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Evacuation creates health gray areas
The Times-Picayune | 09.17.08
Lolis Eric Elie

Two days after Hurricane Gustav passed, the inpatient kidney dialysis unit at Ochsner Medical Center was open and treating patients. The Fresenius Medical Care outpatient dialysis unit nearby was also up and running.

These are facts of which Dr. Will Gabbard, the medical director for both units, is proud.

His colleague Dr. Catherine Staffeld-Coit shares his pride, but offers a cautious caveat. Even though the two dialysis centers are well-prepared in the event of a storm, the only sensible thing for dialysis patients to do when a hurricane warning is sounded is to evacuate.

The recent experiences of these physicians exemplify the conflicted messages residents get in a storm-prone region. While citizens are strongly urged to leave town, local facilities also make preparations with the full knowledge that some won't leave.

--- Clean water, electricity ---

Dialysis is unique among medical treatments. The procedure cleanses the blood, much as kidneys would do, in the event that a patient's kidneys are not functioning properly.

"If someone's kidneys are not working at all, and they don't get dialyzed, we usually expect that they are not going to live two weeks," Staffeld-Coit said.

Two things are necessary for dialysis, in addition to the equipment itself: clean water and electricity. In anticipation of Gustav, Ochsner increased its capacity to filter its own water and generate its own electricity.

The Sunday before Gustav hit New Orleans, Ochsner dialyzed all of the dialysis patients in the hospital. That way, if other patients needed dialysis in the wake of the storm, Ochsner's patients wouldn't be competing with them to use the equipment for the three or four hours required for each session.

Gabbard also contacted Joe Desselle, clinic manager for the 15 Fresenius units in the New Orleans area. Desselle cobbled together a staff with employees from various Fresenius units around town.

Gabbard then sent the word out to medical facilities in the area that the two clinics were open.

--- Dietary considerations ---

For patients who stay behind, the heat, lack of food and lack of water may actually help them survive longer without dialysis. Since the patients aren't ingesting much, there are fewer toxins to be removed.

But the meals provided at shelters are apt to be dangerously high in the very toxins that dialysis patients are told to avoid. Thus, the only sensible option for these patients is evacuation.

"Every storm is a different animal, and it is not necessarily going to present itself in the same way," Staffeld-Coit said. "The damage from this one may be worse than the one before."

http://www.nola.com/news/t-p/metro/index.ssf?/base/news-30/122162884765190.xml&coll=1

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Council may create new hospital board
The Times-Picayune | 09.17.08
By Paul Rioux
St. Bernard bureau

Addressing an ethics dispute involving a public board overseeing construction of a hospital in St. Bernard Parish, a divided Parish Council took the first step Tuesday toward replacing the board with a new one.

The council voted 4-2 to introduce an ordinance to create a new five-member board charged with building a hospital to replace the one destroyed during Hurricane Katrina.

The ordinance is set for a final vote next month, but it could be moot if parish officials negotiate an agreement with two doctors serving on the current board to resign amid conflict-of-interest concerns.

The controversy centers on Drs. Brian Bertucci and Paul Verrette, who work at a temporary medical clinic in Chalmette and are employed by the Franciscan Mission of Our Lady Health System, one of several health care firms vying for a contract to manage the yet-to-be-built hospital.

Bertucci and Verrette have said they would recuse themselves from a vote to award the contract. But some council members said the doctors must resign to comply with strict ethics regulations tied to $40 million in grants for the proposed 40-bed hospital.

Voting to introduce the ordinance to appoint a new board were council members Ray Lauga, George Cavignac, Michael Ginart and Polly Boudreaux. Kenny Henderson and Fred Everhardt opposed the ordinance. Councilman Frank Auderer did not vote and declined to say why after the meeting.

Lauga, who sponsored the ordinance, said that if the Franciscan Mission gets the hospital contract while Bertucci and Verrette are on the board, the firms that were not chosen could sue.

"Everybody I've talked to who has a legal background said this would be an open-and-shut case," he said. "I don't want our hospital project to get tied up in the courts."

Bertucci has dismissed the ethics dispute as "smoke and mirrors" to conceal favoritism for the Ochsner Health System, one of up to four firms expected to submit a hospital management proposal by the Sept. 25 deadline.

"Creating a whole new board is foolish," Bertucci said after the meeting. "It would cause delays, it's divisive and it fragments the community. It's a slap in the face, quite frankly."

Verrette suffered an apparent heart attack after leaving the meeting before the discussion about the hospital board, Bertucci said.
"He left to get some nitroglycerin and had a heart attack," said Bertucci,. He said Verrette was being treated at Tulane University Hospital. "They put a stent in and he's doing OK."

Tensions have risen in recent months with parish residents voicing frustration that three years after Katrina destroyed the privately-owned Chalmette Medical Center a new hospital is still three years away.

Bertucci said he has told Parish President Craig Taffaro he would resign if Taffaro signed an agreement releasing $25 million in Katrina-related state redevelopment grants to the hospital board.

Taffaro said he would not sign over the money until he has resignations from both doctors in hand.

