way." Despite all his accomplishments he is a down-to-earth guy, whose company is down-right enjoyable.

It is our great pleasure and honor to ask our colleagues to join us in paying tribute to our good friend, Morgan Chu, the worthy recipient of 2003's Learned Hand Award.

HONORING THE 62ND ANNIVERSARY OF THE BATTLE OF CRETE

HON. CAROLYN B. MALONEY
OF NEW YORK
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 20, 2003

Mrs. MALONEY. Mr. Speaker, I rise today to mark the 62nd anniversary of the Battle of Crete by introducing this House Resolution which recognizes and appreciates the historical significance of the people of Crete during World War II.

This is a historic event with direct significance to the allies' victory of World War II. On May 20, 1941, thousands of German paratroopers and gliders began landing on Crete. Both the allies and Nazis wanted Crete because of its strategic location. At that time the British controlled the island.

It was a very strong point on the line to India and protected both Palestine and Egypt. The Nazi invasion force included the elite German paratroopers and glider troops. Hitler felt this was to be an easy victory, yet he is quoted to have said shortly after the invasion, "France fell in 8 days. Why is Crete free?"

The invasion of Crete took 11 days. It resulted in more than 6,000 German troops listed as killed, wounded or missing in action. The losses to the elite 7th parachute division were felt so hard by the German military that it surged to their church, sounded the bell, took his rifle and marched his volunteers toward Maleme to write history.

At Paleochora, Father Stylianos Frantzeskis, a priest leading his parishioners into battle was not what the Germans anticipated. He displayed breathtaking bravery in defending their Crete. German soldiers never got used to Cretan women fighting them. They would tear the German soldiers never got used to Cretan women fighting them. They would tear the ground movements that took a year or more were felt so hard by the German military that it signified the end of large-scale airborne operations.

This valiant fight by the Cretan people began in the first hour of the Nazi airborne invasion. In contrast to the European under-ground movements that took a year or more after being invaded to activate.

Young boys, old men and women displayed breathtaking bravery in defending their Crete. German soldiers never got used to Cretan women fighting them. They would tear the dress from the shoulder of suspected women to find bruises from the recoil of the rifle. The penalty was death.

The Times (London) July 28, 1941 report that "five hundred Cretan women have been deported to Germany for taking part in the defense of their native island.

Another surprise for the German soldiers who invaded Crete was the heroic resistance of the clergy. A priest leading his parishioners into battle was not what the Germans anticipated.

At Paleochora, Father Stylianos Frantzeskis, hearing of the German airborne invasion, rushed to his church, sounded the bell, took his rifle and marched his volunteers toward Maleme to write history.

This struggle became an example for all Europe to follow in defyng German occupation and aggression.

The price paid by the Cretans for their valiant resistance to Nazi forces was high. Thousands of civilians died from random executions, starvation, and imprisonment. Entire communities were burned and destroyed by the Germans as a reprisal for the Cretan resistance movement. Yet this resistance lasted for four years.

The battle of Crete was to change the final outcome of World War II. The Battle of Crete significantly contributed in delaying Hitler's plan to invade Russia.

The invasion was delayed from April to June of 1941. The 2-month delay in the invasion made Hitler's forces face the Russian winter. The Russian snow storms and the sub zero temperatures eventually stalled the Nazi invasion before they could take Moscow or Leningrad. This was the beginning of the downfall of the Nazi reign of terror.

This significant battle and the heroic drive of the Cretan people must always be remembered and honored.

Democracy came from Greece and the Cretan heroes exemplified the courage it takes to preserve it.

Today, the courage and fortitude of the Cretan people is seen in the members of the United Cretan Associations of New York which is located in Astoria, Queens. I congratulate the newly elected officials and look forward to working with them.

I request my colleagues to join me in honoring the Cretans in the United States, Greece, and the diaspora.

Resolved,

(1) the General Assembly of the United Nations, in its resolution 48/116, shall be marked as the 62nd anniversary of the Battle of Crete, a victory for the free world that contributed to the outcome of World War II and leading to the defeat of fascism;

(2) observes the memory of the fallen heroes of the Battle of Crete and the Cretan Resistance Movement inflicted heavy casualties upon Nazi German occupation forces;

(3) honors the living men and women of the Cretan Resistance Movement and the people of Crete assisted by the Allied armies;

(4) honors the living men and women of the Cretan Resistance Movement and the people of Crete assisted by the Allied armies;

(5) honors the living men and women of the Cretan Resistance Movement and the people of Crete assisted by the Allied armies;

(6) honours the living men and women of the Cretan Resistance Movement and the people of Crete assisted by the Allied armies;

Whereas the Battle of Crete contributed to saving the free world from Nazi German occupation, thus preserving democracy, freedom, and human dignity;

Whereas the Cretan Resistance Movement was organized with the Nazi German occupation of the island of Crete;

Whereas for 4 years, the Cretan Resistance Movement inflicted heavy casualties upon Nazi German forces, including kidnaping a heavily-guarded Nazi German General, setting an example for all of the people of Europe to follow;

Whereas the people of Crete suffered savage reprisals for their heroic resistance when the Nazi German invaders randomly executed thousands of civilians and burned and destroyed entire communities;

Whereas many participants in the Battle of Crete and the Cretan Resistance Movement later emigrated to the United States and became American citizens; and

Whereas many of these citizens became members of the PanCretan Association of America in Astoria, New York, comprised of Greek Americans with ancestry from the island of Crete and committed to preserving and promoting the rich culture and proud history of Crete, now therefore be it Resolved, that the House of Representa-

INTRODUCTION OF THE RURAL HEALTHCARE ACCESS IMPROVEMENT ACT OF 2003

HON. MAX SANDLIN
OF TEXAS
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 20, 2003

Mr. SANDLIN. Mr. Speaker, I rise today to introduce the Rural Healthcare Access Improvement Act of 2003.

Our rural Medicare providers need help. For too long they have suffered the consequences of inadequate Medicare reimbursements that hurt physicians, hurt hospitals and most of all hurt patients. My constituents in East Texas have shared their concerns with me and I know well that we don't finally start acting to change this, our Nation's healthcare delivery system and our Nation's fellow citizens will suffer irreparably.

Last week Senator GRASSLEY's strongly stood up during the Tax bill debate and offered an amendment that would help our rural providers. It passed in an overwhelming bi-partisan vote of 86-12 in the United States Senate. I applaud his efforts and the support from his colleagues in making the unique needs of our rural communities a priority.

We should not waste any more time in the House of Representatives in meeting the needs of our rural providers. Today, I offer the Rural Healthcare Access Improvement Act of 2003. This bill, similar in scope to Senator GRASSLEY's amendment offers real opportunities to assist our rural health care providers.

As my colleagues know, the Center for Medicare and Medicaid Services uses a reimbursement formula that favors urban areas over rural areas. This formula is deeply flawed though and fails to allow our providers to even begin to assist many of their expenses.

My legislation will directly assist our hospitals by equalizing Disproportionate Share Hospital (DSH) Payments, by equalizing urban and rural "standardized payment" levels, by assisting Critical Access Hospitals, and by establishing a floor on the geographic adjustments of payments for doctors' services. It will also improve reimbursement for home health services, ground ambulance services and hospital outpatient procedures.

We can not wait any longer. Our rural communities are desperately in need of help and we must answer their call.

RESOLVED, That the House of Representa-

CONGRESSIONAL RECORD — Extensions of Remarks E1011

MERCURY IN MEDICINE REPORT

HON. DAN BURTON
OF INDIANA
IN THE HOUSE OF REPRESENTATIVES
Tuesday, May 20, 2003

Mr. BURTON of Indiana. Mr. Speaker, I submit the following report prepared by the staff of the Subcommittee on Human Rights and Wellness, Committee on Government Reform. This report is the result of a three-year investigation initiated in the Committee on Government Reform.
Vaccines are the only medicines that American citizens are mandated to receive as a condition for school and day care attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof of vaccination before their children can remain on the market. According to the Federal Food and Drug Administration (FDA) mission is to "promote and protect health," the FDA uses a subjective barometer in determining mandates. Since the early to mid-1990s, Congress has been concerned about the danger posed by mercury in medical applications, and in 1997, directed the Food and Drug Administration (FDA) to evaluate the human exposure to mercury through foods and drugs. In 1990, following up on the FDA evaluation and pursuant to its authority, the House Committee on Government Reform initiated an investigation into the dangers of exposure to mercury in vaccines. This investigation later expanded to examine the potential danger posed through exposure to mercury in dental amalgams. This full committee investigation built upon the investigations initiated by two of its subcommittees. In January 2003, the investigation continued in the newly formed Subcommittee on Human Rights and Wellness. A primary concern that arose early in the investigation of vaccine safety was the exposure of infants and young children at a much lower level of mercury, a known toxin, through mandatory childhood immunizations. This concern had been raised as a possible underlying factor in the dramatic rise in rates of late-onset or "acquired" autism. The symptoms of autism are markedly similar to those of mercury poisoning. Significant concern has been raised about the continued use of mercury in medical applications decades after the recognition that mercury can be harmful, especially to our most vulnerable children. As our children have required vaccines since birth, this report will address one form of mercury in medical applications, Thimerosal, as a preservative in vaccines. In April 2000, it was estimated that 8,000 children a day were being exposed to mercury in excess of federal guidelines through their mandatory vaccines. One leading researcher made the following statement to the Committee in July 2000: "There is no question that mercury does not belong in vaccines. There are other compounds that could be used as preservatives. And everything we know about childhood susceptibility, neurotoxicity of mercury at the fetus and at the infant level, points out that we should not have these fetuses and infants exposed to mercury. There's no need of it in the vaccines."

The Food and Drug Administration's (FDA) mission is to "promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use." However, the FDA uses a subjective barometer in determining whether a product has known risks that can remain on the market. According to the agency, "at the heart of all FDA's product evaluation decisions is a judgment about whether the benefits of a product, while it will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great—especially for products used to treat serious, life-threatening conditions." This argument—that the known risks of infectious diseases outweigh a potential risk of neurotoxic exposure to thimerosal in vaccines, is one that has continuously been presented to the Committee by government officials. FDA officials have stated that the risk from thimerosal was theoretical: that no proof of harm existed. Upon a thorough review of the scientific literature and internal documents from government, the Committee did in fact find evidence that thimerosal posed a risk. The possible risk for harm from either low dose chronic or one time contact to thimerosal (before which thimerosal is not "theoretical," but very real and documented in the medical literature. Congress has been long concerned about the human exposure to mercury through medical applications. As a result of these concerns, in 1997, Congress instructed the FDA to evaluate the human exposure to mercury through drugs and foods. Through this Congressionally mandated evaluation, the FDA realized that the amount of methylmercury injected in the first six months of life through their mandatory vaccinations exceeded the Environmental Protection Agency's (EPA) limit for a single compound and the amount of methylmercury. The FDA and other Federal agencies determined that in the absence of a standard specific for ethylmercury, the limit for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA's methylmercury standard and determined that existing data for thimerosal-free vaccines, despite the fact that thimerosal had been removed from almost every childhood vaccine produced in the United States. On three occasions in the last 15 years, changes have been made to vaccine policies to reduce the risk of serious adverse effects. First, a transition from oral polio vaccine to injected polio was accomplished in the United States to reduce the transmission of vaccine-induced polio. Second, an acellular pertussis vaccine was developed and a transition from DTP to DTaP was accomplished to reduce the risk of pertussis—induced seizures. And third, when the Rotashield vaccine was linked to a serious bowel condition (intussusception), it was removed from the U.S. market. Ethylmercury has been used in every major childhood vaccine manufactured for use in the United States, except the influenza vaccine, which continues to contain trace amounts. This success, however, does not change the fact that millions of American children were exposed to levels of mercury through vaccines that far exceed current federal guidelines. Many parents, and a growing number of scientists, believe that this mercury exposure may have contributed to the dramatic rise in rates of autism, attention deficit hyperactive disorder, and speech or language delay, and the increased use of thimerosal in medical applications. The scientific evidence in this area is considered by some to still be inconclusive, in large part due to the lack of serious, effective inquiry by our health agencies. The federal government has vigorously pursued the necessary research to determine the extent of the impact of these heightened exposures to ethylmercury on our children. A second concern that arose during the investigation was the continued use of mercury in dental amalgams. Mercury has been used as a component in dental fillings since the Civil War era. The American Dental Association and its member dentists have taken a position that the mercury in fillings, while considered toxic, is only present in the tooth, and is considered toxic when removed from the mouth, is completely safe while in the human mouth. This position seems counter even to the ADA-funded research that shows the daily release of small amounts of mercury vapors in the human mouth where dental amalgams are present, as well as minute chipping and swallowing of the mercury fillings over time. Babies and young children are exposed to this additional mercury. As developing fetuses, babies are exposed to mercury through maternal consumption. If even a small amount of mercury amalgams, they are unknowingly excreting low levels of mercury on a daily basis to their fetuses. Additionally, Medicare and Medicaid are also potentially exposed to mercury. When these children need dental fillings, because of the low cost, only mercury amalgams are available for use. This concern remains under investigation by the Subcommittee on Human Rights and Wellness. II. FINDINGS AND RECOMMENDATIONS A. FINDINGS Through this investigation of pediatric vaccine safety, the following findings are made:

1. Mercury is hazardous to humans. Its use in medicinal products is undesirable, unnecessary and should be minimized or eliminated entirely.

