



Rx Focus

Mercury Exposure: A Cause of Autism?

Over the past decade, fears about toxic exposure to mercury have faded in and out of the media spotlight. The most recent controversy has been whether thimerosal, a mercury-containing preservative that has been used in most immunizations for newborns, is the cause of autism in children. While no study exists that directly and undisputedly links autism to mercury exposure, studies do confirm that a connection is possible.

While the link to autism is unclear, there is no question that human exposure to mercury is dangerous. The US Environmental Protection Agency (EPA) has stringent guidelines in place in order to minimize the risk of mercury exposure through foods and other products. In developing countries, however, such guidelines are not yet in place and many people are exposed to mercury every day. Sources of exposure can range from contaminated foods (primarily fish), thermometers, dental amalgams, mercury-based beauty creams and teething powders, vaccine preservatives, occupational or ritualistic practices, or accidental ingestion, via either occupational or environmental sources. The effect of mercury in the body depends on the extent of the exposure as well as which of the three chemical types of mercury was involved: elemental mercury, inorganic mercury, or organic mercury. The effects of most of these types of mercury are well understood, ranging from brain damage, to organ failure, to death. The type of mercury that is being linked to autism, an

organic form called ethylmercury (contained in thimerosal), is not as well understood.

At high doses, ethylmercury causes blindness and brain damage in adults. In fetal or infant brains, which are in stages of rapid development, high levels of exposure can cause hyperactive reflexes, deafness, blindness, mental retardation, cerebral palsy, or general paralysis. At lower levels of exposure, effects on the brain may be more subtle. Problems with language, learning, attention, and fine motor skills are believed to be the result. Many experts believe that low levels of mercury exposure could also lead to autism.

In 1999, concerns were raised that if infants received all scheduled immunizations, the total amount of mercury they were exposed to may exceed EPA guidelines. This concern was based on the fact that most vaccines included a mercury-containing preservative called thimerosal, and these vaccines were found to increase the level of mercury in the blood of infants. Although the amount of exposure from vaccines was small, scientists and healthcare professionals began to report the possibility that it was enough to cause autism. Autism disorders are characterized by impairment in social interaction, communication, and behavior, including repetitive motor behaviors, speech delays, hypersensitivity to sensory stimuli, and an insistence on sameness. While these autistic behaviors had not been noted with exposure to other types of mercury, the possibility that thimerosal (ethylmercury) could cause them was alarming.

The EPA responded quickly, requesting that all vaccine manufacturers remove thimerosal from their formulations. As of 2003, all recommended childhood vaccinations are available in thimerosal-free formulations. If thimerosal exposure truly does cause autism, logic would state that removing it from all vaccines would lead to substantially fewer autistic children. While one US study showed fewer cases of autism since the removal of thimerosal, studies in Sweden and Denmark, who have used thimerosal-free vaccines since 1992, have seen the number of autism cases continue to rise. Many studies have been conducted in an effort to determine whether mercury is linked to autism, and while it seems probable to many experts, results have not been clear. Scientists are finding themselves divided over the issue. Some studies, including one published in 2004 by the Institute of Medicine, found no evidence that autism is caused by mercury exposure. Other studies have concluded that there is, in fact, a causal association. The issue must continue to be investigated with well-designed clinical trials in order to determine the role that mercury plays in autism, if any. At present, there is more benefit associated with childhood immunizations than risk, and no changes have been made to the recommendations for the vaccination of children.

Some autism experts are not willing to wait for the results of these mercury studies. They believe that overexposure to heavy metals—especially mercury-based preservatives—is the cause of autism. These doctors are prescribing chelation therapy, a treatment that strips the body of excess metals. Chelation therapy

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April Health Observances

National Alcohol Screening Day, April 7th

Sponsored by Screening for Mental Health, Inc.
(www.NationalAlcoholScreeningDay.org)

National Infant Immunization Week, April 24th-30th

Sponsored by the Centers for Disease Control's National Immunization Program
(www.cdc.gov/nip/events/niiw/)

National Autism Awareness Month

Sponsored by the Autism Society of America
(www.autism-society.org)

Cancer Control Month

Sponsored by the American Cancer Society
(www.cancer.org)

National Child Abuse Prevention Month

Sponsored by the Administration for Children and Families' Children's Bureau
(<http://nccanch.acf.hhs.gov/topics/prevention/index.cfm>)

is traditionally used to treat accidental poisoning with heavy metals or a rare condition called Wilson's disease where copper builds up in the body's organs. While some experts believe that these medications lead to great improvements in autistic children, others feel that their use is inappropriate. Chelating agents (i.e.: Chemet, Cuprimine, DMSA, DMPS, TTFD) are not indicated for the treatment of autism, and their use has not been studied in autistic children. In the process of removing excess metal, the drug also removes important minerals such as zinc and iron, potentially leading to serious side effects. Because chelating agents are only appropriate for a select population of patients, these medications are only available through prior authorization with CBCA Rx.

