

## Global Vaccine Perspective

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Many parents and physicians feel a sense of frustration when the request is made to delay immunizations. The doctor is usually disapproving, and the parents may leave the office feeling irresponsible.

### The Thimerosal / MMR Vaccine and Autism Issue

The pro- and anti-vaccine groups are shrewd in their marketing techniques. Many families feel pressured and confused after reading diverse positions written by both sides of the issue. One of the biggest controversies involves thimerosal, a mercury-based preservative used in vaccine production. The harmful effects of exposure to heavy metals such as mercury are well-documented, especially in children and fetuses. Mercury is a known neurotoxin and causes neurological problems like personality changes, nervousness, tremors and dementia. These ailments develop over time; mercury is not excreted and accumulates in the tissues of the body. Accordingly the Food and Drug Administration (FDA) requested that thimerosal be removed from almost all vaccines for children. By 2002 thimerosal was only left in the influenza vaccines as well as in vaccines for anyone older than seven years. That is, thimerosal remains in the flu shot, including the one administered to six-month old babies and pregnant women.<sup>1</sup> Observers and critics would agree that the FDA and the Advisory Committee on Immunization Practices (ACIP), a branch of the Center for Disease Control (CDC), are slow in responding to the repeated and long-standing concerns raised regarding this known neurotoxin.<sup>2</sup> To help alleviate the continued anxiety regarding the uninterrupted use of thimerosal, the Institute of Medicine (IOM), the healthcare think tank for the National Academy of Sciences, reported in 2004 that scientific evidence “favors rejection of a causal relationship” between exposure to thimerosal and autism.<sup>3</sup> The larger issue of thimerosal as an accumulating neurotoxin still remains. The big question is what percentage of mercury accumulation causing neurological problems is due to vaccines?

A great deal of controversy also exists regarding the possible connection between autism and the Measles Mumps Rubella (MMR) vaccine. Compelling information exists on both sides of the argument. The *New England Journal of Medicine* published an article in 2002 that concluded there is “strong evidence against the hypothesis that MMR vaccination causes autism.”<sup>4</sup> The *NEJM* did not initially disclose that 88% of the authors worked for or had financial ties to the vaccine industry and/or the CDC. A libertarian periodical, the *Journal of American Physicians and Surgeons*, published in 2004 that the 2002 *NEJM* article did in fact show a statistically

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<sup>1</sup> A thimerosal-free influenza vaccine has been available for a number of years. The increased cost of this shot is \$1-2 dollars more than the preservative-containing immunization. Health insurance companies do not reimburse physicians for the extra cost of administering this safer immunization so it is not frequently given. Physicians forego the added expense because their flu program is already a breakeven venture.

<sup>2</sup> Other industrialized countries, including Denmark, removed thimerosal from vaccines ten years before the United States.

<sup>3</sup> Danish authorities reported similar findings with a continued increase in the incidence of autism after the 1992 removal of thimerosal-containing vaccines. Data presented in 2003 shows a clear increase in incidence between 1990 and 1995.

<sup>4</sup> The 2005 Yokohama study in Japan also supports this association. They examined the incidence of autism before and after the 1993 withdrawal of MMR, reporting 48 and 86 cases per 10,000 children in two sequential years before withdrawal, doubling to 97 and 161 per 10,000 afterwards in the two years afterwards.

significant association between the MMR vaccine and autism if an age-adjustment is made.<sup>5</sup> Basically this raises the question as to when does a vaccine stop having the potential ability to create an adverse effect.

The National Childhood Vaccine Injury Act of 1986 specified that the IOM study the issue of vaccine safety. These studies were released in 1991 and 1994. Both studies acknowledge the scarcity of research which would determine the degree of vaccine safety. Since that time, the pharmaceutical companies removed most of the thimerosal from their products; changed oral poliomyelitis vaccine to an injectible method as a direct result of numerous vaccine-derived poliomyelitis cases with the oral formulation; and started using acellular rather than whole cell pertussis in the Diphtheria/Tetanus/Pertussis vaccine because it reduces the incidence of seizures and hospitalizations. The government has also improved surveillance methods to monitor adverse events, resulting in the post-market withdrawal of a rotavirus vaccine that directly caused intestinal blockage and issued a warning on the Menactra vaccine regarding a rare side-effect of Guillain-Barre Syndrome.<sup>6</sup> Additionally numerous vaccine safety studies conclude that the vaccine program is safe. Despite these design and monitoring improvements, many parents and a few healthcare providers continue to have vaccine safety concerns. This mistrust of the medical system largely results from contrary research regarding vaccine safety,<sup>7</sup> the perceived influence of a \$10 billion-a-year vaccine industry on healthcare politics, the unknown long term effects of numerous vaccines and the secrecy surrounding the ACIP/CDC policy meetings on vaccines.

