

REVIEW PAPER

Systematic Assessment of Research on Autism Spectrum Disorder (ASD) and Mercury Reveals Conflicts of Interest and the Need for Transparency in Autism Research

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Published online: 8 November 2017

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Abstract Historically, entities with a vested interest in a product that critics have suggested is harmful have consistently used research to back their claims that the product is safe. Prominent examples are: tobacco, lead, bisphenol A, and atrazine. Research literature indicates that about 80–90% of studies *with* industry affiliation found no harm from the product, while only about 10–20% of studies *without* industry affiliation found no harm. In parallel to other historical debates, recent studies examining a possible relationship between mercury (Hg) exposure and

Editors' Note—This article is a revision of the retracted article "Systematic Assessment of Research on Autism Spectrum Disorder and Mercury Reveals Conflicts of Interest and the Need for Transparency in Autism Research" https://doi.org/10.1007/s11948-015-9713-6.

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autism spectrum disorder (ASD) show a similar dichotomy. Studies sponsored and supported by industry or entities with an apparent conflict of interest have most often shown no evidence of harm or no "consistent" evidence of harm, while studies without such affiliations report positive evidence of a Hg/autism association. The potentially causal relationship between Hg exposure and ASD differs from other toxic products since there is a broad coalition of entities for whom a conflict of interest arises. These include influential governmental public health entities, the pharmaceutical industry, and even the coal burning industry. This review includes a systematic literature search of original studies on the potential relationship between Hg and ASD from 1999 to August 2015, finding that of the studies with public health and/or industry affiliation, 86% reported no relationship between Hg and ASD. However, among studies without public health and/or industry affiliation, only 21% find no relationship between Hg and ASD. The discrepancy in these results suggests a bias indicative of a conflict of interest.

Keywords Conflict of interest \cdot Transparency \cdot Autism \cdot Mercury \cdot Toxins \cdot Autism \cdot ASD

Introduction

A possible link between exposure to mercury (Hg) and autism spectrum disorder (ASD) is a recent example of a heated debate over the association between a pervasive toxic exposure and a prevalent and devastating diagnosis. The heated debate began in the late 1990s, when it was suggested that exposure to Hg in vaccines was a risk factor for ASD (Halsey 1999). In this case, as in those before it, whenever there has been a possible link between illness and a toxic exposure, there has been heated debate characterized by adamant denial.

Denial of a toxicant in disease causation can be attributed in part and firstly, to a natural inclination to resist unpleasant theories. A historical illustration of this was acrodynia (also known as Pink Disease). This almost forgotten disease, mostly affecting infants and young children, is a well-studied example of human Hg poisoning (Bjørklund 1995). Hg as the cause of acrodynia was first suggested in 1846, and again in 1922 (Hanson and Pleva 1991). Josef Warkany and Donald M. Hubbard (1948) from the United States (US) demonstrated Hg involvement in 25

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out of 28 cases of acrodynia in 1948. When Hg-containing teething powders were withdrawn from the market in Australia in 1953 (followed later by the US), there was a dramatic fall in the incidence and mortality rate from acrodynia (Bjørklund 1995). However, the role of Hg as the primary source of acrodynia was not universally accepted even as late as 1956 (Dathan and Harvey 1965). Throughout these decades of heated debate, the science indicating that acrodynia was caused by Hg exposure was resisted because, as stated by a historian studying the social and medical aspects of the illness, "poisoning was not a fashionable diagnosis" (Dally 1997).

Resistance to linking a toxic exposure to an illness can also result from a concern for liability. The responsibility for an illness or disability that results from a toxic product is borne by the industry that manufactures it, and resistance to a link between illness and an antecedent exposure is often driven by an industry that fears the consequences, since it is in their best interest to do so (Bridbord and Hanson 2009; Brownell and Warner 2009; Friedman and Richter 2005; Hayes 2004; McComas 2008; Ong and Glantz 2001; Sass 2006). As a result, conflicts of interest enter these debates and the resulting discourse is often marred by misleading information, which, unfortunately, often includes misleading assertions concerning the state of scientific research.

Historically, entities with a vested interest in a product that critics have suggested is harmful have consistently used research to back their claims that a product is safe. Kelly Brownell and Kenneth Warner (2009) reviewed the issue of conflicts of interest in research. They concluded that industry manipulates research information to buy loyalty, instill doubt about criticisms, confuse the public, give ammunition to political allies, and stall or influence government action. This practice, as noted by Brownell and Warner (2009) and many other experts on the subject, continues to the present day (Barnoya and Glantz 2006; Brownell and Warner 2009; Kessler 2001; Mars and Ling 2008; Michaels 2008; Mooney 2006; Schick and Glantz 2007). The following discussion of examples of research conflicts of interest starts with tobacco because much of what we have learned regarding the influencing or "buying" of scientists is from tobacco litigation.

Past and Current Examples of Research Conflict of Interest and Outside Influences

Tobacco

The tobacco industry spent significant funds in their attempts to undermine the science with respect to a link between smoking and lung disease (including issues related to secondhand smoke), calling into question the research that showed harm from smoking (McGarity and Wagner 2008; Tong and Glantz 2007). Evidence indicates that the industry paid prominent scientists to conduct studies with the intent of countering potentially damaging scientific evidence (Cummings et al. 2007). Internal documents revealed that the industry devised a plan to become a major sponsor of medical research in the Draft Recommendations for Cigarette



Manufacturers of 1953 (Brandt 2012). According to Allan Brandt (2012) this "call for new research" was intended to: (1) give the impression that existing studies were inadequate or flawed, referring to them as "junk" science, and (2) to create uncertainty about the harm from tobacco while making the industry appear to be a committed participant in the scientific endeavor (Brownell and Warner 2009). The industry developed research programs that offered funds directly to university-based scientists in order to enlist the support, and develop the financial dependence, of those scientists (Brandt 2012).

Lead

Another example is lead (Pb) poisoning. Pb poisoned the environment for decades while being used in many products (gasoline, paint, and pipes) before action was taken. The first documented case of childhood Pb poisoning in the US was in 1914. By 1930, Pb paint was regulated or banned in most European countries. Nevertheless, the US lead industry fought federal and local regulation of its products and promoted its use for several more decades (Grist 2004).