Bertucci said he would settle for sitting down with Taffaro and signing the documents simultaneously.

"Unfortunately, the level of trust hasn't always been where we all would want it to be," Bertucci said.

http://www.nola.com/news/t-p/metro/index.ssf?/base/news-30/122162895065190.xml&coll=1

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Rising Foe Defies Hospitals' War On 'Superbugs'
The Wall Street Journal | 09.17.08
By LAURA LANDRO

Shortly after being admitted to a Cleveland-area hospital with severe abdominal pain, 52-year-old Maureen O'Hearn was transferred to intensive care. An intestinal infection had distended her abdomen so badly she appeared to be six months pregnant. To save her life, a surgeon had to remove her colon.

The cause of Ms. O'Hearn's illness was an epidemic strain of Clostridium difficile -- C. diff for short -- that is fast emerging as one of the most dangerous and virulent foes in the war against antibiotic "superbugs." C. diff is spawning infections in hospitals in the U.S. and abroad that can lead to severe diarrhea, ruptured colons, perforated bowels, kidney failure, blood poisoning and death.

Katie Lancey follows special procedures for cleaning a patient ' s room at SSM St. Joseph Hospital West in Lake Saint Louis, Mo.

Even as hospitals begin to get control of other drug-resistant infections such as MRSA, a form of staph, rates of C. diff are rising sharply, and a recent, more virulent strain of the bug is causing more severe complications. The Centers for Disease Control and Prevention estimates there are 500,000 cases of C. diff infection annually in the U.S., contributing to between 15,000 and 30,000 deaths. That's up from roughly 150,000 cases in 2001.

"We've been trying to sound the alarm repeatedly since 2004 that the trend is continuing upward," says Cliff McDonald, a CDC epidemiologist. He adds that C. diff, once mainly a concern for older patients, is now a growing risk for pregnant women, children and healthy adults.

Many patients get C. diff infections as an unintended consequence of taking antibiotics for other illnesses. That's because bacteria normally found in a person's intestines help keep C. diff under control, allowing the bug to live in the gut without necessarily causing illness. But when a person takes antibiotics, both bad and good bacteria are suppressed, allowing drug-resistant C. diff to grow out of control.

As a result, hospitals are more closely monitoring and limiting their use of antibiotics. It's a strategy that also has shown some success in preventing the spread of other drug-resistant bacteria. Once patients do contract a C. diff infection, hospitals sometimes can treat them with certain "last ditch" antibiotics, such as vancomycin, but many patients relapse after treatment.

Other efforts to stop the spread of C. diff include isolating infected patients; suiting workers and visitors from head to toe with scrubs, masks and gloves; and blasting patient rooms with super-strength bleach solutions. Milder "green" cleaners don't kill C. diff, undermining some hospitals' efforts to use these products.

Spreading Spores

One problem: C. diff produces spores that can dry out after cleaning and hang around on hospital cart handles, bed rails and telephones for months. Hand cleaning with alcohol, many hospitals' standard practice for keeping staff from spreading infection, can actually help disperse C. diff spores. Many hospitals now have special rules requiring staff to wash their hands with antibacterial soap when dealing with C. diff patients.

Clostridium difficile spores can last a long time and make the bug hard to kill.

Katie Lancey, lead environmental services aide at SSM St. Joseph Hospital West in Lake Saint Louis, Mo., says she spends up to an hour cleaning a room after a C. diff patient leaves. She wears protective garments and wipes down everything in the room with a bleach solution, including the TV, pillows, mattress and lower structure of the bed. "Anything you can think of, you make sure you wipe it down thoroughly," she says.

If a patient coming in to SSM St. Joseph is suspected of having C. diff infection -- severe diarrhea is one symptom -- they are put in isolation even before lab tests come back, says James Hinrichs, the infectious-disease specialist charged with the hospital's C. diff-prevention program. He says that when C. diff patients are discharged, he advises them to eat yogurt with so-called pro-biotics to help restore a healthy balance of bacteria in their intestines. He also tells families to follow strict cleaning and hand-washing rules at home.

The efforts, along with more careful use of antibiotics, have helped SSM St. Joseph reduce the rate of C. diff infections to 0.5 cases per 1,000 patient days currently from 2.5 cases in 2006, Dr. Hinrichs says.

C. diff was first recognized in the 1970s, when it was readily treatable. The more virulent strain was first identified at the University of Pittsburgh Medical Center in 2000, killing 18 patients. By 2004, the new C. diff strain was reported elsewhere in the U.S. and around the world, and studies showed it was producing 20 times more toxin than older strains.

Carlene Muto, medical director of infection control at the University of Pittsburgh, says the hospital was able to reduce its C. diff infections by 50% after the 2000 outbreak and has sustained that rate since then. It instituted strict cleaning practices, restricted its use of antibiotics and began relying on its electronic medical-record system to quickly flag lab tests of patients most at risk so they can be isolated. "You have to be constantly vigilant," Dr. Muto says.

