

## contents

- Feature Article
- Caught in The Web
- Ask Amy
- Did You Know?
- It's the Law
- Science or Science Fiction
- What's New
- Educational Events
- Professional Opportunities



## FEATURE ARTICLE

### *Vaccines, Thimerosal, and Autism: Separating the Facts from the Myths*

Arthur Allen was one of the first to write about the thimerosal controversy. His in depth report was published two and a half years ago in the New York Times Magazine. Since that time, additional reports have been published in Rolling Stone and Salon.com accusing government scientists and their academic colleagues of covering up indisputable evidence of a causal link between thimerosal and autism. The most recent example is [Evidence of Harm: Mercury in Vaccines and the Autism Epidemic, A Medical Controversy](#) by David Kirby. One critic has described Mr. Kirby as "an author subtly influenced by the vaccine paranoia people" and cautioned readers to "beware of books like these because they lead with fear and not knowledge."

Arthur Allen, in response to a Rolling Stone article by Robert Kennedy, Jr. titled Deadly Immunity, stated that, "Aside from a June 25 New York Times article that discussed the parallel realities of parents and scientists studying thimerosal, there has been little mainstream media response. Considering that about 9,000 lawsuits of claims have been filed against thimerosal and

## Caught In The Web

### Amy's Babies Launches New Website

At last! Our new website is up and running. Amy's Babies (formerly Amy's Baby Company) is pleased to announce the launch of its new website. Amysbabies.com combines state of the art technology with user-friendly navigation features that appeal to the 'baby' in all of us. Now parents as well as professionals, can easily access breastfeeding information, services, and products. An expanded shopping cart allows customers to shop at their convenience—anytime, anyplace. Please visit us at [www.amysbabies.com](http://www.amysbabies.com). Don't hesitate to let us know what you think of the new site.

have the potential to wreck the pharmaceutical industry, the debate has high stakes."

This feature article therefore will attempt to reexamine the facts, pose critical questions, and provide objective answers when possible.

### What is thimerosal?

Thimerosal is an organic compound that contains ethyl mercury. It has

## Ask Amy

### Q. Do I need to take fatty acid supplements while I am breastfeeding?

Your best source of nutrients is a diet that contains a variety of healthy foods each day. Human milk contains all the nutrients your healthy, full-term baby needs. Long-chain polyunsaturated fatty acids such as docosahexanoic acid (DHA) and arachidonic acid (ARA) are non-essential fatty acids. They are made in the body from essential fatty acids. As long as a mother's diet includes sufficient amounts of essential fatty acids, there is no evidence that DHA and ARA supplements are needed in either the mother's diet or the breastfed infant's diet. Human milk offers many advantages over supplemented formulas and is one of the few foods that contain both DHA and ARA. Mothers who take fatty acid supplements can increase the level of DHA in their blood and milk and in the blood of their babies. Currently there is no evidence to show that these increases result in any long-term benefits.

been used in vaccines since the 1930s to prevent bacterial and fungal contamination.

### Is thimerosal safe?

Thimerosal contains mercury, a toxic metal. Mercury occurs naturally in the environment (air, soil, water). It has been found in fish (particularly long lived fish such as sharks, tilefish, king mackerel, swordfish) and in small amounts in animal tissues (humans). Mercury is used in dental fillings, thermometers, and vaccines. If large amounts of mercury accumulate in the body over time, death can occur. The Environmental Protection Agency (EPA) has established tolerance levels for mercury based on studies of methyl mercury. The EPA level is ten times less than the lowest level calculated to cause harm.

Mercury exists in several forms: metallic mercury, inorganic mercury, and organic mercury

(methyl mercury, ethyl mercury, phenyl mercury). Thimerosal contains the organic mercury, ethyl mercury. Nearly all of the research done on mercury toxicity has focused on the organic mercury, methyl mercury. Methyl mercury and ethyl mercury are closely related but they have important differences. Different forms of mercury have different health effects. Methyl mercury has a half life of 50 days and accumulates in the body. Ethyl mercury has a half-life of 7-10 days and is less likely to accumulate in the body. Also, ethyl mercury is converted in the body into inorganic mercury and excreted in the stool.

