The Age of Autism: The Amish anomaly

By Dan Olmsted

UNITED PRESS INTERNATIONAL

Lancaster, PA, Apr. 18 (UPI) -- Part 1 of 2.

Where are the autistic Amish? Here in Lancaster County, heart of Pennsylvania Dutch country, there should be well over 100 with some form of the disorder.

I have come here to find them, but so far my mission has failed, and the very few I have identified raise some very interesting questions about some widely held views on autism.

The mainstream scientific consensus says autism is a complex genetic disorder, one that has been around for millennia at roughly the same prevalence. That prevalence is now considered to be 1 in every 166 children born in the United States.

Applying that model to Lancaster County, there ought to be 130 Amish men, women and children here with Autism Spectrum Disorder.

Well over 100, in rough terms.

Typically, half would harbor milder variants such as Asperger's Disorder or the catch-all Pervasive Development Disorder, Not Otherwise Specified -- PDD-NOS for short.

So let's drop those from our calculation, even though "mild" is a relative term when it comes to autism.

That means upwards of 50 Amish people of all ages should be living in Lancaster County with full-syndrome autism, the "classic autism" first described in 1943 by child psychiatrist Leo Kanner at Johns Hopkins University. The full-syndrome disorder is hard to miss, characterized by "markedly abnormal or impaired development in social interaction and communication and a markedly restricted repertoire of activities and interests," according to the Diagnostic and Statistical Manual of Mental Disorders.

Why bother looking for them among the Amish? Because they could hold clues to the cause of autism.

The first half-dozen articles in this ongoing series on the roots and rise of autism examined the initial studies and early accounts of the disorder, first identified by Kanner among 11 U.S. children born starting in 1931.

Kanner wrote that his 1938 encounter with a child from Mississippi, identified as Donald T., "made me aware of a behavior pattern not known to me or anyone else theretofore." Kanner literally wrote the book on "Child Psychiatry," published in 1934.

If Kanner was correct -- if autism was new and increasingly prevalent -- something must have happened in the 1930s to trigger those first autistic cases. Genetic disorders do not begin suddenly or increase dramatically in prevalence in a short period of time.

That is why it is worth looking for autistic Amish -- to test reasoning against reality. Largely cut off for hundreds of years from American culture and scientific progress, the Amish might have had less exposure to some new factor triggering autism in the rest of population.

Surprising, but no one seems to have looked.

Of course, the Amish world is insular by nature; finding a small subset of Amish is a challenge by definition. Many Amish, particularly Old Order, ride horse-and-buggies, eschew electricity, do not attend public school, will not pose for pictures and do not chat casually with the "English," as they warily call the non-Amish.

Still, some Amish today interact with the outside world in many ways. Some drive, use phones, see doctors and send out Christmas cards with family photos. They all still refer to themselves as "Plain," but the definition of that word varies quite a bit.

So far, from sources inside and outside the Amish community, I have identified three Amish residents of Lancaster County who apparently have full-syndrome autism, all of them children.

A local woman told me there is one classroom with about 30 "special-needs" Amish children. In that classroom, there is one autistic Amish child.

Another autistic Amish child does not go to school.

The third is that woman's pre-school-age daughter.

If there were more, she said, she would know it.

What I learned about those children is the subject of the next column.

PART 2: The Age of Autism: Julia

UNITED PRESS INTERNATIONAL

Leola, PA, Apr. 19 (UPI) -- Part 2 of 2.

Three-year old Julia is napping when I arrive at the spare, neat, cheerful house on Musser School Road near the town of Leola in Lancaster County.

She is the reason I have driven through the budding countryside on this perfect spring day, but I really do not need to meet her.

In the last column, I wrote about trying to find autistic Amish people here in the heart of Pennsylvania Dutch country, and noted there should be dozens of them -- if autism occurs at the same prevalence as the rest of the United States.

So far, there is evidence of only three, all of them children, the oldest age 9 or 10. Julia is one of them. I found out about her through a pediatrician in Richmond, Va., Dr. Mary Megson. I had been asking around for quite some time about autism and the Amish, and she provided the first direct link.

Megson said she would give my name to this child's mother, who could call if she chose. A few days later the phone rang. It was Stacey-jean Inion, an Amish-Mennonite woman. She, her husband Brent

and their four children live simply, but they do drive a vehicle and have a telephone. After a few pleasantries, I told her about my trying to find autistic Amish.

Here is what she said, verbatim:

"Unfortunately our autistic daughter -- who's doing very well, she's been diagnosed with very, very severe autism -- is adopted from China, and so she would have had all her vaccines in China before we got her, and then she had most of her vaccines given to her in the United States before we got her.

"So we're probably not the pure case you're looking for."

Maybe not, but it was stunning that Julia Inion, the first autistic Amish person I could find, turned out to be adopted -- from another country, no less. It also was surprising that Stacey-jean launched unbidden into vaccines, because the Amish have a religious exemption from vaccination and presumably would not have given it much thought.

She said a minority of Amish families do, in fact, vaccinate their children these days, partly at the urging of public health officials.

"Almost every Amish family I know has had somebody from the health department knock on our door and try to convince us to get vaccines for our children," she said. "The younger Amish more and more are getting vaccines. It's a minority of children who vaccinate, but that is changing now."

Did she know of any other autistic Amish? Two more children, she said.

"One of them, we're very certain it was a vaccine reaction, even though the government would not agree with that."

Federal health officials have said there is no association between vaccinations and autism or learning disabilities.

"The other one I'm not sure if this child was vaccinated or not," she added.

During my visit to their home, I asked Stacey-jean to explain why she attributed the first case to vaccines.

"There's one family that we know, their daughter had a vaccine reaction and is now autistic. She was walking and functioning and a happy bright child, and 24 hours after she had her vaccine, her legs went limp and she had a typical high-pitched scream. They called the doctor and the doctor said it was fine -- a lot of high-pitched screaming goes along with it.

"She completely quit speaking," Stacey-jean said. "She completely quit making eye contact with people. She went in her own world."

This happened, Stacey-jean said, at "something like 15 months." The child is now about 8.

For similar reasons, Julia Inion's Chinese background is intriguing. China, India and Indonesia are among countries moving quickly to mass-vaccination programs. In some vaccines, they use a mercury-based preservative called thimerosal that keeps multiple-dose vials from becoming contaminated by repeated needle sticks.

Thimerosal was phased out of U.S. vaccines starting in 1999, after health officials became concerned about the amount of mercury infants and children were receiving. The officials said they simply were erring on the side of caution, and that all evidence favors rejection of any link between Autism Spectrum Disorders and thimerosal, or vaccines themselves.