Only 3% to 5% of healthy, non-hospitalized adults carry C. diff in their gut, but that rate is much higher in hospitals and nursing homes, where carriers can spread the bacteria to others. Studies at several hospitals in recent years have shown that 20% or more of inpatients were colonized with C. diff, and a 2007 study of 73 long-term-care residents showed 55% were positive for C. diff. Even though the majority had no symptoms of disease, spores on the skin of asymptomatic patients were easily transferred to the investigators' hands.

The CDC is launching a national surveillance effort to gather more precise data about the prevalence of C. diff. It is working with states to identify local outbreaks. It also is working with Medicare and the Environmental Protection Agency to develop new guidelines for fighting C. diff.

Nursing Home Infections

Ms. O'Hearn, the Cleveland-area patient, says she took an antibiotic for a sinus infection and then visited a nursing home, where she may have picked up the C. diff bug. During her hospital treatment, Ms. O'Hearn says she suffered an irregular heartbeat and dehydration, and required additional surgery to temporarily attach her small intestine to the abdominal wall to bypass the large intestine. "It was the worst nightmare that anyone could imagine," says Ms. O'Hearn, a nurse by training. Though she has returned to work and a more normal lifestyle, she continues to have digestive troubles, and must take medications to regulate her heart.

Kettering Medical Center near Dayton, Ohio, had 305 cases of C. diff last year and has had 165 cases so far this year. Even newborn babies have gotten the disease from their mother during birth, says Rebekah Wang-Cheng, Kettering's medical director for clinical quality. She says that among other measures, the hospital has cut its post-operative antibiotic doses for all joint-replacement surgeries to two from three to avoid C. diff infections. Patients who come into the hospital with suspected pneumonia now get an antibiotic within six hours, instead of four hours previously, to allow more time to assess the need for drugs.

Fecal Transplants

One controversial strategy: fecal transplants. For one patient with recurrent C. diff, Kettering suggested a stool transplant from a relative, to help restore good bacteria in the gut. But Jeffrey Weinstein, an infectious-disease specialist at the hospital, says the patient "refused to consider it because it was so aesthetically displeasing."

The Greater New York Hospital Association in March began a 40-hospital effort to halt the spread of C. diff from patient to patient. This included placing signs on patient rooms with pictures of a bottle of bleach and soap and water to remind staff the room needs special cleaning. The association also asks visitors not to use patient bathrooms.

Hospitals face growing legal concerns if they don't take such measures; relatives of 16 patients who were infected or died from a C. diff outbreak are suing a Quebec hospital, claiming that infection-control practices weren't followed.

C. diff infections can emerge days or weeks after antibiotic therapy. Earlier this year, Marcus Glover, a 40-year-old mailroom worker for the Greater New York Hospital Association, was discharged from hospital after a successful rotator-cuff surgery, which included antibiotic treatment. Ten days later, he landed in an emergency room with a C. diff infection that required another week in the hospital. Mr. Glover avoided the worst complications and was successfully treated with strong antibiotics.

But C. diff can be fatal. Philadelphia radio personality Hy Lit, 73, contracted a C. diff infection at a rehabilitation center after being treated at a hospital owned by Main Line Health System last fall. He died in another Main Line hospital two weeks later. "It was a multiple train wreck, when the bug permeated his bloodstream and his kidneys failed," says his son, Sam Lit. "It was a tragedy to lose him like that."

Main Line says it can't comment on individual patients but adds that it follows stringent prevention guidelines and is conducting ongoing initiatives to control infections in its hospitals.

http://online.wsj.com/article/SB122160848756745487.html

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Damaged Medical School in Galveston Looks for Places for Its Students
The Chronicle of Higher Education | 09.17.08
By KATHERINE MANGAN

Galveston, Tex.

As daylight broke Tuesday over the University of Texas Medical Branch here, a helicopter circled overhead and morning-shift workers began to stream in down below. This was no ordinary day, however. The helicopter was bringing workers from the Federal Emergency Management Administration, rather than patients, and the crews arriving for work were wearing hazardous-materials suits instead of hospital scrubs.

Three days after Hurricane Ike devastated this island community, along with much of the Texas Gulf Coast, the teaching hospital that has survived hurricanes for more than a century was once again getting back on its feet.

The island is under mandatory evacuation, and its leaders describe it as uninhabitable. There is no electricity, running water, gasoline, or groceries. But for hundreds of employees still working this week at the university center, which includes medical and nursing schools, a teaching hospital, and a research facility, the recovery is well under way.

In the main administration building, mattresses and cots are set up in cubicles for staff members who haven't gone home since Ike struck. Some have no homes to return to, and no hotels within hours where they could take a shower or cool off. Although air conditioning was working in parts of the medical center on Tuesday, there was no running water for showers or for flushing toilets.

Signs of Damage

Campus officials say it could be a month or more before the hospital resumes regular operations and is able to bring all of its students and residents back. In the meantime, administrators are working on temporary placements for 557 medical residents and about 2,400 medical, nursing, allied-health, and graduate students. The hospital has about 12,000 employees, 8,000 of whom work in Galveston.