In 1999, the U.S. Food and Drug Administration (FDA) determined that children receiving all of the routinely recommended childhood vaccines would potentially exceed the Environmental Protection Agency (EPA) tolerance levels for mercury (levels based on studies of methyl mercury). So in the interest of safety and out of concern that misinformation regarding thimerosal would lead to widespread refusal of vaccines, the FDA asked vaccine manufacturers to eliminate or reduce the mercury content of vaccines.

Since 2003, all routinely recommended childhood vaccines have been thimerosal-free. Only one childhood vaccine still contains trace amounts of thimerosal (influenza vaccine). Because thimerosal-containing vaccines produce levels of mercury in adults that are so low, experts do not recommend re-

removal of thimerosal from vaccines intended for use in adults and adolescents.

Manufacturers now bottle vaccines in single-dose containers taking care to ensure that the vaccines are not contaminated in the manufacturing and bottling process. This has increased the cost of vaccines and led to recent vaccine shortages. Public health officials are concerned that increased cost and reduced availability will reduce immunization rates and ultimately increase the rate of illness.

### **What is autism?**

Autism Spectrum Disorders are a group of developmental disabilities that are caused by an abnormality in the brain. According to the Centers for Disease Control and Prevention (CDC), 1 in 500 (2/1,000) to 1 in 166 children (6/1,000) have an Autism Spectrum Disorder (ASD). ASDs range from a severe form, autistic disorder (classic autism) to a mild form, Asperger syndrome. If a child has symptoms of either disorder but does not meet the specific criteria of either, he/she is diagnosed with pervasive developmental disorder not otherwise specified (PPD-NOS).

Classic autism affects verbal and nonverbal communication and social interaction. It is usually evident before age three, and negatively affects educational performance. Characteristics of autism include irregularities and impairments in communication, engagement in repetitive activities and stereotyped movements, resistance to environmental change or change in daily routines, and unusual responses to sensory experiences. The term does not include children with characteristics of the disability of serious emotional disturbance.

## *Did You Know?*

### **National Women's Health Information Center Launches New Look!**

The National Women's Health Information Center (NWHIC) has launched a new website [www.WomensHealth.gov](http://www.WomensHealth.gov). NWHIC is a clearinghouse for health information for the Office on Women's Health. Resources include [www.WomensHealth.gov](http://www.WomensHealth.gov), a sister site ([www.GirlsHealth.gov](http://www.GirlsHealth.gov)), and a toll-free resource center (1-800-994-9662). NWHIC serves the United States, Puerto Rico and the U.S. Virgin Islands. NWHIC phone lines (available in English and Spanish) are open Monday through Friday from 9:00 am to 6:00 pm, EST.

### **Emory University Establishes Lactation Rooms**

Emory University under the direction of the President's Commission on the Status of Women (PCSW) currently has five sites campus wide where students and staff can breastfeed their babies or express their milk. More sites are anticipated as space becomes available. In the future, any design plan for new capital buildings or major renovations will address the need for lactation rooms.

Emory's first lactation room opened in 1997, and is thought to be the first of its kind on a college campus. With available space at a premium, the creation of four additional rooms has required considerable creativity. If you would like to learn more about the PCSW's lactation room project, contact the commission at [PCSW-PROJECTS@listserv.cc.emory.edu](mailto:PCSW-PROJECTS@listserv.cc.emory.edu).