Julia's vaccinations in China -- all given in one day at about age 15 months -- may well have contained thimerosal; the United States had stopped using it by the time she was born, but other countries with millions to vaccinate had not.

Stacey-jean said photographs of Julia taken in China before she was vaccinated showed a smiling alert child looking squarely at the camera. Her original adoptive family in the United States, overwhelmed trying to cope with an autistic child, gave Julia up for re-adoption. The Inions took her in knowing her diagnosis of severe autism.

I tried hard -- and am still trying -- to find people who know about other autistic Amish. Of the local health and social service agency personnel in Lancaster, some said they dealt with Amish people with disabilities, such as mental retardation, but none recalled seeing an autistic Amish.

Still, I could be trapped in a feedback loop: The Amish I am likeliest to know about -- because they have the most contact with the outside world -- also are likeliest to adopt a special-needs child such as Julia from outside the community, and likeliest to have their children vaccinated.

Another qualifier: The Inions are converts to the Amish-Mennonite religion (Brent is an Asian-American). They simply might not know about any number of autistic Amish sheltered quietly with their families for decades.

It also is possible the isolated Amish gene pool might confer some kind of immunity to autism -- which might be a useful topic for research.

Whatever the case, Stacey-jean thinks the autistic Amish are nowhere to be found.

"It is so much more rare among our people," she said. "My husband just said last week that so far we've never met a family that lives a healthy lifestyle and does not vaccinate their children that has an autistic child. We haven't come across one yet."

"Everywhere I go (outside the Amish community) I find children who are autistic, just because I have an autistic daughter -- in the grocery store, in the park, wherever I go. In the Amish community, I simply don't find that."

UPI researcher Kyle Pearson contributed to this article.

This ongoing series on the roots and rise of autism aims to be interactive with readers and welcomes comment, criticism and suggestions. E-mail: dolmsted@upi.com

THE GREATER GOOD MOVIE

A Film By Leslie Manookian, Kendall Nelson, And Chris Pilaro

Frequently Asked Questions

1) How many vaccines do kids get today?

26 doses of 9 vaccines by the first birthday
48 doses of 14 vaccines by age 6
and a total of 70 doses of 16 vaccines by age 18

In 1983, CDC recommended:
11 doses of 4 vaccines by the first birthday
22 doses of 7 vaccines by age 6
and a total of 23 doses of 8 vaccines by age 18[1]

2) Is vaccine safety just an issue for new parents?

No. The CDC is now recommending a flu shot every year from cradle to grave as well as many adult booster shots for childhood diseases and new vaccines such as shingles. The pharmaceutical industry has an estimated 200 vaccines in development for use in many population groups, not just children.

3) Are vaccines safe?

A large, long-term clinical study comparing the medium or long-term health outcomes of vaccinated and unvaccinated groups of people has never been done. Moreover, while vaccines are given simultaneously, with as many as 10 vaccines given in one visit, safety studies do not evaluate the safety of simultaneous shots. Nor have the different ingredients of human infant vaccines taken individually or in combination been evaluated in large, long-term clinical studies. Until these studies are done, it is not possible to fully answer this question.

4) What kinds of risks am I taking if I vaccinate my child?

Like all pharmaceutical products, vaccines carry risks. The National Childhood Vaccine Injury Act of 1986, signed by President Ronald Reagan, acknowledged that vaccines can cause injury or death. It set up a trust fund for resolving vaccine injury and death claims and provides compensation to those found to be injured by vaccines. Recent research has shown neurological damage including motor function deficits, cognitive impairment, and behavioral changes in mice given the aluminum in vaccines.[2] Research has also shown chronic cognitive dysfunction, impaired immune function, and autoimmune disease in humans following administration of these same compounds.[3, 4] Despite these findings, large scientific gaps remain and until those gaps are filled, the overall safety of vaccines is difficult to assess.

Vaccine	Contains	Source: Manufacturer's P.I. Dated
Meningococcal (MCV4-Menactra)	formaldehyde, phosphate buffers, Mueller Hinton agar, Watson Scherp media, Modified Mueller and Miller medium, detergent, alcohol, ammonium sulfate	November, 2011
Meningococcal (MCV4-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium	August, 2013
Meningococcal (MPSV4-Menomune)	thimerosal (multi-dose vial only), lactose, Mueller Hinton casein agar, Watson Scherp media, detergent, alcohol	October, 2012
MMR (MMR-II)	Medium 199, Minimum Essential Medium, phosphate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, chick embryo cell culture, WI-38 human diploid lung fibroblasts	December, 2010
MMRV (ProQuad)	sucrose, hydrolyzed gelatin, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, neomycin, bovine calf serum, chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells	August, 2011
Pneumococcal (PCV13 – Prevnar 13)	casamino acids, yeast, ammonium sulfate, Polysorbate 80, succinate buffer, aluminum phosphate, soy peptone broth	January, 2013
Pneumococcal (PPSV-23 – Pneumovax)	phenol.	October, 2011
Polio (IPV – Ipol)	2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, monkey kidney cells, Eagle MEM modified medium, calf serum protein, Medium 199	December, 2005
Rabies (Imovax)	Human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propriolactone	December, 2005
Rabies (RabAvert)	β-propiolactone, potassium glutamate, chicken protein, ovalbuminegg protein, neomycin, chlortetracycline, amphotericin B, human serum albumin, polygeline (processed bovine 14 gelatin), sodium EDTA, bovine serum	March, 2012
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells *[DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]*	June, 2013
Rotavirus (Rotarix)	amino acids, dextran, sorbitol, sucrose, calcium carbonate, xanthan, Dulbecco's Modified Eagle Medium (DMEM) *[Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]*	September, 2012
Smallpox (Vaccinia – ACAM2000)	human serum albumin, mannitol, neomycin, glycerin, polymyxin B, phenol, Vero cells, HEPES	September, 2009
Td (Decavac)	aluminum potassium sulfate, peptone, formaldehyde, thimerosal, bovine muscle tissue (US sourced), Mueller and Miller medium, ammonium sulfate	March, 2011
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate	December, 2010
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal (trace), ammonium phosphate, modified Mueller's media (containing bovine extracts)	February, 2011
Tdap (Adacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, ammonium sulfate, Stainer-Scholte medium, dimethyl-beta-cyclodextrin, modified Mueller's growth medium, Mueller-Miller casamino acid medium (without beef heart infusion)	April, 2013
Tdap (Boostrix)	formaldehyde, glutaraldehyde, aluminum hydroxide, polysorbate 80 (Tween 80), Latham medium derived from bovine casein, Fenton medium containing a bovine extract, Stainer-Scholte liquid medium	February, 2013

Vaccine Excipient & Media Summary

Excipients Included in U.S. Vaccines, by Vaccine

This table includes not only vaccine ingredients (e.g., adjuvants and preservatives), but also substances used during the manufacturing process, including vaccine-production media, that are removed from the final product and present only in trace quantities.
In addition to the substances listed, most vaccines contain Sodium Chloride (table salt).

