Autism, a National Emergency

A SafeMinds Report on the Federal Response

Submitted to the

U.S. House of Representatives
Committee on Oversight and Government Reform

As Testimony to the Hearing:

1 in 88 Children: A Look Into The Federal Response to Rising Rates of Autism

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Introduction

The Coalition for SafeMinds provides the following report as testimony to the United States House of Representatives Committee on Oversight and Government Reform in November 2012.

It is the hope of SafeMinds and the autism community that Congress does not simply conduct a single hearing at the end of the 112th Congress, but uses the hearing and this report to set the stage for ongoing Congressional oversight that looks at a host of issues, many of which are outlined in this report in greater depth. The purpose of Congressional oversight would not simply be to take the measure of Executive and Judicial Branch performance in these matters, but to also insure that all Federal authorities act with integrity, effectiveness and in collaboration with the community so that we can curtail the epidemic rise in autism rates by curtailing exposure to toxicants and other related causes. We need to confirm effective therapies and strategies, insure the availability of services across the lifespan, and where possible find a cure.

The high rate of autism within our society affects every aspect of our society from Medicaid and Social Security to education, transportation, and disability-related jobs. It affects religious communities, and medical research and services. It also affects planning for long-term and group housing, law enforcement training, and military service. Without a focus now in Congress, it is unlikely that federal agencies will adequately address the epidemic as it increases or even as the current population of affected children reaches adulthood and requires greater public services.

Many in the autism community feel that the government is not listening and at times is working against the interests of their family and the needs of those living with autism. There is growing frustration that much of the most important research is not conducted, that logic, common sense, and long established scientific hierarchy on the evidence base are ignored in an attempt to ignore one of the most obvious toxicants in question, and that conflicts of interest, cover-ups and acts of malfeasance and even criminal behavior have not been rigorously addressed. This report will lay out these issues for the Committee and serve, we hope as a spring board for the Committee to engage vigorously in achieving justice and holding accountable those who are responsible for the issues discussed.

Committee Played a Key Role Early On

It was this Congressional Committee under the Chairmanship of Congressman Dan Burton who first acknowledged that autism had become an epidemic. It is because of this Committee that any attention has been paid to the environmental factors at the root of this epidemic. Some of the current members were on the Committee during this time, but many of the Committee members are new and may not be aware of just how much was accomplished during the Committee's earlier investigation.

In the 12 years since SafeMinds first began a legislative education activity in particular with the House Committee on Oversight and Government Reform, there has been some forward motion, but also many lost opportunities, lots of waste, and many frustrations. The Committee's website states:

"We exist to secure two fundamental principles. First, Americans have a right to know that the money Washington takes from them is well spent. And second, Americans deserve an efficient, effective government that works for them. Our duty on the Oversight and Government Reform Committee is to protect these rights.

Our solemn responsibility is to hold government accountable to taxpayers, because taxpayers have a right to know what they get from their government. We will work tirelessly, in partnership with citizen-watchdogs, to deliver the facts to the American people and bring genuine reform to the federal bureaucracy."

About SafeMinds

SafeMinds is a non-profit organization founded to restore health and protect future generations by eradicating the devastation of autism and associated health disorders induced by mercury and other man made toxicants. Since its inception in 2000 SafeMinds has:

- Established the link between mercury and autism through the landmark paper, "Autism, A Novel Form of Mercury Poisoning."
- Been the driving force pushing forward science that links environmental factors, such as mercury, to autism.
- Sponsored almost $1 million in research related specifically to mercury and adverse neurological outcomes. This level of financial commitment establishes SafeMinds as the largest private non-profit organization funding mercury and autism-related research.
- Brought this issue to national attention by publishing peer-reviewed articles, networking with leading scientists in the fields of toxicology and autism research, testifying before government committees and working with David Kirby on the publication of the *New York Times* Bestselling book, *Evidence of Harm*.
- Relentlessly pursued the scientific truth about mercury and neurodevelopmental disorders. SafeMinds provides constant surveillance and vigilance on misinformation about this issue in the media and provides rapid and high-quality responses to this misinformation.

SafeMinds was founded as a result of the peer-reviewed scientific article "Autism: A Novel Form of Mercury Poisoning". Its goals are:

- To eliminate mercury from all medical products, including vaccines, and substantially reduce other environmental exposures to mercury.
- To transform scientific understanding of the causes, time trends, and treatments of autism and other injuries related to mercury and other manmade toxicants.
- To empower citizens to make informed choices about their health by providing information and alternatives to reduce the risk of autism and related health disorders.

SafeMinds ultimate goal is to find the truth — to encourage and support efforts to conduct medical research that provide credible findings to support that the mercury-autism hypothesis is true and to help find treatments that will reverse the damage these children have incurred.

SafeMinds acts in collaboration with numerous other non-profits to build consensus on legislative and other matters.

Keep in mind:

1. Even with a billion dollar investment, we as a nation are failing to address the national emergency that is autism. (Federal officials from the highest levels of government through mid-level supervisors continue to ignore that autism is a national crisis. There is no sense of urgency and often failure to follow through. There is too little progress in too many areas from prevention to long-term care.)
2. Preventing autism can only be addressed if environmental factors are investigated adequately.
3. Recovery/Cure and/or Achieving Optimal health while living with autism can only be achieved by all living with autism (including those who do not have the ability to pay out of pocket) if adequate quality research is conducted to confirm the safety, and effectiveness of therapies including drugs, behavioral interventions, complementary therapies, special dietary approaches, nutritional supplements, and detoxification methods.
4. There is too little accountability and no set metric for evaluating progress, quality of the effort, and compliance with the actual needs of the autism community.
    a. Federal research dollars continue to be disproportionately focused on genetics, while ignoring environmental studies that may play a more immediate role in curtailing the skyrocketing rates by preventing future cases in the near term.
    b. There is too little attention given to confirming the safety and efficacy of treatments commonly used.
5. There are many concerns about waste, fraud and abuse within federal programs especially as it relates to the studies funded to evaluate the autism-vaccine injury matters. These include:
    a. a researcher who failed to write up the initial data on early thimerosal exposure showing a 10 fold increase in risk when compared to zero exposure, and then negotiated and accepted a job with a vaccine manufacturer before presenting the data publicly for the first time;
    b. a researcher who is now at the top of the HHS IG Most Wanted Fugitive list for reportedly stealing between $12 million from an autism grant.
    c. A CDC official who continues to work with and co-author papers with that fugitive from justice.
6. A lack of transparency and failure to provide information through FOIA for years.
7. Failure to disclose the facts on compensation to individuals in the Vaccine Injury Compensation Program who developed autism after suffering a vaccine-induced brain injury.

Autism Is a National Emergency

When autism was first recognized by Dr. Leo Kanner less than 80 years ago at Johns Hopkins University, it was considered very rare. The rates of autism have risen at an alarming pace in the last 30 years.

According to the CDC's[1] ADDM study, 1 in 88 children born in the year 2000 is on the autism spectrum. According to census data, 4,058,814 babies were born in 2000. Using the 1 in 88 statistic, the year the Committee first began looking at autism more than 46,000 children were born across the United States who now at 12 years of age are on the autism spectrum. And if the rates stays exactly the same, since then over 500,000 children have been born in the United States who will be on the autism spectrum. However, the rates are not constant. They continue to grow.

Autism has grown from a national epidemic in 2000 to a national emergency in 2012! Sadly and frustratingly, federal and public health authorities show no sign of treating a 78% increase in autism as an emergency.

Cost of Autism

According to the CDC, "annual medical expenditures per child with an ASD range from $2,100 to $11,200. Additionally, we know that intensive behavioral interventions for a child with an ASD can cost from $40,000 to $60,000 per year [per individual] and that the nonmedical costs of special education for a child with an ASD are about $13,000 per year. Eventually the cost to individual families extends into lost productivity and other financial problems for communities."[2] ($55,100 to $84,200 per child [per year]). Another estimate from the community places the lifetime cost for caring for an individual with autism at $3.2 million.

The Autism Epidemic

When the US House of Representatives Government Reform and Oversight Committee initiated a series of hearings looking at the increased rates of autism, the estimates offered ranged from 1-3 in 10,000 to 1 in 500. On April 6, 2000, a CDC official testified that autism rates in the first US prevalence studies were conducted in the 1980s. The two studies found a prevalence of children with autism of 3.2 and 1.2 per 10,000 respectively. (To convert to the terminology currently being used, this translates to rate of 1 in 3,125 and 1 in 8,334.)[3]

Children born the year of that hearing (2000) had a 1 in 88 chance of being diagnosed with autism by age 8 years: *"The Centers for Disease Control and Prevention (CDC) estimates that about 1 in 88 children has been identified with an autism spectrum disorder (ASD). CDC's estimate comes from the Autism and Developmental Disabilities Monitoring (ADDM) Network, which monitors the number of 8-year-old children with ASDs living in diverse communities throughout the United States. In 2007, CDC's ADDM Network first reported that about 1 in 150 children had an ASD (based on children who were 8 years old in 2002). Then, in 2009, the ADDM Network reported that 1 in 110 children had an ASD (based on children who were 8 years old in 2006). Most recently, the ADDM Network reported that 1 in 88 children had an ASD (based on children who were 8 years old in 2008). This means that the estimated prevalence of*

[1] http://www.cdc.gov/nchs/data/nvsr/nvsr51/nvsr51_04.pdf
[2] http://www.cdc.gov/ncbddd/autism/documents/ADDM-2012-Community-Report.pdf
[3] Autism: Present Challenges, Future Needs – Why the Increased Rates? Committee on Government Reform, US House of Representatives, 106th Congress, Second Session, April 6, 2000, Serial No. 106-180 http://www.gpo.gov/fdsys/pkg/CHRG-106hhrg69622/pdf/CHRG-106hhrg69622.pdf

ASDs increased 23% during 2006 to 2008 and 78% during 2002 to 2008."[4] The MMWR published report of the 2008 study showing 11.3 per 1,000 (1 in 88) is available at http://www.cdc.gov/mmwr/pdf/ss/ss6103.pdf.

When CDC published the 2000 birth cohort study in 2012, they estimated an increase of 23% every two years. Using this estimate, one can project that 1 in 22 children born this year will be diagnosed on the autism spectrum by the time they turn age 8 in 2020.