With all of the controversy surrounding thimerosal-containing vaccinations, autistic children, and proposed treatments for autism, it becomes increasingly clear that the issue must be further investigated. Until the effects of low levels of mercury on the body become clear, expert opinions will remain divided. Scientists remain hopeful that they can uncover what link mercury has to autism in an effort to better understand this complex condition.

References:

1. A comparative evaluation of the effects of MMR immunization and mercury doses from thimerosal-containing childhood vaccines on the population prevalence of autism. *Med Sci Monit*, 2004; 10(3):133-39.
2. Mercury exposure in children: a review. *Toxicology and Applied Pharmacology*, 2004; 198:209.
3. Childhood immunizations and childhood illness. *N Engl J Med*. 2004 Apr 1;350(14):1380-2.
4. *A Radical Approach to Autism*. Amy Dockser Marcus. *The Wall Street Journal*; Online edition. 15 Feb, 2005.



Industry Report

GlaxoSmithKline Violates FDA's Manufacturing Regulations

The FDA and the Justice Department have halted the distribution of GlaxoSmithKline's (GSK) antidepressant Paxil CR and diabetes medication Avandamet because of ongoing concerns about the manufacturing quality of the products. Several inspections of the GSK manufacturing plant in Puerto Rico revealed significant violations of the FDA's good manufacturing practice regulations. Among the violations was the finding that the Paxil CR tablets could split apart. Patients could receive either a portion of the tablet that lacks any active ingredient, or a portion that contains active ingredient but does not have the intended controlled-release effect. The FDA also found that some Avandamet tablets did not have an accurate dose of rosiglitazone, one ingredient in this product. These products have caused no harm to consumers, and the FDA does not believe that these products pose a significant health hazard.

Patients are urged to continue taking these medications, and to talk with their doctors about alternative products.

US Court Halts Sales of Quinapril

A US court has ordered two competitors of pharmaceutical firm Pfizer Inc. to stop selling the generic version of the company's blood pressure drug, Accupril. The US District Court of New

Jersey issued a temporary injunction to immediately halt the sale of the generic, Quinapril, by Teva Pharmaceuticals and Ranbaxy Pharmaceuticals. Pfizer filed a patent infringement suit against the two companies in January of this year, seeing damages for lost sales due to the competition from cheaper generic versions of its drug. The two companies have said they will appeal the court decision, but will comply with the injunction for the time being.

CBCA Rx has removed generic Quinapril from coverage on all plans. The brand name equivalent, Accupril, has been updated in the claims system in order to allow members to receive the brand name product without a penalty.



New Drug Approvals

Trecator 250mg Tablets

Approved: 3/24/05

Chemical Name: Ethionamide tablets, USP

Manufacturer: Wyeth Pharmaceuticals

Approved Indication: Treatment of active tuberculosis, as part of a multi-drug regimen

Average Wholesale Price: \$3.09/tablet (\$90-\$360 per month depending on dosing)

Special Notes: This film-coated tablet will replace the sugar-coated tablet. The new tablet will be more rapidly absorbed, leading to higher peak concentrations. Dosages may need to be re-titrated when switching to the new formulation.



New Generic Approvals

Ciclopirox Olamine Cream

Approved: 1/3/05

Manufacturer: Altana

Brand Name Equivalent: Loprox Cream®

Approved Indication: Topical Antifungal Cream

Desmopressin Acetate Nasal Solution

Approved: 1/27/05

Manufacturer: Bausch and Lomb®

Brand Name Equivalent: DDAVP Nasal Spray

Approved Indication: Treatment of primary nocturnal enuresis and central cranial diabetes insipidus

Fentanyl Transdermal System, 25mcg, 50mcg, or 100mcg

Approved: 1/28/05

Manufacturers: Mylan Technologies

Brand Name Equivalent: Duragesic®

Approved Indication: Treatment of chronic, severe pain



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