Barbara Loe Fisher
Co-founder & President
National Vaccine Information Center
Statement – Public Perspective
Institute of Medicine
Assessment of Studies of Health Outcomes Related to
the Recommended Childhood Immunization Schedule
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Thank you for the opportunity to offer a public perspective at the outset of your deliberations assessing the feasibility of conducting studies to evaluate health outcomes among children, who have and have not been vaccinated according to the federally recommended vaccine schedule.

The non-profit National Vaccine Information Center (NVIC), founded by parents of vaccine injured children in 1982, has called for studies to evaluate health outcomes post vaccination ever since we worked with Congress to include informing, recording, reporting and research provisions in the National Childhood Vaccine Injury Act of 1986. [1] [2] Language in that law emphasized that national public health policy must include mechanisms for increasing vaccine safety and reducing vaccine risks so fewer children will be in need of federal vaccine injury compensation, which to date totals over $2 billion dollars. [3]

Prevention of vaccine adverse effects, however, cannot be achieved without comprehensive understanding of the biological mechanisms for vaccine injury and death and knowledge about which individuals may be disproportionately affected. Therefore, parents supported the inclusion of a congressional request in the 1986 law for the Institute of Medicine to review epidemiological and biological mechanism evidence in the medical literature related to adverse effects of federally recommended vaccines.

In 1991 [4] and 1994, [5] [6] IOM published landmark reports reviewing epidemiological and biological mechanism evidence for adverse effects of nine vaccines. Between 1995 and 1998, the IOM Vaccine Safety Forum was convened and published several reports [7] [8] evaluating methods for improving the safety of vaccines and vaccination programs, followed by nine IOM committee reports [9] reviewing emerging vaccine safety concerns produced between 2001 and 2005. [10]

From the public perspective, however, the 2011 IOM report, *Adverse Effects of Vaccines: Evidence & Causality,* is one of the most important because it reviewed both biological mechanism and epidemiological evidence for eight vaccines recommended and mandated by government for universal use by children and adults. Although there was confirmation in the historic 1991 and 1994 IOM reports that vaccines can cause brain and immune system dysfunction

and that vaccine science gaps hamper complete understanding and evaluation of adverse effects, [11] [12] the 2011 report re-affirmed that fact and also clearly acknowledged biodiversity and increased susceptibility for some individuals to suffer harm from vaccination.[13] The recognition that certain genetic, biological and environmental co-factors can increase the risk of vaccine injury and that all high risk factors are not yet known, is a very important step toward securing support for scientific research that will yield the knowledge required to reduce vaccination risks for those, who are most vulnerable to suffering complications of vaccination.

Being able to define increased individual susceptibility is critical to securing the public's trust [14] in the soundness, fairness and safety of national vaccine policies. In 2011, the U.S. Supreme Court completely shielded pharmaceutical corporations producing and marketing vaccines from liability for the safety of vaccine products in civil court, [15] [16] and liability protection was also extended by Congress to pediatricians and other vaccine providers in the 1986 law.

The public is increasingly distrustful of the one-size-fits-all, universal use approach that is designed to maximize individual vaccine use and increase population coverage. Preventing vaccine injuries and deaths often takes a back seat and is left out of the parent-pediatrician and patient-doctor encounter altogether. [17] [18] Federal vaccine policies and state mandates, which fail to acknowledge biodiversity and the fact that we are not all the same and do not all respond the same way to vaccines - just as we do not all respond the same way to prescription drugs [19] - is appropriately viewed by parents as inherently unequal, unsafe and unethical when the risk of vaccine injury or death for their child turns out to be 100 percent. [20]

In 2002, I joined with other vaccine stakeholders in an experiment in participatory democracy, the Vaccine Policy Analysis Collaborative, which was initiated by Dr. Roger Bernier at the Centers for Disease Control and facilitated by Keystone Center. [21] By the time the stakeholder engagement initiative ended in 2005, there was a deep divide between public representatives, who wanted to focus on the need to conduct better quality vaccine science to inform policy, and representatives from industry, medical trade associations and federal health agencies, who wanted to focus on defining differences in values and beliefs among stakeholders.