2. For decades, ethylmercury was used extensively in medical products ranging from vaccines to topical ointments as preservative and an anti-bacteriological agent.

3. Manufacturers of vaccines and thimerosal—ethylmercury—have never conducted adequate testing on the safety of thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds.

4. Studies and papers documenting the hyperallergenicity and toxicity of thimerosal (mercury) have existed for decades.

5. Autism in the United States has grown at epidemic proportions during the last decade. By some estimates the number of autistic children in the United States is growing between 10 and 17 percent per year. The medical community has been unable to determine the underlying cause(s) of this explosive growth.

6. At the same time that the incidence of autism was growing, the number of childhood vaccines containing thimerosal was growing, increasing the amount of mercury to which infants were exposed threefold.

7. A growing number of scientists and researchers believe that there is a relationship between the increase in neurodevelopmental disorders of autism, attention deficit hyperactive disorder, and speech or language delay, and the increased use of thimerosal in medical applications.
vaccines is plausible and deserves more scrutiny. In 2001, the Institute of Medicine determined that such a relationship is biologically plausible, but that not enough evidence exists to support or reject this hypothesis.

8. The FDA acted too slowly to remove thimerosal from over-the-counter products like cold and flu remedies. Although an advisory committee determined that thimerosal was unsafe in these products in 1980, a rule requiring its removal was not finalized until 1998.

9. The FDA and the CDC failed in their duty to be vigilant as new vaccines containing thimerosal were approved and added to the immunization schedule. In 1985, Hepatitis B and Haemophilus Influenzae Type b vaccines were added to the recommended schedule of childhood immunizations, the cumulative amount of thimerosal to which children were exposed nearly tripled. The amount of thimerosal to which children were exposed through vaccines prior to the 1999 announcement exceeded two safety thresholds established by the Federal government for a closely related substance—methylmercury. The Federal government has established no safety threshold for thimerosal, experts agree that the methylmercury guidelines are a good substitute.

10. Federal health officials have conceded that the amount of thimerosal in vaccines exceeded the EPA threshold of 0.1 micrograms per kilogram of body weight. In fact, the amount of mercury in one dose of DTaP or Hepatitis B vaccines (25 micrograms each) exceeded this threshold many times over. Federal health officials have not conceded that the amount of thimerosal in vaccines exceeded the FDA’s more relaxed threshold of 0.4 micrograms per kilogram of body weight. In most cases, however, it is clear that thimerosal was present in vaccines.

11. The actions taken by the HHS to remove thimerosal from vaccines in 1999 were not sufficiently aggressive. As a result, thimerosal remained in some vaccines for an additional two years.

12. The CDC’s failure to state a preference for thimerosal-free vaccines in 2000 and again in 2004 undermined their responsibility. As a result, many children received vaccines containing thimerosal when thimerosal-free alternatives were available.

13. Since 1990’s, it appears that the sole remaining vaccine given to children in the United States on a regular basis that contains thimerosal. Two formulations recommended for use six months of age and older continue to contain trace amounts of thimerosal. Thimerosal should be removed from these vaccines. No amount of mercury is appropriate in any childhood vaccine.

14. The CDC in general and the National Immunization Program in particular are conflicted in their duties to monitor the safety of vaccines and to also charge the responsibility of purchasing vaccines for resale as well as promoting increased immunization rates.

15. There is inadequate research regarding thimerosal’s neurotoxicity and nephrotoxicity.

16. There is inadequate research regarding the relationship between autism and the use of mercury-containing vaccines.

17. To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under-powered, and fatally flawed. The CDC’s rush to support and promote such research is reflective of a philosophy in looking at the scientific literature to the lack of substantial understanding of its safety. In numerous

B. Recommendations

1. Access by independent researchers to the Vaccine Safety Datalink database is needed for independent replication and validation of CDC studies regarding exposure of infants to thimerosal and autism. The current process to allow access remains inadequate.

2. A more integrated approach to mercury research is needed. There are different routes that mercury takes into the body, and there are different rates of absorption. Mercury bioaccumulates for specific substances and disease registries (ATSDR) clearly states: “This substance may harm you.” Studies should be conducted that pool the results. This has been done thus far, and a comprehensive approach should be developed to rid humans, animals, and the environment of this dangerous toxin.

3. Greater collaboration and cooperation between federal agencies responsible for safeguarding public health in regard to heavy metals is needed.

4. The President should announce a White House conference on autism to assemble the best scientific minds from across the country and mobilize a national effort to uncover the causes of this devastating and tragic pediatric disease.

5. Congress needs to pass legislation to in- clude in the National Vaccine Injury Com- pensation Program provisions to allow families who believe that their children’s autism is vaccine-induced the opportunity to be included in the program. Two provisions are key: First, extending the statute of limitations as recommended by the Advisory Commission on Childhood Vaccines from 3 to 6 years. Second, establishing a one-to-one ratio window for families, whose children were injured after 1986 but who do not fit within the statute of limitations, to have the opportunity to file under the NVICP.

6. Congress should consider legislation that prohibits federal funds from being used to provide products or pharmaceuticals that contain mercury, methylmercury, or ethylmercury unless no reasonable alternative is available.

7. Congress should direct the National Institutes of Health to give priority to research projects studying causal relationships between exposure to mercury, methylmercury, and ethylmercury to autism spectrum disorders, attention deficit disorders, Gulf War Syndrome, and Alzheimer’s Disease.

8. The FDA in general and the National Immunization Program in particular are conflicted in their duties to monitor the safety of vaccines and to also charge the responsibility of purchasing vaccines for resale as well as promoting increased immunization rates.

9. There is inadequate research regarding thimerosal’s neurotoxicity and nephrotoxicity.

10. There is inadequate research regarding the relationship between autism and the use of mercury-containing vaccines.

11. To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under-powered, and fatally flawed. The CDC’s rush to support and promote such research is reflective of a philosophy in looking at the scientific literature to the lack of substantial understanding of its safety. In numerous
Mercury is a known neurotoxin, but methylmercury has been more carefully studied than ethylmercury.

After more than a century of research, its many commercial applications and its widespread presence in the environment, methylmercury received the lion’s share of the attention in the scientific community during the twentieth century. A concise history of the early development of scientific knowledge about methylmercury is found in Dr. Thomas Clarkson’s, “The Three Modern Faces of Mercury:”

The first methylmercury compounds were synthesized in a chemical laboratory in London in the 1890s. Two of the laboratory technicians died of methylmercury poisoning. This so shocked the chemical community during the twentieth century. A concise history of the early development of scientific knowledge about methylmercury is found in Dr. Thomas Clarkson’s, “The Three Modern Faces of Mercury:”

One study that compared the toxicology of ethyl and methylmercury was published in 1985 in the Archives of Toxicology, written by the authors from the United Kingdom of the Medical Research Council of England. The researchers exposed rats to ethyl and methylmercury “to compare total and inorganic mercury concentrations in selected tissues, including the brain, after the daily administration of methyl or ethylmercury and to relate these findings to damage in the brain and kidneys. This study found that both ethyl and methylmercury caused damage to the brain and the kidneys, and both male and female rats were affected differently.”

“...It has been well documented that one of the first toxicity effects of methylmercury in rats is depressed weight gain or even weight loss, based on this criteria, ethylmercury proved to be more toxic than methylmercury...”

Evidence from the FDA and its predecessor organizations that methylmercury was safe. They failed to require industry to conduct adequate testing to determine how thimerosal is metabolized. The FDA failed to require that industry conduct numerous chronic toxicity studies to determine safe exposure level of thimerosal. These basic issues should have been proven prior to the introduction of thimerosal—had they been a single uncontrolled and poorly reported human study in the 1920s, possibly in combination with animal and laboratory studies. How- ever, the shocking welter of thimerosal research was published in a safety study and produced a faulty foundation on which to build a robust vaccine program in which young children would be repeatedly injected with multiple doses of ethylmercury.

During the pre-antibiotic 1920s, meningitis was a killer. Out of sheer desperation, the treating physician at a hospital dealing with dozens of patients facing a sure death from meningitis, tested thimerosal on about two dozen patients. He injected thimerosal intravenously, without apparent side effects. However, the treatment was not successful and all of the patients died. The leading infectious disease specialist of the time, Dr. E. H. B. Phipps, concluded in a report published in 1922 that thimerosal “had not only failed to produce any anaphylactoid or shock symptoms.” In the paper, the authors acknowledged that the thimerosal was “indeed effective in the treatment of the meningitis tested, thimerosal on about two dozen patients facing a sure death from meningitis. The leading infectious disease specialist of the time, Dr. E. H. B. Phipps, concluded in a report published in 1922 that thimerosal “had not only failed to produce any anaphylactoid or shock symptoms.”
were more widely spread in ethylmercury-treated rats.

While there is frequent reference to the paucity of science in understanding the harm that ethylmercury causes, there is a great deal of understanding in the scientific community that government officials have shared with the public. Dr. Baskin spoke during the December 10, 2002 hearing sheds a great deal of light on this concern.

``The mercury amalgams in your mouth, Dr. Weldon: "I have a couple of questions for Dr. Baskin about ethylmercury versus methylmercury. I have some preliminary data that data on methylmercury is fairly good, but we don't have good data on inhalation. I take it from your testimony there is more data on ethylmercury and it's as toxic as methylmercury."

Dr. Baskin: "There is more data, more and more data on ethylmercury. The cells that I showed you dying in cell culture are dying from ethylmercury. Those are human frontal brain cells. You know, there has been a debate about... ethyl versus methyl. But from a chemical point of view, the most chemical compounds that are ethyl penetrate into cells much more readily. Cells have a membrane on them, and the membrane is made of lipids, fats. And ethyl as a chemical compound pieces fats and penetrates fat much better than methyl. So, you know when I began to work with some of the Ph.D.s in my laboratory and discuss this everyone said, 'Oh gosh, you know, we've got to adjust for ethyl because it's going to be worse; the levels are going to be much higher in the cells.' So... I think at best they're equal, but it's likely highly likely that they are worse. And some of the results that we are seeing in cell culture would support that.""

``By neurotoxic, we mean it will damage brain tissues."" The testimony of Dr. Baskin builds upon the Committee's understanding in the scientific community that government officials have shared with the public about the dangers of ethylmercury.

``The mercury amalgams in your mouth... mercury into the environment. In 1972, the federal government halted the use of mercury in hood vaccines until very recently. Dr. Roberta McKee of Merck, a Merck official, in teaching a Grand Rounds review, noted that the minimum risk level would need to be multiplied by ten to reach a level at which harm would be expected through exposure. Dr. Roberta McKee of Merck wrote: "A number of environmental and public health agencies have set a Minimum Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the US Environmental Protection Agency, the Acceptable Daily Intake of the US FDA, and the Tolerable Daily Intake of the WHO. Any exposure to the substance below the MRL is assured to be safe, while exposure to ten times the MRL is assumed to place one at risk of overdose. Exposure at or near the MRL is assumed to be safe, but should trigger deliberate and careful review. Based on Dr. McKee's explanation, many babies were exposed to levels of mercury 10 times the MRL (0.4 micrograms per kilogram of body weight per day) and were exposed to amounts well over ten times the EPA's scientifically validated reference dose for mercury. For example, at a recent Committee meeting, Chairman Dan Burton (R–IN) discussed his own family's experience with vaccine injuries: "My grandson received vaccines for nine different diseases in one day. He may have been exposed to 62.5 micrograms of mercury in one day through his vaccines. According to this weight, the toxic level of mercury he should have been exposed to in one day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused."

