This paper explores the regulatory context for, and societal controversy surrounding the use of the mercury-containing preservative Thimerosal in vaccines. Specifically, this paper reviews the regulatory framework for vaccine safety, including the history and basis for use of Thimerosal as an antibacterial in multi-dose immunizations, and explores the on-going cultural debate regarding the purported (and refuted) link between Thimerosal exposure and the onset of neurodevelopmental disorders, including autism. Because the topics – linked or not – of Thimerosal toxicity and vaccine safety represent both a medical research concern and a public health controversy, the debate is a topical and relevant lens through which to view the intersection of individual rights and issues concerning the limit of government (Federal or state) mandate. Moreover, this particular intersection – between what the scientific and medical establishment considers to be accurate and what segments of the public believe to be true - highlights the suspicion that exists within some portions of the U.S. population concerning both what public health practices like immunization campaigns are for and what science itself does.

Regarding immunizations and their ingredients, it is the U.S. Food and Drug Administration (FDA) that oversees safe vaccine manufacture. Within the FDA, the Center for Biologics Evaluation and Research (CBER) specifically regulates vaccine products under

the Public Health Services Act (PHS Act).[1] In parallel with manufacturing safety, information regarding vaccination and immunization schedules is generated by the Center for Disease Control and Prevention (CDC), an Agency within the Federal Department of Health and Human Services (DHHS). Within the CDC, and as delineated in the PHS Act, the Advisory Committee on Immunization Practices (ACIP) develops recommendations for the public administering of vaccines.[2] The CDC does not set a national immunization requirement, however, as this role is undertaken by the states. That is, on the national level, it is the medical and public health professionals comprising ACIP that certify immunization schedules, and it is state Departments of Health that craft the requirements for how those schedules are implemented. Each state is therefore responsible, for example, for setting immunization requirements for entering public childcare and/or the public school system. Thus, while immunizations are voluntary in the sense that an individual is not required by Federal law to receive them, they are compulsory for participation in various aspects of public life in a way that makes exposure to vaccine ingredients unavoidable for the majority of U.S. citizens.

With the regulatory framework as context, the question regarding the safety of Thimerosal (or Thiomersal) as a vaccine additive has focused on the question of how to define a safe infant and early childhood exposure dosage for this compound. Chemically, Thimerosal is classified as an organo-mercurial and is comprised of a benzene ring and a straight-chain carbon compound (i.e., the "organo-" parts) joined together in the middle by a

[1]Within the PHS Act, legislation in support of improving safety of the childhood immunization schedule is found in Subchapter XIX, Part 2 Subpart C (Assuring a Safer Childhood Vaccination Program in the United States) https://www.fda.gov/regulatoryinformation/legislation/ucm148717.htm
[2]https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-combined-schedule-bw.pdf

mercury atom. In the human body, Thimerosal is broken down into two separate molecules, only one of which – ethylmercury – contains mercury. Thimerosal has been used as an antibacterial preservative for multi-dose vaccines since the FDA approved its use in the 1930s (Hurley et al., 2010).

Overall, routes of toxic exposure for mercury compounds include inhalation, ingestion and transdermal penetration (Magos and Clarkson, 2006). As noted by these researchers, however, the range of symptoms characteristic of mercury-induced toxicity is broad, and diagnosis of mercury poisoning is often delayed in the absence of known industrial exposures. What is known about the toxicity of Thimerosal specifically is derived from either animal studies or studies focused on short term/acute exposure scenarios (e.g., Rohyans et al. 1994). In terms of target systems or organs, Thimerosal, as noted above, is broken down in the body to create the secondary compound ethylmercury which, in humans, principally affects the central nervous system and kidneys. Ethylmercury is also able to pass through the blood-brain barrier as well as the placental barrier, indicating that exposure poses toxicity concerns in utero. As summarized by Clarkson and Magos (2006), within the central nervous system, ethylmercury is converted to inorganic mercury (i.e., it is "de-ethylated") with a half-life ~ 14 days (i.e., within 14 days, half of the initial exposure concentration has been de-ethylated) and a resultant diminishment in neurotoxicity. The half-life of inorganic mercury in the central nervous system is ~ 120 days (Clarkson and Magos, 2006). In the blood, the elimination of ethylmercury, principally by de-ethylation to inorganic mercury, occurs with a half-life of ~18 days, and results in the excretion of inorganic mercury in feces (Clarkson and Magos, 2006).

