Vaccines Provide Effective Protection And FDA Makes Sure They Are Safe

Immunization saves lives— millions of them. In the United States, large-scale vaccination programs have wiped out smallpox and polio and have reduced measles, mumps, rubella, tetanus, diphtheria, *Haemophilus influenzae* meningitis, and whooping cough by 95 percent. Thanks to immunization, flu and pneumonia are much less of a scourge of the elderly and chronically ill. But vaccines, which contain weakened or killed disease-causing bacteria, viruses, or their components, have to be rigorously scrutinized for their effectiveness and safety. This vital task is an important part of the public health mission of the Food and Drug Administration.

Here are the principal protections of vaccine safety:

- The **designs of studies** for testing new vaccines must be approved by the FDA, which also supervises the integrity of most of the trials carried out in the United States.
- The **clinical trials** that establish the vaccines' safety and effectiveness are frequently very large—for example, the trial for Prevnar, a vaccine against invasive pneumococcal diseases, included almost 40,000 infants.
- Following the completion of the studies, **FDA scientists review** the resulting data, the proposed labeling, and the manufacturing protocols, and conduct their own tests of the product.
- **FDA inspectors** make certain that the manufacturing facility can properly produce the vaccine before it is licensed for marketing by the agency.
- When the vaccine is in production, the FDA requires the firm to **test samples** from each lot for safety, potency and purity, and carries out spot-testing of its own.

The FDA also cooperates with the Centers for Disease Control and Prevention (CDC) and other institutions in research to develop even safer vaccines. Since 1996, for example, the agency has licensed several whooping cough vaccines that contain only part of the disease-causing bacterium, and are associated with fewer side effects than the whole cell pertussis vaccines. In March 2001, the FDA approved a newly formulated version of an acellular pertussis vaccine that uses only a trace amount of the mercury-containing preservative thimerosal. In the United States, at present, all routinely administered pediatric vaccines are being produced in either thimerosal-reduced or thimerosal-free forms."

For more information, call 301-827-2000.

Adverse Event Reporting System

The FDA and the CDC jointly operate Vaccine Adverse Event Reporting System (VAERS) that receives 800 to 1,000 reports a month—mostly from physicians—of suspected adverse events associated with the use of vaccines. The FDA continuously reviews and evaluates these reports and monitors overall reporting patterns, as well as trends for individual vaccine lots. The VAERS data make an important contribution to vaccine safety. For example, following the licensure of RotaShield, a vaccine against rotavirus infection, VAERS began receiving reports of bowel obstruction in infants who had received the vaccine. The reports prompted a CDC recommendation that the RotaShield be further studied. Following a consultation with the FDA, the manufacturer withdrew the product from use.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Office of Public Affairs
5600 Fishers Lane
Rockville, MD 20857

Publication No. FS 02-6
(FDA Web site: www.fda.gov)
February 2002