The toxicity of Pb was the subject of heated debate, and the debate was again marked by resistance, conflicts of interest, and misleading information. As reported by Kenneth Bridbord and David Hanson (2009), the Pb industry used their public relations capabilities to advertise the benefits of their products to the general public while casting doubt on the possibility of harm associated with its use. This was achieved, "...in large part, by being the primary supporter of research on health effects of lead and relying upon the scientists that it supported to communicate and interpret this research to the government and the public." (Bridbord and Hanson 2009, p. 1195).

Industry pressure may have influenced policy-makers, because they pursued a strategy that focused on diagnosing children after they were poisoned (the effect) rather than identifying toxic sources (the cause), which in effect allowed children to be exposed to and poisoned by lead for years to come (Grist 2004).

Methylmercury

Minamata disease provides another example of a heated debate about the link between toxicant exposure and the resulting diagnosis. Minamata disease was caused by methylmercury poisoning, where the putative source of the mercury (Hg) was methyl-Hg-cysteine from contaminated fish. The fish were contaminated with methylmercury from the dumping of mercury-tainted waste into water in Minamata, Japan by the Chisso Plant. The disease was attributed to many other causes: infection, explosions, etc., with some of the alternative theories being promoted by the Chisso Plant itself, the company ultimately found to be responsible for the exposure (Takeuchi et al. 1978). Early studies conducted by the Chisso Plant found their industrial waste caused the disease (Smith 2014); however, that information was not published. In fact, even while knowing this information, the Chisso Plant funded research into alternative causes of the disease, other than its own waste (Encyclopedia of the Earth 2009).



Atrazine

Reports of conflicts of interest in research include the herbicide atrazine, which was banned in the European Union in 2004, but is still used in the US (European Commission 2004). Tyrone Hayes (2004) found that financial sponsorship was a strong predictor of study outcome for atrazine research (p=0.009). Thus funding sources varied for studies reporting adverse effects (including government and industry funding), but all of the studies that failed to detect adverse effects were funded by the manufacturer of atrazine.

Bisphenol A

Similar to atrazine research, Frederick vom Saal and Claude Hughes (2005), who studied bisphenol A (BPA), found that no BPA industry-funded studies have ever reported significant effects from low doses of BPA, although more than 90% of government-funded studies reported significant effects from low doses of BPA. Moreover, some of the industry-funded BPA studies that reported no significant effects used a strain of rats that was inappropriate for the study of estrogenic responses (vom Saal and Hughes 2005).

Olestra

Similar results have been reported in food research. For example, among studies supportive of the fat substitute olestra, 80% were funded by the food industry; however, in contrast, only 21% of neutral studies and 11% of studies critical of olestra have been funded by the industry (Levine et al. 2003). All authors affiliated with the maker of olestra have published studies that are supportive of olestra (Levine et al. 2003).

Conflicts of Interest in Mercury Exposure and Autism Research

Conflicts of interest in studies examining Hg exposure and the resulting risk of ASD have been noted (DeSoto and Hitlan 2010). In parallel to other historical debates over potential toxicants and their resulting adverse effects, studies examining the Hg-autism link that were sponsored and supported by entities with apparent conflicts of interest, often show no evidence of harm or no "consistent" evidence of harm from Hg exposure, even in the most vulnerable subjects, human fetuses and infants.

For example, studies on Hg exposure from coal-burning plants conducted by researchers *without* industry affiliation consistently show that Hg exposure from coal burning is a significant risk factor for ASD (Blanchard et al. 2011; Palmer et al. 2006, 2009; Windham et al. 2006). In contrast, Thomas Lewandowski and colleagues (2009), researchers *with* industry affiliation, examined the relationship between Hg release in Texas and ASD and found different results. Lewandowski works for Gradient, a product defense consulting firm that has received substantial



sums from companies to write reports defending products such as cigarettes and BPA (Keim 2007). Lewandowski and colleagues (2009) concluded that Hg emissions are not "consistently" associated with ASD prevalence in Texas school districts.

Another example of such conflict of interest in research is found in studies conducted on the safety of RhoD immune globulin (RhoGAM). Different formulations of Thimerosal (49.55% Hg by weight)-containing RhoGAM were routinely administered to Rh-negative mothers in the US prior to 2002. Studies conducted by researchers *without* industry affiliations found significant increases in maternal Rh-negativity among children with neurodevelopmental disorders (NDs), including ASD (Geier and Geier 2007b; Geier et al. 2008; Holmes et al. 2003). However, Johnson & Johnson, a manufacturer of RhoGAM, approached Judith Miles at the University of Missouri with a significant grant to help defend the company from litigation (Evaluate TM 2012; Osterweil 2007; Wikipedia 2017). The industry-sponsored study by Miles and T. Nicole Takahashi (2007) commenced and concluded that exposure to ethylmercury (or Thimerosal) from RhoGAM was not associated with ASD (Miles and Takahashi 2007).

In ASD, the stakes for industry are particularly high, with millions of children affected globally (DeSoto and Hitlan 2010). As mentioned, more than one industry views this issue through the lens of their own potential culpability: the coal burning industry which expels mercury into the air and the pharmaceutical industry which uses Hg as a preservative in some vaccines. However, the issue of conflicts of interest in research that examines the relationship between Hg exposure and ASD is different from the typical toxic substances and products previously mentioned in that the public health sector, a powerful and influential global and governmental alliance, views this issue through the lens of its own potential culpability. According to internal documents, public health officials are concerned that negative information about Thimerosal (the Hg-based preservative used in some vaccines), if substantiated, might damage the vaccine program, in which the public health system has a vested interest as a result of its role in vaccine distribution and use (Association of American Physicians and Surgeons, Inc. 2005). As reported by the United States Congressional Report of 2003 in regard to the issue of Thimerosal and ASD, "Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry." (Burton 2003).

