Fall 2004

Institute of Medicine Report on Vaccines and Autism: A Case of Political Immunology



THE NATIONAL VACCINE INFORMATION CENTER (NVIC) strongly criticized the May 18, 2004 report on autism and vaccines issued by the Immunization Safety Review Committee of the Institute of Medicine (IOM) and said in a national press release that the report seriously jeopardized IOM's credibility to conduct independent, unbiased analyses of vaccine risks. NVIC also released a letter written by NVIC President, Barbara Loe Fisher, to the National Academy of Sciences on December 18, 2000 expressing concern about the ideological and professional conflicts of interest of members of the Committee.

The IOM report rejected emerging clinical and mechanism evidence. biological including experimental studies in animals, demonstrating a causal relationship between neuroimmune dysfunction and vaccination. But it was statements issued by the IOM Immunization Safety Review Committee calling for an end to research into vaccine-associated autism and suggesting that the costs of caring for autistic children should be eliminated from future cost-benefit analyses of thimerosal risks, that prompted NVIC to brand the report a case of "political immunology."

"This report is a case of political immunology masquerading as real science," said NVIC's Fisher. "With it, the Institute of Medicine takes a step toward weakening its reputation as an independent body capable of making an objective scientific analysis of complex medical risk issues that are influenced by government policy and industry profits."

Earlier IOM Reports Call for More Research—In a 2001 report, the same IOM Committee had rejected a causal relationship between MMR vaccine and autism "at the population level" but stated that "the proposed biological models linking MMR vaccination to autism spectrum disorders, although far from established, are nevertheless not disproved" and called for further research. In another 2001 report, the Committee concluded that there was not enough scientific evidence to determine whether the vaccine mercury preservative thimerosal did or did not cause autism or other neurodevelopmental delays but added that there was enough evidence that mercury can damage the human brain to recommend that mercury preservatives be removed from all vaccines and over-the-counter consumer products. At that time, the IOM again appropriately called for further research into the association between autism and vaccines.

The IOM receives funding from the pharmaceutical industry, government agencies and private foundations to provide "independent" analyses of scientific and public health policy issues. Reportedly, the pharmaceutical companies producing vaccines and CDC officials were "furious" about the IOM's 2001 report taking the position that all mercury preservatives should be removed from vaccines. Parents maintaining their autistic children were poisoned by mercury in vaccines, had attempted to stop the IOM Committee from conducting another analysis on vaccines and

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autism this year. They contended that IOM should not rely on government and industry-led epidemiological studies published in the last two years but should wait for independent biological and clinical studies in progress to be published. The IOM refused to delay the analysis.

"For this Committee to reject emerging biological evidence of a causal relationship between vaccines and brain damage leading to autism in favor of flawed epidemiological studies primarily using old medical records is tragic," said Fisher. "When the real science comes out, demonstrating that vaccines can cause autism in genetically susceptible children, this Committee's conclusions will be meaningless."

A Question of Conflicts of Interest—In her 2000 letter to the National Academy of Sciences when the

"This report is a case of political immunology masquerading as real science..."

Barbara Loe Fisher
 NVIC President

Committee was first appointed, Fisher pointed out that, unlike the 1991 and 1994 reports issued by the Institute under a congressional mandate from the National Childhood Vaccine Injury Act of 1986, the current IOM Committee was assembled at the request of and funded by the federal Department of Health and Human Services (DHHS), specifically the Centers for Disease Control (CDC) and the National Institutes of Health (NIH). DHHS is responsible for the research, development, regulation, policy-making and promotion of mass use of vaccines.

At the time, she questioned whether the Committee could remain objective when assessing vaccine risk issues that affect entrenched public health policy due to the facts that (1) the CDC and NIH were directing and funding the Committee's work and (2) many Committee members had a public health policy background and were receiving

substantial NIH research grants, or were employed by universities receiving substantial NIH, CDC and vaccine industry research grants.

The IOM report is expected to be used by federal health officials and the Department of Justice to deny federal vaccine injury compensation to nearly 5,000 pending cases of vaccine-related autism in which vaccine mercury preservatives are alleged to be involved. The Vaccine Injury Compensation Program (VICP) was created by the National Childhood Vaccine Injury Act.