Autism Prevalence Rates from ADDM Studies

Birth Year	Rate of Autism
1992	1 in 150
1994	1 in 150
1996	1 in 125
1998	1 in 110
2000	1 in 88

"This means that the estimated prevalence of ASDs increased 23% during 2006 to 2008 and 78% during 2002 to 2008."[5]

Projections of Autism Prevalence Rates (23% increase every 2 years)

Birth Year	Rate of Autism	Prevalence Rates (Current & Projected)
2000	1 in 88	11.3 per 1,000
2002	1 in 71	13.9 per 1,000
2004	1 in 58	17.1 per 1,000
2006	1 in 47	21.04 per 1,000
2008	1 in 34	28.88 per 1,000
2010	1 in 28	35.53 per 1,000
2012	1 in 22	43.71 per 1,000

This dramatic increase is not a genetic epidemic. Some observers have claimed this rise is not real. That numbers are going up because of "better diagnosing." While it is true that we now diagnose autism with better tools, there was not some "hidden horde" of overlooked autism cases. The old surveys did not miss 99% of children with autism. Anyone who reads the older surveys will see that the researchers were clearly diligent in finding cases and confident that they found the vast majority of children. Reported rates of autism have risen simply because there are more cases of autism.

The Centers for Disease Control and Prevention (CDC) takes the lead at HHS on tracking the rates of autism. The CDC website states, "CDC is committed to continuing to provide essential data on ASDs, search for risk factors and causes, and develop resources that help identify children with ASDs as early as possible."[6] The Director of the CDC is also the Administrator of the Agency for Toxic Substances and Disease Registry. While the CDC has invested millions into projects to study autism, many of the actions taken may be interpreted as insufficient, corrupt, and openly malfeasant. This past April the publication of the ADDM study which indicated that autism rates in children born in the year 2000 averaged 1 in 88 shocked the nation.

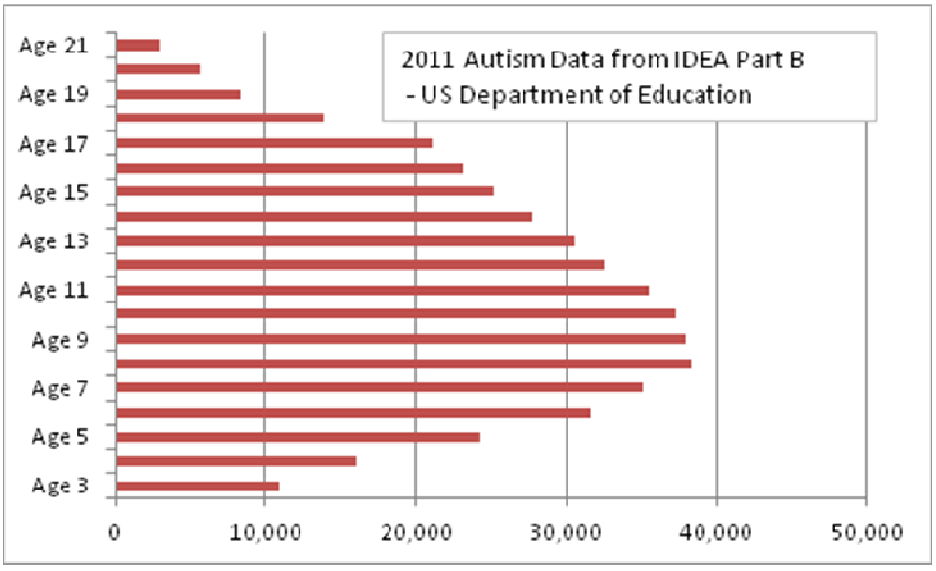
[4] http://www.cdc.gov/ncbddd/autism/documents/ADDM-2012-Community-Report.pdf
[5] http://www.cdc.gov/ncbddd/autism/addm.html
[6] http://www.cdc.gov/ncbddd/autism/index.html

SafeMinds, like many in the autism community, feel the CDC tracking is inadequate. The new data track only 14 states, and took four years to publish. There are inconsistencies in the tracking from report to report and the system is record-based rather than actual screening. The agency is slow to publish and the study lacks the rigor needed to adequately address causes.

While millions have been spent on counting, what can the agency show that has improved the lives of even one of these children? While the CDC has tracked at most 14 sites[7], the Department of Education tracks disability statistics, including autism, annually in every school and even includes pre-school statistics.

Attachment 1 provides a side-by-side comparison of the states in the CDC's ADDM studies and the Department of Education (ED) reporting from 2001 and 2011.
In short, the CDC took four years to publish the 2008 data, showing the dramatic increase from previous studies, setting a prevalence based on 14 sites; while the ED tracks the number of children served under IDEA and reports this annually. You can also see there are striking differences in the growth rate between the CDC and ED data in part because the CDC funded universities to look at certain areas in each state, sometimes not even full counties. The CDC took years and valuable resources to insure the children they included truly were on the autism spectrum, but we have no evidence they have even looked into helping these children, much less done so. Valuable and limited taxpayer resources may be better served if we treated the children rather than simply counting them.

For the school year 2008, a total of 337,795 children aged 3 to 21 with a diagnosis of autism were documented to be receiving IDEA Part B services. By the 2011 school year that number had grown to 455,339. For eight year olds, the age that the CDC is studying in the ADDM trial, the Department of Education's most recent data, updated in September 2012, indicates that there are 38, 344 in the Child Count Database for all 50 states and Puerto Rico.



[7] Whiles states are mentioned as 'sites', in truth all children in the state are not evaluated. For instance the Florida data for the 1998 birth cohort only includes children in the Miami Dade School System.

If the CDC is going to continue the ADDM or other autism prevalence studies, vast improvements are needed to maintain consistency between cycles, to begin studying three year olds, and to report within one year. Taking four years to study and publish prevalence data on the third cycle of a study is too slow and underscores the impression that they are not treating autism as a national emergency.

Origins of Autism

Dr. Leo Kanner is the child psychiatrist who first diagnosed 'infantile autism'[8] at Johns Hopkins University in Baltimore, Maryland. Having been born in Austria in the late 19th century, like many of his medical colleagues in Germany, Dr. Kanner immigrated to the United States in 1924. He began working in Yankton, South Dakota, investigating the apparent lack of 'general paralysis of the insane' in the Native American population.[9] He would take a fellowship at Johns Hopkins and be asked to run the newly established Johns Hopkins Children's Psychiatric Clinic in 1930, where he spent the remainder of his career .

When Dr. Kanner published his text *Child Psychiatry,* he attempted to document every known psychiatric condition in children. It was described at the time as "A brief but weighty consideration of different "schools" and current theories in child psychiatry… Judged for its comprehensiveness, its practicality, its clearness, no other book will take its place for some time, and no other book will so well explain child psychiatry to the pediatrician and the general practitioner."[10]

There is in 1935 no diagnosis of autism or anything that bears similarity known to the medical/psychiatric community.

Mark Blaxill, SafeMinds Board Member, and investigative journalist Dan Olmstead, traced the origins of autism and published the book, *The Age of Autism, Mercury, Medicine, and a Man-Made Epidemic* in 2010. During the course of their investigation, they sought to identify the original 11 families discussed in Dr. Kanner's seminal 1943 paper describing the new condition of "infantile autism". In this paper, Kanner would write, in 1938, five year old Donald T., brought to my clinic from Forest, Mississippi, made me aware of a behavioral pattern not known to me or anyone else theretofore. When I saw a few more children presenting similar characteristics, I reported in 1943 eleven cases…"

Donald T, who Blaxill and Olmstead would discover was Donald Tripplett, still lives in Forest, Mississippi, graduated college, held a job, and plays golf several times a week. His parents would go to Hopkins in 1938 after Donald had endured a year of institutionalization 50 miles from his home. Local medical authorities mistakenly felt Donald would do better with the change of environment. Rather than abandon their son to a life of institutionalization, the

[8] Referred to at the time as "Kanner Syndrome"
[9] General paralysis of the insane (GRI) was often seen in European patients who were treated for syphilis with mercury, the standard of care before the introduction of penicillin.
[10] Earl M. Bond, MD http://ajp.psychiatryonline.org/data/Journals/AJP/2300/240-a.pdf

Tripletts instead took him to Hopkins. Donald would become Case 1. As noted in *Age of Autism*, he is not simply the first case of autism, but the first case of autism recovery.

Off Track Almost Since Day One

The manner in which the medical community has addressed autism has been off track almost since the first case was diagnosed by Dr. Kanner. Initially doctors sought to blame the parents for being cold; then the label of autism was designated solely as a behavior condition and many of the physical symptoms signifying multiple organ system impairment, typically including the gastrointestinal, metabolic and immune systems were all but ignored by the medical and research communities. Compounding this is the discriminatory exclusion of autism from medical insurance. In *Age of Autism*, Blaxill and Olmstead detail how the original 11 children were potentially exposed to neurotoxicants. Had Dr. Kanner or his colleagues explored the why (the possibility of environmental factors) rather than simply detailing the diagnosis, this epidemic might have been prevented.

Individuals and families living with autism have over the last 74 years had to endure many injustices, starting most tragically with concept of the Refrigerator Mother. Bruno Bettelheim, an Austrian art historian who had training in psychology survived a year in a concentration camp and eventually immigrated to the United States. He would focus his career on psychology and served as the director of the Orthogenic School, a home for disturbed children associated with the University of Chicago. He promoted the theory that children became autistic because of cold and emotionally distant mothers, women he referred to as "refrigerator mothers". He claimed that the traumatized unloved child retreated into autism. He established a pattern within psychiatry to blame the parents, rather than to look at environmental factors. This pattern continues even into the 21st century where research has looked at the age of the father, the weight of the mother, and a host of factors that the 'experts' admit only account for less than one percent of cases. The most recent study[11] which grabbed the headlines said that pregnant women who had the flu or suffered a fever for a week during pregnancy doubled their risk of having a child with autism. The study, done in Denmark, found that the risk doubled from one to two percent, but, because it was based on interviews with mothers, it did not actually verify the fevers or flu.

In 1964, Dr. Bernard Rimland a psychologist in San Diego published the book *Infantile Autism: The Syndrome and Its Implications for a Neural Theory of Behavior*. Dr. Rimland documented the similarities between brain injured children and autistic children, liberating parents from the destructive guilt associated with having an autistic child and pointing autism research in the direction it should always have taken: investigation into the biological mechanisms underlying brain and immune system dysfunction.