Additionally, one public health entity, the US Centers for Disease Control and Prevention (CDC), receives millions of dollars in industry gifts and funding, including substantial support from the pharmaceutical industry (Lenzer 2015; Smith et al. 2012). According to Jeanne Lenzer (2015), numerous manufacturers give donations to the CDC through the CDC Foundation. For example, in 2012–2013 Janssen donated \$1.5 million, and in 2011–2012 contributors included Merck (\$915,149), Genzyme (\$762,000), Sanofi-Aventis (\$600,000), and Abbott Laboratories (\$550,000) (Lenzer 2015; Smith et al. 2012). This significant financial relationship further amplifies the potential for conflict of interest on the part of the CDC.



The issue of conflict of interest in ASD can be illustrated by an examination of the published scientific literature. A systematic literature search of original studies from 1999 to August 2015 using the search terms "autism and mercury" reveals evidence of this bias. The results of this search are listed and briefly described in Tables 1 and 2. Table 1 shows the studies on Thimerosal (or mercury) and ASD which were sponsored or co-sponsored by those *with* public health, pharmaceutical industry, or coal-burning affiliation, that is, studies with an apparent conflict of interest. Table 2 shows the studies on Thimerosal (or mercury) and ASD that were conducted by independent researchers *without* public health or industry affiliation.

Similar to historical debates about other toxicants, the findings reveal, that research done with an apparent conflict of interest shows a bias toward the null hypothesis or "no effect" (i.e., no relationship between Hg and ASD). Specifically, of the studies *with* public health or industry affiliation, 86% (12/14) failed to reject the null hypothesis (Table 1), concluding that there was "no effect". However, of the studies *without* public health or industry affiliation, only 21% (13/62) failed to reject the null hypothesis. In other words, about 80% of the studies *without* public health or industry affiliation found evidence of a relationship between Hg exposure and ASD (Table 2). The dramatic discrepancy in these results, 86 versus 21%, provides evidence of biased outcomes, indicative of a conflict of interest.

The Need for Transparency in Autism Research

As mentioned earlier, the stakes in the ASD debate are high. In the past two decades, there has been a dramatic increase in ASD rates. For example, in a study which examined the prevalence and characteristics of developmental disabilities over a 15–20 year time period, with specific focus on concurrent changes in ASD and intellectual disability prevalence (using data from a population-based developmental disabilities surveillance program for 8-year-olds in metropolitan Atlanta), scientists found a 269% increase from 4.2 per 1000 in 1996 to 15.5 per 1000 in 2010 (Van Naarden Braun et al. 2015). ASD is considered to have reached epidemic proportions and is an issue of high national and international concern. The critical importance of this debate only heightens the urgent need for transparency in autism research.

Transparency in autism research, including access to research datasets used, would provide for the review and evaluation of studies and the partiality or impartiality which characterized them, and encourage a system of checks and balances. When study findings are deemed inaccurate and/or biased, transparency in autism research would allow for either confirmation or correction. For instance, in 2004, Patrick Ip and colleagues published a study comparing Hg levels in the blood and hair of both children with ASD and controls, reporting that there was no difference in mean Hg levels (Ip et al. 2004). However, other scientists noted that there did appear to be a significant difference in the mean Hg levels between the groups and subsequently requested the data. Upon re-analysis, the data revealed that there was indeed a significant difference in the mean mercury levels between children with ASD and controls (DeSoto and Hitlan 2007). The authors of the re-



Table 1 Studies that examined the relationship between Thimerosal (or Hg) and autism that were sponsored or co-sponsored by public health and/or had industry affiliation; 12/14 = 86% failed to reject the null hypothesis (86% found no relationship between Hg and ASD)

Study	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Verstraeten et al. (2003) Pediatrics	Assessed the possible toxicity of TCVs among infants	Reported analyses found no significant increased risks for autism	Yes Public health	No
Madsen et al. (2003) Pediatrics	TCVs in Denmark and incidence of autism	Data do not support a correlation between TCVs and autism	Yes Public health and industry ^a	No
Stehr-Green et al. (2003) Am J Pre Med	TCVs and autism	No correlation between TCVs and autism	Yes Public health and industry ^a	No
Hviid et al. (2003) JAMA	To determine whether vaccination with a TCV is associated with autism	Results do not support a causal relationship between TCVs and ASD	Yes Public health and industry ^a	No
Andrews et al. (2004) Pediatrics	Relationship between the amount of TM an infant receives via DTP or DT vaccine and NDs (autism)	No evidence of an association with TM exposure	Yes Public health	No
Price et al. (2010) Pediatrics	TCVs and autism	No findings of increased risk for any of the 3 ASD outcomes	Yes Public health	No
Yau et al. (2014) Environ Res	Prenatal and early-life exposures to Hg	Total Hg in serum collected from mothers during mid- pregnancy and newborn bloodspots were not significantly associated with ASD	Yes Public health	No
Windham et al. (2006) Environ Health Perspect	ASD and environmental exposures, ambient air, San Francisco Bay	Increased risk of ASD associations included Hg, cadmium, nickel, trichloroethylene, and vinyl chloride	Yes Public health	Yes
Schechter and Grether (2008) Arch Gen Psychiatry	Autism prevalence in California after removal of TM from most childhood vaccines	Data do not support the hypothesis that exposure to TCVs during childhood is a primary cause of autism	Yes Public health	No
De Palma et al. (2012) J Aut Dev Disord	Hair toxic metals in autism versus controls	Found no association between autism and hair Hg	Yes Public health	No



Table 1 continued

Study	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Wright et al. (2012) PloS One	Urinary Hg levels between children with ASD and controls—normal $(n = 121)$ and with learning disabilities $(n = 34)$	No statistically significant differences were found between children with ASD and controls	Yes Public health	No
Dickerson et al. (2015) Sci Total Environ	ASD prevalence and proximity to industrial facilities releasing arsenic, lead or Hg	Association between urban residential proximity to industrial facilities emitting air pollutants and higher ASD prevalence	Yes Public health	Yes
Miles and Takahashi (2007) Am J Med Genet A	Association between Rh status, RhoGAM use in pregnancy and autism	No association was found between maternal RhoGAM use and autism	Yes Industry ^b	No
Lewandowski et al. (2009) J Toxicol Environ Health A	Hg exposure from coal-fired power plants and autism in Texas	Analysis suggests Hg emissions not consistently associated with autism prevalence in Texas school districts	Yes Industry ^{c,d}	No

ASD autism spectrum disorder, DT diphtheria and tetanus vaccine, DTP diphtheria, tetanus, and pertussis vaccine, Hg mercury, NDs neurodevelopmental disorders, RhoGAM Rho (D) Immune Globulin, TCVs Thimerosal-containing vaccines, TM Thimerosal

analysis stated: "If there is any link between autism and mercury, it is absolutely crucial that the first reports of the question are not falsely stating that no link occurs." (DeSoto and Hitlan 2007, p. 1308).

