Barbara Loe Fisher
Co-founder & President, National Vaccine Information Center
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Medical Science & Public Trust: the Policy, Ethics & Law of Vaccination in the 20th & 21st Centuries

Before I begin my presentation, I want to thank Claire and Al Dwoskin, whose vision and support for this conference has made it possible for us to be here today. Our paths crossed in 2006 and, since then, their encouragement and support of the work we do at the National Vaccine Information Center has kept the organized vaccine safety and informed consent movement, which was launched in 1982 by parents of vaccine injured children, going strong. Thank you both for all you have done to advance truth in science and protect the right to informed consent to vaccination.

We have come to Jamaica to evaluate vaccine safety science because there is a crisis upon us. This crisis is fueled by a loss of public trust in what many doctors tell people about the safety of vaccines and the risks of infectious diseases.

In the second decade of the 21st century, almost everyone knows someone who was healthy, got vaccinated and was never healthy again. That anecdotal evidence is, in part, fueling a loss of public confidence in the quality and quantity of the science used to justify mandatory vaccination policies.

In the late 20th century, public questioning of vaccine safety began in Europe and the U.S. with persistent reports of healthy children dying and becoming brain damaged after receipt of DPT vaccine and with the launching of the vaccine safety and informed consent movement by American parents of DPT vaccine injured children in 1982. It was legitimized by the passage of the National Childhood Vaccine Injury Act of 1986 that partially shielded vaccine makers and providers from vaccine injury liability. It has been building ever since as dozens of new vaccinations, which do not fit the smallpox or polio model, have been added to mandatory vaccination laws in the past three decades while reports of vaccine related chronic health problems and deaths have increased and doctors inside and outside of government have continued to dismiss vaccine related injuries and deaths as coincidental.

The challenge to doctors promoting mandated use of vaccines by everyone from day of birth and throughout life is being led in large part by the educated, middle class health care consumer in developed countries. Educated health care consumers make up about 40 percent of the U.S. population or roughly 100 million adults, who have earned an associate, bachelor's or graduate college degree.

I am typical of the 40 percent of educated, middle class Americans, who spend more than $19 billion dollars every year to avoid genetically modified foods and chemicals by eating organic. We also pay more than $34 billion dollars out of pocket to get advice from alternative health care professionals. I also count myself among the 69 percent of Americans, who believe that doctors prescribe too many prescription drugs because they are too heavily influenced by pharmaceutical companies.

Most importantly, I am among the 9 out of 10 American parents who, when polled in 2010, said our Number One health care concern was vaccine safety.

Like most educated health care consumers, I do not have a medical degree. However, I am quite capable of doing my own research, including assessing the quality of scientific studies published in the medical literature, if I put my mind to it. I want to trust what my doctor tells me about infectious diseases and vaccines, but I also want to empower myself with information so I can ask my doctor intelligent questions and independently weigh the potential benefits and risks of vaccination for myself and my children. As a parent responsible for nurturing and raising my children, I expect my doctor to work with me as an equal partner and respect the choices I make because I believe it is my right and responsibility to make well informed health care choices for myself and my children based on the best evidence I can find.

Bottom line, I represent the empowered, educated health care consumer of the 21st century, who is changing the practice of medicine, because I am taking control of my health and the health of my children by moving toward a new health paradigm that is based more on respect for the natural order than on indiscriminate use of pharmaceutical products.

When I became a mother for the first time in 1978, there was no information about vaccines available for the American health care consumer. Detailed Information about vaccine benefits and risks was published in medical journals but it was only available to doctors with subscriptions to those journals or with access to medical libraries in hospitals and universities. College educated mothers like me were old enough to remember that polio vaccine saved us from the iron lung and we believed that vaccines were 100 percent safe and effective for everyone, especially children.

It is difficult for young parents today, who grew up with computers, cell phones and the World Wide Web, to imagine what was like in the 1980's when very few families had computers, or what it was like before 1995, when most people did not have cell phones or access to the Library of the World on the internet. The electronic mass communications revolution has taken health care consumers out of the Dark Ages and jettisoned them into a modern Age of Enlightenment. We are in the middle of an Information Renaissance where, with a click of a mouse or a touch on the Smart Phone, we have at our fingertips a diverse collection of

facts with which to make informed health care decisions for ourselves and our children.

