

# Aluminum in Childhood Vaccines Is Unsafe

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## ABSTRACT

Aluminum is a neurotoxin, yet infants and young children are repeatedly injected with aluminum adjuvants from multiple vaccines during critical periods of brain development. Numerous studies provide credible evidence that aluminum adversely affects important biological functions and may contribute to neurodegenerative and autoimmune disorders. **It is impossible to predetermine which vaccinated babies will succumb to aluminum poisoning. Aluminum-free health options are needed.**

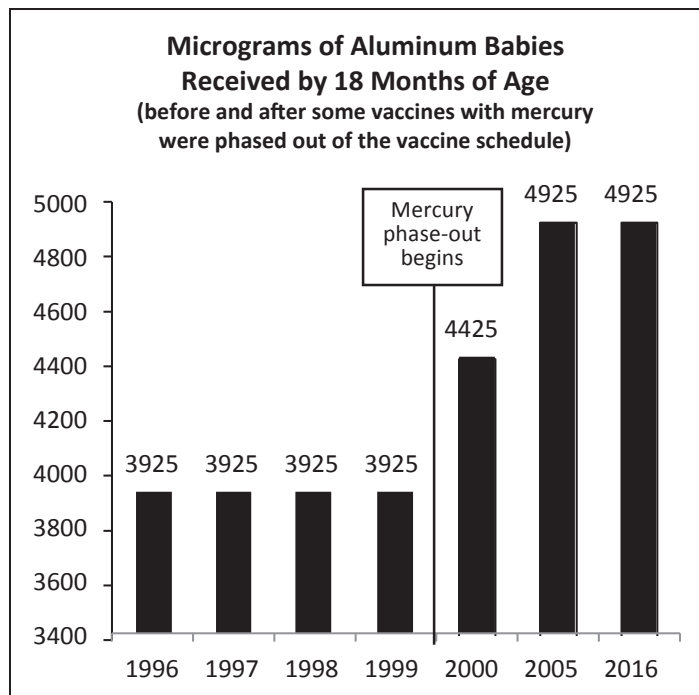
## Introduction

From 1999 through 2002, several vaccines containing mercury were phased out of the childhood immunization schedule. Manufacturing of childhood vaccines with thimerosal ceased in 2001, but those that were not past their expiration date remained on the market for sale until January 2003.<sup>1</sup> They were replaced with low-mercury or “thimerosal-free” vaccines. In the years that followed, autism rates continued to rise, prompting health authorities to assert that autism is not linked to mercury in vaccines and that vaccination policies are safe and appropriate.<sup>2-4</sup> (If mercury in vaccines contributed to autism, then rates should have dropped after mercury was removed.) However, in 2002, during this so-called phase-out period, the Centers for Disease Control and Prevention (CDC) actually added two doses of mercury-containing influenza vaccines to the list of inoculations urged for all babies 6 to 23 months of age.<sup>5</sup> Two years later, the CDC also added *pregnant women in their first trimester* to the list of people officially recommended and actively encouraged to receive influenza vaccines, even though a majority of available doses contained mercury.<sup>6</sup>

In addition to these questionable actions during this highly publicized “phase-out” of mercury, four doses of a new vaccine with high *aluminum* content were added to the childhood immunization schedule in February 2000 (for pneumococcus) and two doses of another aluminum-containing vaccine (for hepatitis A) were added in 2005.<sup>7,8</sup> These changes to the vaccine schedule resulted in a substantial increase of aluminum-containing vaccine doses—from 10 to 16 injections—that babies are still mandated to receive by 18 months of age.

Prior to the mercury phase-out (pre-2000), babies received 3,925 micrograms (mcg) of aluminum in their first year-and-a-half of life. After pneumococcal and hepatitis A vaccines were added to the immunization schedule, babies began receiving 4,925 mcg of aluminum during the same age period—a 25% increase (Figure 1).<sup>9,10</sup> In 2011, CDC recommended that pregnant women receive a pertussis vaccine (Tdap), which also contains aluminum.<sup>11</sup> Studies show that aluminum crosses the placenta and accumulates in fetal tissue.<sup>12</sup> Thus, millions of

babies in utero, infants, and young children were injected with, and continue to receive, unnaturally high doses of neurotoxic substances—mercury and aluminum—long after unsuspecting parents were led to believe that vaccines were purified and made safe.



**Figure 1.** Aluminum Content from Childhood Vaccines

Vaccines containing aluminum were added to the childhood immunization schedule when some vaccines containing mercury were removed. Prior to the mercury phase-out (pre-2000), babies received 3,925 mcg of aluminum by 18 months of age. After pneumococcal and hepatitis A vaccines were added to the schedule, babies began receiving 4,925 mcg of aluminum during the same age period—a 25% increase.

Source: The vaccine manufacturers’ product inserts and the CDC’s annual childhood vaccination schedules.