When a second stakeholder initiative was undertaken by the National Vaccine Advisory Committee to discuss national scientific research agenda priorities, those of us, who represented the public at a 2009 meeting facilitated by Keystone in Salt Lake City, [22] again communicated the need for better quality vaccine science to inform policy. The meeting ended with a call for an independent evaluation of the feasibility of studying children, who are and are not vaccinated according to the federally recommended schedule, to assess health outcomes including biomarkers of immunity and metabolism,

neurodevelopmental disorders, allergies, asthma, immune-mediated diseases, learning disabilities and autism." [23]

The eradication and control of many infectious diseases through universal use of vaccines is often placed at the top of the list of most notable public health program achievements in the past two centuries. Why then, are there public calls today for a study to evaluate potential health differences between vaccinated and unvaccinated children? This is occurring primarily for two reasons: first, unlike prescription drugs given to sick people to make them well, vaccines are given to healthy people to keep them well; and, second, today everybody either has a child or knows a child, who was healthy, got vaccinated, and was never healthy again.

The electronic communications revolution has made more information accessible to more people than any other generation. Educated health care consumers are empowering themselves with information about pharmaceutical products, including vaccines. [24] [25] [26] [27] [28] [29] [30] [31] They are asking doctors questions about the scientific evidence that supports government recommendations that pregnant women be vaccinated with influenza and pertussis vaccine [32] and that children get 69 doses of 16 vaccines from day of birth to age 18, [33] which is three times as many vaccinations as children got 30 years ago. [34]

These questions are being asked because, as the numbers of American children experiencing acute infectious diseases has significantly decreased in the past half century due to mandatory use of multiple vaccines, the numbers of children suffering with chronic disease and disability has dramatically increased. Today, 1 child in 6 is developmentally delayed; [35] 1 in 9 has asthma; [36] 1 in 10 is diagnosed with ADHD; [37] 1 in 110 develops autism; [38] [39] and 1 in 450 becomes diabetic. [40] Millions more have life threatening food and environmental allergies; [41] seizures, [42] mood and behavior disorders; [43] inflammatory bowel disease; [44] juvenile rheumatoid arthritis [45] and other kinds of autoimmune and neurological problems marked by chronic inflammation in the body.

The United States ranked 12th in infant mortality among all nations in 1960 and now ranks number 30. In America, 6 in 1,000 babies die before their first birthday [46] and most of them receive twice as many vaccinations by age one as babies in European countries with much lower infant mortality rates. [47] The rate of diagnosable mental, behavioral or emotional disorders is twice as high among those aged 18 to 25 (29.9%) as among those over age 50 (14.3%). [48] U.S. life expectancy rates are lower than many other developed nations. [49]

Environmental co-factors, such as vitamin deficient, processed foods; chemical contamination of soil, water, air and household products; overuse or misuse of prescription drugs; too little exercise and sleep; and too much stress could be playing a role in the premature deaths and health deterioration of infants, children and young adults. However, the significant change in vaccine schedules during

the past half century, which has altered the way infants and children immunologically experience their environment, [50] [51] cannot be left off the table when it comes to investigating the unexplained child chronic disease and disability epidemic, an epidemic that is bankrupting families, [52] the health care system [53] and public schools, which can't build special education classrooms and train special ed teachers fast enough. [54]

Parents, who have witnessed one healthy child die or suffer vaccine reaction symptoms and regress into chronic illness and disability after vaccination, often choose to give fewer or no vaccines to their subsequent children and are reporting that their partially or unvaccinated children remain healthy. Families, who have never vaccinated their children and are consciously avoiding toxic environmental exposures; eating organic and employing natural health options for healing and staying well, report that their children quickly recover from acute infections without complications and are athletes and honor roll students. Although these real-life experiences are dismissed by some as irrelevant "anecdotal evidence," others view it as compelling empirical evidence they use to keep their well children well.

From a public perspective, the following two questions must be answered without delay:

(1) Is inflexible implementation of one-size-fits-all vaccine policies using an expanded vaccine schedule compromising the health of a growing minority of children, who are biologically susceptible to developing chronic brain and immune system dysfunction after vaccination?

(2) Is the increased use of multiple vaccines to prevent almost all experience with acute infectious disease during infancy and childhood contributing to better long term health on an individual and population basis or is the a priori assumption that more vaccination is better producing unintended consequences?

Educated consumers have noted that too often clinical trials of new vaccines conducted by drug companies are fast tracked to licensure but (1) fail to use inactive placebos as controls; (2) include too few children in the age group that will be targeted for universal use; (3) have inadequate periods of time for follow up of safety and effectiveness; (4) only study healthy children without personal or family histories of vaccine reactions, autoimmunity, allergy, neurological disease or concurrent illness (although children with these medical histories are specifically targeted for vaccination post-licensure with very few medical contraindications listed to guide physicians); (5) fail to study large numbers of children given the experimental vaccine simultaneously with all other vaccines routinely administered simultaneously to children in that age group; (6) dismiss serious health problems, injuries and deaths occurring during the trial as not related to the experimental vaccine without adequate justification; (7) use

questionable surrogate endpoints to demonstrate effectiveness; and (8) lack adequate post-licensure follow-up. [55] [56] [57] [58] [59] [60]

Greater public knowledge about gaps in vaccine science has fueled the calls for methodologically sound studies evaluating the health of vaccinated and unvaccinated individuals conducted by independent researchers, who are not employed by or receive vaccine research grants from either industry or government.