The educated health care consumer in the 21st century is using instant access to more information than has been available to any generation before to challenge the centuries-old paternalistic, authoritarian practice of medicine. Educated health care consumers are engaging in critical thinking and questioning the science that buttresses public health policies, including vaccine policies. Demanding an equal partnership with physicians in making health care choices for themselves and their children, they are refusing to trust without verifying.

And this, at the dawn of the 21st century, is signaling an end to the unquestioning public trust that was automatically accorded to medical doctors and scientists in the 19th and 20th centuries. This historic challenge is coming at precisely the same time that doctors and scientists associated with government, industry, academia and organized medicine are wielding more influence over what kind of health information is made available to the public through the mainstream media, while seeking more authority over what kinds of health care choices individuals are allowed to make.

When I got pregnant in the late 1970's, I joined other middle class college educated women, who were pregnant for the first time, and signed up for prepared childbirth classes taught by women. We had come of age in the 1960's during the civil rights, women's liberation, and environmental protection movements that challenged powerful social institutions and celebrated individual autonomy and empowerment. And we decided we were not going to blindly trust and follow the orders of mostly male obstetricians. We were going to take control of our pregnancy and childbirth by becoming educated about pre-natal nutrition and limiting our exposures to environmental toxins that could hurt our baby.

Unlike mothers delivering babies in the 1940's and 50's, who were drugged into unconsciousness during labor and delivery, we decided we did not want to follow the doctors' orders and subject our babies and ourselves to the toxic effects of heavy anesthesia so we missed celebrating the moment our babies were born. And, despite what doctors told us about the joys of bottle feeding, we knew we were going to breast feed for at least six months rather than go straight to formula because our research told us that breast was best for our newborn baby's health.

When it came to birthing babies, we were going to put our trust in nature, our own bodies and our mother's instinct rather than put our trust in medical doctors and pharmaceutical companies.

But in the 1970's, nobody was talking about vaccines. Given to healthy people to keep them well, vaccines were not viewed as pharmaceutical products marketed by drug companies for profit but as sacred magic bullets that shielded children

from an unpredictable attack by dangerous microorganisms that caused sickness and death. And young educated mothers like me, who had experienced and recovered from measles, mumps, rubella and chickenpox as children, did not use the same critical thinking skills or instincts to take control of neonatal pediatric care that we had used when making decisions about our labor and delivery. We trusted that pediatricians and the vaccines they gave to our children would do no harm.

As the father of America's holistic health care movement, Dr. Robert Mendelsohn, pointed out in 1979: for pediatricians and parents alike, vaccination had become "the new sacrament."

It was in that Dark Age more than 30 years ago, that I faithfully took my first born, Chris, to the pediatrician for the required well baby check ups. Chris was a happy, precocious baby, who exceeded normal developmental milestones and started saying his first words at seven months and speaking in full sentences by the age of two. As a baby and toddler, he was the most precocious of my three children.

After Chris's third DPT shot, a hard, red, hot painful lump developed at the site of the injection that stayed there for weeks and I called the doctor's office. The nurse told me it was a "bad lot of DPT vaccine" and not to worry about it. My faith in the safety of vaccines and in my pediatrician was so complete, I said "Should I bring him down for another one?" I thought she meant the vaccine was not potent enough and my baby would be left unprotected. It never occurred to me that the unusual lump had anything to do with safety and was a warning sign that Chris could have a more serious reaction to the next DPT shot.

When it came time for Chris's fourth DPT shot in the fall of 1980, he was two and a half years old and my bright, cheerful little boy had continued to reach developmental milestones ahead of his peers. He had memorized the name of every card in the deck and was already identifying words in the books we read together every day. One doctor told me he was cognitively gifted.

The day my Mom and I took him for his fourth DPT and oral polio vaccinations, Chris had just come off a round of antibiotics that had been prescribed for him when he had a 48 hour bout with the stomach flu three weeks earlier. He was not running a fever and was bouncing around like usual but he had mild diarrhea, perhaps from the antibiotics, and the doctor examining him dismissed it as unimportant.

Several hours after we got home, I noticed the house was very quiet. I went looking for Chris and found him in his bedroom sitting motionless in a rocking chair staring straight ahead as if he couldn't see me in the doorway. His face was pale and, as I called out his name, I watched his eyes flutter and roll back until I could only see the whites of his eyes. Then his head fell to his shoulder as if he

had suddenly fallen asleep sitting up. I tried to wake him but he did not respond and, when I picked him up, he was like a dead weight in my arms as I carried him to his bed, where he laid without moving.