After founding the Autism Society of America (ASA) in 1965 and establishing the Autism Research Institute (ARI) in 1967, Dr. Rimland began distributing a questionnaire to parents of autistic children. Some 33 years later, he analyzed information he had collected in his databank

[11] 1: Atladóttir HO, Henriksen TB, Schendel DE, Parner ET. Autism After Infection, Febrile Episodes, and Antibiotic Use During Pregnancy: An Exploratory Study. Pediatrics. 2012 Nov 12. [Epub ahead of print] PubMed PMID: 23147969

pertaining to the age of onset of autism. He discovered that before the early 1980's, most of the parents reported their children first showed signs of abnormal behavior at birth or in the first year of life. But after the mid-1980's, there was a reversal of this pattern. By 2000, the numbers of parents reporting that their children developed normally in the first year and a half of life and then suddenly became autistic doubled. Rimland found that children with an onset of autism at 18 months outnumbered the children who were born with autism by 2 to 1. Dr. Rimland recognized and supported that there were environmental factors including the increased exposure of infants to thimerosal (mercury) in their immunizations and other vaccine-injury associated brain injuries that were likely associated with the dramatic upsurge. He reported this to the House Oversight Committee at the April 6, 2000 hearing.[12]

Explanation of Autism - More Than A Behavioral Disorder

As noted above, Autism Spectrum Disorder often referred to as simply Autism or ASD is a complex condition. SafeMinds recognizes that autism is a whole-body condition, not simply a behavioral disorder. Children with autism in the 21st century generally have multiple organ system impairment, typically including the gastrointestinal, metabolic and immune systems. These children often have chronic systemic illness requiring individualized evaluations and care which often includes the use of specialized diets, dietary supplements, pharmaceuticals, behavioral and occupational therapies. Clinical research indicates that children with autism share serious underlying disorders such as:

- Auto-antibodies and impaired immune system function
- Methylation disorders (chemical process that supports toxin excretion)
- Low glutathione levels (glutathione is necessary for toxin excretion)
- High metal toxicity (including mercury, aluminum, lead)
- Mitochondrial dysfunction
- Thyroid dysfunction
- Demyelinization
- MBP “Myelin Basic Protein” antibodies
- Gastrointestinal disease
- Seizure disorders
- Chronic neuroinflammation
- Chronic bacterial, viral, and fungal infections
- Disordered serum chemistries
- Altered metabolic profiles
- Impaired brain connectivity

Clinicians currently base the diagnosis on a series of behaviors which include:

- Lack of or delay in spoken language
- Repetitive use of language and/or motor mannerisms (e.g., hand-flapping, twirling objects)
- Little or no eye contact

[12] http://www.gpo.gov/fdsys/pkg/CHRG-106hhrg69622/pdf/CHRG-106hhrg69622.pdf

- Lack of interest in peer relationships
- Lack of spontaneous or make-believe play
- Persistent fixation on parts of objects

Each individual with autism is unique in how their symptoms present and how severely they are affected. Some will also have other medical conditions (co-morbid diagnoses) such as such as seizure disorders (epilepsy), anxiety or depression. Others have food allergies or have dramatic changes in behavior if exposed to foods that contain gluten or casein. Many people with autism have significant sensory challenges. The level of verbal language varies. The individual may or may not be intellectually impaired. Some individuals with autism are considering 'high functioning' or as having Asperger's Syndrome. Some children are born with autism, often referred to as 'classic autism', and others develop normally and then regress into autism, usually between their first and second birthdays.

What Causes Autism?

There is no single cause of autism. Some of the explanations provided by government agencies and individuals include:

American Recovery and Reinvestment Act of 2009: "As with many complex disorders, the cause of autism is thought to involve some combination of genetic risk and non-genetic environmental exposures. The wide diversity of symptoms among individuals affected by autism suggests that there may be many different causes for autism. The potential for environmental agents to contribute to the incidence of autism has been confirmed in cases where early exposure to certain toxicants (e.g., thalidomide, valproic acid) has led to a markedly increased risk of autism spectrum disorders Although the precise role of the environment in causing autism is unknown, recent studies exploring a range of exposures and potential physiologic vulnerabilities in autism are providing important clues."[13]

National Institute of Child Health and Human Development Scientists: "Scientists don't know exactly what causes autism at this time. Much evidence supports the idea that genetic factors—that is, genes, their function, and their interactions—are one of the main underlying causes of ASDs. But, researchers aren't looking for just one gene. Current evidence suggests that as many as 10 or more genes on different chromosomes may be involved in autism, to different degrees. Some genes may place a person at greater risk for autism, called susceptibility. Other genes may cause specific symptoms or determine how severe those symptoms are. Or, genes with changes or mutations might add to the symptoms of autism because the genes or gene products aren't working properly. Research has also shown that environmental factors, such as viruses, may also play a role in causing autism. While some researchers are examining genes and environmental factors, other researchers are looking at possible neurological, infectious, metabolic, and immunologic factors that may be involved in autism. Because the disorder is so complex, and because no two people with autism are exactly alike, autism is probably the result of many causes."[14]

[13] http://www.niehs.nih.gov/research/supported/recovery/critical/autism/index.cfm
[14] http://www.nichd.nih.gov/publications/pubs/upload/autism_overview_2005.pdf#page=5

National Institute of Neurological Disorders and Stroke: "Scientists aren't certain about what causes ASD, but it's likely that both genetics and environment play a role. Researchers have identified a number of genes associated with the disorder. Studies of people with ASD have found irregularities in several regions of the brain. Other studies suggest that people with ASD have abnormal levels of serotonin or other neurotransmitters in the brain. These abnormalities suggest that ASD could result from the disruption of normal brain development early in fetal development caused by defects in genes that control brain growth and that regulate how brain cells communicate with each other, possibly due to the influence of environmental factors on gene function. While these findings are intriguing, they are preliminary and require further study. The theory that parental practices are responsible for ASD has long been disproved. Twin and family studies strongly suggest that some people have a genetic predisposition to autism. Identical twin studies show that if one twin is affected, there is up to a 90 percent chance the other twin will be affected. There are a number of studies in progress to determine the specific genetic factors associated with the development of ASD. In families with one child with ASD, the risk of having a second child with the disorder is approximately 5 percent, or one in 20. This is greater than the risk for the general population.

Researchers are looking for clues about which genes contribute to this increased susceptibility. In some cases, parents and other relatives of a child with ASD show mild impairments in social and communicative skills or engage in repetitive behaviors. Evidence also suggests that some emotional disorders, such as bipolar disorder, occur more frequently than average in the families of people with ASD."[15]

CDC Representative before Congress in 2000: In an April 6, 2000 Congressional Hearing, Colleen Boyle, PhD, then Chief of the Developmental Disabilities Branch of the CDC, on behalf of the agency testified that "…several infectious diseases are known to cause developmental disabilities including Haemophilis influenza B and congenital rubella syndrome, are known to cause autism. Other known causes of developmental disabilities include nutritional deficiencies such as those of iodine and iron, and environmental exposures including lead and mercury."[16]

An Associated Press article[17] reports, "More than $1 billion has been spent over the past decade searching for the causes of autism. In some ways, the research looks like a long-running fishing expedition, with a focus on everything from genetics to the age of the father, the weight of the mother, and how close a child lives to a freeway. …In the past week, a spate of studies released during National Autism Awareness Month has offered tantalizing new information about potential causes. Research published in the journal Nature widened the understanding of the genetic roots of some cases and confirmed the elevated risks for children with older fathers. Another study, released online Monday in Pediatrics, suggested maternal obesity may play a role…..The causes are believed to be complicated, and not necessarily the same for each child. Some liken autism to cancer -- a small word for a wide range of illnesses. In many cases, autism can be blamed on both genetic problems that load the gun and other factors that pull the trigger…. The U.S. government dramatically increased funding for research of it in the last

[15] http://www.ninds.nih.gov/disorders/autism/detail_autism.htm
[16] http://www.gpo.gov/fdsys/pkg/CHRG-106hhrg69622/pdf/CHRG-106hhrg69622.pdf
[17] http://www.businessweek.com/ap/2012-04/D9U1I7JO2.htm

decade, and now budgets about $170 million a year through the National Institutes of Health. More than a half-dozen foundations and autism advocacy groups have been adding to the pot, putting annual research spending in recent years at more than $300 million. About a third of that has been devoted to finding autism's causes. The lion's share of money for finding a cause has been spent on genetics, which so far experts believe can account for roughly 20 percent of cases…But even genetics enthusiasts acknowledge that genes are only part of the answer. Studies of identical twins have shown that autism can occur in one and not the other, meaning something outside a child's DNA is triggering the disorder in many cases. Some cases may be entirely due to other causes, Dawson said…Said Coleen Boyle, a CDC official overseeing research into children's developmental disabilities: "We're at the infancy of just understanding how these factors relate to autism."

The California Autism Twins Study: A 2011 study on twins at the MIND Institute (Hallmayer et al., 2011) This report describes the results of the California Autism Twins Study:

The chief aims of the study were to (1) collect a sample of twins with validated diagnoses of autism (ASD) from a population-based sample; (2) examine sex-specific concordance rates for narrow and broad definitions of autism (ASD); and (3) determine the extent to which genetic and shared environmental factors underlie susceptibility.

This study is very important in the overall picture of looking at autism because many of the recent studies looking at twins had been with significantly less scientific rigor - either case vignettes or evaluations by telephone interview with parents. The investigators provided:

"The results suggest that environmental factors common to twins explain about 55% of the liability to autism. Although genetic factors also play an important role, they are of substantially lower magnitude than estimates from prior twin studies of autism. Nearly identical estimates emerged for ASD, suggesting that ASD presents the same liability spectrum as strict autism…

Our study provides evidence that the rate of concordance in dizygotic twins may have been seriously underestimated in previous studies and the influence of genetic factors on the susceptibility to develop autism, overestimated. Because of the reported high heritability of autism, a major focus of research in autism has been on finding the underlying genetic causes, with less emphasis on potential environmental triggers or causes. The finding of significant influence of the shared environment, experiences that are common to both twin individuals, may be important for future research paradigms. Increasingly, evidence is accumulating that overt symptoms of autism emerge around the end of the first year of life. Because the prenatal environment and early postnatal environment are shared between twin individuals, we hypothesize that at least some of the environmental factors impacting susceptibility to autism exert their effect during this critical period of life. Nongenetic risk factors that may index environmental influences include parental age, low birth weight, multiple births, and maternal infections during pregnancy. Future studies that seek to elucidate such factors and their role in enhancing or suppressing genetic susceptibility are likely to enhance our understanding of autism."

The Short List of Plausible Environmental Causes of Autism: Environmental Toxicants/Injury

There are a number of resources that provide possible environmental causes of autism. Philip Landrigan of Mount Sinai School of Medicine and a former CDC employee has spent much of his career focused on researching toxic chemicals in the environment and their effects on children's health and development. In 2010, Dr. Landrigan published a list of chemicals now implicated in the causation of neurodevelopmental disabilities.[18]

(1) Lead
(2) Methylmercury
(3) Polychlorinated biphenyls (PCBs)
(4) Arsenic
(5) Manganese
(6) Organophosphate insecticides
(7) DDT
(8) Ethyl alcohol

He further provides that studies have documented that toxic chemicals can damage the developing human brain to produce a spectrum of neurodevelopmental disorders ranging from overt toxicity at high levels of exposure to subclinical dysfunction. The eight chemicals listed may be only the visible tip of the iceberg as so few of chemicals we are exposed to in our everyday life have been tested for neurodevelopmental toxicity. He notes that a recent review of the literature identified 200 industrial chemicals documented to be neurotoxic in adult humans, nearly half of which are high production volume chemicals with a second list of about 1000 chemicals that are neurotoxic in experimental models. Landrigan surmises that many of the chemicals on these two lists have the potential to injury the developing brain and lead to autism. He also provides that prenatal exposures to the drugs thalidomide, misoprostol, valproic acid; exposure to the insecticide chlorphyrifos as well as prenatal rubella infection are linked to the development of autism and other neurological conditions. Landrigan calls for an 'autism discovery strategy which includes among other things, toxicological studies, the development of better screening tools, and neurobiological research.