As these differences in elimination rates suggest, not all forms of mercury are retained in the body in the same way. Relatedly, and as relevant for this examination of Thimerosal, studies conducted through accidental or industrial exposures in humans have also demonstrated that ethylmercury behaves differently in the body than the other more widely studied organo-mercurial, methylmercury (Magos and Clarkson, 2006). The distinction between ethylmercury and methylmercury is significant because toxicity guidelines for ethylmercury (and therefore Thimerosal) exposure in vaccines are based on studies assessing safe exposure concentrations for methylmercury (USEPA, 2001).[3] For these two organo-mercurial compounds, although it appears that they are roughly similar in how they initially partition in the body (into blood) and how they are eliminated (in feces), they differ significantly in how they are stored in tissue and metabolized. Magos and Clarkson (2006) observe, for example, that methylmercury partitions more readily to the brain/central nervous system than ethylmercury and that its half-life for elimination from the body (and specifically the brain) is slower (i.e., ~ 50 days versus ~14 days). In the context of toxicity, the more slowly a compound is eliminated, the greater the potential for multiple exposures to result in cumulative toxicological effects.

This point regarding cumulative toxicity is important in the context of childhood vaccine safety because, prior to 1999 (discussed further below), a child receiving multiple vaccines, such as is suggested by ACIP, would receive multiple doses of Thimerosal

[3]US EPA guidelines specify a maximum *daily* methylmercury exposure or reference dose (RfD) of 0.1µg/kg body weight (USEPA, 2001).

preservative on a schedule that could allow for accumulative exposure. Andrews et al. (2004) note, as example, that prior to the removal of Thimerosal from most infant vaccines, an infant receiving the suggested vaccine complement on the recommended schedule could receive up to 187.5 µg of mercury during the first 6 months of life. Roughly estimated, if it was assumed that vaccines were received monthly for an infant weighing ~10 kg, and considering a blood elimination half-life of ~15 days, it was possible for an infant to exceed the US EPA daily threshold reference dose (RfD) *for methylmercury* of 0.1µg/kg body weight (USEPA, 2001) under the immunization schedule recommended prior to 1999. It is important to note here, however, that because toxicity guidelines for ethylmercury (and therefore Thimerosal) were based on the safe exposure guidelines for the more slowly excreted (and therefore more likely accumulative) methylmercury, the ACIP recommendations for immunization scheduling to protect against over-exposure to ethylmercury (and therefore Thimerosal) were already considered as (and remain) highly protective of human health.

While this use of the more widely studied organo-mercurial methylmercury as a practical basis or proxy for determining a safe ethylmercury exposure criterion is both scientific valid and toxicological reasonable, this approach is not without problems. Specifically, in the case of methylmercury, the chain connecting a history of an industrial accident and evidence of the range of neurodevelopmental effects that can result from exposure to significantly elevated concentrations of methylmercury has only a few links. In this case: in the early/mid 20th century, a chemical plant in Minamata Bay, Japan using mercuric sulfate as a catalyst in the manufacture of acetylaldehyde, was unaware that the

process created methylmercury as a byproduct. Over an unknown interval of time, discharge from the plant was directly contaminating Minamata Bay with industrial-level concentrations of methylmercury (Hightower, 2009). Symptoms of acute methylmercury poisoning started first in the cats. Likely having eaten the fish washed up on the shoreline or fed to them by fisherman, they began behaving strangely with tremors and a muscle weakness that made them appear to dance. When unusual symptoms started appearing in children, those symptoms initially included numbness, difficulty in walking and difficulty with fine motor skills (McAlpine, 1958; Hightower, 2009). Progressive symptoms included effects on speech, hearing, swallowing and vision. Convulsions occurred in some. Patients slipped into comas and died. By the time the full range of neurological and neurodevelopmental effects had been catalogued – both for those living and those who had been exposed in utero – over 2,000 people had been poisoned, an unknown number of them having died specifically from methylmercury toxicity (Hightower, 2009). Litigation against the manufacturer and compensatory claims against the Japanese government continue to this day. While little data are readily available on the concentrations of methylmercury that residents of Minamata Bay were exposed to during that interval, what is known is that, at highest measured concentrations, concentrations of methylmercury in fish from Minamata Bay exceeded 35 μg/g (or mg/kg; or parts per million [ppm])[4] and concentrations in sediment adjacent to the facility discharge reached ~0.2% (as reported in Harada, 1995).