Later that afternoon, I wondered why he was sleeping so deeply and for so long but I thought that maybe he was just taking an unusually long nap; or maybe he was coming down with something, like a relapse of the flu, and his body needed the extra sleep. His forehead was cool, not hot, so I just told myself to let him sleep.

By dinner time, he had been “out” for five or six hours and I called my Mom. She told me I needed to wake Chris up so he could eat dinner. But Chris did not respond to my calling his name, no matter how loud I called it. Finally, I got into the bed and put his back against my chest and rocked back and forth calling his name. Slowly, with great difficulty he struggled to consciousness and started incoherently mumbling words I could not understand until I heard the word “bathroom.” His face was still pale and he was like a limp rag doll in my arms. He could not sit up or stand up on his own so I carried him to the bathroom and held him while he had violent black colored diarrhea, which I took as a sign he was having a relapse of the flu. He fell back into a deep sleep and I carried him back to his bed, where he slept for about 12 more hours.

The next day he seemed unusually quiet and, over the next few weeks, I started noticing he was different. He seemed distant, often unconnected to what was going on around him. His eyes, now ringed with dark circles, had lost their brightness and had a vacant look. He started staring a lot, sometimes drooling slightly when he was staring. He was constantly sick with ear and respiratory infections and had chronic, foamy diarrhea that looked like attic insulation. He became a picky eater, lost a lot of weight and stopped growing. He no longer knew how to identify the deck of cards or the words in the books we tried read to together every day. He had changed from a focused, happy, adaptable little boy into a child, who could not concentrate for more than a few seconds at a time and had a very low tolerance for frustration. He would anger easily or cry inconsolably whenever he failed to do what he used to be able to do.

After eight months of health deterioration, with his pediatricians patting me on the head and telling me not to worry because it was “just a stage he was going through,” I took Chris to another pediatrician, who took one look at him and said he could be suffering from cystic fibrosis or celiac disease. When the tests performed at a major children’s hospital came back negative, the doctors put him on a diet of white rice, cranberry juice and white chicken meat and told me to take him home and “love him.”

My family and I knew Chris had become a totally different child physically, mentally and emotionally in the fall of 1980 but we still did not know why.

Eighteen months later, in April 1982, I turned on the television and watched the Emmy award winning television documentary DPT: Vaccine *Roulette* produced by NBC reporter Lea Thompson. This was the first time American parents had been informed that a routine childhood vaccine could brain damage children and my first instinct was that I had to learn more so I called the station and asked for copies of the supporting medical literature. My confirmation came when I was reading articles in the *Journal of the American Medical Association, the British Medical Journal,* the *Lancet, Pediatrics,* and *New England Journal of Medicine,* that contained detailed clinical descriptions of the symptoms of post-pertussis vaccine induced convulsions, hypotonic/hyporesponsive episodes, and encephalitis, which exactly matched the symptoms of what I had witnessed my son suffer within hours of his fourth DPT shot.

I realized with shock and a profound sense of betrayal, that medical researchers and doctors had been talking to each other about the brain damaging effects of pertussis vaccine for more than 50 years but they never bothered to tell the mothers dutifully bringing their children in to be vaccinated. That failure to communicate is why I did not know how to monitor my son for symptoms of convulsion, collapse/shock and brain inflammation following DPT vaccination and why he could have died in his bed that night and I would never have known why.

Reading the clinical descriptions of DPT vaccine reactions in the medical literature, I realized that if Chris had been a four-month old baby and not a precocious two and a half year old, the regression he underwent following vaccination may not have been so immediately and dramatically apparent. I thought about how many mothers are not with their child like I was to witness a convulsion or collapse/shock, which could easily occur in the middle of the night in a crib; and how many babies are regressing after unidentified vaccine reactions but are not diagnosed until long after the damage has occurred, which prevents even a temporal relationship between vaccine reaction symptoms and brain dysfunction from being recognized.

