tion

unit, the 1st Marine Division, irom September 2007 until July 2009.

The expeditionary force's current commanding general, Lt. Gen. Joseph F. Dunford Jr., has been selected for promotion to general and the position of assistant commandant of the Marine Corps.

GRETEL C. KOVACH

Whooping cough cases grow; vaccinations urged

Health officials are urging people to get vaccinations for whooping cough, as new cases continue to be reported in a statewide epidemic that has killed seven infants, including one in San Diego last week.

The county Health and Human Services Agency reported four new cases in San Diego County this week: a 10-year-old attending Summerbridge San Diego in La Jolla and a 9-year-old attending Turtleback Elementary in Rancho Bernardo, who both were current on the immunizations; and an 11-year-old attending Casillas Elementary summer school in Chula Vista and a 13-year-old in Clairemont who were due for booster shots.

The federal Centers for Disease Control and Prevention recommend that children get doses of DTaP vaccine at 2 months, 6 months, 15-18 months and 4-6 years of age. A dose of Tdap vaccine is recommended at 10-11 years old.

The state Department of Public Health recommends adult booster shots for everyone who has not yet received one, including women who are pregnant.

Whooping cough, or pertussis, is a highly contagious respiratory infection with coldlike symptoms in the early stages. If not treated with antibiotics, it can lead to serious illness or death, particularly in infants.

San Diego County has had 298 cases so far this year compared with 143 cases for all of 2009, officials said. Statewide, 2,174 cases have been reported.

JANET LAVELLE

Military academy settles cadet's hazing lawsuit

CARLSBAD: A settlement has been reached in a lawsuit filed against the Army and Navy Academy in Carlsbad that accused the school of failing to protect one of its cadets from hazing.

The plaintiff's lawyer, Vince Finaldi of Orange County, confirmed Wednesday that the suit was resolved about two weeks ago but declined to discuss details, citing a confidentiality agreement between the parties.

The academy's president, retired Army Gen. Stephen Bliss, also confirmed that the lawsuit had been settled but declined to provide additional information.

At least three lawsuits have been filed against the academy since spring 2008, all of which claimed that the boarding school failed to protect cadets from violence at the hands of peers. The school enrolls about 300 students on the 16-acre, oceanfront campus.

The other lawsuits are still pending.

cerned for the safety of the students, Buss said Wednesday.

DANA LITTLEFIELD

417-home project meets supervisors' approval

NORTH COUNTY: The county Board of Supervisors unanimously approved a project Wednesday near Ramona that would include 417 homes, parks, open space and what some Ramona residents say is muchneeded development.

The Montecito Ranch project has been in the works for 12 years, and would span 935 acres. The development required a oning amendment to allow the homes be on smaller lots, which range from ,000 square feet to 1.8 acres.

The new development will also provide ads that may help traffic flow.

This is one of the most well-planned deelopments I've seen in a long time," said upervisor Dianne Jacob, whose district cludes the proposed/site.

She said she was impressed that the eveloper had altered the plan based on mmunity input. Many residents spoke favor of the project at the meeting; none present opposed it.

The board allowed the development company to move forward with a plan to include a wastewater treatment facility in the development site.

The other option, which county staff recommended, was connecting to the Ramona Municipal/Water District for treatment. Developers and community supporters said this option would be too costly, and could even sink the project.

The water reclamation plan is still subject to the approval of the San Diego Local Agency Formation Commission, which handles jurisdictional boundary changes.

NATHAN SCHARN

Work to start on center for cancer-killing protons

SAN DIEGO: Scripps Health will hold a groundbreaking ceremony today for a \$185 million radiation treatment center that will use beams of protons to destroy certain types of cancer cells.

The Scripps Proton Therapy Center in Mira Mesa will be one of seven facilities in the United States and only the second on the West Coast to use proton therapy.