## *It's The Law*

### Exclusive Breastfeeding Objectives May Become Part of Healthy People 2010.

The office of Disease Prevention and Health Promotion at the U.S. Department of Health and Human Services has invited public comment on proposed changes to the Healthy People 2010 objectives. During the midterm review process, federal agencies and other experts assess the data trends during the first half of the decade, consider new data, and make changes to ensure that Healthy People 2010 remains current and relevant. To view the proposed changes visit [www.healthypeople.gov/data/midcourse/comments/fojective.asp?id=16&subid=19](http://www.healthypeople.gov/data/midcourse/comments/fojective.asp?id=16&subid=19)

### What causes autism?

Genetics is thought to play a key role in the development of autism. Using a strict definition of autism, when one twin has autism, 60% of identical and 0% of fraternal twins have autism. Using a broader definition of autism, when one twin has autism, approximately 92% of identical and 10% of fraternal twins have autism. This data suggest that autism clearly has a genetic component.

Home movie studies provide some of the best data on when symptoms of autism first appear. In one particular study, home movies were taken of children who eventually were diagnosed with autism and children who were not diagnosed with autism.(4) The movies were made before the children received the MMR vaccine. Neurodevelopment specialists viewed the movies and were consistently able to separate autistic from non-autistic children at one year of age. Using sophisticated movement analysis, movies of children eventually diagnosed with autism and children not diagnosed with autism

were coded and evaluated for their capacity to predict autism. Children who were eventually diagnosed with autism were predicted from movies taken at 2-3 months of age. This data clearly show that subtle symptoms of autism are present in early infancy and argue against vaccines as a cause of autism.

Some evidence suggests that autism occurs as a result of in utero events such as viral infection. Children exposed to thalidomide during the first or early second trimester were found to have an increased incidence of autism.(6) Autism occurred in children with ear, but not arm or leg abnormalities. Because arms and legs develop after 24 days gestation, it was concluded that the risk period for autism following receipt of thalidomide must be before 24 days gestation.

Researchers have also reported an increased risk for autism in children with congenital rubella syndrome and tuberculous sclerosis, suggesting that autism is likely due to abnormalities of the central nervous system that occur in utero.

### Do vaccines cause autism?

The controversy surrounding vaccines and autism dates back to 1998 with the publication of a paper by Andrew Wakefield titled, "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children."(10) The authors hypothesize that the measles-mumps-rubella (MMR) vaccine causes a series of events that results in the development of autism. The study describes 12 children with

neurodevelopmental delay (8 with autism). The author notes that each of the 8 autistic children was diagnosed with autism within 1 month of receiving the MMR vaccine.

### **Significant flaws found in study**

Critics argued that the MMR vaccine is administered to nearly all children at a time when many children are diagnosed with autism. Therefore the observation that some children with autism recently received the MMR vaccine is expected. In addition, only vaccinated children were included in the Wakefield study. To determine whether the MMR vaccine causes autism, both vaccinated and unvaccinated children must be studied. Furthermore, in each of the 8 autistic children, symptoms of autism were observed before, not after, the presence of gastrointestinal symptoms, thus refuting the authors' claim that autism is a consequence of gastrointestinal inflammation. Wakefield published a second paper in 2002, in which he examined the relationship between the measles virus and autism. Again critics cited a number of flaws.(9)

While the two studies by Wakefield hypothesize a causal link between the MMR vaccine and autism, five additional studies conclude the opposite.(1-3, 7, 8) Researchers found no difference in the age of diagnosis of autism in vaccinated and unvaccinated children; the onset of regressive symptoms of autism did not occur within 2, 4, or 6 months of receiving the MMR vaccine; and despite a dramatic increase in the number of reported cases of autism, the percentage of children that have received the MMR vaccine has remained the same. The best evidence comes from Denmark, where rates of autism continued to rise despite the removal of thimerosal from all vaccines in 1992.(3)

The result of a critical review of the data was also published in Pediatrics in 2004.(5) Twelve publications met the selection criteria, 10 epidemiologic studies and 2 pharmacokinetic studies. The authors concluded that the data did not support the claim that thimerosal-containing vaccines cause autism.

### **Institute of Medicine finds no link between thimerosal-containing vaccines and autism**

In 2000, in response to a request from the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), the Institute of Medicine (IOM) established an independent expert committee to evaluate the data and determine whether vaccines cause specific health problems.

