IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

N RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER, Various Petitioners,, Plaintiff(s), v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent., Defendant(s).	Case No. Autism Master File **NOTICE OF FILING EXPERT REPORT OF DR. ELIZABETH MUMPER RE JORDAN KING**

COMES NOW, the Petitioners by and through their undersigned counsel, who is a member of the Bar of the Court, and hereby gives notice to the Court and all parties of this Notice of Filing.

DATED this 13th day of December, 2007.

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Professional opinion about the role of thimerosal containing vaccines In the case of Jordan King

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Qualifications:
Background and Qualifications:

MD 1980 Medical College of Virginia
Internship in Pediatrics 1980-81, University of Massachusetts
Residency in Pediatrics 1981-83, University of Virginia
Chief Residency in Pediatrics 1983-84, University of Virginia
Private Practice Pediatrics 1984-1989, Lynchburg, VA
Director of Pediatric Education 1989-2000, Lynchburg Family Practice Residency
CEO, Advocates for Children, 2000-present
Medical Director, Autism Research Institute, 2005 – present
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Experience in Treating Children with Autism Spectrum Disorders

During my pediatrics residency I received the usual and customary training in how to care for children with neurodevelopmental disorders. Since developmental and behavioral problems were a special interest of mine, I attracted a population of such patients during my time in private practice and while teaching in a University of Virginia affiliated family practice residency program.

In 2000, I established Advocates for Children to help meet what I perceived as unmet needs in my community for the increasing numbers of children with neurodevelopmental and behavioral disorders. We have just opened The RIMLAND Center, which will serve as a training facility for clinicians interested in learning about the medical problems of children with autism. We care for children not only in central Virginia, but from other states and countries. At least 500 of our patients have autism spectrum disorders and other neurodevelopmental disabilities. A large proportion of our general pediatric patients have chronic diseases.

Jordan King - case summary:

- Mother had a flu like illness during the 4th month of pregnancy
- Born by vaginal delivery with vacuum extraction
- 20 hour labor with prolonged rupture of membranes, for which his mother received IV antibiotics
- Apgars 8 & 10; normal initial exam and newborn nursery course
- Normal exams at 2, 4 and 6 months
- Mother took antibiotics while nursing him around 3 mos
- Most of his hair fell out around 3 months of age and came back in blonder and curlier
- Medical records note an illness around 4 months of age which included severe lethargy and vomiting
- Clearly documented normal behavioral and physical developmental milestones in the first year of life, specifically, at his 12 month checkup said "mama" and "dada" and understood language well receptively
- Suffered second degree burns on both feet from walking on a heating grate just after his first birthday
- Clearly documented regression with total loss of language, loss of eye contact, stereotypic behaviors, constant humming, and apparent hallucinatory behaviors emerging between 15-20 months
- Chronic diarrhea beginning after the first year of life and lasting for longer than a year, showing improvements after he started on the gluten free, casein free diet
- At two year check up was noted not to be talking at all, only grunting and humming
- Diagnosis of autism by clearly documented impairments in language and social reciprocity, with evidence of stereotypic and repetitive behaviors meeting DSMIV criteria for autism and diagnosis confirmed by specialists in child development
- Laboratory evidence showing medical problems compatible with mercury toxicity
- Laboratory evidence showing the impairment or suboptimal functioning of biologic mechanisms designed to rid Jordan's body of heavy metals such as mercury
- Clearly documented urinary excretion of mercury after interventions designed to improve detoxification mechanisms
- Absence of documented chromosomal abnormalities or dysmorphic features to suggest a classic genetic cause for his autism

Summary of expert medical opinion about the case of Jordan King

- My professional opinions in this case are based on an extensive review of Jordan's complete medical records, my clinical experience, my role

teaching doctors how to evaluate and treat children with autism and the associated medical problems and my extensive review of the medical literature with regards to regressive autism, mercury toxicity, and the interaction between genetic predispositions and environmental factors

