



# IS ALUMINUM the new thimerosal?

A renowned pediatrician and author of  
*The Vaccine Book* scrutinizes the use  
of a common vaccine additive.

BY ROBERT W. SEARS

**Vaccines** have become the most controversial parenting topic of the decade. When parents are considering whether or not to vaccinate their children, one of the things that must be considered is aluminum toxicity.

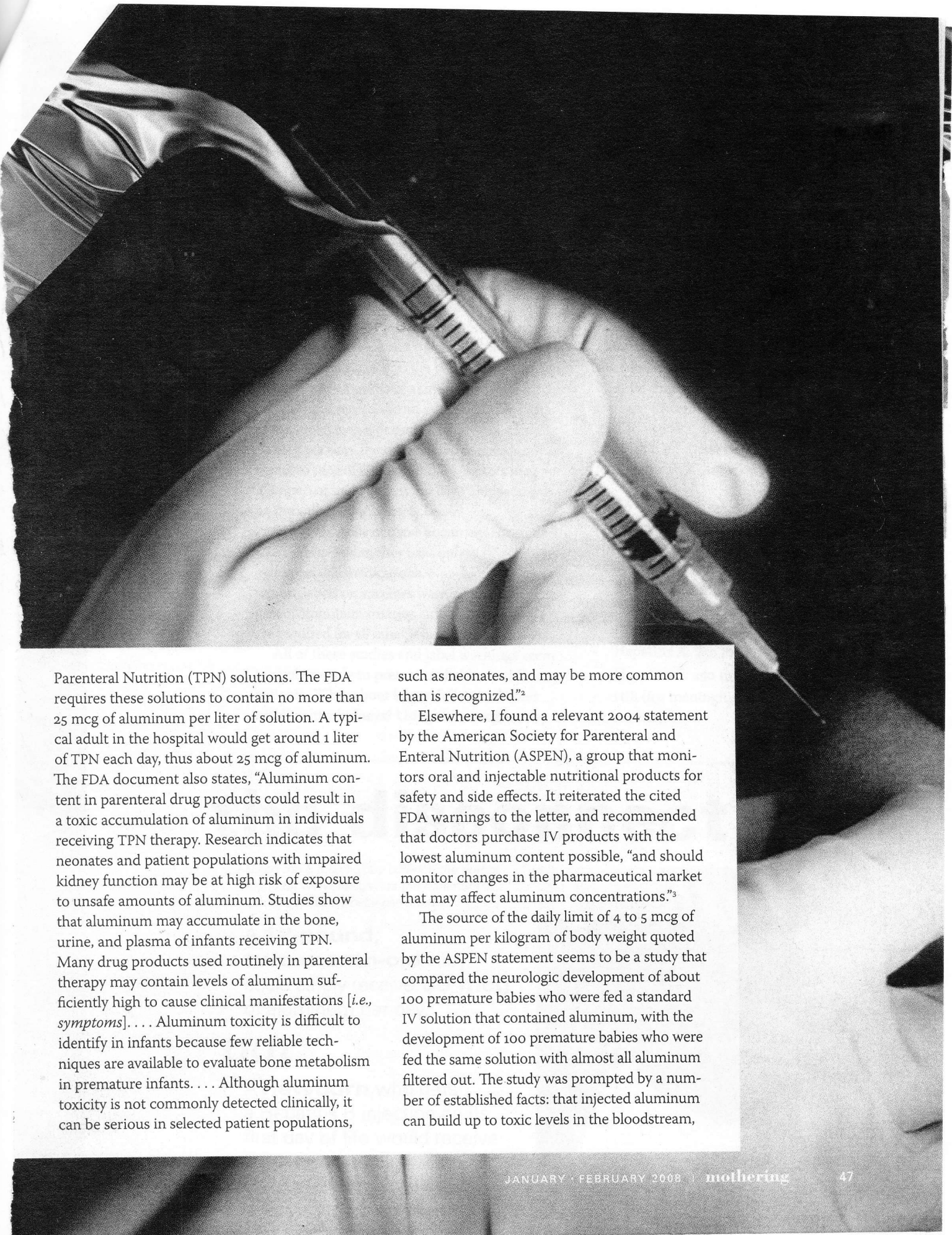
Aluminum is added to a number of vaccines to help them work better. Normally, one wouldn't consider aluminum to be a problem. It's a naturally occurring element that is present everywhere in our environment—in food, water, air, and soil. It's also a main ingredient in over-the-counter antacids. And because the body doesn't absorb aluminum, it's harmless when swallowed.