## Aluminum

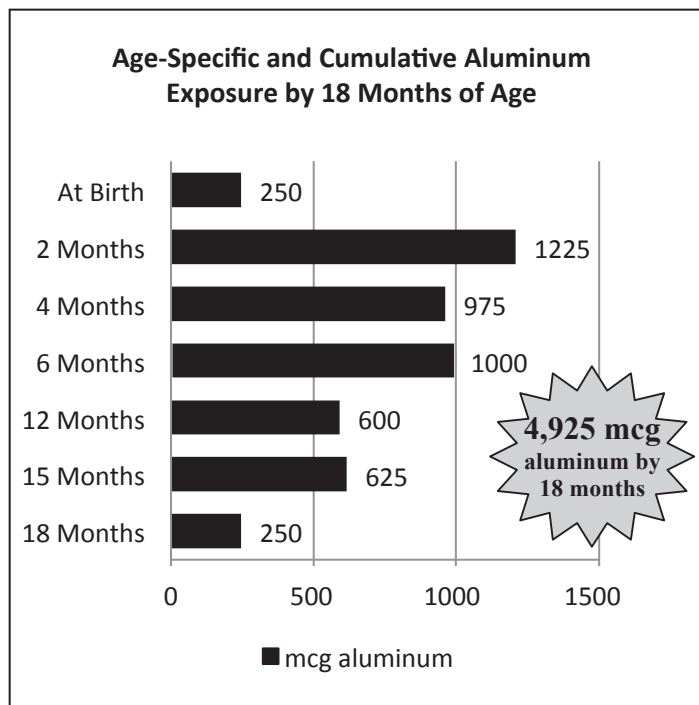
Aluminum adjuvants are added to several vaccines to elicit a more robust immune response and increase vaccine efficacy. In the United States, Canada, Europe, Australia, and many other parts of the world, infants and young children receive high quantities of aluminum from multiple inoculations. For example, in the U.S. the hepatitis B, DTaP (for diphtheria, tetanus and pertussis), pneumococcal (PCV), *Haemophilus influenzae* type b (Hib), and hepatitis A vaccines are all administered during early childhood. Each of these

vaccines contains aluminum, and multiple doses (booster shots) are required (Table 1). Babies are injected with 1,225 mcg of aluminum instantaneously at age 2 months, and 4,925 mcg of accumulated aluminum by age 18 months (Figure 2).<sup>9,10</sup>

**Table 1.** Aluminum Exposures in Early Childhood from Recommended Vaccines

Vaccine	Aluminum Content	Vaccine Schedule
Hep B	250 mcg x 3 doses	Birth, 2, 6 months
DTaP	625 mcg x 4 doses	2, 4, 6, 15 months
PCV	125 mcg x 4 doses	2, 4, 6, 12 months
Hib	225 mcg x 3 doses	2, 4, 12 months
Hep A	250 mcg x 2 doses	12, 18 months

Source: The vaccine manufacturers' product inserts and the CDC's 2016 childhood vaccination schedule.



**Figure 2.** Cumulative Aluminum Exposure from Recommended Childhood Vaccines

Source: The vaccine manufacturers' product inserts and the CDC's 2016 childhood vaccination schedule.

Babies are not the only age group exposed to high quantities of aluminum from vaccines. The HPV vaccine (indicated for the prevention of cervical cancer and genital warts associated with some strains of human papillomavirus) is marketed to pre-teens and adolescents. Each dose in the three-dose series contains 500 mcg of aluminum. The Tdap vaccine (for tetanus, diphtheria, and pertussis) is given to

pre-teens as well, and contains 390 mcg of aluminum.<sup>13</sup> Several adult vaccines also contain aluminum.

Aluminum is neurotoxic and has a long history of well-documented hazards.<sup>14</sup> For example, as early as 1921 The *Lancet* described a 46-year-old metal worker in whom "aluminium produced a rather slow intoxication. In this case it caused memory loss, tremor, jerky movements and incontinence of urine."<sup>15</sup> In 1927, Dr. Victor Vaughn, a toxicologist with the University of Michigan, testified before the Federal Trade Commission that "all salts of aluminum are poisonous when injected subcutaneously or intravenously."<sup>16</sup> By 1951, Chusid et al. showed that chronic epilepsy could be induced in monkeys through intra-cerebral administration of aluminum hydroxide cream.<sup>17</sup> In 1968, Driver et al. performed a similar experiment by placing aluminum hydroxide cream unilaterally on the posterior parietal cortex of six monkeys.<sup>18</sup> From 3 to 8 weeks after surgery, electrical abnormalities could be seen on an electroencephalogram and the monkeys exhibited "episodic twitching of the limbs and face." The animals were also impaired at learning new tasks and at re-learning tasks first learned prior to the intervention.