- My review of the literature, clinical experiences with hundreds of children with regressive autism and conversations with researchers as a result of my role at the Autism Research Institute have led me to agree with the expert reports about causation prepared by Dr. Vas Aposhian, Dr. Richard Deth and Dr. Sander Greenland in this case
- In my best professional judgment, with a reasonable degree of medical certainty, taking into account the specific medical facts about this particular child and applying my general knowledge obtained as described above, it is likely that thimerosal in the childhood vaccines Jordan received was a substantial contributing factor to his neurodevelopmental problems and the development of autism

Analysis of specific facts in the case of Jordan King with regard to thimerosal and its effects

Thimerosal exposure:

- Jordan received his first thimerosal containing vaccine at birth; the Hepatitis B vaccine contained 12.5 mcg of ethylmercury.
- At 2, 4, and 6 months, he received thimerosal containing vaccines according to the customary schedule:
    - 3 DPAT vaccines each containing 25 mcg of ethylmercury
    - 3 Hemophilus vaccines each containing 25 mcg of ethylmercury
    - 2 more Hepatitis B vaccines each containing 12.5 mcg of ethylmercury
- By the time he was 7 months old he had received a total of 187.5 mcg of ethylmercury
- At 25 months, he received DPAT and Hemophilus boosters, adding another 50 mcg of ethylmercury
- At 12 months, he received live viral MMR vaccine and varivax on the same day. Of note, neither vaccine has ever contained thimerosal

In my best medical judgment, review of Jordan's medical case is consistent with an increased vulnerability to the toxic effects of thimerosal exacerbated by other co-existing factors and mercury exposures.

Clinical evidence:

- Maternal antibiotic use during labor would be expected to exacerbate the toxicity of the mercury he received in his Hepatitis B shot at birth
- Maternal antibiotics taken while nursing him around 3 months of age would be expected to alter his gut flora and exacerbate the toxicity of the mercury received during his 4 month well baby shots

- Environmental history revealed exposure to a fungicide added to paint for windowsills, on which the children were noted to put their mouths; fungicides frequently contain mercury
- Exposure to a synthetic pyrethroid pesticide around June 1999; it was during this time that he was noted to lose all words
- The same summer a toluene containing treatment was applied to waterproof the deck and he was exposed to organophosphates, which are know to adversely affect crucial enzymes
- His medical records document that he ate a lot of tuna, which can be a source of methylmercury, thereby adding to his cumulative load
- Jordan demonstrated pica, a known symptom of heavy metal exposure
- He was noted to exhibit profuse daytime sweating, night sweats and excess tearing, all consistent with mercury toxicity
- His geographic location as analyzed by zipcode on scorecard.org is notable for being at the 70%tile for air releases of developmental toxins, 80%tile for total environmental releases of toxicants, and 90%tile for air releases of recognized reproductive toxicants. Clinically this places him at increased risk for synergistic toxicities
- He was noted to live in an industrial part of town in a home that was greater than 60 years old, which is another risk factor for synergistic toxicities

Analysis of this case in relation to the literature:

- Infants are born at risk: 1 in 6 children born today is predicted to have blood levels of mercury high enough to impair neurological development (Stern 2005, Master Ref # 0131)
- Antibiotics exacerbate mercury toxicity (Rowland, 1984)
- Mercury has myriad manifestations of toxicity depending on the biochemical individuality of the victim, route of exposure, dose effects and synergistic toxicities (Blaxill, Redwood et al. 2004, Master Ref # 0259)
- Normal infants immunized per routine recommendations can meet criteria for acute mercury toxicity: The CDC has defined mercury poisoning as a blood mercury level greater than 10 mcg/L (2005). The Stajich study looked at normal infants after hepatitis B vaccination. One infant developed a post vaccine mercury level of 23.6 mcg/L, which meets CDC criteria to qualify as a case of acute mercury poisoning (Stajich, Lopez et al. 2000, Master Ref # 0249). The presence of such high blood levels is consistent with significant inter-individual variability among children receiving thimerosal containing vaccines
- The toxicity of mercury can be potentiated by the presence of other heavy metals. For example, in an animal study on rats, the administration of a mercury salt at a dose of LD1 (the dose that is lethal in 1% of subjects) with 1/20 of the LD1 of a lead salt caused 100% death of the rats
- Of all the heavy metals, mercury is the most toxic nonradioactive substance in the United States (ATSDR 2001, Master Ref # 0262)

In addition, we have evidence that Jordan had impaired methylation biochemistry and deficient detoxification ability which would impair his ability to handle a heavy metal burden.