Based on all available data, SafeMinds proffers that mercury in all its forms not simply methylmercury may lead to autism. This is explained in detail in the paper, "Autism a Novel Form of Mercury Poisoning." Which may be found on our website at: http://www.safeminds.org/research/library/Bernard-et-al-2001.pdf.

In addition to direct chemical exposure leading to neurological injury resulting in autism, exposure to some viruses can lead to encephalitis, or a swelling in the brain. This type of brain injury may lead to the onset of autism. One condition, measles encephalitis may lead to autism[19]. As previously noted to the Oversight Committee, one of the reasons the public health community has promoted vaccination is to prevent the development of autism and other brain

[18] Landrigan PJ. What causes autism? Exploring the environmental contribution. Curr Opin Pediatr 2010; 22(2): 219-225. 5
[19] http://www.jpands.org/vol9no2/bradstreet.pdf

injuries through the 'common childhood illnesses' described below. These officials thought that SSPE was mostly eliminated through immunizations and were unaware at the time that low level measles infection in vaccinated individuals with autism was discovered in their cerebral spinal fluid.

An article[20] in the *British Medical Journal* in 1966 paper provided a description of measles encephalitis and discussed possible causes. "Acute disseminated encephalomyelitis is a rare but serious complication of the common fevers of childhood. It may follow measles, mumps, chicken-pox, influenza, or occasionally rubella. Because measles is the commonest of these diseases, measles encephalitis has been studied in more detail than the others. About one in every 1,000 cases of measles is followed by encephalitis. The three principal theories are, first, that the virus attacks the brain directly; secondly, that the inflammation is due to an immunological reaction; and, thirdly, that the infecting virus activates a latent neurotropic virus…. have found evidence that measles virus does infect the cells of the brain in measles encephalitis, though they did not succeed in isolating the virus in tissue culture." A second type of measles encephalitis, Subacute sclerosing panencephalitis (SSPE) is a rare chronic, progressive encephalitis caused by a persistent infection measles virus. There is no known cure for SSPE.

Failure to Be Forthcoming: Most disturbing to many in the community is the failure of government personnel to be forthcoming to the Congress and to the public about vaccine-induced brain injury and the resulting diagnosis of autism. The EBCALA paper "Unanswered Questions from the Vaccine Injury Compensation Program: A Review of Compensated Cases of Vaccine-Induced Brain Injury"[21] documented 83 cases of autism among those compensated in the Vaccine Injury Compensation Program for vaccine-induced encephalopathy and residual seizure disorder associated with autism since the inception of the program. This study raises many questions for those who manage the program on behalf of the government, especially those who came before the Oversight Committee and testified under oath that there was no link between vaccine injury and autism.

It is important to know that most vaccines have not been studied regarding autism. Only 1 of the seven vaccines given in the first year of life (Hepatitis B) has been studied for associations with autism in children who received it vs. children who did not receive it or were delayed in receiving it. The study found the odds for autism prevalence were 3X higher in the boys who received the vaccine at birth.

When our babies are born pre-polluted, it makes good sense to evaluate the combinations of chemicals in vaccines like mercury, aluminum, and 2-phenoxyethanol with their effects on infants and children. The studies "proving" that thimerosal is safe have poor methodology and have been published by authors with conflicts of interest. Even so, thimerosal is associated with elevated risk of tic disorders and speech delays. Other studies support thimerosal's toxicity at vaccine-level doses. Information received through the Freedom of Information Act showed significant associations between early thimerosal exposure and autism.

[20] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1943040/pdf/brmedj02349-0020.pdf
[21] http://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pelr

We need more research into potentially greater susceptibility to vaccine injury in certain populations.

It is time for the government to fund a large trial of vaccinated and unvaccinated children to see if there are higher autism rates among vaccinated children than among those who have never been vaccinated.

Combating Autism Act

In 2006, the autism community came together and asked Congress to provide legislation and funding to "combat autism." The resulting legislation authorized $850 million for that mission. Frustrating to most in the autism community, the National Institutes of Health (NIH) has not used these resources wisely. Not a single child has received improved treatments as a result of this investment.

In 2011, autism parents asked Congress to fix the bill. A coalition of 70 autism organizations including SafeMinds formed an alliance to push for accountability in the spending and to request that more focus be placed on environmental causation of autism. Due to multiple factors, the House went along with the Senate decision to simply extend the Act for three years. As a result there was no new funding.

The annual funding for all autism research and services is about $230 million. Given the CDC's past estimate of 730,000 people with autism under the age of 21, that works out to $315 per person per year.

Federal Funding is not proportional to Autism's Impact. To compare, the NIH spent the following on research in 2011:

- $169 million on Autism – which affects about 45, 000 US babies each year.
- $79 million on Cystic Fibrosis – which affects about 1,000 US babies each year.
- $228 million on Pediatric AIDS – which affects about 13,500 US babies each year.
- $170 million on Pediatric cancer – which affects about 800 US babies each year

All of these are important, but given the long-term human and cost impacts and autism's rapid rate of growth, in comparison, autism research is grossly underfunded.

There are many other leadership failures which the autism community is challenged with:

President Barack Obama is entering his second term and has an opportunity to keep the promises he made from his first presidential campaign. In 2008, President Obama, while campaigning, called himself the "Autism" President. He promised insurance coverage for autism therapies for all Americans. He promised to create a federal government position responsible for autism

policy. In April 20008, then Candidate Obama stated, "We've seen just a skyrocketing autism rate. Some people are suspicious that it's connected to the vaccines. This person included. The science right now is inconclusive, but we have to research it."[22]

No Autism Czar: Four years ago, newly elected President Obama had the opportunity to fulfill his campaign promise to create a federal policy point person (at the White House) specifically dedicated to autism – an Autism Czar. President Obama came under intense attack from some in Congress for appointing more than three dozen Czars to White House and Administration positions. Two criticisms that have been put forward are (1) that these advisory roles circumvent the Senate Confirmation process for high ranking political appointees; and (2) concerns about a lack of transparency that would be created by a 'czar' system. Judicial Watch published a Special Report[23] in 2011. Nevertheless, autism has reached epidemic proportions in the United States and the overwhelming lack of accountability at the highest levels of government now demands that someone take charge.

"Celebrated" Autism: In what falls into the same category of the now infamous 2009 comments of President Obama on *The Tonight Show* with Jay Leno about his bowling prowess[24], comments issued by the Administration that the White House would be 'celebrating' autism were equally offensive. The White House on at least one occasion invited representatives of numerous autism organizations to the White House for an event which, rather than being an interactive forum to discuss the needs of the autism community, turned out to be a " pat ourselves on the back" party to celebrate autism. In addition to the offensive language of 'celebrating' the fastest growing disability on the planet, there was and remains a frustration of lost opportunities and the waste of resources (time and funds) to have a party when so much has yet to be addressed.

Sadly, so many of the promises of Candidate Obama have not been filled. There is no point person at the White House focused on autism. Neither The White House, nor the Administration has picked up on state-level insurance reform to implement federal insurance reform (of ERISA) to eliminate the 'autism exclusion' that so often denies families from accessing needed services.

Instead, individuals within the Administration have deflected, covered up or misrepresented the truth about evidence of harm from environmental toxicants as they relate to the autism epidemic. These will be detailed below.

Secretary of Health and Human Services Seeks To Silence Families: Kathleen Sebelius was sworn in as the Secretary of the Department of Health and Human Services (HHS) on April 28, 2009. On October 5, 2009, Secretary Sebelius published an Op-Ed stating, "We needed a new focus and new resources because autism has emerged as an urgent public health challenge. As recently as the 1990s, scientists thought autism was a rare disorder that affected 1 in every 2000 kids. Earlier this decade, we revised that estimate to say that 1 in every 150 kids was somewhere

[22] http://voices.washingtonpost.com/fact-checker/2008/04/dr_obama_and_dr_mccain.html
[23] http://judicialwatch.org/press-room/press-releases/judicial-watch-releases-comprehensive-special-report-on-president-obama-s-45-czars/
[24] http://www.msnbc.msn.com/id/29784865/ns/politics-white_house/t/obama-sorry-special-olympics-gaffe/#.UKpBSYawUgI

on the autism spectrum. Our most recent data suggest that autism may be even more common than that. Almost every American I talk to about this issue knows at least one family that is affected by autism. Autism has created new challenges for families, schools, and health care providers. When parents discover that their child has autism today, they're left with a lot of questions, but few answers. What causes autism? How can it be prevented? Which treatments can help? Where can I get needed services? These questions aren't new. And the government has tried to address them in the past, most notably with the Combating Autism Act, which passed in 2006. But there has never been a comprehensive, well-funded effort across government to overcome autism – until now."[25]

The Secretary has overall authority over all of the health agencies as well as the appointment of members to the Interagency Autism Coordinating Committee. Matters specific to the appointments to and the administration of IACC will be addressed in a separate section of this report.

Not Treating Autism Like a National Emergency: The Secretary's participation at the July 2012 IACC meeting along with two representatives from the White House has been viewed by many in the autism community as an example of the pattern of 'running the clock down' by congratulating each other on all of the perceived accomplishments, rather than digging in and using the considerable power and resources of government to treat autism like the national emergency that it is.

The Secretary has been unwilling to engage on some of the most important matters. In fact, one might consider her actions to be counter-productive to the needs of the autism community.

Specifically Acts to Restrict Media Attention to the Autism-Vaccine Injury Dialogue: During an interview by the magazine, *Reader's Digest*, Secretary Sebelius stated that people who question vaccine safety should not be given equal weight by the press, compared to public health officials. She stated, "There are groups out there that insist that vaccines are responsible for a variety of problems despite all scientific evidence to the contrary. **We have reached out to media outlets to try to get them to not give the views of these people equal weight in their reporting** to what science has shown and continues to show about the safety of vaccines."[26]

SafeMinds has been mischaracterized as an anti-vaccine group and we feel it is important to reiterate that we are actually a group of concerned citizens who know too much to stay quiet. The truth is that we actually read the research (not just the abstracts and not just the big journals) and look at the details. The associations between autism and mercury and autism and vaccines are still open questions. The majority of the studies that claim to "prove" that autism is not associated with Thimerosal or MMR (the entire rest of the childhood schedule has never even been looked at in this regard) have significant conflicts of interest, have significant flaws in their methods and/or do not answer the whole question. On the other side of this debate, and rarely mentioned by the press, are the biological studies that continue to be published supporting these associations.

