## Vaccine Hot lots

Withdrawn vaccines

[Hot lots no doubt exist but it is also a way to deflect criticism away from the vaccine.]

## **Industry 'position'** [See Lies]:

"The Food and Drug Administration can withdraw a vaccine batch if there is any question about that particular lot's safety or effectiveness. It has not recalled a vaccine lot because of safety concerns since 1955."--<u>Paul Offit MD</u>

"With the exception of an early lot of polio vaccine in 1955, which was not fully inactivated, there has never been a "hot lot." <u>www.immunizationinfo.org</u>

See: Vaccination mistakes Withdrawn vaccines Contaminants Vaccine production/manufacturing Vaccine Disasters Vaccine storage

[2012 June] Narcolepsy traced to specific vaccine batches A new Swedish study shows that all Swedes who developed narcolepsy from the swine flu vaccine Pandemrix received the vaccine from 12 of the 35 batches, despite the Swedish Medical Products Agency's previous claim that no such connection exists. .....Over 220 Swedes, most of them children, developed narcolepsy as a side effect from the Swine flu vaccine Pandemrix,

[Media June 30, 2002] UK babies given toxic vaccines, admits Glaxo

Recalls of unsafe vaccine are rare--Fresno Bee DPT report 1984

## Quotes

"It is well known that some lots of pertussis vaccine are associated with a disproportionately high number of notifications of adverse events. These are termed "hot lots". However, the manufacturer is protected by law from disclosing the number of doses that derive from a given lot. Therefore, one lacks the denominator of the function which would reveal whether a given lot appears "hot" because it is more toxic, or because it is the source of more doses. Be that as it may, hot lots offer the possibility of danger to children. Nonetheless, I have never heard that a hot lot has been ordered withdrawn on the basis of VAERS surveillance."---<u>Marcel Kinsbourne, M.D.</u>

"In May 1990 we started to track DPT vaccine lot numbers when parents reported their child's hospitalization, injury or death following vaccination to NVIC. Evaluating adverse event reports from more than 90 families, **we found multiple** 

**serious reports were from the same vaccine lot numbers**. NVIC made three separate presentations to government advisory committees between 1990 and 1993, but no substantive action was ever taken by the FDA or CDC. Upon further investigation when the VAERS computer data became available through the Freedom of Information Act, we found.....(6) many lots with very high numbers of reports; and (7) no recall of any lot of vaccine. We do not know how many doses of vaccine are in each lot because the FDA and the drug companies **do not release this information to the public**. Therefore, it is impossible to precisely compare one lot to another for reactivity. There currently are DPT lots on the market that have been associated with large numbers of reports including hospitalizations, injuries and deaths. Vaccine manufacturers and the FDA will not release the number of doses in each lot of DPT vaccine to the public. Therefore it is not possible to totally, accurately compare the reactivity of one lot to another lot. In the past fifty years reports of "hot lots" of vaccines, those that appear to be associated with more injuries and deaths than others, have been reported in the United States and Europe."--NVIC

"In the 40 years that pertussis vaccine has been given to American children, only four lots have been withdrawn from the market as unsafe. Sometimes such lots are called hot lots......Michigan had made too much DPT in its Lansing laboratory and wanted to sell it to other states. That required FDA testing and approval, as with any other manufacturer. However, the FDA denied approval and returned the vaccine, saying It was 300 percent too potent. State health officials disagreed and decided to test the vaccine on children in Ingham County (Lansing). Despite more adverse reactions than usual, health officials released 400,000 doses of the DPT vaccine for use throughout the state a month later."--<u>Fresno Bee DPT report 1984</u>

"Congress requires records to be kept of the lot numbers of vaccines for which unusually large number of "adverse events" (side effects) are reported. But the information is then simply ignored. The "hot lots," as they are called, are not destroyed, but continue to be injected into infants and children. (no use throwing out expensive vaccines--dollars are worth more than lives, just as in the U.K.)."---Dr Rimpland PhD

<u>Menkes JH, Kinsbourne M.</u> Neuropediatrics 21 (1990) 171-176, Workshop on Neurologic Complications of Pertussis and Pertussis Vaccination

In evaluating side-reactions to the vaccine, the following must be kept in mind: Vaccines are not standardized between manufacturers.

For a given manufacturer, vaccines are not standard from one batch to the next.

Unless the vaccine is properly prepared and refrigerated, its potency and reactivity varies with shelf life.

In fact, the whole question of vaccine detoxification has never been systematically investigated.

Listed in order of increasing severity, observed adverse reactions include irritability, persistent, unusually high-pitched crying, somnolence, seizures, a shock-like "hypotensive, hyporesponsive" state, and an encephalopathy. Since the neurologic picture is not specific for pertussis vaccination, its temporal relationship to the vaccination is the critical variable for determining causation.

Although the majority of seizures following pertussis vaccination are associated with fever, it was the consensus of the neurologists attending the workshop, that these do not represent febrile convulsions, but are non-benign convulsions.

The incidence of post-vaccine encephalopathy is difficult to ascertain. The most carefully conducted retrospective case-control study reported that the relative risk of a previously normal infant for the onset of an illness leading to encephalopathy with permanent subsequent disability was 4.2 time greater during the first 72 hours following DPT vaccination than in controls. From this study, the risk for permanent brain damage following DPT has been calculated as 1:310,000 doses. (my note – 1:310,000 doses translates to an actual risk of 1:62,000 – this figure is from the National Childhood Encephalopathy Study which excluded any child whose seizure lasted for less than 30 minutes and who was not hospitalised as a result of their seizure. )

It was the consensus of the workshop, and in particular of the participating neurologists, that although the vaccine may possibly accelerate neurologic signs or symptoms in some children, and a small proportion of apparent complications may be coincidental, there was no inherent difficulty in assigning cause and effect to the vaccine and subsequent permanent neurologic residua.

...In implicating pertussis vaccination in the evolution of subsequent neurologic residua, a careful consideration of the mechanism for vaccine-induced brain damage plays an important supporting role. Pertussis toxin has been shown to alter cellular signalling. It also affects the catecholaminergic and GABAergic systems in the brain. Although normally a protein the size of PT would not be able to cross the blood-brain barrier, factors known to disrupt the blood-brain barrier include brief hypertensive episodes such as might occur during a coughing paroxysm, hypoxia and prolonged seizures, whether or not they are accompanied by hypoxia. In addition, a direct

endotoxin-mediated attack on the endothelial cells could create a local defect of the blood-brain barrier.

In summary, it was the consensus that there is sufficient experimental data to implicate both endotoxin and PT in adverse neurologic reactions to pertussis vaccine.