According to the American Academy of Pediatrics (AAP), "Aluminum is now being implicated as interfering with a variety of cellular and metabolic processes in the nervous system and in other tissues."<sup>19</sup> Bishop et al. published data showing that "aluminum accumulates in the body when protective gastrointestinal mechanisms are bypassed, renal function is impaired, and exposure is high."<sup>20</sup> For example, in premature infants, "prolonged intravenous feeding with solutions containing aluminum is associated with impaired neurologic development" by 18 months of age. More recently, Kawahara et al. published research confirming that "aluminum can cause severe health problems in particular populations, including infants."<sup>21</sup> The authors of this paper also declared that "whilst being environmentally abundant, aluminum is not essential for life. On the contrary, aluminum is a widely recognized neurotoxin that inhibits more than 200 biologically important functions and causes various adverse effects in plants, animals, and humans."

### Neurologic and Autoimmune Disorders

Numerous studies provide compelling evidence that injected aluminum is detrimental to health. For example, a recent paper by Tomljenovic and Shaw affirmed that aluminum is a neurotoxin and may be a co-factor in several neurodegenerative disorders and diseases, including Alzheimer's, Parkinson's, multiple sclerosis, amyotrophic lateral sclerosis (ALS), autism, and epilepsy.<sup>22</sup> According to the authors, "The continued use of aluminum adjuvants in various vaccines for children as well as the general public may be of significant concern. In particular, aluminum presented in this form carries a risk for autoimmunity, long-term brain inflammation and associated neurological complications and may thus have profound and widespread adverse health consequences."

Recent data by Perricone et al. showed that aluminum adjuvants in vaccines have been linked to multiple sclerosis, systemic lupus erythematosus, chronic fatigue syndrome, Gulf War syndrome, macrophagic myofasciitis, arthritis, and autoimmune/inflammatory syndrome induced by adjuvants (ASIA syndrome), an autoimmune disease with neurological and cognitive manifestations.<sup>23</sup> Clinical symptoms associated with vaccine-induced autoimmunity can take months or years to manifest, much longer than the time intervals utilized in most vaccine safety studies.

Although aluminum is a neurotoxin, pre-school children are repeatedly injected with aluminum adjuvants from multiple vaccines during critical periods of brain development. A recent paper published in the journal *Lupus* found that this may lead to neuro-developmental and autoimmune disorders.<sup>24</sup> During early development, the child's blood-brain barrier is more permeable to toxins, and the kidneys are less able to eliminate them. Thus, children have a greater risk than adults of adverse reactions to aluminum adjuvants in vaccines. The authors of this paper issued the following warning: "Because children may be most at risk of vaccine-induced complications, a rigorous evaluation of the vaccine-related adverse health impacts in the pediatric population is urgently needed."

### **Macrophagic Myofasciitis (MMF)**

Some people develop macrophagic myofasciitis (MMF) after receiving an aluminum-containing vaccine.<sup>25-39</sup> MMF is characterized by an aluminum-filled lesion (wound) at the site of an earlier vaccination. MMF lesions occur when the aluminum adjuvant from a vaccine remains embedded in the muscle tissue and causes a continuous immune reaction. The lesions are persistent, long-term granulomas (or inflammatory tumors) found in the quadriceps in children and deltoid muscles of adults, common vaccination sites. Several vaccines contain aluminum hydroxide, which has been identified as the causal factor of MMF lesions.<sup>25</sup>

Although MMF is associated with a macrophagic lesion at the site of vaccination, it is a systemic ailment. Symptoms include chronic fatigue, chronic diffuse myalgia (muscle weakness), arthralgia (joint pain), and disabling headaches. Aluminum's toxic effects can also manifest as impaired psychomotor control, repetitive behavior, speech disorders, sleep disturbances, seizures, confusion, and anxiety, as well as deficits of concentration, learning, and memory. Nearly 20% of patients with MMF develop an autoimmune disease, including neuromuscular and multiple sclerosis-like demyelinating disorders.<sup>26-28</sup>

Several descriptive studies document MMF in pediatric populations. For example, Spanish scientists presented data on seven children younger than 3 years of age with lesions of macrophages on muscle biopsies at the site of vaccination.<sup>29</sup> In three of four cases tested, elevated levels of aluminum in muscle were detected (indicative of a reaction to aluminum

adjuvants in vaccines). All of the children developed hypotonia (a lack of normal muscle tone) and motor or psychomotor delay. Six of the children also had abnormal neuro-imaging, associated with neurological anomalies, including atrophy and abnormal myelination.

In the U.S., Gruis et al. evaluated four cases of MMF in young children with hypotonia, motor delay and failure to thrive, likely due to intramuscular injections of aluminum-containing vaccines.<sup>30</sup> Another team of American physicians evaluated MMF in two fully vaccinated children. Both showed typical aluminum-filled macrophages at muscle biopsies.<sup>31</sup> One child had abnormal pupillary reflexes and urinary retention suggesting dysautonomia while the other child had developmental delay and hypotonia.