Laboratory evidence of impairments:

- Very low zinc levels noted by his physician. Zinc is one of the mechanisms utilized by the body to excrete mercury. Low levels may suggest clinically that the child is utilizing zinc to excrete heavy metals faster than he can replenish it or may reflect inadequate intake. In either event, low zinc levels compromise ability to excrete metals
- His physician noted several markers for low glutathione, which is a crucial component of normal detoxification for mercury
- Amino acid analysis interpreted as demonstrating "impaired xenobiotic detoxification"
- Urine excretion of mercury after chelation and other strategies to improve excretion of mercury show several urine tests in which mercury excretion was markedly elevated. On March 4, 2000, mercury was elevated at 6.8 mcg/gram creatinine (normal 0-3). In December 29, 2000, in response to a provocative challenge, mercury and tin were elevated. In December 2003, mercury was at 21 mcg/gram creatinine (normal <3), literally off the chart. At that time, there was co-existing extreme excretion of tin, at a level of 120 micrograms/gram creatinine (normal <6)
- Evidence on laboratory assessments of intestinal dysbiosis, with metabolites of clostridia. Intestinal inflammation impairs the immune system and interferes with appropriate fecal excretion of heavy metals.
- Functional impairment of normal detoxification mechanisms demonstrated by Metametrix laboratories 6.7.01
- Red blood cell analysis showed low levels of the following essential elements on 4.18.01: chromium, copper, magnesium, molybdenum, selenium and zinc. In my clinical experience, deficiencies in selenium and zinc are particularly common in children with mercury toxicity, as those two essential elements are used to escort zinc out of the body
- Laboratory evidence of pancreatic insufficiency, fat malabsorption and inadequate protein digestion

Clinical evidence compatible with damage from mercury:

- Intestinal dysbiosis, reflecting abnormal intestinal flora
- Chronic diarrhea which resolved dramatically when he was taken off gluten and casein. Mercury has been documented to damage DPPIV (dipeptidyl peptidase) which is a digestive enzyme responsible for breaking down gluten (in wheat products) and casein (in dairy products). In the absence of other reasons, such as celiac disease, to explain his

intolerance to gluten and casein, my best medical judgment is that his mercury exposure was a substantial contributing factor
- Lethargy, sleep disruption, stereotypic behaviors and loss of developmental milestones are all consistent with direct neurotoxic effects of mercury at vulnerable periods of neurologic development.
- Assessment by Dr. John Green from an environmental medicine perspective included concerns about elevated mercury

Clinical evidence of improvement with medical treatment directed at removing mercury and improving the body's natural detoxification and immune mechanisms:

- Dr. Green's medical records outline many laboratory parameters which are consistent with the diagnosis of mercury toxicity
- Dr. Green's medical treatment plans included chelation with agents known to improve mercury excretion
- Dr. Green's treatment plans included strategies to improve Jordan's nutritional status and counteract oxidative stress, which as outlined in Dr. Deth's report to the court is exacerbated by mercury
- Dr. Green's records document slow incremental improvements with treatment
- Dr. Green's records document "doing amazingly well with B12 and glutathione" which work on pathways for detoxification
- Dr. Green's laboratory records document significant mercury excretion in response to a chelation challenge doses
- Dr. Green's laboratory records show significant mercury excretion over time, often in conjunction with tin excretion, as documented on examination of urine toxic metals
- Dr. Green reported with treatment "major changes in a boy who has shown severe dense inaccessibility thus far"

Analysis of Jordan's clinical and laboratory evidence with regard to the medical literature.