By age seven, Chris was diagnosed with minimal brain damage that took the form of multiple learning disabilities, including attention deficit disorder, auditory processing deficit, fine and gross motor skill delay, dyslexia, and severe sequential short term memory delay. He had to be withdrawn from Montessori School and placed in a special education classroom in the public school system. Testing revealed that Chris had retained a remarkable ability to engage in abstract thinking, which is a high cognitive function, testing in the 99th percentile. But he tested in the less than one percentile of the brain's ability to organize incoming information, a very basic cognitive function. That meant he would be able to debate the meaning of Plato's *Republic* but if you gave him three tasks to do in order, he may remember two but not in the right order.

A frustrated kid, who got into a lot of trouble because he could reflect upon the fact he was constantly failing in school no matter how hard he tried, Chris could

not be mainstreamed even in high school. There are many times I have wondered how many learning disabled, hyperactive teenagers and young adults, who are high school dropouts, or end up on drugs, or in prison, or suffering with crippling depression, are unrecognized, uncounted vaccine injury casualties. The milder forms of vaccine induced brain inflammation and chronic brain dysfunction actually may be the more prevalent because they remain the most under-diagnosed, yet the effect on society is just as profound.

Like most learning disabled children and adults filling special education classrooms and the ranks of the underemployed, Chris still struggles to both hide and compensate for his learning disabilities and the discrepancy between what people expect him to do and what he actually can do. At 33, he is a vaccine survivor, a fine young man, a great conversationalist and videographer, who knows he could have been hurt a lot worse that day in 1980.

Chris is among the walking wounded, a growing minority of mildly brain injured adults, who were part of that first wave of learning disabled children in the 1980's for whom special education classrooms had to be built. Were he and his classmates the canaries in the coal mine, a harbinger of what was to come, ignored because, as German immunologist and early DPT vaccine safety critic Dr. Wolfgang Ehrengut once suggested: "What must not be, cannot be"?

When my three children were born, between the late 1970's and 1988, doctors were giving children 23 doses of seven vaccines starting at two months old, including diphtheria, pertussis, and tetanus vaccines in the combination DPT shot; oral polio vaccine (OPV); and measles, mumps, rubella vaccines in the combination MMR shot (MMR). This was the first generation of children who *did no*t experience most of those once prevalent childhood diseases.

That child vaccination schedule of the 70's and 80's stands in stark contrast to the one used in the mid-1940's, when doctors were giving children one dose of smallpox vaccine and several doses of diphtheria and tetanus vaccine in the first two years of life and the majority of children *did* experience and recover from measles, mumps, rubella, pertussis and many other infections, including chicken pox and influenza.

In 2000, doctors were giving children 33 doses of 10 vaccines starting on the day of birth and the special ed classrooms built in the 1980's were overflowing, not only with hundreds of thousands of learning disabled children but with autistic children exhibiting much more severe brain and immune system dysfunction. By 2010, U.S. public health officials and medical organizations were telling doctors to give children 69 doses of 16 vaccines starting on the day of birth through age 18, with 48 of those vaccinations given before age six.

Today, unprecedented numbers of American children are suffering with brain and immune system dysfunction: 1 child in 6 is learning disabled; 1 in 110 develops

autism; 1 in 9 has asthma and 1 in 450 becomes diabetic. Millions more suffer with crippling immune system disorders marked by acute and chronic inflammation, including juvenile rheumatoid arthritis; inflammatory bowel disorders, and severe allergies to casein, gluten, and peanuts while obesity, depression and suicide is also increasing among children.

In the past three decades, U.S. public health officials have enlisted medical scientists and doctors in industry, academia, and trade associations to persuade state legislators to pass laws legally requiring children to get at last three dozen doses of vaccines to attend daycare or school, including college. This is more than 10 times as many vaccinations as were given in the early 20th century. This one-size-fits-all, universally applied public health policy to eradicate a growing list of microorganisms using every vaccine that the pharmaceutical industry develops has created the most highly vaccinated population in the world. And it has driven down the incidence of once common childhood infectious diseases, such as chicken pox, to historic lows in the U.S.

But there is an elephant standing in the middle of the room and it cannot be ignored any longer. The inquisitive, well educated health care consumer, who is being asked to buy and use more and more vaccines every year, sees that elephant quite clearly and is demanding answers to two big questions.

The first question is: Why do the most highly vaccinated children in the world have one of the worst infant mortality rates among developed nations and why are they experiencing an unprecedented chronic disease and disability epidemic that is crippling the health of more of them than any infectious disease epidemic in our nation's history?