[4]For context, US EPA guidelines specify a maximum methylmercury fish tissue concentration of 0.3 mg/kg fish tissue for safe consumption (USEPA, 2009); At the highest measured concentrations of methylmercury in Minamata Bay, fish tissue exceeded this safe consumption concentration by more than 2 orders of magnitude, suggesting that there was no healthy rate or portion size at which fish from the Bay could have been safely consumed.

That this accident represented exposure to methylmercury at concentrations and on a scale entirely unlike exposures resulting from the more typical consumption of seafood, and that the resultant neurological and neurodevelopmental effects went significantly beyond and were specifically unlike symptoms diagnosed now as Autistic Spectrum Disorder (ASD), is a distinction that is unreasonable to expect the public to have made. From the public's vantage, and in the absence of explanatory data, it is certainly reasonable (although incorrect) to link exposure to mercury (at any concentration and in any form) with neurodevelopmental delays (a broad category of diagnoses that includes, but is not limited to, autism), and it is this link, in conjunction with the questionable data that would later be presented in support of it, that ultimately elevated a routine FDA toxicological re-evaluation into the popular spotlight.

In 1997, the FDA, under the mandate of the Modernization Act[5] and with the desire to advance and refine the goal of vaccine safety, recommended that the American Academy of Pediatrics and the US Public Health Service re-evaluate the human health risk assessment on which immunization schedules had been determined. The goal of the re-evaluation was to affirm that infants were indeed receiving a low and safe cumulative exposure to ethylmercury. In 2001, following completion of this evaluation, Thimerosal was removed from the majority of US immunizations (Ball et al., 2001), currently only remaining in some multi-dose DTaP (diphtheria, tetanus, and pertussis) and influenza vaccines.[6] Of interest here is the observation that although the FDA recommended the removal of Thimerosal from the majority of early childhood vaccines, there was little direct evidence at that time of

[5]https://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDAMA/default.htm

[6]https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228#t1

mercury-related Thimerosal toxicity beyond studies noting the potential for hypersensitivity reactions following vaccination (e.g., Osawa et al., 1991; Grabenstein, 1996). Important also from the context of the controversy that was to erupt several years later, removal of Thimerosal from vaccines occurred *prior* to any public concern regarding the use of this ingredient as a preservative, and, in fact, studies of hypersensitivity reactions tended to focus on the non-mercury containing breakdown product of the preservative (thiosalicylate) as the likely culprit (Osawa et al., 1991; Goncalo et al., 1996).

Because the topic of Thimerosal toxicity and vaccine safety is both a medical/scientific issue and a direct public health concern, however, how one reads the FDA recommendation regarding its removal is significantly influenced by one's professional training and personal beliefs; where a scientist may see re-evaluation of available (and necessarily imperfect) toxicity data with an eye toward increasing factors of safety, an individual without the relevant training or belief in hypothesis testing might project explanations for the re-evaluation that include deceit, fraud, or conspiracy. This particular divide – between what the scientific and medical establishment considers to be accurate and what portions of the public choose to believe, highlights the suspicion within some portion of the U.S. public regarding both what public health practices like immunization campaigns are for and what science itself does. Examples of this suspicion, including postings on the websites The Awareness Revolution,[7] Health Impacts News,[8] and Trace Amounts,[9] all espouse variations of the incorrect view that there was more to the FDA decision to remove

[7] http://theawarenessrevolution.com/thimerosal/
[8] (https://healthimpactnews.com/2013/new-published-study-verifies-andrew-wakefields-research-on-autism-again/)
[9] http://traceamounts.com/ten-lies-told-about-mercury-in-vaccines/