- Intermittent larger doses of mercury as given in vaccine injections bypass the normal protective mechanisms found in the gut that are designed to protect against oral exposures. Children have not had the opportunity to evolve mechanisms to protect against injected ethylmercury. My best medical judgment, based on clinical experience and studying the medical literature is that injected thimerosal in bolus doses is associated with more risk of toxicity than a chronic low-dose daily intake of oral mercury (Grandjean and Jorgensen 2005, Master Ref # 0210)
- Numerous mechanisms of thimerosal toxicity have been demonstrated Thimerosal is metabolized to thiosalicylate and ethylmercury, which is taken up by organs and degraded to Hg2+ (Qvarnstrom, Lambertsson et

al. 2003, Master Ref # 0246). Thimerosal is documented to cause DNA damage (Baskin, Ngo et al. 2003, Master Ref # 0253) and inhibit mononuclear phagocytosis (Rampersad, 2005, Master Ref # 0211)

- Urinary mercury levels do not necessarily correlate with the severity of clinical signs and symptoms of mercury poisoning (Gattineni, 2007)
- Pathologic brain injury has been documented in response to thimerosal. Subclinical mercury poisoning induced experimentally in monkeys (levels less than 50 mcg mercury/kg body weight/day) demonstrated pathologic brain changes including decreased numbers of astrocytes and increased activated microglia without any noticeable clinical manifestations (Charleston, Body et al. 1996, Master Ref # 0116)
- Recent autopsy studies of autistic brains demonstrated activation of microglia and the innate immune system, but not adaptive immunity. Burbacher demonstrated in primates that injected organic mercury was associated with persistence of inorganic mercury in the brain (Burbacher, Shen et al. 2005, Master Ref # 0026)
- Patients with autism have been demonstrated to have increased oxidative stress (James, 2004, Master Ref # 0005). "Oxidative stress (endogenous or environmental) may contribute to the development and clinical manifestations of autism" (James, 2006, Master Ref # 0049)
- Improvements and recoveries argue for environmental components. Reported cases of improvements or recoveries from autism have been published in the academic literature [Mundy, 1997, Master Ref # 0145; Dawson, 2003, Master Ref # 0154; Fein, 2005, Master Ref # 0150; Kelley, 2006, Master Ref # 0144]
- Metabolic perturbations are very common in children affected by the recent autism epidemic. James and colleagues described fundamental abnormalities in methylation and transulfuration biochemistry in autistic children when compared to neurotypical control children. Autistic children had low methionine, low cysteine, low reduced glutathione, increased oxidized glutathione, and abnormal redox ratios. Normalization of the redox ratios occurred with nutritional supplementation, including methylcobalamin, betaine and folinic acid (James, Cutler et al. 2004, Master Ref # 0005). These findings were later confirmed in a larger cohort of autistic children compared to neurotypical children (James, Melnyk et al. 2006, Master Ref # 0049)
- Glutathione deficiencies impair ability to excrete thimerosal. Impaired methylation biochemistry leads to glutathione deficiencies, which are present in the vast majority of our autistic patients and over 75% of autistic children (James, Cutler et al. 2004, Master Ref # 0005). Since glutathione is such a crucial intracellular anti-oxidant, has vital roles for detoxification function, and helps regenerate intestinal epithelium, treatment strategies designed to normalize the ratio of reduced to oxidized glutathione often lead to clinical improvements
- Autistic children demonstrate mercury toxicity. One recent prospective study of 115 children with autism demonstrated porphyrinuria when

compared to 119 control children [Nataf et al., 2006, Master Ref # 0065]. When compared to the control group, children with autism had a mean increase of 2.6-fold ($p < 0.001$) in urinary coproporphyrin. A subgroup of these autistic children underwent oral chelation therapy with DMSA which resulted in a significant reduction in mean urinary coproporphyrin and precoproporphyrin ($p = 0.002$), indicating that the urinary porphyrin elevation was not genetic in nature but due to the toxic metals removed [Nataf, 2006, Master Ref # 0065]