This question leads to the second big question: Has the increased administration of multiple vaccines throughout childhood during the past half century, especially in the first three years of life when the brain and immune systems develop most rapidly, been an unrecognized co-factor in the epidemics of chronic disease and disability plaguing so many American children and adults today?

These are two multi-billion dollar questions that the third largest country in the world faces as we struggle to pay an annual $2 trillion dollars for health care – the majority of it to treat chronically ill and disabled children and adults – and begin to understand that both individual and public health is not measured by an absence of experience with infectious disease, it is more importantly measured by an absence of chronic disease.

For future generations, the health care price tag is as unimaginable as the incalculable human cost if we cannot immediately find a way to stop the hijacking of our children's brains and immune systems.

In the search for answers, no stone should be left unturned and no scientific hypothesis should be left off the table. All hypotheses, no matter how politically incorrect or inconvenient, must be fully explored using sound methodology and maintaining high ethical standards. A diverse group of experts representing many different disciplines will be needed to do this science, including neuroimmunology, biochemistry, molecular and cell biology, genetics, neuropathology, toxicology, virology, bacteriology, allergy and autoimmunity, rheumatology, physiology, social science and health services research. And vaccine science in the 21st century will not only have to pass peer review of the medical community, it also will have to withstand the scrutiny of hundreds of millions of educated health care consumers in the U.S. and around the world.

At the end of the day, the goal should not be to conduct science for the express purpose of defending existing public health policy, the goal should be to conduct science that illuminates truth about the impact of infectious disease and vaccination on human health for the purpose of improving the safety and effectiveness of future public health policy. If the science determines that certain vaccine policies must be modified or even abandoned to improve human health, that is a reality that public health officials and doctors must be prepared to accept and address.

Although governments could choose to apply economic or other societal sanctions to force purchase and use of multiple vaccines by the educated middle class, force will never stand the test of time. This is especially true when the World Wide Web can outreach mainstream media, which is strongly influenced by industry and government, and shine a bright light on inadequate science propping up questionable public health policy.

The two Institute of Medicine (IOM) committees, which were charged by Congress under the National Childhood Vaccine Injury Act of 1986 with evaluating the medical literature for evidence that vaccines can cause injury and death, pointed out in 1991 and 1994 that “There are many gaps and limitations in knowledge bearing directly or indirectly on the safety of vaccines. This includes inadequate understanding of the biologic mechanisms underlying adverse events following natural infection or immunization.”

Little has changed in the landscape of new vaccine reaction research funded by government and industry since that assessment was made by Institute of Medicine 20 years ago. And yet, as I highlighted in my 2008 review of the medical literature – *Vaccines, Autism & Chronic Inflammation: The New Epidemic* – from smallpox and polio to pertussis and rubella, the medical literature dating back to the turn of the last century is already rich with evidence documenting that the complications of vaccines containing lab altered viruses and bacteria are often identical to the complications of infectious diseases caused by those same viruses and bacteria, with immune mediated brain inflammation being the most feared complication of both infectious diseases and

vaccination.

The fact that vaccines also contain protein and protein particles, metals, formaldehyde, phenooxyethanol, Polysorbate 80, MSG, foreign DNA and other kinds of adventitious agent contamination from animal and human cell substrates – none of which has been systematically studied for their effect on human health – means that significant questions remain about what kind of biological damage vaccines could be doing. This includes the potential for impairing chromosomal integrity, which has not been evaluated since the tripling of the numbers of doses of vaccines given to children in the past quarter century.

Unfortunately, many doctors and vaccine consumers alike have no idea how little medical science knows about how and why vaccines injure and kill or how and why some individuals suffer serious, fatal complications from infectious diseases while the majority recover from infections without sequelae. This fundamental lack of basic science knowledge about the biological mechanisms of naturally acquired immunity or the more temporary vaccine acquired immunity is why vaccine makers have always struggled and failed to create vaccines that are both effective and safe for everyone.

As an educated health care consumer, when I look at the quality and quantity of vaccine science, I see large gaps in knowledge that must be filled to demonstrate that national vaccine policies are improving human health at the individual and population level. As a vaccine safety and informed consent advocate for three decades, having served for more than 20 years on vaccine advisory and research committees at the Department of Health and Human Services and Institute of Medicine during which I articulated the vaccine safety concerns of educated health care consumers, following is my perspective.