Israeli researchers documented MMF in six Arab children.<sup>32</sup> Reactions included hypotonia, seizures, motor delay, and developmental delay. The authors of this paper believe that genetic predisposition is a factor in determining the prevalence of MMF in different populations.

German researchers documented MMF in a 3-month-old East Indian child following his hepatitis B vaccine at birth, "after which he developed generalized hypotonia, and central nervous system and peripheral nervous system manifestations at one month of age."<sup>33</sup> The child also had respiratory failure, decreased spontaneous movements, apnea spells, and generalized seizures. Aluminum was detected in the muscle biopsy macrophages. The authors recommend that "after vaccination, children should be closely followed to detect these complications at early stages."

Italian researchers believe that MMF in children "is probably more common than reported. Diagnosis requires a high index of suspicion and can be missed if biopsy is performed outside the vaccination site."<sup>34</sup> According to Canadian MMF researchers, "aluminum has been demonstrated to impact the central nervous system at every level, including by changing gene expression. These outcomes should raise concerns about the increasing use of aluminum salts as vaccine adjuvants." Moreover, "based on the current and emerging literature, it seems unlikely that in the future aluminum will be considered safe for human use in any of the current medicinal applications."<sup>28</sup>

### **Animal Studies**

A recent paper by Luján et al. found that sheep developed a new type of autoimmune and inflammatory disorder—ovine autoimmune/inflammatory syndrome induced by adjuvants (ASIA)—after receiving vaccines containing aluminum adjuvants.<sup>40</sup> The condition appears in some sheep two to six days after they are vaccinated. Symptoms of the acute phase include poor response to external stimuli and acute meningoencephalitis. The chronic phase causes muscular atrophy, neurodegeneration of the gray matter of the spinal cord, and death.

Khan et al. conducted several mouse experiments to determine the long-term biological distribution of vaccine-related aluminum nanoparticles.<sup>41</sup> They discovered that aluminum travels from the injection site to distant organs such as the spleen and brain, where aluminum deposits could still be detected one year later. Aluminum remains in monocyte-lineage cells long after vaccination and may cause neurologic and autoimmune disorders. According to these scientists, "Alum has high neurotoxic potential, and administration of continuously escalating doses of this poorly biodegradable adjuvant in the population should be carefully evaluated by regulatory agencies since the compound may be insidiously unsafe."

Scientists also looked at whether Gulf War Syndrome, which afflicted many veterans of Western militaries with cognitive and behavioral deficits similar to ALS (a progressive neurodegenerative disease that destroys nerve cells), could be related to the aluminum-containing anthrax vaccines they received. In a series of studies, mice were injected with adjuvants at doses equivalent to those given to vaccinated U.S. Gulf War veterans.<sup>42,43</sup> The aluminum-injected mice exhibited significant deficits in memory and motor functions. Testing showed motor neuron loss and progressive deficiencies in strength. The mice also had pathological abnormalities that are characteristic of neurological diseases such as Alzheimer's and dementia. According to the authors of these studies, "The demonstrated neurotoxicity of aluminum hydroxide and its relative ubiquity as an adjuvant suggest that greater scrutiny by the scientific community is warranted."<sup>43</sup>

Israeli scientists recently evaluated an aluminum adjuvant and the HPV vaccine Gardasil to determine behavioral and inflammatory effects.<sup>44</sup> Female mice were injected with either aluminum or Gardasil in amounts equivalent to human exposure, or they received a true placebo. (Vaccine safety trials for the HPV vaccine did not provide the control group with an inert substance or true placebo; the "control" group was injected with aluminum.) The Gardasil and aluminum-injected mice spent significantly more time exhibiting depressive behavior when compared to the placebo-injected mice. In addition, anti-HPV antibodies from the sera of Gardasil-injected mice showed cross-reactivity with the mouse brain protein extract. Analysis revealed microglial activation in the hippocampi of Gardasil-injected mice. According to the authors, "It appears that Gardasil via its aluminum adjuvant and HPV antigens has the ability to trigger neuroinflammation and autoimmune reactions, further leading to behavioral changes."

## Autism

There is evidence that aluminum in vaccines may be linked to autism. For example, the *Journal of Inorganic Biochemistry* published data showing a highly significant positive linear correlation between the amount of aluminum infants receive from their vaccines and the rates of autism

in several developed nations (Pearson  $r = 0.89-0.94$ ).<sup>45</sup> The authors of this ecological study commented on their findings: "Our results...suggest that a causal relationship may exist between the amount of aluminum administered to preschool children at various ages through vaccination and the rising prevalence of autism spectrum disorders."

In another recently published paper, Shaw et al. found that genetic predispositions may sensitize some children to central nervous system damage induced by aluminum-containing pediatric vaccines.<sup>46</sup> Moreover, vaccines with aluminum adjuvants are *injected* into the body, bypassing protective barriers of the gastrointestinal tract and skin. Absorption of aluminum by this mode is more efficient than through ingestion, increasing the likelihood of a toxic outcome. The authors summarized their findings: "Evidence has now emerged showing that autism may in part result from early-life immune insults induced by environmental xenobiotics. One of the most common xenobiotic with immuno-stimulating as well as neurotoxic properties to which infants under two years of age are routinely exposed worldwide is the aluminum vaccine adjuvant."