Thimerosal from vaccines than the timely decision to review and update immunization schedule decisions that were (and are) based on underlying human health exposure data. Controversial claims made in web forums for the justification behind the FDA vaccine decision run the conspiracy gamut and include attempts to cover up the accidental or purposeful mishandling of data, the use and/or misuse of statistics to obscure examples of vaccine toxicity, collusion between Federal agencies and pharmaceutical companies for personal financial gain, and the silencing of independent physicians and researchers who challenge accepted Agency views.[7,8,9]

In considering the history of this particular public health concern, the specific event that arguably sparked the controversy was the 1998 publication of article in the British medical journal Lancet entitled *Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children* (Wakefield et al., 1998). In this study, 12 children, many of whom, it later became apparent, were already suffering from observable developmental delays, had been given the MMR vaccine and had presented to their physician with symptoms including language regression and gastrointestinal distress. As described in the paper, while the authors' observations were not consistent with causality – that is, there was no explicit claim in the paper that the MMR vaccine caused those symptoms – they did present an association that suggested a coincidence in timing between administration of the vaccine and onset of symptoms potentially ascribable to "environmental triggers." While thousands of papers are published every year, this one hit a particular public nerve, and while there are many details regarding this study that are important, two things happened in the aftermath of this publication that were so disjointed that it is fair to say that if you agree with

one of them, you can't support the other: 10 of the 13 authors on the original paper signed a formal retraction of their names as well as the paper's conclusions, and (the then still) Dr. Wakefield began to inch his public discussion of the paper's conclusions away from coincidence and towards causality: that some aspect of the MMR vaccine – more specific than a general "environmental trigger" – was *causing* autism.

In 2003 – 2004, a father-son research team, one of whom at the time was a practicing physician (and has since been stripped of his medical license for grievous ethical violations in regards to an invented/proscribed treatment for autism in children[10]) published a series of papers that were the first to attempt to specifically identify the "trigger" by linking autism with exposure to Thimerosal. In a 2003 paper in Experimental Biology and Medicine entitled *Neurodevelopmental Disorders after Thimerosal-Containing Vaccines*, Geier and Geier (2003a) wrote:

> *The hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders is not established and rests on indirect and incomplete information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given in children. The hypothesis is biologically possible, but the possible relationship between thimerosal from vaccines and neurodevelopmental disorders of autism, attention deficit/hyperactivity disorder (ADHD), and speech or language delay remains seriously suspect.*

Their research focused on the DTaP vaccine and utilized the CDC-maintained Vaccine Adverse Events Reporting System (VAERS) database to assess the relationship between receipt of the vaccine and the potential for adverse developmental and physiological response. In their study, adverse responses following administration of the Thimerosal-containing DTaP vaccine (n = 6575 over the interval 1992 – 2000) were compared with

[10]http://articles.chicagotribune.com/2012-11-05/news/ct-met-autism-doctor-20121106_1_autism-doctor-david-geier-mark-geier (Accessed March 14, 2017)

adverse responses following administration of the Thimerosal-free vaccine (n = 1516 over the interval 1997 – 2000). Adverse responses considered for this study included developmental effects, specifically autism, speech disorders and mental retardation, and acute effects including seizures, gastroenteritis, and vasculitis. While acknowledging the significant possibility of data bias in this style of epidemiological evaluation, and stating clearly that additional research to support their claim was needed, the authors concluded that there was a weak association between receiving the Thimerosal-containing DTaP vaccine and the appearance of neurodevelopmental disorders. This 2003 publication was followed over the subsequent year by at least three others publications by the same authors, all focusing on the same data set and subject to the same possibilities of data bias, and all reaching or reiterating the same conclusion regarding the link between the vaccine additive and neurodevelopmental disorders (Geier and Geier 2003b, 2004a, and 2004b). It would not be an understatement to write that for those seeking validation for the belief of conspiracy, fraud, or data mishandling by government agencies, these publications were a gold mine.