I didn't think much about aluminum when, 13 years ago, I began researching vaccines. In fact, the early seminars on vaccine education that I offered to parents included a brief statement that aluminum was nothing to worry about. But as I read each product insert and saw the number of micrograms (mcg) of aluminum contained in several vaccines, I wondered, "Has anyone determined what a safe level of injected aluminum actually is?" I didn't have to wonder for long,

because the answer is easy to find; go to [www.fda.gov](http://www.fda.gov), search on "aluminum toxicity," and you'll find several documents about aluminum.

The first document I came across discusses the labeling of aluminum content in injected dextrose solutions (the sugar solutions added to intravenous fluids in hospitals): "Aluminum may reach toxic levels with prolonged parenteral administration [*i.e., injected into the body*] if kidney function is impaired. . . . Research indicates that patients with impaired kidney function, including premature neonates [*i.e., babies*], who received parenteral levels of aluminum at greater than 4 to 5 micrograms per kilogram of body weight per day, accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading [*i.e., toxic buildup in certain body tissues*] may occur at even lower rates of administration."<sup>1</sup> For a tiny newborn, this toxic dose would be 10 to 20 mcg; for an adult, it would be about 350 mcg.

The second document discusses aluminum content in IV feeding solutions, or Total



Parenteral Nutrition (TPN) solutions. The FDA requires these solutions to contain no more than 25 mcg of aluminum per liter of solution. A typical adult in the hospital would get around 1 liter of TPN each day, thus about 25 mcg of aluminum. The FDA document also states, "Aluminum content in parenteral drug products could result in a toxic accumulation of aluminum in individuals receiving TPN therapy. Research indicates that neonates and patient populations with impaired kidney function may be at high risk of exposure to unsafe amounts of aluminum. Studies show that aluminum may accumulate in the bone, urine, and plasma of infants receiving TPN. Many drug products used routinely in parenteral therapy may contain levels of aluminum sufficiently high to cause clinical manifestations [*i.e., symptoms*]. . . . Aluminum toxicity is difficult to identify in infants because few reliable techniques are available to evaluate bone metabolism in premature infants. . . . Although aluminum toxicity is not commonly detected clinically, it can be serious in selected patient populations,

such as neonates, and may be more common than is recognized."<sup>2</sup>

Elsewhere, I found a relevant 2004 statement by the American Society for Parenteral and Enteral Nutrition (ASPEN), a group that monitors oral and injectable nutritional products for safety and side effects. It reiterated the cited FDA warnings to the letter, and recommended that doctors purchase IV products with the lowest aluminum content possible, "and should monitor changes in the pharmaceutical market that may affect aluminum concentrations."<sup>3</sup>

The source of the daily limit of 4 to 5 mcg of aluminum per kilogram of body weight quoted by the ASPEN statement seems to be a study that compared the neurologic development of about 100 premature babies who were fed a standard IV solution that contained aluminum, with the development of 100 premature babies who were fed the same solution with almost all aluminum filtered out. The study was prompted by a number of established facts: that injected aluminum can build up to toxic levels in the bloodstream,

## Repevax

Diphtheria, Tetanus, Pertussis (Acellular, Component) and Poliomyelitis (Inactivated) Vaccine, adjuvanted

**Manufacturer** Sanofi Pasteur MSD

**Recommendations** from the age of three years

**Active Ingredients** purified diphtheria toxoid, purified tetanus toxoid, purified antigens, purified pertussis toxoid, purified filamentous haemagglutinin, purified fimbrial agglutinogens 2+3, purified pertactin, inactivated poliomyelitis virus type 1, inactivated poliomyelitis virus type 2, inactivated poliomyelitis virus type 3, aluminum phosphate as adjuvant.

**Product Description** <http://emc.medicines.org.uk/emc/assets/c/html/displaydoc.asp?documentid=15256>

- HPV: 225 mcg
- Pediarix (DTaP–Hepatitis B–Polio combination): 850 mcg
- Pentacel (DTaP–HIB–Polio combination): 330 mcg
- Pneumococcus: 125 mcg

In other words, a newborn who gets a Hepatitis B injection on day one of life would receive 250 mcg of aluminum. This would be repeated at one month with the next Hep B shot. When, at two months, a baby gets its first big round of shots, the total dose of aluminum could vary from 295 mcg (if a non-aluminum HIB and the lowest-aluminum brand of DTaP are used) to a whopping 1225 mcg (if the Hep B vaccine is given along with the brands with the highest aluminum contents). These doses are repeated at four and six months. With most subsequent rounds of shots, a child would continue to get some aluminum throughout the first two years. But the FDA recommends that premature babies, and anyone with impaired kidney function, receive no more than 10 to 25 mcg of injected aluminum at any one time.