The Committee repeatedly heard from government officials that merely exceeding the guideline was not cause for concern. One Merck official, in teaching a Grand Rounds session to staff in November of 1999, postulated that the minimum risk level would need to be multiplied by ten to reach a level at which harm would be expected through exposure. Dr. Roberta McKee of Merck wrote: "A number of environmental and public health agencies have set a Minimum Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the US Environmental Protection Agency, the Acceptable Daily Intake of the US FDA, and the Tolerable Daily Intake of the WHO. Any exposure to the substance below the MRL is assured to be safe, while exposure to ten times the MRL is assumed to place one at risk of overdose. Exposure at or near the MRL is assumed to be safe, but should trigger deliberate and careful review. Based on Dr. McKee's explanation, many babies were exposed to levels of mercury 10 times the MRL (0.4 micrograms per kilogram of body weight per day) and were exposed to amounts well over ten times the EPA's scientifically validated reference dose for mercury. For example, at a recent Committee meeting, Chairman Dan Burton (R–IN) discussed his own family's experience with vaccine injuries: "My grandson received vaccines for nine different diseases in one day. He may have been exposed to 62.5 micrograms of mercury in one day through his vaccines. According to this weight, the toxic level of mercury he should have been exposed to in one day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused."To the added effect, based on the methylmercury ingestion guidelines, the Chairman's grandson would have

Dr. David Baskin during the Committee's December 10, 2002 hearing sheds a great deal of light on this concern. And if you look at the studies, the studies in cell culture would support that."

As the dangers of mercury have become better understood, the United States and other governments around the world have taken actions to reduce the release of mercury into the environment. In 1972, the federal government halted the use of mercury in hood vaccines until very recently. Dr. Roberta McKee of Merck, a Merck official, in teaching a Grand Rounds review, noted that the minimum risk level would need to be multiplied by ten to reach a level at which harm would be expected through exposure. Dr. Roberta McKee of Merck wrote: "A number of environmental and public health agencies have set a Minimum Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the US Environmental Protection Agency, the Acceptable Daily Intake of the US FDA, and the Tolerable Daily Intake of the WHO. Any exposure to the substance below the MRL is assured to be safe, while exposure to ten times the MRL is assumed to place one at risk of overdose. Exposure at or near the MRL is assumed to be safe, but should trigger deliberate and careful review. Based on Dr. McKee's explanation, many babies were exposed to levels of mercury 10 times the MRL (0.4 micrograms per kilogram of body weight per day) and were exposed to amounts well over ten times the EPA's scientifically validated reference dose for mercury. For example, at a recent Committee meeting, Chairman Dan Burton (R–IN) discussed his own family's experience with vaccine injuries: "My grandson received vaccines for nine different diseases in one day. He may have been exposed to 62.5 micrograms of mercury in one day through his vaccines. According to this weight, the toxic level of mercury he should have been exposed to in one day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused."To the added effect, based on the methylmercury ingestion guidelines, the Chairman's grandson would have

For ethyl because it's going to be worse; the levels are going to be much higher in the cells. So... I think at best they're equal, but it's likely highly likely that they are worse. And some of the results that we are seeing in cell culture would support that."

The testimony of Dr. Baskin builds upon the Committee's understanding in the scientific community that government officials have shared with the public about the dangers of ethylmercury.

As the dangers of mercury have become better understood, the United States and other governments around the world have taken actions to reduce the release of mercury into the environment. In 1972, the federal government halted the use of mercury in hood vaccines until very recently. Dr. Roberta McKee of Merck, a Merck official, in teaching a Grand Rounds review, noted that the minimum risk level would need to be multiplied by ten to reach a level at which harm would be expected through exposure. Dr. Roberta McKee of Merck wrote: "A number of environmental and public health agencies have set a Minimum Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the US Environmental Protection Agency, the Acceptable Daily Intake of the US FDA, and the Tolerable Daily Intake of the WHO. Any exposure to the substance below the MRL is assured to be safe, while exposure to ten times the MRL is assumed to place one at risk of overdose. Exposure at or near the MRL is assumed to be safe, but should trigger deliberate and careful review. Based on Dr. McKee's explanation, many babies were exposed to levels of mercury 10 times the MRL (0.4 micrograms per kilogram of body weight per day) and were exposed to amounts well over ten times the EPA's scientifically validated reference dose for mercury. For example, at a recent Committee meeting, Chairman Dan Burton (R–IN) discussed his own family's experience with vaccine injuries: "My grandson received vaccines for nine different diseases in one day. He may have been exposed to 62.5 micrograms of mercury in one day through his vaccines. According to this weight, the toxic level of mercury he should have been exposed to in one day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused."To the added effect, based on the methylmercury ingestion guidelines, the Chairman's grandson would have
developing nervous system of the unborn. While it is true that the primary function of fish that are safe to eat, you can prevent mercury called methylmercury that can exceed the "ten times the RML" and therefore was placed at "risk of overdose." In fact, with a 62.5 microgram exposure alone, the EPA, ATSDF, and FDA levels would have been exceeded by 30 times. Because the FDA chose not to recall thimerosal-containing vaccines in 1999, in addition to all of those already injured, 8,000 children a day could be a risk of "an overdose" for at least an additional two years.

It should also be noted that none of the Federal guidelines on mercury exposure have been included specific provisions for safe exposure limits for infants and children. It is widely accepted that infants and young children are more sensitive to the toxic effect of mercury or other neurotoxins than adults. "Exposures early in life are reasonably of greater health concern ... because of greater brain organ susceptibility."

The FDA has conceded in recent years that many children received doses of ethylmercury may contain high levels of mercury and the EPA's minimal risk level for methylmercury. However, it is also clear that many infants received methylmercury that exceeded the FDA's higher threshold.

3. Warnings Have Been Issued About Mercury in Seafood

The FDA's actions regarding the risk of medical exposures to mercury have differed greatly when compared to regulations regarding exposures to mercury. The agency has a long history of issuing warnings to the public to monitor their fish consumption due to concerns about mercury exposure. During the 1990's, the FDA repeatedly issued warnings advising pregnant women and young children to avoid certain fish, or to limit their consumption of these fish because of their mercury content. In September of 1994, the FDA issued an advisory entitled, "Mercury in Fish: Cause for Concern?" in which they stated:

"Wordfish and Shark taste great—especially grilled or broiled. But reports which state that these and other large predatory fish may contain mercury concentrations in excess of the Food and Drug Administration's 1 part per million (ppm) limit has dampened my appetite for these delicacies. "There is no doubt that when humans are exposed to high levels of methylmercury that poisoning and problems in the nervous system. The types of symptoms reflect the degree of exposure.

"During prenatal life, humans are susceptible to the toxic effects of high methylmercury exposure because of the sensitivity of the developing nervous system ... Methylmercury easily crosses the placenta, and the mercury concentration rises to 30 percent higher in the fetal red blood cells than in those of the mother ... none of the studies of methylmercury poisoning victims have clearly shown the level at which newborns can tolerate such exposure. Pregnant women and women of child bearing age, who may become pregnant, however, are advised by FDA experts to limit their consumption of shark and swordfish to no more than once a month."

Similarly, a March 2003 FDA advisory stated:

"Some fish contain high levels of a form of mercury called methylmercury that can harm an unborn child's developing nervous system if eaten regularly. By being informed about methylmercury and knowing the kinds of fish that are safe to eat, you can prevent any harm to your unborn child and still enjoy the health benefits of eating seafood."

The FDA has also been criticized for not finalizing a rule to ban ethylmercury products. Although the FDA went through that 18–year regulatory process to remove thimerosal from vaccines, the agency has not yet finalized a ban on ethylmercury products. In 1982, the FDA advisory panel concluded that thimerosal was not generally recognized as safe: "The Panel concludes that thimerosal was not generally recognized as safe" finding. As a result of the panel's work, in 1982, the FDA issued a proposed rule to ban thimerosal from OTC topical products. In addition to raising questions about the general effectiveness of thimerosal, the FDA found that thimerosal was too toxic for OTC use. Among the findings that they published were the following:

"In 1982, the FDA advisory panel concluded that thimerosal was highly allergenic and that it is reasonable to expect humans to be equally allergic.

"The FDA concluded that while it has been suggested that hypersensitivity may be due to the thiosalicylate portion of the molecule and not the ethylmercury, this was not confirmed.

"In a Swedish study which found in healthy subjects the following levels of hypersensitivity to thimerosal: 10% of school children; 16% of military recruits; 18% of twins, and 26% of medical students.

"In 1982, the FDA advisory panel concluded that thimerosal was not generally recognized as safe. The Panel concludes that thimerosal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergy potential. It is not effective as a topical antimicrobial because its bacteriostatic action can be reversed."

Despite this strong finding, the FDA's proposed ban on the OTC use of thimerosal was not finalized until 1998. During that time, the FDA convened a panel of experts to review the risks and benefits of thimerosal. At the time of the FDA's advisory committee meeting, 1998, the agency was concerned that the use of thimerosal in vaccines and other medical products was necessary to protect public health. As a result of the panel's recommendations, the FDA issued a proposed rule to ban thimerosal from OTC topical products. The agency then convened a panel of experts to review the risks and benefits of thimerosal. At the time of the FDA's advisory committee meeting, 1998, the agency was concerned that the use of thimerosal in vaccines and other medical products was necessary to protect public health. As a result of the panel's recommendations, the FDA issued a proposed rule to ban thimerosal from OTC topical products. The agency then convened a panel of experts to review the risks and benefits of thimerosal. At the time of the FDA's advisory committee meeting, 1998, the agency was concerned that the use of thimerosal in vaccines and other medical products was necessary to protect public health. As a result of the panel's recommendations, the FDA issued a proposed rule to ban thimerosal from OTC topical products. The agency then convened a panel of experts to review the risks and benefits of thimerosal. At the time of the FDA's advisory committee meeting, 1998, the agency was concerned that the use of thimerosal in vaccines and other medical products was necessary to protect public health. As a result of the panel's recommendations, the FDA issued a proposed rule to ban thimerosal from OTC topical products. The agency then convened a panel of experts to review the risks and benefits of thimerosal. At the time of the FDA's advisory committee meeting, 1998, the agency was concerned that the use of thimerosal in vaccines and other medical products was necessary to protect public health.

Have areas that might have been contaminated by mercury surveyed and decontaminated, if necessary.

4. Over the Course of Two Decades, the FDA Suggested Removing Thimerosal From Many Medicinal Products...
contained thimerosal. On July 9, 1999, the American Academy of Pediatrics joined the U.S. Public Health Service in issuing a joint statement recommending the removal of all thimerosal from vaccines. On its website, the FDA provides the following rationale for its policy on thimerosal:

"Over the past several years, because of an increased awareness of the theoretical potential for neurotoxicity of even low levels of organomercurials, and because of the increased number of thimerosal-containing vaccines that have been added to the infant immunization schedule, concerns about the use of thimerosal in vaccines and other products have been raised. Indeed, because of these concerns, the Food and Drug Administration has worked with, and continues to work with, vaccine manufacturers to reduce or eliminate thimerosal from vaccines."

In 1999, the FDA was criticized by some for not taking more forceful action to remove thimerosal from vaccinations; as a result of the FDA decision to seek a gradual removal, many children continued to receive injections of the DTap, Hib, and Hepatitis B vaccine that contained mercury well into 2001. Mercury-containing vaccines manufactured in the United States, up to today, continue to be administered to infants and small children in the United States and abroad.

E. Thimerosal is still used in some medical products

While the FDA has taken steps over the last 20 years to remove ethylmercury from topical ointments and most pediatric vaccines, a number of medical products continue to contain this preservative.

Some nasal and ophthalmic products containing thimerosal remain on the market. About 75 percent of the flu vaccines, recently recommended to be given to children as young as six months, contain at least trace amounts of thimerosal.

Vaccines containing thimerosal continue to be manufactured in the United States and delivered through the World Health Organization (WHO) to Third World Countries. The WHO has approved the use of multi-dose vials and to use preservatives, including thimerosal, to address storage and transportation issues.

