

STATEMENT ON REPORTS OF FEBRILE SEIZURES IN INFANTS FOLLOWING INFLUENZA VACCINE ADMINISTRATION

Sanofi Pasteur has been notified by the U.S. Food and Drug Administration (FDA) of reports of febrile seizures in children 6 months through 23 months of age who had also received influenza vaccine. At this point no correlation between influenza vaccine and febrile seizures has been established. Adverse events after vaccination may be causally related to vaccine or may be coincidental.

Recommendations for the use of influenza vaccine in children have **not** changed. The Centers for Disease Control (CDC) recommends that all people 6 months of age and older receive the influenza vaccine each year. Parents or guardians of children who received an influenza vaccine do not need to take any action unless they believe their child experienced an adverse event following the vaccination. It is important that anyone who experiences an adverse reaction to vaccination notify their health care provider. Health care providers should report adverse events to the vaccine manufacturer as well as to VAERS.

Febrile seizures are fairly common in children. About 2 to 5 percent of children 6 months to 5 years of age will have at least one febrile seizure. Febrile seizures can occur with any condition that causes a fever, including typical childhood illnesses like a cold, the flu, an ear infection, or a rash illness. They are most common after infections, including those that can be prevented by vaccination. Febrile seizures can occur after vaccination, but this is uncommon.

These reports, which were received through the Vaccine Adverse Event Reporting System (VAERS), identified a potential safety signal. The signal represents a higher than expected number of reports of febrile seizures following influenza vaccination compared with historical data. The FDA is continuing to investigate these events to determine if the reported cases indicate that there is an actual increase in febrile seizures related to influenza vaccination.

Protecting the public's health and ensuring patient safety are Sanofi Pasteur's highest priorities. We take reports of adverse events very seriously. As a result, we closely investigate all adverse event reports we receive and continuously monitor our safety database. Reporting rates of febrile seizure after administration of our influenza vaccine have been stable for years even as distribution of the pediatric formulation has increased.

Sanofi Pasteur is working closely with FDA in the investigation of these events and will thoroughly assess all cases of febrile seizure and any other adverse experiences reported following administration of our vaccine.

One of the most important components of the U.S. vaccine safety monitoring system is the prompt reporting of suspected adverse events. Vaccine recipients, their parents, or guardians should be instructed to report any suspected adverse reaction to their health-care professional who should report these events to Sanofi Pasteur, 1-800-822-2463. All reports to Sanofi Pasteur are forwarded to VAERS. Direct reporting to VAERS is also encouraged. The toll-free number for VAERS forms and information is 1-800-822-7967. Reporting forms may also be obtained at the VAERS website at www.vaers.hhs.gov.