The destruction Ike left behind is evident in all directions. Outside an emergency-room entrance, a half-dozen palm trees lie on their sides, alongside a white boat named "Tranquilo" that washed ashore.

Yellow tubes snake into soggy buildings, pumping in air to dehumidify rooms that had been flooded with up to three feet of water. For the past few days, crews have been pulling up soggy carpets, hauling off debris, and replacing broken windows.

Within a few blocks of the medical center, live oak trees that were ripped from their roots are toppled onto homes.

On Tuesday university officials said they had just learned it could be as soon as within two days—rather than the two weeks they were expecting—before some power is restored to the medical center. However, it could be weeks before the entire island's power is back on, along with other essential services.

Medical-center crews are focusing on getting the infrastructure, research, and educational programs back in place while a federal Disaster Medical Assistance Team temporarily takes over patient care. Patients are either treated and released, or transported to other hospitals. Officials say they are optimistic that by shaving some time off vacations and study periods, the medical center will be able to allow all of its students to complete the year and graduate on time. But that's going to require some juggling and cooperation from the state's other medical schools.

A Necessary Dispersal

Department heads are working on finding temporary placements where medical residents and clinical students can practice for at least a month. Even if the hospital reopens sooner, it won't have the patient base those doctors-in-training need. A resident in general surgery, for instance, has to perform a certain number of gallbladder operations, and a resident in ophthalmology needs to operate on a certain number of cataracts.

"I've gotten calls from administrators at programs as far away as Washington, D.C., offering training sites," said Thomas A. Blackwell, associate dean for graduate medical education. "Lots of offers have come from Louisiana. They know what this is like."

The school will also have to work with Medicare to make sure the $30-million a year it receives for residency training follows students to their temporary placements.

The allied-health school is considering working with the University of Texas Health Science Center at San Antonio to place some of its students, and the nursing school is looking for options to allow its students to continue some of their studies online.

Temporarily handing over patient care to the federal team allowed the hospital to give breaks to clinicians who had been working around the clock since a few days before Ike arrived.

"Nobody wanted to make the decision, but it was an obvious one that had to be made, just like evacuating the hospital," said Garland D. Anderson, executive vice president and provost.

Two days before Ike struck, its target appeared to be far enough down the coast that the medical school might be able to avoid the kind of costly and difficult evacuation it had made for Hurricane Rita in 2005. "As it got closer and closer," Dr. Anderson said, "we said, This is too big a storm. We have to evacuate." On Thursday, all 260 of the patients in its teaching hospitals were transported to facilities in Austin and San Antonio (The Chronicle, September 12).

Help for Storm Victims

During and immediately after the storm, the hospital's emergency room treated more than 100 people for a variety of ailments and injuries. Among them were people with chronic illnesses who had been off their medication, patients suffering chest pain or asthma, and many people suffering from emotional stress.

Dr. Anderson, who was wearing the blue scrubs he has lived in for the past several days, laughed when he was asked how many hours he has worked each day since the storm. "I don't remember— more than 12." His palms were sweaty and he had dark circles under his eyes as he slumped in a chair, recounting the past several days.

He said that in the aftermath of the hurricane, the medical center lost not only city power but some of its emergency generators.

Doctors, residents, and other staff members hauled equipment up dark, slippery stairs, using flashlights. The lack of electricity and the flooding required them to relocate entire units, including the pharmacy, up and down as many as eight floors. At the height of the storm, members of the group had to move their emergency-operations center after they heard a loud explosion and smelled smoke that was wafting into the building from a nearby boatyard that had caught fire. They had to move it again when a generator failed.

Rescuing Research

A failed generator also forced them to haul temperature-sensitive laboratory specimens, animal cages, and supplies up and down stairs. "People's life work is sitting in a corner in the freezer. It's very vulnerable when the power goes off," said Michael J. Megna, the medical center's facilities-planning and emergency-preparedness officer. "You never know what breakthrough might be sitting on a table that could be washed away."

Some 225,000 pounds of dry ice was delivered to the hospital to help safeguard research and medications.

Temperatures in the buildings soared into the 90s in areas that did not have air conditioning. Phones weren't working, so runners carried messages between buildings. In the medical center, as in the city itself, conditions are still far from safe or sanitary.

Galveston Mayor Lyda Ann Thomas has warned the estimated 20,000 residents who ignored evacuation orders to leave, saying the city faced a potential public-health crisis. Among other things, officials are worried that all of the standing water could result in an outbreak of mosquito-borne diseases.

At the medical center, campus employees and contractors lined up for tetanus shots before heading back out into the muck to resume cleanup and repair work on the hospital grounds.

Pamela G. Watson, dean of nursing, had just returned to her Galveston home on Tuesday and found that it had been flooded with three feet of water. She will probably be staying in a hospital room on the campus while she works on getting the nursing school back on its feet.

Many of the plans the medical center implemented came about as a result of lessons learned in Hurricane Katrina, said David L. Callender, president of the University of Texas Medical Branch. "We have, unfortunately for the people of New Orleans, benefited from their misfortune, and we owe them a great deal."

http://chronicle.com/daily/2008/09/4634n.htm?rss

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TV also sends health messages
USA TODAY | 09.17.08
By Mary Brophy Marcus

The television medical drama Grey's Anatomy apparently has more to offer than Patrick Dempsey's rakish smile and a good cry. A new survey reports watching the show also may increase a viewer's health smarts.

