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November 19, 2007

VIA UPS DELIVERY

Clerk
United States Court of Federal Claims
717 Madison Place, NW
Washington, D.C. 20005

Re: In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder, or a Similar Neurodevelopmental Disorder v. Secretary of Health And Human Services
Autism Master File
Our File No. 054500 - Omnibus Autism Proceeding

Dear Clerk of Court:

Enclosed for filing in the case file captioned above is the original and two copies of the medical expert report of petitioners' expert Elizabeth A. Mumper, M.D. in the compensation claim of William Mead. This report is submitted both in support of petitioners' theory that exposure to the mercury contained in certain pediatric vaccines was a substantial contributing cause of some or all of the injuries at issue in the Omnibus Autism Proceeding, and in support of William's individual claim. Petitioners anticipate relying on this testimony in hearings on "test cases" currently scheduled for May 2008.

A copy of this expert report is simultaneously being filed in Mead v. Secretary of Health and Human Services, Case No. 03-0215V.

Very truly yours,

Thomas B. Powers
Attorney at Law

Enclosures
cc: John Fabry, Esq., Williams Kherkher Hart Boundas, LLP (via UPS and email)
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Special Master George Hastings, US Court of Federal Claims (via UPS and email)
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Staff Attorney, Joseph Lowe, US Court of Federal Claims (via email)

Professional opinion about the role of thimerosal containing vaccines In the case of William Mead (DOB 5.5.98), Case No. 03-0215V

Report Submitted November 19, 2007

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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
Founder, RIMLAND Center, 2007

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 have over 3000 patients, and have grown by word of mouth to 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.

William Mead - case summary:

- Born by vaginal delivery after normal birth
- Apgars 8 & 9; normal initial exam and newborn nursery course
- Around 3 months of age, developed reactive airway disease, which recurred and required nebulizer treatments and intermittent steroid prescriptions until reportedly resolving after biomedical interventions undertaken as a result of his autism diagnosis
- Around 5 months of age, developed the first of many ear and respiratory infections which were treated with multiple courses of antibiotics
- Chronic diarrhea for over a year, beginning after MMR and varivax according to the parents, and continuing for over a year, and for which multiple traditional medical tests failed to define an etiology
- Evidence of chronic yeast infections, by physical examination documenting Candidal skin rashes and oral thrush, and by laboratory documentation of yeast metabolites in the urine and yeast found on stool microscopy
- Clearly documented normal behavioral and physical developmental milestones in the first year of life
- Clearly documented regression with loss of language, loss of eye contact, social withdrawal, toe walking, twirling and stereotypic and self-stimulatory behaviors emerging between 15-18 months
- Diagnosis of autism by clearly documented impairments in language and social reciprocity, with evidence of stereotypic and repetitive behaviors meeting DSM-IV criteria for autism
- Clearly documented improvements after interventions designed to treat underlying medical problems, many of them associated with mercury toxicity
- Presence of laboratory evidence showing medical problems compatible with mercury toxicity
- Presence of laboratory evidence showing the impairment or suboptimal functioning of biologic mechanisms designed to rid William's body of heavy metals such as mercury
- Clearly documented evidence of the presence of mercury above the reference ranges in the child's body, with subsequently clearly documented 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
- Documentation from University of Oregon developmental medical specialists that William did not appear to have "classic autism," but was clearly developmentally normal initially, then regressed

Summary of expert medical opinion about the case of William Mead

- My professional opinions in this case are based on a careful review of William'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 lead me to agree with the expert reports about causation prepared by Dr. Vas Aposhian, Dr. Richard Deth and Dr. Sander Greenland in the Omnibus Autism Proceeding.
- 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, **thimerosal in the childhood vaccines William received was a substantial contributing factor to his neurodevelopmental problems and the development of autism.**

Analysis of specific facts in the case of William Mead with regard to thimerosal and its effects

Thimerosal exposure:

- William received his first thimerosal containing vaccine on day 2 of life; the Hepatitis B vaccine contained 12.5 mcg of ethylmercury.
- At 2, 4, and 7 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 23 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 William's medical case is consistent with an increased vulnerability to the toxic effects of thimerosal exacerbated by co-existing antibiotic use.