Advocates say it uses a stronger, more focused beam than other radiation treatments to kill malignant cells without damaging nearby tissue or causing secondary

The therapy often is used to treat tumors in the spine, head, lungs and prostate. According to the National Cancer Institute, 60 percent to 75 percent of the nearly 1.5 million people diagnosed with cancer each year will undergo some form of radiation therapy.

Grading has begun for the Scripps center on Summers Ridge Road, and the facility is expected to open in spring 2013 with the capacity to treat 2,400 patients



VENISON SERVED IN HUNGER INITIAT

Melba Massey was one of more than 1,000 hom Vincent de Paul Village in East Village on Wedn made with some of the 400 pounds of venison as part of its "Hunt.Fish.Feed." national initia donated 200 pounds of fish that will be used la

annually.

The other West Coast proton therapy center is at Loma Linda University Medical Center in San Bernardino County.

Lemon Grove sales tax measure dies in council

LEMON GROVE: Residents in Lemon Grove won't be voting on a proposed sales tax increase anytime soon.

Supporters of a half-cent tax increase failed to convince enough Lemon Grove City Council members Tuesday to place the measure on the November ballot. Although three of the four council members present voted to approve the ballot measure, four votes are needed to put a proposed tax to a public vote.

The vocal and divisive crowd was chastised several times by Mayor Mary Teresa Sessom to stop clapping during

the meeting.

Councilwoman Mary England cast the sole dissenting vote. She is president and CEØ of the La Mesa Chamber of Commerce and in 2009 supported that city raising its taxes. Sessom and Councilmen George Gastil and Jerry Jones voted in favor of putting the measure on the ballot. mal Councilman Jerry Selby, who supports

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(ER · U-T

SUSAN SHRODER • U-T Police say fire started

SOUTH COUNTY

A man who told authorities he intended to light charcoal in a grill sparked a 2-acre brush fire that burned up a canyon near homes north of Otay Mesa Road on Wednesday, fire and police officials said.

seat belts, he said. They died

of massive head injuries.

by man lighting grill

Local residents off Ocean View Hills Parkway, west of Interstate 805, told San Diego police they saw a dirty, bearded man in a dark trench coat come out of the canyon as the flames were spreading at noon.

Police detained him before jailing him on suspicion of recklessly causin a vegetation fire, a felon said Maurice Luque, a Sa Diego Fire-Rescue Depar ment spokesman.

Luque said Michael Jone Boyle, 54, told authorities he had lit a charcoal fire a barbecue grill but did not intend to set the surrounding brush on fire.

The fire took about 45 minutes t o control, with a firefighting helicopter making water drops.

PAULINE REPARD • U-T

HEALTH

THREE MORE LOCAL KIDS **GET WHOOPING COUGH**

As county cases climb to 412 this year, health officials continue vaccination push

Three new cases of whooping cough have been reported in San Diego County this week, and public health officials are reminding parents to make sure their children are immunized before starting the new school year.

An epidemic of whooping cough, or pertussis, has swept California this year, with 3,311 cases reported as of Tuesday, including eight infant deaths. One was a 1-month-old boy in San Diego.

In San Diego County, 412 cases have been reported, according to the Health and Human Services Agency.

The three latest local cases involved a 3- and 5-yearold who were up-to-date on immunizations and a 10year-old due for a booster shot, county officials said.

Whooping cough is a highly contagious respiratory illness that leads to severe and long-lasting coughing attacks and possible lung damage.

Infants are at greatest risk of serious illness or death from the disease. Health officials are urg-

Vaccine clinics

The county is holding vaccination clinics each weekend until Sept. 26. The clinics are from 10 a.m. to 4 p.m.

Saturdays: San Ysidro Port of Entry, 720 E. San Ysidro Blvd., San Diego.

Sundays: At six Northgate Markets - 2909 Coronado Ave., San Diego; 1410 S. 43rd St., San Diego; 1058 Third Ave., Chula Vista: 1346 S. Mission Road, Fallbrook; 1150 E. Vista Way, Vista; 606 N. Escondido Ave., Escondido.

ing anyone in contact with babies and children to get vaccinated. Children are urged get one dose of DTaP vaccine at ages 2 months, 4 months, 6 months, 15-18 months and 4-6 years.

