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Induced Autism The Legal and Ethical Implications of Inoculating Vaccine Manufacturers from Liability

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INDUCED AUTISM: THE LEGAL AND ETHICAL IMPLICATIONS OF INOCULATING VACCINE MANUFACTURERS FROM LIABILITY

HELIA GARRIDO HULL*

"As to diseases, make a habit of two things— to help, or at least to do no harm."[1]

INTRODUCTION

Matthew's birth represented the single most important moment in his young parents' lives. He was a beautiful, perfectly formed, eight-pound, ten-ounce boy with black hair and slate blue eyes. During his first few months, he was playful and affectionate. He learned to sit up, walk, utter simple words, and count. A glimpse of his toothless smile and rosy cheeks warmed the hearts of everyone involved in his care. By eighteen months, Matthew's medical evaluations indicated that he met every important developmental milestone and exhibited signs of normal development. Nobody noticed that the little angel was quickly slipping into the darkness of his own deteriorating ability to communicate his simplest needs or desires.

Matthew became fascinated with lining up blocks and cars, spinning the wheels of his mother's vacuum cleaner, and turning light switches on and off. Once he began an activity, he would repeat the process over and over again with such persistence and concentration that he often failed to respond when his parents called for him. When forced to stop an activity, Matthew threw tantrums—kicking and biting anyone within reach. Increasingly, Matthew's parents found him sitting in the same spot for hours, staring motionless at something in the distance that only he could see. Over time, Matthew became more withdrawn and eventually stopped responding to his parents, no longer willing to look into their eyes or otherwise acknowledge their presence. Heartbroken and scared,

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[1] 1 HIPPOCRATES, EPIDEMICS § XII, at 165 (T. E. Page et al. eds., W. H. S. Jones trans., 1923).

Matthew's parents sought treatment for their son's unexplained behaviors. They soon learned that treatment was expensive and intervention programs were hard to find. Matthew's parents used the equity obtained from the sale of their large home to fund his care. Eventually, Matthew's father resigned from his job so he could provide Matthew with constant supervision.

Attempts to work on Matthew's motor skills had limited success and frequently resulted in tear-filled responses similar to panic attacks. Despite nearly three years of intervention, Matthew remained incapable of communicating at an age-appropriate level. He often screamed in pain and frustration, throwing objects around the room in an emotional tirade. When overwhelmed by noise and confusion, he often bit himself or picked at his nails until they bled. Matthew's behavior improved in the carefully structured environment of his school for special needs children, but once he was home, amid the unpredictable and noisy hubbub of a large family, he acted out of control.

Now six, Matthew shows no sign of improvement and may actually be regressing. His parents desperately cling to the hope that Matthew will one day return from the world only he fully comprehends. Yet, they are emotionally and financially exhausted from their long journey in search of their son. Moreover, they are worried that they have neglected the needs of their other children and of each other. Forlorn, Matthew's parents now face the most difficult decision of their lives—whether to place Matthew in a residential program where he can receive the constant supervision and care he requires.

Welcome to the world of an autistic child, and to the heartache and sacrifice experienced by those who love him.[2]

For many parents of autistic children, the pain and heartbreak experienced in learning that their child is afflicted with an incurable

[2] Unlike many other medical disorders, autism is extremely difficult to diagnose early in life. *See* Autism Society of America, Understanding Autism: Diagnosis and Consultation, http://www.autism-society.org/site/PageServer?pagename=DiagnosisConsultation (last visited Sept. 2, 2005) [hereinafter Diagnosis and Consultation]. Two children equally afflicted with the disorder may express symptoms in widely different ways. *See* Autism Society of America, Understanding Autism: What Is Autism?, http://www.autism-society.org/site/PageServer?pagename=whatisautism (last visited Sept. 2, 2005) [hereinafter What Is Autism?]. One may be relatively high functioning, while the other may require extensive intervention. *See id.* Matthew, a fictional character, represents a child who exhibits the most common symptoms and behavioral patterns observed in children suffering from autism. For a list of common symptoms and behavioral problems, see *id.*

disorder would likely be eclipsed only by the horror of knowing that it may have been prevented. A growing body of evidence suggests that many children may have developed autism from exposure to toxic concentrations of mercury contained in vaccines routinely administered as part of the government's mandatory vaccination program.[3] More disturbing, perhaps, is the fact that mercury is an unnecessary component that does not contribute to the efficacy of a vaccine; it is added only as a means to prolong a vaccine's shelf life and to maximize profit for vaccine manufacturers.[4]

This Article considers the link between compulsory childhood vaccination and the prevalence of autism in the United States, and comments on the current legal and regulatory framework that shields vaccine manufacturers from liability for vaccine-induced injuries. Part I provides an overview of the etiology of autism and its dramatic increase in the United States. Part II considers the history of compulsory vaccination and its benefits to society. Part III provides an overview of mercury and its known harm to humans, and includes a summary of the actions taken by the federal government to limit human exposure to mercury. Part IV discusses mercury and vaccines and considers the link between mercury in vaccines and the development of childhood autism. Part V provides an overview of the National Vaccine Injury Compensation Program and the unique problems faced by claimants seeking relief for mercury-induced autism. Part VI discusses the federal government's response to the proposed link between mercury exposure and autism. Finally, Part VII provides analysis and recommendations.

I. AUTISM

A. Background

The term autism first appeared in scientific literature in 1943 when psychiatrist Leo Kanner recorded his observations of children between two and eight years old,[5] whom he described as being excessively withdrawn and self-preoccupied.[6] Since then, autism has been the subject of countless studies designed to identify its cause.

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[3] *See* discussion *infra* Parts II, IV.

[4] *See* discussion *infra* Part IV.A.

[5] *See* Leo Kanner, *Autistic Disturbances of Affective Contact*, 2 NERVOUS CHILD 217 (1943).

[6] *See id.* at 242.

While the exact cause remains unknown,[7] studies indicate that autism is a lifelong neurological disorder having many etiologies possibly involving the interaction of genetics, environmental triggers, and other factors.[8] Most experts generally agree that autism results from neurological abnormalities within the central nervous system.[9]

Observations of autistic and non-autistic children show that they have significant differences in brain structure and function.[10] Most autistic children suffer from mild to severe brain dysfunction,[11] manifesting in mild to severe disabilities that impair verbal and nonverbal communication, as well as social skills.[12] Studies have indicated that less than 30% of autistic individuals have normal-range intelligence.[13] Males are four times more likely than females to suffer from autism, which suggests that genes play some role in its development.[14]

B. Prevalence

The incidence of autism is consistent around the world, and is not affected by racial, ethnic, or social boundaries.[15] Currently, no cure exists[16] for the approximately 1.5 million Americans diagnosed with autism,[17] but new research suggests that some children may experience

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[7] *See* What Is Autism?, *supra* note 2.

[8] *See* Neil Risch et al., *A Genomic Screen of Autism: Evidence for a Multilocus Etiology*, 65 AM. J. HUM. GENETICS 493, 493 (1999); Patricia M. Rodier & Susan L. Hyman, *Early Environmental Factors in Autism*, 4 MENTAL RETARDATION & DEVELOPMENTAL DISABILITIES RES. REV. 121, 121 (1998).

[9] *See* What Is Autism?, *supra* note 2.

[10] *See* B.F. Sparks et al., *Brain Structural Abnormalities in Young Children with Autism Spectrum Disorder*, 59 NEUROLOGY 184, 189–90 (2002).

[11] Suzanne Steffenburg, *Neuropsychiatric Assessment of Children with Autism: A Population-Based Study*, 33 DEVELOPMENTAL MED. & CHILD NEUROLOGY 495, 507 (1991) (finding that approximately 90% of autistic individuals studied had evidence of brain abnormality).

[12] *See* Risch et al., *supra* note 8, at 493.

[13] *See* Michelle Dunn, *Neurophysiologic Observations in Autism and Implications for Neurologic Dysfunction*, *in* THE NEUROBIOLOGY OF AUTISM 45, 45 (Margaret L. Bauman & Thomas L. Kemper eds., 1994).

[14] Amy Herman, *Neurobiological Insights into Infantile Autism*, HARV. BRAIN, Spring 1996, at 19, 20.

[15] What Is Autism?, *supra* note 2.

[16] *See* Cure Autism Now, Treating Autism, http://www.cureautismnow.org/kb/supercat/treating/index.jsp (last visited Sept. 4, 2005).

[17] What Is Autism?, *supra* note 2.

limited improvement with timely intervention.[18] Recent reports suggest that the incidence of autism in the United States continues to rise. According to statistics compiled by the Department of Education, between 1992 and 2001 the number of autistic children aged six to twenty-one who were provided with special education services under the Individuals with Disabilities Education Act (IDEA) increased by an average of 544% per state.[19] Studies indicate that the incidence of autism continues to increase at a rate of 10–17% per year nationally,[20] affecting upwards of one of every 250 children.[21] Some researchers estimate that by the end of the next decade, autism may affect nearly four million Americans.[22] Although a part of this increase may be attributed to increased awareness and diagnosis,[23] the dramatic rise seems to suggest that other factors must be involved.

Individuals afflicted with regressive autism (characterized by normal development from birth through the first eighteen to twenty-four months) and late-onset autism (characterized by normal development from birth to three years of age)[24] have shown the most significant prevalence increases in autism. Prior to 1990, roughly two-thirds of children diagnosed with autism were autistic from birth and one-third developed autism sometime

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[18] *See* Ralph Ankenman, Medication in Autistic Children, http://www.madisondoctrine.com/autism.html (last visited Sept. 4, 2005); *see also* Cure Autism Now, *supra* note 16 (discussing dietary and hormonal treatment, and chelation therapy for children poisoned by mercury as possible interventions that may aid autistic children).

[19] *See* The Autism Autoimmunity Project, The United States Autism Epidemic: Our Bitter Harvest, http://www.taap.info/shame.html (last visited Sept. 4, 2005) (identifying the number of children aged six to twenty-one who were provided special education services related to autism under IDEA).

[20] What Is Autism?, *supra* note 2.

[21] NAT'L INST. OF MENTAL HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVS., REPORT TO CONGRESS ON AUTISM 2 (2003), *available at* http://www.nimh.nih.gov/autismiacc/autismreport2003.pdf.

[22] What Is Autism?, *supra* note 2.

[23] *See* The Autism Autoimmunity Project, *supra* note 19.

[24] *See* Autism Spectrum Disorder Fact Sheet, http://peninsulautism.org/factsheet.htm (last visited Sept. 4, 2005); NAT'L INST. OF CHILD HEALTH & HUMAN DEV., U.S. DEP'T OF HEALTH & HUMAN SERVS., AUTISM OVERVIEW: WHAT WE KNOW 5 (2005), *available at* http://www.nichd.nih.gov/publications/pubs/autism_overview_2005.pdf. A sudden and often dramatic loss of language, social, cognitive, and fine motor skills follow each of these types of autism. Autism Spectrum Disorder Fact Sheet, *supra*.

after their first birthday.[25] From the 1990s to present, this trend reversed as less than one-third of autistic children are now diagnosed as such at birth, and more than two-thirds are diagnosed sometime after their second birthday.[26] This indicates that regressive and late-onset forms of autism are most likely caused by exposure to environmental toxins rather than genetic factors.[27]

C. Research Funding

Currently, the annual cost of autism on the United States economy is approximately $90 billion.[28] Based on the number of children diagnosed with autism, and its current projected rate of increase, in five years this cost is expected to approach $400 billion annually.[29] Despite the meteoric rise in the number of children diagnosed with autism, federal funding for autism continues to lag far behind that allocated for research on other diseases.[30] In 2003, the National Institute of Health (NIH) allocated $70.5 million of its nearly $27 billion budget to autism research, but allocated $845 million to diabetes research and more than $2.7 billion to HIV/AIDS

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[25] James B. Adams et al., Advice for Parents of Young Autistic Children (2004) (unpublished working paper), http://puterakembara.org/rm/AdviceForParents.shtml. The statistics were compiled based on the responses to questionnaires completed by thousands of autism families. *Id.*

[26] *Id.*

[27] If genes cause regressive and late-onset autism, then the dramatic increase in both forms of autism observed over the last decade may only be explained by a sudden genetic mutation in the human gene pool. However, there is no evidence to suggest that such a mutation has occurred.

[28] *See* Press Release, Autism Soc'y of Am., Autism Cost to Economy in Billions (June 30, 2003), http://www.autism-society.org/site/News2?news_iv_ctrl=articles&page=NewsArticle&id=5828. The calculation was derived from a study conducted by the London School of Economics in 2001 based on 1.5 million individuals diagnosed with autism. *Id.*; *see also* Centers for Disease Control and Prevention, Fact Sheet: CDC Examines Autism Among Children, http://www.cdc.gov/ncbddd/fact/autism1.htm (last visited Sept. 4, 2005) ("Special education costs for a child with autism are more than $8,000 per year, with some specially structured programs costing about $30,000, and care in a residential school costing $80,000–$100,000 per year.").

[29] *See* Autism Soc'y of Am., *supra* note 28.

[30] STAFF OF S. SUBCOMM. ON HUMAN RIGHTS & WELLNESS, 108th CONG., MERCURY IN MEDICINE: TAKING UNNECESSARY RISKS, 75–76 (Comm. Print 2003) [hereinafter MERCURY REPORT]. The report, which was initiated by the Committee on Government Reform, investigated the risks and harms associated with the use of mercury in vaccines. *See id.* at 3.

research.[31] The Centers for Disease Control and Prevention (CDC) decreased its allocation for autism research from $11.7 million in 2002 to $10.2 million in 2003.[32] However, during the same period, it allocated $933 million to HIV/AIDS research and $62 million to diabetes research.[33]

The failure of federal health agencies to make finding the cause of, or cure for autism a national priority is startling, given autism's prevalence and its long-term economic impact on society. Parents and already under-funded educational systems face ever-increasing pressure to provide proper care for children with autism.[34] With limited exceptions, autistic children require long-term educational accommodation and rehabilitative therapy that may cost upwards of $100,000 per year, or more.[35] State and federal funding has not kept up with the demand for educational and rehabilitative programs for autistic children, not only forcing many parents to make dramatic life changes in order to provide for their children, but also leaving school districts with no choice but to turn an increasing number of autistic children away.[36]

II. COMPULSORY VACCINATION

As early as 1022 AD, Buddhist nuns practiced a primitive form of vaccination to prevent disease by "grind[ing] up scabs taken from a person infected with smallpox into a powder, and then blow[ing the material] into the nostrils of a non-immune person."[37] The majority of those "inoculated," who survived, exhibited immunity to smallpox.[38] Edward Jenner recognized in the late 1700s that milkmaids who developed cowpox

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[31] *Id.*; *see also* OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT OF THE U.S., BUDGET OF THE U.S. GOVERNMENT: FISCAL YEAR 2003, at 143 (2002) [hereinafter FISCAL YEAR 2003 BUDGET].

