



IN TIME

FDA DESIGNATES CHILDHOOD PNEUMOCOCCAL VACCINE FOR FAST TRACK DEVELOPMENT

-Madison, NJ, March 11, 1999

Wyeth Lederle Vaccines investigation of a seven-valent pneumococcal conjugate vaccine for the prevention of invasive pneumococcal disease in children has been designated for the "fast-track" development program by the U.S. Food and Drug Administration (FDA).

The fast-track program is designed to facilitate development and expedite review of new drugs or biologicals that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Under the fast-track rules, the FDA has agreed to let the company file a "rolling" Product License Application (PLA). The "rolling" application allows the FDA to evaluate individual components of a licensure application for approval before the entire application is submitted. Pneumococcus bacteria (also known as Streptococcus pneumonia) is a cause of several illnesses including bacterial meningitis (brain and spinal cord infection), a potentially fatal condition that leaves many children with life-long disabilities such as mental retardation seizures, deafness, or impaired vision. It is also a major cause of bacteremia (bloodstream infection), pneumonia, sinusitis, and otitis media (ear infection)

Each year in the U.S., pneumococcal disease accounts for an estimated 3,000 cases of bacterial meningitis, 50,000 cases of bacteremia, 500,000 cases of pneumonia, and seven million cases of otitis media, among all age groups. Worldwide, pneumococcus is the leading cause of bacterial pneumonia and meningitis in both adults and children.

Earlier this year, data from a major clinical trial conducted by Kaiser Permanente, involving 38,000 children at 23 sites in California, showed that the vaccine was highly effective against

invasive pneumococcal disease caused by seven prevalent serotypes (strains) of the bacteria. Those serotypes in the vaccine are also commonly associated with antibiotic resistance. ■

NEW VACCINE INFORMATION STATEMENTS AVAILABLE

-February 23, 1999

Six new Vaccine Information Statements (VIS) have been completed and are available for distribution. They include: three new VIS's for vaccines recently added to the vaccine injury table (hepatitis B, Hib, and varicella), one revised because of a new ACIP statement (MMR), one that was revised because of recent changes in ACIP recommendations (polio) and one brand new vaccine recently added to the recommended childhood immunization schedule (rotavirus). They are available on both the Immunization Action Coalition's website (immunize.org) and the National Immunization Program's website (cdc.gov/nip) Need a refresher course on what to do with VIS's? Some of the legal requirements concerning their use are as follows:

- 1 Before a vaccine is administered to anyone (this includes adults!) you must give the patient or the parent/guardian a copy of the VIS available for that vaccine. Make sure you give your patient time to read the VIS prior to the administration of the vaccine.
- 2 You must record in your patient's chart the date the VIS was given.
- 3 You must also record on the patient's chart the publication date of the VIS, a date which appears on the bottom of each VIS.

Effective June 1, 1999, the most current VIS sheets should have the following publication dates:

Hib	12/16/98
MMR	12/16/98
Hepatitis B	12/16/98
Varicella	12/16/98
Polio	2/1/99
DTaP	8/15/97
Td	6/10/94
Rotavirus	12/1/98 (interim). ■

NEW INFORMATION ON ROTAVIRUS

On March 19, 1999, CDC released the Advisory Committee on Immunization Practice's recommendations "Rotavirus Vaccine for the Prevention of Rotavirus Gastroenteritis Among Children for Use in Infants." Published in the MMWR, Recommendations and Reports, Vol. 48, No. RR-2, these recommendations concern the use of an oral, live rotavirus vaccine licensed by the Food and Drug Administration on August 31, 1998. The ACIP's summary statement is as follows:

"Rotavirus affects virtually all children during the first 5 years of life in both developed and developing countries, and rotavirus infection is the most common cause of severe gastroenteritis in the United States and worldwide. In the United States, rotavirus is a common cause of hospitalizations, emergency room visits, and outpatient clinic visits, and it is responsible for considerable health care costs. Because of this large burden of disease, several rotavirus vaccines have been developed. One of these vaccines an oral, live, tetravalent, rhesus-bases rotavirus vaccine (RRV-TV) was found to be safe and efficacious in clinical trials among children in North America, South America, and Europe and on the basis of these studies is now licensed for use among infants in the U.S."