Last Updated September 2013

All reasonable efforts have been made to ensure the accuracy of this information, but manufacturers may change product contents before that information is reflected here. If in doubt, check the manufacturer's package insert.

Vaccine	Contains	Source: Manufacturer's P.I. Dated
Adenovirus	sucrose, D-mannose, D-fructose, dextrose, potassium phosphate, plasdone C, anhydrous lactose, micro crystalline cellulose, polacrilin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye, human serum albumin, fetal bovine serum, sodium bicarbonate, human-diploid fibroblast cell cultures (WI-38), Dulbecco's Modified Eagle's Medium, monosodium glutamate	March, 2011
Anthrax (Biothrax)	aluminum hydroxide, benzethonium chloride, formaldehyde, amino acids, vitamins, inorganic salts and sugars	May, 2012
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, iron ammonium citrate, lactose	February, 2009
DT (Sanofi)	aluminum potassium sulfate, peptone, bovine extract, formaldehyde, thimerosal (trace), modified Mueller and Miller medium, ammonium sulfate	December, 2005
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-Phenoxyethanol, Stainer-Scholte medium, modified Mueller's growth medium, modified Mueller-Miller casamino acid medium (without beef heart infusion), dimethyl 1-beta-cyclodextrin, ammonium sulfate	July, 2012
DTaP (Infanrix)	formaldehyde, glutaraldehyde, aluminum hydroxide, polysorbate 80, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium	July, 2012
DTaP-IPV (Kinrix)	formaldehyde, glutaraldehyde, aluminum hydroxide, Vero (monkey kidney) cells, calf serum, lactalbumin hydrolysate, polysorbate 80, neomycin sulfate, polymyxin B, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium	July, 2012
DTaP-HepB-IPV (Pediarix)	formaldehyde, gluteraldehyde, aluminum hydroxide, aluminum phosphate, lactalbumin hydrolysate, polysorbate 80, neomycin sulfate, polymyxin B, yeast protein, calf serum, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium, Vero (monkey kidney) cells	August, 2012
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, formaldehyde, gutaraldehyde, bovine serum albumin, 2-phenoxethanol, neomycin, polymyxin B sulfate, Mueller's Growth Medium, Mueller-Miller casamino acid medium (without beef heart infusion), Stainer-Scholte medium (modified by the addition of casamino acids and dimethyl-beta-cyclodextrin), MRC-5 (human diploid) cells, CMRL 1969 medium (supplemented with calf serum), ammonium sulfate, and medium 199	July, 2012
Hib (ActHIB)	ammonium sulfate, formalin, sucrose, Modified Mueller and Miller medium	November, 2012
Hib (Hiberix)	formaldehyde, lactose, semi-synthetic medium	March, 2012
Hib (PedvaxHIB)	aluminum hydroxphosphate sulfate, ethanol, enzymes, phenol, detergent, complex fermentation medium	December, 2010

March 12, 2014
HUFFPOST HEALTHY LIVING

The Vaccine-Autism Court Document Every American Should Read

Posted: 02/26/08 02:38 PM ET

Below is a verbatim copy of the US Government concession filed last November in a vaccine-autism case in the Court of Federal Claims, with the names of the family redacted. It is the subject of my post yesterday.

Every American should read this document, and interpret for themselves what they think their government is trying to say about the relationship, if any, between immunizations and a diagnosis of autism spectrum disorder.

If you feel this document suggests that some kind of link may be possible, you might consider forwarding it to your elected representatives for further investigation.

But, of course, if you feel that this document in no way implicates vaccines, then let's just keep going about our business as usual and not pay any attention to all those sick kids behind the curtain.

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

CHILD, a minor,

by her Parents and Natural Guardians,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

RESPONDENT'S RULE 4(c) REPORT

In accordance with RCFC, Appendix B, Vaccine Rule 4(c), the Secretary of Health and Human Services submits the following response to the petition for compensation filed in this case.

FACTS

CHILD ("CHILD") was born on December --, 1998, and weighed eight pounds, ten ounces. Petitioners' Exhibit ("Pet. Ex.") 54 at 13. The pregnancy was complicated by gestational diabetes. Id. at 13. CHILD received her first Hepatitis B immunization on December 27, 1998. Pet. Ex. 31 at 2.

From January 26, 1999 through June 28, 1999, CHILD visited the Pediatric Center, in Catonsville, Maryland, for well-child examinations and minor complaints, including fever and eczema. Pet. Ex. 31 at 5-10, 19. During this time period, she received the following pediatric vaccinations, without incident:

Vaccine Dates Administered

Hep B 12/27/98; 1/26/99

IPV 3/12/99; 4/27/99

Hib 3/12/99; 4/27/99; 6/28/99

DTaP 3/12/99; 4/27/99; 6/28/99

Id. at 2.

At seven months of age, CHILD was diagnosed with bilateral otitis media. Pet. Ex. 31 at 20. In the subsequent months between July 1999 and January 2000, she had frequent bouts of otitis media, which doctors treated with multiple antibiotics. Pet. Ex. 2 at 4. On December 3,1999, CHILD was seen by Karl Diehn, M.D., at Ear, Nose, and Throat Associates of the Greater Baltimore Medical Center ("ENT Associates"). Pet. Ex. 31 at 44. Dr. Diehn recommend that CHILD receive PE tubes for her "recurrent otitis media and serious otitis." Id. CHILD received PE tubes in January 2000. Pet. Ex. 24 at 7. Due to CHILD's otitis media, her mother did not allow CHILD to receive the standard 12 and 15 month childhood immunizations. Pet. Ex. 2 at 4.

According to the medical records, CHILD consistently met her developmental milestones during the first eighteen months of her life. The record of an October 5, 1999 visit to the Pediatric Center notes that CHILD was mimicking sounds, crawling, and sitting. Pet. Ex. 31 at 9. The record of her 12-month pediatric examination notes that she was using the words "Mom" and "Dad," pulling herself up, and cruising. Id. at 10.