Clinical evidence:

- William received his 2 month shots at a time when he was sick with a respiratory infection and documentation of rhonchi in his lungs. This was consistent with American Academy of Pediatrics policy not to withhold immunizations during illness, but my clinical experience reviewing the medical histories of hundreds of children with regressive autism and review of the toxic effects on mercury on the immune system and developing nervous system has caused me to disagree with this practice.

- At 2 ½ months of age, he developed reactive airway disease, for which he was treated with albuterol, a beta agonist There are 8 more visits prior to the age of 2 in which he was diagnosed with reactive airway disease. At times he was treated with steroids in addition to beta agonists. At this time he had already received 75 mcg of mercury via thimerosal-containing vaccines. Mercury is known to be an immune disrupter and exacerbates allergy and autoimmunity. I am concerned that thimerosal exposure contributed to his allergy symptoms and asthma flares. He also had a genetic predisposition for asthma with a family history of allergies in both grandfathers and asthma in one grandfather.
- At 5 months of age, he developed his first ear infection and was treated with antibiotics. He received at least 8 more courses of antibiotics prior to the age of 2. He was frequently on antibiotics or just finishing a course of antibiotics when he received thimerosal containing vaccines. As referenced in Dr. Aposhian's report to the court, it is documented in the medical literature that antibiotics potentiate the toxicity of mercury. My best medical judgment is that concurrent antibiotic use with exposure to thimerosal-containing vaccines was a substantial contributing cause to the development of neurodevelopmental problems.
- Examination of his growth curve shows that his weight was around the 90th percentile prior to 7 months of age, then dropped to around the 50th percentile, which can suggest chronic illness, malabsorption, or other causes of failure to thrive. As Dr. Aposhian articulated in his report to the court, toxicities of mercury are dependent on a number of factors with regard to kinetics, antibiotic use, and concurrent exposures to other toxins. Included in my differential diagnosis of potential causes of the change in his growth pattern would be consequences of thimerosal exposure, reaching a threshold effect in which he was not able to compensate for the toxic load and developed health consequences which affected his growth.

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, Ex. 0131).
- Antibiotics potentiate mercury toxicity (Rowland, 1984, Ex. 0187)
- Mercury has myriad manifestations of toxicity: Mercury is the classic prototype demonstrating the ability of heavy metals to have 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, Ex. 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. 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, Ex. 0249). The presence of such high blood levels is consistent with significant inter-individual variability.

In addition, we have evidence that William had impaired methylation biochemistry, aberrant cellular functioning and deficient detoxification ability with improvements in clinical status when his methylation biochemistry, cellular redox status and detoxification systems were improved.

Laboratory evidence of impairments:

- Low intracellular zinc levels (5.1 mcg/ml with normal 10.5-13.7). 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 a heavy metal faster than he or she can replenish it or may reflect inadequate intake. In either event, low zinc levels compromise ability to excrete metals.
- Low plasma amino acids (alanine, arginine, asparagine, cystine, glutamine) documented at the Massachusetts General Hospital lab
- Mercury level in the hair low at 0.38 ppm (ref range 0.00-1.00) at a time when had documented high body burden of mercury and excretion with the help of a chelating agent. This can reflect impaired ability to excrete mercury in the hair, and implies a mercury efflux disorder as described by Dr. Aposhian.
- Multiple abnormalities in the citric acid cycle, which is a crucial cycle for maintaining appropriate energy production for the cell) demonstrated by Metametrix laboratories 11.4.02.
- Evidence on multiple laboratory assessments at different points in time of intestinal dysbiosis, with aberrant growth of yeast, clostridia and other harmful bacteria. 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 11.4.02
- Low levels of Vitamin A (27 mcg/dl – normal 30-90). Vitamin A is crucial for wound healing, vision, and immune function.
- Red blood cell analysis showed low levels of the following essential elements on 5.24.01: 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.
- Poor antioxidant functional status 1.17.01 demonstrating need for Vitamins A, C, and E, zinc, lipoic acid and coenzyme Q10. This is evidence of impairment in his body's mechanisms for detoxification.
- Deficiencies in essential fatty acids, particularly Omega 3's (eicosapentaenoic and docosahexaenoic) and multiple (6 of 7 measured) Omega 6's. Essential fatty acids are crucial for cell membrane functioning and cell signaling mechanisms; they are also important natural anti-inflammatories, so William would be expected to show impairments in those areas.
- Deficiencies in IgG (686 mg/dl – normal 800-1700) and IgA (69 mg/dl – normal 100-490) documented 1.11.01. This is evidence of immune deficiencies which would impair his ability to fight infections.

- Dramatically low digestive enzymes documented at Massachusetts General.
- Abnormal intestinal permeability demonstrated by high lactulose/mannitol ratio (0.15 – normal <0.07) 1.25.01. This is evidence of damage to the tight junctions in his intestine. Such damage allows larger than normal peptides and food particles to penetrate the intestinal membrane, which is meant to function as a protective border, and allows the immune system to recognize and react against food particles. This is part of the explanation of why his clinical status improved with removal of gluten and casein.

Clinical evidence compatible with damage from mercury:

- Multiple episodes of otitis media and respiratory infections suggestive of immune dysregulation. Mercury has been documented to damage certain lymphocytes, which are white blood cells responsible for fighting infection.
- Reactive airway disease with subsequent asthma and multiple food allergies. Mercury is an immune disrupter, upsetting the balance between TH1 immunity, which defends the body against bacteria, viruses and fungal infections and TH2 immunity.
- Recurring episodes of 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.
- Multiple episodes of teeth grinding, muscle spasms, tensing, stereotypic behaviors and loss of developmental milestones are all consistent with direct neurotoxic effects of mercury at vulnerable periods of neurologic development. When nutritional and medical interventions directed towards enhancing his body's detoxification pathways were undertaken, these symptoms improved.
- Assessment by Dr. John Green from an environmental medicine perspective included concerns about a "strikingly elevated mercury" and "strikingly low zinc."

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, many of which I have listed above.
- Dr. Green's medical treatment plans included chelation with agents known to improve mercury excretion, although the degree to which mercury in brain tissue can be mobilized is unknown to the best of my knowledge.

- Dr. Green's treatment plans included strategies to improve William'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 treatment plans included strategies to enhance his poorly functioning immune system, through the use of oral Baygam and intravenous gamma globulin.
- Dr. Green's records document substantial gains in understanding, language acquisition and cognitive processing with treatment, but a challenging series of medical problems, including recurring yeast problems, rashes, inflammation in the bowel and intermittent exacerbations of his autistic behaviors.
- Dr. Green's records document "significant and steady improvements particularly related to chelation therapy."
- Dr. Green's laboratory records document significant mercury excretion in response to a chelation challenge dose on several different occasions.
- Dr. Green's laboratory records show significant mercury excretion over time, often in conjunction with lead excretion, as documented on examination of urine toxic metals.
- Dr. Green's medical records reflect times when he made "significant progress with lots of language," "articulation is improving," "more cooperative than he's ever been," "quite verbal," etc. reflecting that William's autism was not a static encephalopathy, but responsive to interventions.

Analysis of William'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, Ex. 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, Ex. 0246). Thimerosal is documented to cause DNA damage (Baskin, Ngo et al. 2003, Ex. 0253) and inhibit mononuclear phagocytosis (Rampersad, 2005, Ex. 0211).