A booster shot of Tdap vaccine is recommended for everyone 10 years or older.

For more information, call (866) 358-2966.

JANET LAVELLE • U-T

EDUCATION

SCHOOL BOARD TRUSTEE **WANTS WRITE-IN CHANCE**

Nakamura, third in primary, petitioned court to allow it despite S.D. city code ban

SAN DIEGO

A Superior Court judge will decide whether San Diego school board trustee Katherine Nakamura can It we election as a writeSan Diego Unified School District.

The incumbent barely campaigned last spring, saying she was too busy working to balance the dis-



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NORTH COUNTY OT

UT 10/7/10

10 CHICKENPOX CASES AT ESCONDIDO SCHOOLS

ESCONDIDO

A chickenpox outbreak has been reported at two Escondido schools, the county's Health and Human Services Agency said Wednesday.

Seven students ranging from 4 months to 15 months old have been diagnosed with the virus at the Escondido Community Child Development Center, and three students between 15 and 17 have been diagnosed at Escondido High School.

The agency said there is no known connection between the cases at the two sites.

Two of the three high school students had received two immunizations for chickenpox, and the third had one. Six of the seven children at the Child Development Center were immunized. People who have been vaccinated tend to experience a milder case of the illness, public-health officials said.

Chickenpox is a highly contagious condition that spreads through coughing, sneezing and contact with chickenpox blisters.

Symptoms include blis-

terlike lesions, mostly on the face, scalp, chest and back. Potential complications increase after puberty, including bacterial infection, pneumonia and dehydration.

JONATHAN HORN • U-T

Escondido to honor city worker who died

ESCONDIDO

The city will lower flags to half-staff at all city facilities Friday in honor of an employee who died of cancer Aug. 4.

The city chose Friday to honor Tom Foley, a senior wastewater treatment plant operator, because that is when Foley's family plans to scatter his ashes off the coast in Santa Barbara.

Foley, an Oceanside resident, had worked for the city since November 1994. He is survived by his wife, Margot, and sons, Sean and Dimitri. Colleagues described Foley as an avid horseman and kayaker who loved the ocean.

City policy allows flags to be lowered on the day of a city employee's interment.

MICHELLE BREIER • U-T

EDUCATION

BOARD INCUMBENT GETS TO PURSUE WRITE-IN BID

Win won't automatically seat Nakamura, who lost district primary to two others

SAN DIEGO

San Diego Unified school board incumbent Katherine Nakamura will continue her write-in campaign for a third term, but victory at the polls on Nov. 2 may not guarantee her a seat on the dais.

Superior Court Judge
David Oberholtzer directed the county registrar's
office Wednesday to tally
votes for Nakamura, but
he did not rule on whether
she will be allowed to hold
office for another four
years if she gets the most
votes. He left that to a possible court challenge if she
wins.

"If there is a contest, we'll hear it," he said. "But there's got to be somebody who objects."

The candidates on the ballot, who finished ahead of Nakamura in the June primary, are Kevin Beiser and Steve Rosen.

Nakamura claimed the city's election code, which the school district follows, is unconstitutional because it prohibits write-in can-



Katherine Nakamura

didates from general elec-

Despite his refusal to give Nakamura a clear ruling on whether she could take office if she attracts the most votes, Oberholtzer said he expects anyone who wins an election to be seated.

"The person with the most votes is going to sit at the table," he said. "Doesn't that just make sense?"

Oberholtzer's statements fell in line with the school district's argument that "it's not the role of the judicial branch or the judge to tell the district what they have to do if something in the future occurs," said Mark Bresee, the district's general counsel.

Nakamura said she considers the judge's statements a victory.