At a July 19, 2000 pediatric visit, the pediatrician observed that CHILD "spoke well" and was "alert and active." Pet. Ex. 31 at 11. CHILD's mother reported that CHILD had regular bowel movements and slept through the night. Id. At the July 19, 2000 examination, CHILD received five vaccinations - DTaP, Hib, MMR, Varivax, and IPV. Id. at 2, 11.

According to her mother's affidavit, CHILD developed a fever of 102.3 degrees two days after her immunizations and was lethargic, irritable, and cried for long periods of time. Pet. Ex. 2 at 6. She exhibited intermittent, high-pitched screaming and a decreased response to stimuli. Id. MOM spoke with the pediatrician, who told her that CHILD was having a normal reaction to her immunizations. Id. According to CHILD's mother, this behavior continued over the next ten days, and CHILD also began to arch her back when she cried. Id.

On July 31, 2000, CHILD presented to the Pediatric Center with a 101-102 degree temperature, a diminished appetite, and small red dots on her chest. Pet. Ex. 31 at 28. The nurse practitioner recorded that CHILD was extremely irritable and inconsolable. Id. She was diagnosed with a post-varicella vaccination rash. Id. at 29.

Two months later, on September 26, 2000, CHILD returned to the Pediatric Center with a temperature of 102 degrees, diarrhea, nasal discharge, a reduced appetite, and pulling at her left ear. Id. at 29. Two days later, on September 28, 2000, CHILD was again seen at the Pediatric Center because her diarrhea continued, she was congested, and her mother reported that CHILD was crying during urination. Id. at 32. On November 1, 2000, CHILD received bilateral PE tubes. Id. at 38. On November 13, 2000, a physician at ENT Associates noted that CHILD was "obviously hearing better" and her audiogram was normal. Id. at 38. On November 27, 2000, CHILD was seen at the Pediatric Center with complaints of diarrhea, vomiting, diminished energy, fever, and a rash on her cheek. Id. at 33. At a follow-up visit, on December 14, 2000, the doctor noted that CHILD had a possible speech delay. Id.

CHILD was evaluated at the Howard County Infants and Toddlers Program, on November 17, 2000, and November 28, 2000, due to concerns about her language development. Pet. Ex. 19 at 2, 7. The assessment team observed deficits in CHILD's communication and social development. Id. at 6. CHILD's mother reported that CHILD had become less responsive to verbal direction in the previous four months and had lost some language skills. Id. At 2.

On December 21, 2000, CHILD returned to ENT Associates because of an obstruction in her right ear and fussiness. Pet. Ex. 31 at 39. Dr. Grace Matesic identified a middle ear effusion and recorded that CHILD was having some balance issues and not progressing with her speech. Id. On December 27, 2000, CHILD visited ENT Associates, where Dr. Grace Matesic observed that CHILD's left PE tube was obstructed with crust. Pet. Ex. 14 at 6. The tube was replaced on January 17, 2001. Id.

Dr. Andrew Zimmerman, a pediatric neurologist, evaluated CHILD at the Kennedy Krieger Children's Hospital Neurology Clinic ("Krieger Institute"), on February 8, 2001. Pet. Ex. 25 at 1. Dr. Zimmerman reported that after CHILD's immunizations of July 19, 2000, an "encephalopathy progressed to persistent loss of previously acquired language, eye contact, and relatedness." Id. He noted a disruption in CHILD's sleep patterns, persistent screaming and arching, the development of pica to foreign objects, and loose stools. Id. Dr. Zimmerman observed that CHILD watched the fluorescent lights repeatedly during the examination and

would not make eye contact. Id. He diagnosed CHILD with "regressive encephalopathy with features consistent with an autistic spectrum disorder, following normal development." Id. At 2. Dr. Zimmerman ordered genetic testing, a magnetic resonance imaging test ("MRI"), and an electroencephalogram ("EEG"). Id.

Dr. Zimmerman referred CHILD to the Krieger Institute's Occupational Therapy Clinic and the Center for Autism and Related Disorders ("CARDS"). Pet. Ex. 25 at 40. She was evaluated at the Occupational Therapy Clinic by Stacey Merenstein, OTR/L, on February 23, 2001. Id. The evaluation report summarized that CHILD had deficits in "many areas of sensory processing which decrease[d] her ability to interpret sensory input and influence[d] her motor performance as a result." Id. at 45. CHILD was evaluated by Alice Kau and Kelley Duff, on May 16, 2001, at CARDS. Pet. Ex. 25 at 17. The clinicians concluded that CHILD was developmentally delayed and demonstrated features of autistic disorder. Id. at 22.

CHILD returned to Dr. Zimmerman, on May 17, 2001, for a follow-up consultation. Pet. Ex. 25 at 4. An overnight EEG, performed on April 6, 2001, showed no seizure discharges. Id. at 16. An MRI, performed on March 14, 2001, was normal. Pet. Ex. 24 at 16. A G-band test revealed a normal karyotype. Pet. Ex. 25 at 16. Laboratory studies, however, strongly indicated an underlying mitochondrial disorder. Id. at 4.

Dr. Zimmerman referred CHILD for a neurogenetics consultation to evaluate her abnormal metabolic test results. Pet. Ex. 25 at 8. CHILD met with Dr. Richard Kelley, a specialist in neurogenetics, on May 22, 2001, at the Krieger Institute. Id. In his assessment, Dr. Kelley affirmed that CHILD's history and lab results were consistent with "an etiologically unexplained metabolic disorder that appear[ed] to be a common cause of developmental regression." Id. at 7. He continued to note that children with biochemical profiles similar to CHILD's develop normally until sometime between the first and second year of life when their metabolic pattern becomes apparent, at which time they developmentally regress. Id. Dr. Kelley described this condition as "mitochondrial PPD." Id.

On October 4, 2001, Dr. John Schoffner, at Horizon Molecular Medicine in Norcross, Georgia, examined CHILD to assess whether her clinical manifestations were related to a defect in cellular energetics. Pet. Ex. 16 at 26. After reviewing her history, Dr. Schoffner agreed that the previous metabolic testing was "suggestive of a defect in cellular energetics." Id. Dr. Schoffner recommended a muscle biopsy, genetic testing, metabolic testing, and cell culture based testing. Id. at 36. A CSF organic acids test, on January 8, 2002, displayed an increased lactate to pyruvate ratio of 28,1 which can be seen in disorders of mitochondrial oxidative phosphorylation. Id. at 22. A muscle biopsy test for oxidative phosphorylation disease revealed abnormal results for Type One and Three. Id. at 3. The most prominent findings were scattered atrophic myofibers that were mostly type one oxidative phosphorylation dependent myofibers, mild increase in lipid in selected myofibers, and occasional myofiber with reduced cytochrome c oxidase activity. Id. at 7. After reviewing these laboratory results, Dr. Schoffner diagnosed CHILD with oxidative phosphorylation disease. Id. at 3. In February 2004, a mitochondrial DNA ("mtDNA") point mutation analysis revealed a single nucleotide change in the 16S ribosomal RNA gene (T2387C). Id. at 11.