[32] MERCURY REPORT, *supra* note 30, at 76–77.

[33] *Id.*

[34] *See* Rod Paige, Sec'y, U.S. Dep't of Educ., Remarks at the Autism Summit (Nov. 19, 2003), http://www.ed.gov/news/speeches/2003/11/11192003.html?exp=5.

[35] *See* Centers for Disease Control and Prevention, *supra* note 28.

[36] *See* Paige, *supra* note 34. Paige noted that the U.S. Department of Education provided $9.2 million in funds for autism-related programs. This is woefully inadequate considering the Office of Special Education had $8.5 billion to spend in 2003. *See* FISCAL YEAR 2003 BUDGET, *supra* note 31, at 110.

[37] Heather Brannon, The History of Smallpox: The Rise and Fall of a Disease, http://dermatology.about.com/cs/smallpox/a/smallpoxhx.htm (last visited Sept. 5, 2005).

[38] *See id.*

did not develop the more deadly disease, smallpox.[39] In a highly criticized experiment, Jenner inoculated an eight-year-old boy with pus taken from a cowpox pustule, then exposed the boy to smallpox six weeks later.[40] Miraculously, the boy did not develop smallpox.[41] "Jenner coined the term 'vaccine' from the word 'vaca' [sic] which means 'cow' in Latin."[42] These early experiments led to the development of vaccines that continue to be used by health agencies around the world to control or eradicate disease.[43]

A vaccine is a preparation of weakened or killed pathogenic bacteria or virus known to cause a particular disease, which, once introduced into the human body, stimulates the synthesis of antibodies or cellular immunity to the disease.[44] In some cases, the introduction of the vaccine causes serious adverse effects, including death.[45] Because the percent of the population expected to suffer adverse effects from vaccination is statistically insignificant compared to the percent that will benefit from vaccination,[46] Congress requires every U.S. citizen to prove that he or she has received the full compliment of selected vaccinations to be eligible to attend public school, day care, or to receive federal financial assistance.[47]

Over the past fifty years, this program of compulsory vaccination has contributed to the successful eradication or control of once common deadly

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[39] Bonnie A. Maybury Okonek & Pamela M. Peters, Vaccines—How and Why?, http://www.accessexcellence.org/AE/AEC/CC/vaccines_how_why.html (last visited Sept. 5, 2005).

[40] Brannon, *supra* note 37.

[41] *Id.*

[42] *Id.*

[43] *See* Maybury Okonek & Peters, *supra* note 39.

[44] *See* National Immunization Program, Centers for Disease Control and Prevention, How Vaccines Prevent Disease, http://www.cdc.gov/nip/publications/fs/gen/howvpd.htm (last visited Sept. 5, 2005).

[45] National Immunization Program, Centers for Disease Control and Prevention, Vaccine Side Effects, http://www.cdc.gov/nip/vacsafe/concerns/side-effects.htm (last visited Sept. 5, 2005).

[46] *See id.*

[47] *See* MERCURY REPORT, *supra* note 30, at 3. The CDC and its Advisory Committee for Immunization Practices (ACIP) provide states with a list of recommended vaccinations. National Immunization Program, Centers for Disease Control and Prevention, Recommendations of the ACIP, http://www.cdc.gov/nip/publications/acip-list.htm (last visited Sept. 5, 2005). A citizen may be exempted from compulsory vaccination upon proof of existing immunity, or based on philosophical, religious, or medical reasons. *See* National Vaccine Information Center, Legal Exemptions to Vaccination, http://nvic.org/state-site/legal-exemptions.htm (last visited Sept. 5, 2005).

or debilitating diseases, including diphtheria, tetanus, measles, pertussis, rubella, mumps,[48] and haemophilus influenzae type b.[49] In spite of this success, the efficacy of administering certain vaccines continues to be questioned.[50] Until recently, many of the vaccines administered to children contained toxic levels of mercury, a substance shown to "cause immune, sensory, neurological, motor, and behavioral dysfunctions similar to traits . . . associated with autism."[51] An increasing body of scientific evidence suggests that as a result of the government's compulsory vaccination program, autism may have been induced in thousands of children inoculated with vaccines containing mercury.[52]

III. MERCURY

A. Background

Mercury exists naturally in the environment[53] and is one of the most toxic metals on earth, second only to plutonium.[54] Thousands of tons of mercury are released into the environment annually through degassing of the Earth's crust and oceans,[55] and through human activities such as burning wastes and fossil fuels.[56] Humans are most frequently exposed to mercury in the form of methylmercury (MeHg) contained in fish and dental amalgams.[57] Ingestion of methylmercury is known to result in

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[48] World Health Organization, Immunization, Vaccines and Biologicals: The History of Vaccination (2003), http://www.who.int/vaccines-diseases/history/history.shtml.

[49] Directors of Health Promotion and Education, Haemophilus Influenzae Type b, http://www.astdhpphe.org/infect/hib.html (last visited Sept. 5, 2005).

[50] *See* MERCURY REPORT, *supra* note 30, at 3.

[51] Sallie Bernard et al., *Autism: A Unique Type of Mercury Poisoning*, 56 MED. HYPOTHESES 462, 462 (2001), *available at* http://www.vaccinationnews.com/DailyNews/July2001/AutismUniqueMercPoison.htm.

[52] *See, e.g.*, MERCURY REPORT, *supra* note 30, at 3, 31–32.

[53] Thomas W. Clarkson, *The Toxicology of Mercury*, 34 CRITICAL REVS. CLINICAL LABORATORY SCI. 369, 370 (1997).

[54] Talk About Curing Autism, Mercury-Autism FAQ, http://www.tacanow.com/mercury.htm (last visited Sept. 25, 2005).

[55] Judith E. Foulke, *Mercury in Fish: Cause for Concern?*, 28 FDA CONSUMER, Sept. 1994, at 5, 5–6.

[56] *See* U.S. Environmental Protection Agency, Mercury: Human Exposure, http://www.epa.gov/mercury/exposure.htm (last visited Sept. 5, 2005) [hereinafter Mercury Exposure].

[57] OFFICE OF AIR QUALITY PLANNING & OFFICE OF RESEARCH AND DEVELOPMENT, U.S. ENVTL. PROT. AGENCY, 1 MERCURY STUDY REPORT TO CONGRESS, at 3–22 (1997), *available at* http://www.epa.gov/ttn/oarpg/t3/reports/volume1.pdf [hereinafter MERCURY STUDY].

developmental disorders that manifest in neurological, immune, sensory, motor, and behavioral dysfunctions in humans.[58] Methylmercury is a potent neurotoxin that primarily affects the central nervous system, and is most toxic to the developing brain because of its ability to cross the blood-brain barrier and target nerve cells and nerve fibers.[59] Humans bio-magnify methylmercury in brain tissue at greater concentrations than in any other organ.[60]

B. Federal Concern Regarding Mercury Exposure

As early as 1972, the use of mercury compounds for many industrial processes was banned in the United States based on evidence that mercury "leached into the environment and found its way into the human food chain."[61] In the ensuing years, the government's focus turned to the potential dangers of exposure to mercury contained in over-the-counter health care products.[62] In 1982, the Food and Drug Administration (FDA) reviewed eighteen over-the-counter products including topical ointments, diaper rash creams, and contraceptives that contained the methylmercury-based preservative thimerosal.[63] The review found each of the products to be unsafe or ineffective for their stated purpose of killing bacteria to prevent infections.[64] The study concluded that "thimersal [sic] is not safe for [over-the-counter] topical use because of its potential for cell damage if applied to broken skin and its allergy potential."[65] In response to the study, the FDA issued an advance notice of a proposed rule to "classify over-the-counter (OTC) mercury-containing drug products for topical antimicrobial use" as unsafe and misbranded.[66] Despite no clear opposition from manufacturers, the proposed ban on thimerosal use in non-prescription

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[58] *See* AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, U.S. DEP'T OF HEALTH & HUMAN SERVS., TOXICOLOGICAL PROFILE FOR MERCURY 55, 137, 230 (1999), http://www.atsdr.cdc.gov/toxprofiles/tp46.pdf.

[59] *See* Theodore A. Sarafian et al., *Cellular Resistance to Methylmercury*, 17 NEUROTOXICOLOGY 27, 32–33 (1996); *see also* Thomas W. Clarkson, *Mercury: Major Issues in Environmental Health*, 100 ENVTL. HEALTH PERSP. 31, 35 (1993).

[60] *See* Clarkson, *supra* note 59, at 35.

[61] *See* MERCURY STUDY, *supra* note 57, at 3–8.

[62] *See* Mercury-Containing Drug Products for Topical Antimicrobial Over-the-Counter Human Use; Establishment of a Monograph, 47 Fed. Reg. 436 (proposed Jan. 5, 1982) (to be codified at 21 C.F.R. pt. 333).

[63] *See id.* at 438.

[64] *See id.*

[65] *Id.* at 441.

[66] *Id.* at 436.

health care products was not finalized until 1998, approximately sixteen years later.[67]

Mercury released into the marine environment enters the food chain at the lowest levels and is biomagnified as a result of predation.[68] "The concentrations of methylmercury in large [predacious] fish can be over a million-fold larger than in the surrounding water."[69] Recognizing that many of these fish were marketed to consumers, in 1994 the FDA warned consumers about the risk of eating large quantities of certain marine fish.[70] The publication warned pregnant women to limit their consumption of certain fish because it was unknown how much mercury a developing fetus could tolerate, or what effect consumption of methylmercury had on the developing fetus.[71] It noted that because methylmercury passes through the placenta easily, mercury concentrations in fetal red blood cells are 30% higher than in maternal red blood cells.[72] "[W]hen humans are exposed to high levels of methyl mercury [sic] . . . problems in the nervous system can occur."[73] Seven years later, the FDA issued a safety advisory acknowledging that methylmercury contained in fish can cause harm to an unborn child's developing nervous system, and announced that "the primary danger from methylmercury in fish is to the developing nervous system of the unborn child."[74]

Despite its clear concern for the safety of consumers exposed to mercury through health care products and consumption of fish, the FDA inexplicably approved several new childhood vaccines containing thimerosal during the early 1990s for inclusion in the recommended

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[67] *See* Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients, 63 Fed. Reg. 19,799 (Apr. 22, 1998) (codified at 21 C.F.R. § 310.545(a)(27)–(28), (d)). The text of the final rule states that the agency received no comments or data relating to the safety and effectiveness of mercury-containing drug products in response to its 1982 notice. *Id.*

[68] *See* Mercury Exposure, *supra* note 56.

[69] *Id.*

[70] *See* Foulke, *supra* note 55, at 5.

[71] *See id.* at 7.

[72] *Id.*

[73] *Id.* (quoting Mike Bolger, Ph.D., FDA toxicologist).

[74] Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, An Important Message for Pregnant Women and Women of Childbearing Age Who May Become Pregnant About the Risks of Mercury in Fish (March 2001), http://www.cfsan.fda.gov/~dms/admehg.html.

schedule of childhood vaccination.[75] The FDA approved the new vaccines despite strong evidence of the direct harm caused to cells from the topical application of thimerosal,[76] and without ever requiring the pharmaceutical industry to conduct extensive safety studies on the use of thimerosal in vaccines or its metabolic route through the human body.[77]

C. Federal Safe Reference Dose of Mercury

The Environmental Protection Agency (EPA) has established a safe exposure level, or "reference dose," for methylmercury of 0.1 μg per kilogram of body weight per day.[78] Under this guideline, a ten-pound child (approximately 4.5 kilograms) theoretically could be exposed to 0.45 micrograms of mercury per day without experiencing any harmful effects. The EPA's reference dose is four times as strict as the FDA's reference dose of 0.4 μg per kilogram of body weight per day,[79] and nearly five times as strict as the World Health Organization's (WHO) reference dose of 0.47 μg per kilogram of body weight per day.[80] Under the FDA and WHO standards, the same ten-pound child may safely be exposed to 1.8 and 2.1 micrograms of mercury per day, respectively.

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[75] *See FDA & CDC Bumbling at the Expense of Mercury-Poisoned Children*, VACCINATION NEWS, May 14, 2003, http://www.vaccinationnews.com/DailyNews/2003/June/04/FDA&CDCBumblingAt4.htm. In the early 1990s two new vaccines—Hib and hepatitis B—were added to the routine childhood immunization schedule for vaccines administered to children. *Id.*; *see also* Centers for Disease Control and Prevention, General Recommendations on Immunization, Recommendations of the Advisory Committee on Immunization Practices (ACIP) (Jan. 28, 1994), http://aepo-xdv-www.epo.cdc.gov/wonder/prevguid/p0000348/p0000348.asp (noting that the Hib and hepatitis B vaccines contain thimerosal). The addition of these two vaccines increased the amount of mercury administered to children in the first six months of life from seventy-five micrograms of mercury (three DTP injections) to 187.5 micrograms (three DTP, three Hib, and three hepatitis B injections). *See* Vaccines: Vaccinations and Mercury, http://www.healing-arts.org/children/vaccines/vaccines-mercury.htm (last visited Sept. 12, 2005).

[76] *See* 150 CONG. REC. E1011, E1016 (2003).

[77] *See id.* at E1012.

[78] CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., THIMEROSAL IN VACCINES (2005), http://www.fda.gov/cber/vaccine/thimerosal.htm [hereinafter THIMEROSAL IN VACCINES]. A microgram is denoted as μg.

[79] Mark R. Geier & David A. Geier, *Thimerosal in Childhood Vaccines, Neurodevelopment Disorders, and Heart Disease in the United States*, 8 J. AM. PHYSICIANS & SURGEONS 6, 6 (2003).

[80] THIMEROSAL IN VACCINES, *supra* note 78.