Research released Tuesday by the Kaiser Family Foundation indicates many people who tune in to prime time's top-rated shows remember health messages in episodes.

In one survey, Kaiser experts worked with Grey's Anatomy scriptwriters to plant health information in an episode that aired in May.

The story line included an HIV-positive woman and her husband who learn she is pregnant. The woman, who is distraught and blames a broken condom, is told by her doctor that with proper treatment, her baby has a 98% chance of being born healthy and not contracting HIV, the virus that causes AIDS.

Three random telephone surveys of about 1,500 regular viewers were conducted one week before the show aired, one week after it aired and again six weeks later. The objective was to measure the impact of the message about mother-to-child HIV transmission, says Victoria Rideout, vice president and director of Kaiser's Program for the Study of Media and Health.

Before watching the episode, 15% of viewers were aware that with proper treatment, an HIV mother's baby has a 98% chance of being born healthy. One week after the show, 61% were aware of that information. Six weeks later, 45% remembered the information correctly.

"I was astounded" by the number of viewers who "picked up on factual health info about HIV embedded in the show, and that they remembered it weeks later," Rideout says.

A second study, also released Tuesday by Kaiser and the University of Southern California's Annenberg Norman Lear Center, indicates that health content is prevalent on prime-time TV. An analysis of three seasons (2004-2006) of top-10 shows reported nearly six out of 10 episodes had at least one health-related story line.

"People are very hungry for information about health. Entertainment media who embed correct health information are doing a societal good," says Linda Rosenstock, dean of the UCLA School of Public Health, who was not involved in the study.

A lot of inaccurate health messages are on television, says Sandra de Castro Buffington of Hollywood, Health & Society, an Annenberg program that provides health information to entertainment writers and producers.

However, done responsibly, embedding accurate health content in entertainment television could have a major public health impact, says Jay Bernhardt of the Centers for Disease Control and Prevention.

"It could help change behaviors about health," he says.

http://www.usatoday.com/news/health/2008-09-16-tb-health-message_N.htm?loc=interstitialskip

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Overweight kids likely to have more headaches, study finds
USA TODAY | 09.17.08
By Marilyn Elias

The more overweight children and teenagers are, the more frequent and disabling their headaches, according to the first national study to look at possible links between obesity and headaches in kids.

A great payoff of slimming down is that heavy kids tend to gain some relief from headaches, says Andrew Hershey, a pediatric neurologist at Cincinnati Children's Hospital Medical Center, who led the study at seven U.S. headache centers. The report on 913 children and teenagers, followed for six months, is published online in Headache.

Adult obesity already has been tied to headaches, so helping kids get into the normal weight range could prevent years of pain and disability, Hershey says.

Chronic headaches are common in childhood, with surveys suggesting they're experienced by anywhere from one out of four to one out of 10 kids. In Hershey's study, some had headaches nearly every other day. The more overweight a child, the more headaches and the worse the pain.

But the overweight children who had lost weight three months after their first visit reported about half as many headaches as the heavy kids who continued to gain weight. On the other hand, gaining or losing weight had little effect on headaches for kids of a normal weight.

Children and teens in pain from headaches may be less physically active, prompting them to pack on pounds, Hershey speculates.

Also, there's some evidence that adults with migraines have low levels of leptin, a hormone that causes a feeling of fullness after eating. This can encourage overeating, Hershey says.

So the heavy kids with headaches may have low leptin levels, too, Hershey suggests. That would help account for the tie between their extra weight and headaches.

Childhood headaches also could be due to dehydration. "Overweight kids don't like to drink water, and they're very often dehydrated, which leads to headaches," says Melinda Sothern, an exercise physiologist who has treated thousands of heavy children at Louisiana State University Health Sciences Center in New Orleans.

Stress, too, triggers headaches, and the bullying faced by heavy children can be terribly stressful, adds Matthew Davis, a pediatrician at the University of Michigan's C.S. Mott Children's Hospital. Parents of overweight and obese kids rated bullying as their top health concern for children, far higher than parents of normal-weight children, in a new online poll directed by Davis.
"We know from other studies that these overweight kids tend to be the targets of bullies, and that their overall quality of life is lower," he says.

http://www.usatoday.com/news/health/weightloss/2008-09-16-overweight-kids-headaches_N.htm

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FDA blocks generic drug imports from India
USA TODAY | 09.17.08
By Rita Rubin

WASHINGTON — The Food and Drug Administration has issued an "import alert" to block approximately 30 generic drugs made by two plants in India from entering the USA, officials said Tuesday.

"To date, we have seen no evidence of harm to consumers from drugs produced at these facilities," Douglas Throckmorton, deputy director of the Center for Drug Evaluation and Research at the FDA, told reporters. "Based on what we know today," he added, consumers shouldn't stop taking the drugs, which include cholesterol-lowering statins, antibiotics and antivirals.