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"The vaccine is an oral, live preparation that should be administered to infants between the ages of 6 weeks and 1 year. The recommended schedule is a three dose series, with doses to be administered at ages 2, 4, and 6 months. The first dose may be administered from the ages of 6 weeks to 6 months; subsequent doses should be administered with a minimum interval of 3 weeks between doses. The first dose should not be administered to children aged greater than or equal to 7 months because of an increased rate of febrile reactions after the first dose among older infants. Second and third doses should be administered before the first birthday. Implementation of these recommendations in the U.S. should prevent most physician visits for rotavirus gastroenteritis and at least two-thirds of hospitalizations and deaths related to rotavirus." ■

PUBLIC HEARING HELD SCHOOL, DAYCARE ENTRY REQUIREMENTS

The school and day care immunization regulations are undergoing several important changes to bring them up to date with current national immunization recommendations. State statutes (Connecticut General Statutes Sections 19a-7f and 10-204a) require CT school and daycare immunization requirements to be consistent with the national ones. There are a number of proposed changes to day care and school entry immunization requirements. Among them are two requirements for varicella vaccine which had been proposed to go in effect in August 1999. One is a requirement that all children born 1/1/97 or more recently be immunized prior to entry into licensed day care. The other requirement that all children without a history of chickenpox be immunized prior to 7th grade entry. A public comment period, culminating in a public hearing on March 18, was part of the regulatory process to review the proposed changes. Although most of the comments received were in support of the proposed varicella vaccine requirements, there was a plea from school physicians and nurses that the implementation of the 7th grade entry requirement be postponed until August 2000. Many children who will be entering 7th grade in August 1999 have already had their health assessment and it would be costly to go back and add varicella to it. In the wake of the public hearing, the proposed regulations will be revised to change the implementation date of the day care entry requirements to January 2000 and the implementation of the 7th grade entry requirement to August 2000. For children who have a history of chickenpox, the proposed regulations will still call for a physician note that the child has a history of chickenpox with month and year of chickenpox noted.

The proposed changes include:

DAY CARE

Varicella added to the vaccination requirements for children born 1/1/97 or after beginning in January 2000.

SCHOOL

Varicella added to the vaccination requirements for children born 1/1/97 entering KG-1st grade and for adolescents entering the 7th grade beginning in August of 2000.

Hepatitis B required for 7th graders beginning in August of 2000 and 8th graders beginning in August of 2001. The 7th graders must show proof of at least one dose of Hep B upon entry and by the time they enter 8th grade must have the whole series completed (3 doses Hep B vaccine)

Measles vaccination required for children entering KG-1st grade beginning in August of 2000. Children entering KG-1st grade will be required to have 2 doses of measles containing vaccine upon entry.

DTaP/Polio modification

The 4th dose of DTaP and 3rd dose of polio vaccine will be required before school entry. At least one of the doses for both DTaP and polio must be given on or after the fourth birthday but prior to school entry.

ROTAVIRUS ADDED TO REPORTABLE SIGNIFICANT FINDING LIST FOR 1999

Rotavirus is the leading cause of severe childhood diarrhea in the U.S. and is responsible for up to 600 hospitalizations per year in children 0-4 years of age in CT. On August 31, 1998, the Food and Drug Administration approved the Wyeth-Lederle Rotavirus vaccine Rotashield, making rotavirus a vaccine preventable disease. The vaccine is likely to be distributed in Connecticut sometime this summer through the state Vaccines for Children Program. To monitor the burden, epidemiology, and potential preventability of confirmed rotavirus infection in the vaccine era, rotavirus gastroenteritis has been added to the Department of Public Health's list of Reportable Diseases and Laboratory Findings.

NATIONAL IMMUNIZATION PROGRAM RELEASES NATIONAL IMMUNIZATION SURVEY DATA

The National Immunization Survey (NIS) is an ongoing survey that provides national estimates of vaccination coverage among children aged 19-35 months based on data for the most recent 12 months for each of the 50 states, the District of Columbia, and 27 other selected urban areas. CDC initiated the NIS in April of 1994 to monitor vaccination coverage levels as part of the Childhood Immunization Initiative (CII), a national strategy to ensure high vaccination coverage of children during the first 2 years of life. The current report represents NIS findings for July 97-June 98.

NIS uses a quarterly random-digit-dialed sample of telephone numbers for each survey area to collect vaccination information for all eligible children. For completeness and verification, vaccination data are also requested from the vaccination providers. Provider data are weighted to represent the entire group of children surveyed and to account for household non-response, birthrate data and the lower vaccination coverage levels among children in households without telephones.

According to the results of the survey, Connecticut and Massachusetts ranked 3rd nationally with an 86% immunization coverage rate (4 DTP, 3 Polio and 1 MMR) for two old year children. Alabama and Vermont were ranked 1st at 88% and Maine ranked 2nd at 87%.