HAILEY PERSINGER . U-T

MIKE LEE . U-T



Jose, 24, and BROOKS • U-T

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GREEN-CAREER CLASSES AVAILABLE TO JOBLESS

Cuyamaca College offers free instruction on landscaping and water conservation

RANCHO SAN DIEGO

Cuyamaca College is reaching out to those who are jobless and have green thumbs.

With the help of a \$400,000 grant, the Rancho San Diego campus is offering free courses to 100 unemployed and underemployed people who are looking for careers in landscaping and water

'History Alive' series speaker is retired cop

LEMON GROVE

(Ex3)

Rick Carlson — cofounder of the San Diego Police Museum, foreman of the county grand jury and a retired detective — will be the next speaker in the "History Alive" series presented monthly by the Lemon Grove Historical Society. GOVERNMENT & POLITICS

CITY WEBSITE TRACKS CAMPAIGN FINANCING

SAN DIEGO

Want to know how much is being raised for campaigns in the city of San Diego but don't want to pour through hundreds of pages of documents?

The city's Ethics Commission has launched a new website it plans to update throughout the election season that tracks the finances of each campaign, from City Council candidates to Proposition D, the proposed sales tax

raised quickly on both sides of the sales tax debate. In less than two months, the Yes on D campaign has collected about \$168,000, including \$100,000 and \$50,000 respectively from the city's fire and police unions.

The No on D campaign raised nearly \$147,000, including roughly \$35,000 each from two business groups — the Lincoln Club of San Diego County and the San Diego Restaurant and mer.

SWINE FLU

CONTINUED FROM A1

CDC bracing for flood of side-effect reports

reports per day from doctors and patients. In previous years, the typical daily count was 150.

"It's important for people to know that we are actively looking" for potential problems, said Dr. Anne Schuchat, director of the CDC Influenza Division.

San Diego County's health officials said the child who died from an H1N1 infection was a 5-year-old girl who attended Howard Pence Elementary School in Otay Mesa.

The patient, who was otherwise healthy, experienced flu symptoms for two days before coming to Rady Children's Hospital in San Diego late Friday. She collapsed in the emergency room and suffered heart failure early Saturday morning.

She was the 82nd child to die from the disease in the United States.

Immunologists aren't expecting major adverse reactions from the vaccine for swine flui, partly because none showed up in clinical testing on more than 3,000 people this sum-

But they won't know for sure until the shots have been given to large populations. Some complications might only appear in one of every 100,000 people receiving inoculations.

Officials at the CDC are bracing for a flood of side-effect reports from individuals inclined to blame H1N1 vaccinations for almost any medical complication. Among their biggest challenges will be separating normally occurring health problems from those that could be linked to inoculation.

Members of the CDC surveillance team will look for unusual patterns, said Dr. Jane Gidudu, acting head of the team. They will immediately flag and investigate reports of serious reactions, she said.

The team has reviewed 11 cases of minor side effects and one serious report that involved a 29-year-old woman from Minnesota who developed a flu-like illness after getting the vaccine.

Additionally, the CDC has asked neurologists to report new cases of Guillain-Barré syndrome, a rare nerve disorder that was associated with the last nationwide swine flu vaccination campaign in 1976.

The disease, which can cause paralysis and death, surfaced in several hundred people who received a shot that year. More than 30 of them died.

Scientists were never able to directly link the vaccine to the syndrome and the problem hasn't resurfaced since, even as hundreds of millions of seasonal flu shots have been administered.

On the testing front, the National Institutes of Health has launched a series of clinical trials to determine whether it's safe to give higher doses of H1N1 vaccine to pregnant women, asthmatics and children with HIV. All three groups have a higher risk of a poor immune-system response to the inoculation.

UCSD Medical Center is participating in the of pregnant women.

s week, the CDC started shipping the atch of 200,000 swine flu shots to clinics, rs' offices, drugstores and other regis-



Dr. Wilma Wooten, San Diego County's public health officer, spoke at a news conference yesterday. Nelvin C. Cepeda / Union-Tribune

ONLINE RESOURCES

- For doctors and patients to report reactions to the HINI vaccine, go to vaers.hhs.gov/index.
- For lists of flu shot clinics in the county, go to sdiz.org/flu/index.html. People also can call the 211 phone service.
- For a comprehensive guide to influenza, go to uniontrib.com/more/fluprep.

about 20,000 of the doses, said Dr. Dean Sidelinger, the county's deputy public health officer.

