

Testimony

Barbara Loe Fisher, Co-founder & President

National Vaccine Information Center

California Senate Committee on Health and Human Services

"Childhood Immunization Mandates: Politics vs. Public Health

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Senator Ortiz and members of the Committee, thank you for inviting me to participate in this hearing on the politics and public health issues involved in vaccine mandates. This is the first hearing of its kind in any state that I am aware of and, as usual, California is leading the way in looking at progressive ways to address the very real health care concerns of citizens.

I am appearing here on behalf of the 4,500 California parent and health professional members of the National Vaccine Information Center, which is a 40,000-member national, non profit organization founded in 1982 by parents of vaccine injured children. My organization worked with Congress in the 1980's to create the National Childhood Vaccine Injury Act of 1986 and we were instrumental in helping to obtain the safer DTaP vaccine licensed in 1996 for America's babies. Our mission is to prevent vaccine injuries and deaths through public education and we support the availability of vaccines for all who want to use them but we also endorse the ethical principle of informed consent and believe that the zealous enforcement of vaccine mandates threaten that principle.

My 20-year experience as a vaccine safety consumer advocate includes co-authorship of the 1985 book DPT: A Shot in the Dark, which was used as a reference by the Institute of Medicine in its historic reports on vaccine adverse events in 1991 and 1994, as well as appointments to the National Vaccine Advisory Committee in 1988 and the Institute of Medicine Vaccine Safety Forum in 1995. I am currently the consumer voting member of the FDA Vaccines and Related Biological Products Advisory Committee.

Personally, I come here as a parent of a son who had a neurological reaction to his fourth DPT shot at age two and a half that caused brain dysfunction, including multiple learning disabilities and attention deficit disorder (ADD), but who was fortunate not to lose his life or be left with mental retardation, uncontrolled epilepsy, autism, or other severe disabilities like so many of the vaccine injured children I have come to know. When my son had his vaccine reaction in 1980, children in America were told to get 23 doses of 7 vaccines. Today, children are told to get 37 doses of 11 vaccines. In those 22 years since my son had his vaccine

reaction, the numbers of American children with learning disabilities, attention deficit disorder and asthma have doubled; diabetes has tripled; and the incidence of autism has reached epidemic proportions, increasing 200 to 600 percent in every state, marking a staggering 3400 percent increase in the prevalence of autism in our children.

Nobody knows why this has happened. But everyone at the Centers for Disease Control and American Academy of Pediatrics, the two medical groups that make vaccine policy in this country, vigorously deny that the many vaccines they have urged be mandated in the past quarter century could have anything to do with why more and more of our so children are chronically ill. They say that vaccines only rarely cause chronic health problems.

Yet, the haunting question remains: if we have wiped out polio and almost eliminated measles, mumps, rubella, whooping cough and other childhood diseases with vaccines - why are so many of our children stuck on sick? Why are our special education classrooms so crowded that we can't find enough money or train teachers fast enough to care for these learning disabled, hyperactive, autistic, asthmatic, diabetic, emotionally disturbed, sick children?

Something is wrong with this public health report card.

And before we go any further and mandate one more vaccine for daycare or kindergarten entry - whether it is Prevnar or hepatitis A or some other vaccine - we had better find out if the repeated manipulation of the immune system with lab altered viruses and bacteria adulterated with mercury, aluminum, formaldehyde and other toxins, which are administered to our babies from birth through the first five years of life when the brain and immune system is developing at its most rapid rate, is contributing to these skyrocketing increases in chronic illness in our children. Without basic science research into the biological mechanisms of vaccine injury and death and without methodologically sound, long term studies which follow groups of highly vaccinated, lesser vaccinated and unvaccinated children over time to measure for all morbidity and mortality outcomes, it is illogical and scientifically irresponsible to assume that there is no connection between the ever increasing numbers of vaccines we mandate for children and the ever increasing rates of chronic disease in our children. Making this kind of scientific investigation a societal program and funding priority would, at the very least, give us a better understanding of the genetic and other biological factors which predispose certain children to vaccine-induced immune and brain dysfunction, including whether there is a complex interaction between genetic factors, a particular vaccine or combination of vaccines and simultaneous exposures to environmental contaminants such as pesticides, molds and other toxic insults.

I understand that you are looking at whether the process for mandating childhood vaccines in California could be improved. You have a difficult job to do because when you make laws, you often rely upon expert advice in areas where you don't feel you have enough expertise. Medicine is an area that a lot of us feel like we don't have the knowledge or expertise to make independent decisions.

As a mother who graduated from college but never went to medical school or got a Ph.D., I urge you not to totally defer to the experts on this one. You are smart or you wouldn't have been elected. As legislators, you educate yourselves about everything from freeway construction to pollution to the death penalty. Those are complex issues just like this one - and it doesn't take a medical degree to tell the difference between a good scientific study and a bad one.

I voted "NO" when I was asked in 1999, as the consumer member of an FDA Committee, to vote on whether Wyeth Lederle, the manufacturer of Prevnar, had proved the vaccine is safe. I was the only "no" vote, but I voted "no" with confidence. I remembered being taught in a high school science class that when correctly employing the scientific method to prove an hypothesis in an experiment, you cannot compare two unknowns. The Prevnar pre-licensure clinical trials, which Wyeth Lederle paid Kaiser Permanente to conduct, compared two experimental vaccines against each other. To compound this basic methodological flaw, Kaiser and Wyeth Lederle, allowed most of the children in the trial to be given the more reactive DPT vaccine rather than use the safer, less reactive DTaP vaccine. This placed the children in that five-year experiment in greater danger and allowed the drug company to write off the seizures that occurred as being caused by DPT and not Prevnar, when in fact, they didn't know. Even so, the groups of children who got Prevnar suffered more seizures, higher fevers, more irritability and other reactions than did the children who got the other experimental vaccine. It was a no-brainer as far as I was concerned: Kaiser and Wyeth Lederle had proved nothing about Prevnar vaccine safety.

