Safe Minds charges mercury study conclusions flawed

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through three, levels would be much higher." Moreover, she notes, this was a very large baby (95th percentile) who received a conservative dose of thimerosal (about 60 percent of what a typical infant vaccinated during the 1990s received). Given this infants' significant mercury level, she says it is likely that the peak levels of a significant number of two-month-old children given the full 62.5 mcg of mercury would exceed 6 ppb.

"For these reasons alone," Bernard says, "the results of the Pichichero study are anything but 'reassuring' to parents whose children were exposed to thimerosal as infants."

Bernard says the Pichichero study indicates that the half life of ethylmercury in infants is about 6-7 days, and notes, "Pharmacologically, this period would be considered a very long half and a long time for a toxic substance to be circulating in the body.... In a developing brain a few days are significant time periods for an agent that interferes with cell division and organization."

Bernard also notes that Pichichero has acknowledge financial ties to Eli Lilly, the company that developed thimerosal. According to Safe Minds, the researcher "has also claimed financial ties to a number of vaccine manufacturers, including manufacturers of thimerosal-containing vaccines."

Bernard concludes that the study "has little [or] no value as a safety assessment of thimerosal from vaccines, and its conclusions are overreaching, perhaps reflecting a bias on the part of its lead author towards absolving licensed vaccines of any adverse effects."

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"Mercury concentrations and metabolism in infants receiving vaccines containing thimerosal: a descriptive study," M. E. Pichichero, E. Cernichiari, J. Lopreiato, and J. Treanor, *The Lancet*, Vol. 360, No. 9347, November 30, 2002, 1737-41. Address: M. E. Pichichero, Department of Immunology, University of Rochester, Rochester, New York.

—and—

"Safe Minds assessment of the pichichero thimerosal study," Sallie Bernard, www.safeminds.org.

Risperidone: both effectiveness, adverse effects reported

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sistent erections that can lead to penile dysfunction and even the need for penile prostheses. Munarriz and colleagues say they have treated several patients with risperidone-induced priapism in their own practice.

Studies raise other concerns

Other researchers, too, are raising concerns about risperidone's effects on the cardiovascular system, particularly when the drug is given to older patients or those with existing cardiovascular problems.

Analyzing data from four placebo-controlled trials conducted by the drug's manufacturer and involving elderly patients with dementia, Eric Wooltorton found that "cerebrovascular adverse events were twice as sommmon in the risperidone-treated group as in the placebo group." He adds, "A further search of international databases of postmarketing adverse events revealed 37 cases of such events in elderly dementia patients taking risperidone, of which 16 (43 percent) were fatal."

Wooltorton warns that doctors should be cautious about administering risperidone to patients with a history of heart failure, heart attacks, ischemia, strokes or other cerebrovascular disease, or conduction abnormalities.

In addition to its potential cardiovascular risks, risperidone has recently been linked to an elevated risk of depression in individuals with Tourette syndrome, a neurological disorder that sometimes co-occurs with autism.

H. C. Margolese and colleagues analyzed data from 58 adult and adolescent patients with Tourette's who had been treated with risperidone. The researchers report that 17 of the patients, or nearly 30 percent, developed major depressive disorder, including one patient who later committed suicide. Nine of the 17 patients had prior histories of depression.

The researchers note that their findings are consistent with previous research showing an incidence of depression of up to 30 percent in patients with Tourette's undergoing short-term trials of risperidone.

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"Risperidone in children with autism and serious behavioral problems," James T. McCracken et al., *New England Journal of Medicine*, Vol. 347, No. 5, August 1, 2002, 314-321. Address: Lawrence Scahill, Yale Child Study Center, P.O. Box 207900, New Haven, CT 06520, lawrence.scahill@yale.edu.

—and—

"Risperidone in children with autism and serious behavioral problems: letters," Louis Sandler; Guy Valiquette; and Ricardo Munarriz et al., *New England Journal of Medicine*, Vol. 347, No. 23, December 5, 2002, 1890-1. Address not listed.

—and—

"Risperidone (Risperdal): increased rate of cerebrovascular events in dementia trials," *Canadian Medical Association Journal*, Vol. 167, No. 11, November 26, 2002, 1269-70. Address not listed.

—and—

"Depression and dysphoria in adult and adolescent patients with Tourette's disorder treated with risperidone," H. C. Margolese, L. Annable, and Y. Dion, *Journal of Clinical Psychiatry*, Vol. 63, No. 11, November 2002, 1040-4. Address: H. C. Margolese, Clinical Psychopharmacology Unit, Allan Memorial Institute, McGill University Health Centre, Montreal, Quebec, Canada.

British study links additives to children's behavior problems

A just-released study conducted three years ago and sponsored by the British government adds to evidence that food colorings adversely affect children's behavior.

The study apparently was "shelved" by the government after criticism that it relied on parents' reports about their children's behavior, rather than on observations by professionals. Food Commission research officer Kath Dalmeny criticized this rationale, saying, "Any study involving children often relies on parental observation. Taking children out of their home environment or having them observed by strangers can itself affect the results."

According to the researcher, approximately one quarter of the children exhibited increased rates of tantrums, hyperactivity, or other behavioral problems following ingestion of the additives.

The study, conducted by researchers from the UK's Asthma and Allergy Research Centre, evaluated the effects of five different food additives on 277 three-year-old children. The additives were combined in liquid, in amounts similar to those allowed in foods.

According to the researchers, approximately one quarter of the children exhibited increased rates of tantrums, hyperactivity, or other behavioral problems following ingestion of the additives. While dismissing the findings as "inconclusive," the Food Standards Agency acknowledged that they were "in line with previous reports by other organizations." Among those reports is a 2000 review by the Center for Science in the Public Interest (see ARRI 14/1), which found that 17 of 23 controlled studies reported evidence that some children's behavior seriously worsens after they consume artificial colors or "problem" foods such as milk or wheat.

Editor's note: It is quite strange that researchers claim that parents, who know their children's behavior intimately, are somehow less capable of judging behavioral changes than are "experts" who are completely unfamiliar with the children, see them in artificial settings, and spend only a few moments observing them. Researchers would be wiser to listen to parents, who are the most qualified judges of whether an intervention helps or harms their children.

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"Food additives cause tantrums," BBC News, October 25, 2002.

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"'Lost' study links food additives to tantrums," Robert Uhlig, UK Telegraph, October 25, 2002.