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Articles

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FDA approves acellular pertussis vaccine

By Debra Fleischman
Assistant Editor

The U.S. Food and Drug Administration (FDA) announced Dec. 17 it has approved the use of an acellular pertussis vaccine in the United States.

The acellular vaccine approved has been successfully used in Japan since 1981 to protect Japanese children 2 years of age or older against pertussis. The FDA approved the vaccine for use in the United States for only the fourth and fifth immunizations in the recommended series of five immunizations. The current whole-cell vaccine is recommended for the first three immunizations.

Currently, the Academy recommends pertussis immunization as a combined diphtheria-tetanus-pertussis (DTP) vaccine at ages 2 months, 4 months, and 6 months; at 15 months to 18 months; and a preschool booster between the ages of 4 years to 6 years.

The AAP Committee on Infectious Diseases last May recommended consideration of the introduction of acellular pertussis vaccine in the United States. The committee based its recommendation on evidence from epidemiologic experience in Japan, results of a Swedish trial and responses of 17- to 24-month-old recipients in a U.S. clinical trial. The recommendation was published as a Policy Statement in the May 1991 AAP News.

At press time, AAP officials had just learned of the FDA's approval. The AAP Committee on Infectious Diseases plans to issue a revised statement on the use of acellular pertussis vaccines in the near future.

Researchers have reported that side effects with current pertussis immunization, such as fever and redness at the injection site, occur less frequently with the use of acellular pertussis vaccines. The acellular vaccine is made from only part of the pertussis organism.

"The experience in Japan and Swedish trials have provided evidence that acellular vaccines can prevent pertussis with fewer local and systemic reactions," the May 1991 AAP Policy Statement notes.

Reported cases of pertussis declined in Japan as the acellular vaccines gained acceptance and vaccination rates increased, the policy statement notes. The committee also stated that because the severity of pertussis diminishes with increasing age, the benefits of acellular vaccines with fewer minor reactions outweigh uncertainties about their efficacy when given as booster doses after initial immunization in infancy.

Research is being conducted to determine if the acellular vaccine will be effective in preventing pertussis when used for primary immunization in early infancy, FDA officials say.

"We're hopeful it will be," U.S. Public Health Service Director James Mason, M.D., stated in a Dec. 17 news release. "In the meantime, no parents should delay getting their children's whooping cough vaccine or other immunizations and thus miss out on protection they need in their most vulnerable early years."

As many as 90 percent of non-immune household contacts acquire pertussis, according to the FDA. Since routine immunization against pertussis became common in the United States, the number of reported cases of disease and of deaths has declined from about 120,000 cases with 1,100 deaths in 1950 to an annual average in recent years of about 3,500 cases with 10 deaths, according to the FDA.

The FDA-approved pertussis vaccine component is produced by Takeda Chemical Industries Ltd. of Osaka, Japan. It will be combined with diphtheria and tetanus toxoids manufactured by Lederle Laboratories, of Wayne, N.J.

Lederle will be taking orders for the new vaccine immediately, spokesman Craig Engesser said. The vaccine will be available in mid-January. The vaccine will cost $155.60 for a 10-dose vial, which averages about $11 per dose. The $155.60 includes a $45.60 federal excise tax required by the government, Engesser said.

Lederle will distribute the product in the United States under the brand name Acel-Imune.

Copies of the May 1991 Policy Statement, "The Status of Acellular Pertussis Vaccines: Current Perspective," are available from the AAP Publications Office, 141 Northwest Point Blvd., PO Box 927, Elk Grove Village, IL 60009-0927; (800) 433-9016.

Message from the Executive Director

Dr. Strain announces plans for 1993 retirement

To the Members of the American Academy of Pediatrics:

All good things must come to an end. I've had the good fortune to serve as Executive Director of the Academy for the past five and a half years and it's nearing the time for me to step down. I've given notice to the Academy's Executive Board that I intend to retire June 30, 1993.

Through the years, I've had the opportunity to watch the Academy grow in numbers, programs and influence. I served as Colorado Chapter chairman in the late '60s, as alternate district chairman and district chairman for District VIII during the '70s and as president of the Academy in 1982-83. I've participated in Academy activities as a member, an elected official and finally as executive director. There is no organization that has done more to advance the cause of children's health in this country than the American Academy of Pediatrics. Continuing education of pediatricians, standard setting, research on systems of health care, establishing principles of child health care financing, public education and advocating for children at the state and federal levels have had a significant impact on the health of this nation's children.

Much of the success of the Academy lies with pediatricians who are engaged in patient care or are teaching in medical centers, or carrying out important research activities. These are the pediatricians who give their time to serve children by participating in Academy activities. The Academy couldn't begin to be as effective as it is without the volunteer efforts of our members.

Jerry Dallege

Dr. Strain: "I have no doubts the Academy will continue to prosper."

I'm very proud of the Academy. I'm proud to have been associated with it through the years. I'm proud of the Academy's accomplishments and what it has meant to children and pediatricians. I have no doubt that it will continue to grow and prosper and be an even more important organization in shaping the future of child health care in this country.

I've elected to write this letter to the members of the Academy at this time to give the search committee sufficient time to look for my replacement. The Committee has been appointed with Dr. Dan Shea serving as chairman.

Recruitment ads will appear in the pediatric journals and personal calls will be made. I urge you to contact Dr. Shea if you have someone you would like to recommend to the search committee. I'm confident that when the search is completed, a new Executive Director will be selected who will lead the Academy to even greater achievements in the years ahead.

Sincerely,

James E. Strain, MD
Executive Director