Parents Protest Closed Vaccine Database At IOM Meeting

At the request of the Centers for Disease Control (CDC), the Institute of Medicine convened a committee and held a public meeting on August 23, 2004 to examine the CDC's procedures for sharing data from the CDC-operated Vaccine Safety Datalink (VSD) with independent researchers. Parents, who believe their autistic children were poisoned by mercury preservatives in vaccines, held a demonstration in front of the Institute of Medicine before the meeting began, charging that the CDC was using the IOM to try to keep the information on vaccine risks in the database closed to public scrutiny.

Most of the presentations at the meeting were made by CDC officials. However, independent researchers Mark Geier, M.D., Ph.D., who received NVIC's "Courage in Science" award in 2002, was invited to speak along with his son, David. The Geiers recounted how CDC officials repeatedly tried to block them from accessing VSD data used by the CDC to publish studies denying a causal link between mercury preservatives and neurodevelopmental delays, including autism.

A Matter of Public Trust—NVIC President Barbara Loe Fisher was invited to speak from the perspective of a consumer group. She told the Committee, "The hallmark of good science is replication and the hallmark of good government is transparency," and "the public has good reason to be appalled at the description of the lengths to which CDC officials have gone to deny independent continued on page 3

researchers access to vaccine risk information in the publicly-funded VSD." Fisher maintained that the public trust is lost when government hides information about vaccine risks from the public and that preventing research into vaccine risks is unacceptable, especially when the CDC admits that 1 in 6 American children today have been diagnosed with a developmental disorder or behavioral problem. She added that 3 million children in public schools are classified as learning disabled and 94,000 more are classified as autistic; 4 million children have been diagnosed with ADHD and 9 million with asthma; 300,000 children have juvenile rheumatoid arthritis and 1 in 400 to 500 children are now diabetic.

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"... the public has good reason to be appalled at the description of the lengths to which CDC officials have gone to deny independent researchers access to vaccine risk information in the publicly-funded VSD."

Barbara Loe Fisher
 NVIC President

At the IOM meeting on Aug. 23, NVIC announced the launching of a national petition called "Show Us the Vaccine Data." It was posted on an on-line petition site on Sept. 3 and, within 72 hours, had secured more than 2,000 signatures, making it the number-one performing petition on that site. By the end of the first week, the petition had more than 6,000 signatures. The petition has become a living testament to the devastating effects that vaccine reactions have on the lives of families, with the majority of signers describing how their children's health was ruined following vaccination. NVIC's goal is to secure 100,000 signatures before presenting it to Secretary of Health Tommy Thompson. To sign the petition, go to www.nvic.org/petition.htm.

Show Us The Vaccine Data Petition

Whereas, Vaccines are given to healthy children and carry an inherent risk of injury or death; and federal officials recommend vaccines for universal use and states base their mandatory vaccination laws on those recommendations; and

National monitoring of vaccine reactions is almost nonexistent because there is no enforcement of a 1986 federal law requiring doctors to report adverse events to the federal government; and

The vast majority of vaccine safety studies are conducted by government health officials promoting the mandatory use of vaccines and drug companies selling vaccines; and

The government bases its research and conclusions that licensed vaccines are safe on unpublished data, including data contained in closed government-operated databases, like the Vaccine Safety Datalink (VSD); and

Because the hallmark of good science is replication and the hallmark of good government is transparency.

Therefore, We call on Secretary of Health, Tommy Thompson, to provide the public, especially non-government, non-industry-affiliated vaccine researchers, with full, open and timely access to all government vaccine safety monitoring data, including the Vaccine Safety Datalink (VSD).

Parents Speak Out

Below are comments from parents signing the petition when answering the question:

"Have you or a family member experienced a vaccine reaction?"

"My daughter began having seizures a couple of days after receiving her first DPT vaccination at the age of five months. She is now 24, developmentally disabled, and has a seizure disorder."

"My son presented with autism symptoms the week after his third hepatitis B shot at 9 months old. Today he is a 9-year-old autistic boy...." "My daughter was hospitalized after her first DPT. We put off all other immunizations until 3 years 4 months when she got the MMR. After the MMR she began hand flapping, non-stop teeth grinding and chronic diarrhea..."