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[25] http://www.icare4autism.org/news/2009/10/op-ed-fight-to-overcome-autism-gets-major-boost-higher-priority/
[26] http://www.rd.com/health/wellness/h1n1-the-report-card/

Most troubling in the Secretary's comments is the admission that a Federal Agency is openly seeking to suppress free speech and to control whom the media gives 'air time'. This is an abuse of power that threatens our Constitution and all that we as a nation hold dear. Furthermore, it is, in our opinion, the penultimate act of malfeasance of the agency to suppress public dialogue so that parents can make informed decisions. We may never know the full extent of the harm done by denying the public the whole story.

SafeMinds agrees with a quote from Abraham Lincoln that Congressman Dan Burton has frequently used during hearings looking into the autism epidemic: "*I am a firm believer in the people. If given the truth, they can be depended upon to meet any national crisis. The great point is to bring them the real facts.*"

We are in a national crisis – the rates of autism have skyrocketed with no emphasis by the Secretary on prevention or to raise the alarm through words and deeds.

Centers for Disease Control and Prevention

While we have previously discussed the CDC's surveillance issues, there are other matters that bear mention. One of the greatest challenges to asking the CDC to honestly address the investigation of autism is their direct conflict of interest with one of the prevailing environmental factors – vaccine injury. The CDC is the HHS agency charged with promoting immunizations and insuring full compliance with vaccine policies.

Their reluctance or unwillingness to address the issue has shown itself in every incidence over more than two decades when the topic has arisen. As a result, there have been many lost opportunities to truthfully address the concerns of parents, leading to an undermining of faith by many in the Public Health Service in general and the CDC in particular. This was only compounded in 2009 in top examples of the 'revolving door' between HHS and the pharmaceutical industry when the outgoing CDC Director Dr. Julie Gerberding, was named president of Merck & Co Inc's vaccine division.[27] Dr. Gerberding had run the agency for 7 years.

Knew about epidemic by 1999 with Brick township study

In April 2000, the CDC issued a report[28] entitled, Prevalence of Autism in Brick Township, New Jersey, 1998: Community Report" The report was part of the '4 part plan' initiated as the result of a request made by Senator Robert Torricelli and Congressman Christopher Smith after a citizen's group in Brick Township, New Jersey contacted the New Jersey Department of Health and Senior Services (DHSS) in late 1997 with concerns about an apparently larger than expected number of children with autism in Brick Township. In the introduction of the report the CDC admits that the citizens' were concerned that environmental factors were a factor.

[27] http://www.reuters.com/article/2009/12/21/us-merck-gerberding-idUSTRE5BK2K520091221
[28] http://www.cdc.gov/ncbddd/developmentaldisabilities/documents/brick-report.pdf

The CDC worked with its sister agency, the Agency for Toxic Substances and Disease Registry and developed a four part plan:

1. Prevalence investigation
2. Literature review of environmental factors associated with autism
3. Investigation of environmental pathways for human exposure in the community
4. Community education and involvement activities

The CDC confirmed a rate of 6.7 cases per 1,000 of autism in Brick Township and noted in the report that it was the first such study of autism prevalence in the United States. In essence, the rates of autism in this community in 1998 were 1 in 150. The rates for autism appeared to be higher in the younger children.

In preparing for the April 2001 House Oversight Committee hearing on autism, the Committee learned that the CDC consciously chose not to study the immunization records of the children they evaluated in Brick, even though parents had requested this be included in the study. Congressman Burton stated during the hearing, "*We have an epidemic on our hands that we cannot ignore any potential path that may lead to any the epidemic*."

VSD – Conflict and Corruption

The Vaccine Safety Datalink (VSD) project is a collaborative effort between CDC's Immunization Safety Office and 10 managed care organizations (MCOs). The VSD project was established in 1990 to monitor immunization safety and address the gaps in scientific knowledge about rare and serious events following immunization. The VSD project includes a large linked database that uses administrative data sources at each MCO. Each participating site gathers data on vaccination (vaccine type, date of vaccination, concurrent vaccinations), medical outcomes (outpatient visits, inpatient visits, urgent care visits), birth data, and census data.[29]

When the concerns of mercury in vaccines and a link to the autism epidemic arose, the CDC embarked on a VSD evaluation. The study was assigned to Thomas Verstraeten, MD an epidemiology fellow from Belgium. Through the federal Freedom of Information Act (FOIA), and other similar requests, SafeMinds gained access to documents and realized that the data presented at the Simpsonwood retreat was, in fact, not the original statistical data.

Dr. Verstraeten's original statistical analysis which SafeMinds named the "Generation Zero" analyses followed a straightforward methodology that was relatively unaffected by biases applied later and was considerably more sensitive with respect to detecting mercury exposure effects than the later reports.

- Most notably, these initial analyses compared disease risk in the highest exposure population groups to disease risk in zero exposure population groups. Using this method, the elevated risk of autism for the highest exposure levels at one month ranged from 7.6 to 11.4 times the zero exposure level. This increased risk level corresponds to the tenfold increase in autism rates seen since vaccine mercury exposures increase starting in 1990.

[29] http://www.cdc.gov/vaccinesafety/Activities/VSD.html

- In addition, the target study population had not yet been subject to numerous exclusions and adjustments applied later, the cumulative effect of which was to reduce the reported impact of mercury exposure on children's health outcomes.

The results of the Generation Zero analyses are striking and more supportive of a causal relationship between vaccine mercury exposure and childhood developmental disorders (especially autism) than any of the results reported later. Details of the SafeMinds review of this data are available on our website.[30],[31] and were discussed in an interview with UPI.[32]

The CDC called together their group of internal and external advisors for a closed door meeting at the Simpsonwood Retreat Center in Georgia on June 7-8, 2000, to discuss the report produced by Dr. Verstraeten with his second generation of data. To skirt transparency policies on holding government meetings, Dr. Walter Orenstein, then Director of the CDC's National Immunization Program called the meeting "individual simultaneous consultation" in conjunction with the initial meeting of the Advisory Committee on Immunization Practices (ACIP), working group on thimerosal. Attendees to this meeting included the Chairman of the ACIP, Dr. John Modlin; numerous other members of the ACIP, representatives from CDC, VICP, NIH/ NIAID, the American Academy of Pediatrics, the American Academy of Family Practice, representatives from WHO and the European Agency for the Evaluation of Medicinal Products. Also present were representatives of vaccine manufacturers (Barbara Howe, Smith Kline Beecham; Jo White, North American Vaccine; Ted Staub, Aventis Pasteur). Not present were patient groups such as SafeMinds or the National Vaccine Information Center, the public, or even legislative staff (who were actively working a vaccine safety investigation.) Information about Simpsonwood including the transcript and key quotes are available on the SafeMinds website.[33]

In discussing the findings of the study to the group at Simpsonwood, Dr. Verstraeten stated, "We have found statistically significant relationships between the exposures and outcomes for these different exposures and outcomes. First, for two months of age, an unspecified developmental delay, which has its own specific ICD9 code. Exposure at three months of age, Tics. Exposure at six months of age, an attention deficit disorder. Exposure at one, three and six months of age, language and speech delays which are two separate ICD9 codes. Exposure at one, three and six months of age, the entire category of neurodevelopmental delays, which includes all of these plus a number of other disorders."

As a means to address the vaccine injury questions, the CDC contracted with the Institute of Medicine to conduct a series of reviews regarding vaccine injury and autism. Just over a year later on July 16, 2001, the IOM Committee conducted a meeting in Boston in which Dr. Verstraeten was to present his findings publicly for the first time. He opened his presentation by announcing that he had 'just that morning' accepted a job with Glaxo Smith Kline that would take him back to his home country of Belgium as an Associate Director of Epidemiology in their Biologics division. Government policies typically require an individual to recuses themselves from involvement in an activity when a financial conflict of interest arises. It is unclear at what

[30] http://www.safeminds.org/research/library/GenerationZeroPowerPoint.pdf
[31] http://www.safeminds.org/research/library/GenerationZeroNotes.pdf
[32] http://www.upi.com/Health_News/2005/07/26/The-Age-of-Autism-Generation-Zero/UPI-22711122409437/
[33] http://www.safeminds.org/government-affairs/foia/simpsonwood.html

point in the evaluation of the data (from the Generation Zero, to the Generation One and Simpsonwood to the other three subsequent runs of the data in which the relationship between thimerosal exposure and neurological injury is washed out) that Dr. Verstraeten began negotiating with Glaxo for a job, which he accepted just prior to publicly discussing his findings for the first time. There is no paper trail that SafeMinds has uncovered that the CDC was aware of his employment negotiations, or that he discussed it and was officially told he could continue working on the VSD project.

In 2004 SafeMinds reviewed the above referenced article and voiced concerns regarding data analysis and related conclusions put forth in this investigation in a letter to the editor of the journal *Pediatrics* and to the "Post Publication Peer Review" (P3R) website. At that time we called for an external audit of the research ethics and supervisory protocols involved in preparing sequential versions of the Vaccine Safety Database (VSD) for public review and ultimate publication. We did not receive a response to our request. Since this time additional concerns have come to light which call into question the study's conclusion of "no consistent significant associations between thimerosal containing vaccines (TCVs) and neurodevelopmental outcomes". These concerns include:

- A recently released report from the Department of Health and Human Services in October of 2006 which identified several inherent weaknesses in the ability of the Vaccine Safety Database utilized in the Verstraeten study which reduces the ability of the database to identify associations between thimerosal exposure and adverse neurological outcomes like autism.
- Alterations in the entrance criteria and study design protocols were made after viewing initial findings and not reported in the published version of the investigation. The study authors were well aware that these alterations would result in a decrease in statistical significance and in some instances, findings to disappear entirely.
- Datasets used in the study were disaggregated which reduced the power to detect associations which were only found when the datasets were combined. One of the study authors acknowledged that the data must be combined to have the power to detect associations, although in the final published versions of the study after this acknowledgement, the HMO's were disaggregated.
- Conflicts of interest were not divulged in the publication of the article. The lead author of the investigation was employed by a vaccine manufacturer and another author who previously acknowledged receiving funding and consulting fees from vaccine manufacturers did not acknowledge any funding conflicts.

SafeMinds attempted to present these concerns to the HHS office charged with protecting the integrity of the research process. However, attempts to engage the HHS Office of Research Integrity (ORI) to look into this pervasive pattern of bias and conscious manipulations of samples and statistics in order to produce a negative finding regarding the dangers of thimerosal exposure in infants and children were rebuffed. The ORI refused to investigate matters including the suppression and falsification of data, ignoring the scientific misconduct.