Recent research published in the *Journal of Toxicology* found that aluminum exposure produces adverse effects in living organisms and is especially damaging to the central nervous system.<sup>47</sup> Aluminum from vaccine adjuvants crosses the blood-brain and blood-cerebrospinal fluid barriers, provoking harmful immuno-inflammatory responses in neural tissues. Yet, clinical studies on vaccine safety often give aluminum-containing injections to a "control" group as a harmless "placebo" despite evidence that aluminum is toxic to humans and animals. The use of aluminum as a placebo cannot be justified. According to the authors of this paper, "Studies on animal models and humans have shown that aluminum adjuvants by themselves cause autoimmune and inflammatory conditions. These findings plausibly implicate aluminum adjuvants in pediatric vaccines as causal factors contributing to increased rates of autism spectrum disorders in countries where multiple doses are almost universally administered."

In another recent animal study, young mice were injected with either high or low levels of aluminum adjuvants (designed to correlate with U.S. or Scandinavian childhood vaccine schedules).<sup>48</sup> Significant changes in the mice were observed, affirming the role of aluminum adjuvants in adversely altering the central nervous system. The authors commented on their findings: "These current data implicate aluminum injected in early postnatal life in some central nervous system alterations that may be relevant for a better understanding of the etiology of autism spectrum disorders."

## Vaccine Industry Conferences and Concerns

In May 2000—3 months *after* the CDC added the aluminum-containing pneumococcal vaccine to the recommended immunization schedule for children—the U.S.



Department of Health and Human Services (HHS) sponsored a Workshop on Aluminum in Vaccines.<sup>49,50</sup> The workshop, given in San Juan, Puerto Rico, was attended by members of the vaccine industry, including government officials, immunologists, pathologists, vaccine manufacturers, metal ion specialists, and other interested people. It was organized to increase knowledge about aluminum as an adjuvant in vaccines, investigate potential adverse reactions associated with aluminum in vaccines, and develop a research agenda on the effect of aluminum in the human body. Experts from around the world were invited to give their presentations on vaccines and aluminum.

Dr. Romain Gherardi, a specialist in neuromuscular disease and professor at the Mondor Institute of Biomedical Research, showed that MMF without vaccination does not occur. In fact, it often begins after receiving a hepatitis B vaccine. Myalgia was present in 94% of patients with MMF, and 85% of these people were disabled. Although 30% of patients had their first myalgias within 3 months after their last vaccination, 20% of patients' symptoms took longer than 2 years to manifest. These myalgias begin in the calves and legs, then progress to diffuse myalgia. Fatigue was present in 93% of patients with MMF, and 87% of these people were disabled. In addition, 34% of MMF patients had autoimmune disease, including multiple sclerosis and arthritis.<sup>50, pp 48-74</sup>

In June 2000, the CDC sponsored a conference on thimerosal (mercury) in vaccines, although aluminum was discussed as well.<sup>51</sup> CDC scientists analyzed the agency's Vaccine Safety Datalink (VSD) database containing thousands of medical records of vaccinated children and found statistically significant relationships between mercury in vaccines and developmental delay, tics, and attention deficit disorder.<sup>51, pp 40-41</sup> However, Dr. Tom Verstraeten, CDC epidemiologist, analyzed the data and determined that the injuries could have been caused by aluminum in the vaccines.<sup>51, p 77</sup> It is also possible that the neurological damage was due to the synergistic effects of both aluminum and mercury in the vaccines given to the affected children.

Although millions of children every year are required to receive vaccines containing aluminum and mercury, evidence supporting the safety of this practice is lacking. For example, according to Dr. Richard Johnston, immunologist and professor of pediatrics at the University of Colorado School of Medicine, "Aluminum and mercury are often simultaneously administered to infants, both at the same site and at different sites. However...there is absolutely no data, including animal data, about the potential for synergy, additivity or antagonism, all of which can occur in binary metal mixtures."<sup>51, p 20</sup> Dr. Alison Maule, who attended the Workshop on Aluminum in Vaccines, voiced similar concerns: "We need to bear in mind that we are not only putting aluminum in here, we are putting in mercury.... Often these effects are additive but there is always the possibility of synergy. We know nothing about that."<sup>50, p 106</sup> Dr. Vito Caserta, chief medical officer for the Vaccine Injury Compensation