Of additional concern to the Committee, but not discussed in detail within this report, is the continued use of thimerosal in adult vaccines. There is a growing emphasis on adult immunizations, including getting boosters to childhood immunizations. Additionally, all new military recruits, active duty, and reserve forces that are deploying overseas are routinely given a large number of vaccines, many containing ethylmercury. These vaccines are often given consecutively and all in the same day.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>No. Doses</th>
<th>Initial entry</th>
<th>Troops in US</th>
<th>Deployed Region or other</th>
<th>Thimerosal content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
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<td>N/A</td>
<td>6 + annual</td>
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</tr>
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<td>Diph</td>
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<td>N/A</td>
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<tr>
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<td>3 + booster</td>
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</tr>
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<td>3 (Korean)</td>
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</tr>
<tr>
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<td>1 Annual</td>
<td>1 Annual</td>
<td>1 Annual</td>
<td>0</td>
</tr>
<tr>
<td>MMR (Live)</td>
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<td>N/A</td>
<td>3 booster</td>
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<tr>
<td>Meningococcal (MCV)</td>
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<tr>
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<td>N/A</td>
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<tr>
<td>Pneumococcal 13: PPV-23</td>
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<td>N/A</td>
<td>1 (Pertussis)</td>
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<tr>
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</tr>
<tr>
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<td>N/A</td>
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<td>0</td>
</tr>
<tr>
<td>Smallpox (Live)</td>
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<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Tet, DT (25 mcg)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
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<td>0</td>
</tr>
<tr>
<td>Tet, DT (105 mcg)</td>
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<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Tdap</td>
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<td>N/A</td>
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</tr>
<tr>
<td>Varicella (Live)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Yellow Fever (Live)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Possible Total Thimerosal Exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(EPA Safety Limit: 0.1 mcg/kg of body weight per day)

The Committee calculated the bolus dose exposure of adult males and females below:

Adult weight with exposure rates according to EPA Safety Limit

100 pound: 0.1 mcg/45.359 kg of body weight per day = 4.54
120 pound: 0.1 mcg/54.431 kg of body weight per day = 5.44
150 pound: 0.1 mcg/68.039 kg of body weight per day = 6.8
180 pound: 0.1 mcg/81.647 kg of body weight per day = 8.16

It is clear from this chart that with a maximum safe limit of 8.16 micrograms in a day, individuals receiving either 110.5 micrograms or 135.5 micrograms in one day may be at risk for injury from mercury exposure. Even in keeping with the safety margin of 10 times the safety limit, as reported by Dr. Roberta Morgan McKee of Merck, individuals at each of these weights would be exposed to levels of mercury that would be expected to put them at risk for adverse reactions.

The Committee received documentation from one Air Force pilot who suffered from serious symptoms of Gulf War Syndrome. After failing to have his medical issues resolved through the military or the Veterans Administration (VA) medical system, Capt. Frank Schmuck, a pilot, became so ill that he was no longer able to fly. He sought medical treatment outside the military medical system and was tested for heavy metals, and was found to have toxic levels of mercury in his system. After he returned to good health and has resumed flying. Gulf War Syndrome victims are not routinely tested for heavy metal toxicity or treated by chelation therapy by the military or the VA. Given the lack of progress in finding other successes with recovery from this condition, this is an issue that both the Department of Defense (DOD) and the VA should be vigorously evaluating on behalf of Gulf War veterans.

<table>
<thead>
<tr>
<th>Vaccine No.</th>
<th>Doses</th>
<th>Initial entry</th>
<th>Troops in US</th>
<th>Deployed Region or other</th>
<th>Thimerosal content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polio Inactivated IPV</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Rubella</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Smallpox (Live)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Tet, DT (25 mcg)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Tet, DT (105 mcg)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Tdap</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Varicella (Live)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
<tr>
<td>Yellow Fever (Live)</td>
<td>1 booster</td>
<td>N/A</td>
<td>N/A</td>
<td>1 booster</td>
<td>0</td>
</tr>
</tbody>
</table>

Autism was once considered a rare disease that affected an estimated 1 in 10,000 individuals in the United States. The Committee held its first hearing on the dramatic rise in autism in April of 2000. At the time, Federal agencies were estimating that autism affected 1 in 500 children in the United States. By 2010, the National Institutes of Health had adjusted that rate to 1 in 250 children in the United States. The Autism Society of America estimates that the number of autistic children is growing by 10 to 17 percent each year.

In that first hearing, Chairman Burton reported that according to U.S. Department of Education statistics, requests for services for school-age children with autism spectrum disorders had risen dramatically in every state.

Mr. Burton: “California has reported a 273 percent increase in children with autism since 1988... Florida has reported a 571 percent increase in autism... Maryland has reported a 273 percent increase in autism... Georgia...”

In 1999, there were 2,462 children ages 3 to 21 in Indiana diagnosed with autism. That is one-fourth of 1 percent of all the school children in Indiana, or 1 out of every 400. This increase is not just better counting. If we want to find a cure, we must first look to the cause.”

In July 2000, Dr. Stephanie Cave shared her observations about the rapid growth of autism and the pressures it is placing on families and medical professionals: “I am in family practice in Baton Rouge, Louisiana, and have had to express my own concerns to you and to the members of the committee for allowing me to testify. I am presently treating over 300 autistic children, with an additional 130 waiting to get in.”

“We are treating children from all over the United States and getting calls from many places around the globe. This is truly an epidemic. If you have any idea that it is not, I invite you to sit in my office for 2 hours.”

2. Studies Are Documenting the Incredible Growth of Autism

In the 1990’s, the CDC conducted two prevalence studies that confirmed dramatic spikes in autism cases. One was conducted in Brick Township, New Jersey, the other in Atlanta, Georgia.

In late 1997, after noticing an apparently larger than expected number of children with autism in their community, a citizen’s group in Brick Township, New Jersey, contacted the New Jersey Department of Health and Senior Services (DHSS). Because of the complexity of the disorder and the concerns that environmental factors might play a role, the New Jersey DHSS, U.S. Senator Robert Torricelli, U.S. Representative Christopher Smith contacted the CDC and the ATSDR for assistance. In response, the CDC...
conducted an extensive prevalence investigation.

The rate of autism among children in Brick Township was 4 per 1,000 (1 in 258) children ages 3 to 21 in 1986. The prevalence of the more broadly defined autism spectrum disorder was 6.7 per 1,000 (1 in 150) children. It is important to note that even though the families of Brick Township requested that the CDC include an evaluation of a possible link between autism and their children's immunizations, they were not done. Their evaluation of the cause of the cluster of autism in Brick Township was inconclusive.

The CDC's Atlanta study confirmed the dramatic results of the Brick Township study. The CDC found that 1.987 of the 289,456 children aged 3 to 10 years in metropolitan Atlanta in 1986 were autistic (1 in 146). These numbers were 10 times higher than studies conducted in the 1980s and early 1990s.

Last November, a study on autism in California determined that the number of autistic individuals in that state has nearly tripled. Equally important, the study stated that the increase was real, and could not be explained by changes in diagnostic criteria or better diagnoses. The study, funded by the state legislature and conducted by the University of California at Davis, determined that the number of autistic people in that state grew by 273% between 1987 and 1998.

The main author of the study, Dr. Robert Byrd, is assigning the increase to some degree to environmental factors. He noted that the number of autistic people in that state grew by 273% between 1987 and 1998.

By 1954, Kanner began modifying his "Blaming the Mother" position in light of evidence that brothers and sisters of autistic children were often well-adjusted, high functioning children. These findings suggested that autism was not a result of genetic or "institutional inadequacies" as well as bad parenting. In 1971, Kanner admitted that Mothers were not to blame. However, psychoanalyst Bruno Bettelheim continued purporting the "rejecting parent" theme. Bettelheim, a holocaust death-camp survivor, insisted that the cause of autistic children was due to the rejection of their mothers that they had traumatized the child by failing to provide enough love or attention.

However, a California psychologist and father of an autistic child, Bernard Rimland, Ph.D., in 1964 disproved Dr. Bettelheim's theories through the publication of his landmark book Infantile Autism: The Syndrome and Its Implications for a Neural Theory of Behavior. In this book, Dr. Rimland methodically dismantled the psychoanalytic theory of autistic behavior. He specifically a neurological, basis for autistic behavior. Dr. Rimland documented the similarities between brain injured children and children with severe mental retardation from the destructive guilt associated with having an autistic child and pointing autism research in the direction of investigating the biological mechanisms underlying the brain and immune dysfunction symptoms and their possible causes.

In 1966, Rimland established the Autism Society of America (ASA). In 1967 he established the Autism Research Institute (ARI) and began distributing a questionnaire on autism to parents. After 36 years of research, his databank includes information on 2.5 million autistic individuals. He has 25 micrograms of ethylmercury and was given 3 times in the first six months of life (75 micrograms of ethylmercury) and a total of 4 times in two years (100 micrograms of ethylmercury).

After 1986, some children went from getting 25 micrograms in one day or 75 micrograms in the first six months of life to getting 62.5 micrograms of ethylmercury in a day or 187.5 micrograms in the first six months of life. This would be in addition to the 25 micrograms in each month of life. The total removal of thimerosal from vaccines and autism spectrum disorders. However, a California psychologist and father of an autistic child, Bernard Rimland, Ph.D., in 1964 disproved Dr. Bettelheim's theories through the publication of his landmark book Infantile Autism: The Syndrome and Its Implications for a Neural Theory of Behavior. In this book, Dr. Rimland methodically dismantled the psychoanalytic theory of autistic behavior. He specifically a neurological, basis for autistic behavior. Dr. Rimland documented the similarities between brain injured children and children with severe mental retardation from the destructive guilt associated with having an autistic child and pointing autism research in the direction of investigating the biological mechanisms underlying the brain and immune dysfunction symptoms and their possible causes.

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As was noted previously, the effects of ethylmercury have not been studied as carefully as methylmercury, and the Federal Government has not set safety thresholds for ethylmercury exposure. Because of the obvious similarities between the two, however, when the FDA reviewed the introduction of new vaccines containing thimerosal in 1999, they compared it to the Federal limits for (ingested) methylmercury exposure. They were compelled to admit at that point that the cumulative exposure from thimerosal in vaccines exceeded the EPA's threshold for exposure to methylmercury. This led the
FDA to recommend the removal of thimerosal from most pediatric vaccines in 1999, more than a decade after the Hepatitis B vaccine was added to the schedule.

In the late 1990s, the concern was growing. With a rise in autism diagnoses and the increasing number of vaccines being given to infants, many parents and health care providers were becoming concerned. The Institute of Medicine published Adverse Effects of Pertussis and Rubella Vaccines in 1998, which raised concerns about thimerosal's safety. The report concluded that the cumulative dose of thimerosal in vaccines over the first 2 years of life may exceed the upper limit of safety for methylmercury. This was based on the assumption that a child who at best weighs 10 kilograms would receive a total of 237.5 micrograms of thimerosal from vaccines, which is the maximum safe level of methylmercury, according to the EPA.

In 1992, an Army doctor in Baltimore, William R. Gibson, reported a concern that thimerosal in the Australian pertussis vaccine was linked to autism. He raised concerns about thimerosal: "Some investigators claim that if a patient's skin is sensitive to mercury, it may cause a reaction to any compound containing mercury. We have investigated 5 patients with autism and found that 4 were sensitive to thimerosal and to any other organic or inorganic mercury compounds with which they were tested. . . ."

In 1993, Dr. Ellis published a case report in the Archives of Ophthalmology, which states: "The positive results of patch tests demonstrated that the patient was not sensitive to tincture of merthiolate but was sensitive to 1:5000 merthiolate ophthalmic ointment and that merthiolate is capable of causing ocular injury in infirm persons or patients with a precarious membrane in the eye unless it has been previously desensitized by patch tests that the patient is not sensitive to the ointment. Therefore, the package should be labeled to warn the consumer that such tests should be made prior to the use of merthiolate ophthalmic ointment and that the patient may become sensitized to merthiolate while using the ophthalmic ointment, it may be advisable to withdraw this product from the market before a case of permanent ocular damage occurs, in spite of the fact that no cases of ocular injury due to merthiolate have been reported."

Taken from an October 1978, letter from William R. Gibson to Dr. Alan Baskett, of the Commonwealth Laboratories in Victoria Australia regarding a concern that thimerosal in the Australian pertussis vaccine was linked to autism in mice: "The difference in the effect of merthiolate with Bordetella pertussis to supplement B-adrenergic blockade. Again, it was not believed that this blockade should be used in children but later it was recognized that increased motility resulted and that this could be causative. As with other chemicals of its generation, data relating to its safety and pharmacological effects in animal models are sparse."

In August of 1998, an FDA internal "Point Paper" was prepared for the Internal Immunization Working Group. This document, prepared almost a full year before the Public Health Service—American Academy of Pediatrics joint statement made the following recommendation: "For investigational vaccines indicated for multiple immunization, the use of single dose vials should be required to avoid the need of preserving in multi-dose vials. . . Of concern here is the potential neurotoxic effect of mercury. Consideration of relating cumulative doses of this component in early infancy . . ."

