## The Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. Since 1990, VAERS has received over 123,000 reports, most of which describe mild side effects such as fever. Very rarely, people experience serious adverse events following immunization. By monitoring such events, VAERS can help to identify important new safety concerns.

## Reporting to VAERS

Who can file a VAERS report: Anyone can submit a VAERS report. Most reports are sent in by vaccine manufacturers (42%) and health care providers (30%). The rest are submitted by state immunization programs (12%), vaccine recipients or their parent/guardians (7%), and other sources (9%).

What adverse events should be reported: VAERS encourages the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. Report such events even if you are unsure whether a vaccine caused them.

The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination.

A copy of the Reportable Events Table can be found on the next page (F-2), or obtained by calling VAERS at 1-800-822-7967 or by downloading it from http://vaers.hhs.gov/pubs.htm.

**Filing a VAERS report:** Use a VAERS report form (see page F-4) to report any adverse event. You can get pre-addressed postage paid report forms by calling VAERS at 1-800-822-7967, or download a printable copy of the VAERS form from the following Internet sites:

- The VAERS Web site at http://vaers.hhs.gov/
- The Food and Drug Administration's Web site at www.fda.gov/cber/vaers/vaers.htm
- The Centers for Disease Control and Prevention Web site at www.cdc.gov/vaccines/ Instructions are included with the form. You may use a photocopy of the VAERS form to submit a report.

## For more information:

- Send e-mail inquiries to info@vaers.org
- Visit the VAERS Web site at: http://vaers.hhs.gov
- Call the toll-free VAERS information line at (800) 822-7967
- Fax inquiries to the toll-free information fax line at (877) 721-0366