As another instance, Polly R. Sager, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Disease (NIAID), US National Institutes of Health (NIH), made a presentation entitled, "NIAID Studies on Thimerosal" to the Institute of Medicine (IOM) of the U.S. National Academy of Sciences on February 9, 2004 (Institute of Medicine, Sager 2004). In her presentation, she presented crucial evidence on the comparative distribution and persistence of Hg in brain and blood following methyl-Hg and Thimerosal administration to infant monkeys mimicking the US childhood vaccine schedule of the 1990s by other investigators (Burbacher et al. 2005). It was later discovered,



^aStatens Serum Institut (Danish vaccine manufacturer; functions under the auspices of the Danish Ministry of Health)

^bRhoGAM was manufactured by Ortho-Clinical Diagnostics, Inc. which was owned by Johnson and Johnson

^cGradient, a product defense consulting firm that has received substantial sums from companies to write reports defending products such as cigarettes and BPA (Keim 2007)

^dElectric Power Research Institute

Table 2 Studies that examined the relationship between Thimerosal (or Hg) that were conducted by independent researchers *without* public health or industry affiliation; 13/62 = 21% failed to reject the null hypothesis (i.e., 21% found no relationship between Hg and ASD). One or more co-authors of the present study are co-authors of 20 of the studies included in the Table. Those studies are indicated by an asterisk

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Rose et al. (2015) J Toxicol	Human LCL in autism versus controls exposed to TM	Autism LCLs exhibited greater reduction in ATP- linked respiration, maximal respiratory capacity, and reserve capacity, compared to control LCLs	No	Yes
Geier et al. (2015)* Biol Trace Elem Res	Risk of a PDD following TM exposure from Hib	Cases of autism/PDD were significantly more likely to have had TM exposure from Hib	No	Yes
Geier et al. (2014b)* J Biochem Pharmacol Res	Risk of a ND following TM exposure from DTaP	Cases of autism were significantly more likely to have had TM exposure from DTaP	No	Yes
Geier et al. (2014a)* Int J Environ Res Public Health	Dose-dependent relationship between TM exposure and NDs	Cases of autism/PDD more likely than controls, per microgram of TM exposure	No	Yes
Alabdali et al. (2014) Behav Brain Func	Concentration of two toxic heavy metals, lead and Hg were measured in red blood cells, plus glutathione-s- transferase (GST) and vitamin E	ASD had significantly higher lead and Hg levels and lower GST activity and vitamin E concentrations compared with the controls. The levels of heavy metals (Hg and lead), GST and vitamin E were correlated with the severity of the social and cognitive impairment measures	No	Yes
Macedoni- Lukšič et al. (2015)* Biol Trace Elem Res	Levels of metals in blood (aluminum, lead, Hg) in ASD compared to children with neurological disorders	No significant difference in blood levels of metals between the groups was found	No	No
Geier et al. (2013)* Transl Neurodegener	Thimerosal-containing vaccine administration as a risk factor for ASD in VAERS and VSD	Cases of autism were significantly more likely to have had TM exposure from HepB	No	Yes



Table 2 continued

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Sharpe et al. (2013) J Toxicol	Human B lymphocytes in autism versus controls	Autism families showed TM hypersensitivity; none of control individuals displayed this response; the TM concentration required to inhibit cell proliferation in these individuals was only 40% of controls	No	Yes
Albizzati et al. (2012) Minerva Pediatr	Metals in blood, urine and hair samples from children with autism and children with neuropsychiatric disorders, unspecified	No difference was found between children with autism and children with neuropsychiatric disorders, unspecified	No	No
Abdullah et al. (2012) J Aut Dev Disord	Heavy metals in children's tooth enamel	No significant differences in levels of these neurotoxicants for children with ASDs compared with TD children	No	No
Geier et al. (2012)* Int J Environ Res Public Health	Hair toxic metal concentrations and ASD severity	Increasing hair Hg concentrations significantly correlated with increased ASD severity	No	Yes
Rahbar et al. (2013) Neurotox Res	Investigate the association between blood Hg concentrations in children and ASDs	Found no association between blood Hg concentrations in children and ASDs	No	No
Adams et al. (2013) Biol Trace Elem Res	Investigated both the level of toxic metals in children with autism and the possible association of those toxic metals with autism severity in whole blood, RBCs, and urine	Found a strong association of levels of toxic metals with variation in the degree of severity of autism for all the severity scales. Cadmium (whole blood) and Hg (whole blood and RBC) were the most consistently significant variables	No	Yes
van Wijngaarden et al. (2013) Epidemiology	Evaluated the association between prenatal methylHg exposure and ASD phenotype	Prenatal exposure to methylHg was not associated with ASD phenotypic behaviors	No	No
Yasuda and Tsutsui (2013) Int J Environ Res Public Health.	Hair concentrations of 26 trace elements in children with autistic disorders	Individuals had high burden of aluminum, cadmium and lead, and 2.8% or less from Hg and arsenic burden	No	Yes



