FEAT DAILY NEWSLETTER Sacramento, California http://www.feat.org
"Healing Autism: No Finer a Cause on the Planet"

September 13, 2000

'Minimal Risk' FDA Conclusions On Chicken Pox Vaccine Challenged

Also: * Child MMR Vaccine Warning
* Late Events Calendar Additions

[From Barbara Loe Fisher of the National Vaccine Information Center.]
http://www.909shot.com

Calling the FDA report on adverse events associated with varicella zoster (chicken pox) vaccine published in today's Journal of the American Medical Association a "breakthrough" in the follow-up and public disclosure of reports made by doctors and parents to the Vaccine Adverse Event Reporting System (VAERS), the National Vaccine Information Center (NVIC) applauded public release of the VAERS data but challenged the authors' conclusions that the vaccine's risks are minimal.

"We have been getting reports from parents that their children are suffering high fevers, chicken pox lesions, shingles (herpes zoster), brain damage and dying after chicken pox vaccination, especially when the vaccine is given at the same time with MMR and other vaccines. This FDA report confirms our concern that the chicken pox vaccine may be more reactive than anticipated in individuals with both known and unknown biological high risk factors," Barbara Loe Fisher, president of NVIC.

In the VAERS data made public today, it was reported that VAERS had received 67.5 adverse event reports per 100,000 doses of chicken pox vaccine sold between March 1995 and July 1998 for a total of 6,574 reports. 82 percent of the adverse event cases occurred in individuals who received chicken pox vaccine only. Admitting that underreporting made the figures "highly variable fractions of actual event numbers," the authors revealed that approximately 4 percent of cases (about 1 in 33,000 doses) were serious, including shock, convulsions, encephalitis, thrombocytopenia and 14 deaths. The VAERS data has lead to the addition of 17 adverse events to the

manufacturer's product label since the vaccine was licensed for use in 1995, including secondary bacterial infections (cellulitis), secondary transmission (infection of close contacts), transverse myelitis, Guillain Barre syndrome and herpes zoster (shingles).

"We have been waiting for the FDA to follow-up on VAERS reports and then disclose and utilize the VAERS data to increase our knowledge about vaccine reactions and possible high risk factors. This is how parents and Congress expected the vaccine adverse event reporting system to be utilized when it was centralized under the National Childhood Vaccine Injury Act of 1986. However, the conclusions drawn by the authors do not match the substance of the data presented," said Fisher.

Based on today's published report on chicken pox vaccine, the National Vaccine Information Center is calling for a halt to simultaneous administration of chicken pox vaccine in combination with other vaccines, particularly MMR, until the vaccine can be further evaluated for short and long term reactivity, particularly in immune compromised individuals such as asthmatics and those sick at the time of vaccination.

"This vaccine should not be mandated," said Fisher. "There are too many questions about the true adverse event and efficacy profile of this relatively new live virus vaccine and it is up to the manufacturer marketing the vaccine and the federal agencies regulating the vaccine to conduct further follow-up of this important VAERS report," said Fisher.

* * *