The CDC-Danish Collaboration

Autism, Cerebral Palsy, and Fetal Alcohol Syndrome are among the conditions the CDC sought to study through a collaborative agreement with Denmark to access their extensive linked database system of medical records.

It is this same project that produced several of the 16 studies which the agency points to as proof that there no link between autism and vaccine injury. These studies have been analyzed by a number of sources including SafeMinds. These findings are available on our website.[34]

In October 2012, the name of Poul Thorsen was added to the top of the list of the HHS Office of Inspector General's "Most Wanted" List.[35] He was indicted in April 2011 for 22 counts of money laundering and fraud. He is mentioned in this report because of the key role he played in developing the body of research that the CDC presents as evidence against a vaccine injury – autism link.

Dr. Poul Thorsen came to the CDC from Denmark in 1997 as a visiting scientist and used his influence within the Division of Birth Defects, Child Development, and Disability and Health to garner a grant for from the agency to the Danes to look at a number of public health issues. He then returned Denmark to manage the grants, which would over time garner more than $16 million in CDC funds.

The entire Thorsen Saga is detailed in the attached SafeMinds Report, "Poul Thorsen, MD, PhD, CDC Researcher – Fugitive from Justice".

The Interagency Autism Coordinating Committee (IACC)

The committee is tasked with the development of the strategic plan and summary of advances, monitoring all federal activities regarding autism and to reporting back to the Secretary recommendations or concerns. The Committee is not tasked with establishing public policy or implementing research or service programs. It is unclear, since the Committee has no true authority, who it will turn to make sure that such critical activities occur.

For example, there is no mechanism in place to assure that high priority research objectives that would help to fill knowledge gaps or rapidly advance our understanding of the disease in the plan ever get funded. The vast majority of funded research is investigator driven. Once funded, research projects are then assessed to determine if they help to fulfill a research objective. This mechanism has resulted in vast over representation of certain research areas, such as genetics, while other critical areas of research are completely unfunded. We need the federal agencies responsible for funding research to create RFAs that request specific research proposals, create fast track mechanisms for review and funding to assure that critical research is conducted.

[34] http://www.safeminds.org/news/documents/Vaccines%20and%20Autism.%20Epidemiology%20Rebuttal.pdf
[35] https://oig.hhs.gov/fraud/fugitives/index.asp

Last year the IACC sent two letters to the Secretary regarding wandering and elopement http://iacc.hhs.gov/publications/2011/iacc_letter_sebelius_wandering_020911.pdf and the unnecessary use of seclusion and restraint in individuals with autism. http://iacc.hhs.gov/publications/2011/iacc_advisory_letter_sebelius_seclusion_restraint_090711.pdf Both letters included specific policy recommendations for addressing the committee's concerns.

The only response was a perfunctory thank you. tThere, in essence, was no follow up. http://iacc.hhs.gov/publications/2011/iacc_response_letter_sebelius_wandering_032311.pdf

According to the National Autism Association from September 2011 to July 2012 there have been total of 194 reported Incidents of wandering with 17 deaths. This is an urgent matter that deserves action on behalf of the Secretary and the agencies of jurisdiction. The second letter, sent September 7th 2011, outlined the unnecessary and dangerous use of seclusion and restraint in a variety of settings that receive Federal funding such as schools and residential treatment facilities. The letter contained several recommendations that the IACC as a committee felt required immediate Federal attention. When the lack of response was mentioned to the Secretary at the July IACC meeting, she simply deflected responsibility for the matter to the Department of Education.

The IACC was first established under the Children's Health Act of 2000. The House and Senate conferees in the FY 2003 appropriations for the Departments of Labor, Health and Human Services and Education, Conference Report 108-10, requested that the IACC "convene a panel of outstanding scientists to assess the field of autism research, and identify roadblocks that may be hindering progress in understanding its causes and best treatment options." In response to this request, the IACC convened a panel of science experts who developed an Autism Research Matrix which outlined goals and activities for the next 10 years.

When the new IACC was established under the 2006 CAA the research matrix established in 2003 was abandoned and a completely new research plan was developed following much of the same process. A new team of approximately 50 experts were brought in to help create the new strategic plan. Many of the selected experts were recipients of NIH research funding although they were not required to report conflicts of interest and were able to advocate for the inclusion of their areas of research interest in the strategic plan. The continual development of new research initiatives and direction without fully evaluating previous research initiatives is costly and duplicative.

When CAA was reauthorized last year only 3 of the previous public members were invited back to serve on the committee. It took 10 months to establish a new committee and much of the first meeting was spent doing introductions and orienting new committee members. There was no public discussion of conflicts of interest at this meeting. The first item on the agenda of the new IACC was the update of the strategic plan. Again experts will be brought in to advise the committee and new initiatives will be developed. These new experts also apparently are not being required to provide conflicts of interest disclosures in the manner that advisory members are.

The IACC currently tracks the funding of research initiatives outlined in the strategic plan but has yet to create any mechanism for evaluating if a specific research objective has actually been met or to gauge the effectiveness of the research investment with regard to advancement of the science that directly translated to effective treatments and prevention of the disease. A core value of the IACC is accountability. In an effort to provide accountability, research objectives were created that were specific, measurable, achievable, realistic and time bound. For example objective 3.3/3SB in the strategic plan reads "Within the highest priority categories of exposure for ASD, identify and standardize at least three measures for identifying markers of environmental exposure in biospecimens by 2011. Recommended budget is $3,500,000 over 3 years." It is critical that the current objectives in the strategic plan are evaluated to determine if they have been fulfilled before the committee moves forward with updates or new objectives. Unfortunately there are no plans for that to happen at present.

Throughout the past 6 years several issues regarding leadership of the IACC have arisen. These include concerns regarding the process used to create and update the strategic plan with regard to outside expert influence over objectives who stand to benefit from their participation without acknowledgement of their conflicts. The committee does not have input on the development of the meeting agendas. Often there is lack of time allotted for committee work which results in the need for additional meetings and increased costs.

There have been violations of the standards for conducting meetings, such as discussion and vote by the committee on items not published on the agenda, which resulted in the withdrawal of support for the IACC strategic plan from the largest autism advocacy organization Autism Speaks who in a press release called for the "administration to restore the intent of the CAA to respect and value community input". http://www.autismspeaks.org/about-us/press-releases/autism-speaks-withdraws-support-strategic-plan-autism-research-decries-unexp January 15, 2009.

The Chairman also makes unilateral decisions in chairing committee deliberations such as refusing to fully acknowledge motions with seconds made by committee members and dismisses the issue without adequate discussion or vote in violation of Robert's Rules of Order. There have also been issues regarding a lack of professionalism among Federal members. According to a report in Nature, October 20th 2009, Dr. Landis, the Director of the NIH Institute for Neurological Disorders and Stroke apologized for her "unprofessional" behavior and said "I understand how my comments triggered frustration and anger" in the autism community. http://blogs.nature.com/news/2009/10/open_access_are_publishers_dou.html

In the 2011 IACC Strategic Plan recognized that the increasing prevalence of autism has created a national health emergency. In an effort to mobilize the necessary resources both from the Federal and private sector we need HHS to officially declare autism a national health emergency. Autism is a complex medical condition medical condition like AIDS, Alzheimer's and cancer, and it should be treated as a priority medical condition for purposes of health insurance and coverage of medically-indicated evaluations and treatments. Autism is not a mental health condition and responsibility for oversight for autism research should be removed from NIMH and an Office of ASD Research should be created under the Director of NIH.

The IACC is tasked with the monitoring and coordination of all efforts within HHS related to autism. Unfortunately, the committee is composed of high level Federal officials and public members who meet approximately four times a year, which severely limits their ability to adequately perform this task. The committee is also constrained by the fact that it functions purely in an advisory capacity as discussed above. The NIH Office of the Director is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components. Under the Office of the Director are several offices, such as that for AIDS research, that are responsible for the coordination of the scientific, budgetary, legislative, and policy elements of the NIH AIDS research. An Office of ASD Research modeled after the Office of AIDS Research to fortify and expand the activities of the IACC and to implement necessary policies to effectively respond to this urgent health emergency is essential. The Office of ASD Research would be responsible for annual comprehensive trans-NIH planning, budgeting, portfolio assessment processes, establishing scientific priorities and ensuring that research dollars are invested in the highest priority areas of scientific opportunity and are aligned with the vision, mission and values of the Strategic Plan for Autism Research as directed by the Combating Autism Act. Having one entity responsible for ASD research would help to prevent the fragmentation that currently exists with multiple institutes conducting ASD research and ensure proper accountability, oversight and public participation

Genetics Research Over budget while Environmental Underfunded: There has been no attempt to determine cumulative funding to date for objectives in the strategic plan. For example, please consider items related to genetics and environmental research identified in question # 3 "What caused this to happen and can it be prevented?" in the strategic plan. There are three objectives in this chapter that have been present in the plan since it was first developed in 2008:

3.8 Identify genetic risk factors in at least 50% of people with ASD by 2014.
Recommended budget $33,900,000 over 6 years

3.6 Determine the effect of at least 5 environmental factors on the risk of subtypes of ASD in the pre- and early postnatal period of development by 2015:
Recommended budget $25,100,000 over 7 years

3.3 Within the highest priority categories of exposure for ASD, identify and standardize at least three measures for identifying markers of environmental exposure in biospecimens by 2011.
Recommended budget $3,500,000 over 3 years.

In reviewing each of these objectives in the 2008, 2009, and 2010 research portfolio analysis we were able to determine cumulative spending to date for each objective.

Objective	Budget	2008	2009	2010	Totals
3.8 or 3.L.B.	$33,900,900/ 6 yrs	$37,043,410	$49,905,587	$34,432,884	$121,381,881.00
3.6 or 3.L.C.	$25,100,000/ 7 yrs	$1,803,628	$1,992,228	$820,320	$4,616,176.00
3.3 or 3.S.B.	$3,500,000/ 3 yrs	$713,227	$ 0	$0	$713,227.00

An evaluation of cumulative funding reveals that we are almost 400% over budget for the genetic objective and extremely under budget (approximately 20% of budget) for the environmental objectives. In addition, objective 3.3 was identified as a short term objective earmarked for completion in 2011. But for the last two years there was no funding toward this goal and this critical research objective remains unfulfilled. The genetic research initiative should be evaluated for success and specific RFAs with special emphasis panels should be developed to fast track the environmental objectives.