In 2000, the National Academy of Sciences recognized the EPA reference dose as the appropriate standard for assessing risk associated with human exposure to mercury.[81] Notwithstanding its higher margin of error, the EPA reference dose may not be appropriate to adequately assess the risk posed to very young children.[82] In calculating its reference dose, the EPA considered "neurological abnormalities observed in progeny of women who consumed bread prepared from methylmercury-treated seed grain."[83] The reference dose is based on the assumption that mercury has a half-life in the human body of seventy days.[84] However, the study failed to consider that the half-life of mercury lodged in the human brain might actually be measured in years or decades,[85] or that brain tissue absorbs five times more mercury than other tissue.[86] The study also failed to consider the effects of mercury exposure on very young children who are unable to effectively excrete mercury.[87] Further, the reference assumes a mercury-free starting point and does not account for cumulative prenatal or postnatal mercury exposure from the mother.[88] More importantly, the reference dose does not consider how injections of mercury impact the body or its effects on infants genetically susceptible to heavy metal poisoning.[89]

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[81] Press Release, The Nat'l Academies, EPA's Methylmercury Guideline Is Scientifically Justifiable for Protecting Most Americans, but Some May Be at Risk (July 11, 2000), http://www4.nationalacademies.org/news.nsf/isbn/0309071402?opendocument.

[82] *See id.*

[83] 7 MERCURY STUDY, *supra* note 57, at 2–4.

[84] *See id.*

[85] R.J. Hargreaves et al., *Persistent Mercury in Nerve Cells 16 Years After Metallic Mercury Poisoning*, 14 NEUROPATHOLOGY & APPLIED NEUROBIOLOGY 443, 443, 450 (1988).

[86] *See* Thomas W. Clarkson, *The Three Modern Faces of Mercury*, 110 ENVTL. HEALTH PERSP. 11, 12 (Supp. 1 2002) (noting that the concentration of methylmercury in the fetal brain is about five to seven times that in maternal blood).

[87] *See Mercury in Medicine—Are We Taking Unnecessary Risks?: Hearing Before the H. Comm. on Government Reform*, 106th Cong. 177 (2000) [hereinafter *Hearing*]; *see also* Clarkson, *supra* note 86, at 12–13.

[88] *See* Nicolina Sørensen et al., *Prenatal Methylmercury Exposure as a Cardiovascular Risk Factor at Seven Years of Age*, 10 EPIDEMIOLOGY 370, 370, 371, 373 (1999); Philippe Grandjean et al., *Human Milk as a Source of Methylmercury Exposure in Infants*, 102 ENVTL. HEALTH PERSP. 74, 74, 77 (1994).

[89] *See* Bernard Rimland, *Defeat Autism Now! 2002: Progress at Warp Speed!*, 16 AUTISM RES. REV. INT'L (Autism Research Inst., San Diego, Cal.) No. 2, 2002, at 3, http://www.autismwebsite.com/ari/newsletter/daneditorial2002.htm.

D. Mercury Poisoning

The symptoms observed in children who suffer from mercury poisoning are strikingly similar to the symptoms observed in autistic children.[90] In fact, almost every major characteristic of autism has been exhibited in children suffering from mercury poisoning.[91] Children suffering from either malady exhibit psychiatric disturbances; speech, language, and hearing deficits; sensory abnormalities; cognitive impairments; behavioral changes; visual impairments; physical disturbances; imbalances, central nervous system pathology, abnormalities in biochemistry and neurochemistry; and a host of other problems.[92] In addition to neurological damage, mercury poisoning is also associated with a cascade of other health problems, including immune system suppression, gastrointestinal dysfunction, and cardiovascular irregularities similar to those exhibited by autistic children.[93] Individuals suffering from mercury poisoning often experience a long latent period between the time of exposure and the onset of overt symptoms.[94] Because the symptoms of autism are markedly similar to those of mercury poisoning, many scientists believe that inoculation with mercury-based vaccines may represent a significant etiological factor in some forms of autism.[95] In fact, at least one researcher has suggested that autism may be a unique form of mercury poisoning.[96]

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[90] *See* Bernard et al., *supra* note 51, at 462–64.

[91] *See id.*

[92] *Id.* at 463, 465.

[93] *See id.*

[94] *See id.* at 466.

[95] *See, e.g.*, Richard Sadovsky, *Is There a Connection Between Vaccines and Autism?*, 65 AM. FAM. PHYSICIAN 942, 942 (2002) (noting that "regressive autism" may be associated with immunization); David A. Geier & Mark R. Geier, *Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-Up Analysis*, 23 INT'L J. TOXICOLOGY 369, 375 (2004); Mark F. Blaxill et al., *Thimerosal and Autism?: A Plausible Hypothesis that Should not Be Dismissed*, 62 MED. HYPOTHESES 788, 788 (2004).

[96] Bernard, *supra* note 51, at 462.

IV. MERCURY IN VACCINES

A. Background

Vaccines are typically packaged in single or multi-dose vials.[97] In an effort to reduce price and increase shelf life, manufacturers package many of the vaccines routinely administered to children as part of the national immunization program in multi-dose vials.[98] Because multi-dose vials are susceptible to contamination due to repeated puncture of the vial septum, a non-toxic preservative capable of killing or preventing the growth of microbial and viral agents must be added to the vaccine.[99] From its introduction in the mid-1930s until recently, the mercury-based preservative thimerosal has been added to most childhood vaccines.[100]

The identification of autism coincides with the introduction and proliferation of vaccines containing thimerosal.[101] Between 1970 and 1990, a period of increased childhood vaccination with thimerosal-containing DTP vaccines, the incidence of autism increased from approximately 1 in 2,000 to 1 in 1,000.[102] Since the introduction of the thimerosal-containing Hib and hepatitis B vaccines to the routine childhood immunization schedule in the early 1990s, the incidence of autism has increased to approximately 1 in 250 individuals.[103] One epidemiological study found the prevalence of some forms of autism to be as high as 1 in 150 children.[104]

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[97] *See* Paul K. Drain et al., *Single-Dose Versus Multi-Dose Vaccine Vials for Immunization Programmes in Developing Countries*, 81 BULL. WORLD HEALTH ORG. 726, 727 (2003), *available at* http://www.scielosp.org/pdf/bwho/v81n10/v81n10a07.pdf.

[98] *See id.*

[99] *See* 21 C.F.R. § 610.15(a) (2005) (requiring the addition of a non-toxic preservative to multi-dose vials of vaccines); *see also* THIMEROSAL IN VACCINES, *supra* note 78.

[100] THIMEROSAL IN VACCINES, *supra* note 78.

[101] Leo Kanner's initial identification of autism resulted from studying children born in the 1930s, *see* Kanner, *supra* note 5, the same period that thimerosal was introduced. MERCURY REPORT, *supra* note 30, at 10.

[102] *See* David A. Geier & Mark R. Geier, From Epidemiology, Clinical Medicine, Molecular Biology, and Atoms, to Politics: A Review of the Relationship Between Thimerosal and Autism (Jan. 2004), http://www.rhinoed.com/Thimerisol%20and%20 Autism%20Part%201.htm; C. Gillberg & L. Wing, *Autism: Not an Extremely Rare Disorder*, 99 ACTA PSYCHIATRICA SCANDINAVICA 399, 400–01 (1999).

[103] Geier & Geier, *supra* note 102; *see also supra* note 75 and accompanying text.

[104] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, PREVALENCE OF AUTISM IN BRICK TOWNSHIP, NEW JERSEY, 1998: COMMUNITY REPORT (2000), http://www.cdc.gov/ncbddd/ *(continued)*

In 2001, thimerosal was removed from, or reduced to trace amounts in almost all vaccines routinely administered to children in the U.S.[105] Left in the wake of decades of government sponsored mercury poisoning may be thousands of children with mercury-induced autism, or less severe mercury-induced developmental disabilities. Although the removal of thimerosal was a positive step in protecting children, the current regulatory scheme here and abroad is woefully inadequate to address the harm already caused to children through mercury poisoning or to prevent future generations from similar harm. Despite the move away from thimerosal-containing vaccines, no law prevents health agencies from re-introducing thimerosal into pediatric vaccines in the future.[106] While most pediatric vaccines administered to children in the United States today are manufactured in either thimerosal-free or thimerosal-reduced formulations,[107] thimerosal is still added in high concentrations to certain flu vaccines given to pregnant women, the elderly, and to children.[108]

Despite a worldwide increase in the number of children diagnosed with autism,[109] and the ongoing debate regarding the efficacy of adding mercury-based preservatives to childhood vaccines, health agencies around the world continue to vaccinate children with thimerosal-containing vaccines.[110] Due, in part, to the risk of contamination from use of preservative-free vaccines[111] and the lack of definitive evidence demonstrating harm caused by thimerosal,[112] the WHO continues to recommend administering thimerosal-containing vaccines to children.[113]

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dd/report.htm (finding autism in four of every thousand children aged three to ten years, and autism spectrum disorder in 6.7 of every thousand children aged three to ten).

[105] National Vaccine Program Office, Centers for Disease Control and Prevention, IOM Report on Thimerosal-Containing Vaccines and Neurodevelopmental Disorders: Questions and Answers, http://www.hhs.gov/nvpo/vacc_safe/thim-qa.htm (last visited Aug. 31, 2005) [hereinafter IOM Report].

[106] *See* H.R. 881, 109th Cong. § 2(6) (2005).

[107] IOM Report, *supra* note 105. The mercury present in thimerosal-reduced formulations results from the manufacturing process. *Id.*

[108] *See id.*

[109] *See* discussion *supra* Part I.B.

[110] *See, e.g.*, WHO EXPERT COMM. ON BIOLOGICAL STANDARDIZATION, WORLD HEALTH ORG., TECHNICAL REPORT SERIES, FIFTY-THIRD REPORT annex 4, at 95–97 (2004) [hereinafter TECHNICAL REPORT SERIES].

[111] *See* THIMEROSAL IN VACCINES, *supra* note 78.

[112] *See* World Health Org., *Vaccines and Biologicals*, 37 WKLY. EPIDEMIOLOGICAL REC. 305, 306 (2002).

[113] *See id.*

Presumably, the higher cost of single-dose vials[114] has also contributed to this determination. As a result, millions of children remain at risk of mercury poisoning.

B. Amount of Mercury in Childhood Vaccines

When the childhood immunization schedule rapidly expanded to include new vaccines, apparently no one thought to calculate the actual amount of ethylmercury[115] that was added to each vial.[116] This may be because the total amount of thimerosal contained in each vial of vaccine is identified as a mercury derivative, and listed as a small fractional percent of the whole vaccine.[117] However, when that percentage is converted into micrograms, the amount contained in each vial is revealed.[118] For example, several vaccines originally listed the thimerosal content as 0.01%.[119] This is equivalent to 100 micrograms of thimerosal per milliliter of vaccine.[120] Thimerosal is 49.6% ethylmercury (eHg) by weight.[121] Therefore, because a vaccine is typically administered in 0.5 milliliter doses, the actual amount of ethylmercury contained in the dose is twenty-five micrograms.[122] Prior to thimerosal's removal in 2001,[123] several childhood vaccines contained twenty-five micrograms of ethylmercury per

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[114] *See* Drain et al., *supra* note 97, at 727.

[115] Ethylmercury is the type of mercury contained in thimerosal, while methylmercury is the environmental contaminant found in certain fish, for example. National Immunization Program, Centers for Disease Control and Prevention, Mercury and Thimerosal Q & A, http://www.cdc.gov/nip/vacsafe/concerns/thimerosal/faqs-mercury.htm (last visited Sept. 15, 2005) [hereinafter Mercury and Thimerosal Q & A].

[116] *See, e.g.*, MERCURY REPORT, *supra* note 30, at 52 (citing Dr. Halsey, Director of the Institute of Vaccine Safety at Johns Hopkins University).

[117] *Id.*

[118] *See id.*

[119] *See* William M. Egan, Food & Drug Admin., Presentation to the Food and Drug Administration Center for Biologics Evaluation and Research Vaccines and Related Biological Products Advisory Committee: Thimerosal in Vaccines (Sept. 14, 1999), http://www.fda.gov/ohrms/dockets/ac/99/backgrd/3544b1f.pdf.

[120] *See* THIMEROSAL IN VACCINES, *supra* note 78.

[121] Mercury and Thimerosal Q & A, *supra* note 115; *see* Egan, *supra* note 119.

[122] THIMEROSAL IN VACCINES, *supra* note 78.

[123] S.J. James et al., *Thimerosal Neurotoxicity Is Associated with Glutathione Depletion: Protection with Glutathione Precursors*, 26 NEUROTOXICOLOGY 1, 1 (2005).

dose,[124] and several others contained ethylmercury in concentrations exceeding the EPA, FDA, and WHO's reference dose.[125]

As a result of compulsory vaccination prior to 2001, the typical American child was injected with 187 micrograms of ethylmercury by the age of six months.[126] By age two, that amount increased to 237 micrograms.[127] Based on the recommended childhood immunization schedule, on the day of birth a child received a hepatitis B shot containing 12 micrograms of ethylmercury.[128] For a ten-pound baby, that single dose contained more than twenty-five times the EPA's reference dose for mercury.[129] More startling, perhaps, is the fact that physicians routinely administered multiple vaccines in a single day.[130] For example, children injected with both DTP and Hib vaccines in one visit at the age of four months received 50 micrograms of mercury, more than 60 times the EPA reference dose.[131] Because the smallest newborns can weigh significantly less than the largest newborns,[132] the same injections can be considerably more toxic.[133] The accumulation of mercury within the developing

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[124] Vaccines: Vaccinations and Mercury, *supra* note 75.

[125] *See* Neil A. Halsey, *Limiting Infant Exposure to Thimerosal in Vaccines and Other Sources of Mercury*, 282 J. AM. MED. ASS'N 1763, 1763–64 (1999).

[126] *See* Geier & Geier, *supra* note 102.

[127] *See* David A. Geier & Mark R. Geier, *A Two-Phased Population Epidemiological Study of the Safety of Thimerosal-Containing Vaccines: A Follow-Up Analysis*, 11 MED. SCI. MONITOR CR160, CR161 (2005).

[128] *See id.*; *see also* Tim O'Shea, Autism and Mercury: The San Diego Conference (2002), http://www.thedoctorwithin.com/articles/autism_mercury.html (reporting on a lecture given by Stephanie Cave, M.D.).

[129] *See* Halsey, *supra* note 125, at 1763. The EPA reference dose is 0.1 micrograms per kilogram of body weight per day. *Id.* A ten-pound baby weighs 4.5 kg. Thus, under the EPA guidelines, the baby could safely ingest 0.45 micrograms per day. Twelve micrograms is more than twenty-five times that amount.