From the scientific perspective, what followed next was an attempt to address the problem that was both Dr. Wakefield's and the Geier research team's opinions. In 2009, Gerber and Offit (2009) published a review entitled *Vaccines and Autism: A Tale of Shifting Hypotheses* that summarized the 20 epidemiological studies that they believed met criteria for peer-review and data quality, and that had tested for any association between either the MMR vaccine or Thimerosal and autism. For these 20 publications, including ecological, case-controlled, retrospective cohort, and prospective cohort studies, and involving many thousand children, the researchers found no statistically significant or defensible support for

an association between the vaccine, the preservative, and the disorder. That is, in their belief, there was no rational explanation for the continued belief that exposure to Thimerosal caused autism. In support of this conclusion, a 2008 study in California had also demonstrated, here based on assessment of the state's Department of Developmental Services (DDS) autism client database, that autism diagnoses in California did not decrease in the years following the 2001 removal of Thimerosal from the majority of infant vaccines (as would have been hypothesized to occur if there was a causal link between Thimerosal exposure and autism) (Schechter and Grether, 2008). This result – that the timing of Thimerosal removal from vaccines bore no correlation to reported autism rates – was further substantiated by a population-based Danish study that had reached the same conclusion (Madsen et al., 2003). Following on the results of these studies– as well as others – the CDC, in 2013, concluded that *no reputable scientific studies have found an association between Thimerosal in vaccines and autism* (CDC, 2013).

That the scientific community has reached an Agency-supported consensus on the safety of vaccines, including consensus on the absence of evidence linking Thimerosal exposure to the development of autism, has not meant that the public unequivocally agrees with this consensus. The apparently widespread nature of this disagreement was highlighted in January 2017 when newly elected U.S. President Donald Trump suggested the appointment of Robert Kennedy Jr., a noted environmental lawyer with no medical training, to head a commission on vaccine safety.[11] The simple nature of this announcement is

[11] https://www.washingtonpost.com/politics/trump-to-meet-with-proponent-of-debunked-tie-between-vaccines-and-autism/2017/01/10/4a5d03c0-d752-11e6-9f9f-5cdb4b7f8dd7_story.html?utm_term=.b01f2af9ec4f (Accessed on March 14, 2017)

problematic on many levels, including the proposed selection of an individual with no scientific or medical background to chair a commission on a medical/scientific topic, as well as the inference that such a commission is actually needed. Equally problematic, although more challenging to frame in a sociological context, is an underlying concern: that by using the Presidential platform to suggest that an individual's distrust of vaccines (in this case, Donald Trump's) has equal policy-level merit to the international medical/scientific consensus regarding the safety of immunizations, the result of this suggested equivalence will be a normalization of scientific skepticism, the outcome of which would be a challenge – not simply to the vital concept of herd immunity – but to the underlying broad belief that public health medicine is necessary and of value. And in fact, this challenge appears to already be occurring, as the CDC is reporting localized outbreaks of measles in communities in which vaccination schedules are not being followed.[12] These outbreaks highlight a broadening of concerns regarding public health and safety, the result of which – both in terms of decreased public trust in science/medicine/public health, and the potential for widening outbreaks of vaccine-preventable diseases – may prove challenging for society to manage. Indeed, that the U.S. has been spared many 20th – 21st century epidemics of vaccine-preventable diseases is *because* of vaccines, not *in spite* of them, a distinction that the current U.S. President does not appear to endorse.

Moreover, what is also clear from an examination of this topic is that it may prove impossible in a climate of suspicion for a distrustful public to hear the distinction between statements that there is no evidence that Thimerosal in vaccines is responsible for a

[12] https://www.cdc.gov/measles/cases-outbreaks.html (Accessed on March 14, 2017)

'holocaust' among children (as Robert Kennedy, Jr. described it),[13] and the statement that unusual reactions to immunizations do occur. That the Vaccine Injury Compensation Program (VICP) exists within Federal DHHS, and that payouts from that program have occurred in instances in which infants have suffered both neurological and developmental impacts following receipt of immunizations, highlights the reality that there are undeniable risks associated with vaccination (e.g., Offit, 2008). That there are risks, however, and that the risks distribute to *individuals*, some of whom may be suffering from underlying conditions that heighten susceptibility (but that may or may not yet have been diagnosed at the time of infant vaccinations), while benefits distribute as well to *community*, creates yet another complicating nuance to the mass media discussion of the value of public health medicine.