A mechanism is needed to effectively communicate with those individuals at NIH who are responsible for making research funding decisions the objectives that need to be fast tracked for funding. In 1997, at the request of Congress, the NIH formed the Autism Coordinating Committee (NIH/ACC) to "enhance the quality, pace and coordination of efforts at the NIH to find a cure for autism". Members of the committee are the NIH agencies who conduct ASD research. Unfortunately there is little information available regarding this committee on the NIH website (meeting schedules, agenda, or minutes to meetings) to determine how the ACC functions. http://www.nimh.nih.gov/health/topics/autism-spectrum-disorders-pervasive-developmental-disorders/nih-initiatives/nih-autism-coordinating-committee.shtml

In addition to determining cumulative funding for each research objective we also need to evaluate the return on our research investments. Did the funding result in peer reviewed publications? Did the funding advance our understanding of autism and lead to effective treatments, improved services or prevention of the disease? These are critical questions that must be asked and answered before we continue down the same path.

Members of the stakeholder community are disappointed with the slow pace NIH research in response to what the IACC has recognized as a "national health emergency". Recognizing the enormous and rising burden that autism places on the families and support services that are caring for this new generation of children and young adults with autism we need to focus research in areas that can yield meaningful near term results.

Since the establishment of the IACC under the CAA the prevalence of autism has continued to increase. In the IACC report to Congress in 2003 it the CDC stated "we do not know the exact prevalence of autism, estimates range from 1 in 400 to 1 in 1,000 in the United States". In April of this year the Centers for Disease Control and Prevention (CDC) reported an autism prevalence rate in the United States of 1 in 88 children (1 in 54 boys and 1 in 252 girls).

The estimated costs for autism in the U.S. have tripled since 2006 and are now estimated to have reached $126 billion per year. This figure expands on previous estimates by including indirect costs such as lost family income and productivity in addition to the direct costs of autism-associated care. The researchers also estimated autism's lifetime costs for one individual to be more than $2.3 million for a person with an autism and intellectual disability and $1.4 million for a person without intellectual disability. Intellectual disabilities affect approximately 40 percent of individuals with autism spectrum disorders.

Clearly autism has reached epidemic proportions and truly represents a global health emergency. These new numbers also make it clear that we must urgently accelerate our investment in resources and implementation of meaningful research to ensure that we realize the goals of the CAA for finding the cause, prevention and treatment of autism. To accomplish this goal we need to take a critical look at our current efforts and strongly consider a change in leadership and direction.

In reviewing the IACC autism research portfolio analysis reports for years 2008, 2009, and 2010 that align with question 3, it is apparent that the majority of spending continues to focus on the genetic underpinnings of ASD. The 2010 ASD Research Portfolio Analysis conducted by the NIH Office of Autism Research and Coordination documented that genetic risk factors accounted for 63% of funding, projects that considered only environmental factors accounted for 5%, while projects that examined Gene-Environment interactions accounted for 25%, and epigenetics received 7% of the ASD research funding in Question 3 (See Attachment)

The DSM-V Controversy

Compounding the challenges within the government the autism community is further challenged with an attempt to change the definition of autism. The official Diagnostic Criteria for autism is issued by the American Psychiatric Association in their Diagnostic and Statistical Manual-IV, Text Revision (DSM-IV-TR). This is the diagnostic criteria referenced by federal agencies . The revised DSM – version 5 is slated for release in May 2013. There are a number of controversies associated with the DSM-5, including concern as outlined in a New York Times article, that the proposed changes, if implemented, would narrow the definition, thus reducing the number of individuals included in prevalence studies and reducing access to needed services by individuals knocked out of the diagnosis category. This article details a study by Dr. Fred Volkmar of the Yale Child Study Center which found that only 45% of 372 high-functioning people with autism from the dataset of a DSM-IV study done in 1993 would meet the new criteria for an autism spectrum disorder. By excluding them from DSM-V, their access to services would likely be eliminated.

SafeMinds joined with a number of other autism organizations to notify the APA Working Group of our concerns which include:

1) Impact on Medicaid and disability services
2) Impact on insurance coverage
3) Impact on school services/early intervention
4) Impact on Epidemiology Research
5) Impact on biomedical research

A full explanation of review of these concerns is available on the SafeMinds website.

Conclusions

Autism is a national emergency. SafeMinds and the entire autism community request that the Oversight Committee and others in the Congress engage aggressively in conducting oversight to address the numerous issues mentioned in this report. We need accountability, we need adequate research, and we need sustained Congressional involvement. We hope that this hearing is the first of many. We ask Congress specifically to address:

CDC Cover-ups
Research Focus and Accountability
Agency Coordination and Transparency to the Public
Poul Thorsen
Failures to Comply with FOIA
Unequal emphasis on genetics versus environmental factors
The Unanswered Questions within the Vaccine Injury Compensation Program
Reform of the Vaccine Injury Compensation Program

Attachments:
Side-by-Side Comparison of ADDM Data with Department of Education Data
Autism in US Schools
IACC Strategic Plan Objectives - Question #3
Poul Thorsen, MD, PhD, CDC Researcher – Fugitive from Justice

Attachment 1

Side-by-Side Comparison of ADDM Data with Department of Education Data

Site of Study	Study begun in 2000 Published 2007 1994 birth cohort 1 in 150	Study begun in 2006 Published in 2009 1998 birth cohort 1 in 110	Study begun in 2008 Published in 2012 2000 birth cohort 1 in 88	CDC'sADDM Annualized Increase Birth Years 1994-2000	Autism in US Schools in 2001	Autism in US Schools in 2011	Total % Increase	Average Annual % Increase
	Number of Children with Autism age 8 out of a Total Population of 8 year olds at Site in Study				Students with Autism, Ages 3-21 as tracked by the US Department of Education (ideadata.org) (Statewide – not restricted to CDC sites)			
Alabama 32 counties in north and central Alabama		212 out of 35,126	174 out of 36,566	6.4%	849	4819	567%	15.3%
Arizona 2000 – 1 county including metropolitan Phoenix 2006 – Maricopa County – 2008 - A subset of Maricopa County including metropolitan Phoenix, Arizona	295 out of 45,322	504 out of 41,650	507 out of 32,601	12%	1213	8349	688%	19.2%
Arkansas Pulaski County (metropolitan Little Rock, Arkansas)			52 out of 4,940		766	3220	420%	13.9%
Colorado 1 county (Arapahoe) in metropolitan Denver		54 out of 7,184	91 out of 7,725	11.3%	505	4370	865%	21.7%
Florida 1 county (Miami-Dade) in south Florida **Dropped from ongoing 2010/2012 studies**		116 out of 27,615	211 out of 29,366		4473	22,066	493%	15.6%
Georgia (done by CDC) 5 counties: Clayton, Cobb, DeKalb, Fulton, and Gwinnett (metropolitan Atlanta)	285 out of 43,593	474 out of 46,621	601 out of 50,427	8%	2188	12,449	568%	17.1%
Maryland 2000 4 counties plus Baltimore City 2006/2008 6 counties: Anne Arundel, Baltimore, Carroll, Cecil, Harford, and Howard	118 out of 21,532	243 out of 26,489	336 out of 27,022	9.2%	2304	9232	401%	13.4%

Attachment 1

Side-by-Side Comparison of ADDM Data with Department of Education Data

Missouri 5 counties: St. Louis, St. Louis City, Franklin, Jefferson, and St. Charles		321 out of 26,533	357 out of 25,668	1.6%	1723	8027	465%	15.0%
New Jersey 2000 – 4 counties including city of Newark 2008 - Union County (metropolitan Newark, New Jersey)	295 out of 29,714		145 out of 7,082	10.6%	3322	14,434	434%	14.3%
North Carolina 2006 – 10 counties 2008 11 counties: Alamance, Caswell, Chatham, Davidson, Durham, Forsyth, Guilford, Orange, Randolph, Rockingham, and Wake		230 out of 22,195	525 out of 36,913 .	11.5%	2635	13,274	504%	15.8%
Pennsylvania 1 county - Philadelphia County **Dropped from ongoing 2010/2012 studies.**		150 out of 17,886	245 out of 18,440	16.9%	4039	23,405	579%	17.3%
South Carolina 23 counties: Allendale, Bamberg, Barnwell, Beaufort, Berkeley, Charleston, Chesterfield Clarendon, Colleton, Darlington, Dillon, Dorchester, Florence, Georgetown, Hampton, Horry, Jasper, Lee, Marion, Marlboro, Orangeburg, Sumter, and Williamsburg	155 out of 24535	196 out of 22,681	264 out of 23,769	10.5%	973	4461	458%	14.8%
Utah **Part of 1 county in northern Utah**			45 out of 2,123	16.9%	642	4293	669%	18.9%
West Virginia Statewide	104 out of 23,055				326	1493	458%	14.8%
Wisconsin 10 counties: Dane, Green, Jefferson, Kenosha, Milwaukee, Ozaukee, Racine, Rock, Walworth, and Waukesha		257 out of 34,058	267 out of 34,451	7.3%	2130	8885	417%	13.9%

safeMinds

Autism in US Schools Increased 15.5% per Year, Over the Past 11 Years
Students with Autism, Ages 3-21 – www.ideadata.org
$1.466 Trillion Price Tag Looming

State	# in 2000 Birth Years 1979-1997	# in 2011 Birth Years 1990-2008	Total % Increase	Average Annual % Increase	ADDM annualized % increase Birth Years 1994-2000
Alabama	849	4819	567%	15.3%	6.4%
Alaska	222	927	418%	13.9%	
Arizona	1213	8349	688%	19.2%	12%
Arkansas	766	3220	420%	13.9%	
California	13979	71595	512%	16.0%	
Colorado	505	4370	865%	21.7%	11.3%
Connecticut	1377	6859	498%	15.7%	
Delaware	325	1137	350%	12.1%	
Dist. Of Columbia	119	648	544%	16.7%	
Florida	4473	22066	493%	15.6%	
Georgia	2188	12449	568%	17.1%	8%
Hawaii	364	1390	382%	13.0%	
Idaho	319	2118	664%	18.8%	
Illinois	4330	17903	413%	13.8%	
Indiana	3077	12416	404%	13.5%	
Iowa	665	759	114%	1.2%	
Kansas	710	2834	399%	13.4%	
Kentucky	1032	4378	424%	14.0%	
Louisiana	1266	3864	305%	10.7%	
Maine	594	2801	472%	15.1%	
Maryland	2304	9232	401%	13.4%	9.5%
Massachusetts	806	13281	1648%	29.0%	
Michigan	4706	15370	327%	11.4%	
Minnesota	2793	15278	547%	16.7%	
Mississippi	419	2779	663%	18.8%	
Missouri	1723	8027	465%	15.0%	11.6%
Montana	188	456	243%	8.4%	
Nebraska	374	2323	621%	18.1%	
Nevada	483	4191	868%	21.7%	
New Hampshire	397	1943	489%	15.5%	
New Jersey	3322	14434	434%	14.3%	10.6%
New Mexico	231	1738	752%	20.1%	
New York	6752	24533	363%	12.4%	