And another question: why did the CDC's policymaking committee vote to recommend "universal use" of Prevnar by all children before the FDA Committee even got a chance to review the data and take a vote about whether it should be licensed at all? The same thing happened with the ill-fated Rotavirus vaccine for infant diarrhea that was pulled off the market in 1999, less than a year after it was released, because it was causing bowel obstructions in babies. The CDC had voted to recommend that all babies get rotavirus vaccine weeks before the FDA Committee voted on scientific proof of safety and efficacy. And before the FDA Committee even got a chance to vote on Prevnar, Wyeth Lederle and Kaiser Permanente officials were being quoted in national press releases that Prevnar was an ear infection vaccine - when their own trial data showed that the vaccine only decreased a

child's chance of getting an ear infection by 7 percent!

The FDA has never licensed Prevnar as an ear infection vaccine but lots of doctors in America tell parents it is because that is how the vaccine has been promoted. No wonder Prevnar vaccine was the number one best selling new pharmaceutical introduced to the market in the year 2000 - generating more than \$450 million for Wyeth Lederle that year.

Which brings us to the uncomfortable issue of conflicts of interest that exist when experts, who sit on vaccine advisory committees, also get paid by vaccine manufacturers to conduct clinical trials on vaccines they make and sell. It happens too often and it contributes to the erosion of trust in the integrity of a mass vaccination system where the same doctors, who report parents to child social services for child abuse if the parent doesn't want the child vaccinated with every mandated vaccine, are the same doctors who refuse to obey the 1986 law and report injuries and deaths following vaccination to the federal Vaccine Adverse Event Reporting System (VAERS). The estimate is that less than 10 percent, perhaps less than one percent, of all doctors report serious health problems that follow vaccination. So instead of the some 12,000 reports that are made every year, there may be as many as 120,000 to 1.2 million vaccine-related adverse events occurring annually that nobody is counting or following up on. And this means that the more than 3,000 Prevnar vaccine adverse events that have been reported to VAERS since 2000 and the more than 2,500 hepatitis A vaccine adverse events that have been reported since 1996 are only a fraction of what has really occurred.

The truth is we really don't know how many children are getting seriously ill and dying following vaccination in America every year. Doctors and public health officials, anxious to persuade themselves and the public that vaccine risks are minimal, use the remarkably unscientific argument that it is all a "coincidence" when something bad happens to a child after vaccination - the vaccine is never, ever to blame. And so more and more parents, who took a bright, healthy, normally developing child to a doctor's office for routine vaccinations, are coming forward with their dead and damaged children asking you to fix a mass vaccination system they know is broken.

I urge you not be afraid to rely on your intelligence and common sense to evaluate the merits, potential risks, and very real costs associated with mandating new vaccines such as Prevnar and hepatitis A. There are more than 200 experimental vaccines being developed to prevent everything from tooth decay to stomach ulcers, as well as a supervaccine to be given at birth that will inject raw DNA from 20 to 30 different viruses and bacteria directly into the cells of newborns. The vaccine manufacturers and physician special

interest groups that will lobby you for mandates know that drug companies and doctors have been protected from liability for vaccine injuries and deaths since the 1986 vaccine injury compensation law was passed. I worked with Congress in the early 1980's on that law and have watched it be turned into a cruel joke as 2 out of 3 vaccine injured children are denied federal compensation for their often catastrophic vaccine injuries because the DHHS and the Department of Justice officials fight every claim, viewing every award to a vaccine injured child as admission that vaccines can and do cause harm.

Please remember that when you mandate, rather than recommend, a medical procedure like vaccination that carries a risk of injury or death, it sets the stage for violation of informed consent, an ethical standard that has guided the practice of medicine since World War II. One of the reasons I traveled from Virginia to be here today is to defend the human right to informed consent which is embodied in the religious and personal or conscientious belief exemption to vaccination now protected in California law. In many other states, public health and education officials are determined to eliminate these exemptions from the law. We have examples of parents in Wyoming, New York and other states being detained by state government officials and interrogated for hours about the sincerity of their deeply held religious or conscientious beliefs only to find their previously held exemptions revoked; their children barred from attending school and a threat that their child will be taken away from them.

Those exemptions are the closest we come in America to preventing the unchecked implementation of utilitarianism, which attempts to justify the forced sacrifice of some in service to others. There is nothing that causes a crisis of trust in government more than when the people live in fear of a law that forces them to risk their lives or the lives of their children without their consent. I hope that this Committee, in considering any new vaccine mandates or other laws which force vaccination - even in times of emergency - will protect the inviolability of the informed consent ethic which, at its most basic level, respects the right of the individual to voluntarily decide what he or she is willing to die for.

We do have a specific recommendation for improving the process by which vaccines are considered for mandates, but in recognition of the time constraints today, I will submit the fact sheet and recommendations that the National Vaccine Information Center and California Vaccine Awareness have prepared to you in writing. Again, I am honored to be here and thank you for this opportunity to share my thoughts with you.