"My child, now age 11, developed persistent lymphadenopathy at age 2.5 after a hospital gave him a TD and a tetanus booster at the same time because I did not have his vaccination records with me when I rushed him to emergency for a cut on the head. I held off giving him the MMR. When it was administered prior to entering school, he regressed into autism within weeks."

"After hepatitis B [vaccination], my two-week-old daughter had a seizure but we were told by a young and naïve neurologist that there was nothing wrong and to "keep vaccinating." After DTaP, she developed chronic diarrhea. Failure to thrive at 8 months, and pervasive developmental disorder (PDD) at 24 months."

"No, we selectively vaccinate."

"No, as we did not have our children vaccinated. I treat vaccine reactions as a alternative practitioner..."

"My son, my beautiful son."

"When my 1-year-old got the MMR he went into a catatonic state with high fever. Now at 4, he does not talk and is severely autistic."

"My daughter has moderate autism as well as other disabilities. She started having many problems after the first hepatitis B shot at age one month. She has shown high mercury levels in her hair analysis. She also has hypotonia, chronic GI problems, diagnosed with ulcerative colitis and multiple food allergies. She has severe sensory disorder and OCD. She is only 10 years old. ..."

"My son was advanced in all developmental areas until after a set of vaccinations around his seventh month. A couple of weeks after the last set of his vaccinations, he woke up screaming, refused to let me touch him, and instead of using the few words he had, he hummed all day flipping a tag on one of his toys. At 20 months he was officially diagnosed with severe autism ... this was after a year of intense work with him to bring him back after the vaccines. My son has not hugged or kissed me in over a year."

"I have never heard about this until my cousin sent me a link. I say show the vaccine [data] if you have nothing to hide. Give some to outside scientists to study. What the h--- is your mental malfunction? You're lucky it is not my kid. You would receive more than a petition."

Two Mercury Petitions Pending at FDA

In December 2001, NVIC filed a citizen's petition with the Food and Drug Administration (FDA) that called for "the immediate suspension and expedited revocation of all vaccines containing thimerosal for which there is an existing thimerosalfree formulation." The petition was filed on behalf of members of NVIC who support the withdrawal of mercury-containing vaccines from vaccine stocks. NVIC has never received a written response from the FDA. In a recent follow-up telephone call to the FDA, NVIC director, Kathi Williams was told, "We have never missed the 180-day turnaround to respond to a petition but we did this time and there is no good explanation of why." NVIC was told that a response would be issued in a couple of months.

On August 23, 2004 a second petition was filed by CoMed (Coalition for Mercury-free Drugs). Among other actions, the CoMed petition calls on the FDA to "suspend the approval or licensing of any FDA-regulated product that contains thimerosal or any other mercury-based compounds as a preservative, or adjuvant, in the final formulation unless the total level of said compounds is not more than 0.5 micrograms of mercury per dose for vaccines..."

Federal regulations require that a citizen's petition be answered within 180 days of filing. ■

Mothering Magazine Tells NVIC Story

In a cover article in the Sept./Oct. issue of *Mothering Magazine*, NVIC co-founder and president. Barbara Loe Fisher.



Magazine, NVIC co-founder and president, Barbara Loe Fisher, discussed the association between increased vaccination of children and the dramatic rise in chronic disease and disability in children in the past quarter century. In the article, she described what happened to her two-and-a-half year old son, Chris, after his fourth DPT shot in 1980. She also talked about the many vaccine reaction reports that NVIC has taken over the past 22 years and outlined the central issues of the vaccine safety debate as more and more American children get vaccinated and become learning disabled, autistic, asthmatic, diabetic and chronically ill with other brain and immune system disorders. For more information go to www.Mothering.com.

"... there have never been any prospective, large, long-term studies comparing the long-term health of highly vaccinated individuals versus those who have never been vaccinated at all."

Barbara Loe Fisher
 "Vaccines and Chronic Illness:
 The New Epidemic"
 Mothering Magazine, Sept./Oct. 2004

California Limits Mercury in Vaccines



In early August 2004, NVIC issued a "Call to Action" to California members in support of the Mercury-Free Act of 2004 (AB 2943) sponsored by Assemblyperson Fran Pavley (D-41st). The legislation strictly limited the amount of mercury in vaccines or products used by pregnant women and very young children in the state of California after 2006. It passed the California Senate 22-13 on Aug. 24, passed the Assembly August 25 on a bi-partisan 48-21 vote, and was signed into law by Governor Arnold Schwarzenegger on September 28.