ANNOUNCEMENT!!!

**CDC'S SATELLITE BROADCAST:
IMMUNIZATION UPDATE**

WILL BE ON SEPTEMBER 16, 1999

9:00 AM TO 11:30 AM AND

12:00 PM TO 2:30 PM

*Call the State Immunization Program at (860) 509-7929
for the location nearest you*



REGISTRY UPDATE



Representatives from ACS Government Solutions Group were at 410 Capitol Ave. March 22-26 to provide training on the CT Immunization Registry and Tracking System to Immunization Program Staff. Modifications to the registry will continue to be made and ACS will return for further training sessions in the next few months. The registry is expected to roll out statewide throughout 1999-2000.

IAP Coordinators are now contacting immunization providers in their respective areas to announce the deployment of the registry and to determine which practices will be going on-line. By state law, all immunization providers will be required to report immunization histories to CIRTSS either by fax or on-line. Those providers in non-IAP areas will be contacted by CIRTSS personnel.

April 18th-24th is: National Infant Immunization Week

ACTIVITIES PLANNED FOR CONNECTICUT

BRIDGEPORT:

A week long children's health fair during the week of April 19-23, 1999 will be held at several locations in the area including the Bridgeport Health Department, WIC, the North End clinic and East Side Clinic. The fair will run from 9 AM to Noon each day. Immunization will be promoted.

DANBURY:

A special varicella vaccine clinic will be held during the week of April 18-24, 1999. Location and times to be determined. Call the Danbury VNA for details at (203) 792-4120.

MERIDEN:

Volunteers will represent the health department and the Immunization Program at a Daffodil Festival at Hubbard Park in Meriden on April 24th from 11 AM to 5 PM and on April 25th from 12 PM to 5 PM. Immunization awareness and education will be presented throughout both days. The festival is an annual event consisting of many activities including health promotion, crafts, a food tent, a carnival of rides, music and a parade.

MIDDLETOWN:

A children's health fair will be held at the Westbrook YMCA on April 24th from 12 PM to 4 PM where there will be immunization materials distributed.

NAUGATUCK VALLEY:

A Family Health & Resource Fair will be held on April 24, 1999 from 10 AM to 3 PM at Warsaw Park, Pulaski Highway, Ansonia. It will feature a teddy bear clinic to show children using their bears how to be immunized while explaining the importance of immunization to the parents. There will also be free gifts, health screenings, balloon art, face painting, Sparkles the Clown, and many demonstrations from child health and safety organizations.

NEW BRITAIN:

A free immunization clinic will be held on April 22, 1999 at the New Britain Community Health Center from 4 PM to 8 PM. All vaccines will be offered, and it will be open to the public.

The New Britain Immunization Program's web site will be unveiled. Web users can access the site containing much useful immunization information at www.dgnc.com/nbhealth/immunization

The New Britain Immunization Program will host an "Immunization Day" on opening weekend for the New Britain Rock Cats baseball team. The event will take place on April 18, 1999 at 2 PM. All those parents who bring their child's immunization record card will receive a free ticket for their child with a paid adult ticket.

NEW HAVEN:

There will be a Mayor's Youth Exposition on April 24th, 1999 from 12:00 PM to 5:00 PM at the New Haven Coliseum where immunization material will be distributed and promoted.

NEW LONDON:

The annual Kids Care Fair will be held April 17, 1999 from 10:00 AM to 2:00 PM at the New London mall. There will be an immunization booth with all current educational information as well as the New London Immunization Coordinator to answer questions. In addition, displays by the police and fire departments, and entertainment by the town clown will add to the fun. This event will be advertised by the local radio station Q105.

NORTH EAST DISTRICT:

A radio interview with a local pediatrician will be broadcast on April 20, 1999 on WINY Radio at 7 AM. They will be discussing the current issues surrounding childhood immunization.

NORWALK:

During a car seat safety check held at Norwalk Health Department on April 24, 1999 from 10 AM to 12 PM, immunization information will be given to all parents. A free prize will be given to each parent who brings a copy of their child's immunization record.

STAMFORD:

A Kids Health Fair is planned for April 24, 1999 from 9 AM to 1 PM at the Stamford School Readiness Program on Hillendale Avenue in Stamford. "Chicken Pox", the school nurse dressed as a chicken, will go from class to class passing out red stickers to the children, asking them to place them anywhere on the face, hands, etc. where chicken pox may show up. Children in the school will also participate in an immunization coloring contest a week before the fair. Participating children will be given a "Meanie Baby" called Chicken Pox, and all art work will be displayed in the lobby of the government Center in Stamford. The health fair itself will focus on health education, health promotion, and accident prevention. The Stamford Immunization Program will offer the chicken pox vaccine to Vaccine For Children-eligible children.

