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In 1982 after the national broadcast of the award winning television documentary "DPT: Vaccine Roulette", Kathi Williams, Jeff Schwartz and I joined with other Washington, D.C. area parents, whose children had been injured by the whole cell pertussis vaccine, and co-founded DPT, a non-profit consumer organization that today operates the National Vaccine Information Center. Our mission has always been to prevent vaccine injuries and deaths through public education and one of the first goals we set was to promote the development of a safer pertussis vaccine.

To that end, I co-authored with Harris Coulter the book DPT: A Shot in the Dark published by Harcourt Brace Jovanovich in 1985, reputed to be, according to one of the three law firms that scoured it for accuracy and documentation, the most thoroughly vetted book since All The Presidents Men. I didn't fully appreciate what that meant until the Wall Street Journal and New York Times reviewed it.

Our organization also worked with Congress to create the National Childhood Vaccine Injury Act of 1986, to which we contributed the inclusion of important vaccine safety provisions such as the legal requirement that vaccine providers report adverse events following vaccination; that providers keep permanent records of the manufacturer's name and lot number; that providers record adverse events in a patient's medical records; that providers give parents benefit and risk information before children are vaccinated; that a centralized vaccine adverse events reporting system be created; and that HHS be required to do research into expedited development of a safer pertussis vaccine.

I think it is no exaggeration to state that if parents had not launched a vaccine safety movement in 1982 in the U.S., we would not be here today talking about not just one - but a dozen - purified pertussis vaccines that have been developed and tested in the past decade. Without the consumers' call to action, there would have been no national priority in America to fund new pertussis vaccine trials.

This is a fact that speaks to the pivotal role that consumer activist groups in every country can play in creating public awareness and support for constructive change within public health systems traditionally structured for efficient implementation rather than for innovation or change. While we wish it had not taken 14 years for this day to come, we appreciate your acknowledgment and including us in your deliberations and

we congratulate all of you on the work you have done to make purified pertussis vaccine not just a dream but a reality.

The National Vaccine Information Center has been contacted by several hundred thousand parents and health care providers during the past two years alone. We receive more reports of health problems occurring in children who have been injected with DPT or DPTH, using whole cell pertussis vaccine, than any other other vaccination. It has been that way since 1982.

We are not talking about sore arms and a little fussiness. Mothers don't pick up the phone and call us long distance when their babies have red arms or spit up their formula or run a little fever or cry like they do when they are hungry. Mothers are used to their babies doing that.

We are talking about healthy babies who, within hours after vaccination, are screaming and shrieking for hours in a way the mothers have never heard before; are turning blue and going limp and lapsing into unconsciousness; are running fevers over 103 degrees that, in some cases, lead to febrile convulsions; are having afebrile convulsions that can't be controlled with medication; and are losing the ability to hold their heads up or roll over. Some of these babies go on to die and their deaths are misclassified as sudden infant death syndrome. Other mothers report that, after experiencing acute pertussis vaccine reactions, their babies go on to suffer from failure to thrive, chronic otitis media, asthma or severe personality and cognitive changes that ultimately result in diagnoses of varying degrees of developmental delays.

Many of these mothers tell us that their doctors categorically deny the vaccine reaction had anything to do with the child's sudden change in health status and refuse to obey the law and make a report to the government's Vaccine Adverse Event Reporting System (VAERS). Some parents can't get information from their doctor, which is also required by law, on the vaccine manufacturer's name or lot number. Rarely does anyone from a health agency contact parents whose children have been hospitalized, injured or died following DPT vaccination to find out what happened to their children.

Many parents are still given no vaccine information material to read beforehand and do not know how to recognize a DPT vaccine reaction. So their children are injected with more pertussis vaccine after reactions have already occurred and are damaged by re-vaccination.

Few parents know about the existence of the federal vaccine injury compensation program. And only 25 percent of parents whose children were injured by pertussis vaccine and apply for federal compensation are actually awarded compensation, a percentage so low as to make the compensation program almost useless as a societal response to caring for children for whom vaccine risks were 100 percent.

As second generation pertussis vaccines head toward the marketplace, the National Vaccine Information Center is concerned about implementation of the use of acellular vaccines for several key reasons:

First, even though in 1991 the FDA licensed acellular pertussis vaccines produced by U.S. manufacturers for the fourth and fifth booster doses, parents have found that acellular pertussis vaccine is still not available in public health clinics or even in many private pediatrician's offices around the country. There are parents who would like to give their toddlers booster doses of a purified pertussis vaccine but can't find it.

Why, if every major study in the past decade has found that whole cell is two to eight times more reactive than acellular, can American parents still not find acellular pertussis vaccine five years after it was licensed in America for use in toddlers? Is availability going to continue to be a problem after the FDA licenses acellular pertussis vaccines for use in infants? Will the whole cell vaccine be replaced with acellular or will it stay on the market, still preferred by public health clinics and private pediatricians because it is cheaper and because the official position continues to be that the whole cell vaccine only causes minor reactions and anything more serious that happens is only a coincidence?