The few published studies, which have evaluated health outcomes of vaccinated and unvaccinated children, have been small retrospective studies. [61] After a four-year collaboration between NVIC and researchers at University of Illinois-Chicago to investigate development of asthma and hay fever among vaccinated and unvaccinated children, the study results were published in 2005 in the *Journal of Allergy and Clinical Immunology*. [62] Researchers found that "In multiple regression analyses there were significant and dose dependent negative relationships between vaccination refusal and self-reported asthma or hay fever [and] self reported eczema and current wheeze." A retrospective Canadian study found that delay in administration of DPT vaccine was protective against development of asthma. [63]

The National Vaccine Information Center supports the funding of a large, prospective study conducted in accordance with IRB approval processes, informed consent and voluntary participation. Pregnant women would volunteer to enroll in the first trimester and their infants/children would be followed for 15 years to evaluate all morbidity and mortality outcomes and measure pathological changes in immune and brain function of pregnant women, their fetuses and children. Pregnant women would agree to either be vaccinated or remain unvaccinated during pregnancy and choose to give their children all federally recommended vaccines on schedule; use an alternative schedule; or have their children remain unvaccinated.

Assuming the study was sufficiently powered and the sample large enough, at the end of six years preliminary results should reveal whether there are significant differences in miscarriage incidence and fetal/infant death, as well as differences in brain and immune function as evidenced by learning disabilities; ADD/ADHD; autism spectrum disorder; seizure disorders; inflammatory bowel disease; asthma; severe allergies; diabetes; juvenile rheumatoid arthritis; mood and behavior disorders and other health outcomes.

The combination of epidemiological and pathological evidence should help to identify genetic, biological and environmental factors that increase or decrease risks of infant death or development of chronic disease and disability among children with different exposures. The identification of children with increased susceptibility to suffering vaccine injury and death would enable parents and

doctors to make informed clinical decisions that are consistent with the precautionary principle [64] when administering vaccines to high risk children.

Other study designs could be considered if a prospective study of pregnant women and their children is judged to be not feasible. For example, a prospective randomized control trial could be conducted in vaccinated and unvaccinated primates. Additionally, a retrospective case control study of pregnant women and children, who had different vaccine schedule exposures or remained unvaccinated, could also be conducted with statistical controls used to adjust for effects due to potential confounding variables. Also the health outcomes of vaccine injured children awarded federal compensation could be compared to their siblings, who have received fewer or no vaccines. This study could yield important information about genetic, biological and environmental high-risk co-factors.

Public confidence in vaccine science that anchors national vaccine policy and law must be strong or the public will reject future mass vaccination initiatives, even if the heel of the boot of the state is used to try to force compliance. [65] [66] When children, who have experienced vaccine reaction symptoms and health deterioration after previous vaccinations, are being denied medical exemptions and medical care by increasingly hostile pediatricians throwing parents out of their offices if they refuse to give their children every federally recommended vaccine on schedule, there is a serious problem with implementation of mass vaccination policies in America.

Lack of respect for informed consent rights [67] [68] [69] and erosion of parental rights, [70] driven by organized efforts by public health officials and medical trade organizations to remove non-medical vaccine exemptions in public health laws,[71] [72] [73] [74] [75] [76] is further eroding public confidence in mass vaccination policies and creating fear and distrust of those doctors inside and outside of government, who inflexibly enforce them. [77] With all civil liability and accountability for vaccine injuries and deaths having been removed from vaccine manufacturers and vaccine providers, public health officials and members of the scientific community have a special social responsibility and moral obligation to ensure that the risks of vaccination are not disproportionately borne by individuals, who are at greater genetic, biological and environmental risk for suffering vaccine harm.

The National Vaccine Information Center maintains that good science will lead to wise and compassionate vaccine policies that secure public confidence because every life is being respected and protected, including those with increased susceptibility to suffering adverse responses to vaccination. [78] The gaps in vaccine science must be filled immediately, starting with methodologically sound research into health outcomes of vaccinated and unvaccinated children.

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