- 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). Recent autopsy studies of autistic brains demonstrated activation of microglia and the innate immune system, but not adaptive immunity (Vargas 2005, Ex. 0069; Courchesne 2005 –Autism at the Beginning, Ex. 0104).
Burbacher demonstrated in primates that injected organic mercury was associated with persistence of inorganic mercury in the brain (Burbacher, Shen et al. 2005, Ex. 0026).

- Patients with autism have been demonstrated to have increased oxidative stress [James, 2004, Ex. 0005]. "Oxidative stress (endogenous or environmental) may contribute to the development and clinical manifestations of autism" [James, 2006, Ex. 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, Ex. 0145; Dawson, 2003, Ex. 0154; Fein, 2005, Ex. 0150; Kelley, 2006, Ex. 0144]. William's improvements argue against purely genetic causes for his autism and make thimerosal exposure more likely as a contributing factor.

- 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, Ex. 0005). These findings were later confirmed in a larger cohort of autistic children compared to neurotypical children (James, Melnyk et al. 2006 Ex. 0049). My clinical experience has validated the methylation and transulfuration abnormalities described by Dr. James, and our patients demonstrate clinical improvements when we utilize strategies to support methylation biochemistry, as occurred in William.

- 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 Ex. 0005). Since glutathione is such a crucial intracellular anti-oxidant, has vital roles for detoxification function, modulates T cell function, and helps regenerate intestinal epithelium, treatment strategies designed to normalize the ratio of reduced to oxidized glutathione often lead to clinical improvements, and was part of William's therapeutic regimen.

- 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, Ex. 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, Ex. 0065]. This test was not widely used in the autism community at the time William began treatments for the mercury toxicity diagnosed by Dr. Green, so we do not have the advantage of knowing what the impact of mercury toxicity on his porphyrin pathways was prior to chelation.

- 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, Ex. 0094). Multiple documented incidences in William's medical records of deterioration in functioning and exacerbation of autistic symptoms when his intestinal problems were not well controlled or he was exposed to gluten and/or casein raise concern that he is in this clinical category.

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. After conversion in the brain to inorganic mercury (Hg++), the half-life is measured in years, based on Burbachers' earlier studies on adult primates, leading to neuroinflammation and astrocyte death after six months of accumulation.
- 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 predipositions, 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 understanding of the medical literature some of which is cited above and my clinical experience, William is a child whose neurodevelopmental problems were exacerbated by mercury exposure in vaccines.
- Delayed manifestations of neurotoxicity as evidenced by emerging symptoms of autism many months after his exposure to mercury in vaccines are consistent with the pattern of developmental toxins.
- Clinically, he fits the picture of a child with genetic predispositions which acted together with environmental triggers to develop neurologic impairments. For example, he had a genetic predisposition to asthma, with a susceptibility to environmental triggers (one of which could include mercury) resulting in him manifesting asthma.
- Thimerosal reduces cellular glutathione, which is the body's major intracellular anti-oxidant, and serves vital roles in maintaining the gut epithelium, preserving immune function, and enabling adequate detoxification. William demonstrated problems in all these areas.
- 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 with impaired methylation biochemistry.
- William had documented mercury exposures via thimerosal, demonstrated mercury toxic loads, clinical problems compatible with the expected effects of thimerosal toxicity and improvements in his clinical status following measures to treat his oxidative stress, detoxification systems, and immune functioning, leading me to conclude that thimerosal was a substantial contributing factor in the development of his autism.

Sincerely,

Elizabeth Mumper, MD
Medical Director, Autism Research Institute
CEO, Advocates for Children
Founder, RIMLAND Center

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guiding families to good health

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In the case of William Mead

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 William's medical condition.

Elizabeth Mumper MD Nov 19, '07

Elizabeth Mumper, MD November 19, 2007

CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2007, I served the foregoing **Expert Report Re William Mead from 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.

WILLIAMS LOVE O'LEARY & POWERS, P.C.

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