As a medical doctor, my first instinct was to worry that these aluminum levels far exceed what may be safe for babies. My second instinct was to assume that the issue had been properly researched, and that studies had been done on healthy infants to determine their ability to rapidly excrete aluminum. My third instinct was

to search for these studies. So far, I have found none. It's likely the FDA thinks that the kidneys of healthy infants work well enough to excrete aluminum before it can circulate through the body, accumulate in the brain, and cause toxic effects. However, I can find no references in FDA documents that show that using aluminum in vaccines has been tested and found to be safe.

So I did what any pediatrician would do. I turned to the American Academy of Pediatrics (AAP), who in 1996 published a policy statement, "Aluminum Toxicity in Infants and Children," that made the following points:

- Aluminum can cause neurologic harm.
- A study from 30 years ago showed that human adults increase their urine excretion of aluminum when exposed to higher levels of the metal, which suggests that adults can clear out excess aluminum.
- Adults taking aluminum-containing antacids don't build up high levels of aluminum in their bodies.
- Reports of infants with healthy kidneys show elevated blood levels of aluminum from taking antacids.
- People with kidney disease who build up bloodstream levels of aluminum greater than 100 mcg per liter are at risk of toxicity.
- The toxic threshold of aluminum in the bloodstream may be lower than 100 mcg per liter.
- The buildup of aluminum in tissues has been

**Above:**  
A quick look at the ingredients of Repevax reveals the presence of aluminum in the form of aluminum phosphate.

bones, and brain; that preemies have decreased kidney function and thus a higher risk of toxicity; that an autopsy performed on one preemie whose sudden death was otherwise unexplained revealed high aluminum concentrations in the brain; and that aluminum toxicity can cause progressive dementia. The infants who were given IV solutions containing aluminum showed impaired neurologic and mental development at 18 months, compared to the babies who were fed much lower amounts of aluminum. Those who got aluminum received an average of 500 mcg of the metal over a period of 10 days, or about 50 mcg per day. The other group received only about 10 mcg of aluminum daily—4 to 5 mcg per kilogram of body weight per day.<sup>4</sup> This seems to be the source of this safety level.

However, none of these documents or studies mentions vaccines; they look only at IV solutions and injectable medications. Nor does the FDA require labels on vaccines warning about the dangers of aluminum toxicity, although such labels are required for all other injectable medications.

All of these studies and label warnings seem to apply mainly to premature babies and kidney patients. What about larger, full-term babies with healthy kidneys? Using the 5 mcg/kg/day

criterion from the first document as a *minimum* amount we know a healthy baby could handle, a 12-pound, two-month-old baby could safely receive at least 30 mcg of aluminum per day. A 22-pound one-year-old could receive at least 50 mcg safely. Babies with healthy kidneys could probably handle much more than this, but we at least know that they can handle this much. However, these documents don't tell us what the maximum safe dose would be for a healthy baby or child, and I can't find such information anywhere. This is probably why the ASPEN group suggests, and the FDA requires, that all injectable solutions be limited to 25 mcg; we at least know that that level *is* safe.

#### CALCULATING ALUMINUM IN VACCINES

Here are the current levels of aluminum per shot of the following vaccines, as listed on each vaccine's packaging:

- DTaP (for Diphtheria, Tetanus, and Pertussis): 170–625 mcg, depending on manufacturer
- Hepatitis A: 250 mcg
- Hepatitis B: 250 mcg
- HIB (for meningitis; PedVaxHib brand only): 225 mcg

## the disconnect

Using the 5 mcg/kg/day criterion the author found on [www.fda.gov](http://www.fda.gov) as the minimum amount a healthy baby can handle:

**A 12-pound, two-month-old baby could safely receive 30 mcg of aluminum per day.**

**but**

**A newborn who gets a Hepatitis B injection on its first day of life would receive 250 mcg of aluminum.**



"Although aluminum toxicity is not commonly detected clinically, it can be serious in selected patient populations, such as neonates, and may be more common than is recognized." —FDA

seen even in patients with healthy kidneys who receive IV solutions containing aluminum over extended periods.<sup>5</sup>

However, nowhere in this paper was there any mention of aluminum in vaccines.