Table 2 continued

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Blaucok-Busch et al. (2012) Maedica (Buchar)	Examined whether DMSA treatment reduced heavy metal burden and symptoms in ASD	Levels of cadmium, Hg, and lead were reduced and ASD symptoms showed improvements	No	Yes
Blaurock-Busch et al. (2012) Maedica (Buchar)	Assessed the levels of ten toxic metals and essential elements in hair samples of children with autism, and correlated the level of these elements with the severity of autism	Elevated hair concentrations were noted for aluminum, arsenic, cadmium, Hg, antimony, nickel, lead, and vanadium in autism versus controls	No	Yes
Hodgson et al. (2014)* Exp Biol Med (Maywood)	Investigated redox and methylation metabolites, level of protein homocysteinylation and hair Hg levels in autism and controls	Hg levels were markedly elevated in the hair of autistic subjects versus control subjects; glutathione in autistic subjects was significantly below control levels, while levels of homocysteine and S-adenosylhomocysteine were elevated	No	Yes
Stamova et al. (2011) Neurotox Res	Correlations between gene expression and Hg levels in blood of boys with and without autism	Findings suggest different genetic transcriptional programs associated with Hg in autism compared to controls	No	Yes
Blaurock-Busch et al. (2011) Maedica (Buchar)	Exposure to Hg and other heavy metals in children with autism spectrum disorder versus controls	Statistically significant differences in the mean urine levels of aluminum, barium, cerium, Hg, and lead	No	Yes
Obrenovich et al. (2011) Biol Trace Elem Res	Hair toxic metals in autism versus controls	Abnormal markers of thiol metabolism, as well as a significant alteration in deposition of several heavy metal species, particularly arsenic, Hg, copper, and iron in hair samples between the groups	No	Yes
Shandley and Austin (2011) J Toxicol Environ Health A	To test the hypothesis that individuals with a known hypersensitivity to Hg (pink disease survivors) may be more likely to have descendants with an ASD	Prevalence rate of ASD among the grandchildren of pink disease survivors (1 in 22) to be significantly higher than the comparable general population prevalence rate (1 in 160)	No	Yes



Table 2 continued

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Lakshmi Priya and Geetha (2011) Biol Trace Elem	Lead and Hg in hair and nails autism versus controls	Significant elevation in the levels of toxic metals lead and Hg in both hair and nail samples in autism	No	Yes
Res		versus controls		
Geier et al. (2010)*	Blood Hg levels in autism and controls	Hg levels were 1.9-fold significantly increased among subjects diagnosed	No	Yes
Acta Neurobiol Exp (Warsaw)		with an ASD (21.4 µg/L) in comparison to controls (11.4 µg/L)		
Hertz-Picciotto et al. (2010)	Blood Hg levels in autism versus controls	After accounting for dietary and other differences in Hg	No	No
Environ Health Perspect		exposures, total Hg in blood not statistically different		
Majewska et al. (2010)	Levels of hair Hg in autism versus controls	Autistic children significantly differed from healthy peers in the concentrations of Hg in hair	No	Yes
Acta Neurobiol Exp				
Gallagher and Goodman (2010)	Association between TM- containing HepB vaccination of male	Threefold greater odds for autism diagnosis	No	Yes
J Toxicol Environ Health A	neonates and autism			
James et al. (2009)	Effects of TM on, and GSH levels of, LCLs derived	TM resulted in greater decrease in GSH/GSSG ratio and increase in free radical generation in autism versus control cells	No	Yes
FASEB J	from autistic children and controls,			
Palmer et al. (2009)	Power plant emissions and autism	For every 1000 lb of industrial release, there	No	Yes
Health Place		was a corresponding 2.6% increase in autism rates and a 3.7% increase associated with power plant emissions		
Geier et al. (2009)*	Maternal dental amalgams and autism severity	Subjects with ≥ 6 amalgams were 3.2-fold significantly	No	Yes
Acta Neurobiol Exp	·	more likely to be diagnosed with autism (severe) in comparison to ASD (mild) than subjects with ≤ 5 amalgams		
Young et al. (2008)*	Ecological study of TM containing vaccines and risk of NDs	Increased risk of an ASD diagnosis with TCVs	No	Yes
J Neurol Sci	risk of NDs			



Table 2 continued

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Geier et al. (2008)*	Maternal Rh-negativity/TM-containing RhoGAM	Increase in ASD with maternal Rh-negativity	No	Yes
Neuro Endocrin Lett				
Geier and Geier (2007b)*	Maternal Rh-negativity/TM-containing RhoGAM	Increase in ASD with maternal Rh-negativity	No	Yes
J Matern Fetal Neonatal Med				
Geier and Geier (2007a)*	Regressive autism and TM exposure	Significant dose–response relationship between the	No	Yes
J Toxicol Environ Health A	•	severity of the regressive ASDs and total Hg dose children received from TCVs/RhoGAM		
Zhang and Wong (2007) Environ Int	Examined Hg exposure increases in China	Evidence suggests an increase in autism related to increasing Hg exposure	No	Yes
Adams et al. (2007)	Level of Hg, lead, and zinc in baby teeth in autism versus controls	Children with autism had significantly (2.1-fold) higher levels of Hg	No	Yes
J Toxicol Environ Health A				
Soden et al. (2007)	24-h provoked urine excretion test for heavy	Excess chelatable body burden of arsenic, cadmium, lead, or Hg is zero	No	No
Clin Toxicol (Phila)	metals in children with autism			
DeSoto and Hitlan (2007)	Re-analysis of Ip et al. (2004) study data	Significant relation does exist between the blood levels of Hg and ASD; in the autistic group, severity of autism was inversely related to hair Hg levels	No	Yes
J Child Neurol	(mentioned below)			
Walker et al. (2006)	Heat shock protein transcripts and MT	No apparent differences between autistic and non-	No	No
Neurotoxicology	exposed to TM in autism versus controls	autistic sibling responses in this very small sampling group		
Singh and Hanson (2006)	Metallothionein (MT) and anti-MT in autism and	MT and anti-MT were no different suggesting no TM	No	No
Pediatr Allergy Immunol	controls exposed to TCVs	induced MT-autoimmunity in autism		
Palmer et al. (2006)	Hg release, special education rates, and autism disorder	Association between environmentally released	No	Yes
Health Place		Hg and special education rates were fully mediated by increased autism rates.		