I will begin by asking a question that I asked myself in the early 1980's when I was researching and writing the book, *DPT: A Shot in the Dark*, which I co-authored with medical historian Harris Coulter and was published by Harcourt Brace Jovanovich in 1985. That question is: why did my precocious little boy, Chris, suffer a vaccine reaction that left him brain injured while Chris's good friend, Timmy, who lived across the street and also got four DPT shots, did not suffer a vaccine reaction and went on to become a straight A honor student?

Between 1983 and 1985, while I was interviewing more than one hundred parents of DPT vaccine injured children, whose case histories were detailed in *A Shot in the Dark* and later reviewed by an Institute of Medicine committee for the 1991 IOM report on *Adverse Effects of Pertussis & Rubella Vaccines,* I concluded that biodiversity is a big part of the answer to that question. That is, there are genetic and biological differences among individuals that, depending upon the types and numbers of vaccines given, along with the potential influence of other environmental co-factors, combine to make the host-vaccine interaction a very risky one for some children like my son.

Like most Americans, I am of mixed heritage: part Norwegian, Irish, Scottish, English, German and Jewish. Our family has been populated with teachers and writers, doctors and nurses, musicians and artists, builders and business owners, soldiers and historians and, with our contributions to society, we have carried with us a genetic vulnerability to atypical immune responses manifested by a history of severe food, environmental and prescription drug allergies; and autoimmune disorders, including rheumatoid arthritis, thyroid disorders, diabetes, inflammatory bowel disease, eczema and migraine. My mother, a nurse, died of lupus. My father, 92, wears a penicillin allergy bracelet. My grandmother died of complications from Parkinson's. My children's biological father, a member of Menza, has multiple sclerosis. My oldest son suffered a serious neurological reaction to DPT at age two and did not completely recover; my youngest son developed a pseudo tumor of the brain after he received DT and oral polio vaccinations at age four and, thankfully, did fully recover and went on to graduate with honors from high school and college.

The day Chris reacted to his fourth DPT shot, the evidence suggests he was biologically, environmentally and genetically at high risk for a DPT vaccine reaction. First, he had suffered a severe local reaction to his third DPT shot; second, he was not entirely well the day of vaccination because he had recently completed a 10-day course of antibiotics and still had mild diarrhea; third, he had a personal history of milk allergy and a strong family history of allergy and autoimmunity; and fourth, he was injected with a crude whole cell pertussis vaccine that contains, among other ingredients:

1. PERTUSSIS TOXIN, which is lethal toxin still used by researchers to reliably induce brain inflammation, specifically experimental autoimmune encephalomyelitis (EAE). After lab animals are injected with pertussis toxin, they suffer encephalopathy manifested by varying degrees of brain dysfunction. Pertussis toxin is still bioactive in DTaP vaccine because it is chemically and not genetically detoxified and can revert to toxicity.

2. ENDOTOXIN, which is a lipopolysaccaride that is part of the cell wall of gram negative bacteria and produces a defensive inflammatory immune response, including the release of histamine, which can lead to swelling, diarrhea, collapse, shock and death. Antibiotics kill bacteria rapidly and the dying bacteria release large amounts of endotoxin in the body. There is still bioactive endotoxin in DTaP vaccine.

3. ALUMINUM (.25 to .85 mg) as an adjuvant to stimulate the immune system to mount a strong inflammatory response. Injected aluminum is associated with chronic brain and immune system dysfunction.

4. MERCURY (1:10,000) as a preservative in the form of thimerosal. Injected mercury is associated with chronic brain and immune system dysfunction.

The day that Chris got his fourth DPT shot, for him, it was a perfect storm and nobody, including his mother and doctor, knew it.

Why? Because back in 1980, there had been little bench science conducted for the express purpose of understanding the biological mechanisms for vaccine injury and death. There were no scientific studies systematically investigating potential environmental, biological and genetic factors that place some individuals at higher risk than others for suffering vaccine complications, including (1) re-vaccination after severe local reactions; (2) vaccination during acute illness or recent recovery from illness; (3) vaccination during antibiotic or recent antibiotic use; (4) personal history of allergy or autoimmunity, including milk and/or gluten allergy; (5) strong family history of allergy and/or autoimmunity.