[130] The National Autistic Society, Briefing on Mercury and Autism, http://www.nas.org.uk/nas/jsp/polopoly.jsp?d=108&a=3227 (last visited Sept. 15, 2005).

[131] *See* O'Shea, *supra* note 128.

[132] *See* Neal A. Halsey, Dir., Inst. for Vaccine Safety, Presentation at a National Vaccine Advisory Committee Workshop on Thimerosal and Vaccines: Perspective on the Use of Thimerosal-Containing Vaccines (Aug. 11–12, 1999), http://www.vaccinesafety.edu/sld010.htm.

[133] *See* Neal A. Halsey, Dir., Inst. for Vaccine Safety, Presentation at a National Vaccine Advisory Committee Workshop on Thimerosal and Vaccines: Perspective on the Use of Thimerosal-Containing Vaccines (Aug. 11–12, 1999), http://www.vaccinesafety.edu/sld011.htm.

nervous system of these children likely caused substantial neurological injury.[134]

There are no federal safety guidelines for exposure to ethylmercury,[135] but studies suggest that ethylmercury is toxicologically similar to methylmercury.[136] In fact, some researchers believe that ethyl-based mercury compounds pose a far greater threat of harm to the developing brain due to their greater ability to penetrate the lipid membrane covering cells.[137] Had the amount of ethylmercury been listed on each vaccine label in micrograms, the true amount administered to children could have been discovered, and its harmful effects eliminated or mitigated much earlier.[138] As a direct result of mandatory childhood immunizations with vaccines containing thimerosal, thousands of U.S. children have been injected with quantities of mercury far in excess of the daily safety thresholds established by the EPA, FDA, and WHO.

C. Time of Administration

Research has demonstrated that childhood exposure to a fixed dose of mercury at two months of age poses a greater potential risk of harm than the same dose administered at six months of age.[139] This is because a six-month-old child weighs more and the brain, the toxin's target organ, is most susceptible to toxic insult from heavy metals during its early development.[140] Moreover, in very young children, the blood-brain barrier remains open, allowing mercury to easily pass into the central nervous system and cause harm.[141] Prior to 2001, the typical American child was

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[134] *See* Arthur Allen, *The Not-So-Crackpot Autism Theory*, N.Y. TIMES, Nov. 10, 2002, § 6 (Magazine), at 66 (citing Dr. Neal Halsey, Director of the Institute for Vaccine Safety at Johns Hopkins University).

[135] THIMEROSAL IN VACCINES, *supra* note 78.

[136] *See* L. Magos et al., *The Comparative Toxicology of Ethyl- and Methylmercury*, 57 ARCHIVES TOXICOLOGY 260, 260 (1985) ("[N]eurological signs and symptoms of methyl- and ethylmercury intoxication are identical.").

[137] *See* MERCURY REPORT, *supra* note 30, at 15–16 (testimony of David Baskin, M.D., Professor of Neurosurgery and Anesthesiology, Baylor College of Medicine).

[138] *See* Allen, *supra* note 134.

[139] Halsey, *supra* note 132.

[140] *Id.*; *see also* Gary J. Myers & Philip W. Davidson, *Prenatal Methylmercury Exposure and Children: Neurologic, Developmental, and Behavioral Research*, 106 ENVTL. HEALTH PERSP. 841, 842 (Supp. 3 1998).

[141] *See* Patricia M. Rodier, *Developing Brain as a Target of Toxicity*, 103 ENVTL. HEALTH PERSP. 73, 75 (Supp. 6 1995).

poisoned through injection of toxic concentrations of mercury several times by six months of age due to compulsory vaccination.[142]

The amount of mercury injected into a child as a result of mandatory immunization may be devastating to a brain going through rapid, complex, and critical developmental changes.[143] Mercury's affect "on the developing brain differs in both mechanism and outcome from its action on the mature organ."[144] Studies reveal that prenatal mercury exposure affects the most basic processes in brain development.[145] This can result in severe brain damage, manifestations of neurological abnormalities, or delayed neurological development.[146] Certain children genetically incapable of metabolizing heavy metals as effectively as other children are particularly vulnerable to brain injury.[147] Further, because "bile production is minimal in infancy," young children have decreased ability to excrete metals from the body.[148] As a result, introduced mercury remains in the body of a child longer than in an adult, greatly increasing its potential to cause damage.[149] "When added to a vaccine, [the mercury is] even more dangerous because the vaccines trigger immune reactions that increase the permeability of the [gastrointestinal] tract and blood brain barrier,"[150] allowing for greater absorption of the mercury in critical organs.

D. Studies Linking Autism to Vaccine Administration

The first symptoms of some types of autism often appear around the same time children are vaccinated.[151] This fact, and the fact that vaccines

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[142] Vaccines: Vaccinations and Mercury, *supra* note 75; *see also* Leslie K. Ball et al., Ctr. for Biologics Evaluation & Research, U.S. Food & Drug Admin., Presentation at an Institute of Medicine Workshop, Risk Assessment of Thimerosal in Childhood Vaccines (July 16, 2001), http://www.iom.edu/subpage.asp?id=7465.

[143] *Hearing*, *supra* note 87, at 176 (statement of Dr. Stephanie Cave). *See generally* Rodier, *supra* note 141 (discussing why the developing central nervous system is particularly susceptible to toxins).

[144] Clarkson, *supra* note 86, at 13.

[145] *Id.* at 14.

[146] *Id.*

[147] Rimland, *supra* note 89, at 3.

[148] *Hearing*, *supra* note 87, at 177 (statement of Dr. Stephanie Cave).

[149] *See id.* at 176.

[150] *Id.*

[151] *See* National Immunization Program, Centers for Disease Control and Prevention, MMR Vaccine and Autism (Measles, Mumps, and Rubella) Fact Sheet, http://www.cdc.gov/nop/vacsafe/concerns/autism/autism-mmr-mmr-facts.htm ("[S]igns of autism may appear at around the same time children receive the MMR vaccine.").

are typically administered to children on the same schedule nationally,[152] has led many to postulate that there is a link between inoculation with mercury-containing vaccines and the development of autism,[153] a theory vaccine manufacturers[154] and federal health agencies[155] categorically deny.

Studies investigating the link between mercury in vaccines and autism have produced mixed results. In the 1990s, the CDC conducted two autism prevalence studies in Atlanta and Brick Township, New Jersey.[156] Each of the studies produced results showing a dramatic increase in the rate of autism among children.[157] Despite a request by the Brick Township study participants, the CDC failed to consider the possible link between autism and immunization.[158]

In 1999, a California study reported that the number of reported cases of autism in that state grew by 273% between 1987 and 1998,[159] and concluded that the increase could not be explained by changes in diagnostic criteria or better diagnoses.[160] These and other studies provide evidence of a dramatic spike in the incidence of autism, but they do not reveal the whole picture. For example, the California study included only those children that had been professionally diagnosed with level one DSM-IV autism[161]—the most severe cases of autism.[162] The studies do not

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[152] *See* Ctrs. for Disease Control & Prevention, *Recommended Childhood and Adolescent Immunization Schedule—United States 2005*, 53 MORBIDITY & MORTALITY WKLY. REP. Q-1, Q-2 (2005).

[153] *See, e.g.*, *Hearing*, *supra* note 87, at 176–77; Geier & Geier, *supra* note 102.

[154] *See* Mark Benjamin, *UPI Investigates: The Vaccine Conflict*, UNITED PRESS INT'L, July 21, 2003, http://www.upi.com/view.cfm?StoryID=20030718-012134-4422r.

[155] Gardiner Harris & Anahad O'Connor, *On Autism's Cause, It's Parents vs. Research*, N.Y. TIMES, June 25, 2005, at A1.

[156] *See* CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 104; Marshalyn Yeargin-Allsopp et al., *Prevalence of Autism in a US Metropolitan Area*, 289 J. AM. MED. ASS'N 49, 53 (2003). The study was conducted by scientists from the CDC's Center on Birth Defects and Developmental Disabilities. *Id.* at 49.

[157] CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 104; Yeargin-Allsopp et al., *supra* note 156, at 53.

[158] *See* MERCURY REPORT, *supra* note 30, at 28. The CDC determined that the evidence was inconclusive as to the cause of the rise in autism. *Id.*

[159] M.I.N.D. INST., REPORT TO THE LEGISLATURE ON THE PRINCIPAL FINDINGS FROM THE EPIDEMIOLOGY OF AUTISM IN CALIFORNIA: A COMPREHENSIVE PILOT STUDY 2 (2002), http://www.ucdmc.ucdavis.edu/mindinstitute/newsroom/study_final.pdf.

[160] *Id.* at 5.

[161] *See id.* at 3.

address those individuals with less severe forms of autism spectrum disorder, such as pervasive developmental disorder (PDD), pervasive developmental disorder not otherwise specified (PDD-NOS), or Asperger's Syndrome, which also result from neurological injury.[163]

In June 2000, the CDC held an internal meeting to discuss a study conducted by then-CDC employee, Dr. Thomas Verstraeten, which linked mercury in vaccines to neurological damage.[164] The study identified a significant correlation between the injection of thimerosal-containing vaccines and neurological injury, and noted that "the risks of tics, ADD, language and speech delays, and developmental delays in general may be increased by exposures to mercury from thimerosal-containing vaccines during the first six months of life."[165] Notably, the study found that children receiving vaccines containing thimerosal were 2.48 times more likely to develop autism than children who were not vaccinated.[166] This rate is significant because federal courts have acknowledged that in vaccine cases, a relative risk greater than 2.0 establishes that there is a greater than 50% chance that the injury was caused by the vaccine.[167] Dr. Verstraeten's study, thus, suggested a clear connection between thimerosal and autism. Remarkably, the study was never released to the public.[168] An independent study conducted using the same Vaccine Safety Datalink employed in the Dr. Verstraeten's study found that "children are [twenty-seven] times more likely to develop autism after exposure to three

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[162] *See* Martin L. Kutscher, Autistic Spectrum Disorders: Sorting It Out 5–7, 18, http://www.pediatricneurology.com/aspergers.pdf (last visited Sept. 17, 2005).

[163] *See id.* at 5–6.

[164] *See* MERCURY REPORT, *supra* note 30, at 36 & n.86 (referencing a closed meeting among members of the CDC, FDA, Advisory Committee on Immunization Practices (ACIP), and the pharmaceutical industry to discuss an internal study that found a significant statistical correlation between vaccination with thimerosal-containing vaccines and neurological conditions associated with autism).

[165] *Id.* at 36–37 (quoting Dr. Thomas Verstraeten).

[166] Thomas Verstraeten et al., Thimerosal VSD Study Phase 1 Update (Feb. 29, 2000), http://nomercury.org/science/documents/ThimerosalVSDstudy_2-29-00.pdf (referring to children exposed to 62.5 μg of thimerosal by the age of three months).

[167] *See* Cook v. United States, 545 F. Supp. 306, 308 (N.D. Cal. 1982).

[168] MERCURY REPORT, *supra* note 30, at 36 n.86; *see also* Harris & O'Connor, *supra* note 155 ("Parent groups, led by SafeMinds, replied that documents obtained from the disease control centers showed that early versions of the study had found a link between thimerosal and autism.").

thimerosal-containing vaccines" than children who receive the same number of thimerosal-free versions.[169]

In 2001, the Institute of Medicine (IOM) studied the hypothesis that inoculations with thimerosal-containing Measles, Mumps, and Rubella (MMR) vaccine is causally associated with the development of autistic spectrum disorders (ASD).[170] The IOM found that there is a statistically significant relationship between thimerosal exposure and a list of neurodevelopmental delays, and that the correlation is dose related.[171] However, it concluded that the evidence favored rejection of a causal relationship between MMR vaccination and the development of autism.[172] The study noted, however, that the causal relationship between childhood thimerosal exposure and the development of autism is biologically plausible.[173] In 2004, the IOM reevaluated the issue in light of new epidemiological evidence but again concluded that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism."[174] Based on the IOM studies, federal agencies refuse to acknowledge a link between vaccination and the development of autism.[175]

A recent study indicates that postnatal exposure to thimerosal can lead to the development of autism-like damage in autoimmune-disease-susceptible mice.[176] The study is significant because it represents the first animal model study evaluating the effects of the administration of low-dose ethylmercury on the developing nervous system.[177] The results from this and other recent studies[178] provide the strongest evidence to date that

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[169] Press Release, Nat'l Autism Ass'n, CDC Data Leads Scientists to Shocking Discovery (Feb. 9, 2004), http://www.nationalautismassociation.org/press2-06-04.php.

[170] *See* IMMUNIZATION SAFETY REVIEW COMM., INST. OF MED., IMMUNIZATION SAFETY REVIEW: THIMEROSAL-CONTAINING VACCINES AND NEURODEVELOPMENTAL DISORDERS 95–96 (Kathleen Stratton et al. eds., 2001).

[171] *See id.* at 4.

[172] *Id.* at 103.

[173] *Id.* at 100.

[174] IMMUNIZATION SAFETY REVIEW COMM., INST. OF MED., IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 7 (2004).

[175] *See* Harris & O'Connor, *supra* note 155.

[176] *See* M. Hornig et al., *Neurotoxic Effects of Postnatal Thimerosal Are Mouse Strain Dependent*, 9 MOLECULAR PSYCHIATRY 833, 833 (2004).

[177] *See id.* at 842.

[178] *See, e.g.*, Geier & Geier, *supra* note 127, at CR160 (finding that exposure to mercury from thimerosal-containing vaccines administered in the U.S. "was a consistent significant risk factor for the development of [neurodevelopmental disorders]"); Mark F. Blaxill et al., *supra* note 95.

injection with a small dose of ethylmercury can lead to behavioral and neurological changes in the developing brain, and provide strong support for the theory that autism may result, in part, from mercury poisoning through vaccination.

