This is an article that I wrote a few years ago about Pediarix, the first 5-in-1 vaccine brought to market in 2003. Pediarix is DTaP + Polio + Hepatitis B. It is an example of the lack of safety studies, identification of antibody as marker of effectiveness, and negating serious side effects with the stork of a pen.

Be sure to review the package insert that can be found at http://www.VaccineSafety.edu

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The Scoop on Pediarix: the New 5-in-1 Vaccine

By Dr. Sherri Tenepnny

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The pharmaceutical industry has shown its true colors on this one.

The goal of creating Pediarix, a new 5-in-one combination vaccine for diphtheria, tetanus, pertussis, hepatitis B and polio, is clearly stated in the GlaxoSmithKline (GSK) press release: "Combination vaccines will allow more vaccines to be added to the 'crowded' pediatric vaccination schedule." With more than 200 vaccines currently under development, it is certain that many more will be added to the childhood and adolescent vaccination schedules. To accommodate the new additions, many combination vaccines are in the pipeline, including:

- DTaP, IPV, and HepB
- DTaP, IPV, and HiB
- DTaP, IPV, HepB, and HiB
- DTaP, IPV, HepB, HiB and Hepatitis A

Scientifically, the D-T-aP is three separate vaccine antigens, and the polio vaccine contains three viruses, so it is actually six vaccines. After adding the projected number of antigens in the "combination vaccines," the fictional vaccine Omnivax portrayed in Michael Palmer's book "Fatal,"which combined 30 vaccines into one shot, does not seem so "fictional."

It is certainly disturbing for parents to see their babies receive five to seven separate vaccinations at the 2-, 4- and 6-month "well-baby visits." However, reducing the total number of shots by combining them, rather than eliminating unnecessary shots, is nothing more than creating a deceptive "placebo" for concerned parents.

Even when familiar vaccines are combined, the mixture is considered to be a new product. The vaccine must be subjected to clinical trials as though it were brand-new.[2] After reviewing several of the studies that allowed this vaccine to come to market, similar investigational flaws were discovered for this vaccine trial as in all others: safety is not "proven" through the studies, and "effectiveness" is defined only as the presence of antibodies.

The design of all vaccine safety studies is seriously flawed. A scientifically sound safety study would compare the new vaccine to an inert substance, such as sterile water or saline. In addition, current vaccine safety studies compare a new vaccine to a vaccine with a "known side effect profile."

These flaws are bad enough, but the design of the Pediarix study coordinated by the UCLA Center for Vaccine Research, Research and Education Institute, was even more bizarre.

Various combinations of vaccines were given to 400 children who had been divided into four groups:

- Group A received 3 doses of Pediarix + the HiB vaccine
- Group B received 2 doses of Pediarix + HiB; the third vaccine was [DTaP + HepB] + oral polio
- Group C received 3 doses each of [DTaP + HepB], IPV (injectable polio), and HiB
- Group D received 3 doses each of DTaP, HepB, HiB and oral polio

The conclusion?
The researchers found that the antibody levels of each of the vaccines were nearly the same in all groups, therefore, "the use of the pentavalent combination vaccine will greatly reduce the number of required injections during the first 2 years of life, thereby simplifying the immunization schedule, enhancing compliance and facilitating acceptance of additional injections engendered by introduction of newer vaccines."[3]

That's proving convenience but does NOT prove safety.

If the [DTaP + HepB] vaccine looks unfamiliar to you, it is because it has not been approved. In the Pediarix study, five licensed vaccines and two investigational combination vaccines (also manufactured by GSK) were evaluated simultaneously.[4] **The FDA appears to be granting permission to compare one experimental vaccine to another**. I wonder if the parents knew that their children were being used as truly "experimental subjects"? This type of "research" goes far beyond what can possibly be defended on scientific grounds and borders on being criminal.

The same study further concluded that, "there were no vaccine-related serious adverse events in any group after any vaccine dose."

But if the study is read carefully, evidence to the contrary exists:

> "***Two subjects withdrew from the study because of serious adverse events*** that were determined by the safety monitor to be unrelated to vaccination. One subject in Group A was diagnosed with a **seizure disorder** 14 days after the first immunization. Another subject in Group B had a **neuroblastoma** detected 6 weeks after the first immunization. **Six other reported serious adverse events** involved hospitalizations for bronchiolitis/pneumonia (4), meningitis (1) and apnea (1) and ***were also determined to be unrelated to vaccination."[5]***

Why is it that whenever an adverse event occurs during the course of a vaccine clinical trial, that "event" is never related to vaccination?

Every consumer should ask to read the package insert on every vaccine, but be sure to read this one carefully. [6]

Here is a partial list of the additives, adjuvants and contaminants:

- **VERO (monkey) cells** -- potentially containing the SV40 virus incriminated in several different cancers, including leukemia.
- **Bovine extract, bovine casein and calf (bovine) sera**-- It is common knowledge that bovine blood products can be contaminated with viruses, and bovine viral diarrhea virus (BVDV) is the one most often contaminating fetal bovine serum. [7]
- **Formaldehyde** -- a chemical that has caused cancer in laboratory animals and may cause cancer in humans. There is no known threshold level below which cancer risk does not exist. The World Health Organization recommends that exposure should not exceed 0.05 ppm (parts per million).[8]
- **Glutaraldehyde**-- a toxic chemical that is used for cold sterilization of medical and dental equipment. There is no Occupational Safety and Health Administration (OSHA) permissible exposure limit. The National Institute for Occupational Safety and Health (NIOSH) recommends that exposure to glutaraldehyde be under 0.2 ppm.[9]
- **2-Phenoxyethanol** – a component found in antifreeze, the vaccine contains 2.5 mg of this compound.
- **Thimerosal** --this mercury compound is used in the production of Energix, the hepatitis B fraction of the vaccine. It is used during the initial manufacturing process and then removed by a process using cysteine. However, up to 12.5ng (nanograms) remain

The vaccine also contains these substances: **neomycin, polymyxin B, polysorbate 80 and less than five percent yeast protein**.
The instructions on the package insert caution to "shake well before administering" and describe the vaccine as a "turbid white suspension" consisting of the many particles in the solution.

Is this something that you would want to have injected into your arm? Into your baby's arm? **Don't bet on it**. The long-term studies on combination vaccines will most likely prove that the biological warfare coming through a needle is just that: war -- on the immune system.

References:

[1] http://www.keepkidshealthy.com/ newsletters.html
[2] New vaccine supply and financing: a case study of combined vaccines in developing countries.
[3] Sylvia H. Yeh, MD. et.al. Safety and immunogenicity of a pentavalent diphtheria, tetanus, pertussis, hepatitis B and polio combination vaccine in infants. Ped Inf. Dis. J. 2001;20:973-980.
[4] Sylvia H. Yeh, Ibid.
[5] Sylvia H. Yeh, Ibid.
[6] Pediarix package insert
[7] European Commission on Health and Consumer Protection Directorate-General. Scientific Committed on Animal Health and Animal Welfare. Adopted 25 October, 2000.
[8] IAQ fact sheet: formaldehyde.
[9] FMSCME Fact sheet: glutaraldehyde.