CHILD returned to the Krieger Institute, on July 7, 2004, for a follow-up evaluation with Dr. Zimmerman. Pet. Ex. 57 at 9. He reported CHILD "had done very well" with treatment for a mitochondrial dysfunction. Dr. Zimmerman concluded that CHILD would continue to require services in speech, occupational, physical, and behavioral therapy. Id.

On April 14, 2006, CHILD was brought by ambulance to Athens Regional Hospital and developed a tonic seizure en route. Pet. Ex. 10 at 38. An EEG showed diffuse slowing. Id. At 40. She was diagnosed with having experienced a prolonged complex partial seizure and transferred to Scottish Rite Hospital. Id. at 39, 44. She experienced no more seizures while at Scottish Rite Hospital and was discharged on the medications Trileptal and Diastal. Id. at 44. A follow-up MRI of the brain, on June 16, 2006, was normal with evidence of a left mastoiditis manifested by distortion of the air cells. Id. at 36. An EEG, performed on August 15, 2006,

showed "rhythmic epileptiform discharges in the right temporal region and then focal slowing during a witnessed clinical seizure." Id. At 37. CHILD continues to suffer from a seizure disorder.

ANALYSIS

Medical personnel at the Division of Vaccine Injury Compensation, Department of Health and Human Services (DVIC) have reviewed the facts of this case, as presented by the petition, medical records, and affidavits. After a thorough review, DVIC has concluded that compensation is appropriate in this case.

In sum, DVIC has concluded that the facts of this case meet the statutory criteria for demonstrating that the vaccinations CHILD received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder. Therefore, respondent recommends that compensation be awarded to petitioners in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii).

DVIC has concluded that CHILD's complex partial seizure disorder, with an onset of almost six years after her July 19, 2000 vaccinations, is not related to a vaccine-injury.

Respectfully submitted,

PETER D. KEISLER
Assistant Attorney General

TIMOTHY P. GARREN
Director
Torts Branch, Civil Division

MARK W. ROGERS
Deputy Director
Torts Branch, Civil Division

VINCENT J. MATANOSKI
Assistant Director
Torts Branch, Civil Division

s/ Linda S. Renzi by s/ Lynn E. Ricciardella
LINDA S. RENZI
Senior Trial Counsel
Torts Branch, Civil Division
U.S. Department of Justice
P.O. Box 146
Benjamin Franklin Station
Washington, D.C. 20044
(202) 616-4133

DATE: November 9, 2007

PS: On Friday, February 22, HHS conceded that this child's complex partial seizure disorder was also caused by her vaccines.

Now we the taxpayers will award this family compensation to finance her seizure medication. Surely ALL decent people can agree that is a good thing.

By the way, it"s worth noting that her seizures did not begin until six years after the date of vaccination, yet the government acknowledges they were, indeed, linked to the immunizations of July, 2000, - DK

PARENT RATINGS OF BEHAVIORAL EFFECTS OF BIOMEDICAL INTERVENTIONS

Autism Research Institute • 4182 Adams Avenue • San Diego, CA 92116

The parents of autistic children represent a vast and important reservoir of information on the benefits—and adverse effects—of the large variety of drugs and other interventions that have been tried with their children. Since 1967 the Autism Research Institute has been collecting parent ratings of the usefulness of the many interventions tried on their autistic children.

The following data have been collected from the more than 27,000 parents who have completed our questionnaires designed to collect such information. For the purposes of the present table, the parents responses on a six-point scale have been combined into three categories: "made worse" (ratings 1 and 2), "no effect" (ratings 3 and 4), and "made better" (ratings 5 and 6). The "Better:Worse" column gives the number of children who "Got Better" for each one who "Got Worse."

DRUGS	Parent Ratings: Got Worse[A]	No Effect	Got Better	Better: Worse	No. of Cases[B]
Actos	19%	60%	21%	1.1:1	140
Aderall	43%	26%	31%	0.7:1	894
Amphetamine	47%	28%	25%	0.5:1	1355
Anafranil	32%	39%	29%	1.1:1	440
Antibiotics	33%	50%	18%	0.5:1	2507
Antifungals[C]					
Diflucan	5%	34%	62%	13:1	1214
Nystatin	5%	43%	52%	11:1	1969
Atarax	26%	53%	21%	0.8:1	543
Benadryl	24%	50%	26%	1.1:1	3230
Beta Blocker	18%	51%	31%	1.7:1	306
Buspar	29%	42%	28%	1.0:1	431
Chloral Hydrate	42%	39%	19%	0.5:1	498
Clonidine	22%	32%	46%	2.1:1	1658
Clozapine	38%	43%	19%	0.5:1	170
Cogentin	20%	53%	27%	1.4:1	198
Cylert	45%	35%	19%	0.4:1	634
Depakene[D]					
Behavior	25%	44%	31%	1.2:1	1146
Seizures	12%	33%	55%	4.6:1	761
Desipramine	34%	35%	32%	0.9:1	95
Dilantin[D]					
Behavior	28%	49%	23%	0.8:1	1127
Seizures	16%	37%	47%	3.0:1	454
Fenfluramine	21%	52%	27%	1.3:1	483
Haldol	38%	28%	34%	0.9:1	1222
IVIG	7%	39%	54%	7.6:1	142
Klonapin[D]					
Behavior	31%	40%	29%	0.9:1	270
Seizures	29%	55%	16%	0.6:1	86
Lithium	22%	48%	31%	1.4:1	515
Luvox	31%	37%	32%	1.0:1	251
Mellaril	29%	38%	33%	1.2:1	2108
Mysoline[D]					
Behavior	41%	46%	13%	0.3:1	156
Seizures	21%	55%	24%	1.1:1	85
Naltrexone	18%	49%	33%	1.8:1	350
Low Dose Naltrexone	11%	52%	38%	4.0:1	190
Paxil	34%	32%	35%	1.0:1	471
Phenobarb.[D]					
Behavior	48%	37%	16%	0.3:1	1125
Seizures	18%	44%	38%	2.2:1	543
Prolixin	30%	41%	28%	0.9:1	109
Prozac	33%	32%	35%	1.1:1	1391
Risperidal	21%	26%	54%	2.6:1	1216
Ritalin	45%	26%	29%	0.6:1	4256
Secretin					
Intravenous	7%	50%	43%	6.4:1	597
Transderm.	9%	56%	35%	3.9:1	257
Stelazine	29%	45%	26%	0.9:1	437
Steroids	34%	30%	36%	1.1:1	204
Tegretol[D]					
Behavior	25%	45%	30%	1.2:1	1556
Seizures	14%	33%	53%	3.8:1	872
Thorazine	36%	40%	24%	0.7:1	945
Tofranil	30%	38%	32%	1.1:1	785
Valium	35%	42%	24%	0.7:1	895
Valtrex	8%	42%	50%	6.7:1	238
Zarontin[D]					
Behavior	34%	48%	18%	0.5:1	164
Seizures	20%	55%	25%	1.2:1	125
Zoloft	35%	33%	31%	0.9:1	579