In this regard, I think it is important to point out that the Nationwide Multicenter Acellular Pertussis Trial comparing whole cell to acellular pertussis vaccines only included about 2,000 infants and some 6,000 vaccinations, less than half the total number of vaccinations evaluated in the 1979 Cody-Baraff UCLA study comparing reactivity of DT and DPT vaccines. In the Multicenter trial some of the groups studied contained less than 100 babies, such as during the comparison of reactivity when Hib vaccine was injected simultaneously with pertussis vaccine.

Even with these relatively small numbers, serious events such as convulsions, hypotonic hyporesponsive episodes, and death did occur in both whole cell and acellular vaccine recipients, as did reports of continuing health problems such as seizures and developmental delays at the one year follow-up. Although study authors go to some lengths to disassociate certain acute adverse events, such as otitis media and respiratory infections following vaccination or long term health problems, such as continuing seizure disorders and developmental delays, from being causally related to the vaccine, scientifically this remains an open question.

Causal relationships between vaccines and temporary or permanent health problems will remain an open question until molecular biologists and neuroimmunologists precisely define the biological mechanism for response to vaccination and pathological profiles are developed to distinguish vaccine-associated adverse events from other events. The lack of well designed long term studies comparing unvaccinated to vaccinated children for all morbidity and mortality outcomes in order to determine true background rates for immune and neurological dysfunction occurring in American children independent of vaccination further confounds the picture, just as simultaneous administration of OPV and Hib vaccines in

a study to compare reactivity rates between whole cell and acellular pertussis vaccines confounds the picture.

These gaps in knowledge become more apparent with each new vaccine or combination vaccine that is added to the already crowded mandatory vaccination schedule. These gaps in knowledge will become even more obvious when you start giving pregnant women and other adults pertussis vaccine without having precisely defined biological mechanisms for adverse response or identified genetic markers for high risk individuals. When adults start suddenly exhibiting immune and neurological dysfunction following vaccination, it is going to be a lot harder to convince them that they had an underlying genetic or metabolic disorder just waiting to be expressed and that the first manifestation just happened to coincide with the administration of the vaccine.

The National Vaccine Information Center maintains that it is critical that basic science research be conducted into defining the biological mechanism at the molecular level for human response to vaccination as distinguished from response to normal infection so that adverse events associated with pertussis vaccines and other vaccines can be distinguished from those that are not vaccine-related and, most importantly, so that genetic markers for high risk individuals can be identified and lab tests developed to pre-screen them out.

With regard to children at high risk of reacting to pertussis vaccine, we also believe it is important to communicate to the public that the same contraindications that apply to whole cell pertussis vaccine also apply to acellular pertussis vaccine. Certainly, the Multicenter study demonstrated that children "who experienced an adverse reaction at one inoculation was more likely to experience the same adverse reaction at a subsequent inoculation." Infants in the Multicenter study were withdrawn from the study because of severe reactions such as prolonged, inconsolable or high pitched crying in both whole cell and acellular groups.

Apparently, in the Swedish trial conducted by Gustafsson et al severe local reactions, together with other general symptoms, were considered a contraindication to further vaccination with either whole cell or acellular vaccines. If this one contraindication has been in effect in 1980, my son would not be brain damaged today. The Swedish authors also excluded children from the study if they had suspected immune or neurological dysfunction such as failure to thrive, uncontrolled convulsions, infantile spasms, or immunosuppression. Unfortunately, we receive reports of American children in these high risk groups who do receive pertussis vaccine despite severe reactions or pre-existing high risk conditions.

Finally, the National Vaccine Information Center is concerned that adequate systems are still not in place within America's mass vaccination infrastructure to evaluate and monitor the reactogenicity of currently licensed vaccines and that this will hamper evaluation and monitoring of newly licensed vaccines. We must have universal standardization of lot numbers. At its core, post marketing surveillance will

never succeed if 90 percent of all doctors fail to report adverse events following vaccination, as is now the case. And doctors will continue to refuse to report serious adverse events following vaccination if they continue to be told by colleagues they trust that serious adverse events following vaccination have nothing to do with the vaccine just administered.

The doctors may believe the vaccine had nothing to do with it, but the mothers don't. And that simple fact will continue to haunt the mass vaccination program until the basic science research is done, credible vaccine safety evaluation systems are put in place, and parents believe that physicians are acting as caring partners with them in helping to prevent vaccine reactions.

The development of second generation pertussis vaccines is an important milestone in the history of vaccination because it marks the first time consumers, industry, research science and government worked together to successfully effect a major improvement in a licensed, universally recommended vaccine. That success can stop here or it can lead the way to greater scientific knowledge and the saving of lives through a continuing commitment to expanded scientific research, vaccine safety improvements, and institutional reform. With 200 new vaccines in the research pipeline and 100 in clinical trials, many of which are scheduled for mandatory use in America, the public is going to insist upon that commitment so that fewer children are sacrificed on the battlefield of the War on Disease. We stand ready to work with you to meet that commitment.