### **Studying the Evidence**

A prospective, randomized, double-blinded placebo controlled trial, the “best” source of evidenced-based medicine, could settle the vaccine safety question. Unfortunately, this type of research will never be undertaken for numerous legal, financial, ethical and political reasons. Retrospective studies remain though; these types of studies allow researchers the opportunity to identify statistically significant causal relationships after the fact. The greater power of a prospective study is that potential risk is minimized as a result of analyzing the causal relationships before exposing the general population.

Highlighting the importance for the need of retrospective studies is the fact that the most rapid period of brain development begins in the third trimester of pregnancy and continues over the first two years of extra-uterine life. Furthermore a child’s immune system is not matured until the age of two to three years. The medical community does not know how the 32-plus immunizations provided before the age of two years affect these immature and underdeveloped systems.<sup>8</sup> Unfortunately, vaccine discussions by the ACIP/CDC to determine the official US Immunization Schedule are closed to public scrutiny; the answers and/or thought-processes addressing these and other charged questions remain sealed and left to public debate.

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<sup>5</sup> A class-action lawsuit filed by families of autistic children has been filed against the US Secretary of Health and Human Services. A 2008 verdict in the first and only completed case ruled that vaccines caused autism in this one particular child.

<sup>6</sup> Guillain-Barre syndrome is an inflammatory disorder in which your body's immune system attacks your nerves, typically causing severe weakness and numbness that usually starts in your extremities and quickly worsens. Eventually your whole body can become paralyzed, even the muscles used for breathing.

<sup>7</sup> The journal *Neurology* reported in 2004 that immunization with the recombinant hepatitis B vaccine is associated with an increased risk of multiple sclerosis. For more information, see <http://www.neurology.org/cgi/content/abstract/63/5/838>.

<sup>8</sup> See Dr. Donald Miller’s article at <http://www.lewrockwell.com/miller/miller15.html> for more information. He is a Harvard Medical School graduate and full professor at the University of Washington School of Medicine.

Public health officials cannot adequately explain why an explosion of neurological and immune system disorders has occurred in our nation's children as the number of immunizations increases.<sup>9</sup> The Vaccine Adverse Events Reporting System (VAERS), operated by the CDC and FDA, reports that an average of 1,523 children-a-year has a serious reaction, which by regulatory definition include death, life-threatening illness, hospitalization or prolongation of hospitalization, or permanent disability. This is a very small number when compared to the number of millions of children who are vaccinated multiple times each year. However, the VAERS numbers only represent quick-onset adverse cases and do not represent those individuals who develop late-onset neurological or immunologic vaccine effects.<sup>10</sup>

One consideration that vaccine advocates do not address is the constructive role that contracting childhood illnesses play in the maturation of a person's immune system. Or, to put it another way, does removing natural infection from the human experience have any adverse consequences? Could the fact that cancer has become a leading cause of death result partly from vaccines? The journal *Cancer* published that women who had mumps during childhood are found to be less likely to have ovarian cancer than women who did not have this infection.<sup>11</sup>

### **The Legalities of Vaccines**

The United States created the Vaccine Injury Compensation Program (VICP) to offset its compulsory position on vaccines. A 1986 federal law provides that, in lieu of suing manufacturers for negligent design or warning, those claiming to be injured by vaccines may choose to file claims against the government in the Federal Court of Claims. That is, families may be compensated for vaccine injury from the government while the medical industry is *immune* from product liability lawsuits. Congress intended for the vaccine program to provide individuals with a swift, flexible and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation. Despite the streamlined approach, cases require years of legal work with most families unable to afford the legal costs. Since 1986, the US government has paid out more than \$1.8 billion through the VICP.<sup>12</sup>

Despite the IOM's 2004 scientific findings that thimerosal does not cause autism, a class-action lawsuit was filed against the US Secretary of Health and Human Services by more than 5,100 children with alleged MMR and/or thimerosal vaccine-induced autism. The lawsuit seeks to establish a causal relationship between the MMR vaccine and/or thimerosal and abnormal neurological development.<sup>13</sup> Medical personnel at the Division of Vaccine Injury Compensation, Department of Health and Human Services (DVIC) ruled that the facts of the first case presented meets the statutory criteria for demonstrating that the vaccinations this child received significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of

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<sup>9</sup> Additional theories for this dramatic increase include food additives and hormones, the stresses of modern living as well as ubiquitous and ever increasing exposure to electromagnetic waves.