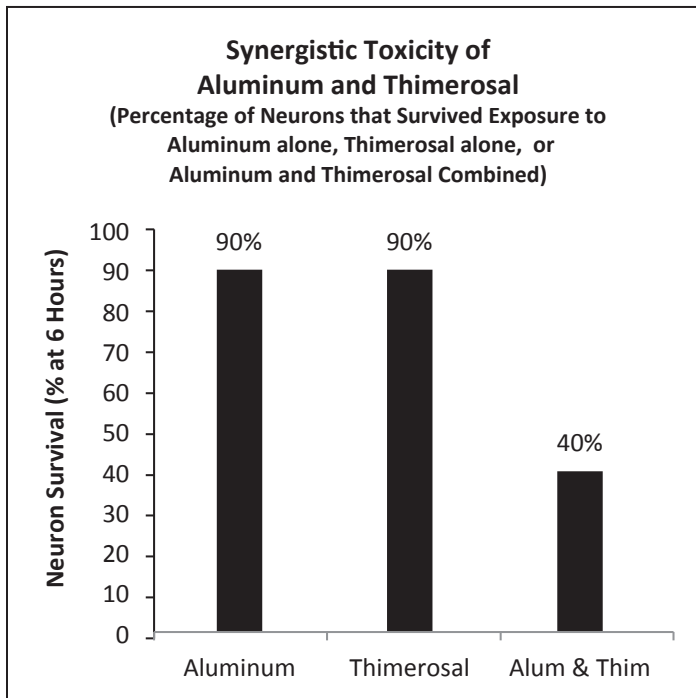
Program, had this to say: "One of the things I learned at the aluminum conference in Puerto Rico...that I never really understood before, is the interactive effect of different metals when they are together in the same organism. It is not the same as when they are alone, and I think it would be foolish for us not to include aluminum as part of our thinking with this."<sup>51, p 234</sup> Dr. William Weil, pediatrician, former member of the National Institutes of Health, and representative for the AAP Committee on Environmental Health, was also present at the CDC conference and made his concerns known: "In relationship to aluminum, being a nephrologist for a long time, the potential for aluminum and central nervous system toxicity was well established by dialysis data. To think there isn't some possible problem here is unreal."<sup>51, pp 24-25</sup>

Some health authorities who oversee federal vaccine initiatives candidly acknowledge their limited understanding of metals—aluminum and mercury—that are added to several vaccines. For example, Dr. Martin Myers, director of the National Vaccine Program Office and host of the HHS-sponsored Workshop on Aluminum in Vaccines, made a frank admission: "Perhaps the most important thing that I took away from the last meeting was that those of us who deal with vaccines have really very little applicable background with metals and toxicological research."<sup>49, pp 1-2</sup> Dr. Neal Halsey, director of the Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, and former member of the CDC's Advisory Committee on Immunization Practices (ACIP), was also present at the workshop on aluminum. He had concerns regarding missing data: "We do not seem to have information on the age-related toxicity of aluminum, especially when we are dealing with very young infants.... We do not know whether or not there is a difference in susceptibility by age, as there [is] with other metals."<sup>50, pp 83-84</sup>

Some health authorities seemed to admit that even if aluminum is dangerous, it would be burdensome to remove it. For example, according to Dr. John Clements with the World Health Organization's Expanded Programme on Immunization, "There are not easy and obvious substitutes to aluminum adjuvants.... The existing vaccines, if they change the adjuvant for any reason, would need to be resubmitted for clinical trials for safety and efficacy and it would take a great deal of time to do that."<sup>50, p 75</sup> Furthermore, "Aluminum is not perceived, I believe, by the public as a dangerous metal. Therefore, we are in a much more comfortable wicket in terms of defending its presence in vaccines."<sup>49, p 64</sup>

Note: In 2005, 5 years after conference attendees spoke out about a lack of data on the effects of mixing different metals in childhood vaccines, Dr. Boyd Haley, former professor of medicinal chemistry and chairman of the chemistry department at the University of Kentucky, published a study in which he investigated the effect of combining aluminum hydroxide with thimerosal.<sup>52</sup> In this study, cultured neurons showed no significant cell death six hours after they were exposed to just aluminum; more than 90% survived. Thimerosal alone also caused few neurons

to die after six hours of exposure. Again, more than 90% survived. However, when cultured neurons were exposed to aluminum and thimerosal, only about 40% survived after six hours, clearly demonstrating synergistic toxicity (Figure 3).



**Figure 3.** Survival of Neurons Exposed to Aluminum, Thimerosal, or Both

### Unconvincing Evidence of Adjuvant Safety

Although several high-level representatives of the CDC, World Health Organization (WHO), American Academy of Pediatrics, Institute for Vaccine Safety, National Vaccine Program Office, and Vaccine Injury Compensation Program who attended the conferences on aluminum and thimerosal had serious concerns about the potential hazards associated with aluminum in vaccines, a conference report and workshop summary published in the journal *Vaccine* 2 years later declared that “the message from this conference for the global public should stress the safety of both these adjuvants and these vaccines,” despite acknowledging that “we don’t know” how aluminum adjuvants interact with the immune system and how it is processed by infants and children.<sup>53</sup> The conference report minimized risks by claiming that aluminum has been used as a vaccine adjuvant for more than 70 years and “has an established safety record with low incidence of reported adverse events.” However, no one is warning vaccine recipients to consider the possibility that their adverse event could be related to aluminum in their vaccines nor encouraging them to report it to health authorities. Furthermore, research indicates that many people who have adverse reactions to aluminum-containing vaccines won’t

exhibit symptoms for several weeks, months, or years, so it’s very difficult for vaccine recipients to recognize that the vaccines they received some time ago may be related to their current disabling autoimmune ailments.