Table 2 continued

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Al-Ayadhi (2005) Neurosciences	Hair metals in autism versus controls	Higher levels of toxic heavy metals Hg, lead, arsenic, antimony and cadmium in	No	Yes
(Riyadh)		autistic spectrum disorders as compared to the controls		
Geier and Geier (2006)*	Dose (50 vs. 25 micrograms) of Hg from TM in VAERS	Increased odds ratios for autism with higher doses of	No	Yes
J Toxicol Environ Health A		TM		
Fido and Al- Saad (2005)	Toxic metals in the hair of children with autism differ	Children with autism had significantly $(p < 0.001)$	No	Yes
Autism	from age- and sex-matched healthy controls	higher in-hair concentration levels of lead, Hg and uranium		
Geier and Geier (2005)*	Association between TCVs DTaP comparison to TM-	Exposure to Hg from TCVs administered in the US was a consistent significant risk factor for autism	No	Yes
Med Sci Monit	free DTaP and autism in VAERS and VSD			
Geier and Geier (2003a)*	Dose of TCVs and autism in VAERS and USDE data	Dose–response curves showed increases in odds	No	Yes
Pediatr Rehabil		ratios of NDs (autism) from both VAERS and USDE closely and linearly correlated with increasing doses of TM-containing childhood vaccines		
Geier and Geier (2003b)*	TM-DTaP and NDs in VAERS	An association was found between TM-DTaP and autism	No	Yes
Exp Biol Med Vojdani et al.	Measured immunoglobulin	TM binds to lymphocyte receptors and/or tissue enzymes, resulting in autoimmune reaction in children with autism	No	Yes
(2003) Int J Immunopathol Pharmacol	(IgG, IgM and IgA) antibodies against CD26, CD69, streptokinase, gliadin and casein peptides and against ethyl Hg bound to human serum albumin in autism			
Ip et al. (2004) J Child Neurol	Hair and blood Hg levels and autism	No difference in the mean Hg levels	No	No
Singh and Rivas (2004) J Biomed Sci	A study of Hg-induced antinuclear and antilaminin antibodies in autistic and normal children who had been pre-administered with TCVs	Serum level of these two autoimmune markers did not significantly differ between autistic and normal children	No	No



Table 2 continued

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Geier and Geier (2004)* Med Sci Monitor	Hg doses from TCVs on population prevalence of autism	Evidence showing a direct relationship between increasing doses of Hg from TCVs and autism	No	Yes
Blanchard et al. (2011) Rev Environ Health	Occurrence of autism as related to distribution of Hg in ambient air	Risk of autism is greater in the geographic areas of higher levels of ambient Hg	No	Yes
Mrozek-Budzyn et al. (2011) Przegl Epidemiol	Association of TCVs exposure with the risk of autism	No evidence of an association between TCVs and autism	No	No
Holmes et al. (2003)* Int J Toxicol	Relationship between autism and hair Hg levels	Hg levels statistically different from controls and correlated with symptom severity. Mothers in the autistic group had significantly higher levels of Hg exposure through RhoGAM and amalgam fillings	No	Yes
Mostafa and Al- Ayadhi (2015) J Clin Cell Immunol	Blood Hg levels and seropositivity of anti-MBP autoantibodies in autistic children	Serum levels of blood Hg were significantly higher in autistic children than healthy controls; increased levels of blood Hg were found in 48% of autistic patients, and 72% of autistic children had anti-MBP auto-antibodies. There was a significant positive association between the elevated levels of blood Hg and anti-MBP auto-antibodies in autistic children	No	Yes
Yassa (2014) Environ Toxicol Pharmacol	Blood and hair samples from 45 children from Upper Egypt with autism, 2–10 years of age and 45 controls in the same age range	High level of Hg and lead among those children with autism, with significant decline in the blood level of lead and Hg with the use of DMSA as a chelating agent	No	Yes
Khan et al. (2014) J Physiol Pharmacol	Brain Hg levels measured in extracortical regions autism versus controls	Brain Hg levels measured in extracortical regions in children with autism versus controls were not different	No	No



Table 2 continued

Study Journal	Evaluated	Conclusion	Affiliation with public health or industry	Found effect
Roberts et al. (2013) Environ Health Perspect	Associations between U.S. EPA -modeled levels of hazardous air pollutants at time and place of birth and ASD	Overall measure of metals were significantly associated with ASD, with odds ratios ranging from 1.5 (for overall metals measured) to 2.0 (for diesel and Hg)	No	Yes
Mostafa and Refai (2007) Egypt J Pediatr Allergy Immunol	Serum antineuronal antibodies and blood Hg levels were estimated between autism and controls	Higher seropositivity for antineuronal antibodies and higher blood Hg in autism versus controls. Seropositivity of antineuronal antibodies had positive association with elevated blood Hg (found in 70% of autistic children). Both markers positively associated with behavioral abnormalities, autistic regression, EEG abnormalities	No	Yes
Biamonte et al. (2014) Neurotoxicology	Mice exposed to MeHg during the prenatal and early postnatal period, either at subtoxic dose or at toxic dose	Higher MeHg dose caused dramatic reduction of PCs in all mice and "autism- like" features (loss of sociability, preference for sameness) in genetically susceptible mice	No	Yes
Bradstreet et al. (2003)* J Am Phys Surgeons	Children with ASD and controls treated with multiple doses of DMSA	Children with ASD excreted sixfold greater Hg than controls	No	Yes
DeSoto and Hitlan (2012) J Environ Protection	Examined Hg-related fish advisories and rate of autism	Hg-related fish advisories are found to be a strong predictor of a state's autism rate, $r = 0.48$, $p < 0.001$	No	Yes

anti-MBP anti-myelin basic protein, ASD autism spectrum disorder, CD cluster of differentiation, DMSA dimercaptosuccinic acid, DTaP Diphtheria, Tetanus, acellular Pertussis, EEG electroencephalography, EPA Environmental Protection Agency, GSH glutathione, GSSG oxidized glutathione, HepB Hepatitis B vaccine, Hg mercury, Hib Haemophilus influenzae Type b vaccine, LCL lymphoblastoid cell lines, ND neurodevelopmental disorder, PDD pervasive developmental disorder, MeHg methylHg, MT metallothionein, PCs Purkinje cells, RhoGAM Rho (D) Immune Globulin, RBC red blood cells, TCVs Thimerosal-containing vaccines, TD typically developing, TM Thimerosal, USDE US Department of Education, VAERS Vaccine Adverse Events Reporting System, VSD Vaccine Safety Datalink



following Sager's presentation, that the data she presented did not convey the actual extent that Hg distributed and persisted in the monkey brain following Thimerosal administration. She was eventually forced to supply in her own words, "Corrected Slide Submitted to IOM May 3, 2004". However, even with the corrections, errors remain in the "Corrected Slide" and the information did not reflect the data ultimately published by the study investigators (Burbacher et al. 2005). As a consequence, in evaluating the relationship between Thimerosal exposure and ASD risk, the IOM was unable to consider accurate and true data as to the distribution and persistence of Hg in the monkey brain following Thimerosal administration mimicking the US childhood vaccine schedule of the 1990s.