V. NATIONAL VACCINE INJURY COMPENSATION PROGRAM

A. Background

Because some individuals will suffer adverse effects or death from the introduction of a pathogen into their bodies, vaccines are generally considered unavoidably unsafe—incapable of being made completely safe no matter how carefully they are manufactured.[179] As such, manufacturers that place properly prepared, but unavoidably unsafe vaccines on the market are subject to liability for injuries resulting from their use only where "the potential harmful effects of the product outweigh the legitimate public interest in its availability."[180] Despite this fact, many vaccine manufacturers have been sued by those injured by vaccines.[181]

Congress enacted the National Childhood Vaccine Injury Act of 1986[182] (Vaccine Act) to quell drug company threats that they would stop making vaccines without liability protection,[183] and in recognition of a need to balance the benefit of compulsory vaccination with its inherent risk.[184] To implement the Vaccine Act, Congress established the National Vaccine Injury Compensation Program (VICP).[185] The VICP was established to ensure a steady supply of vaccines by insulating manufacturers from tort liability, stabilizing vaccine costs, and providing adequate compensation for those individuals who suffer injury from vaccine-related injuries.[186] The VICP is designed to provide an expedient

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[179] *See* H.R. REP. No. 99-908, pt. 1, at 6 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6346–47; *see also* Swayze v. McNeil Labs., Inc., 807 F.2d 464, 468 (5th Cir. 1987).

[180] *Swayze*, 807 F.2d at 468.

[181] *See* discussion *infra* Part V.E.1–5.

[182] Pub. L. No. 99-660, §§ 301–23, 100 Stat. 3755 (1986) (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2000)).

[183] *See* H.R. REP. NO. 99-908, at 6–7.

[184] *See id.* at 7.

[185] 42 U.S.C. § 300aa-10 (2000).

[186] *See* Health Resources and Services Administration, U.S. Department of Health and Human Services, National Vaccine Injury Compensation Program (VICP), http://www.hrsa.gov/osp/vicp/ (last visited Dec. 12, 2004) [hereinafter VICP].

"no-fault alternative to the traditional tort system."[187] The Program applies to injuries proven to result from any of the vaccines the CDC recommends for routine administration to children.[188]

B. Implementation of the VICP

The Department of Health and Human Services (HHS), the Department of Justice (DOJ), and the "Vaccine Court," a special tribunal of the United States Court of Federal Claims, jointly administer the VICP.[189] Individuals who suffer injury through vaccination and who seek more than $1,000 in damages are required to seek compensation under the Vaccine Act.[190] Qualified claimants must file a petition for compensation with the Vaccine Court before filing a state or federal civil action against a vaccine manufacturer.[191] Such claims must be filed within twenty-four months of a vaccine-related death[192] and within thirty-six months of "the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [a vaccine-related] injury."[193] A special master appointed by the court hears each claim and determines whether compensation is warranted.[194] The decision of the special master may be appealed to the Court of Federal Claims and then to the Federal Circuit Court of Appeals.[195] Claimants may elect to accept the award authorized

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[187] *Id.*; *see also* Shalala v. Whitecotton, 514 U.S. 268, 269 (1995) (noting that the Vaccine Act "establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system").

[188] *See* VICP, *supra* note 186.

[189] *Id.*

[190] *See* 42 U.S.C. § 300aa-11(a)(2)(A) (2000) ("No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . , and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death . . . .").

[191] *See id.* § 300aa-11(a)(1)–(2)(A).

[192] *Id.* § 300aa-16(a)(3).

[193] *Id.* § 300aa-16(a)(2).

[194] *Id.* § 300aa-12(d)(1), (3)(A).

[195] *Id.* § 300aa-12(e)–(f).

by the court or file a civil action.[196] State and federal courts are required to dismiss vaccine-related claims that have not first been presented to the Vaccine Court for consideration and to dismiss those filed after expiration of the Act's statute of limitation.[197]

C. Qualified Claimants Under the VICP

To be eligible for compensation under the VICP, a claimant must demonstrate five essential circumstances. First, the claimant must have received one of the vaccines listed on the Vaccine Injury Table.[198] Second, that vaccine must have been received or manufactured in the United States.[199] Third, the claimant must have sustained one of the injuries associated with the vaccine, as set forth on the Vaccine Injury Table.[200] Fourth, the claimant must have suffered residual effects for more than six months after receiving the vaccine.[201] Finally, the claimant cannot have previously received compensation for the injury.[202]

The Vaccine Injury Table is a list of selected vaccines, specific injuries or conditions causally related to vaccination, and the time frames in which the injury or condition must occur after vaccine administration for a claimant to be eligible for compensation under the Act.[203] The Table includes all vaccines routinely administered to children.[204]

Entitlement to compensation may be demonstrated by introducing proof of actual causation or by showing by a preponderance of the evidence that the first symptom or manifestation of the onset of the injury occurred within the Table's allowable time period after vaccination.[205] If a claimant demonstrates that the first symptom occurred within the time period identified in the Table, he or she is entitled to a presumption that the

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[196] *Id.* § 300aa-21(a). The claimant may make this election after the decision of either the Court of Federal Claims or the Circuit Court of Appeals, depending on the action taken. *Id.*

[197] *See id.* § 300aa-11(a)(2)(B).

[198] *Id.* § 300aa-11(c)(1)(A).

[199] *Id.* § 300aa-11(c)(1)(B).

[200] *Id.* § 300aa-11(c)(1)(C).

[201] *Id.* § 300aa-11(c)(1)(D).

[202] *Id.* § 300aa-11(c)(1)(E).

[203] *Id.* § 300aa-14(a).

[204] *See* 42 U.S.C. § 300aa-14(a), (e)(2).

[205] *Id.* § 300aa-13(a)(1)(A) (noting that compensation shall be awarded where the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by § 300aa–11(c)(1)).

vaccine caused the injury.[206] Once the presumption is created, the petitioner may seek compensation for the injury or aggravation and for any acute complication or sequela of the illness, disability, injury, or condition, to the extent that it is shown they result from the aggravation.[207] The Secretary of Health and Human Services, as respondent, may rebut this presumption by demonstrating through a preponderance of the evidence that the injury complained of resulted from factors unrelated to the administration of the vaccine, such as infection, toxins, trauma, or metabolic disturbances that are not related to the vaccine involved.[208]

D. Awards Under the VICP

The VICP is funded through a $0.75 per dose excise tax charged against vaccine manufacturers.[209] The revenue from the tax is deposited into a federal trust fund to compensate successful claimants.[210] Awards to the estate in a vaccine-related death case are limited to $250,000, plus attorney's fees and costs.[211] However, there is no cap on the amount of compensation that may be awarded to an individual injured as the result of receiving a vaccine listed in the Table.[212] An award may cover all actual and projected expenses that have been or will be incurred by or on behalf of the victim for "rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and services expenses, . . . and facilities determined to be reasonably necessary."[213]

Through 2002, the average award under the program totaled $824,463 per injured claimant.[214] Despite VICP's lower burden of proof, few claimants have been successful in linking their injuries to vaccination; of the nearly 8,000 claims filed since the inception of the program,

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[206] Cucuras v. Sec'y of the Dep't of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

[207] *See* 42 U.S.C. § 300aa-15(a)(1)(A).

[208] *See id.* § 300aa-13(a)(1)(B)–(2)(A).

[209] 26 U.S.C. § 4131(b)(1) (2000).

[210] *Id.* § 9510(a)–(b)(1), (c)(1)(A).

[211] 42 U.S.C. § 300aa-15(a)(2), (e).

[212] *See id.* § 300aa-15(a)(1)(A)–(B).

[213] *Id.* § 300aa-15(a)(1)(B)(iii).

[214] *See* Health Resources and Services Administration, U.S. Department of Health and Human Services, Commonly Asked Questions About the National Vaccine Injury Compensation Program, http://www.hrsa.gov/osp/vicp/qanda.htm (last visited Sept. 17, 2005).

approximately 20% have resulted in an award.[215] No court has awarded compensation to a victim of vaccine-induced autism.[216]

E. Unique Problems of Autism Claims

Injuries alleged to have resulted from the administration of mercury-containing vaccines are considered vaccine–related injuries;[217] thus, claimants must first file a petition for compensation in the Vaccine Court.[218] However, the Vaccine Table does not list autism as a disorder causally linked to vaccination,[219] and the onset of the first symptom that triggers the running of the statute of limitations under the Act remains largely a matter of speculation.

Autism is very difficult to detect early in life because no single symptom is indicative of the disorder,[220] and many commonly observed symptoms are often exhibited by children suffering from other unrelated conditions.[221] Children with the same clinical diagnosis may exhibit widely different characteristics, act very differently from one another, and demonstrate varying skills.[222] Due to the mystery surrounding the disorder, approximately half of all children with autism are not diagnosed until they are between the ages of four and six.[223] Parents of children with autism are often incapable of discovering that their child suffers from autism until multiple symptoms combine to indicate its presence.[224] This makes it exceedingly difficult to timely file a claim under the VICP.[225] The first indication of a developmental disorder, although not directly linked to autism, may in fact be used to bar a claim as untimely if the parent failed to

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[215] *See* Press Release, National Vaccine Information Center, Vaccine Safety Group Calls Liability Protection with No Compensation for the Vaccine Injured "Heartless" (Jan. 17, 2003), http://www.909shot.com/PressReleases/pr011703.htm ("Since the VICP has been in operation, there have been 7,580 applications by victims of childhood vaccinations and 1,783 awards for a total of $1.4 billion.").

[216] *See* discussion *infra* Parts III–V.

[217] Laughter v. Aventis Pasteur, Inc., 291 F. Supp. 2d 406, 410–11 (M.D.N.C. 2003).

[218] 42 U.S.C. § 300aa-11(a)(2)(A).

[219] *See id.* § 300aa-14(a).

[220] Autism Society of America, Common Characteristics of Autism, http://www.autism-society.org/site/PageServer?pagename=autismcharacteristics (last visited Aug. 29, 2005).

[221] Diagnosis and Consultation, *supra* note 2.

[222] Autism Society of America, *supra* note 220.

[223] Daniel Yee, *CDC Seeks Earlier Detection of Autism, Developmental Disorders*, ASSOCIATED PRESS, Feb. 21, 2005, http://abcnews.go.com/Health/wireStory?id=518699.

[224] *See* Diagnosis and Consultation, *supra* note 2.

[225] *See* 42 U.S.C. § 300aa-16(a)(2)–(3) (2000).

bring an action within three years from the date the symptom was observed.[226] Because of the difficulty of detecting autism and the time between vaccination and diagnosis, the statute of limitations often expires long before the link between these two events is realized. As a result, many claims brought on behalf of autistic children have been forever barred through the passage of the Act's limitation period, forcing many parents to either make dramatic life changes to pay for treatment and intervention programs, or to bypass treatment entirely.

To avoid the harsh result of discovering a compensable injury too late, claimants have advanced a number of liability theories for mercury-related injuries based on narrow exceptions to the Vaccine Act. These claims have alleged that (1) thimerosal is an adulterant or contaminant and therefore claims associated with thimerosal-related injuries are not covered by the Vaccine Act;[227] (2) vaccines containing thimerosal are improperly designed and provided to the public with insufficient warning;[228] (3) the Vaccine Act is unconstitutional as applied to children with autism;[229] (4) the possible link between mercury and autism warrants long-term medical monitoring for broad populations of children who were exposed to toxic quantities of mercury in vaccines;[230] and (5) due to the passage of time between vaccination and the onset of autism, children suffering from mercury-induced autism are not "qualified litigants."[231] Claims for loss of consortium, loss of service, and emotional distress are not required to be filed in Vaccine Court.[232]

1. Thimerosal: Adulterant or Contaminant?

The Vaccine Act does not apply where an injury or death is the result of an adulterant or contaminant intentionally added to a vaccine.[233] In an effort to revive a claim barred under the Act by passage of the statute of limitations, parents of autistic children have filed state and federal lawsuits asserting that because mercury is toxic, the thimerosal contained in

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[226] *See id.* § 300aa-16(a)(2).

[227] *See* discussion *infra* Part V.E.1.

[228] *See* discussion *infra* Part V.E.2.

[229] *See* discussion *infra* Part V.E.3.

[230] *See* discussion *infra* Part V.E.4.

[231] *See* discussion *infra* Part V.E.5.

[232] Moss v. Merck & Co., 381 F.3d 501, 505 (5th Cir. 2004).

[233] 42 U.S.C. § 300aa-33(5) (2000).

vaccines is an adulterant or contaminant.[234] The Act does not define adulterant or contaminant, but incorporates each term as applied under the federal Food, Drug, and Cosmetic Act (FDCA).[235] Under the FDCA, a drug is deemed to be adulterated, *inter alia,* if it has not been packaged in accordance with "good manufacturing practice[s],[236] . . . if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health,"[237] or if any substance has been "mixed or packed therewith so as to reduce its quality or strength."[238]

The HHS has asserted that the terms adulterant and contaminant "do not include any component [or] ingredient listed in a vaccine's product license application and product label."[239] Every court to address this issue has ruled that thimerosal is a constituent material, because it was an intended and approved component of the vaccine.[240] Therefore, courts have held that children who sustain a vaccine–related injury for injuries resulting from the administration of thimerosal-containing vaccines are proper claimants under the Vaccine Act and are required to file a petition with the Vaccine Court.[241]

Mercury is a deleterious or poisonous substance.[242] As such, under the FDCA, mercury is considered an adulterant when added to cosmetics or

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[234] *E.g.*, Cheskiewicz v. Aventis Pasteur, Inc., 843 A.2d 1258, 1265 (Pa. Super. Ct. 2004).

[235] Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680, at *17 (Fed. Cl. Oct. 11, 2002).

[236] 21 U.S.C. § 351(a)(2)(B) (2000).

[237] *Id.* § 351(a)(3).

[238] *Id.* § 351(d).

[239] Emily Marcus Levine, U.S. Dep't. of Health and Human Servs., Presentation: Thimerosal/Autism Litigation: Recent Trends, Decisions & Legislation (Feb. 5, 2003), http://www.hhs.gov/nvpo/meetings/feb2003/levine.ppt.

[240] *See* Cheskiewicz v. Aventis Pasteur, Inc., 843 A.2d 1258, 1265–66 (Pa. Super. Ct. 2004) (noting that every federal court to have ruled on the issue has held that injuries resulting from thimerosal in vaccines are vaccine-related).

[241] *E.g.*, Moss v. Merck & Co., 381 F.3d 501, 504 (5th Cir. 2004); Wax v. Aventis Pasteur, Inc., 240 F. Supp. 2d 191, 193–94 (E.D.N.Y. 2002) (citing Health Resources and Services Administration, U.S. Department of Health and Human Services, Commonly Asked Questions About the National Vaccine Injury Compensation Program, http://www.hrsa.gov/osp/vicp/qanda.htm#17 (last visited Sept. 18, 2005)); Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680, at *5; Troxclair v. Aventis Pasteur, Inc., 864 A.2d 1147, 1151 (N.J. Super. Ct. App. Div. 2005).