.......

Those shipments could arrive by the end of the week, said Ken August, a spokesman for the state Department of Public Health.

The federal government has ordered 250 million doses of swine flu shots. Typically, fewer than 100 million Americans seek seasonal flu shots each year.

Registered vaccinators in San Diego County have ordered 410,900 doses so far, Sidelinger said

Vaccination clinics could open at many local schools in November — once the flow of supplies becomes large enough to support large-scale operations, he said. Some campuses will give the shots during school hours to students and staff, while others will hold night clinics for people in nearby communities.

Dr. Mark Sawyer understands why some people might hesitate to get inoculated.

"We are creating a flu vaccine at a time when we don't normally create one, but it's just the timing," said Sawyer, a pediatric infectious disease specialist at Rady Children's Hospital and a faculty member for the UCSD School of Medicine. "There is nothing about this vaccine that is experimental or rushed."

Dr. Josef Zwass, co-chair of the immunization task force for Kaiser Permanente in San Diego County, plans to get vaccinated as soon as possible. "I'm one of those people who hates shots," he said. "I hated them as a child, and I still have to sit down and slow my breathing. But I will get it."

A segment of the public will remain unconvinced that the H1N1 vaccine is safe, said Dr. Francesca Torriani, medical director for infection prevention at UCSD Medical Center.

"There are some people who feel that this has been an engineered virus," she said. "For them, there's always the possibility of a conspiracy."

Those who don't get vaccinated not only increase their own risk of falling ill, but also reduce the overall ability of inoculations to limit the spread of swine flu, Torriani said.

"If they don't get the disease, they will be



Arthur Cashin, the director of floor operations 10,000" cap, while holding the 2009 version, at

MARKETS CONTINUED FROM AT

Investors expect growth to be slow, bumpy

ward move is a good indicator that the economy is on the mend. "Changes in the stock market often lead the economy by six months or so, so it could be an indicator of future growth," he said.

On the other hand, the market can be speciacularly wrong, as when stocks surged to all-time highs in October 2007, just two months before the country entered one of its worst recessions.

In yesterday's trading, the Dow jumped 144.80 points, or 1.47 percent, to close at 10,015.86, its highest point since October 2008. Since hitting a 12 year low of 6,547.05 in March, the Dow has skyrocketed 53 percent — one of the most dramatic rises in the history of the market.

The broad-based Standard & Poor's 500 yesterday rose 18.8 points, or 1.75 percent, to 1,092.02. The tech-heavy Nasdaq composite index grew by 32.34 points, or 1.51 percent, to 2,172.23.

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FLU SHOT CLINIC



TO RECEIVE A FLU SHOT YOU MUST:

- ☐ Meet a minimum age requirement. *If under 18 years of age, please see management.
- ☐ Not had an anaphylactic-type reaction to latex.
- □ Not have an allergy to chicken eggs and/or egg products.
- □ Not have an allergy to Thimerosal (used as a preservative in vaccines).
- ☐ Not be exhibiting symptoms other than mild coughing, runny nose, and/or diarrhea.
- □ Not have a history of Guillain-Barré Syndrome.
- □ Not had a serious reaction after receiving a prior influenza and/or pneumonia vaccination.
- ☐ Meet any CDC eligibility requirements required at the date of service.

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Ex5

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news for us on their rapath President xecutive Scott The bad news

pring of 2010, delivered the of the Phase 1 zer officials indirere considering deal.

they were still the finish line, cutives hedged They continued scout over anner at a restaurant in San Francisco.

Lpath took on the code name "Lexington" in negotiation documents drafted by Pfizer, Pancoast said.