- Certain genetic susceptibilities could cause some children to be more vulnerable to mercury toxicity. Thimerosal was given to three different mice strains at doses that replicated the childhood immunization schedule from the 1990's. Thimerosal was able to produce an autism-like illness in one mouse strain with a genetic sensitivity to mercury. The researchers found "strain-dependent, ethylmercury-based disruption of normal programs of neural development and synaptogenesis. These findings implicate genetic influences and maturational factors as critical determinants of postnatal thimerosal-related sequelae and highlight the importance of interactions of gene, environment, and timing in the pathogenesis of neurodevelopmental disorders." (Hornig 2004, Master Ref # 0015)
- Abnormal immune responses to dietary proteins and brain cells: Vojdani et al. demonstrated immune responses to dietary proteins, gliadin, and cerebellum peptides in children with autism. A sub-group of patients with autism produced antibodies against Purkinje cells and gliadin peptides, providing further evidence of a link between the gut, brain and immune system (Vojdani, O'Bryan et al. 2004, Master Ref # 0094)

Thimerosal effects:

Referring to Dr. Vas Aposhian's report submitted to the court:

- He cited Pichicherio's work on non-autistic children and Burbacher's work with primates as evidence for deposition of mercury in the brain after thimerosal containing vaccines
- He reported that Pardo and Vargas documented the presence of neuroinflammation with activation of the brain's innate immune system
- He explained the concept of developmental windows of increased vulnerabilities to toxins
- He articulated the concept that there are variable vulnerabilities to exposure to mercury, based on other modifying factors and genetic predispositions, citing the fact that not all children exposed to mercury containing teething powders developed Pink disease
- He reviewed the toxicokinetics of thimerosal

Referring to Dr. Richard Deth's report submitted to the court:

- He described the detrimental effects of thimerosal on cellular redox status and glutathione levels

- His experiments demonstrated the potent inhibition of neuronal methionine synthase by thimerosal at concentrations far below the plasma level of one thimerosal containing vaccine
- He reported that thimerosal is known to be toxic to human cortical neurons, and induces apoptosis (programmed cell death)
- He described how thimerosal interferes with cellular production of glutathione, which is a crucial mechanism for the body to deal with heavy metal toxicity
- He explained how thimerosal induces oxidative stress and interferes with sulfate metabolism, which is crucial for getting rid of toxins and heavy metals

Summary:

- In my best medical judgment based on my clinical experience and understanding of the medical literature some of which is cited above, Jordan is a child whose neurodevelopmental problems were exacerbated by mercury exposure in vaccines
- I am particularly concerned that he had evidence of other exposures to mercury and other toxins, so was likely to have experienced cumulative effects
- Thimerosal reduces cellular glutathione, which is the body's major intracellular anti-oxidant. Jordan demonstrated markers for glutathione deficiency
- Thimerosal has devastating effects on methylation biochemistry, which ironically is the main way the body attempts to deal with heavy metal toxicity. My clinical experience in conjunction with my understanding of the published works of Drs. James and Deth, lead me to have grave concerns about the clinical consequences of thimerosal exposure in this child as it was noted that he improved significantly when his methylation biochemistry was improved therapeutically
- Jordan had documented mercury exposures via thimerosal and environmental sources and demonstrated mercury toxic loads. He had clinical symptoms compatible with the expected effects of thimerosal toxicity leading me to conclude that thimerosal was a substantial contributing factor in the development of his autism

New references:

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In the case of Jordan King:

The opinions expressed in this report are held by me to a reasonable degree of medical and scientific likelihood. I reserve the right to supplement this report in light of any additional scientific or medical literature that may be published during the pendency of this claim in the NVICP, or in light of any relevant change in Jordan King's medical condition.

Elizabeth Mumper 12/12/07

Elizabeth Mumper, MD Date

References Cited in This Report

Master Reference Number	AUTHOR	TITLE	CITATION	DATE
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CERTIFICATE OF SERVICE

I hereby certify that on December 13, 2007, I served the foregoing **Notice of Filing Expert Report of Dr Elizabeth A. Mumper, M.D.** on the following individual(s):

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By United Parcel Service, next business day delivery and email.

Petitioners specifically authorize the Court and the Office of Special Masters to post this document, and any attachments or exhibits thereto, on the Court/OSM website, expressly waiving any confidentiality as to the contents of these materials. Petitioners expressly wish to publicly disclose this filing in any other forum designated by the Court or the OSM.

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