A few years later, the FDA published a study, Mitkus et al., in which the authors concluded that “the benefits of using vaccines containing aluminum adjuvant outweigh any theoretical concerns.”<sup>54</sup> This study is often cited as a confirmation that injecting babies with multiple doses of aluminum-containing vaccines is safe. However, there are major flaws in the FDA’s analysis:

1. To determine an aluminum intake “minimal risk level” (MRL) for humans, a single animal study was used.<sup>55</sup> This study found that mice could receive up to 26 milligrams of aluminum per kilogram of body weight per day (26 mg/kg/day) with no adverse effects. After considering differences between mice and humans (and other factors), this number was reduced to create a margin of safety, and an MRL of 1 mg/kg/day was established for humans, including infants.<sup>56</sup> But there is a problem: 26 mg/kg/day is not a safe amount of aluminum for animals. Several studies confirm that animals are harmed by much lower quantities of aluminum—3.4 to 6.1 mg/kg/day—and at least three of these studies were published before the FDA paper in 2011, so the FDA study was fallacious at its inception.<sup>57-60</sup> Rats that were given just 6.1 mg/kg/day aluminum (30 mg/kg/day  $AlCl_3$ ) needed significantly more repetitions to learn a maze when compared to a control group.<sup>57</sup> Rats that were given just 5.6 mg/kg/day aluminum (50 mg/kg/day  $AlCl_3 \cdot 6H_2O$ ) had significantly impaired spatial learning and memory abilities when compared to a control group. They also had cellular shrinking, plus behavioral, biochemical, and histological alterations.<sup>58</sup> Rats that were given just 3.4 mg/kg/day aluminum (17 mg/kg/day  $AlCl_3$ ) “showed behavioral, biochemical, and histological changes similar to those associated with Alzheimer’s disease.”<sup>60</sup>

2. The MRL for humans is derived from dietary aluminum fed to mice. But infants are *injected* with aluminum. Injected aluminum bypasses the gastrointestinal tract and has unique toxic properties compared to aluminum that is ingested. To determine the safety of injected aluminum, scientists must conduct experiments with injected—not ingested—aluminum.

3. After vaccines containing aluminum adjuvants are injected into the body, aluminum nanoparticles can be transported by monocyte-lineage cells to draining lymph nodes, blood and spleen—and may also penetrate the brain.<sup>41</sup> Aluminum is unsafe even in trace quantities. For example, just 50 nanomolars of aluminum are sufficient to generate reactive oxygen species (ROS), or oxidative stress, in human primary neuronal-glia cell cultures and induce inflammatory gene expression.<sup>61</sup> In another study, just 10 nanomolars of aluminum increased C-reactive protein (CRP) levels four-fold, causing inflammation in human brain microvessel endothelial cells.<sup>62</sup> But the FDA assumes, without evidence, that these poorly biodegradable aluminum nanoparticles,

which have been detected in body organs up to a year after vaccination, are harmless, and they are not calculated by the FDA as part of the aluminum “body burden” until they dissolve.

4. The “retention function for aluminum,” a mathematical equation that the FDA used to help estimate levels of aluminum in infants, was derived from data on only one person, an adult (rather than from numerous infants), and an estimate on the rate of absorption of aluminum hydroxide following injection was based on data from just two rabbits.

The FDA paper also falsely claimed that “occasional irritation (dermal) at the site of injection is the only adverse effect that has been reported in the published literature” following injections of aluminum-containing vaccines. And the clinical symptoms in patients diagnosed with MMF “are considered to be due to separate, coincidental immune or neurological disorders that are unrelated to the presence of aluminum in vaccines.”<sup>54</sup> The Global Advisory Committee on Vaccine Safety, established by WHO, welcomed the FDA’s analysis endorsing the safety of aluminum in vaccines.<sup>63</sup> The CDC vigorously defends the presence of aluminum in vaccines as well.<sup>64</sup> Clearly, FDA, CDC, and WHO agree on continuing indefinitely with their current policies of injecting babies with multiple doses of aluminum-containing vaccines.