The talks were intense and often lasted late into the night, he said. The outcome of the work had the potential to catapult the San Diego company into a new level of success or sink it.

"There were a lot of emotions," Pancoast said.

On Dec. 16, the companies signed the final agreement that gave Lpath a \$14 million upfront payment and up to \$497.5 million in future

velopment budgets in the face of shrinking drug sales from patent expirations and competition from generic brands.

In 2009, six biotechnology companies in San Diego signed partnerships worth up to \$1.3 billion. In 2010, local drug developers signed 15 deals worth up to \$6.3 billion.

A partnership typically delivers a modest upfront payment — often in the tens of millions of dollars — to a biotechnology company to pay for clinical trials. The rest of the money is deliv-

Pharma hold back investments until experimental therapies have shown some promise in midstage human trials and cherry-pick the best-looking candidates, Rastetter said.

"It becomes more cost-effective for them to pay up to a single company" through a licensing partnership, he said.

In more recent years, the process has become a two-way street of sorts as an increasing number of biotechs have licensed experimental therapeutic molecules from global drug jected Idec's pitches, said Rastetter, who headed the company at the time.

However, Idec had found an ally in David Ebersman, a New York stock analyst who later pitched Rituxan to Genentech when he was hired by the drug company.

Rituxan was approved by the FDA in 1997. By 2008, worldwide sales of the drug had topped \$8 billion annually.

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THE STREET

:o pay \$1.2B ical Data

Laboratories Inc. nost in 10 months

over investor concerns that its \$1.2 billion purchase of Clinical Data Inc. won't add to earnings in time to offset losses from patent expirations on Forest's biggest drug.

Forest agreed to pay \$30 a share in cash, a 12 percent discount from Clinical Data's last closing price, to gain the new antidepressant Viibryd, the companies said Tuesday in a statement. New York-based Forest will pay an additional \$6 a share if the drug meets certain sales goals and said it expects the purchase to add to earnings no earlier than fiscal 2014.

Forest has been looking to license new drugs to replace Lexapro, an antidepressant that accounts for 56 percent of the company's sales and is set to lose patent protection next year.

Forest's goal of leveraging its existing sales force to turn Viibryd into a product with more than \$1 billion in annual sales isn't realistic in a market dominated by generic competition, said David Amsellem, an analyst at Piper Jaffray & Co.

"As a general rule, I think the days of the blockbuster antidepressant are largely behind us," Amsellem said.

Forest fell \$1.43, or 4.2 percent, to close at \$32.90.

BLOOMBERG NEWS

SUPREME COURT TOSSES SUIT LINKING VACCINES, SEIZURES

Ruling cites vaccine court, which had rejected parents' claims

MARK SHERMAN . ASSOCIATED PRESS

WASHINGTON

The Supreme Court closed the courthouse door Tuesday to parents who want to sue drugmakers over claims that their children developed autism and other serious health problems from vaccines. The ruling was a stinging defeat for families dissatisfied with how they fared before a special no-fault vaccine court.

The court voted 6-2 against a couple who sued the drugmaker Wyeth in Pennsylvania state court for health problems they say their daughter, now 19, suffered from a vaccine she received in infancy.

Justice Antonin Scalia, writing for the court, said Congress set up a special vaccine court in 1986 to handle such claims as a way to provide compensation to injured children without driving drug manufacturers from the vaccine market. The idea, he said, was to create a system that spares the drug companies the costs of defending themselves against parents' lawsuits.

Justices Ruth Bader Ginsburg and Sonia Sotomayor dissented. Scalia's opinion was the latest legal setback for parents who felt they got too little or nothing at all from the vaccine court.

Such was the case for Robalee and Russell Bruesewitz of Pittsburgh, who filed their lawsuit after the vaccine court rejected their claims for compensation. According to the lawsuit, their daughter, Hannah,

was a healthy infant until she received the diphtheria, tetanus and pertussis vaccine in April 1992. The vaccine was made by Wyeth, now owned by Pfizer.