<sup>10</sup> Please see the VAERS website for information on data collection at <http://vaers.hhs.gov/info.htm>.

<sup>11</sup> See <http://www.dfhcc.harvard.edu/news/announcements/article/283/233/> for a summary from Harvard Medical School.

<sup>12</sup> The program is funded through the collection of a 0.75 cent excise tax from each patient for each administered vaccine. To date, the fund has accumulated \$2.5 billion. For an insight to the complexities of filing a claim, see *The Guidelines for Practice under the National Vaccine Injury Compensation Program* at <http://www.uscfc.uscourts.gov/osm/OSM.Guidelines.pdf>.

<sup>13</sup> For more information, see the Court of Federal Claims Vaccine Program link at <http://www.uscfc.uscourts.gov/OSM/AutismDocket.htm>.

autism spectrum disorder. More than 5,000 additional cases are pending with the Special Masters<sup>14</sup>. The outcome of these cases will have an enormous impact on the pharmaceutical companies; on the local, state and federal health departments; on the children and families involved in this case; on the future role of vaccines and the extent to which they will be used; as well as on the continued trust Americans have for the medical community. The 2010 session of the United States Supreme Court is deciding if vaccine makers should be held responsible for adverse events and a decision is expected in the spring of 2011.

### **An International Perspective**

A communitarian ethic increasingly governs health care in the United States. It places a greater value on the health of the community than on the health of a particular individual. Public health officials recognize that these vaccines will harm a small percentage of genetically-susceptible individuals, but their rationale is that it is for the common good. The vaccine schedule, endorsed by the FDA and ACIP/CDC, states that, "Your child can safely receive all vaccines recommended for a particular age during one visit." Public health officials, however, have not established the additive and deleterious contribution of repeated immunizations with thimerosal/mercury-containing vaccines, the safety and possible long-term effects of injecting more than 32 vaccines in a child before the age of two years, the "shelf-life" for possible adverse events for each vaccine, the resolution of contradictory research regarding vaccine safety, the thought process behind the closed-door meetings by which government agencies decide on the US vaccine policy and the benign nature of political influence from a multibillion dollar industry.

Japan, Sweden, Italy and several other industrialized countries utilize an informed-consent rather than a compulsory-basis when deciding to administer vaccines.<sup>15</sup> Their governments made the change once the medical establishment realized the frequency with which adverse vaccine reactions occurred, both early-onset and late-onset symptoms as well as proven and unproven causal relations. These governments felt they could not adequately understand the complexity of the issues surrounding vaccines and placed the responsibility on the doctors and families. That is, since 1991 physicians in Japan educate each family regarding the advantages and disadvantages of vaccines and emphasize parental decision-making in regards to their timing. Vaccines may be started as early as three months old and must be completed by 7.5 years old.<sup>16</sup> *Parents electing not to vaccinate their children at younger ages must accept the risk that their child might contract the disease that the vaccine against it most likely would have prevented.* The World Health Organization (WHO) reported in 2006 that Japan has had a slight increase in vaccine-preventable illnesses since 1991 for measles and diphtheria only; the incidence of pertussis, mumps and rubella has decreased during the same time period. Additionally, Japan meets the WHO vaccine coverage guidelines of 97-99% administration for all required vaccines; they simply start vaccinating at an older age.<sup>17</sup>

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<sup>14</sup> Special Masters are attorneys who are appointed for four-year terms by federal judges assigned to the US Court of Claims. The special master has two primary functions: case management, which involves overseeing the collection of information and setting time frames for its submission; and decision making, which involves determining the types of proceedings necessary for presenting the relevant evidence and ultimately weighing the evidence in rendering a final, enforceable decision.