Examples of Studies that Illustrate the Importance of Transparency in Autism Research

A number of ASD and Hg studies, sponsored by entities with an apparent conflict of interest, appear to have arrived at questionable conclusions. Moreover, the authors of these studies have, unfortunately, failed to make their datasets available to others for further evaluation, exemplifying the need for transparency in autism research.

As expressed by Patricia Baskin and Robert Gross (Baskin and Gross 2015), editors of the journal *Neurology*, on the need for greater transparency in research in general: "The responsibility for promoting greater openness in research falls not only to the individuals performing the work, but to the funders of the work (including government, foundation, and industry sponsors), institutions where the work is being done, and to journal editors and peer reviewers, who do the final check on the quality of the research before it is released to readers." The following examples illustrate this point.

Verstraeten et al. (2000, 2003)

In the late 1990s, in a study sponsored by the CDC, Thomas Verstraeten and colleagues (2000) "categorized the cumulative ethyl-Hg exposure from [T]himer-osal[-]containing vaccines after one month of life and assessed the subsequent risk of degenerative and developmental neurologic disorders and renal disorders before the age of six" (Verstraeten et al. 2000, File 10 25 of 334). The authors applied proportional hazard models adjusting for Health Management Organization, year of birth, and gender, and they excluded premature babies. The original reported results showed that the relative risk (RR) of developing a neurologic development disorder was 1.8 (95% confidence intervals [CI] 1.1–2.8) when comparing the highest exposure group at 1 month of age (cumulative dose > 25 μ g) to the unexposed group. Similarly, they "...also found an elevated risk for the following disorders: autism (RR 7.6, 95% CI = 1.8–31.5), non-organic sleep disorders (RR 5.0, 95% CI = 1.6–15.9), and speech disorders (RR 2.1, 95% CI = 1.1–4.0)" (Verstraeten et al. 2000, File 10 25 of 334) in the highest exposure group. These findings, presented to the Epidemic Intelligence Service Annual Conference, CDC in Atlanta,



GA, in 2000, remained as an abstract (Verstraeten et al. 2000) and were never published as a full paper.

Subsequently published results from this study (Verstraeten et al. 2003) diverged from the aforementioned results presented in 2000 (Bernard 2004; Put Children First 2006). The study published in 2003 concluded that "No consistent significant associations were found between TCVs [Thimerosal-containing vaccines] and neurodevelopmental outcomes." (Verstraeten et al. 2003, p. 1039). When the dataset was requested by independent researchers (including M. Geier, one of the co-authors of the present article) through Representative Dave Weldon, M.D. (15th District, Florida) of the US Congress, it was unavailable and remains so. Explaining the unavailability of this dataset, the IOM stated: "Analytic data files from some previously published VSD studies had not been archived in a standard manner, so it was difficult to respond expeditiously to requests to reanalyze published VSD [Vaccine Safety Datalink] studies." (Institute of Medicine 2005, p. 34). In response to its own recommendation to make VSD datasets available to independent researchers, the IOM further stated, "The committee recognizes that implementation of this recommendation probably can affect only future VSD studies because earlier versions of study datasets may not have been archived for current or completed studies." (Institute of Medicine 2005, p. 64).

Yau et al. (2014)

In 2013 Vincent Yau and colleagues, in conjunction with the California Department of Public Health, submitted a study to the Journal of Autism and Developmental Disorders, entitled, "Prenatal and neonatal peripheral blood Hg levels and autism spectrum disorders." The conclusion stated by the authors was that the "Results indicate that levels of total mercury in serum collected from mothers during midpregnancy and from newborn bloodspots were not significantly associated with risk of ASD." However, in Table 4 of the study, the geometric mean maternal serum Hg concentrations between the general population (0.32) and the ASD group (0.48) had a p value of 0.05. Thus, maternal serum blood Hg levels were significantly higher in the ASD group than in the general population, although the study authors failed to state this. The study was published later in the journal Environmental Research without addressing this issue. To date, the California Department of Public Health (CDPH), University of California at Davis (UC Davis), and Kaiser Permanente, as well as individual authors, have failed to release the dataset from the study for further evaluation despite receiving numerous requests for this information. The CDPH stated that they did not have the complete dataset and that they are required to make sure the data are destroyed after the studies are over (personal communication, Martin Kharrazi, CPDH, 6/25/2015). UC Davis refused to release the dataset claiming, "researcher's privilege, based upon a strong Constitutional interest in the right of scholars to conduct research without interference, an aspect to the academic freedom recognized as 'special concern of the First Amendment'." (Personal communication, Michele M. McCuen, Legal Analyst, Office of the Campus Counsel, Office of the Chancellor and Provost, University of California, 8/21/2015). Kaiser Permanente (KP) refused to release the dataset claiming, "The



Freedom of Information Act (FOIA) only applies to federal agencies. It does not apply to an institution like KP." (Personal communication, Caroline Milner, National Research Compliance Officer, National Compliance in Research Program, Kaiser Foundation Research Institute, 8/7/2015).

Uno et al. (2015)

In 2015, Yota Uno and colleagues published a study in the journal *Vaccine* investigating the relationship between the risk of ASD and early exposure to the combined Measles-Mumps-Rubella (MMR) vaccine, or exposure to Thimerosal from vaccinations in Japanese children. The authors concluded that there were no significant differences in the timing of MMR vaccination or Thimerosal dosage between children with ASD and controls for any age group. However, there was a statistical error that nullified the conclusions offered by the authors. This error was found in Table 2 at 24 months of age. From the values provided in Table 2 of the study, it was evident that the difference between cases and controls at 24 months was indeed statistically significant with a high degree of confidence. Thus, there was a statistically significant yet unacknowledged relationship between Thimerosal exposure and the risk of ASD. The journal *Vaccine* was notified of the error.

