

August 2004

Dear Health Care Provider:

As a health care professional involved with vaccinations, you can help to ensure the optimal safety of the U.S. immunization program by promptly and accurately reporting any significant adverse event that occurs following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

VAERS is the national program that monitors the safety of vaccines after they are licensed and is jointly administered by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). FDA and CDC analyze VAERS data to identify potential new vaccine safety concerns that may need further study. Additional information and results of analyses are available at <u>http://www.vaers.org</u>.

Reporting to VAERS is one of the Standards for Child and Adolescent Immunization Practices (<u>http://www.cdc.gov/nip/publications/pink/appendices/B/ped_standards.pdf</u>). The National Childhood Vaccine Injury Act of 1986 mandates that health care providers report specific adverse events that occur after vaccination. The events that require reporting to VAERS are listed in the Table of Reportable Events and can be found at <u>http://www.vaers.org/reportable.htm</u>. Providers are also encouraged to report adverse events that are not listed in the Table of Reportable Events.

Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

There are three ways to report to VAERS:

- 1) Online via a secure website at https://secure.vaers.org/VaersDataEntryintro.htm,
- 2) Fax a completed VAERS form to 877-721-0366, or
- 3) Mail a completed VAERS form to VAERS, P.O. Box 1100, Rockville, MD 20849-1100.

A VAERS form is included in this mailing and also may be downloaded from the VAERS web site at <u>http://www.vaers.org/pdf/vaers_form.pdf</u>. Alternatively, you may request a VAERS form by sending an email to <u>info@vaers.org</u>, by calling toll-free 800-822-7967, or by sending a faxed request to 877-721-0366.

For additional information on VAERS or vaccine safety, visit the VAERS website at <u>http://www.vaers.org</u> or call 800-822-7967.

Thank you in advance for your support of our nation's immunization programs. Together we can ensure that vaccines continue to be as safe and effective as possible.

Sincerely,

Stephen L. Cochi

Stephen L. Cochi, M.D., M.P.H. Acting Director National Immunization Program Centers for Disease Control and Prevention

Enclosure

The C Dec

Jesse L. Goodman, M.D., M.P.H. Director Center for Biologics Evaluation and Research Food and Drug Administration