The FDA learned about potential problems with the Dwas and Paonta Sahib plants in August 2005 and inspected them earlier this year, said Deborah Autor of the agency's Office of Compliance for drugs. Ranbaxy has a total of four India plants that make drugs for the U.S. market. It also has three U.S. plants under the name Ohm Laboratories.

According to an FDA press release, the inspection found "extensive deviations" from current good manufacturing practice requirements, such as "inaccurate written records of the cleaning and use of major equipment."

In a separate, criminal investigation, the Justice Department filed a motion in July with the U.S. District Court in Maryland stating that "allegations from reliable sources and supporting documents indicate a pattern of systematic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information."

In response to information contained in that motion, Michigan Democrats Rep. John Dingell, chair of the House Committee on Energy and Commerce, and committee member Rep. Bart Stupak began investigating whether the FDA knowingly allowed drugs produced at the Ranbaxy plants to continue to be sold in the USA.

The criminal case is a separate matter, Autor said. "We have done what we think is the appropriate next step in our civil investigation."

On its website, Ranbaxy says it's India's largest drugmaker and ranks among the world's top 10 manufacturers of generics. Ranbaxy spokesmen in India and in New Jersey did not reply to requests for comment.

Except for one, the drugs made at the two Ranbaxy plants are also made by other companies, Throckmorton said, so "we anticipate no drug shortages." The one exception is capsules of the antiviral drug gancyclovir, he said, so the FDA won't detain shipments of that drug from Ranbaxy.

Until Ranbaxy corrects the deficiencies, the FDA will maintain the import alert and withhold permission from the company to market any new products in the USA, Autor said.

http://www.usatoday.com/news/health/2008-09-16-drugs-india_N.htm

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LSUA will offer 4-year nursing degree
The Town Talk | 09.16.08
By Karina Donica

When nursing student Eva Guillory heard her university was planning to launch a Bachelor of Science degree in nursing she said, "thank you."

As she completes her associate's degree at Louisiana State University at Alexandria this fall she is already making plans to go to the next level of her career and pursue a bachelor's degree in nursing.

Getting a bachelor's will not only open the doors for a supervisory position in nursing, but it also will give her a better insight into her field of study, she said.

LSUA officials announced Monday that the bachelor's program, which they have been planning for years, recently was approved by the Louisiana Board of Regents and the LSU Board of Supervisors.

The new degree is the latest of about 14 bachelor's degree options since LSUA became a four-year degree granting institution in 2001.

In a time when health care needs nationwide have become a major policy challenge not only due to its high cost but also because of a nursing shortage crisis, the new program at LSUA will help fill that void, LSUA Chancellor David Manuel said.

"It's extremely important that we do everything that we can to improve on the shortage of nurses," Manuel said, adding that the new degree will serve Central Louisiana's needs well.

According to the latest projections from the U.S. Bureau of Labor Statistics published in the November 2007 Monthly Labor Review, more than one million new and replacement nurses will be needed by 2016, said the American Association of Colleges of Nursing.

Locally, LSUA has had a strong associate's degree program for 48 years and the new bachelor's program will complement and build on that foundation, said Dorothy Lary, chair of the Department of Nursing.

Students interested in the program can register to attend the regular classroom setting or take some courses online, Lary said.

Manuel said LSUA seeks to make its new bachelor's degree program not just viable but a leading nursing program in Louisiana. The program will accept from 50 to 75 students.

The degree for most students will require 50-60 hours of college course work beyond the associate degree requirements, the majority of which will be in advanced nursing classes. Additional nursing faculty with doctoral degrees is being hired for the program.
Thomas Armstrong, who spearheaded the BSN effort as vice chancellor for academic and student affairs, said the new degree "enhances supervisory and management opportunities, prepares students for graduate school and positions them to become a nurse practitioner, nurse anesthetist or teach at a school of nursing."

Officials from Christus St. Frances Cabrini and Rapides Regional Medical Center commended LSUA's contribution to quality work force in area hospitals. The two hospitals have worked in several partnerships with the university including tuition assistance, allowing flexible schedules for student nurses and mentoring.

"Our hospitals over 40 years could not have been adequately staffed without the superb nursing staff that we have," from their associate's degree program, said LSUA grad Celeste Bordelon, who is the clinical director of Christus St. Frances Cabrini and an adjunct faculty member at LSUA.

Bordelon said there are many nurses that are thrilled the new program will allow them to advance their education without having to move away.

Stephen Wright, with Christus St. Frances Cabrini, commended the partnership between the university and hospitals, but said much more remains to be done to keep up with the demand for nurses.

Wright described the new degree program as a "platform" into the future.

"Quite frankly we don't want to stop here ... what we would like to see in the future is that LSUA will not only have a four-year degree program but will have a master's degree program as well," Wright said.

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FDA defends plastic linked with health risks
Yahoo News | 09.16.08
By RICARDO ALONSO-ZALDIVAR and LINDSEY TANNER
Associated Press

With scientists at odds about the risks of a chemical found in plastic baby bottles, metal cans and other food packaging, the government on Tuesday gave consumers some tips on how to reduce their exposure to BPA even as it said the substance is safe.