In 1987, the Safety Working Party of the European Agency for the Evaluation of Medicinal Products issued its working paper, "Assessment of the Toxicity and Immunogenicity of Thimerosal in Medicinal Products." The Working Party concluded:
There is ample evidence from the literature that thimerosal (thimerosal) may cause sensitization and subsequent allergic reactions... the use of thimerosal is vaccines of thimerosal in accordance with various national vaccine programs may in certain cases result in approximately two times higher intake of ethylmercury during the first six months of life than what can be considered reasonably safe. Given the great uncertainty of the estimations of safe levels in young children, it is suggested to restrict the use of thimerosal-preserved vaccines... In the case of this accident of this naval man, it was shown that he had developed mercury poisoning compared to autism, this is the duck test, and you folks are trying to tell us that you can’t take this off the market. Everyone affected with mercury poisoning compared to autism is the duck test, and you folks are trying to tell us that you can’t take this off the market. Everyone affected with mercury poisoning compared to autism is the duck test, and you folks are trying to tell us that you can’t take this off the market.

We are asking you to do more than analyze it. We are asking you to tell this body and the American people that it is more conclusive. It passes the duck test, and we need you to respond. We need that to come off the market now because you think that this is—do you think that we are elevating the case today? I just wait until it gets in the courts. This case could dwarf the tobacco case. And we would expect you to do something now because it starts taking place. Denial is not proper right now.

"You know, I still go back to the fact—I still go back to the duck test. Mr. Egan, [FDA] I will address this to you. You know, it was shown in the last panel that autistic symptoms emerge after vaccination. It was shown the first six months of life and in general may be increased by exposures to mercury from thimerosal-containing vaccines during the first six months of life."

This issue will be discussed in more detail in another section of this report. The Committee and the public have been frustrated by the Department of Health and Human Services reluctance to accept that all forms of mercury are toxic and that children have likely been harmed by the FDA’s approving the use of thimerosal-containing vaccines in general and in not monitoring the increased exposure to mercury through vaccines.

During the July of 2000 hearing on mercury, Congresswoman Helen Chenoweth-Hage (R-ID) eloquently expressed the views of many.

Mrs. Chenoweth-Hage: “...I have a staffer who is in the Navy Reserve right now, but he used to be active with the airborne divisions, and he was in for a test at a military hospital, and upon taking his temperature, they broke a thermometer, and mercury splattered across his glasses and on his eyes. Luckily, the first thing they did was to check mercury poisoning compared to autism, this is the duck test, and you folks are trying to tell us that you can’t take this off the market.

"Liam was a normally developing baby until June 27, 1997, when he received his MMR and Hib vaccines. He did everything he was supposed to do. He cooed, rolled over, cried, crawled, pulled up and walked on time. He said ‘Mama,’ he said ‘Daddy,’ when testifying before the Vaccine Safety Datalink..."

"But when he was 17 months old, shortly after he had received the shots, he started exhibiting some different behaviors. He was constantly taking off his shoes. He would stand there until I dressed or undressed him; he would stand there for hours in front of the television and would not move if you blocked the view. He could not tolerate playing in the sandbox anymore. He did not want to sing any of his favorite songs; he would cover his ears and scream ‘No.’"

"In Liam’s case, we have no doubt that he developed his autism as a direct result of an adverse vaccine reaction.”

"Many in the medical community continue to dismiss this as mere happenstance because autism often coincides with the time of vaccination, and state that there is no scientific evidence to back this up. My question to you is: How long does it take for a coincidence to surface time and time and time again, case after case after case, before it can become a viable hypothesis, especially when the solution to solving the problem seems so apparent?"

At the same hearing, the Committee heard testimony from Jena Smith of Denham Springs, Louisiana. At the time, she was the mother of five-year-old twins, one of whom was autistic. Her testimony made equally clear her conviction that her son’s autism was caused by a series of vaccinations given on the same day.

"I recommend that you read this, side-by-side, page after page of analysis of the symptoms of autism compared to the symptoms of ethylmercury poisoning compared to autism, this is the duck test, and you folks are trying to tell us that you can’t take this off the market.

"We are asking you to do more than analyze it. We are asking you to tell this body and the American people that it is more conclusive. It passes the duck test, and we need you to respond. We need that to come off the market now because you think that this is—do you think that we are elevating the case today? I just wait until it gets in the courts. This case could dwarf the tobacco case. And we would expect you to do something now because it starts taking place. Denial is not proper right now.

"You know, I still go back to the fact—I still go back to the duck test. Mr. Egan, [FDA] I will address this to you. You know, it was shown in the last panel that autistic symptoms emerge after vaccination. It was shown the first six months of life and in general may be increased by exposures to mercury from thimerosal-containing vaccines during the first six months of life."

This issue will be discussed in more detail in another section of this report. The Committee and the public have been frustrated by the Department of Health and Human Services reluctance to accept that all forms of mercury are toxic and that children have likely been harmed by the FDA’s approving the use of thimerosal-containing vaccines in general and in not monitoring the increased exposure to mercury through vaccines.

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During this time, Jesse continued to progress, starting to talk and interact with all the children around him.

"At times, Jacob was so withdrawn that we couldn’t get to him."

"For us, there is no denying that in Jacob’s case of autism, the answer does not lie in genetics, but in a catalyst."

The thousands of hours of research that we have spent searching and retracing his regression continue to point to the fact that the road of Jacob’s autism began when his immune system was devastated by thimerosal.

The final blow was the adverse reaction to the host of vaccines he received 16 months later. We are certain that for Jacob, the catalyst was his vaccine.

Testifying two years later, on April 18, 2002, Autism Society of America President Lee Grossman stated that autism is a brain injury and the lay public, to stand together to get this disease acknowledged.

I think the stories I have heard that many of our members tell, that many of these people in the audience will tell you, is that they believe that there is evidence that there is a direct link between vaccines causing their child’s autism. I think it is imperative for us, the advocates in the room, for ASA, and for Congress, for the lay public, to stand together to get this question answered, answered immediately.

B. Many parents of autistic children have filed petitions for compensation or lawsuits against vaccine manufacturers.

Many petitions were filed with the VICP, many parents have filed lawsuits against vaccine manufacturers and manufacturers have paid both such lawsuits. One such lawsuit was filed in Texas in May of 2001 on behalf of five-year-old Joseph Alexander Counter (Counter v. American Home Products). According to parents and attorneys, he was diagnosed with autism and then was found to have high levels of mercury exposure.

A growing number of respected scientists believe that a relationship between thimerosal and autism exists.

As of October 2002, more than 875 families had filed petitions for compensation under the Vaccine Injury Compensation Program (VICP), alleging that their children’s injuries were caused by the receipt of vaccines. A number of children with autism have been found to have thimerosal in their systems.

The IOM stated that the epidemiological evidence available at the time showed no association at a population level between MMR vaccine and autism. However, the authors cautioned that if the vaccine triggered autism, it might have gone unnoticed because of the small number of children who were predisposed to an adverse reaction.

The IOM recommended further research to determine if exposure to thimerosal is a risk factor for autism disorders in a small number of children. They also called for targeted studies to follow up on anyPsiX number of children who had received thimerosal in their vaccines.

A growing number of respected scientists and researchers are convinced that there is a relationship between thimerosal in childhood vaccines and the growing incidence of autism. A number of these scientists have testified before the Committee.
and Neurodevelopmental Disorders." They found insufficient evidence to accept or reject a connection between thimerosal in vaccines and autism. They did, however, state that such a connection is "biologically plausible," and recommended much more research on the issue.

The report summarized: "The committee concludes that although the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders is not established, further studies are warranted to collect and incorporate information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given in children, the hypothesis is biologically plausible."

"The committee concludes that the evidence is inadequate to accept or reject a causal relationship between exposure to thimerosal from vaccines and the neurodevelopmental disorders of autism, ADHD, and speech or language delay."

The IOm noted that it had reviewed the results of one unpublished epidemiological study that detected a "statistically significant but weak association" between exposure to vaccines containing thimerosal and several types of developmental disorders, including attention deficit disorder, speech and language delay, tics, and general neurodevelopmental delay. Phase I of the study, which was performed with data from the CDC's Vaccine Safety Datalink, (VSD) uncovered the aforementioned associations.

Phased II of the study, which provided enough data to analyze only speech delays and attention deficit disorder, did not detect an association between those disorders and thimerosal-containing vaccines.

After briefing on both phases of the study, the IOM's Immunization Safety Review Committee agreed that they were inconclusive. The VSD Study is discussed at greater length in Section VII.

The IOm also noted with some discomfort that thimerosal had not been removed from all vaccines and medicines given to children and pregnant women. The report specifically cited the influenza vaccine, the diphtheria, tetanus, and pertussis vaccine, and some nasal sprays. The IOm urges, "full consideration should be given by appropriate professional societies and government agencies to removing thimerosal from vaccines." After briefings on both phases of the study, the IOM's Immunization Safety Review Committee agreed that they were inconclusive. The VSD Study is discussed at greater length in Section VII.

In his testimony, Dr. Haley described his laboratory research on thimerosal:

"I was requested to do an evaluation of the potential toxicity of non-thimerosal containing thimerosal as a "preservative" versus those vaccines not containing thimerosal. The results were very dramatic as shown in the accompanying Table attached to this document. In our preliminary studies, vaccines containing thimerosal as a preservative consistently demonstrated in-vitro toxicity that was dramatically greater than the non-thimerosal or low-thimerosal containing vaccines."

"Our results are very consistent with the report of Dr. Godfrey of New Zealand that thimerosal-containing vaccines versus non-thimerosal containing vaccines as observed in cell culture studies reported in 1986. The chemical rationale for this toxicity is that the mercury thiomerosal compound would release ethyl-mercury as one of its breakdown products. Ethyl-mercury is a well-known neurotoxin. Further, the alternative to thimerosal is a compound of aluminum cation plus significant levels of formaldehyde, also found in these vaccines, would make the vaccine mixture of even greater risk. The other reason is that mercury is removed by the renal system. Inability to rid the body of these toxicants would greatly increase the damage they can be of doing in infants."

Dr. Haley's concerns about the inability of infants to fend off the adverse effects of mercury were echoed by Dr. David Baskin. Dr. Baskin is a neurosurgeon and a professor of neurosurgery and anesthesiology at Baylor College of Medicine. He has been involved in extensive research on the central nervous system and serves on scientific advisory boards of the National Institutes of Health. Testifying before the Committee in December of 2002, Dr. Baskin said: "Infants' brains are more sensitive. We know the blood-brain barrier, the barrier to drugs between the blood and the brain, is virtually gone in infants."

In all respects, all researchers testify before the committee have hypothesized that some children must have a genetic predisposition that makes them more vulnerable to neurological damage from mercury. An exchange between Congressman Burton and Dr. Baskin at the December 10, 2002, hearing reflected this emerging consensus:

Mr. Burton: "Do you really believe from your studies that the mercury is a contributing factor to the cases of autism we have in this country?"

Dr. Baskin: "Yes."

Mr. Burton: "Do you think it's a large contributing factor, or do you have any percentages? I mean, I know this is a tough question and everything, but you have done a lot of research."

Dr. Baskin: "I think it's hard to look at a particular child and say, 'I think this is happening.' On the other hand, there is probably an environment-gene interaction. In other words, a lot of children get the injection and don't become autistic, but only specific children in a certain subgroup of children are able to handle toxins. . . . I don't think we yet know the answer to that.

In his testimony the previous year, Dr. Haley of the University of Kentucky described one possible genetic risk factor. He stated that there is a protein in the brain, called APO-E, that removes dangerous waste materials from the brain. He added that some individuals are born with a variety of this protein that is very efficient at removing mercury, and some individuals are born with a variety of this protein that is very ineffective at removing mercury:

"If you look at the activity of the APO-E proteins, this can be reflected in the fact that it is a housekeeping protein that clears the brain of waste materials. If you have APO-E4 you can carry out two atoms of mercury for every atom of APO-E that goes out. If you have APO-E4, you can carry out none."

Dr. Burton: "Okay."

Mr. Burton: "Dr. Mike Godfrey of New Zealand took this and looked at autistic children. When he did the screen of autistic children, there was a huge preponderance of them that were APO-E4. Does that indicate that this is a genetic risk factor, which deserves further study. And it does imply that the inability
to detoxify the cerebral spinal fluid may be at least part of the neurological aspect of this disease.