From the originally provided data, the following results were documented for Children, age 24 months: Unpaired t test mean of sample 1 from summary data = 804.2 (n = 189) mean of sample 2 from summary data = 632.1 (n = 224).

Assuming equal variances, the combined standard error = 71.8, df = 411, t = 2.40 one sided p = 0.0085 two sided p = 0.017, 95% confidence interval for difference between means = 30.88–313.32 power (for 5% significance) = 90.07%.

Assuming unequal variances, the combined standard error = 72.06, df = 394.17, t(d) = 2.39 one sided p = 0.0087 two sided p = 0.0174, 95% confidence interval for difference between means = 30.45–313.75 power (for 5% significance) = 66.35%. An unpaired t test assumes unequal variances and is a more conservative test.

When the journal *Vaccine* was made aware of the statistical error, it notified the authors. Following this notification, the authors changed the data values in their study (mean and standard deviation) for the controls in Table 2 at 24 months from 632.1 (715.1) to 676.8 (719.5). However, no explanation for the error or justification for the change was given. To date, the journal *Vaccine* and the study authors have refused requests to release the study dataset for further evaluation.

Although there was no response from any of the study authors, the journal *Vaccine* stated (in response to the notification of the error and the request for the dataset) that, "Following the feedback from your group, the authors have made a minor correction to Table 2 and an acknowledgement thereof is made in the article. We are grateful for sharing your observations with us. As appropriate action has been undertaken, we now consider this matter to be resolved." (Personal communication, Alina Helsloot, Executive Publisher Immunology and Microbiology, Elsevier and Gregory Poland, Editor in Chief, *Vaccine*, 4/9/2015).



Summary and Conclusion

Historically, entities/industries with a vested interest in a product whose safety is in dispute have consistently used research to back their claims that a product is safe. The effects of a funding source on research outcomes have been examined, and it has been shown that industry or responsible entity affiliated studies are far more likely to yield outcomes favorable to that industry/entity (Boone et al. 2014). When this conflict of interest influences research, the resulting scientific debate on products, toxicants, etc. can be confounded by misleading information. Indeed, this is precisely the outcome desired by the sponsors of such conflicted research (Brandt 2012; Bridbord and Hanson 2009; Brownell and Warner 2009).

A conflict of interest in autism research has been noted, particularly when examining Hg exposure and the risk of ASD (DeSoto and Hitlan 2010). However, conflicts of interest in this debate are different from other cases because not only industries (e.g., the coal-burning industry and the pharmaceutical industry), but also public health institutions view this issue through the lens of their own potential culpability. Further complicating the matter is the fact that public health entities often control access to the relevant datasets. Indeed, a systematic examination of the research literature in the Hg-autism debate shows that research funded by these conflicted entities is more likely to yield conclusions favorable to that industry/entity, that is, finding no relationship between Hg exposure and the risk of ASD.

Transparency in autism research is of utmost importance. The current examples of studies offering questionable conclusions clearly illustrate the need for openness and accountability. ASD is an issue of high national and international concern, where the stakes are high and researchers and policymakers need to be cognizant of the issue of conflicts of interest in autism research (DeSoto and Hitlan 2010).

One way of achieving improved openness and transparency in autism research would be for authors, journals, and funding sources to require greater openness and data sharing. As mentioned, the responsibility for promoting greater openness in research falls not just to the authors, but to the funders, institutions, and journal editors (Baskin and Gross 2015). The examples provided in this analysis suggest that some authors, journals, and institutions could improve in the area of helping to promote greater openness.

The Proceedings of the National Academy of Sciences of the United States of America (PNAS) has developed and adopted standards concerning the responsibilities of authorship in the biological sciences. It is referred to as the Uniform Principle for Sharing Integral Data and Materials Expeditiously or "UPSIDE". In October of 2001, a National Academies committee evaluated the responsibilities of authors to share data and materials referenced in their publications, the role of journals to impose requirements for data and material sharing, and whether a common set of requirements for sharing does or should exist (Cozzarelli 2001, 2004; Cech 2003). They established that authors are obligated to release data and materials to enable others to verify or replicate published findings. They stated that one "upside" to this is it keeps science honest (Cozzarelli 2001, 2004; Cech 2003). In an article by Nicholas R. Cozzarelli, Editor-in-Chief of PNAS, he



described some of the comments of the board members and these comments may be relevant to the current discussion (Cozzarelli 2001). Two of the comments are as follows:

I am one of the few people here who represents the private sector at this point, and I would love to be able to publish in prestigious journals and withhold the data. But I think it is wrong.

Scientific journals should play no role in the protection of the private interests of authors, or in shielding data from the community. Protection is far afield of the mission of journals, and shielding is antithetical to it.

Identifying causative factors for ASD is already a challenging task for the scientific community, demanding the highest standards of openness and transparency. Any departure from these standards represents a disservice to all.

Acknowledgements This study was supported by the non-profit 501(c)(3) Institute of Chronic Illnesses, Inc., and the non-profit 501(c)(3) CoMeD, Inc.

Compliance with Ethical Standards

Conflict of interest Janet Kern is a board member of the Council for Nutritional and Environmental Medicine (CONEM) and Geir Bjørklund is that organization's founder and president. Mark Geier and David Geier do work under the auspices of the non-profit Institute for Chronic Illnesses, Inc. Lisa Sykes, Mark Geier and David Geier are officers of the Coalition for Mercury-free Drugs (COMeD, Inc). Richard Deth is on the scientific advisory board of the National Autism Association. Brian Hooker is on the board of Focus for Health. James Love has been involved in amalgam litigation. Boyd Haley is involved in the development of a mercury-chelating agent. Some of the authors have a personal as well as a professional interest in autism. In addition, some authors have been involved in litigation related to vaccines and autism.

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