To put this in perspective: Because the body of the average adult contains about 5 liters of blood, receiving more than 500 mcg of aluminum in the bloodstream all at once will be toxic if the kidneys aren't working well. (Toxicity has also been seen in patients with healthy kidneys.) Because a newborn's body contains about  $\frac{1}{2}$  liter (300 milliliters) of blood, more than 30 mcg of aluminum floating around in the bloodstream could be toxic if the baby's kidneys aren't working well. The body of a toddler or preschool-age child contains about 1 liter of blood, so more than 100 mcg in his system could be toxic—and, as we've seen, babies can receive more than 1000 mcg of injected aluminum all at one time. Fortunately, this amount doesn't all go into the blood at once, but is slowly diffused into the bloodstream over a period of time from the muscle or skin where it was injected.

But that is the main point of this article. No one has measured the levels of aluminum absorption by the bloodstream when it is injected into the skin and muscle of infants, or the levels of excretion from the body via urination. All of the FDA and AAP documents that I've read state that aluminum *might* be a problem, but that they haven't studied it yet, so we should limit the amount of aluminum included in injectable solutions. But, again, no one is talking about the levels of aluminum in vaccines.

What I think may have happened is that because aluminum used to be found in only one vaccine—DTP, an older version of the current DTaP vaccine—no one thought much about it. Then, in the 1980s, the PedVaxHib brand of Hib meningitis vaccine was released, which also included aluminum; but other brands of Hib vaccine did not, so again, no one thought much about it. In the 1990s, the Hepatitis B vaccine began to

be widely used; in the 2000s, the Pneumococcus vaccine; and, more recently, the Hepatitis A vaccine. Administering one aluminum-containing vaccine at a time involves only a small amount of the metal; administering four such vaccines simultaneously is a different story. It seems this issue has simply escaped everyone's attention. Or has it?

#### LIMITED STUDIES LIMIT THINKING

Several years ago, some suspected cases of aluminum toxicity resulted in various neurologic and degenerative problems. The Cochrane Collaboration, a group that studies health-care issues around the world, wanted to look at a very large study group to see if there was a real correlation between neurologic problems and the aluminum in vaccines. They investigated all the reported side effects of one aluminum-containing vaccine, DTP (no longer used), and looked for any evidence that such vaccines caused more side effects than non-aluminum vaccines. Other than more redness, swelling, and pain at the injection site, they found no indication that an aluminum-containing vaccine caused any more problems, and concluded that no further research should be undertaken on this topic.<sup>6</sup> That is a very bold statement. Most researchers will draw conclusions from the findings of their own research; it's unusual to say that no one else should do any more research into the matter.

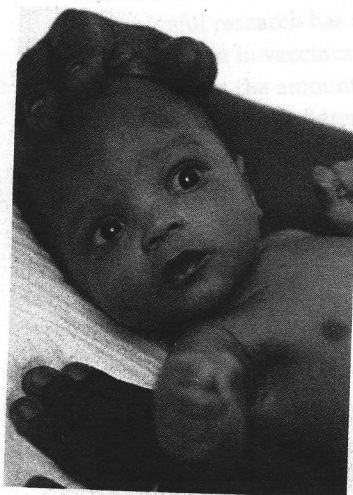
This is especially surprising because of the limitations of the Cochrane Collaboration's study. They looked at the effects of only one standard aluminum-containing vaccine, rather than the effects of all four being administered at once. They didn't study aluminum metabolism itself. They didn't test aluminum levels in children after vaccination, nor did they explore whether or not the amount of aluminum in vaccines builds up in the brain or bone tissues. They looked only for evidence of external symptoms of aluminum toxicity, not internal effects. Nor did they do their own research; instead, they reviewed all

Nor does the FDA require labels on vaccines warning about the dangers of aluminum toxicity, although such labels are required for all other injectable medications.

available studies conducted by other investigators. Despite all this, the Cochrane Collaboration study essentially closed the book on investigating aluminum toxicity from vaccines, without really having opened it in the first place.