Dr. Baskin described research he is conducting which demonstrates what the effects of mercury are when it is not removed from brain tissue: "Let me turn to some studies that we're doing at Baylor College of Medicine. We have the opportunity to actually grow human frontal cortex cells in cell culture. So these are cells from the front part of the brain that normally develop in vivo, incarceterate these cells with thimerosal at various doses, and we use a number of very sophisticated techniques to detect cell death and cell damage."

Here are some pictures from our cell culture experience, and you can see the arrows pointing to those little knobs sticking off the cell. These are the cells committing the suicide program and breaking themselves into tiny little pieces with a very low dose of mercury.

"Here is a slide where you see a lot of blue cells. These are the cells that don't take up. In order for something to turn blue, the cell has to have holes punched in their membranes. And guess what? At an extracellular concentration of thimerosal, the cells are blue. It means that stuff grabs a hold of the membrane and punches holes into it, so that the dye can penetrate, not only into the cytoplasm but into the very center of the cell, the nucleus, where all the DNA exists."

"Don't forget, we did this in adult brain cells. They showed that infant brain cells are much more sensitive, so there's a real cause for concern."

Dr. Baskin testified that other researchers in his field have reported similar results: "At the recent International Meeting for Autism Research at the Society for Neuroscience, a number of investigators around the world are finding similar findings. At Columbia University, there's now a model in mice who were injected with low doses of thimerosal very similar to what's given in human vaccines. At the University of California, there's a new model of mice who were injected with low doses of thimerosal that are very similar to what's given in human vaccines."

E. Research on the effects of thimerosal has come under increasing criticism, especially from parents, that the FDA continues to take these issues seriously."

"To date, the existing data do not demonstrate a causal relationship between vaccines and autism. Nonetheless, I want to assure this committee, the public, and especially parents, that the FDA continues to take these issues seriously."

"That said, we have committed a large amount of staff time and funding to try to further elaborate these issues and have designed a whole series of studies that have been described in our written testimony that we believe will address these issues."

She further stated: "There are not data to—there are no established harms associated with this. I know the public has an objection, and a number of studies are underway, but we do not have data that support known hazards associated with thimerosal contained in vaccines at this point."

Later in 2002, Dr. Karen Midtun, Director of the FDA's Office of Vaccines Research and Review, expressed his own views: "Our review showed no evidence of harm caused by thimerosal used as a preservative in vaccines except for local hypersensitivity reactions."

"During the first 6 months of life, cumulative exposure to mercury could have exceeded the more conservative limits in the EPA's cumulative limits for methylmercury and ethylmercury among some infants."

"There is no question that the cumulative amount of ethylmercury in individual vaccine formulations used and the weight of the infant..."

"In 1999, Dr. Halsey became concerned that the use of thimerosal was a preservative in many vaccines led to some children being exposed to mercury. He asked vaccine manufacturers to reduce the amount of thimerosal in vaccines. He persuaded one company to stop using thimerosal in vaccines for the 1999 season."

"As a precaution and in an effort to make vaccines as safe as possible, Dr. Halsey worked with the American Academy of Pediatrics and the Public Health Service..."

E. Research on the effects of thimerosal has been too limited to draw conclusions..."
Perhaps Dr. Thomas Verstraeten conducted the broadest review of a possible relationship between thimerosal and neurological disorders in 2000. This study reviewed several epidemiological records from the Vaccine Safety Datalink maintained by the CDC. As noted earlier, Phase I of this study purported to find a statistically significant association between thimerosal and some neurological disorders. However, this study has never been published. Moreover, because the data used in the study comes from the Vaccine Safety Datalink, and because the medical records in this database are jealously guarded by the CDC, the data used in this study has never been made public, even after a 20-year window length in the next section of this report.

In November of 2002, a study on thimerosal conducted at the University of Rochester was published in The Lancet. The authors studied 40 children who were given vaccines containing thimerosal, and 21 children who were given vaccines without thimerosal. Samples of blood, stools and urine were obtained from 3 to 28 days after vaccination to determine how much mercury remained in the blood and how much was expelled in the urine and in stools.

The authors found low levels of mercury in the blood and stool, and only high levels of mercury in their stools, indicating to them that ethylmercury has a shorter half-life than methylmercury, and that mercury was absorbed through the gastro-intestinal tract. According to the authors:

"We have shown that very low concentrations of blood mercury can be detected in infants aged 2-6 months who have been given vaccines containing thimerosal. However, no children had a concentration of blood mercury above 20 parts per billion, which is the concentration thought to be safe in cord blood."

"The authors went on to conclude:"

"Overall, the results of this study show that amounts of mercury in the blood of infants receiving vaccines formulated with thimerosal are well below concentrations potentially associated with toxic effects. Coupled with 60 years of experience with administration of thimerosal-containing vaccines, we conclude that thimerosal-containing vaccines pose little risk to full-term infants, but that thimerosal-containing vaccines should not be administered to infants with very low birth weight, premature infants."

Skeptic's of a vaccine-autism connection hailed this study. However, its value is limited by a number of criticisms that have been raised since its publication. Some of the most commonly cited shortcomings were discussed in testimony at the Committee's December 10 hearing by Baylor University's Dr. Baskin:

1. The sample size was very small: Only 40 children who received thimerosal were studied. All children were vaccinated. A total number of children were genetically predisposed to injury by mercury, the chances of a sample of 40 children detecting such a trend would be very low. In his testimony, Dr. Baskin stated:

"The sample size, as you said, Dr. Weldon, was small. Autism occurs in one in 150 kids. So if this child had some random variability in their blood to absorb more mercury or have it remain in the blood longer or be more sensitive in their brain, if they only checked 40 kids, it may not have found one with a predisposition to autism."

2. The sample was not random: In his testimony, Dr. Baskin commented on this point:

"The sample wasn't random. They didn't take kids from different portions of the population in different areas. If there's some metabolic difference based on race or sex or where you live or other things, they wouldn't have found it."

3. Blood samples were drawn too late to detect peak levels of mercury:

"In an effort to determine how long it takes mercury to be expelled from an infant's body, the University of Rochester study measured the half-life of injected ethylmercury. If the authors drew blood from their subjects at varying times between 23 and 28 days after shots were administered. However, as Dr. Baskin notes, peak levels of mercury in the blood are expected to appear within 24 hours:

"We know the stool levels were high, but if you actually measured the blood levels, they said it was somewhere between 23 and 27 days later. The peak mercury levels after injection occur within 24 hours. So if they were drawing blood later than that, and much later than that, of course the levels weren't going to be high. But the mercury will jump from the injection to the stool; it goes through the blood. At some point it was high because it was high in the stool."

4. The study did not measure the effects of mercury on infants, only the levels of mercury:

While the University of Rochester study measured the levels of mercury in infants' bodies at various times beyond peak levels, it did not attempt to determine the effects of the mercury. This limitation was clearly brought out in an exchange between Congressman Burton and Dr. Christopher Portier, Director of the Environmental Tobacco Program at the National Institute of Environmental Health Sciences:

Mr. Burton: "Does the study recently published in The Lancet identify the effects of mercury on infants who are vaccinated with thimerosal?"

Dr. Portier: "No."

Given the small sample size, the failure to measure mercury at peak levels, and the study's inability to measure the effects of the ethylmercury present in the bodies of the subjects, it is difficult to understand how the study's authors arrived at a conclusion that, "the thimerosal in routine vaccines poses very little risk to full-term infants." If anything, the limitations of this study point out the need for much more research to be done. As Dr. Baskin pointed out:

"They described this as a descriptive study, and that's exactly what it was. It provides a data base, but it's not a base, but the interpretation is inaccurate."

VII. EVIDENCE OF ETHYL MERCURY'S TOXICITY WAS NEGLECTED BY MANUFACTURERS AND FEDERAL REGULATORS FOR YEARS

Evidence of ethylmercury's toxicity was available to Federal regulators and the private sector almost from the product's inception. For far too long, both neglected this evidence. Despite evidence dating to the 1930s that ethylmercury in medicines was potentially hazardous, little was done to remove it from a number of products until the 1990s. Even then, regulatory actions to remove thimerosal and other mercury compounds from medical products proceeded at a glacial pace. The decision to remove thimerosal from a number of childhood vaccines was not finalized until 1998. The removal of thimerosal from several childhood vaccines in the United States wasn't accomplished until after the turn of the century. Today, the vaccine for influenza given to infants still contains trace amounts of ethylmercury.

As previously discussed in this study, thimerosal, ethylmercury, has been used as a preservative or anti-bacterial agent in a range of products, including antiseptic ointments, cosmetics, antiseptic solutions, diaper rash treatments, contraceptive products, and perhaps most importantly, vaccines. Several years after an FDA advisory committee recommended thimerosal wasn't safe for use in topical ointments, new childhood vaccines containing thimerosal were being approved and added to the recommended schedule. Nobody had analyzed the potential impact of the increased cumulative amount of mercury to which young children were being exposed. In fact, Congress had not enacted legislation in 1997 requiring the FDA to study the amounts of mercury being used in FDA-approved products. It is questionable that the FDA has ever analyzed mercury in vaccines at all.

It is no wonder that, in its report on thimerosal, the Institute of Medicine commented:"

"The presence of mercury in some vaccines can raise doubts about the entire system of vaccine safety. The Institute has recommended that the potential of the risk of thimerosal in vaccines may contribute to a perception among some that careful attention to vaccine components has been lacking."

It is clear that the guiding principal for FDA policymakers has been to avoid shaking the public's confidence in vaccines. For this reason, many FDA officials have stubbornly denied that thimerosal may cause adverse reactions. Ironically, the FDA has given the thimerosal issue more forcefully, and removed thimerosal from vaccines earlier, may have done more long-term damage to the public's trust in vaccines. The issue was confronted head-on.

Given the serious concerns about the safety of thimerosal, the FDA should have acted years earlier to remove this preservative from vaccines and other medicines.

B. Thimerosal manufacturers accumulated evidence of the toxicity of thimerosal

Eli Lilly and Company of Indianapolis licensed thimerosal in 1930. It was marketed under a number of brand names, and it was used extensively both in topical ointments to prevent infections and as a preservative in a variety of medicines. However, it now appears that Lilly was more forceful, and removed thimerosal from vaccines earlier, may have done more long-term damage to the public's trust in vaccines. The issue was confronted head-on.

Eli Lilly was not the only manufacturer of thimerosal or other ethylmercury products. In fact, they phased out their production of thimerosal in 1974. However, Eli Lilly initially patented this product and had a longer history with it than any other company. Therefore, it is appropriate to review Lilly's history with it than any other company. Therefore, it is appropriate to review Lilly's track record in ensuring the safety and reliability of this product.

Review of internal Eli Lilly documents dating back 70 years suggests that the only study of thimerosal involving human subjects was done prior to 1930. For the next seven decades, Lilly spokespeople would refer to that original study as evidence of thimerosal's safety. However, it is now clear that this uncontrolled study was woefully inadequate.

As previously discussed in this study, an intravenous solution containing thimerosal was tried as an experimental treatment for meningitis. While the treatment was found to be ineffective, the doctor who conducted the study concluded that the solution caused no harmful side effects. It is clear today that such a limited number of subjects, all suffering from the same serious illness, would...
hardly qualify as a sufficiently sized random sample, and a study such as this one would be of very little value by today's standards. In fact, an internal Eli Lilly memo from 1972 candidly described the clinical trial as follows:

"Considering the type of patient involved, one might question these observations (the appearance of no deleterious action) as providing any indication of any harmful effects of high doses of Merthiolate in humans, in particular, more long term effects."

In 1973, the FDA requested additional data on Merthiolate from Eli Lilly, Lilly's Director of Regulatory Affairs, E.A. Burrows, responded with a ringing defense of Lilly's product on February 14, 1973:

"Due to the length of time this product has been on the market, its efficacy and safety have been proven by over forty years of use throughout the world. Because of this long period of use, it would be difficult to get recognized researchers to conduct new studies for efficacy or safety. They believe that over forty years of wide usage has proven efficacy and safety beyond that which could be done in special studies."

Despite Mr. Burrow's contentions, numerous individuals have noted the lack of data on thimerosal and suggested the need for more research:

An April 24, 1969, intra-office memo stated:

"After some field experience with the merthiolate solution, we have to know pretty definitely what to expect from merthiolate on the market before they put it on the market... We can expect to have the stronger ointment and jelly used without complaint which avoided the use of the strong solutions without some sort of definite evidence that we will not repeat our solution experience."