Drug Companies Oppose Bill—The bill's sponsor, Assemblyperson Pavley, has a long and distinguished record of public service. She is the great granddaughter of the famous lawyer, William Jennings Bryan, and the mother of an adult developmentally delayed son. Her legislation was strongly opposed by flu vaccine manufacturers

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Aventis Pasteur and Chiron, as well as the California Conference of Local Health Officers. The bill was enthusiastically supported by families, especially those of vaccine-injured autistic children. After the bill passed the legislature, Rick Rollens, the father of an autistic son and former secretary of the California Senate as well as co-founder of the M.I.N.D. Institute at UC-Davis, commented that lawmakers "basically said no to special interests" profits and yes to children's health."

NVIC's Action Alert to California members included a copy of an editorial in *The Los Angeles Times* endorsing the bill, as well as information about how NVIC members could visit and write to their legislators. After passing both houses of the legislature, the bill was sent to Governor Arnold Schwarzenegger for his signature, and NVIC issued another Action Alert informing members about how to visit and write to the Governor to make their voices heard. Parent groups representing autistic children also actively promoted the bill in California.

Similar legislation strictly limiting mercury, that is a known neurotoxin, in vaccines has been passed in Iowa and is pending in several other states.

NVIC: Warning in 2001 Smallpox Report Confirmed

Just three months after September 11, 2001, NVIC published a comprehensive report on smallpox and smallpox vaccine questioning the safety and necessity of the government's plan to vaccinate all Americans against the theoretical use of weaponized smallpox by bioterrorists. The special report published in THE VACCINE REACTION also criticized proposed legislation to force Americans to use the highly reactive smallpox vaccine without informed consent whenever government officials persuade elected officials there is an "imminent" threat of a bioterrorist attack. Those early warnings by NVIC in 2001 proved prophetic in the light of a July 2004 Senate report on pre-war intelligence that said there is "no evidence" Iraq ever weaponized smallpox.

Using Fear to Force Vaccination—NVIC's report, "Smallpox and Forced Vaccination: What Every American Needs To Know," detailed the difficulty of weaponizing smallpox, which included (1) theft of smallpox virus from secure facilities in the US or Russia; (2) technical expertise and laboratories to culture and maintain the virus; (3) ability to transport the virus in liquid or powder form without destroying its effectiveness; (4) the technology to evade U.S. security systems and deliver it to large numbers of Americans. In an editorial, Barbara Loe Fisher suggested that federal officials were using

the fear generated by the September 11 terrorist attack to push for legislation that would force mass use of smallpox vaccine and eliminate the right to informed consent to vaccination. She commented:

"Certainly, America should have a sound, workable emergency plan in place in the event of a bioterrorism attack, but not one that places the life and liberty of the majority of citizens in the hands of an elite few, who will have the power to take both from citizens without their consent."

Health Care Workers Say No—Despite little evidence that the weaponized smallpox threat was real, there was very real evidence that the old, crude smallpox vaccine stored in warehouses for decades was a threat to individual and public health. Nevertheless, US military and federal health officials insisted that all health personnel, who would be "first responders" after a bioterrorist attack, be vaccinated, and instituted a mandatory smallpox vaccination of all U.S. military service personnel. It quickly became apparent once civilian and military personnel began being vaccinated that NVIC's early warning about the extreme reactivity of the smallpox vaccine and the potentially exaggerated theoretical risk of a bioterrorism attack using smallpox as a weapon was

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right on target. By late 2002, civilian health care workers were refusing to take the vaccine and the government's plans for mass vaccination were essentially abandoned.