[242] *See* discussion *supra* Part III.D.

food.[243] Interestingly, however, it is not considered an adulterant or contaminant when added to prescription drugs, including vaccines.[244] Manufacturers, healthcare agencies, and courts have justified this result based on the theory that drugs cannot be made entirely safe and still achieve the desired result.[245] In essence, there has been collective acceptance of the risk posed from including a toxic component in a drug where its benefit to society outweighs the harm that results from its use.[246] While this basis for protecting manufacturers from liability for adding toxic components to drugs may have merit where inclusion of the component adds to the efficacy of a drug, it fails where only financial benefit is derived from its use and where the component's beneficial bacteriostatic properties can be obtained through use of a non-toxic alternative.

Thimerosal was listed as a component part of several vaccines,[247] and an approved constituent of the vaccine.[248] However, several facts suggest finding that thimerosal is an adulterant or contaminant. First, it is a non-essential component of a vaccine and does nothing to promote the desired effect of the vaccine.[249] Mercury is an adulterant in cosmetics and food because it is a non-essential ingredient, and because the harm that results from its inclusion is not offset by any measurable benefit. Similarly, the known harm caused by mercury exposure is not offset by the bacteriostatic properties of thimerosal. Other mercury-free preservatives having similar properties could have been used to protect against contamination.[250] Second, federal health agencies have known for decades that mercury is a

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[243] *See* 21 U.S.C. § 361(a) ("A cosmetic shall be deemed to be adulterated [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof . . . ."); § 342(a)(1) ("A food shall be deemed to be adulterated [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . .").

[244] *See id.* § 351; *Leroy*, 2002 WL 31730680, at *17 (finding that thimerosal is not an adulterant in a vaccine using the FDA's definition of an adulterant of a drug).

[245] *See* H.R. REP. NO. 99-908, pt. 1, at 6 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6346 (discussed *supra* notes 180–81 and accompanying text).

[246] *See* Swayze v. McNeil Labs., Inc., 807 F.2d 464, 468 (5th Cir. 1987).

[247] Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health, Components of Vaccines, http://www.vaccinesafety.edu/components.htm (last visited Sept. 27, 2005).

[248] *See* Owens v. Am. Home Prods. Corp., 203 F. Supp. 2d 748, 755 n.10 (S.D. Tex. 2002) (citing 21 C.F.R. § 610.15 (2002)).

[249] MERCURY REPORT, *supra* note 30, at 64.

[250] *Id.* at 69–70.

cumulative toxin that causes substantial damage to the central nervous system,[251] yet they have elected to vaccinate children with mercury-containing vaccines at a critical stage of their development.[252] Third, the FDA approved the use of thimerosal in vaccines without ever calculating the actual amount of mercury contained in each dose administered to children.[253] It is now known that the amount of mercury contained in each dose administered to children exceeded all federal safety guidelines several times over.[254]

The addition of thimerosal to vaccines exposed hundreds of thousands of children to mercury poisoning,[255] likely manifesting in a cascade of mild to severe injuries that otherwise would not have occurred through use of the vaccine alone. This demonstrates that the addition of thimerosal reduced the quality of the vaccine administered. Fourth, the amount of mercury contained in each dose was never properly identified on the vaccine's label, providing physicians with insufficient information to assess the harm associated with vaccination.[256] There can be little doubt that had physicians been properly informed regarding the concentration of mercury contained in pediatric vaccines, they would have demanded thimerosal-free vaccines earlier and switched to single dose vials that did not contain thimerosal.[257]

The manufacture and approval of thimerosal-containing vaccines for use in childhood immunization, with full knowledge of the harm caused by mercury exposure, violated a federal law that mandates that "[a]ny preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient."[258] To permit manufacturers and federal health agencies to avoid liability based on their own inadequate disclosure of the risk posed by use of thimerosal-containing vaccines is simply unconscionable. Federal health agencies have avoided liability for their negligence based on canons

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[251] *See id.* at 4.

[252] *See* Ctrs. for Disease Control & Prevention, *supra* note 152, at Q-2.

[253] *See* Allen, *supra* note 134.

[254] *See* MERCURY REPORT, *supra* note 30, at 7.

[255] *Supra* notes 126–29 and accompanying text.

[256] *See supra* note 138 and accompanying text.

[257] *See, e.g.*, Allen, *supra* note 134.

[258] 21 C.F.R. § 610.15 (2005).

of statutory construction that permit courts to defer to an agency's interpretation of a statute it is charged with administering.[259]

Based on the failure of federal health agencies to address the harm posed through the addition of thimerosal to vaccines, courts interpreting the Vaccine Act and the FDCA should ignore the self-serving interpretations of federal agencies and look to the plain meaning of the terms used.

2. Design Flaw and Failure to Warn

Generally, a vaccine is considered unavoidably unsafe and incapable of being made completely safe no matter how carefully it is manufactured.[260] This principle reflects the fact that the pathogen, whether dead or weakened, is a biological organism capable of triggering a life-threatening immune response in certain individuals.[261] It is not possible to alter the structure of the pathogen to make it acceptable to all individuals and maintain the immunological benefits provided by its introduction.[262]

Courts reviewing vaccine injury claims have interpreted the provisions of the Vaccine Act to bar claims against vaccine manufacturers based on strict liability or negligence, design defect, and failure to warn theories of liability.[263] Although factually different, each decision suffers from the same logical fallacy, i.e., applying the terms of the Vaccine Act to bar a claim based on a risk that Congress never accepted. In mandating childhood vaccination, Congress was well aware that a certain percentage of the population would suffer adverse effects or even death from the introduction of a dead or weakened pathogen but accepted the risk based on the potential health benefits vaccination provided to society.[264] Congress never considered or accepted the risk posed by non-essential,

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[259] *See* Chevron U.S.A. Inc. v. National Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (noting that the Court has "long recognized that considerable weight should be accorded to an execute department's construction of a statutory scheme it is entrusted to administer").

[260] *See* H.R. REP. NO. 99-908, at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367 (noting that the Committee intended that the principle in Restatement (Second) Torts Section 402A, comment k, regarding "unavoidably unsafe" products apply to the vaccines covered, and that such products not be the subject of liability in the tort system).

[261] *See supra* notes 179–80 and accompanying text.

[262] *See supra* notes 179–80 and accompanying text.

[263] *See, e.g.*, Mead v. Aventis Pasteur, Inc., No. CV01-1402-BR, 2002 WL 31973718, at *2 (D. Or. June 7, 2002); Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680, at *3, *9 (Fed. Cl. Oct. 11, 2002).

[264] *See* MERCURY REPORT, *supra* note 30, at 4.

mercury-based preservatives added to vaccines. In fact, Congress specifically mandated that any preservative added to a vaccine must not be toxic to its recipient.[265] While the vaccine alone may not be considered defective, the addition of thimerosal renders the combined product defective because the risk posed by the introduction of mercury is completely avoidable, and any benefit derived is outweighed by the harm caused by its use.

Some courts have held that the Vaccine Act does not bar suits against thimerosal manufacturers directly.[266] However, other courts have effectively precluded recovery from manufacturers by holding that a developer, inventor, and patent holder of thimerosal has no ongoing duty to warn of alleged dangers of thimerosal added to vaccines that are distributed and sold by others.[267]

3. Unconstitutional as Applied

Claims have been filed in state and federal courts asserting that the Vaccine Act's time limitation violates equal protection, due process, and jury trial guarantees under the federal Constitution. In *Blackmon v. American Home Products Corp.*,[268] parents of minor children brought a products liability action against pharmaceutical companies alleging neurological injuries from vaccinations containing thimerosal.[269]

The parents argued that the Vaccine Act's three-year limitations period violated their children's right to equal protection because it "discriminates

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[265] 21 C.F.R. § 610.15(a) (2005).

[266] *E.g.*, Moss v. Merck & Co., 381 F.3d 501, 503–04 (5th Cir. 2004) (allowing suit against thimerosal manufacturer to proceed without first going through Vaccine Court because the manufacturer of a component of a vaccine was not a "vaccine manufacturer" within the meaning of the Vaccine Act); Toussaint v. Merck & Co., No. Civ. A. 02-3411, 2003 WL 21406178, at *2 (E.D. La. June 12, 2003) (holding that the exclusive jurisdiction of the Vaccine Court does not apply to manufacturers, suppliers, and distributors of thimerosal); Owens v. Am. Home Prods. Corp., 203 F. Supp. 2d 748, 758–59 (S.D. Tex. 2002) (holding that chemical manufacturers who supplied thimerosal to vaccine manufacturers, but who did not manufacture or administer the vaccines themselves, were not subject to the Vaccine Act's tort suit bar).

[267] *E.g.*, John & Jane Doe 2 v. Ortho-Clinical Diagnostics, Inc., 335 F. Supp. 2d 614, 627 (M.D.N.C. 2004) (holding that Eli Lilly and Co. had no duty to warn plaintiffs or other manufacturers of the dangers of thimerosal); Murphy v. Aventis Pasteur, Inc., 270 F. Supp. 2d 1368, 1377 (N.D. Ga. 2003).

[268] 328 F. Supp. 2d 647 (S.D. Tex. 2004).

[269] *Id.* at 650. The claimants originally filed their actions in state court, but the defendants had it remanded to federal court based on diversity jurisdiction. *Id.*

against children with latent vaccine-related injuries."[270] The court disagreed, holding that even though the provisions of the Act deprived the children of the opportunity to present their claims on the merits, the Act did not violate their right to equal protection because the three-year limitation period "reflects Congress's decision to provide repose to vaccine manufacturers by limiting the time frame in which injured parties can pursue claims for vaccine-related injuries."[271] The court determined that "the limitations provision [was] rationally related to a permissible legislative end"—a policy judgment that the benefits afforded by the National Vaccination Program required some protection for manufacturers.[272]

In *Blackmon*, the parents also argued that the dismissal of their claim would violate due process guarantees because they did not, and could not, know that their minor child's developmental injuries were caused by exposure to thimerosal-containing vaccines until after the thirty-six month statute of limitations period had expired.[273] The parents argued that their children's autism was thimerosal-induced, and that they did not become symptomatic until months after receiving vaccines containing thimerosal.[274] The court disagreed, opining that "[t]he mere fact that certain victims fail to discover and file their claims before the limitations period expires, while regrettable, does not render the limitation unreasonable."[275] The court also found that that the parties failed to conduct a timely investigation.[276]

Finally, the parents asserted that the Vaccine Act was unconstitutional as applied to children with autism because its statute of limitations provision denies such children their right to a jury trial.[277] Again, the court disagreed, noting that Congress retains the inherent ability "to abrogate common-law rights and remedies to the extent that they interfere or conflict with duly enacted regulatory schemes."[278] The court noted that the Act does not strip plaintiffs of their right to a jury trial because as long as

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[270] *Id.* at 655; *accord* U.S. CONST. amend. V.

[271] *Blackmon*, 328 F. Supp. 2d at 655.

[272] *Id.*

[273] *Id.*; *accord* U.S. CONST. amend. V.

[274] *Blackmon*, 328 F. Supp. 2d at 655–56.

[275] *Id.* at 656–57.

[276] *Id.* at 656.

[277] *Id.* at 657; *accord* U.S. CONST. amend. VII.

[278] *Blackmon*, 328 F. Supp. 2d at 657 (citing Granfinanciera, S.A. v. Nordberg, 492 U.S. 33, 53 (1989)).

they file their claim initially in the Vaccine Court, they remain free to bring a civil claim in state or federal court.[279]

The *Blackmon* court's conclusions missed the point of the Vaccine Act and provide an expedient basis for the Vaccine Court to deny a claim. The express purpose of the Act is to provide compensation for those injured as a result of vaccination.[280] The limitations period contained in the Act represents a congressional determination to provide repose to vaccine manufacturers based on the benefit vaccines provide to society.[281] Congress recognized that a small percent of the population is vulnerable to certain types of injuries as the result of vaccination.[282] These injuries are listed in the Vaccine Injury Table.[283] Notably, the Table provides a timeline within which the first sign of the injury is expected to occur.[284] For those vaccines administered to children, the timeline is listed in hours and days.[285] Based on this, the thirty-six month statute of limitation provides ample time for injured parties to link vaccination to their injury and to file a petition for compensation. However, the Table does not list timelines for injuries associated with autism and does not provide a timeline applicable to thimerosal-related injuries.[286] Collectively, these facts demonstrate that the statute of limitations provision in the Vaccine Act reflected a legislative intent to provide a period of repose for the injuries caused by the pathogen, not those resulting from exposure to the preservative. Nothing in the Act suggests that Congress ever considered that type of harm or the propriety of shielding manufacturers from liability for those types of injuries.

By strictly applying the terms of the Vaccine Act, courts continue to deny otherwise proper claims based on Congress's failure to consider latent effects associated with the administration of thimerosal-containing vaccines. In effect, the courts' strict interpretation of the Act has created a legal catch-22 scenario for autism-related claims, whereby claimants are prohibited from filing a claim without proof of causation and then are

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[279] *Id.* at 658.

[280] H.R. REP. NO. 99-908, at 3 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6344.

[281] *Blackmon*, 328 F. Supp. 2d at 655.

[282] H.R. REP. NO. 99-908, at 4.

[283] 42 U.S.C. § 300aa-14(a) (2000).

[284] *Id.*

[285] *Id.*

[286] *See id.*

barred by expiration of the statute of limitations when proof of causation is finally discovered.[287]

While limiting manufacturers' liability for placing beneficial but potentially harmful products on the market constitutes a permissible legislative act, such protection should not extend to manufacturers that place toxic substances into their products to increase profit margins, particularly when non-toxic alternatives are available.