Within hours of getting the DPT shot, the baby suffered a series of debilitating seizures. Hannah continues to suffer from residual seizure disorder, the lawsuit said.

A federal trial judge and the 3rd U.S. Circuit Court of Appeals ruled in favor of Wyeth. Indeed, state and federal appeals courts have almost always sided with the vaccine manufacturer in preventing the lawsuits from going forward.

Scalia confirmed that outcome Tuesday. He said that when a vaccine is properly prepared and is accompanied by proper directions and warnings, lawsuits over its side effects are not allowed under the 1986 law.

The American Academy of Pediatrics, representing more than 60,000 doctors, praised the decision. "Childhood vaccines are among the greatest medical breakthroughs of the last century," said Dr. Marion Burton, the group's president. "Today's Supreme Court decision protects children by strengthening our national immunization system."

The vaccine court has paid out more than \$1.9 billion to more than 2,500 people who claimed a connection between a vaccine and serious health problems.

Justice Elena Kagan recused herself from the case because she had worked on it while serving in the Justice Department.





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Feds checking post-vaccine seizures in young kids January 20, 2011 2:38 PM EST

ATLANTA (AP) — Government officials are investigating an apparent increase in fever-related seizures in young children after they got a flu shot.

The U.S. Food and Drug Administration on Thursday said there have been reports of 36 seizures this flu season in children ages 6 months through 2 years. All the seizures occurred within one day after the youngsters got a vaccine called Fluzone, which is made specifically for younger children.

Ten of the children were hospitalized, but all recovered.

The maker of the flu shot says there's no clear link between the vaccine and seizures, and they may have been coincidental.

Online:

FDA notice: http://tinyurl.com/FDAnotice

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U.S. Department of Health & Human Services

FD/ U.S. Food and Drug Administration

Home > Vaccines, Blood & Biologics > Safety & Availability (Biologics) > Vaccine Safety & Availability

Vaccines, Blood & Biologics

Fluzone Vaccine Safety

FDA and CDC Update on Fluzone Influenza Vaccine and VAERS Reports of Febrile Seizures in Children January 20, 2011

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) routinely monitor the safety of all U.S. vaccines by using several vaccine safety surveillance systems, including the Vaccine Adverse Event Reporting System (VAERS)¹. VAERS collects and analyzes information from reported adverse events (health problems or possible side effects) that occur after vaccination.

FDA and CDC have recently detected an increase in the number of reports to VAERS of febrile seizures following vaccination with Fluzone (trivalent inactivated influenza vaccine or TIV, manufactured by Sanofi Pasteur, Inc.). Fluzone is the only influenza vaccine recommended for use for the 2010-2011 flu season in infants and children 6-23 months of age. These reported febrile seizures have primarily been seen in children younger than 2 years of age. Data from VAERS are preliminary and serve as a sign or indication that further investigation is warranted. Further investigations are under way to assess whether there could be an association between influenza vaccination and febrile seizures, or if other factors could be involved. FDA and CDC have seen no increase in VAERS reports of febrile seizures in people older than 2 years of age following vaccination with TIV, and no increase after live attenuated influenza vaccine (FluMist, the nasal spray vaccine). In the cases reported, all children recovered and no lasting effects have been seen. Recommendations for the use of flu vaccine in children have not changed.

FDA and CDC will continue to conduct studies and provide additional information to the public and health care providers as it becomes available.

Information on Febrile Seizures

Febrile means "relating to a fever" or an unusually high body temperature. In some children, having a fever can cause a seizure. Although febrile seizures can be frightening for the child's caregivers, nearly all children who have a febrile seizure recover quickly and have no long term effects. Febrile seizures may occur with any common childhood illnesses that may cause fever, such as ear infections, colds, influenza and other viral infections, and they sometimes happen after vaccination. With regard to influenza infection, one study estimated that seizures occur in 1% of children under 5 years of age with laboratory-confirmed influenza and 9% of children who are hospitalized due to influenza virus infection.[1]

Approximately 1 in 25 (4%) young children will have at least one febrile seizure in their lifetime usually between 6 months and 5 years of age with the peak age between 14 and 18 months of age.