The Immunization Safety Review Committee published a series of reports between 2001 and 2004. The committee concluded that neither thimerosal-containing vaccines nor the MMR vaccine is associated with autism.

A second IOM committee met in February 2005, composed of different scientists. According to Committee Chair, John C. Bailar III, "concerns about access and transparency have accompanied the development and functioning of the Vaccine Safety Datalink data sharing program, and consequently some people's trust in the reliability of findings from VSD studies has eroded. Taking steps to improve the independence, transparency, and fairness of VSD procedures will help enhance confidence in the data sharing program and

in research based on this important tool for evaluating vaccine safety."

The Vaccine Safety Datalink is a large, linked database of patient information that was developed jointly by CDC and several private managed care organizations in 1991. It includes data on vaccination histories, health outcomes, and characteristics of more than 7 million patients of eight participating health organizations. Researchers from CDC and the managed care groups have used VSD information to study whether health problems are associated with vaccinations. The subsequent VSD data sharing program was launched in 2002 to allow independent, external researchers access to information in the database.

### **Are vaccines safe?**

Vaccines have significantly reduced and, in some cases, eliminated, many childhood diseases. In the past, polio, rubella, measles, diphtheria, tetanus, chickenpox, and pertussis (whooping cough) were among the diseases that caused thousands of deaths each year. Today, as a result of immunizations, these diseases rarely occur. A widespread decline in immunizations would lead to outbreaks of serious diseases that now occur rarely.

Any discussion of vaccine safety must include a discussion of the benefits of immunizations as well as the risks. All vaccines have possible side effects. Most side effects are mild and include fever, rash, and tenderness or swelling at the shot site. Some side effects can be severe, for example, the pertussis vaccine can cause persistent crying, high fever, and seizures. While these side effects seldom cause permanent damage, they can be frightening for parents. But if you compare the potential risks of vaccines and the established risks of disease, vac-

cines, with few exceptions, are the safer choice for both children and adults.

### **What parents and health professionals need to know**

- Few things in medicine work 100% of the time.
- Few things in medicine are risk-free.
- Researchers are working continually to improve the safety of immunizations.
- A decline in immunization rates will lead to an increase in disease.

To illustrate this fact: In 1974, when 80% of Japanese children were vaccinated for pertussis (whooping cough), only 393 cases of pertussis occurred and none of the victims died. The following year information was circulated that the pertussis vaccine was no longer needed and that it was unsafe. By 1976 only 10% of Japanese infants were vaccinated and in 1979 over 13,000 cases of whooping cough were reported along with 41 deaths. These are the risk/benefit ratios that parents as well as professionals must consider.

- The only time it is safe to stop giving immunizations is when a disease has been eradicated worldwide.

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7. Taylor B, Miller E, Lingam R, Andrews N, Simmons A, Stowe J. Measles, mumps, and rubella vaccination and bowel problems or developmental regression in children with autism: population study. *BMJ* 2002;324(7334):393-6.
8. Taylor B, et al. Autism and measles, mumps, and rubella vaccine: no epidemiological evidence for a causal association. *Lancet* 1999;353:2026-2029.
9. Uhlmann V, et al. Potential viral pathogenic mechanism for new variant inflammatory bowel disease. *Journal of Clinical Pathology: Molecular Pathology* 2002;55:1-6.
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Agency for Healthcare Research and Quality (AHRQ) released two new evidence-based reports on the effects of omega-3 fatty acids. The reports were requested and funded by the National Institute of Health's Office of Dietary Supplements and conducted by three of AHRQ's Evidence-based Practice Centers: Southern California-RAND, Tufts-New England Medical Center, and the University of Ottawa. The first report, *Effects of Omega-3 Fatty Acids on Child and Maternal Health*, noted the absence of a safety profile (i.e., moderate-to-severe adverse events). Pregnancy outcomes were either unaffected by omega-3 fatty acid supplementation, or the results were inconclusive. Results concerning the impact of the intake of omega-3 fatty acids on the development of infants are primarily, although not uniformly, inconclusive. Select to read the [summary](#). The second report, *Effects of Omega-3 Fatty Acids on Mental Health*, revealed that nothing can yet be concluded concerning the clinical utility of omega-3 fatty acids as supplemental treatment for any other psychiatric disorder or condition or as a primary treatment for all psychiatric disorders or conditions. Select to read the [summary](#). A print copy of the summaries and the full reports are available by sending an e-mail to [ahrqpubs@ahrq.gov](mailto:ahrqpubs@ahrq.gov).