The most obvious way to study this matter would be to inject various amounts of aluminum into children and see what happens to them internally. We know from the FDA documents that aluminum toxicity does occur from other types of injectable treatments; that it accumulates in the brain and bones in toxic amounts; that this may occur more commonly than is recognized; and that aluminum toxicity is hard to detect by looking for external symptoms. The question remains: What happens when these amounts of aluminum are injected via vaccines?

Vaccine manufacturers may have begun to wonder about the same thing; I found some interesting research in the product insert of the new HPV vaccine, Gardasil. In researching the safety of Gardasil, Merck & Co., Inc., the vaccine's developer and manufacturer, added a step to their testing procedure by injecting aluminum into a separate group of test subjects used as a safety control group. They then compared the side effects of the Gardasil vaccine with a saline placebo that contained neither Gardasil nor aluminum, as well as with the placebo containing no Gardasil but the same amount of aluminum as the vaccine. They found that the placebo containing aluminum was much more painful than the saline placebo, and about as painful as the full HPV shot. The aluminum placebo also caused much more redness, swelling, and itching than the saline placebo, though not quite as much as the full HPV shot.



Unfortunately, Merck looked only at the effects of aluminum at the injection site. Nor did they state in the Gardasil product insert what role the aluminum placebo played in all the other standard side effects, such as fever and flu-like symptoms. Nor did they study the body's internal metabolism of aluminum. However, their research did show how irritating aluminum can be when injected into the muscles. It was a good first step.

If aluminum can be toxic, why not just remove it from vaccines, as is being done with the preservative thimerosal, which contains the neurotoxin mercury? It's not that simple. Aluminum is an *adjuvant*; in other words, it helps vaccines work more effectively. When the metal is mixed with a vaccine, the body's immune system more easily recognizes the vaccine and creates antibodies against the disease. Thimerosal was easy to omit, because it has nothing to do with the efficacy of the vaccine itself. But the pharmaceutical companies would need good evidence that aluminum is harmful before

they would invest in coming up with new, aluminum-free vaccines. (The Cochrane Collaboration report pointed out that removing aluminum from vaccines would then require extensive trials of the reformulated vaccines.)

What, exactly, does a toxic level of aluminum do to the brain? While no one has studied healthy babies to see how much, if any, aluminum builds up in the brain from the amounts of aluminum used in vaccines, the study on IV feeding solutions in premature babies mentioned above revealed that aluminum impaired their neurologic and mental development.<sup>8</sup> But that was in premature babies, not healthy, full-term infants. I found several animal studies

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involving aluminum and/or aluminum-containing vaccines that did show neurologic harm. Not only did aluminum build up in the brain and cause damage, but some of the damage looked similar to what is seen in the brains of Alzheimer's patients.<sup>9-13</sup> However, it's hard to draw conclusions about aluminum's effects on humans from studies of animals. What we need are more studies of human infants.

#### A CALL FOR BETTER RESEARCH

There is good evidence that large amounts of aluminum are harmful to humans. Because no meaningful research has specifically been done on aluminum in vaccines, there is no existing evidence that the amount in vaccines is harmful to infants and children. However, no one has actually studied aluminum levels in healthy human infants after vaccination to make sure it is safe. Should we now stop and research this matter? Or should we just go on, continuing

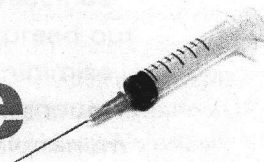
to hope that it is safe to use aluminum as an adjuvant in vaccines?

Vaccine policy makers and advocates may read this article, review my perspective, and initiate research studies to explore the risks of aluminum. I would hope that those researchers do not conduct a retrospective review of all the old vaccine safety studies and journal articles to look for the side effects of aluminum. As the FDA, AAP, and others have stated, aluminum toxicity can't be detected by external observation alone. It would be a waste of time, and a grave disservice to the health of America's children, to have several such reports show up in the medical literature. The only way the issue of aluminum safety can be put to rest is to conduct real-time studies on thousands of infants and measure aluminum levels after vaccination.

In such a study, the researchers should look not only at blood levels. They should also find out whether or not aluminum accumulates in the body, where it accumulates, how the body eliminates it,

BE ON

## the safe side



If you want to be extra-cautious and limit your babies' exposure to aluminum, you can do the following:

- Ask your doctor to order the brand of HIB vaccine that does not contain aluminum.
- Ask your doctor to avoid the brand of DTaP with the highest amount of aluminum. However, you should be aware that the DTaP with the lowest percentage of aluminum includes a trace of mercury, and cow tissue is used in its manufacture. The brand of DTaP with a moderate amount of aluminum does not contain mercury and does not use cow tissues. (An exhaustive list of which brands to avoid and which brands to seek out can be found in my *The Vaccine Book*.)