Thirty years later, there is still no real acknowledgement by mainstream medicine that the unique combination of genes we are each born with, the genes which give us our individual physical, mental and emotional strengths and weaknesses, our special talents and limitations, and which play a major role in defining who we are and what we will become, can also make us more or less vulnerable to suffering complications from atypical manipulation of the immune system by vaccination. There is open acknowledgement that genetic variation plays a role in individual susceptibility to prescription drug reactions that kill more than 100,000 people in the US every year and injure more than two million, but there is little or no acknowledgement that genetics plays a role in individual susceptibility to vaccine reactions. And if emerging scientific evidence linking major histocompatibility complex genes responsible for allergy and autoimmunity with above average intelligence is demonstrated, then one size fits all universal use vaccine policies may be penalizing the brightest and the best, with profound consequences for every society.

Other potential co-factors that could raise the risk for development of brain and immune system dysfunction include exposures to pesticides, chemicals and other environmental toxins; overuse of antibiotics and prescription drugs; nutritionally compromised and contaminated food sources and unhealthy lifestyles. But there is a compelling argument to be made that the dramatic increase in chronic brain and immune dysfunction in children in the past half century, especially the rising number of reports of regression in previously healthy children in the past three decades, is due to an early environmental exposure that is being experienced by all children but which is harming an expanding minority of them.

Many biological responses are at least partially under genetic control. If, for example, adverse responses to vaccination are tied to the genes responsible for predisposition to autoimmunity and immune-mediated neurological dysfunction, then it is possible that the addition of more doses of vaccines to the routine

schedule in the past three decades has affected more and more children with that genetic predisposition. So the pool of genetically susceptible children has not changed but the environmental triggers have increased.

Therefore, when all children only were exposed to DPT and polio vaccine in the 1960's, a small fraction of those genetically vulnerable to vaccine complications responded adversely. But with the addition of the combination measles, mumps, and rubella to the routine schedule in the late 1970's and, then, Hib, hepatitis B and chicken pox in the late 1980's and 1990's, far more of those genetically vulnerable to atypical manipulation of the immune system by vaccination have been brought into the vaccine adverse responder group.

This was the hypothesis that I presented in 2001 to the Institute of Medicine Immunization Review Committee. In their 2002 published report on *Multiple Immunizations & Immune Dysfunction,* this is how the IOM addressed that hypothesis:

"*The committee was unable to address the concern that repeated exposure of a susceptible child to multiple immunizations over the developmental period may also produce atypical or non-specific immune or nervous system injury that could lead to severe disability or death (Fisher, 2001). There are no epidemiological studies that address this. Thus, the committee recognizes with some discomfort that this report addresses only part of the overall set of concerns of some of those most wary about the safety of childhood immunizations."*

Unfortunately, the validity of most epidemiological studies that have investigated and dismissed chronic health problems associated with vaccination have been compromised by what is *not* known about the biological mechanisms and genetic high risk factors for vaccine complications. This lack of knowledge has made it far too easy for doctors inside and outside of government to put policy before science by using an a priori assumption that vaccination is safe and that increased use of multiple doses of vaccines over the past half century has *not* negatively affected the long term health of many children and adults at the population level. It is an a priori assumption that is as unscientific and potentially dangerous as the assumption that an individual child's regression following vaccination is only coincidentally and not causally related to vaccination.

Without pathological profiles to define vaccine injury and death, the coincidence assumption will continue to be used to dismiss vaccine adverse events in clinical trials and those reported to the federal Vaccine Adverse Events Reporting System (VAERS) for the purpose of maintaining the status quo, with all the inherent risks that assumption carries with it. Epidemiological studies will continue to be fatally flawed by the coincidence assumption in the absence of objective, science-based criteria for determining what is and is not vaccine-induced. This is especially true when, for the past 30 years, the great majority of American children have been vaccinated with at least DPT, MMR and polio

vaccines. Therefore, the true background rates in unvaccinated children for mental retardation, medication resistant seizure disorders, learning disabilities, attention deficit hyperactivity disorder, asthma, diabetes and other chronic disease, is unknown.

And this is why for the past decade, the National Vaccine Information Center has been calling for a large, prospective, case controlled study similar to the big heart and cancer studies that last several decades, which would enroll children at birth and compare short and long term health outcomes of three groups of children: those who receive all government recommended vaccines on schedule; those who receive fewer vaccines with an alternative schedule; and those who remain unvaccinated. However, we maintain that the study cannot be confined to clinical observation of all morbidity and mortality outcomes, such as comparison of the rates of learning disabilities, autism, asthma, diabetes and other brain and immune system disorders in each group, but also must contain a bench science component that evaluates pathological changes at the cellular and molecular level to measure over time the similarities or potential differences in immune and brain development and function between the three groups.