BIOMEDICAL/ NON-DRUG/ SUPPLEMENTS	Parent Ratings: Got Worse[A]	No Effect	Got Better	Better: Worse	No. of Cases[B]
Calcium[E]	3%	60%	36%	11:1	2832
Cod Liver Oil	4%	41%	55%	14:1	2550
Cod Liver Oil with Bethanecol	11%	53%	36%	3.4:1	203
Colostrum	6%	56%	38%	6.8:1	851
Detox. (Chelation)[C]	3%	23%	74%	24:1	1382
Digestive Enzymes	3%	35%	62%	19:1	2350
DMG	8%	50%	42%	5.3:1	6363
Fatty Acids	2%	39%	59%	31:1	1680
5 HTP	11%	42%	47%	4.2:1	644
Folic Acid	5%	50%	45%	10:1	2505
Food Allergy Trtmnt	2%	31%	67%	27:1	1294
Hyperbaric Oxygen Therapy	5%	30%	65%	12:1	219
Magnesium	6%	65%	29%	4.6:1	301
Melatonin	8%	26%	66%	8.3:1	1687
Methyl B12 (nasal)	10%	45%	44%	4.2:1	240
Methyl B12 (subcut.)	6%	22%	72%	12:1	899
MT Promoter	8%	47%	44%	5.5:1	99
P5P (Vit. B6)	11%	40%	48%	4.3:1	920
Pepcid	11%	57%	32%	2.9:1	220
SAMe	16%	62%	23%	1.4:1	244
St. Johns Wort	19%	64%	18%	0.9:1	217
TMG	16%	43%	41%	2.6:1	1132
Transfer Factor	8%	47%	45%	5.9:1	274
Vitamin A	3%	54%	44%	16:1	1535
Vitamin B3	4%	51%	45%	10:1	1192
Vit. B6/Mag.	4%	46%	49%	11:1	7256
Vitamin C	2%	52%	46%	20:1	3077
Zinc	2%	44%	54%	24:1	2738
SPECIAL DIETS					
Candida Diet	3%	39%	58%	21:1	1141
Feingold Diet	2%	40%	58%	26:1	1041
Gluten-/Casein-Free Diet	3%	28%	69%	24:1	3593
Low Oxalate Diet	7%	43%	50%	6.8:1	164
Removed Chocolate	2%	46%	52%	28:1	2264
Removed Eggs	2%	53%	45%	20:1	1658
Removed Milk Products/Dairy	2%	44%	55%	32:1	6950
Removed Sugar	2%	46%	52%	27:1	4589
Removed Wheat	2%	43%	55%	30:1	4340
Rotation Diet	2%	43%	55%	23:1	1097
Specific Carbohydrate Diet	7%	22%	71%	10:1	537

A. "Worse" refers only to worse behavior. Drugs, but not nutrients, typically also cause physical problems if used long-term.
B. No. of cases is cumulative over several decades, so does not reflect current usage levels (e.g., Haldol is now seldom used).
C. Antifungal drugs and chelation are used selectively, where evidence indicates they are needed.
D. Seizure drugs: top line behavior effects, bottom line effects on seizures
E. Calcium effects are not due to dairy-free diet; statistics are similar for milk drinkers and non-milk drinkers.

Our Story

Letter from Lisa Ackerman, Founder

In September 1999, the word "autism" rang through my ears like a cannon shot across the bow. My husband and I knew something was not going well with our son Jeff, but we would have never guessed it was autism.

Following that fateful visit with the neurologist, we visited many other professionals including medical doctors, speech pathologists, audiologists, and behaviorists. The list seemed endless. The common message we were given: Autism has no hope, no cure. In fact, the first three medical doctors recommended that my family find "institutional placement" for Jeff who was the ripe old age of 2½ years at the time.

Refusing to give up on our son, my husband and I spent hundreds of hours talking to any and all parents of a child diagnosed with autism, reading dozens of recommended books, watching countless hours of educational videos, and of course, surfing the internet constantly. We were determined that our beloved son would grow far beyond his label and that he would have a future that was wonderful and amazing despite his autism diagnosis. Early on, the most important step for us was to GET BUSY. It was up to us, HIS PARENTS, to make a difference for his future.

The early days of our son's diagnosis were frustrating. Those countless hours spent researching, reading, talking – wasn't there a better way? Wasn't there SOMEONE who had already done the same research and search for answers before, who could have brought us up-to-speed much sooner for us to help our son faster?

Fast forward to November 2000, when our daughter Lauren (at the advanced age of 16) recommended that we start a parent support group. Both my husband and I felt we were not qualified but we definitely wanted the company of other families going through the same struggles for social gatherings and to share information, especially new research and treatments options as they became available. We also hoped to build a community where parents would be inspired by each other's steadfast hopes for their children's futures and who would be passionate about autism education for themselves and other similarly struggling families and raising awareness in the general public.

TACA began with a small handful of families in a living room in 2000. Today, we serve well over 31,000 families around the United States. From a grassroots beginning in Southern California, TACA expanded nationwide and now has a physical presence via our Chapters in 19 states and a virtual presence in the rest of the nation.

...

Where is my son Jeff now? He is a teenager at a typical high school learning same curriculum as his typical peers with a great grade point average. He still has a part-time aide. He talks, makes jokes, gives out hugs, plays on the high school golf team, socializes with typical friends, and is

an active member of the society with a bright future. He also happens to be the sweetest, kindest person I know and is practically always smiling. That is a far cry from his early diagnosis and the initial prognosis for his future.

TACA's goal is to provide education, support, and information to parents to help their children diagnosed with autism be the very best they can be, with the hope of recovery.