A Food and Drug Administration advisory committee met as a major study linked bisphenol A to possible risks of heart disease and diabetes. The scientific debate could drag on for years.

"Right now, our tentative conclusion is that it's safe, so we're not recommending any change in habits," said Laura Tarantino, head of the FDA's office of food additive safety. But she acknowledged, "there are a number of things people can do to lower their exposure."

For example, consumers can avoid plastic containers imprinted with the recycling number '7,' as many of those contain BPA. Or, Tarantino said, they can avoid warming food in such containers, as heat helps to release the chemical.

More than 90 percent of Americans have traces of BPA in their bodies, but the FDA says the levels of exposure are too low to pose a health risk, even for infants and children. Other scientists, however, say BPA has been shown to affect the human body even at very low levels.

And Tuesday a study released by the Journal of the American Medical Association suggested a new concern about BPA. Using a health survey of nearly 1,500 adults, the study found that those exposed to higher amounts of BPA were more likely to report having heart disease and diabetes. Because of the possible public health implications, the results "deserve scientific follow-up," its authors said.

The study is preliminary, far from proof that the chemical caused the health problems. Two Dartmouth College analysts of medical research said it raises questions but provides no answers about whether the ubiquitous chemical is harmful.

FDA officials said they are not dismissing such findings. "We recognize the need to resolve the concerning questions that have been raised," said Tarantino, acknowledging that more research is needed. But the FDA is also arguing that the studies with rats and mice it relied on for its assessment are more thorough than some of the human research that has raised doubts.

The agency has asked an outside scientific panel for a second opinion on BPA's safety, and the medical journal article was released to coincide with the advisers' hearing. The FDA has the power to ban or limit use of BPA in food containers and medical devices.
Past animal studies have suggested reproductive and hormone-related problems from BPA. The JAMA study is the largest to examine possible BPA effects in people and the first suggesting a direct link to heart disease, said scientists Frederick vom Saal and John Peterson Myers, both longtime critics of the chemical.

Still, they said more rigorous studies are needed to confirm the results.

Vom Saal is a biological sciences professor at University of Missouri who has served as an expert witness and consultant on BPA litigation. Myers is chief scientist at Environmental Health Sciences, a Charlottesville, Va., nonprofit group. They wrote an editorial accompanying the JAMA study.

BPA is used in hardened plastics and in a wide range of consumer goods, including the lining of metal cans, eyeglass lenses and compact discs. Many scientists believe it can act like the hormone estrogen, and animal studies have linked it with breast, prostate and reproductive system problems and some cancers.

Researchers from Britain and the University of Iowa examined a U.S. government health survey of 1,455 American adults who gave urine samples in 2003-04 and reported whether they had any of several common diseases.

Participants were divided into four groups based on BPA urine amounts; more than 90 percent had detectable BPA in their urine.

A total of 79 had heart attacks, chest pain or other types of cardiovascular disease and 136 had diabetes. There were more than twice as many people with heart disease or diabetes in the highest BPA group than in the lowest BPA group. The study showed no connection between BPA and other ailments, including cancer.

No one in the study had BPA urine amounts showing higher than recommended exposure levels, said co-author Dr. David Melzer, a University of Exeter researcher.

Drs. Lisa Schwartz and Steven Woloshin of the Dartmouth Institute for Health Policy and Clinical Practice said the study presents no clear information about what might have caused participants' heart disease and diabetes.

"Measuring who has disease and high BPA levels at a single point in time cannot tell you which comes first," Schwartz said.

The study authors acknowledge that it's impossible to rule out that people who already have heart disease or diabetes are somehow more vulnerable to having BPA show up in their urine.
The American Chemistry Council, an industry trade group, said the study is flawed, has substantial limitations and proves nothing.

But Dr. Ana Soto of Tufts University said the study raises enough concerns to warrant government action to limit BPA exposure.

"We shouldn't wait until further studies are done in order to act in protecting humans," said Soto, who has called for more restrictions in the past.

An earlier lab experiment with human fat tissue found that BPA can interfere with a hormone involved in protecting against diabetes, heart disease and obesity. That study appeared online last month in Environmental Health Perspectives, a monthly journal published by the National Institutes of Health.

One of the FDA's outside advisers was skeptical of the JAMA study. "For diabetes, I really don't see it," said Dr. Garret FitzGerald of the University of Pennsylvania. As for a link to heart disease, FitzGerald questioned why the JAMA study did not also find high blood pressure problems in the people exposed to higher amounts of BPA.

Toxicology experts from another government agency have studied BPA and recently completed their own report. They found no strong evidence of health hazards from BPA, but unlike the FDA, said there was "some concern" about possible effects on the brain in fetuses, infants and children.

Several states are considering restricting BPA use, some manufacturers have begun promoting BPA-free baby bottles, and some stores are phasing out baby products containing the chemical. The European Union has said BPA-containing products are safe, but Canada's government has proposed banning the sale of baby bottles with BPA as a precaution.