A further nuance to consider here, as well, is that while a range of behavioral deficits and neurological delays can manifest in young children following immunization, this does not mean that all such deficits and delays are diagnosable as *autism*. What is important here is the distinction between the specific (i.e., *X vaccine causes Y clinical effect*) and the general (i.e., *vaccines cause autism*), the first statement focusing on science and the second playing into public fear. It is a valid and ongoing concern that if the effort is not continuously made to redirect the public discussion of immunization safety back toward that first statement of scientific fact and the protection of the public's health, then the risk exists that the public health infrastructure, including state and Federal agencies, as well as VICP, will ultimately

[13] https://www.washingtonpost.com/politics/trump-to-meet-with-proponent-of-debunked-tie-between-vaccines-and-autism/2017/01/10/4a5d03c0-d752-11e6-9f9f-5cdb4b7f8dd7_story.html?utm_term=.55d00a0e2d7f (Accessed March 14, 2017)

find themselves in the position of being unable to support and protect the very individuals with whose safety they have been charged with ensuring.

As explored in this paper, the development and utilization of Thimerosal as a preservative in multi-dose vaccines can be seen as a story tracing two simultaneous arcs – a scientific and regulatory arc focused on ensuring public health through the revision and improvement of risk-based standards, and a social arc on which distrust of government and regulation can allow for controversy to develop regarding the sometimes invisible workings of the scientific/medical research review process. As with all iterative processes, particularly those such as immunization requirements that are perceived as having a direct and coercive impact on individual decision making, how science and policy making are enacted can appear from the outside as though a perceived change in direction is the result of invisible machinations that, in reality, do not exist.

In the context of Thimerosal, as example, the decision to remove this preservative from the majority of infant and early childhood vaccines was as the result of regulatory review rather than evidential support of neurodevelopmental risks. That is, that there was little apparent scientific or regulatory disagreement regarding the value of removing this ingredient from immunizations was not suggestive that the ingredient, at the concentrations it was being administered, was specifically neurologically dangerous. Rather, and more likely, it was determined through the process of review that by replacing multi-dose vaccines with single dose vaccines, antimicrobial preservatives would no longer be required and it would be possible to eliminate a source of infant and early childhood mercury exposure, a '*good*

idea', from any vantage on the issue. With this background as context, the controversial, and ultimately discredited, research later suggesting that there was a direct causal link between the preservative and neurodevelopmental risks was in many ways the inevitable result of many factors, including the ingredient (already in the public eye because of concerns regarding contamination in fish), its industrial exposure history (in locations such as Minamata Bay, Japan), the demographic perceived as being at risk (infants), the apparent and unexplained increase in the incidence of diagnosed autism in children (due, in part, to a broadening of the diagnostic criterion, as well as to other still unknown environmental and/or genetic factors), and a cultural tendency to misapply Occam's razor (ascribing a direct causal relationship to factors that were only non-specifically connected). Indeed, the suggestion of this false causal relationship ultimately created a cultural backstory of Government collusion/fraud that remains as contentious and unsupported as the mercury-autism link itself.

References
[all peer-reviewed articles downloaded from UMass Amherst Research Library]

Andrews, N., E. Miller, A. Grant, J. Stowe, V. Osborne, and B. Taylor. 2004. Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association. Pediatrics. 114(3): 584-591.

Ball, L.K., R. Ball, D. Pratt. 2001. An Assessment of Thimerosal Use in Childhood Vaccines. Pediatrics. 107(5): 1147-1154.

Centers for Disease Control and Prevention (CDC). 2013. Understanding Thimerosal, Mercury, and Vaccine Safety. Fact Sheet Accessed on: March 14, 2017. https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-thimerosal-color-office.pdf.

Clarkson, T.W. and L. Magos. 2006. The Toxicity of Mercury and Its Chemical Compounds. Critical Reviews in Toxicology. 36: 609 – 662.