Today, there are many, many treatment options that help alleviate many of the symptoms suffered by our children diagnosed with autism. Let us share our collective, hard-won knowledge and experience with your family so your child's treatment can begin right away. Ask about the autism journey because we are families with autism who have already "been there and done that" with many of our children. Some of us are still working hard everyday with our children for whom we never give up hope. We are Families with Autism Helping Families with Autism.

The autism journey is not an easy one. It's a marathon, not a sprint; so take each minute, hour, or day, one at a time. It will be difficult, but it will also be incredibly rewarding, because it will change your life, your family's life, and most importantly, the lives of your children with autism to all enjoy a brighter future.

I wish all families treating and caring for their children with autism the very best possible outcomes for their children as they continue forward on the autism journey.

God Bless,

Lisa Ackerman

Founder

About SafeMinds

SafeMinds was founded to raise awareness, support research, change policy and focus national attention on the growing evidence of a link between mercury and neurological disorders such as autism, attention deficit disorder, language delay and learning difficulties. Our mission is to restore health and protect future generations by eradicating the devastation of autism and associated health disorders induced by mercury and other man made toxicants.

In April of 2000, SafeMinds founders put forth the first definitive work reviewing the link between mercury and Autism Spectrum Disorders. This effort showed that the autism presentation mirrored mercury toxicity. This research was key to propelling the issue into the awareness of the public and government officials. The resulting report, "Autism: A Novel Form of Mercury Poisoning" (Bernard, Enayati, Redwood, Roger, Binstock) was and remains recognized as a cornerstone document to the discourse on medical mercury exposure and toxicity and its effects on health.

Since this historical report, SafeMinds has sponsored almost one million dollars in research related specifically to mercury and adverse neurological outcomes. This level of financial commitment establishes SafeMinds as the largest non-profit organization funding mercury and autism-related research. SafeMinds relentlessly pursues the scientific truth about mercury and neurodevelopmental disorders through direct funding of research, as well as providing constant surveillance and vigilance on misinformation about this issue in the media, government officials and agencies.

The work of SafeMinds' parent advocate founders is documented in several highly publicized journalistic reports including Robert F. Kennedy's 2005 *Rolling Stones* article Deadly Immunity, and David Kirby's 2005 book *Evidence of Harm, Mercury in Vaccines* and the *Autism Epidemic: A Medical Controversy*.

A SmartVax Approach to Vaccines

SHARE

A parent could gauge a child's risk of vaccine-injury, and optionally make changes to the child's vaccine schedule to reduce this risk, by following this SmartVax approach to vaccines:

- **Step 1 -- Vaccine Decisions to make during pregnancy:** Decide whether the pregnant mother will get the flu vaccine during pregnancy and will be tested for HepB, and then decide whether the newborn will get the HepB vaccine at birth (see Vaccine Decisions to Make During Pregnancy)
- **Step 2 -- High-Risk Subgroups**: Determine whether your child is in a high-risk subgroup for vaccine-injury. Some children, such as children currently suffering a moderate or severe illness, are at a higher risk of vaccine injury than others. Other risk factors include premature birth, family history of asthma or autoimmune diseases, poor health at time of vaccination, etc. (see High-Risk Subgroups)
- **Step 3 -- Adverse-Reaction History:** Analyze whether your child or child's siblings have had severe or even slight adverse reactions to vaccines (e.g eczema, ear-aches), as such reactions indicate a far higher risk of vaccine-injury (see Learn how to recognize the symptoms of a vaccine reaction)
- **Step 4 -- Individualized Vaccine Schedule:** Weigh the risks vs benefits of each vaccine, including consideration on the timing of each vaccine, and then optionally define an individualized schedule that minimizes risk for the child (to get started, go to Define an Individualized Vaccine Schedule)
- **Step 5 -- Prepare for Pediatrician Visit:** Prepare yourself to ask questions of your pediatrician and discuss an individual vaccine schedule (see Preparing for the Pediatrician Visit)
- **Step 6 -- If you Choose not to Vaccinate:** There are steps you need to take (see CDC brochure What to Do if You Choose not to Vaccinate)
- **Step 7 -- Vaccine Pre-Inspection:** Before your child receives vaccines, insist on reading the vaccine product insert to ensure that the vaccine doesn't contain a mercury compound called "thimerosal" or "thiomersal". Also ensure that you child is receiving the proper vaccines per your individualized schedule, as there are different combinations of vaccines
- **Step 8 -- Post-Vaccination Care & Monitoring:** Minimize risks post-vaccination by avoiding Tylenol since it reduces the body's ability to detoxify, and monitor carefullly for any severe reactions such as fever over 103 degrees and for mild reactions such as eczema and chronic ear-aches. The National Vaccine Information Center (NVIC), an organization that encourages consumers to become fully informed regarding vaccines, provides information on how to recognize and report a suspected vaccine injury (see Monitor for vaccine reactions)

08895751 (Rev. March 2004)

Hepatitis B Immune Globulin (Human)

BayHep B®

Solvent/Detergent Treated

DESCRIPTION

Hepatitis B Immune Globulin (Human) — BayHep B® treated with solvent/detergent is a sterile solution of hepatitis B hyperimmune immune globulin for intramuscular administration; it contains no preservative. BayHep B is prepared by cold ethanol fractionation from the plasma of donors with high titers of antibody to the hepatitis B surface antigen (anti-HBs). The immune globulin is isolated from solubilized Cohn Fraction II. The Fraction II solution is adjusted to a final concentration of 0.3% tri-n-butyl phosphate (TNBP) and 0.2% sodium cholate. After the addition of solvent (TNBP) and detergent (sodium cholate), the solution is heated to 30 °C and maintained at that temperature for not less than 6 hours. After the viral inactivation step, the reactants are removed by precipitation, filtration and finally ultrafiltration and diafiltration. BayHep B is formulated as a 15–18% protein solution at a pH of 6.4–7.2 in 0.21–0.32 M glycine. BayHep B is then incubated in the final container for 21–28 days at 20–27 °C. Each vial contains anti-HBs antibody equivalent to or exceeding the potency of anti-HBs in a U.S. reference hepatitis B immune globulin (Center for Biologics Evaluation and Research, FDA). The U.S. reference has been tested against the World Health Organization standard Hepatitis B Immune Globulin and found to be equal to 217 international units (IU) per mL.