- All available brands of the Hepatitis A and B, Pneumococcus, and HPV vaccines contain the same percentage of aluminum, so there are no options to choose from here.
- Parents can limit the number of aluminum-containing vaccines given at any one time; this would mean coming in for extra, "shot-only" visits in between checkups. In *The Vaccine Book*, I detail a vaccination schedule that allows your child to get every vaccine in a timely manner, while receiving only one aluminum-containing vaccine at a time.
- Avoid any combination vaccines that contain more aluminum than the individual shots would.

—ROBERT W. SEARS

The only way the issue of **aluminum safety** can be put to rest is to **conduct real-time studies** on thousands of infants and measure aluminum levels after vaccination.

and at what rate. Once I see such research, and have determined to my satisfaction that aluminum has been proven safe, I will post an update on [www.thevaccinebook.com](http://www.thevaccinebook.com), and revise future editions of the book accordingly. If such research finds that aluminum may *not* be safe, then I would expect a new vaccine schedule to be adopted in which the administering of vaccines is spread out to minimize the amount of aluminum a child receives at any given time. I would also expect vaccine manufacturers to begin finding ways to reduce or remove aluminum from vaccines without compromising their effectiveness. We need to know the answers to some questions: Why does one brand of Hib vaccine require aluminum to make it work while another brand does not? Why does one brand of DTaP vaccine contain four times as much aluminum as another?

#### LEARNING FROM THE PAST

I worry that aluminum may end up being another thimerosal. I am relieved that, as of 2002, the mercury-containing preservative had been removed from most vaccines. But according to an article in the *Los Angeles Times*, Merck & Co., the makers of several vaccines, knew in 1991 that the cumulative amount of mercury in vaccines given to infants by six months of age was about 87 times the level then thought to be safe.<sup>14</sup> The article includes a copy of an internal memo, written by one of Merck's research doctors and sent to the president of Merck's vaccine division, clearly stating the doctor's worry about mercury overload. What was done with that information back in 1991? We'll never know. What we do know is that vaccine manufacturers knew that we were overdosing babies, but that the mercury wasn't removed from vaccines until 10 years later. This was because few paid attention to the potential problems with mercury. When we did find out, we hoped it wasn't harmful, we did extensive research to try to show that it wasn't, and we slowly removed it from most vaccines.

The issue of mercury toxicity from vaccines is moot for infants receiving vaccines today, as long

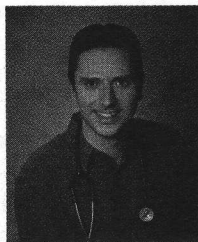
as doctors and parents choose a flu shot without mercury, know which brands of vaccines still contain barely detectable traces of mercury, and are aware that some plain Tetanus and Diphtheria-Tetanus vaccines still contain mercury (though these last vaccines are not parts of the routine vaccine schedule). [For a current list of vaccines and their thimerosal contents, go to [www.vaccine-safety.edu/thi-table.htm](http://www.vaccine-safety.edu/thi-table.htm).—Ed.]

What *isn't* moot is the question of aluminum toxicity. As doctors, we can choose certain vaccine brands that contain less or no aluminum. We can be careful about giving only one aluminum-containing vaccine at a time. And we can talk about it instead of sweeping the issue under the rug. I pray that my fears about aluminum are unfounded, and that objective studies performed by completely independent groups with no ties to vaccine manufacturers or political organizations show that it is safe. If not, I would hope that manufacturers would start to reduce or eliminate the aluminum content of their vaccines as soon as possible. I know this won't be an easy task, but our children are worth it.

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For more information, see [www.thevaccinebook.com](http://www.thevaccinebook.com).

For the Notes to this article, see [www.mothering.com/articles/growing\\_child/vaccines/aluminum-new-thimerosal-notes.html](http://www.mothering.com/articles/growing_child/vaccines/aluminum-new-thimerosal-notes.html).



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*Premature Baby Book, and The Baby Sleep Book, and author of The Vaccine Book. He has made several appearances on national television and is the chief editor and writer of [www.askdrsears.com](http://www.askdrsears.com) and [www.thevaccinebook.com](http://www.thevaccinebook.com). Sears is the father of three boys (14, 11, and 5).*

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