## SCIENCE OR SCIENCE FICTION

### *Two New Evidence Reports on Effects of Omega-3 Fatty Acids*

## WHAT'S NEW

## *More is Better! Quintessence Breastfeeding Challenge 2005*

Just like breastfeeding more is better. Breastfeeding mothers and babies are invited to participate in the Quintessence Breastfeeding Challenge 2005. It's a wonderful opportunity for health care providers, breastfeeding supporters and breastfeeding mothers to participate in a celebration of breastfeeding. Previous participants described the event as a "joyful" and "fun" experience. The Quintessence Breastfeeding Challenge celebrates breastfeeding by providing encouragement and support for women in communities worldwide. Health promotion through media attention is invaluable. Community-based events can be as simple as several breastfeeding mothers at a local coffee shop or a much larger event. It's easy to participate – simply register your site or contact an existing site – [www.babyfriendly.ca](http://www.babyfriendly.ca). Quintessence Foundation is a nonprofit educational foundation.

### **CDC Releases Report on Exposure to Environmental Chemicals**

The Centers for Disease Control and Prevention (CDC) has released their Third National Report on Human Exposure to Environmental Chemicals. The report shows a significant decline in exposure to second-hand smoke, as well as decreases in children's blood lead levels. It also suggests a need for more research into the health effects of exposure to low levels of cadmium, which could be associated with subtle kidney injury and low bone mineral density. An executive summary and a link to the full report are available at [www.cdc.gov/exposurereport/](http://www.cdc.gov/exposurereport/).

### **ILCA 2006 Call for Proposals**

Proposals are now being accepted online for the 2006 Conference and Annual Meeting, Interdisciplinary Breastfeeding Practice - Integration through Innovation, July 12-16, 2006 at the Wyndham Franklin Plaza Hotel in Philadelphia, Pennsylvania, USA. Speaker guidelines can be found at [www.ilca.org/conference/Proposal.php](http://www.ilca.org/conference/Proposal.php). The submission site can be found at [www.abstractsonline.com/submit/login.asp?mkey=%7BE3F71C0D%2DAE45%2D496F%2D91DD%2D01960E34CC7D%7D](http://www.abstractsonline.com/submit/login.asp?mkey=%7BE3F71C0D%2DAE45%2D496F%2D91DD%2D01960E34CC7D%7D). The deadline for proposal submissions is October 31, 2005. For questions regarding the submission process contact Judi Lauwers at [judilauwers@ilca.org](mailto:judilauwers@ilca.org).

### **EDUCATIONAL EVENTS**

\*An asterisk indicates those events where Amy Spangler will be speaking.

October 12-16, 2005\*  
CAPPA Conference  
Anaheim, California USA  
[www.CAPPA.net](http://www.CAPPA.net)

October 18, 2005\*  
Overlook Hospital Professional Education Conference  
Summit, New Jersey USA  
Fran Drigun  
[Fran.drigun@ahsys.org](mailto:Fran.drigun@ahsys.org)

October 20-22, 2005  
Human Lactation: Current Research & Clinical Applications  
Amarillo, Texas USA  
[www.ibreastfeeding.com](http://www.ibreastfeeding.com)

### **PROFESSIONAL OPPORTUNITIES**

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Amy's Babies is pleased to present the Feeding Times. Published four times a year, the Feeding Times focuses on issues of interest to parents and health professionals. Amy's Babies provides educational resources and services for parents and health care professionals. For additional information about our products and services please visit our website at [www.amysbabies.com](http://www.amysbabies.com)

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