4. Medical Monitoring

In *Ashton v. Aventis Pasteur, Inc.*,[288] the parents of an autistic child appealed the trial court's denial of their class action claim against several vaccine manufacturers.[289] The parents sued on behalf of their minor children and other similarly situated plaintiffs seeking damages and compensation for medical monitoring[290] for "further injuries" and "further harm" attributed to exposure to thimerosal contained in vaccines they received.[291] The complaint alleged that, as a result of vaccinations, each child was poisoned by 237.5 micrograms of toxic mercury.[292] The parties brought the claim in state court because the thirty-six month limitations period under the Vaccine Act had expired.[293] The court refused to address the merits of the medical monitoring claim because the plaintiffs failed to "exhaust their remedies in the Vaccine Court."[294] In denying relief, the court noted that because the request for medical monitoring resulted from exposure to a substance contained in the vaccine, each plaintiff must first exhaust his or her remedies in the Vaccine Court.[295] Inexplicably, the court simply disregarded the fact that the remedies were necessarily exhausted

[287] *See* Strauss v. Am. Home Prods. Corp., 208 F. Supp. 2d 711, 716 (S.D. Tex. 2002) (holding that filing late in the Vaccine Court does not give a claimant the ability to sue in court); Dickey v. Connaught Labs., Inc., 777 N.E.2d 974, 978 (Ill. App. Ct. 2002) (holding that the plain language of the Vaccine Act forces claimants to file their claim in the Vaccine Court, within the Act's statute of limitations, before they can file in state court); McDonald v. Lederle Labs., 775 A.2d 528, 529 (N.J. Super. Ct. App. Div. 2001) (holding that failure to meet the Vaccine Act's statutory time allowance effectively bars a claimant from bringing a civil suit).

[288] 851 A.2d 908 (Pa. Super. Ct. 2004).

[289] *Id.* at 909.

[290] *Id.* at 909–10.

[291] *Id.* at 913.

[292] *Id.* at 911.

[293] *See id.* at 913.

[294] *Id.* at 914.

[295] *See id.* at 913–14.

through passage of the limitations period. As a result, plaintiffs were left without recourse to have their claim heard anywhere.

5. Qualified Litigants

In *Cheskiewicz v. Aventis Pastuer, Inc.*,[296] parents brought suit on behalf of their son against vaccine manufacturers alleging that their son was injured by exposure to mercury contained in childhood vaccines.[297] The child was born in 1994 and received the mercury-containing vaccines between May 1994 and December 1995.[298] At eighteen-months "[h]e began losing language and motor skills and became withdrawn and non-interactive. In May 2001, seven years [after] he was administered his first vaccine, [the child] was diagnosed as suffering from disintegrative autism resulting from mercury toxicity."[299] Having missed the deadline under the Vaccine Act, the parents filed a products liability claim in civil court.[300] The lawsuit was initiated "approximately six and one-half years after the first manifestation of [the child's] symptoms and three and one-half years after the expiration of the Vaccine Act's thirty-six month statute of limitations."[301] The parents argued that the Vaccine Act did not apply to their claim because they could not have become aware of a connection between their child's symptoms and the vaccines until after expiration of the three-year limitation period.[302] Stated differently, the parents alleged that the first symptom was their child's diagnosis.[303] Furthermore, the parents claimed that because they were unable to file their claim within thirty-six months from the onset of the child's first symptom, they did not qualify as litigants under the Act, i.e., because they failed to comply with the statute of limitations they were not bound by it.[304]

The court disagreed and dismissed the case,[305] holding that injuries resulting from thimerosal are vaccine-related, and claims related to such injuries must first be filed in the Vaccine Court where claimants must

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[296] 843 A.2d 1258 (Pa. Super. Ct. 2004).

[297] *Id.* at 1260.

[298] *Id.* at 1261.

[299] *Id.*

[300] *Id.*

[301] *Id.*

[302] *Id.* at 1262.

[303] *See id.*

[304] *Id.* at 1263.

[305] *Id.* at 1265.

exhaust their administrative remedies.[306] The court acknowledged that its decision would have an especially harsh result because the Vaccine Court would likely rule that any claim brought by the plaintiff was untimely.[307] Other courts have also strictly construed the thirty-six month limitations period.[308]

Thus, under every legal theory advanced to date, claims brought on behalf of autistic children for vaccine-related injuries have failed. Despite increasing evidence that autism may be linked to mercury poisoning, and an incalculable body of evidence describing the harm caused through mercury exposure, the federal government continues to make it more difficult for an autistic child to receive compensation under the Vaccine Act.

VI. FEDERAL ACTION REGARDING MERCURY IN VACCINES

A. Background

Congress has long been concerned about the risk of human exposure to mercury. In 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), which required the FDA to "compile a list of foods and drugs that contained intentionally introduced mercury," study its effect on the human body, and restrict its use if found to be harmful.[309] Because of studies conducted pursuant to FDAMA, the FDA realized for the first time that the amount of mercury infants were exposed to in the first six months of life through mandatory vaccination exceeded the federal reference dose several times over.[310]

On July 7, 1999 and June 22, 2000, a number of federal health agencies issued two joint statements recommending removal of mercury from the nation's pediatric vaccine supply as soon as possible.[311] The

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[306] *Id.* at 1262–64.

[307] *Id.* at 1264.

[308] *E.g.*, Strauss v. Am. Home Prods. Corp., 208 F. Supp. 2d 711, 716 (S.D. Tex. 2002); Dickey v. Connaught Labs., Inc., 777 N.E.2d 974, 977 (Ill. App. Ct. 2002); Nestlen v. Wyeth, No. 0201-00126, 0106-05780, 2003 WL 23531954, at *5 (Or. Cir. Ct. 2003) (noting that a different interpretation would allow qualified applicants under the Act to avoid the Vaccine Court altogether, defeating the purpose of the Act).

[309] Pub. L. No. 105-115, § 413, 111 Stat. 2296, 2376–77 (1997) (codified at 21 U.S.C. § 393 note (2000) (FDA Study of Mercury Compounds in Drugs and Foods)).

[310] *See supra* discussion accompanying notes 75–80.

[311] *See* National Immunization Project, Centers for Disease Control and Prevention, Joint Statement (Concerning Thimerosal) of the American Academy of Pediatrics (AAP) and the U.S. Public Health Service (PHS) (July 7, 1999), http://www.cdc.gov/nip/

(*continued*)

recommendation to remove thimerosal was based on the theoretical potential for neurotoxicity from exposure to even low levels of mercury.[312] Despite this acknowledgement, a CDC Advisory Committee refused to issue a public statement announcing a preference for thimerosal-free vaccines, based in part on concerns over the financial health of the vaccine industry.[313]

As a result of the FDA and CDC's failure to take action to remove thimerosal from childhood vaccines, "almost two years passed before the three major thimerosal-containing vaccines—DTaP, Hib, and Hepatitis B—were being manufactured in thimerosal-free formulations."[314] Consequently, in addition to all those children already injured, approximately 8,000 children per day continued to be placed at risk of mercury poisoning for up to an additional two years.[315] Sadly, their exposure may have been the result of the federal health agencies' unwillingness to acknowledge their own error.[316] This is particularly troubling given the fact that the delay in using thimerosal-free vaccines was not related to the normal lag time associated with research and development.[317] The only modification required to provide thimerosal-free

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vacsafe/concerns/thimerosal/thimerosal-AAP&PHS.htm [hereinafter AAP Joint Statement]; National Immunization Project, Centers for Disease Control and Prevention, Joint Statement Concerning Removal of Thimerosal from Vaccines (June 22, 2000), http://www.cdc.gov/nip/vacsafe/ concerns/thimerosal/joint_statement_00.htm [hereinafter Removal of Thimerosal].

[312] *See* AAP Joint Statement, *supra* note 311; Removal of Thimerosal, *supra* note 311.

[313] MERCURY REPORT, *supra* note 30, at 68–69 (quoting Roger Bernier, Remarks at the Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices Conference 269 (June 21, 2000), http://nomercury.org/science/documents/ ACIP_Transcript_6-21-00.pdf, wherein Dr. Bernier states that making a recommendation for thimerosal-free vaccines was not warranted because "[i]t could entail financial losses of inventory if current vaccine inventory is wasted. It could harm one or more manufacturers and may then decrease the number of suppliers.").

[314] *Id.* at 63.

[315] *Id.* at 3.

[316] *See id.* at 63 (reviewing an email from Dr. Peter Patriarca, Dir., Div. of Viral Prods., Food & Drug Admin. to Martin Meyers, Acting Dir., CDC National Vaccine Program Office, stating that "hastening the removal of thimerosal from vaccines would: . . . 'raise questions about the FDA being "asleep at the switch" for decades by allowing a potentially hazardous compound to remain in many childhood vaccines, and not forcing manufacturers to exclude it from new products'").

[317] *See id.* at 63–64.

vaccines was to place the vaccine in a single dose vial.[318] Ironically, at a time when the government was actively attempting to cover up mistakes or justify its inaction based ostensibly on protecting the public's confidence in the national immunization program,[319] the European community was actively taking steps to remove thimerosal from vaccines, specifically recommending that, based on the possible risk posed, vaccines without thimerosal should be used for the vaccination of infants and toddlers.[320]

B. Congressional Inconsistency

As a result of a three-year investigation into the use of mercury in vaccines, Congress concluded that "[o]ur public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry,"[321] and that federal health agencies "failed in their duty to be vigilant as new vaccines containing thimerosal were approved and added to the immunization schedule."[322] Congress specifically found that federal health agencies failed by not acknowledging that "the amount of thimerosal [contained] in vaccines exceeded every Federal guideline" for mercury exposure, by not "requir[ing] manufacturers to remove thimerosal from vaccines by a specific date," and by failing to "urge pediatricians to choose thimerosal-free vaccines" when they were available.[323] Congress opined that the HHS is "inherently conflicted in its multiple roles of promoting immunization, regulating manufacturers, looking for adverse events, managing the vaccine injury compensation program, and developing new vaccines."[324] Congress also opined that the CDC's failure to state a preference for

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[318] *See* 21 C.F.R. § 610.15 (2005).

[319] *See* MERCURY REPORT, *supra* note 30, at 66 (reviewing an email from an FDA official stating that "the Public Health Service was concerned that stating a preference for thimerosal-free vaccines could 'result in unwarranted loss of confidence in immunization programs in the US and internationally'"). The email "referenc[ed] a conference call between the American Academy of Pediatrics, Committee on Infectious Disease, Committees on Environmental Sciences and Fetal Neonatal Issues, and Representatives from the FDA, CDC, NIH, NVP, [a]cademicians, toxicologists, mercury experts," and others.

[320] *See id.* at 67.

[321] *Id.* at 79–80.

[322] *Id.* at 7.

[323] *Id.* at 67.

[324] *Id.* at 77.

thimerosal-free vaccines that were being manufactured was "an abdication of their responsibility."[325]

Further, Congress found that "[t]himerosal used as a preservative in vaccines [is] likely related to the autism epidemic,"[326] "the FDA should have acted years earlier to remove this preservative from vaccines and other medicines,"[327] and "it appears that protecting the industry's profits took precedent over protecting children from mercury."[328] Based on these findings, some members of Congress began a campaign to amend the Vaccine Act to increase the amount of compensation available to the estates of those killed as the result of vaccination and to extend the statute of limitations to six years.[329] Despite the removal of thimerosal from most childhood vaccines, there remains no law prohibiting manufacturers from re-introducing thimerosal back into those vaccines or from including it in new vaccines.[330] Another bill seeks to establish a law limiting the amount of mercury that may be added to vaccines to one microgram or less.[331] The bills continue to make their way through congressional subcommittees.

Unfortunately, Congress's apparent willingness to provide greater opportunities to those injured because of vaccination has been tempered by the realities of the marketplace. The number of manufacturers of vaccines in the U.S. has declined from twenty-six manufacturers in 1967 to only four today.[332] A number of vaccines are produced by only one manufacturer, leaving the U.S. population at significant risk of critical shortages.[333] For example, during the 2004–2005 flu season, the U.S.

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[325] *Id.* at 63–64.

[326] *Id.* at 79.

[327] *Id.* at 57.

[328] *Id.* at 69.

[329] H.R. 1349, 108th Cong. §§ 3, 7 (2003). Section 3 of the bill seeks to amend § 2115(a)(2) of the Public Health Service Act (42 U.S.C. § 300aa-15(a)(2)) by increasing the amount of the award provided to the estate for vaccine-related deaths from $250,000 to $300,000. *Id.* § 3. Section 7 seeks to amend § 2116(a) of the Public Health Service Act (42 U.S.C. § 300aa-16(a)) to increase the statute of limitations to six years. *Id.* § 7(a); *see also* H.R. 1297, 109th Cong. §§ 3, 7 (2005) (proposing the same).

[330] H.R. 881, 109th Cong. § 2(6) (2005).

[331] *Id.* § 3(b). Section 3(b) seeks to amend Title III of the Public Health Service Act (42 U.S.C. § 201-300bbb) to ban vaccines if a dose of the vaccine "contains one or more micrograms of mercury in any form." *Id.*

[332] H.R. 650, 109th Cong. § 2(a)(5) (2005).

[333] *See* National Network for Immunization Information, Immunization Policy: Vaccine Supply and Shortages, http://www.immunizationinfo.org/immunization_policy_ detail.cfv?id=78 (last visited Sept. 30, 2005).

experienced a critical shortage of the influenza virus that left many in need of vaccination without recourse.[334] In response to this problem, House Bill 650[335] (H.R. 650) was introduced in Congress to provide greater protection to vaccine manufacturers and to make it more difficult for a claimant to prove that an injury is vaccine-related.[336] H.R. 650 seeks to create federal preemption over all state actions involving vaccine-related injuries, and to force claimants not satisfied with the Vaccine Court's award to bring their civil action in federal court.[337] Further, the Bill seeks to eliminate the argument that mercury is an adulterant by defining a vaccine to "include[] any preservative, ingredient, or component of a vaccine."[338] Because there is no clear scientific evidence that exposure to thimerosal-containing vaccines is linked to the development of autism,[339] attorneys face a significant hurdle in proving that their client's injury is linked to the administration of a vaccine. H.R. 650 has a chilling effect on petitioners harmed by thimerosal-containing vaccines because it provides for suspension or disbarment of an attorney who files multiple frivolous lawsuits.[340]

Another purpose of H.R. 650 is to ensure that all procedures and evidence be subject to the more difficult rules and requirements set forth by the United States Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[341] Under *Daubert*, the court acts as a "gatekeeper" of scientific evidence and is charged with evaluating the reliability of scientific evidence based on narrower considerations than those required under the alternative test[342] outlined in *Frye v. United States*.[343] *Daubert* has been spurned by many states, including New York, Illinois, Florida, and California,[344] which have retained the more lenient *Frye* standard,[345]

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[334] *CDS Announces Plan to Help Get Flu Vaccine to Most Needy*, SENIOR J., Oct. 12, 2004, http://www.seniorjournal.com/Spotlights/FLU2004/4-10-12FluPlan.htm.

[335] H.R. 650, 109th Cong. (2005).

[336] *See id.*

[337] *Id.* § 3(a)(2)–(3).