An August 1973, memo regarding the possible use of thimerosal in contact lens solution states:

"When Merthiolate breaks down are the degradates toxic or irritant? Our files yield no test information on the irritancy of degraded merthiolate."

"Would we recommend the use of merthiolate solution to store and sterilize contact lenses? In the absence of appropriate data, a positive recommendation could not be made, this use does not seem unreasonable and probably not harmful."

A December 1972, memo states:

"A review of some data being generated by the current concern for mercury in the environment would be advisable to obtain data on the metabolic deposition of Merthiolate."

An August 1973, memo entitled, "Merthiolate Toxicity," acknowledged:

"The effects of long-term, intravenous use in man is not known, no long-term toxicity tests have been performed in animals."

Perhaps more disturbing is that Lilly's files contained numerous papers and reports documenting the toxicity and hyper-sensitivities of Merthiolate. Although these papers and case reports strongly suggested the need for much more research, there apparently was little follow-up. A July 1980 letter from the Pittman-Moore Company indicated that Merthiolate was not appropriate for use in dogs:

"We have obtained marked local reaction in about 50% of the dogs injected with serum containing dilutions of Merthiolate, varying in in 40,000 to 1 in 5,000, and we have dem-onstrated conclusively that there is no con-nection between the lot of serum and the re-action. In other words, Merthiolate is unsat-isfactory as a preservative for serum in-jecting the same strength of the serum in dogs do not show the local reaction, but in some in-stances, the reaction is extremely severe. I might say that we have tested Merthiolate on human beings it gave human beings a more severe marked local reaction than does phenol or tricresol."

A 1947 paper published by an Army physician in Baltimore reported that Merthiolate was causing contact dermatitis in his patients. He concluded:

"No eruption or reactions have been observed or reported to Merthiolate internally, but it may be dangerous to inject a serum containing Merthiolate into a patient sensitive to Merthiolate."

A 1968 paper from an Arizona doctor reported the case of a woman who suffered repeated multiple reactions to Merthiolate applied to her skin. She reportedly suffered chills and fever and had small vesicles and erythema in the area of her Merthiolate application. After her recovery, the physician wrote a letter for which she was being surgically treated appeared after repeated application of a tincture of Merthiolate. She continued applying the Merthiolate to her body, which became too raw and painful to continue use, and then sought medical care.

A 1950 New York Academy of Sciences article entitled, "Dangers of Skin Burns from Thimerosal," reported the case of a woman who received severe burns resulting from a chemical interaction between thimerosal and aluminum. The article suggested that thimerosal and aluminum should not be used together. Later in 1973, Lilly's legal department recommended new labeling language for thimerosal products. "Do not use when aluminum may come in contact with treated skin." Unfortunately, thimerosal and aluminum were used together in the DTP and DTaP vaccines.

C. The FDA was painfully slow to require the removal of mercury from over-the-counter (OTC) products.

In 1974, the FDA undertook a comprehensive review of the safety and effectiveness of over-the-counter medicines. As one facet of this review, a panel of experts was assembled to review the safety and efficacy of over-the-counter drugs, "Antimicrobials. The Advisory Review Panel on OTC Miscellaneous External Drug Products began this review in 1975. In 1980, the panel delivered its report to the FDA recommending banning mercury, and found them all either unsafe or ineffective for their stated purpose of killing bacteria to prevent infections."

In terms of safety, the panel stated that, "mercury compounds as a class are of dubious value for anti-microbial use." They stated that, "mercury inhibits the growth of a number of bacteria. Occasional do's kill them." In fact, the panel cited a 1935 study of the effectiveness of thimerosal in killing staphylococcus bacteria on chick heart tissue. The study concluded that thimerosal was 35 times more toxic to the heart tissue it was meant to protect than the bacteria it was meant to kill.

In terms of efficacy, the panel cited a number of studies demonstrating the highly allergic nature of thimerosal and related organ-containing mercury products. For instance, they cited a Swedish study that showed that 10 percent of school children, 16 percent of military recruits, 18 percent of twins, and 26 percent of patients responding with a skin sensitizer were sensitive to thimerosal. They stated that while organic mercury compounds like thimerosal were initially developed to decrease the risk of polio, the mercury that was actually found was more toxic than bicarbonate of mercury for certain human cells.

By way of summary, they stated the fol-

"The Panel concludes that thimerosal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin, and it's action is not effective as a topical antimicrobial because its bacteriostatic action can be reversed."

Despite the fact that the expert committee found thimerosal and other ethyl-mercury compounds unsafe and ineffective for over-the-counter products, the FDA would not formally require the removal of mercury from these products for another 18 years. The submission of the committee's report in 1980 set in motion a tortuous bureaucratic process that would not result in the banning of mercury from over-the-counter products until 1998. The advisory committee recommended new labeling notice of Proposed Rules or Notice of Proposed Rules regarding these products in 1980, 1982, 1990, 1991, 1994 and 1995. It is difficult to understand why the expert panel's 1980 findings on thimerosal's safety and toxicity are ignored by the FDA to further and immediately require the use of thimerosal in vaccines. Surely there must have been concern that if it was not safe to apply ethylmercury to the surface of an individual's skin, it might not be safe to inject ethylmercury deep into an infant's tissue. The Director of the FDA's National Center expressed such a concern at a 1999 meeting for Toxicological Research, Dr. Bernard Schwartz, who went on to serve as the Acting Director of the FDA for nearly a year. "One thing I haven't heard discussed, the fact that we know that ethylmercury is a skin sensitizer when it's put on the skin, and now we're injecting this IM (intramuscularly) at a time when the immune system is just developing, the functionality of the immune system is just being set at this age. So now we're injecting a sensitizer every time we're giving a chemical of that kind repeatedly IM."

Different branches of the FDA regulate over-the-counter products and vaccines. Vaccines are regulated by the Center for Biologics Evaluation and Research (CDER). Vaccines are regulated by the Center for Biologics Evaluation and Research (CDER).
Evaluation and Research (CBER). This, however, is little justification for the lack of coordination. The FDA’s determination that mercury was unsafe and should be removed from many childhood vaccines was not even acknowledged in the Federal Register no fewer than five times prior to the FDA’s belated review of mercury in vaccines.

What prompted the FDA to review mercury in vaccines was not its own regulatory process, but rather an act of Congress. In 1997, Congress passed and the President signed into law the Food and Drug Administration Modernization Act (FDAMA). Among other things, this law required the FDA to compile a list of foods and drugs that contained mercury and determine whether thimerosal was unsafe in tipoidal ointments. One of the FDA’s actions was to study its effects on the human body, and restrict its use if found to be harmful.

E. Federal regulators moved too slowly to remove thimerosal from vaccines

Once the FDA did initiate its review of mercury in vaccines, it kicked off a vigorous debate among Federal regulators over the dangers of using thimerosal in childhood vaccines. This debate, which at times pitted one health-care bureaucracy against another, spanned nearly three years. Given the fact that almost twenty years had passed since thimerosal was introduced and determined to be thimerosal, it is surprising that there was any further debate at all.

There was tremendous reluctance on the part of some officials to admit that a mistake had been made in allowing ethylmercury to be used in vaccines. There was great lack of data in others caused by the lack of data specifically on ethylmercury. However, the institutional resistance to change was counter-balanced by the general feeling that there was more ethylmercury in childhood vaccines than previously thought, and that nobody had thought to calculate the cumulative amounts. The essence of the debate was captured in a 1999 e-mail from a former FDA official weighing the pros and cons of taking action. He opined that hastening the removal of thimerosal from vaccines would: "...raise questions about FDA being 'asleep at the switch' for decades by allowing a potentially hazardous compound to remain in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various existing regulations and recommendations for use. (We must keep in mind the dose of ethylmercury was not generated by 'rocket science'.) Conversion of the thimerosal to ethylmercury and ethylmercury bioswaps involves ninth grade algebra. What took the FDA so long to do the calculations? Why didn’t CDC and the advisory bodies recommend the action? We opined that hastening the removal of thimerosal from vaccines would:

1. The recommended guidelines for exposure to methylmercury were a good starting point for reviewing exposure to ethylmercury;
2. The amount of ethylmercury in children’s vaccines exceeded the EPA’s guidelines for exposure to methylmercury.

An exchange of e-mails in October of 1998 makes clear that Dr. Leslie Ball was already skeptical of thimerosal's dangers and favorability to removing thimerosal. Dr. Marion Gruber of the Office of Vaccine Safety at the CDC also stated that, if there was any question, the safest course of action should be taken, and thimerosal was not essential to vaccines. In point of fact, we have no proof that thimerosal either out of vaccines or to leave it in. In fact, somebody should perform the adequate studies to evaluate the conclusions on the toxicity of thimerosal or its metabolized forms.

Dr. Ball’s response on October 15, 1998, to Dr. Hastings’ conclusion was sharp: "I disagree about the conclusion regarding no basis for removal of thimerosal. On a strictly scientific basis, yes, there are no data that have looked at the specific issue of thimerosal in vaccines. However, there are data that would argue for the recommendation of removal from vaccines. There is data on methylmercury exposure in infants and the knowledge that thimerosal is not an essential component to vaccines. In addition, the scientific community is moving to ban thimerosal."

In a 2002 interview with Committee staff, Dr. Ball confirmed that it was her opinion that, if there was any question, the safest course of action should be taken, and thimerosal should be removed.

An important part of the FDA’s review was a comparison of the amount of ethylmercury in vaccines to the recommended safe levels for exposure to methylmercury established by the EPA. Dr. Barry Rumack, a consultant to the FDA, developed a pharmacokinetic model to analyze the amount of mercury to which infants were being exposed by reviewing the two Committee two charts developed from that model dated June 28, 1999. Both charts demonstrate what has now become widely accepted knowledge. Most children in the 1990s received doses of ethylmercury in their vaccines that exceeded the EPA’s limits for exposure to methylmercury (0.1 micrograms per kilogram of body weight for the first six months of their lives. Even more significantly, the charts also indicate that most children received doses of ethylmercury that exceeded the EPA’s limits for exposure to methylmercury (0.1 micrograms per kilogram of body weight for the first six months of their lives). For at least the first two months of their lives.

Federal officials have never publicly acknowledged this second fact. In public statements and Congressional testimony, they have acknowledged only that the EPA’s scientific expectations were exceeded. The simple math makes clear that most infants also breached the FDA’s higher limit of 0.4 micrograms per kilogram.

Dr. Neal Halsey, director of the Institute of Vaccine Safety at Johns Hopkins University, acknowledged this important fact, however. As previously mentioned, Dr. Halsey analyzed data that showed thimerosal should be removed from vaccines. On June 22, 1999, Dr. Halsey presented the results of his research to the Medical Policy Coordinating Committee and the Committee on Infectious Diseases andReview (CBER). Dr. Halsey attended that meeting. The next day, on June 23, 1999, Dr. Halsey wrote a letter to the members of the American Academy of PEDIATRICS Committee on Infectious Diseases, which he chaired. He stated:

“We must follow the three basic rules: (1) we must keep in mind the dose of ethylmercury was not generated by ‘rocket science’. Conversion of the thimerosal to ethylmercury involves ninth grade algebra. What took the FDA so long to do the calculations? Why didn’t CDC and the advisory bodies recommend the action? We opined that hastening the removal of thimerosal from vaccines would...”

One document written by Dr. Ball estimated that exposure to mercury in vaccines could total roughly 80 to 100 micrograms per year. Background levels were included in all calculations prepared by the European Medical Research Council, which was at the time reviewing thimerosal in vaccines. If background levels of mercury had been incorporated into the FDA’s and CDC’s calculation, the results would have been even more pronounced, possibly even leading to more aggressive measures to remove thimerosal. It is unfortunate that this simple, and scientifically expected step was not taken.

The issue of what to do with thimerosal in vaccines came to a head in the summer of 1999. In June and July, a series of meetings involving the Public Health Service, the American Academy of Pediatrics, and other agencies, was held involving the FDA, the CDC, the American Academy of Pediatrics Committee on Infectious Diseases, and the World Health Organization were all exceeded.

Another noteworthy fact is that the charts produced by Dr. Rumack, and the FDA’s analysis, failed to take into consideration the background levels of mercury to which children are exposed from other sources. Dr. Ball pointed out this weakness in her 1999 e-mail: "These calculations do not account for other sources of Hg [mercury] in the environment, e.g., breast milk."

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The fact that more forceful action to remove thimerosal from the vaccine marketplace was not taken in 1999 is disappointing, just as disappointing, and even more difficult to understand, is the fact that the CDC, on two separate occasions, refused to publicly state a preference for thimerosal-free vaccines.