Smallpox Vaccine Deaths and Injuries—The result of this flawed smallpox mass vaccination plan reportedly has resulted in close to 900 vaccine adverse events, including one confirmed death, reported in nearly 40,000 civilian first-responders vaccinated. At least one death and 75 cases of heart inflammation caused by the vaccine in the military vaccination program has been reported. In the meantime, federal officials convinced Congress to pass legislation which accelerates development of "bioterrorism" vaccines and gives power to public health officials to strip citizens of informed consent rights and force vaccination whenever the government declares an "imminent" public health emergency. Many state legislatures have also passed similar legislation, although NVIC and state vaccine safety and informed consent advocates have instituted stronger informed consent protections in some state laws, including Connecticut.

NVIC Highlights



Savannah Jillani and NVIC's Barbara Loe Fisher in Charlotte, North Carolina after the Parents Advocating Vaccine Education (PAVE) 2004 Conference on May 5, at which Fisher spoke to several hundred parents about "Vaccination: The Right to Know and the Freedom to Decide." At the end of the day, 12-year old Savannah sang "Angel" and dedicated it to children who have died from vaccine reactions.

NVIC Counsels Parents Reporting Vaccine Reactions



Geeta Barr at NVIC headquarters in Vienna, Virginia

NVIC has operated a Vaccine Reaction Registry since it was founded in 1982. Over the past 22 years, requests for information and reports of vaccine reactions have been increasing. Today, NVIC receives more than 200 phone calls every month from parents requesting general information and about 50 vaccine reaction reports ranging from

mild local reactions to severe reactions ending in death or permanent health problems.

Everyone on the NVIC staff has taken vaccine reaction reports including Diane Brisk, R.N., who recently left the NVIC staff after seven years. Today, Geeta Barr is the NVIC staff member who most frequently interviews parents reporting vaccine reactions. The experience and knowledge Geeta gained from attending medical school helps her with a job that can be intellectually and emotionally challenging.

More Parents Reporting Vaccine Reactions—Since she joined NVIC in 2000, Geeta has noted an increase in reports of young infants dying after vaccination; toddlers regressing into autism after receiving multiple vaccinations; onset of seizures in 4 to 6 year olds and an increase in reports of adults having reactions after hepatitis B and A vaccines, tetanus boosters and flu vaccinations. "Grieving continued on page 8

parents call to talk to me about how their infants suddenly died after getting DTaP, HIB, pneumococcal, polio and hepatitis B vaccines all on the same day. Some of them are being charged with murder because there is bleeding in the brain that doctors insist is a result of shaking the baby even though there are no other signs of physical trauma."

Nursing students and adult health care professionals are continuing to report joint and muscle pain and weakness, chronic fatigue and inability to think clearly after hepatitis B vaccination. "These are high functioning individuals who get a hepatitis B shot and then cannot finish school or go to work. They become totally unable to function."

Doctors Don't Listen To Parents—Many parents, who report that one of their children regressed into autism after vaccination, are seeking advice from NVIC about vaccinating their other children because their pediatricians are insisting that vaccines do not cause autism and pressuring them to keep vaccinating the autistic child as well as siblings. The most difficult conversations are with mothers of brain-injured children who tell me that their instincts told them their child was having vaccine reaction symptoms but their pediatricians told them not to worry and to keep on vaccinating."

When doctors refuse to acknowledge a parent's report that their child reacted to vaccination or throw

"We always tell parents to do as much research as possible and talk to several health care professionals before making a vaccination decision."

> — Geeta Barr NVIC

them out of the office when they ask questions or want to choose an alternative vaccination schedule, they often eventually find their way to NVIC. "When a parent reports a vaccine reaction that has left their child with a severe health problem, a lot of times it helps them to know that it has happened to other children. They are so relieved to find someone who takes what happened to their child seriously and can help them find doctors who will offer healing therapies or lawyers who will help them navigate through the Vaccine Injury Compensation Program. And often we help them report the child's vaccine reaction to the Vaccine Adverse Event Reporting System (VAERS) when their doctor refuses to do it."