[338] *Id.* § 3(a)(4).

[339] *See* World Health Org., *supra* note 112, at 306.

[340] H.R. 650 § 4; *see also* FED. R. CIV. P. 11(b), (c).

[341] 509 U.S. 579 (1993); *see also* H.R. 650 § 2(b)(2); FED. R. EVID. 702.

[342] *Daubert*, 509 U.S. at 589, 592–93.

[343] 293 F. 1013 (D.C. Cir. 1923).

[344] *See* Phillips v. Indus. Mach., 597 N.W.2d 377, 387–88 (Neb. 1999).

[345] *Frye*, 293 F. at 1014.

because *Daubert* benefits the defendant by allowing the court to exclude plaintiffs' scientific evidence.[346]

Mercury-induced injuries are not addressed in the Vaccine Injury Table.[347] As such, the beneficial presumptions afforded to claimants who prove a Table injury is inoperative. Therefore, petitioners must show that the child's injury was "caused-in-fact" by the vaccination in question.[348] The burden is on the petitioner to prove by a preponderance of the evidence that the vaccination caused the injury.[349] The petitioner may show this by demonstrating that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause of the injury.[350] The petitioner must supply "proof of a logical sequence," supported by a reputable medical or scientific explanation, "of cause and effect showing that the vaccination was the reason for the injury."[351]

The effect of applying *Daubert* to vaccine-related injuries brought on behalf of autistic children has been devastating. In *Easter v. Aventis Pasteur, Inc.*,[352] a parent filed a claim against a vaccine manufacturer claiming her autistic child's co-morbid conditions were caused by exposure to ethylmercury contained in vaccines.[353] The court granted the defendants' motion to strike the plaintiff's expert witness because the expert's evidence was not sufficiently scientifically reliable to be admissible—it did not rule out the possibility that the cause of the child's

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[346] *See* United States v. Scheffer, 523 U.S. 303, 311 n.7 (1998) (explaining that under *Frye*, "scientific evidence must gain the general acceptance of the relevant expert community to be admissible," but under *Daubert*, expert testimony is admissible only if the trial judge determines it meets the requirements of Federal Rule of Evidence 702). Rule 702 provides, "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as a expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." FED. R. EVID. 702.

[347] *See* 42 U.S.C. § 300aa-14(a) (2000).

[348] *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii)(I), 300aa-13(a)(1)(A).

[349] *See, e.g.*, Hines v. Sec'y of the Dep't of Health and Human Servs., 940 F.2d 1518, 1525 (Fed. Cir. 1991); Carter v. Sec'y of the Dep't of Health and Human Servs., 21 Cl. Ct. 651, 654 (1990); Strother v. Sec'y of the Dep't of Health and Human Servs., 21 Cl. Ct. 365, 369–70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991); Shaw v. Sec'y of the Dep't of Health and Human Servs., 18 Cl. Ct. 646, 650–51 (1989).

[350] Shyface v. Sec'y of Health and Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999).

[351] *Strother*, 21 Cl. Ct. at 370; *accord Shaw*, 18 Cl. Ct. at 651; *Carter*, 21 Cl. Ct. at 654.

[352] 358 F. Supp. 2d 574 (E.D. Tex. 2005).

[353] *Id.* at 575.

autism also caused the co-morbid conditions.[354] Furthermore, the expert admitted that he could not conclusively prove that thimerosal caused the autism.[355] By striking the plaintiff's expert witness, the court denied the plaintiff an opportunity to have a jury decide whether her child's injuries were substantially related to his exposure to ethylmercury. In effect, by applying the *Daubert* test to strike the plaintiff's expert witness, the court impermissibly moved away from the preponderance of the evidence standard by requiring greater proof of causation. As the court noted in *Knudsen v. Secretary of the Department of Health and Human Services*,[356] "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program."[357]

Because autism likely results from a combination of sources,[358] it is impossible to rule out other factors that may contribute to the disorder. Based on the conflicting scientific evidence regarding the link between autism and mercury-containing vaccines, application of the *Daubert* test will necessarily deny petitioners relief until the scientific evidence demonstrating a link crystallizes. Because thimerosal was removed from most vaccines in 2001,[359] and the symptoms of late-onset autism begin to appear around eighteen-months,[360] if a link between autism and mercury-containing vaccines is not established in the next several years, manufacturers will escape liability completely for thousands of injured children through application of the Act's statute of limitations.

VII. RECOMMENDATIONS

The FDA approved several vaccines containing thimerosal for use in the federal government's mandatory childhood immunization program without ever determining the actual quantities of mercury contained per dose administered.[361] Faced with mounting evidence, federal health agencies elected to do nothing to remove mercury from vaccines despite their own studies that demonstrated that mercury was a cumulative toxin

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[354] *Id.* at 577.

[355] *See id.*

[356] 35 F.3d 543 (Fed. Cir. 1994).

[357] *Id.* at 549.

[358] *See supra* notes 7–9 and accompanying text.

[359] *See* IOM Report, *supra* note 105.

[360] *See* Adams et al., *supra* note 25.

[361] *See* Allen, *supra* note 134.

capable of causing significant neurological damage to children.[362] As a result of the FDA's failure in its mission to promote and protect the public health by helping safe and effective products reach the market,[363] a large and unknown number of children have been unnecessarily poisoned by vaccines containing quantities of mercury that exceeded every federal safety standard several times over.

Congress concluded, after conducting a three-year study into the link between autism and mercury in vaccines, that the near epidemic rise in childhood autism in the United States was likely the result of exposure to thimerosal-containing vaccines.[364] Yet, claims brought on behalf of autistic children for vaccine-related injuries continue to be dismissed by the courts,[365] leaving countless children with no recourse to have their claim heard on the merits. These facts suggest change is warranted.

A. Amend Vaccine Injury Table

The Secretary of Health and Human Services must amend the Vaccine Injury Table.[366] Because the HHS failed in its mandate to promote safer vaccines, the Vaccine Injury Table should be amended to address symptoms of neurological damage associated with mercury poisoning commonly observed in autistic children. The current format of the Table only considers injuries expected to occur through the introduction of a biological or viral organism into the body.[367] Congress did not take into consideration the effects associated with preservatives added to the vaccine because it did not know of the danger. As a result, claimants administered toxic doses of mercury who suffer neurological injury do not benefit from the presumption that their injury was the result of vaccination and must prove actual causation.[368] This result is inconsistent with the intent and purpose of the National Victims Injury Compensation Act, which was developed to provide adequate compensation to those injured because of

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[362] *See* discussion *supra* Part VI.A–B.

[363] U.S. Food & Drug Administration, FDA's Mission Statement, http://www.fda.gov/opacom/morechoices/mission.html (last visited Sept. 17, 2005) (providing that the FDA's mission is to promote and protect the public health by helping safe and effective products reach the market in a timely way, and by monitoring products for continued safety after they are in use).

[364] *See* MERCURY REPORT, *supra* note 30, at 79.

[365] *See* discussion *supra* Part V.E.2–5.

[366] 42 U.S.C. § 300aa-14(c)(1) (2000) (providing for administrative revision of the Vaccine Injury Table).

[367] *See id.* § 300aa-14(a).

[368] *See supra* notes 342–51 and accompanying text.

vaccination.[369] Had Congress accepted the risk associated with thimerosal, it is highly likely that it would have included the known effects of mercury poisoning in the Table. Amending the Vaccine Table to address symptoms associated with autism would ensure that petitions alleging mercury-related injuries would be evaluated according to the evidentiary standards Congress sought to employ in vaccine-related personal injury cases.

Mercury-induced autism claims present complex factual, medical, and legal issues that should not be subject to unilateral dismissal by judges with no medical training and limited ability to understand the complexities of autism. Because this science has not crystallized, *Daubert* should not be used to prevent expert testimony on either side of the issue. Congress sought to provide compensation to injured victims upon proof that a link between vaccination and the injury is biologically plausible, not absolutely certain.

Although scientists disagree whether the administration of thimerosal-containing vaccine causes autism, there is undisputed evidence that exposure to mercury causes neurological injury,[370] and that autistic children are neurologically impaired.[371] Because federal health agencies failed to evaluate the effects of injecting large quantities of mercury into children,[372] and because vaccination is mandatory,[373] any question regarding the link between autism and vaccination should be resolved in favor of the children who were never given a chance to refuse vaccination. Although the immediate monetary impact of such a change may be significant, unless federal health agencies re-introduce mercury-based preservatives into childhood vaccines, the impact will be short-lived as the number of mercury-based claims decrease.

B. Extend the Statute of Limitations

Autism is difficult to detect early in life and is often not diagnosed clinically until a child is several years old.[374] Typically, by the time a child is diagnosed with late-onset autism, more than three years have passed since the first symptom was observed.[375] As a result, he or she is barred

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[369] *See* VICP, *supra* note 186.

[370] *See* discussion *supra* Part III.D.

[371] *See* Bernard et al., *supra* note 51, at 465 tbl. 2.

[372] *See supra* notes 75–77 and accompanying text.

[373] *See* Ctrs. for Disease Control & Prevention, *supra* note 152, at Q-2.

[374] *See* Autism Disorder Fact Sheet, *supra* note 24.

[375] *Id.*

from bringing a claim in the Vaccine Court.[376] Because the parent did not comply with the provision of the Vaccine Act, he or she is also barred from bringing a claim in state or federal court and is left without recourse to have the claim heard on its merits.[377] This is an unfair result because the same claimants are barred from bringing a claim unless they have a good faith basis to bring a claim based on evidence of the disorder. Thus, the solution is to extend the statute of limitations in the Vaccine Act to six years. This would provide sufficient time for claimants to collect evidence, or receive a diagnosis, upon which a good faith claim may be based.

C. Establish a National Monitoring Program

Many children have already been diagnosed with autism. For them, the only recourse is to seek damages and medical expenses under the unfavorable provisions of the Act. However, for those children recently exposed to thimerosal prior to its removal in 2001, symptoms of autism may be starting to emerge. For those children, there may be hope. New studies have shown that it may be possible to reverse, or at least mitigate, the effects of mercury poisoning with timely intervention.[378] A national research and medical monitoring program should be established to monitor the health and development of all children vaccinated under the national vaccine program during the three years immediately preceding removal of thimerosal from vaccines.

The program would provide two major benefits. First, the program would provide each child exposed to mercury poisoning the best chance of mitigating its effects. Even if only a small fraction of children experience moderate improvement as a result of timely intervention, a significant amount of money allocated to provide long-term care to those individuals could be utilized to provide care for others. Second, the program would provide the best evidence of the long-term effects of injecting large quantities of mercury into children. Existing studies are inherently limited in their application because they attempt to link mercury exposure to

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[376] *See* 42 U.S.C. § 300aa-16(1) (2000) (stating a thirty-six month statute of limitations to file a petition under the Vaccine Act).

[377] *See id.* § 300aa-21(c).

[378] *See, e.g.*, Simon Baron-Cohen, *Autism: Research into Causes and Intervention*, 7 PEDIATRIC REHABILITATION 73, 76 (2004); Mark R. Geier & David A. Geier, *The Potential Importance of Steroids in the Treatment of Autistic Spectrum Disorders and Other Disorders Involving Mercury Toxicity*, 64 MED. HYPOTHESES 946, 948–53 (2005); John Wray et al., *Language Disorders and Autism*, 182 MED. J. AUSTL. 354, 358 (2005).

autism based on epidemiological and other evidence. Because no law exists to prevent federal health agencies from re-inserting mercury into vaccines in the future,[379] a long-term medical monitoring study will provide federal health agencies with clear evidence regarding the propriety of such actions. The program should be paid for by the industry that profited from the convenience of packaging mercury in multi-dose vials, and the federal health agencies that chose to elevate cost control over safety.

D. Remove Thimerosal from All U.S. Produced Vaccines

The elimination of mercury from most vaccines administered to American children has not adequately addressed the problem. Vaccines containing thimerosal continue to be manufactured in multi-dose vials in the United States and delivered to third world countries through the World Health Organization.[380] The WHO has continued to require the use of multi-dose vials containing thimerosal to address the more difficult storage and transportation issues in those areas of the world.[381] As a result, children in developing countries continue to receive high doses of mercury through vaccination. Although a switch to single-dose vials may not be financially feasible in those nations, the hands-off approach the United States has taken with regard to the sale of such vaccines is deplorable. Children in undeveloped areas of the world continue to face health risks long since eradicated in more developed nations. Because mercury is a cumulative toxin that remains in the brain for extended periods,[382] and because children are exposed to mercury from other sources,[383] the United States should mandate that all vaccines manufactured by American companies be mercury-free. The United States should encourage the WHO to use single-dose vials, or, at a minimum, work with health agencies using multi-dose vials to ensure that children are not given bolus dose injections. Further, the United States should also recommend a schedule of immunization that staggers vaccinations so that mercury introduced through one vaccination has been metabolized and excreted to the greatest possible extent prior to the administration of additional

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[379] *Supra* note 330 and accompanying text.

[380] *See* Global Advisory Committee on Vaccine Safety, World Health Organization, Thimerosal and Vaccines: Questions and Answers, http://www.who.int/vaccine_safety/topics/thiomersal/questions/en/index.html (last visited Aug. 31, 2005).

[381] *See* TECHNICAL REPORT SERIES, *supra* note 110, at 2.

[382] *See* MERCURY STUDY, *supra* note 57, at 3–23.

[383] *See id.* at 2–4.

mercury-containing vaccines. Saving lives from diseases does not justify destroying others where such harm may be avoided.

CONCLUSION

Congress was well aware of the inherent risk of inoculating children with potentially lethal vaccines when it mandated childhood vaccination, but it considered the risk acceptable. The Vaccine Act reflects a congressional determination that the disappearance or unavailability of childhood vaccines would cause far greater harm than the inevitable, but limited, number of injuries caused by the vaccines themselves. The National Vaccine Injury Compensation Program was established to ensure that all children injured by vaccines have access to sufficient compensation for their injuries.[384]

Congress never considered or accepted the risk associated from adding a non-essential toxic preservative to vaccines. When government regulators and pharmaceutical companies discovered that childhood vaccines might be linked to the sudden national increase in autism, they did nothing to prevent further injury in an effort to protect the national vaccine program. Because the Vaccine Act does not address injuries caused by preservatives added to vaccines, a large number of children harmed through the administration of vaccines containing mercury-based thimerosal have been left without recourse and have received no compensation for their injuries.

[384] *See* VICP, *supra* note 186.