North Carolina	2635	13274	504%	15.8%	11.5%
North Dakota	135	715	530%	16.4%	
Ohio	2543	17779	699%	19.3%	
Oklahoma	675	3586	531%	16.4%	
Oregon	2945	8644	294%	10.3%	
Pennsylvania	4039	23405	579%	17.3%	16.9%
Rhode Island	357	1987	557%	16.9%	
South Carolina	973	4461	458%	14.8%	10.5%
South Dakota	262	834	318%	11.1%	
Tennessee	1088	6752	621%	18.0%	
Texas	7131	36550	513%	16.0%	
Utah	642	4293	669%	18.9%	16.9%
Vermont	218	923	423%	14.0%	
Virginia	2228	13065	586%	17.4%	
Washington	1684	9471	562%	17.0%	
West Virginia	326	1493	458%	14.8%	
Wisconsin	2130	8885	417%	13.9%	7.3%
Wyoming	115	735	639%	18.4%	
Total for All 50 States and D.C.	**93,624**	**458,209**	**489%**	**15.5% per year**	

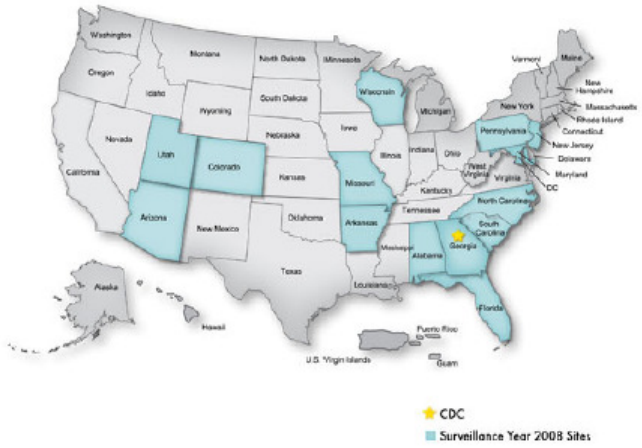
Lifetime cost of medical care for a person with autism is estimated at 3.2 million dollars (Ganz, 2006). Multiplied by the number of children with autism currently in our schools, the total for their lifetime care is a staggering $1,466,000,000. That's a trillion and a half dollars with no end in sight. Right now, the financial costs of autism are straining school budgets around the country. In a very short time, however, these services will be provided through Medicaid and Social Security as children "age out" at 21.

Annual federal research funding for autism in 2011 was $169 million dollars. That is only $369 per child with autism as reported by the schools. Given the long-term costs of care, more research into prevention is critically needed. Federal dollars are primarily being spent on brain imaging and genetic studies instead of focusing on treatment and prevention studies. In 2009, NIH funding of purely genetic studies was 6 times as much as funding for purely environmental studies (detailed brief available). The rapidly increasing numbers above cannot possibly be explained by genetic causation. Therefore, research funding needs to be reallocated and, if possible, specifically appropriated for environmental research.

The Centers for Disease Control (CDC) autism surveillance is inadequate. It is outdated when it is published, covers only 14 states at best, and provides little useful information for planning services needed. The 1 in 88 number the CDC reported in April,

2012, based on 14 states, was for children born in the year 2000 who are already 12 years old. The survey of 8 year-olds was done in 2008 and took over 3 years to publish, demonstrating a complete lack of urgency. In the chart above, the last column represents the percentage change in autism rates reported by the CDC in April for those states available. Because the changes are reported over 6 years (2002-2008 surveillance years), we have adjusted to an annualized rate allowing for compounding. Note that in all states, the CDC rates of increase are lower than those reported by the schools in the same states.

The coverage of the CDC surveillance is also inadequate. This is a map of the states included in the ADDM network. What is misleading is that none of these states is fully covered and, in fact, 6 states are represented by surveillance of a single county (Arizona, Arkansas, Florida, New Jersey, Pennsylvania, and Utah. There is no surveillance of the West Coast or Massachusetts with its outlying 29% annual increase in the schools.



Also, the CDC collects no medical information from the records it uses, even though rates of co-morbid seizures and psychiatric disorders, non-verbal or minimally verbal individuals, and medications taken, for example, would be useful in order to plan for the needs of these populations when they reach adulthood.

Finally, we need better information to inform policy decisions. The CDC claim that the rapid growth in autism is likely due to diagnostic expansion at the high-functioning end of the spectrum, while providing no prevalence numbers for functioning levels to support this claim. Why have the CDC failed to do surveillance of adult rates of autism? A study by McDonald and Paul, in 2010, found a change point year in autism incidence of 1988. Why have the CDC not investigated autism rates in the United States prior to 1992? The bottom line is that the CDC are not providing thorough prevalence estimates, nor are they providing the information needed to proactively address the autism epidemic.

Attachment

IACC Strategic Plan Objectives - Question #3				
Q3. What caused this to happen and can it be prevented?				
Funding initiatives for 2008, 2009 and 2010	2008	2009	2010	Total Funding
	3.2	3.S.A.	3.S.A.	
Coordinate and implement the inclusion of approximately 20,000 subjects for genome-wide association studies, as well as a sample of 1,200 for sequencing studies to examine more than 50 candidate genes by 2011. Studies should investigate factors contributing to phenotypic variation across individuals that share an identified genetic variant and stratify subjects according to behavioral, cognitive, and clinical features.	$4,065,392	$13,926,663	$16,688,932	$34,680,987
	IACC Recommended Budget: $43,700,000 over 4 years.			
	3.3	3.S.B.	3.S.B	
Within the highest priority categories of exposures for ASD, identify and standardize at least three measures for identifying markers of environmental exposure in biospecimens by 2011.	$713,227	$0	$0	$713,227
	IACC Recommended Budget: $3,500,000 over 3 years.			
	3.4	3.S.C	3.S.C	
Initiate efforts to expand existing large case-control and other studies to enhance capabilities for targeted gene – environment research by 2011	$4,703,867	$8,033,454	$4,824,779	$17,562,100
	IACC Recommended Budget: $27,800,000 over 5 years.			
	3.5	3.S.D.	3.S.D	
Enhance existing case-control studies to enroll racially and ethnically diverse populations affected by ASD by 2011.	$84,628	$103,827	$0	$188,455
	IACC Recommended Budget: $3,300,000 over 5 years.			
	NA	3.S.E.	3.S.E	
Support at least two studies to determine if there are subpopulations that are more susceptible to environmental exposures (e.g., immune challenges related to infections, vaccinations, or underlying autoimmune problems) by 2012.	-	$1,739,200	$1,162,679	$2,901,879
	IACC Recommended Budget: $8,000,000 over 2 years.			

Funding initiatives for 2008, 2009 and 2010	2008	2009	2010	Total Funding
	3.1	3.S.F.	3.S.F	
Initiate studies on at least 10 (5) environmental factors identified in the recommendations from the 2007 IOM report "Autism and the Environment: Challenges and Opportunities for Research" as potential causes of ASD by 2012.	$7,600,673	$2,952,960	$166,362	$10,719,995
	IACC Recommended Budget: $56,000,000 over 2 years.			
	NA	NA	3.S.G	
Convene a workshop that explores the usefulness of bioinformatic approaches to identify environmental risks for ASD by 2011.	-	-	$0	$0
	IACC Recommended Budget: $35,000 over 1 year.			
	NA	NA	3.S.H	
Support at least three studies of special populations or use existing databases to inform our understanding of environmental risk factors for ASD in pregnancy and the early postnatal period by 2012. Such studies could include:	-	-	$1,527,866	$1,527,866
Comparisons of populations differing in geography, gender, ethnic background, exposure history (e.g., prematurity, maternal infection, nutritional deficiencies, toxins), and migration patterns; and				
Comparisons of phenotype (e.g., cytokine profiles), in children with and without a history of autistic regression, adverse events following immunization (such as fever and seizures), and mitochondrial impairment. These studies may also include comparisons of phenotype between children with regressive ASD and their siblings.				
Emphasis on environmental factors that influence prenatal and early postnatal development is particularly of high priority. Epidemiological studies should pay special attention to include racially and ethnically diverse populations.				
	IACC Recommended Budget: $12,000,000 over 5 years.			

Funding initiatives for 2008, 2009 and 2010	2008	2009	2010	Total Funding
	NA	NA	3.S.I	
Support at least two studies that examine potential differences in the microbiome of individuals with ASD versus comparison groups by 2012.	-	-	$53,960	$53,960
	IACC Recommended Budget: $1,000,000 over 2 years.			
	NA	NA	3.S.J	
Support at least three studies that focus on the role of epigenetics in the etiology of ASD, including studies that include assays to measure DNA methylations and histone modifications and those exploring how exposures may act on maternal or paternal genomes via epigenetic mechanisms to alter gene expression, by 2012.	-	-	$5,072,389	$5,072,389
	IACC Recommended Budget: $20,000,000 over 5 years.			
	NA	NA	3.S.K	
Support two studies and a workshop that facilitate the development of vertebrate and invertebrate model systems for the exploration of environmental risks and their interaction with gender and genetic susceptibilities for ASD by 2012.	-	-	$733,922	$733,922
	IACC Recommended Budget: $1,535,000 over 3 years.			
	3.7	3.L.A.	3.L.A	
Conduct a multi-site study of the subsequent pregnancies of 1,000 women with a child with ASD to assess the impact of environmental factors in a period most relevant to the progression of ASD by 2014.	$2,742,999	$3,740,812	$2,971,093	$9,454,904
	IACC Recommended Budget: $11,100,000 over 5 years.			
	3.8	3.L.B.	3.L.B	
Identify genetic risk factors in at least 50% of people with ASD by 2014.	$37,043,410	$49,905,587	$34,432,884	$121,381,881
	IACC Recommended Budget: $33,900,000 over 6 years.			

Funding initiatives for 2008, 2009 and 2010	2008	2009	2010	Total Funding
	3.6	3.L.C.	3.L.C	
Determine the effect of at least five environmental factors on the risk for subtypes of ASD in the pre- and early postnatal period of development by 2015.	$1,803,628	$1,992,228	$820,320	$4,616,176
	IACC Recommended Budget: $25,100,000 over 7 years.			
	3.9	3.L.D.	3.L.D	
Support ancillary studies within one or more large-scale, population-based surveillance and epidemiological studies, including U.S. populations, to collect data on environmental factors during preconception, and during prenatal and early postnatal development, as well as genetic data, that could be pooled (as needed), to analyze targets for potential gene/environment interactions by 2015.	$17,297,788	$9,135,505	$11,464,011	$37,897,304
	IACC Recommended Budget: $44,400,000 over 5 years.			
Other Not specific to any objective	$6,791,000	$8,512,980	$1,312,450	$16,616,430
Total Funding for Question 3	$80,028,784	$100,043,216	$81,231,647	$261,303,647