<sup>15</sup> Please see the National Institute of Health's article on the *Development of Vaccination Policy in Japan* at <http://www.nih.gov/JJID/55/101.pdf>.

<sup>16</sup> This end-age of 7.5 years allows a child to begin vaccines as late as four years.

<sup>17</sup> Information on other vaccine-preventable illnesses is not available.

<http://www.who.int/vaccines/globalsummary/immunization/countryprofileresult.cfm?C='JPN'>.

## Vaccines and Nutrition

Vaccine proponents in the US argue that childhood vaccinations are essential to public health and that adequate and timely immunizations are the single most valuable thing a doctor can do for a patient. They cite the remarkable decrease in the number of deaths or other injuries from vaccine-preventable childhood illnesses. Likewise, the WHO promotes mass vaccination but claims *adequate nutrition* is the best approach against common infectious diseases and adequate immune function. The WHO recognizes that the mortality rates for many vaccine-preventable diseases in the US decreased by over 90% in the early 20<sup>th</sup> century and this was before vaccines for these diseases were introduced.<sup>18, 19</sup> This astonishing epidemiologic result was due to better nutrition, cleaner water and improved sanitation. The continued success of a reduced incidence of these illnesses is also due in part to vaccines.

## Conclusion

Parents and physicians must consider the truth about immunizations.

- First, this is a complicated decision that is only becoming more complicated as new vaccines are added.
- Second, a parent's decision, no matter how carefully considered, is not risk-free. Injury to a child can result from either choosing to vaccinate or choosing not to vaccinate.
- Third, the typical physician visit is too short to clearly cover the complexity of vaccination.
- Fourth, a balanced decision cannot be made regarding immunization if a parent feels pressured, frightened or uninformed.
- Fifth, a doctor must provide vaccines to patients using the US vaccine schedule or be considered to be in "mal-practice."

It is not difficult to understand the frustration felt by parents and physicians on this topic. Doctors have their hands tied in regards to this issue; the law should be changed to permit forthright discussions with patients.

The large majority of parents follow the US vaccine schedule but a boisterous minority is too uncomfortable and suspicious of the toxic ingredients, mixed safety reports and secretive circumstances surrounding the creation of the US immunization policy. If a parent does have a strong conviction against the administration of vaccines at a young age, a medical, religious or philosophical vaccine exemption may be obtained for their child(ren). A medical exemption requires previous medical documentation that a vaccine has caused a severe adverse reaction. A religious exemption is obtained through the county health department. A philosophical exemption is also available through the health department but in only a few states around the country. These documents serve to act as a medical release and allow a non- or under-vaccinated child to attend public school. Private schools can refuse to admit these students. Home-schooled children do not have these requirements.

Stepping back from the vaccine issue, this controversy reflects the larger social issue of an individual's rights. This is the story of how the most vulnerable individuals fit into society and,

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<sup>18</sup> See Table 2 at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056803.htm>.

<sup>19</sup> See [http://www.healthsentinel.com/graphs.php?id=23&event=graphs\\_print\\_list\\_item](http://www.healthsentinel.com/graphs.php?id=23&event=graphs_print_list_item) for mortality tables of vaccine preventable diseases.

conversely, how a community controls its citizens. Regardless of the outcome of the current autism case, of scientific evidence or of the means by which vaccine policy is decided, this spirited debate will continue. One side will think that the government, representing big business, is suppressing the “dangerous truth” about vaccines through off-the-record politicized discussions in a judge’s chamber or through pharmaco-approved secret meetings within the ACIP/CDC. The other will feel that medicine, using rationalism and objectiveness as its compass, should direct the controlling laws of human experience, and individuals should surrender their illogical and conflicting beliefs to the god of science.

For most families, the decision to administer a vaccine echoes both of these sentiments. This is both a rational *and* an emotional decision regarding the anticipated health and happiness of one’s offspring and legacy. The medical establishment should openly discuss the pros and cons of scientific studies as well as reasons for alternative vaccine habits in other industrialized countries with their patients. Physicians, as patient advocates, must also demand that ACIP/CDC open all past and upcoming vaccine policy discussions. Once the vaccine vault is open, initial investigations can examine the scientific basis for the limitedness of vaccine initiation and study their long term effects. Physicians will succeed in improving vaccine promotion by understanding the liberty that immunizations represent.