### **Aluminum Toxicity Acknowledged for Parenteral Nutrition**

Although the FDA’s recent paper advocates the continued use of aluminum in childhood vaccines, FDA has known for many years that aluminum can be dangerous. For example, some infants require parenteral nourishment (administered by intravenous injection). All parenteral nutritional formulas contain aluminum. According to the FDA, “when medication and nutrition are administered orally, the gastrointestinal tract acts as an efficient barrier to the absorption of aluminum, and relatively little ingested aluminum actually reaches body tissues. However, parenterally administered drug products containing aluminum bypass the protective mechanism of the gastrointestinal tract and aluminum circulates and is deposited in human tissues.”<sup>65</sup>

In a 1997 study published in the *New England Journal of Medicine*, scientists assessed 182 infants who received intravenous injections of nutritional formula that contained differing quantities of aluminum.<sup>20</sup> They calculated that infants who received aluminum at greater than 4 to 5 mcg/kg/day would lose 1 point per day on the Bayley Mental Development Index ( $p = 0.03$ ). Babies who score low on this test are at risk for subsequent developmental and educational problems. This study contributed to FDA’s decision to set limits on aluminum content in parenteral drug products and require warning labels on the package inserts—safety measures that were never required with aluminum-containing vaccines. In the Code of Federal Regulations, Title 21, published in the Federal Register, aluminum toxicity levels are revealed:

**WARNING:** This product contains aluminum that may be toxic.... Research indicates that patients with impaired kidney function, including premature neonates, who receive [injections] of aluminum at greater than 4 to 5 mcg per kilogram of body weight per day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates.<sup>66</sup>

This means that for a 6-pound baby with impaired kidney function, 11-14 mcg of injected aluminum would be toxic. The hepatitis B vaccine given at birth contains 250 mcg of aluminum—20 times higher than safety levels indicated for preemies. Babies weigh about 12 pounds at two months of age when they are injected with 1,225 mcg of aluminum from their CDC-recommended vaccines—50 times higher than safety levels for preemies.

Healthy babies may be able to handle quantities of aluminum above FDA toxicity levels indicated for patients with impaired kidney function. However, no one knows how much more aluminum is safe because adequate studies were never conducted. In addition, babies are not screened for renal function prior to vaccination. Therefore, it is impossible to know ahead of time which babies will succumb to aluminum poisoning. Instead, parents are expected to play Russian roulette with their children.

### **Summary**

Aluminum adjuvants are added to several vaccines to elicit a more robust immune response and increase vaccine efficacy. Infants and young children throughout the world receive high quantities of aluminum from multiple inoculations. Incremental changes to the vaccination schedule during the past several years significantly increased the quantity of aluminum in childhood shots. Numerous studies provide compelling evidence that injected aluminum can be detrimental to health. Aluminum is capable of remaining in cells long after vaccination and may cause neurologic and autoimmune disorders. During early development, the child’s brain is more susceptible to toxins and the kidneys are less able to eliminate them. Thus, children have a greater risk than adults of adverse reactions to aluminum in vaccines.

Millions of children every year are injected with vaccines containing mercury and aluminum despite well-established experimental evidence of the potential for additive or synergistic toxicity when an organism is exposed to two or more toxic metals. Dr. Haley’s study in which cultured neurons died at an accelerated rate following concurrent exposure to aluminum and thimerosal provides evidence of an enhanced detrimental effect. In addition, aluminum toxicity levels published by FDA indicate that two-month-old babies who are vaccinated according to CDC guidelines may

be receiving quantities of aluminum that are significantly higher than safety levels.

## Conclusion

Toxic metals such as aluminum do not belong in prophylactic medications administered to children, teenagers, or adults. Vaccines are normally recommended for healthy people, so safety (and efficacy) standards must be impeccable. Parents, especially, should not be compelled to permit their loved ones to receive multiple injections of toxic metals that could increase their risk of neurodevelopmental and autoimmune ailments. Safe alternatives to current disease prevention technologies are urgently needed.

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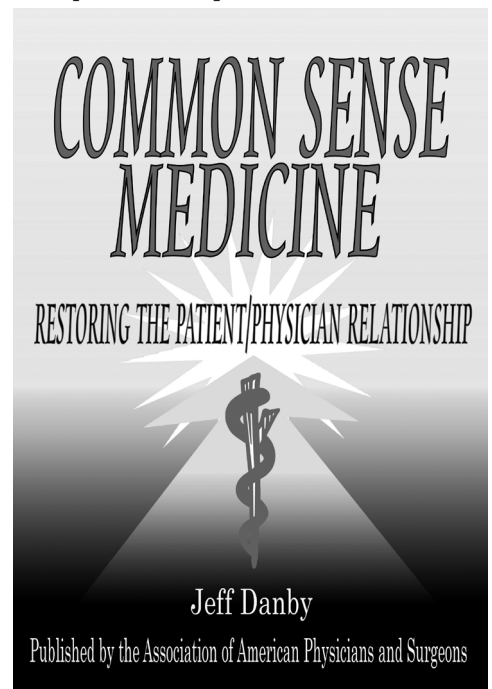
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