The removal and inactivation of spiked model enveloped and non-enveloped viruses during the manufacturing process for BayHep B has been validated in laboratory studies. Human Immunodeficiency Virus, Type 1 (HIV-1), was chosen as the relevant virus for blood products; Bovine Viral Diarrhea Virus (BVDV) was chosen to model Hepatitis C virus; Pseudorabies virus (PRV) was chosen to model Hepatitis B virus and the Herpes viruses; and Reo virus type 3 (Reo) was chosen to model non-enveloped viruses and for its resistance to physical and chemical inactivation. Significant removal of model enveloped and non-enveloped viruses is achieved at two steps in the Cohn fractionation process leading to the collection of Cohn Fraction II: the precipitation and removal of Fraction III in the processing of Fraction II + IIIW suspension to Effluent III and the filtration step in the processing of Effluent III to Filtrate III. Significant inactivation of enveloped viruses is achieved at the time of treatment of solubilized Cohn Fraction II with TNBP/sodium cholate.

CLINICAL PHARMACOLOGY

Hepatitis B Immune Globulin (Human) provides passive immunization for individuals exposed to the hepatitis B virus (HBV) as evidenced by a reduction in the attack rate of hepatitis B following its use.[1-6] The administration of the usual recommended dose of this immune globulin generally results in a detectable level of circulating anti-HBs which persists for approximately 2 months or longer. The highest antibody (IgG) serum levels were seen in the following distribution of subjects studied: [7]

DAY	% OF SUBJECTS
3	38.9%
7	41.7%
14	11.1%
21	8.3%

Mean values for half-life were between 17.5 and 25 days, with the shortest being 5.9 days and the longest 35 days. [7]

Cases of type B hepatitis are rarely seen following exposure to HBV in persons with preexisting anti-HBs. No confirmed instance of transmission of hepatitis B has been associated with this product.

In a clinical study in eight healthy human adults receiving another hyperimmune immune globulin product treated with solvent/detergent, Rabies Immune Globulin (Human), BayRab®, prepared by the same manufacturing process, detectable passive antibody titers were observed in the serum of all subjects by 24 hours post injection and persisted through the 21 day study period. These results suggest that passive immunization with immune globulin products is not affected by the solvent/detergent treatment.

INDICATIONS AND USAGE

Recommendations on post-exposure prophylaxis are based on available efficacy data and on the likelihood of future HBV exposure for the person requiring treatment. In all exposures, a regimen combining Hepatitis B Immune Globulin (Human) with hepatitis B vaccine will provide both short- and long-term protection, will be less costly than the two-dose Hepatitis B Immune Globulin (Human) treatment alone, and is the treatment of choice.[8]

BayHep B is indicated for post-exposure prophylaxis in the following situations:

Acute Exposure to Blood Containing HBsAg

After either parenteral exposure, e.g., by accidental "needlestick" or direct mucous membrane contact (accidental splash), or oral ingestion (pipetting accident) involving HBsAg-positive materials such as blood, plasma or serum. For inadvertent percutaneous exposure, a regimen of two doses of Hepatitis B Immune Globulin (Human), one given after exposure and one a month later, is about 75% effective in preventing hepatitis B in this setting.

Perinatal Exposure of Infants Born to HBsAg-positive Mothers

Infants born to HBsAg-positive mothers are at risk of being infected with hepatitis B virus and becoming chronic carriers.[5,8-10] This risk is especially great if the mother is HBeAg-positive.[11-13] For an infant with perinatal exposure to an HBsAg-positive and HBeAg-positive mother, a regimen combining one dose of Hepatitis B Immune Globulin (Human) at birth with the hepatitis B vaccine series started soon after birth is 85%–95% effective in preventing development of the HBV carrier state.[8,14] Regimens involving either multiple doses of Hepatitis B Immune Globulin (Human) alone or the vaccine series alone have 70%–90% efficacy, while a single dose of Hepatitis B Immune Globulin (Human) alone has only 50% efficacy.[8,15]

Sexual Exposure to an HBsAg-positive Person

Sex partners of HBsAg-positive persons are at increased risk of acquiring HBV infection. For sexual exposure to a person with acute hepatitis B, a single dose of Hepatitis B Immune Globulin (Human) is 75% effective if administered within 2 weeks of last sexual exposure.[8]

Household Exposure to Persons with Acute HBV Infection

Since infants have close contact with primary care-givers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant less than 12 months of age with Hepatitis B Immune Globulin (Human) and hepatitis B vaccine is indicated if the mother or primary care-giver has acute HBV infection.[8]

Administration of Hepatitis B Immune Globulin (Human) either preceding or concomitant with the commencement of active immunization with Hepatitis B Vaccine provides for more rapid achievement of protective levels of hepatitis B antibody, than when the vaccine alone is administered.[16] Rapid achievement of protective levels of antibody to hepatitis B virus may be desirable in certain clinical situations, as in cases of accidental inoculations with contaminated medical instruments.[16] Administration of Hepatitis B Immune Globulin (Human) either 1 month preceding or at the time of commencement of a program of active vaccination with Hepatitis B Vaccine has been shown not to interfere with the active immune response to the vaccine.[16]

CONTRAINDICATIONS

None known.

WARNINGS

BayHep B is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in

such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Bayer Corporation [1-800-288-8371].

The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.

BayHep B should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations. Epinephrine should be available.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, Hepatitis B Immune Globulin (Human) should be given only if the expected benefits outweigh the risks.

PRECAUTIONS

General

BayHep B should **not** be administered intravenously because of the potential for serious reactions. Injections should be made intramuscularly, and care should be taken to draw back on the plunger of the syringe before injection in order to be certain that the needle is not in a blood vessel.

Intramuscular injections are preferably administered in the anterolateral aspects of the upper thigh and the deltoid muscle of the upper arm. The gluteal region should not be used routinely as an injection site because of the risk of injury to the sciatic nerve. An individual decision as to which muscle is injected must be made for each patient based on the volume of material to be administered. If the gluteal region is used when very large volumes are to be injected or multiple doses are necessary, the central region MUST be avoided; only the upper, outer quadrant should be used.[17]

Laboratory Tests

None required.

Drug Interactions

Although administration of Hepatitis B Immune Globulin (Human) did not interfere with measles vaccination,[18] it is not known whether Hepatitis B Immune Globulin (Human) may interfere with other live virus vaccines. Therefore, use of such vaccines should be deferred until approximately 3 months after Hepatitis B Immune Globulin (Human) administration. Hepatitis B Vaccine may be administered at the same time, but at a different injection site, without interfering with the immune response.[16] No interactions with other products are known.

Pregnancy Category C

Animal reproduction studies have not been conducted with BayHep B. It is also not known whether BayHep B can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. BayHep B should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

Local pain and tenderness at the injection site, urticaria and angioedema may occur; anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.[19]

OVERDOSAGE

Although no data are available, clinical experience with other immunoglobulin preparations suggests that the only manifestations would be pain and tenderness at the injection site.