The FDA advisory panel is expected to make its recommendations to the FDA late next month.

http://news.yahoo.com/s/ap/20080916/ap_on_he_me/med_bisphenol_safety;_ylt=Alf1pRjq8_wVPYUHzOlGfpEDW7oF

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CMS Issues Rules That Restrict Insurance Agents' Marketing of Medicare Advantage, Prescription Drug Plans
Kaiser Network | 09.16.08

CMS on Monday issued new rules governing insurance companies, agents and brokers regarding the marketing of Medicare prescription drug plans and Medicare Advantage plans, the AP/San Francisco Chronicle reports (Freking, AP/San Francisco Chronicle, 9/15). The new rules -- some of which were mandated by Medicare legislation passed earlier this year -- will take effect Oct. 1, the first day marketing efforts for the Medicare open enrollment period that begins Nov. 15 are allowed.

The rules will prohibit unsolicited sales pitches, including telemarketing and door-to-door sales; meals at sales presentations; promoting products not related to health care at sales presentations; conducting sales presentations at physicians' offices or other locations where health care services are provided; and attempting to sell plans at events billed as educational (Young, The Hill, 9/15).

In addition, commission for sales agents will be required to conform to a structure used in other parts of the insurance industry. First-year commission for a new customer cannot exceed 200% of the commission for the next five years, in order to remove the incentive for agents to "churn" beneficiaries between different plans each year (Armstrong, CQ HealthBeat, 9/15).

The rules also include stricter requirements for CMS reviews of marketing materials. CMS will perform about 900 "secret shopper" reviews of sales presentations. CMS also will monitor print and broadcast advertisements, listen to recorded calls between plans and customers and verify that plans are reporting agents and brokers in violation of the rules to federal and state authorities (The Hill, 9/15). Penalties for violations will include fines of up to $25,000 per beneficiary affected or potentially affected (CQ HealthBeat, 9/15).

Comments

CMS Acting Administrator Kerry Weems said, "These regulations give insurers bright-line guidance on what types of marketing activities are acceptable and what types are not acceptable," adding, "Medicare beneficiaries can be assured that we will monitor marketing activities and move aggressively with enforcement measures or actions if these rules are violated." According to The Hill, the Bush administration with the rules was seeking to "allay insistent criticism for congressional overseers and advocates for senior citizens" regarding sales practices.

Senate Finance Committee Chair Max Baucus (D-Mont.), who sponsored the bill, said, "CMS is moving in the right direction by following the new Medicare law's call to draw clear lines that will weed out unscrupulous marketing agents who prey on seniors for profit. Now, CMS must follow up and follow through for seniors in Medicare." He added that the Finance Committee "will watch CMS to make sure the effort to protect seniors doesn't stop here" (The Hill, 9/15).

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Panel Discusses Proposals To Expand Medicaid To Cover More Low-Income Adults
Kaiser Network | 09.16.08

Panel members on Monday during an event sponsored by the Alliance for Health Reform said that Medicaid would require significant changes to expand coverage to low-income adults who currently do not qualify for the program, CQ HealthBeat reports. According to a report recently released by the AARP Public Policy Institute, low-income adults who do not qualify for Medicaid account for more than half of U.S. residents without health insurance.

Under current law, only pregnant women, individuals with disabilities, those who care for a dependent child and those older than age 65 qualify for Medicaid. States can apply for federal waivers to expand their Medicaid programs to cover other populations. However, according to Stan Dorn, author of the report and a research associate at the Urban Institute, the Medicaid waiver application process is difficult, and the federal government does not provide additional matching funds for states that cover other populations under their programs.

Proposals

Dorn outlined three proposals under which the federal government could expand Medicaid to cover low-income adults who currently do not qualify for the program. Under one proposal, the federal government could maintain the current waiver application process but remove budget neutrality requirements to allow states to receive additional matching funds, Dorn said.

Barbara Coulter Edwards, a principal with Health Management Associates and former director of the Ohio Medicaid program, raised concerns about whether states could afford the proposal. She said, "States have to balance budgets ... (and) Medicaid is countercyclical. When the economy is the worst, the demand is the greatest. In the last recession, several states began to back away from eligibility expansions they put in place because they had to balance their budgets."

Dorn said that the federal government also could replace categorical eligibility requirements for Medicaid with requirements based only on income. Panel members raised concerns that the proposal could result in the loss of Medicaid coverage for some groups, such as pregnant women.

Under a third proposal, the federal government could establish a new Medicaid eligibility category that would include all adults with incomes less than a certain level. Panel members raised concerns that the proposal would increase administrative work for states and require additional funds.

According to Nina Owcharenko, a senior policy analyst at the Heritage Foundation Center for Health Policy Studies, public support for such proposals likely would decrease in the event that they required tax increases. "People are concerned with the amount of taxes they have to pay," Owcharenko said, adding, "How much (are) Americans willing to pay for certain reforms?" (Nylen, CQ HealthBeat, 9/15).

A webcast of the forum is available online at kaisernetwork.org.

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