Geier, M.R. and D.A. Geier. 2003a. Neurodevelopmental Disorders after Thimerosal-Containing Vaccines: A Brief Communication. Experimental Biology and Medicine. 228(6): 660-664.

Geier, M.R. and D.A. Geier. 2003b. An Assessment of the Impact of Thimerosal on Neurodevelopmental Disorders. Pediatric Rehabilitation. 6: 97-102.

Geier, M.R. and D.A. Geier. 2004a. Neurodevelopmental Disorders Following Thimerosal-Containing Chiildhood Immunizations: A Follow-Up Analysis. International Journal of Toxicology. 23: 369 – 376.

Geier, M.R. and D.A. Geier. 2004b. A Comparative Evaluation of the Effects of MMR Immunization and Mercury Dose from Thimerosal-Containing Childhood Vaccines on the Population Prevalance of Autism. Medical Science Monitoring. 10(3): 33-39.

Gerber, J.S. and P.A. Offit. 2009. Vaccines and Autism: A Tale of Shifting Hypotheses. Clinical Infectious Diseases. 48:456–61.

Goncalo M, A. Figueiredo, and S. Goncalo. 1996. Hypersensitivity to Thimerosal: The Sensitivity Moiety. Contact Dermatitis. 34:201-203.

Grabenstein, J.D. 1996. Immunologic Necessities: Diluents, Adjuvants, and Excipients. Hospital Pharmacy. 31:1387-1401.

Harada, M. 1995. Minamata Disease – Methylmercury Poisoning in Japan Caused by Environmental Pollution. Critical Reviews in Toxicology. 25(1): 1-24.

Hightower, J.M. 2009. Diagnosis: Mercury, Money, Politics and Poison. Island Press. 310p.

Hurley, A.M., M. Tadrous, and E.S. Miller. 2010. Thimerosal-Containing Vaccines and Autism: A Review of Recent Epidemiological Studies. Journal of Pediatric Pharmacology and Therapeutics. 15:173–181.

Madsen, K.M., M.B. Lauritsen, C.B. Pedersen, P. Thorsen, A.-M. Plesner, P.H. Andersen and P.B. Mortensen. 2003. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population-Based Data. Pediatrics. 112(3): 604-606.

Magos, L. and T.W. Clarkson. 2006. Overview of the Clinical Toxicity of Mercury. Annals of Clinical Biochemistry. 43: 257–268.

McAlpine, D. and S. Araki. 1958. Minamata Disease: An Unusual Neurological Disorder Caused by Contaminated Fish. Lancet. 2(20): 629-631.

Offit, P.A. 2008. Vaccines and Autism Revisited: The Hannah Poling Case. The New England Journal of Medicine. 358(20): 2089-2091.

Osawa, J., K. Kitamura, Z. Ikezawa, H. Nakahma. 1991. A Probable Role for Vaccines Containing Thimerosal in Thimerosal Hypersensitivity. Journal of Contact Dermatitis. 24(3): 178 – 182.

Rohyans J, P.D. Walson, G.A. Wood, W.A. MacDonald. 1994. Mercury Toxicity Following Merthiolate Ear Irrigations. Journal of Pediatrics. 104: 311-313.

Schechter, R. and J.K. Grether. 2008. Continuing Increases in Autism Reported to California's Developmental Services System. Archives of General Psychology. 65(1): 19 – 24.

USEPA. 2001. Water Quality Criterion for the Protection of Human Health: Methylmercury. Chapter 4: Risk Assessment for Methyl- mercury. Office of Sciences and Technology, Office of Water, Washington, DC. Downloaded on April 18, 2017.

USEPA. 2009. Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion. EPA 823-R-09-002. U.S. Environmental Protection Agency, Office of Water. Washington, D.C. Downloaded on April 18, 2017.

Wakefield, A.J., S.H. Murch, A. Anthony, J. Linnell, D.M. Casson, M. Malik, M. Berelowitz, A.P. Dhillon, M.A. Thomson, P. Harvey, A. Valentine, S.E. Davies, and J.A. Walker-Smith. 1998. Ileal-Lymphoid-Nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children. The Lancet. 351: 637-641.