TORRINGTON:

The fourth annual "Be Wise: Immunize" children's immunization fair will take place on Friday, April 23, 1999 from 10 AM to 4 PM at Brooker Memorial, 157 Litchfield Street in Torrington. Free shots will be given as well as entertainment including animals, clowns, and face painting. Refreshments will be served.

WATERBURY:

An "Immunization Awareness Day" has been planned for April 20 and 22, 1999 at the McDonald's on Chase Ave. in Waterbury. The Waterbury Immunization Program will speak to parents regarding the importance of immunization and will provide free immunization coloring books and crayons, and baby bibs with the Immunization Program's phone number. McDonald's will provide parents with food coupons and balloons.

WINDHAM:

Pins will be worn by over 200 health care providers and community health organizations throughout the area promoting immunization. The pins say, "Love Them, Immunize Them".

WEST HAVEN:

Baby bibs promoting immunization will be given out at the West Haven Community Health Center at all well child visits during the week of April 18-24, 1999.

HARTFORD:

All hospitals in Hartford, as well as several others throughout the state will emphasize and promote immunization in the Emergency Room.

♥ ASK THE EXPERTS! ♥

Editor's note: This information was provided by epidemiologists from the Connecticut Department of Public Health's Immunization Program and the Immunization Action Coalition.

♥ **What does chickenpox have to do with shingles?**

In 15-20% of persons who get chickenpox, the chickenpox virus will remain in the body near the spinal cord. As a person ages or if their immune system becomes weaker, the virus will reactivate and come back in the form of shingles. Shingles usually occurs in older adults, but some children and young adults will also get shingles.

♥ **What are the symptoms of chickenpox and shingles?**

In most cases, chickenpox is a mild disease. Early symptoms may include aching, fever, and sore throat. Then chickenpox turns into a very itchy skin rash that can develop into as many as 400-500 open sores before scabbing over! These sores can become infected. Shingles is usually a localized and very painful form of chickenpox. It is painful because the virus especially affects the roots of your nerves in addition to causing a local rash and fever. In some people the virus will spread throughout their body.

♥ **How serious are chickenpox and shingles?**

If you think chickenpox is always a mild disease, you need to know more. While most people recover after one week, some do not. Every year in the United States, around 10,000 people are hospitalized and up to 100 people die from complications of chickenpox alone. Shingles can be even more severe. Every year in the U.S., more than 30,000 people are hospitalized and more than 1,000 people die from complications of shingles. Chickenpox is not a disease to take lightly.

♥ **Who should get chickenpox vaccine?**

Children over the age of 12 months who have never had chickenpox should get vaccinated against this disease. Young children are not the only ones who need chickenpox vaccine. If teens or adults get chickenpox, they have a greater risk of serious complications. If you or your teenager haven't had chickenpox, talk to your doctor or nurse about getting vaccinated.

♥ **How safe is chickenpox vaccine?**

Chickenpox vaccine is safe and effective. This vaccine has been used since the early 1970's in several areas of the world and studied in the United States since the early 1980's. It is approved for general use in many countries of the world, including the U.S. In the U.S. alone, more than 10

million persons have already been vaccinated. Although the vaccine was specifically designed to prevent chickenpox, preliminary data suggest that the vaccine is also effective in preventing shingles.

♥ **Does the vaccine have side effects?**

The most common side effects are mild and may include pain and redness at the injection site. Mild fever and fussiness may also occur. Because the vaccine is a weak form of the chickenpox virus, a very mild case of chickenpox may develop in 1 of every 20 persons who get the vaccine.

♥ **Will chickenpox vaccine be required for entry into day care and school?**

Yes it will. Proposed changes to the Connecticut immunization law for entry into day care and school will require all children born on or after January 1, 1997 to be immunized against chickenpox. Also, beginning soon, all children entering seventh grade will need to show proof of immunization or have a doctor's note that says the doctor has reviewed the child's medical history and believes the child has already had chickenpox.

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH IMMUNIZATION PROGRAM MORBIDITY REPORT

Disease	1/1/99-4/6/99	Total 1998
Measles	0	0
Mumps	0	3
Rubella	0	29
CRS (Congenital Rubella Syndrome)	0	0
Diphtheria	0	0
Tetanus	0	0
Pertussis	5	49
Hib	0	2

IAP ON TIME SPRING '99

Publication of the Connecticut State Department of Public Health, Immunization Program



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