The potential role that vaccination has played in the current epidemic of chronic disease and disability often marked by chronic inflammation in the body, cannot be separated from the simultaneous lack of exposure by children to once common childhood infectious diseases. The specter of the hygiene hypothesis looms over an international vaccine program that is encouraging the development of more than 200 vaccines now in stage three trials around the world, many of which will be marketed worldwide and added to the mandatory list in America. Medical science must find out whether mass vaccination programs have harmed child health not only by repeatedly atypically manipulating the immune system during the developmental period, but also by removing early experience with childhood infections that may have naturally assisted with effective immune system development, preparing the way for healthy immune and brain function throughout life.

Medical science also would do well to remember the lessons learned from overuse of antibiotics that have created lethal antibiotic resistant strains of bacteria, as evidence is already emerging to suggest a similar threat is posed by the overuse of vaccines. This raises a larger ethical question: Who in society should have the power to conduct an uncontrolled, unmonitored scientific experiment on mankind by re-engineering the natural order in a vacuum of scientific knowledge about the potential for a catastrophic outcome?

Politicians bowing to pharmaceutical company lobbyists eager to cash in after September 11, 2001 on the national fear of well publicized, still phantom bioterrorism weapons did not consider this when further protecting industry and public health officials from liability for vaccine injuries and deaths.

Finally, I cannot close without briefly commenting about mandatory vaccination policies and the ethical principle of informed consent to medical risk taking, about which I have written extensively since 1996, and which will be the main focus of my work from now on.

Because vaccines are pharmaceutical products that carry an inherent risk of injury or death, which can be greater for some than others, informed consent to vaccination can be defined as a human right. One-size-fits all mandatory vaccination policies are, in part, a de facto selection of those genetically vulnerable to vaccine injury and death for sacrifice in the name of the greater good. There is nothing moral or noble about a government health policy that punishes individuals for the genes they inherited.

Therefore, the seminal 1905 U.S. Supreme Court case, *Jacobsen v. Massachusetts*, which gave the states power to mandate vaccination based on a utilitarian rationale popular at the turn of the 20th century, was a deeply flawed legal decision from a medical and ethical standpoint. The danger inherent in that flawed legal decision was best illustrated when, in 1927, US Supreme Court Justice Oliver Wendall Holmes used *Jacobsen* to justify the state enforced sterilization of a woman judged to be mentally retarded. Justice Holmes said flatly "The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes."

The judges of the Nuremberg Tribunal completely discredited the utilitarian pseudo-ethic that doctors and scientists charged with crimes against humanity utilized to defend themselves at The Doctor's Trial at Nuremberg after World War II. The judges made it clear that, when the greater good is defined by those who benefit from devaluing the life of the individual so they can justify forcing the sacrifice of some for the theoretical well being of others, the very fabric of civilized society is torn apart.

The human right to individual autonomy and self determination when making life and death health care decisions must trump any public health policy requiring individuals to engage in medical risk taking without their voluntary informed consent. There is no single freedom that is more important to defend than the freedom to decide what you are willing to risk your life your child's life for because, without that freedom, we are all vulnerable to exploitation by those wielding power without conscience.

When I became a mother, I learned for the first time how vast the boundary of human love really is and how strong the biological imperative can be when it comes to a mother's natural instinct to protect her own child from harm. There is nothing on this earth that can compete with a mother's innate instinct, which is hardwired into her DNA, to make sure her child survives. Public health officials and doctors promoting the mandatory use of vaccines in a vacuum of scientific knowledge should remember that when placing a higher value on the elusive

community immunity than on the life of a single child.

In the 21st century, the crisis is upon us and there is no time to waste because what may be at stake is nothing less than the biological integrity of the human race. Enlightened and courageous doctors and scientists like those gathered at this conference, can help re-instill public trust in medical science and change national health policies to make them safer.

By laying aside a priori assumptions, you can create new vaccine science to help replace old vaccine policy that has failed so many. And then those, for whom the risks of vaccination have been 100 percent, will no longer be swept under the carpet, and the way will be open for vaccine safety and compassionate public health policy to become a national priority for every nation.

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