Most Parents Well Educated—Geeta has observed that most people she talks to are well educated and *continued on page 9*

NVIC Highlights



NVIC Director Kathi Williams exchanges her "No Forced Vaccination – Not In America" t-shirt with a young Austrian boy who gave her a "Kiropraktik" t-shirt at the July 16-18 World Chiropractic Alliance European Conference in Innsbruck, Austria where NVIC's President spoke about vaccines to several hundred European chiropractors.

either have done some research before contacting NVIC or intend to do more research. "They definitely feel more comfortable about sitting down with the information and trying to make a decision after talking to us. I may direct them to call their county health department or refer them to our Web site links to the CDC and FDA. I have found that most people are looking for *all* the information and they want to talk with someone who isn't afraid of their questions about vaccines and diseases. These are smart people who want to understand both sides of the story and they don't want to be told what to do – they just want all the information they can get and the freedom to make their own decision."

Geeta, whose father is a medical doctor and mother is director of a nursing school, was born in the United States but moved to southern India when she was 11 years old. She attended medical school in Dominica and after graduating, became interested in the holistic approach to health care and taught in college. She says she likes her work with NVIC

because "I like to help people become educated about health care issues so they can feel more comfortable and take responsibility for the decisions they make. Most people think it can't happen to them and when it does, they are surprised to learn they should have done a lot more research. It is sometimes sad and frustrating to talk to parents every day who tell me the same stories over and over again about how their children were fine one day and then, after vaccination, got so sick. Sometimes it feels like we aren't getting anywhere but we can't stop doing this work. If we are able to save one child or one family it is worth it and we have to keep going."

NVIC's Web site, which is the largest and oldest consumer-operated vaccine safety Web site, averages 30,000 to 40,000 hits per month and NVIC's free internet e-news service communicates with more than 5,000 subscribers almost every day. To report a vaccine reaction or sign up for NVIC's e-news service, go to www.NVIC.org. ■

NVIC Highlights



NVIC co-founders Fisher and Williams with Dr. Carch at Miami Children's Hospital after giving a presentation Apr. 28 on "Doctors and Parents Preventing Vaccine Reactions" to pediatric residents during National Immunization Week

So Many Sick Children—"The American people want to know why so many highly vaccinated children are so sick. They want and deserve an answer to that question. Openly and honestly analyzing information on vaccine risks contained in government databases, such as the VSD, is one place to begin. And it is up to all of us, parents and health care professionals, government officials and industry, to continue searching for the answer to that question until we have found it. It doesn't matter where we have to look, or what we have to spend, or how many times we have to examine a biologically plausible but politically incorrect hypothesis to find that answer. All that matters is finding the answer because the biological integrity of our children and our nation's future hangs in the balance." Her entire presentation and slides can be viewed on NVIC's Web site at www.NVIC.org.

At the end of the meeting, there was an hour and a half of public comment time. The meeting room was filled with parents of vaccine-injured autistic children, who challenged CDC officials and questioned whether the IOM Committee was being pressured by the CDC and industry to keep the VSD

closed to outside researchers. Representatives from autism groups, including SAFEMINDS, National Autism Association, Moms Against Mercury, CoMed, NoMercury.org and Unlocking Autism, many of whom had participated in the morning demonstration, spoke about how their families had been affected by vaccine-related autism. NVIC informed the Committee and CDC officials that NVIC stands united with autism parent groups in demanding full public disclosure of all government-held vaccine risk data.

NVIC has urged full public disclosure by federal public health officials of both Vaccine Safety Datalink data and Vaccine Adverse Event Reporting System (VAERS) data on the risks of vaccines, including the safety of vaccine additives such as thimerosal, since the late 1990s. NVIC has also been calling for independent, nongovernmental, non-industry research into the genetic and other biological high-risk factors of vaccine-associated brain and immune system dysfunction, including autism, for the past two decades.

Parents

HELP PREVENT VACCINE REACTIONS — IF YOU VACCINATE, ASK EIGHT:

- 1. Is my child sick right now?
- 2. Has my child had a bad reaction to a vaccination before?
- **3.** Does my child have a personal or family history of:
 - vaccine reactions
 - · convulsions or neurological disorders
 - severe allergies
 - immune system disorders

- 4. Do I know if my child is at high risk of reacting?
- 5. Do I know how to identify a vaccine reaction?
- 6. Do I know how to report a vaccine reaction?
- **7.** Do I know the vaccine manufacturer's name and lot number?
- 8. Do I know I have a choice?

Ask your doctor for thimerosal (mercury) free vaccinations. MAKE INFORMED VACCINATION DECISIONS

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National Vaccine Information Center

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