legislation "were completely separate."

But, as in many states where cervical cancer legislation has been considered, there have been ties between drug makers and members of government. In 2006, one of Merck's newly hired Virginia lobbyists was Sandra D. Bowen, who had spent years as Virginia's secretary of administration. And Bill Bolling, the state's lieutenant governor, became an outspoken participant in the "Ending Cervical Cancer in Our Lifetime" campaign, a program started in 2006 by the National Lieutenant Governors Association and financed largely by Merck and Glaxo.

"This is an important public health issue," said Randy Marcus, Mr. Bolling's spokesman.

In Texas, Merck hired Gov. Rick Perry's former chief of staff as a lobbyist, and contributed \$6,000 to the governor and \$38,000 to other legislators. Last February, Mr. Perry ordered that all schoolgirls be inoculated with Gardasil, a pronouncement that was overturned by the Texas Legislature, 181 to 3, a few months after the financial conflicts were revealed.

Early last year, Merck announced that it would no longer actively lobby for state mandates. But Dr. Haupt defended the initial impulse, saying that historically such school requirements had been a successful way to increase access to and financing for vaccines.

Other forms of lobbying continue: Merck and Glaxo have both paid into a program run by Cornerstone Government Affairs, a Washington firm, to lobby the C.D.C. and Congress for more federal money for vaccines.

In Britain, drug makers paid for breakfast meetings with politicians and visited the nurses and family practitioners who are the backbone of the National Health Service, urging them to offer the vaccine.

In Belgium, the health minister approved the vaccine before the country's health technology evaluation committee had finished deliberating.

Unanswered Questions

Many questions about the vaccines remain unanswered, including how long immunity will last. Even commercials for Gardasil say — in small print — that “the duration of protection has not been established.”

Dr. Harper said that in the data from Merck's clinical trials, which she helped conduct, the vaccine was no longer protective after just three years in some girls. “The immunity of Gardasil will not last — that is dangerous to assume,” she said.

She said she believed that at least one booster shot, and probably more, would be needed over a lifetime. Dr. Haupt of Merck said that the “durability of immunity” would ultimately be defined through widespread use of the vaccine, but that the company's research strongly suggested that immunity would be long lasting — far more than five years.

Other independent experts worry that eliminating the two cancer-causing HPV strains covered by Gardasil and Cervarix might allow the other cancer-causing strains of HPV to increase in frequency, reducing the vaccine's effect. But Dr. Haupt said such “theoretical possibilities” should not deter rapid distribution of an important vaccine. “We'll worry about whether boosters are needed down the road,” he said.

The question of side effects, however, has nagged the vaccine.

The Centers for Disease Control asks health care centers to report side effects through its Vaccine Adverse Events Reporting System; reporting is voluntary. There have been 9,749 reports, almost all from doctors and nurses, of patients experiencing adverse events after receiving the vaccine, the agency announced in a joint report with the Food and Drug Administration at the end of June. Ninety-four percent of them were not serious, ranging from arm pain to fainting, and 6 percent were classified as serious, including blood clots, paralysis and at least 20 deaths.

But 16 million doses of the drug have been distributed by Merck in the United States, and in a population so large, “by chance alone some serious adverse effects and deaths” will occur, the F.D.A. and C.D.C. said.

The agencies said there was no indication that the deaths or serious side effects were caused by the shot, concluding that “Gardasil continues to be safe and effective and its benefits continue to outweigh its risks.”

Both the agencies and Merck acknowledge that there does appear to be a high rate of fainting, so doctors are now advised to observe patients for 15 minutes after receiving a shot.

For some couples, the vaccine has raised agonizing questions over how to safeguard their children's health. Phillip and Barbara Tetlock, both professors at the University of California at Berkeley, are asking whether Gardasil shots that their daughter, Jenny, received last year contributed to her illness, an extremely rare form of progressive paralysis that has left her bed bound and needing assistance to breathe at age 14.

The Tetlocks, who are not pursuing legal action, are appealing to the C.D.C. and Merck for more data and searching for other girls with similar conditions through their blog (www.jenjensfamily.blogspot.com). “Her

parents are scientists — they know better than to assume Gardasil caused her disease,” said Terry Murray, a close friend speaking for the family. “But you have to explore the possibility.”

Dr. Harper said she believed the vaccine was generally safe. She vaccinated her own children. But with Gardasil’s use having grown so fast, she added, “you inevitably find adverse events that you wouldn’t have suspected.”

“The Tetlocks are right to ask these questions,” she added.

Dr. Haupt of Merck said that the company knew of the case but saw no “causal association.”

Worth the Cost?

Countries and consumers must decide whether it is worth preventing cervical cancer with a costly vaccine.

Cervical cancer is the second-leading cause of cancer death in women, with 500,000 new cases worldwide each year. But more than 90 percent of them are in developing countries, according to the World Health Organization; 274,000 women died of this cancer in 2006, nearly 95 percent in developing countries.

Where there are Pap smear programs, few women die of cervical cancer. In the United States, it is responsible for 12,000 new cases a year and 3,600 deaths, most in women who did not get Pap smears, said Laurie Markowitz, head of the HPV working group at the C.D.C. (Women with H.I.V. are predisposed to the cancer.)

Pap smears work by detecting abnormal cells that are cancer precursors and that can be destroyed using techniques like lasers and cryotherapy or, rarely, surgery. As with any screening test, and most vaccines, the process is not 100 percent effective, and a small number of women with precancerous cells escape detection with false negative tests, for example. But because the transformation from abnormal cell to cancer normally takes a decade, and frequent Pap smears are recommended, it has been a successful strategy — though the vaccine, used properly, might well prove a useful adjunct.

Indeed, cervical cancer does not even make the American Cancer Society’s list of 10 deadliest cancers. Among American women, it causes well under a 10th of the number of deaths caused by lung cancer or breast cancer.

Though classified as a sexually transmitted disease, HPV is nearly universal and generally benign. Eighty percent of people will contract it in their lifetime and most will clear it on their own.

Dr. Haupt of Merck said the vaccines’ price was worth it for the deaths prevented and the tests avoided. “Most of the old vaccines are undervalued,” he said.

Dr. Abramson said he thought his C.D.C. advisory committee did the right thing in recommending Gardasil. “Cervical cancer is a worthwhile disease to prevent in a country that has the resources,” he said. He believes it should be available to those who want it.

Still, he said he was shocked to hear of proposals to mandate the vaccine for students. “Are you really going to say a girl can’t start school because she hasn’t had this vaccine?” he said.

Meanwhile, the vaccines’ proponents are moving to the next frontier: older women and boys. Merck recently applied for approval to market the vaccine to women 26 to 45 and is conducting studies on vaccinating boys, who can get genital warts from HPV.

One rationale for inoculating boys is that entire populations should be vaccinated to achieve what is called herd immunity. But critics ask whether it is worth conducting a campaign on the scale of the one used against polio to eliminate a generally harmless virus.

Said Dr. Raffle, the British cervical cancer specialist: “Oh, dear. If we give it to boys, then all pretense of scientific worth and cost analysis goes out the window.”

Andrew Lehren contributed reporting.

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