Parents and caregivers should contact their child's health care provider if they have any questions or concerns.

About Influenza and Influenza Vaccination

The risk of severe influenza illness is higher among young children, especially children under 2 years of age. Approximately 9 out of 10,000 children 6-23 months of age require hospitalization each season for reasons related to influenza. Flu vaccine is the best way to protect against becoming ill with the flu.

Recommendations for the use of flu vaccine in children have not changed. CDC recommends² that all persons ages 6 months and older receive a flu vaccine each year.

FDA and CDC Actions

FDA and CDC are conducting further analyses to investigate this preliminary finding in VAERS and will provide additional information as it becomes available. FDA is also working closely with the manufacturer to obtain additional information and investigate the situation further.

[1] Poehling KA, Edwards KM, Weinberg GA, Szilaglyi P, Staat MA, Iwane MK, et al. The underrecognized burden of influenza in young children. N Engl J Med. 2006 Jul 6;355(1):31-40.

Links on this page:

- 1. http://vaers.hhs.gov/index
- 2. http://www.cdc.gov/flu/professionals/acip/recommendations.htm



III Taccinics not

harmful to kids

Autism not part of ills examined by researchers

By Alicia Chang ASSOCIATED PRESS

LOS ANGELES — A mercury-based preservative once used in many vaccines does not raise the risk of neurological problems in children, concludes a large federal study that researchers say should reassure parents about the safety of shots their kids received a decade or more ago.

However, the study did not examine autism, the developmental disorder that some critics blame on vaccines. A separate study due out in a year will look at that issue, said scientists at the federal Centers for Disease Control and Prevention, who led the latest analysis and published results in today's New England Journal of Medicine.

They found no clear link between early exposure to the preservative thimerosal and problems with brain function and behavior in children ages 7 to 10. The results are in line with past research that found no connection between vaccines and neurological problems or autism.

Thimerosal has not been used in childhood vaccines since 2001, though it is still in some flu shots. The new findings apply to children immunized before then, or exposed to the preservative through shots their mothers received while pregnant. Thimerosal was put in vaccines to prevent contamination from bacteria.

Some doctors say the CDC study should reassure parents worried about the safety of vaccines.

"It's good news for families," said Dr. Michael Goldstein, vice president of the American Academy of Neurology, who works in private practice in Salt Lake City. "There's no evidence that these vaccines have caused injury."

The study involved 1,047 children who were exposed to

varying levels of thimerosal while in the womb or after birth in the 1990s. The children belonged to four health maintenance organizations that are part of a federal project to study the side effects of vaccines. Their mercury exposure was determined through medical and immunization records and interviews with parents.

Each child was tested for speech and language skills, motor coordination and intelligence. Parents, teachers and trained specialists also rated stuttering, attention span and tic disorders such as head shaking, eye blinking and neck jerking. A total of 42 neurological problems were analyzed.

On balance, researchers did not find a consistent pattern between increasing thimerosal exposure and the risk of these problems. However, they said one finding merited further study: Boys exposed to higher mercury levels seemed to have more tic problems — a link seen in previous research.

"The doses of mercury that children were exposed to because of immunization doesn't cause neuropsychological damage," said Dr. Bruce H. Cohen, a Cleveland Clinic pediatric neurology specialist who had no role in the study.

The CDC study was reviewed by an independent panel of scientists and statisticians who oversaw its design, reviewed results and contributed to writing the report.

The panel included one vaccine opponent — Sallie Bernard, executive director of the consumer group SafeMinds. Though Bernard had a role in planning the study, she asked to be listed as a "dissenting member" because she disagreed with the study's conclusions.

The research was led by William Thompson, a CDC epidemiologist who once worked for vaccine maker Merck & Co. Four other researchers have received fees from drug companies and one has served as a consultant to a CDC committee on immunization.

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