In June of 2000, the CDC’s Advisory Committee on Immunization Practice met in Atlanta. Among other things, the Advisory Committee was called upon to recommend whether the CDC should issue a public statement of preference for thimerosal-free vaccines. At the time, the industry was in the midst of introducing thimerosal-free childhood vaccines, and several vaccines containing thimerosal were still on the market. Of particular concern was the DTaP vaccine. In June of 2000, three of the four DTaP manufacturers (Aventis Pasteur, North American Vaccine and Wyeth) were still producing DTaP with thimerosal. Only SmithKline Beecham produced a thimerosal-free DTaP.

In addition, because manufacturers of the Hepatitis B and Hib vaccines had just recently converted to formulas that were thimerosal-free, older versions of these vaccines containing thimerosal were still in inventories and being used around the country. As a statement of preference, the CDC would have been a clear signal to pediatricians not to use vaccines containing thimerosal, when thimerosal-free versions were available. This action would have substantially reduced the exposure to ethylmercury for many infants. Despite this knowledge, the advisory committee voted unanimously not to state a clear commitment to reduce as expeditiously as possible the mercury content of their vaccines.

As a result of the limited steps taken in 1999, public loss of confidence remained on the market for nearly two years. GlaxoSmithKline’s Hepatitis B vaccine did not become thimerosal-free until March of 2000, and Glaxo’s DTaP vaccine did not become thimerosal-free until March 2001. In addition, thimerosal-containing vaccines on the shelves in doctor’s offices around the country would continue to be used. Perhaps the most disturbing fact is that thimerosal-free versions were available.

The financial health of the industry should never have been a factor in this decision. The financial health of vaccine manufacturers certainly should never have been more important to the Federal health officials than the health and well-being of America’s children. The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neurotoxicity of thimerosal, they surely were overprotective toward children—and there were substantial doubts—the prevailing consideration should have been how best to protect children from potential harm. However, it appears that protecting the industry’s profits took precedence over protecting children from mercury doses.

In opting not to state a preference for thimerosal-free vaccines, the Advisory Committee shrugged off two sensible proposals that were presented during the meeting. A representative of SmithKline Beecham (now GlaxoSmithKline) stated that her company could supply sufficient amounts of thimerosal-free vaccines, that the CDC had the youngest infants receiving the initial doses of DTaP could receive thimerosal-free doses: "I think it’s important that you know there was a statement that went out to the entire U.S. market right now for all five doses immediately, we would be able to supply the vast majority of the U.S. market for the primary immunizations that is with targeting of the first three doses." Given the repeated concerns expressed about the effects of thimerosal on the developing central nervous system in very young babies, ensuring thimerosal-free doses for the first three boosters of DTaP would seem to merit serious consideration. However, this submission was passed over without any comment.

Later in the discussion, Dr. Neal Halsey made another suggestion that would limit the exposure of infants to ethylmercury. He suggested that the Advisory Committee adopt a policy that no child should receive more than one thimerosal-containing vaccine per day: "Roger, you said that after July, the maximum exposure will be 75 micrograms. My understanding from what the developing central nervous system in very young babies, ensuring thimerosal-free doses for the first three boosters of DTaP would seem to merit serious consideration. However, this submission was passed over without any comment.

Again, it appears that this seemingly sensible proposal received no serious consideration.

A year later, in June of 2001, the Advisory Committee again rejected the idea of expressing a preference for thimerosal-free vaccines. This time, the Advisory Committee’s inaction in this policy was an abdication of their responsibility. As a result of their inaction, children will continue to receive vaccines containing ethylmercury at a time when there were serious doubts about its safety.\*\*
What makes the CDC’s decision even more vexing is that just prior to the Advisory Committee meeting in 2000, a study conducted by the CDC suggested that there was at least a suggestion between thimerosal and several types of neurological disorders.

The study initiated in 1999, reviewed the medical records of 110,000 children in the CDC’s Vaccine Safety Datalink (VSD). The VSD is a massive database that tracks the medical histories of thousands of patients belonging to seven major health maintenance organizations. Phase I of the study was designed to screen data for potential associations between thimerosal-containing vaccines and selected neurological disorders. Phase II was designed to test the hypotheses generated in the first phase.

Phase II uncovered a significant association between exposure to thimerosal during the first three months of life, and tics, attention deficit disorder, language, and speech delays and general developmental delays. The study did not find a correlation between thimerosal and autism because the sample size of children diagnosed with autism was not large enough.

The findings of Dr. Verstraeten, the primary author of the study, set off a debate within the Federal health agencies. The Simpsonwood panel determined that the VSD study failed to confirm the findings supported by the VSD, although weak, association, but that the implications—for obvious reasons—are profound. Therefore, the consultants were unanimous in their view that further investigation should be pursued with a degree of urgency and, parenthetically, not only for public health policy in this country, but for public health policy around the world.

Documents reviewed by the committee indicate that Dr. Verstraeten was not pleased with the response to his study. During the Simpsonwood panel meeting, Dr. Verstraeten wrote: “When I saw this, and I went back through the literature, I was actually stunned by what I saw—because I thought it was plausible.”

A month later, he sent an e-mail to Dr. Philippe Grandjean, the author of several studies on thimerosal, that read: “I know that much of this is very hypothetical and, personally, I would rather not have this whole neonatal period—it’s what’s the week or what’s the day or what’s the series of windows during fetal development, the neonate is very important, and for some of these [disorders] because of the children are just not old enough to be diagnosed. So the crude incidence rates are probably much lower than what you would expect because the cohort is still very young.”

Dr. Colleen Boyle of the CDC raised this issue receive continued attention. The IOM said that it “does not exclude the possibility that MMR vaccines could contribute to ASD” and recommended “this issue receive continued attention.” The IOM urged the following research recommendations:

- Use accepted and consistent case definitions and assessment tools (autism spectrum disorder) in order to enhance the precision and comparability of results from surveillance, epidemiological, and biological investigations.
- Explore whether exposure to MMR vaccine is a risk factor for ASD in a small number of children.
- Deep targeted investigations of whether or not measles vaccine strain virus is present in the intestines of some children with ASD.
- Encourage all who submit reports to VAERS or any diagnosis of ASD thought to be related to MMR vaccine to provide as much detail and as much documentation as possible.
- Case Reports in VAERS or elsewhere of “rechallenge” should be identified, documented, and followed up.

The neurotoxicity of ethylmercury. The neurotoxicity of dental amalgams containing mercury.

Immune system and gastrointestinal system dysfunction after vaccination.

In 2001, the Institute of Medicine concluded that much more research is needed to establish possible relationships between vaccines and autism spectrum disorder. In its report on an alleged relationship between the MMR vaccine and autism, the IOM noted that it “does not exclude the possibility that MMR vaccines could contribute to ASD” and recommended “this issue receive continued attention.” The IOM urged the following research recommendations:

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- Encourage all who submit reports to VAERS or any diagnosis of ASD thought to be related to MMR vaccine to provide as much detail and as much documentation as possible.
- Case Reports in VAERS or elsewhere of “rechallenge” should be identified, documented, and followed up.

Study the possible effects of different MMR immunization exposures.
In its report on thimerosal-containing vaccines and autism, the IOM stated that there was not enough evidence to reach any conclusions regarding the possible relationship between thimerosal and autism spectrum disorders. The IOM called for the following types of research:

- Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines;
- Further investigation of the children who did not receive thimerosal-containing doses of vaccines during clinical trials;
- Epidemiological studies comparing the prevalence of neurological disorders in children who received vaccines before thimerosal was removed to children who received vaccines after it was removed.

An increased effort to identify the primary sources and levels of prenatal and postnatal exposure to thimerosal;

- Clinical research on how children metabolize and excretethimerosal.

Theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal on background mercury exposure from other sources;

- Research in appropriate animal models on neurodevelopmental effects of ethylmercury;
- Rigorous investigations of thimerosal as a treatment for neurodevelopmental disorders;

- Research to identify a safe, effective, and inexpensive alternative to thimerosal for countries that decide they want to follow the example of Europe and the United States and discontinue its use.

One concern that has been raised many times is that responsibility for research into autism and related issues at the NIH has been fragmented. Responsibility is divided among the National Institute of Mental Health, the National Institute of Neurological Diseases and Stroke, the National Institute of Child Health and Human Development, and the National Institute of Environmental Health Sciences. Greater overall coordination is needed. The NIH needs to develop a strategic plan on autism research to bring diverse activities together under a strategy and timeline, and focus research on the most pressing research needs.

Another concern is the lack of a sufficient investment into research on autism and its causes. Autism is growing at epidemic proportions and nobody knows why. The rates of autism doubled during the Committee’s investigation, yet funding for research on autism lags badly behind funding for other serious diseases. The NIH, with a budget of $27 billion for the fiscal year, invested just $5.8 Million towards autism research. Much of that research has been focused on looking for genetic causes of autism, which is important, but it does not address the possible connection to vaccine injury. To put the spending on autism in perspective, the Committee compared it to the spending on two other serious epidemics—HIV/AIDS and diabetes. At the same time that the NIH was spending $56 Million on autism research, they spent $688 Million on diabetes research and over $2.2 Billion on HIV/AIDS research.

The Centers for Disease Control and Prevention has also been negligent in addressing the research needs regarding vaccine injury and autism. In April 2002, the CDC invested $11.3 Million on autism, while spending $92 Million on diabetes, and $952 Million on HIV/AIDS. With spending on vaccine research one of the lowest priorities for AIDS, it is obvious that CDC is not addressing the autism epidemic with enough rigor. Instead, at the time of the Committee’s April 2002 hearing, the CDC actually planned to cut autism research spending to $10.2 Million.

Another concern has been the CDC’s bias against theories regarding vaccine-induced autism. Rather than aggressively work to replicate clinical findings with lab-based experiments, the CDC has focused its efforts on non-scientific rebuttals to the Wakefield autism enterocolitis studies, the CDC funded researchers who also worked for vaccine industry lobby groups, and in some cases, publication-based epidemiological studies to look at the possible correlation between vaccine injury and a subset of the population that might be injured. The CDC has also put too heavy a focus on epidemiological findings. While epidemiological studies are important, they are not a substitute for focused, clinical research. Chairman Burton expressed some of these concerns at the June 2002 hearing:

- "Officials at HHS have aggressively denied any possible connection between vaccines and autism. They have waged an information campaign endorsing one conclusion on an issue where the science is still out. This has significantly undermined public confidence in the public health establishment, especially those who are charged with balancing the dual roles of assuring the safety of vaccines and increasing immunity. Parents come to us with concerns that integrity and an honest public health response to a crisis have been left by the wayside in lieu of protecting health agenda to fully immunize children. Parents are increasingly concerned that the Department may be inherently conflicted in its multiple roles of promotion, regulation of manufacturers, looking for adverse events, managing the vaccine injury compensation program, and developing new vaccines. Families sharing my concern that vaccine manufacturers have too much influence as well. How will HHS restore the public’s trust?"

- "It is clear that inadequate scientific evidence exists to understand fully the likely damage done to a generation of children who were repeatedly exposed to significant levels of mercury through their mandatory childhood immunizations. While the use of safe and effective vaccines for dangerous infectious diseases is very important, the lack of quality data addressing the risk of adverse reactions is a severe deficiency which has undermined public support for this important public health tool."

IX. CONCLUSIONS

It is obvious from all accounts that there is a crisis in the United States regarding the dramatic rise in autism rates and the resulting strain placed on families, the education system, and State Medicaid and disability programs. A further crisis will ensue in the next two decades when we see an explosion in the need for adult services and long-term housing.

In further attempt to raise the level of awareness of the autism epidemic, in November of 2002, Chairman Burton called upon the President to announce a White House Conference on autism, a national effort to determine why autism has reached epidemic proportions in this country. Chairman Burton suggested this would be a valuable data that showed a relationship between the best minds from across the country to chart a course of scientific research to uncover the underlying causes of this epidemic. . . . Mr. President, you are in a unique position to provide the leadership that is necessary to organize a national effort to resolve these problems. . . . The Centers for Disease Control and Human Services adequately addresses the concerns of families of whose children have possible vaccine-induced autism. The continued response from agency officials that "there is no proof of harm" is a disingenuous response. The conclusive proof does not mean that there is no connection between thimerosal and vaccine-induced autism. What the lack of conclusive proof does indicate that the agency has not in its duties to assure that adequate safety studies were conducted prior to marketing. Furthermore, in the last two decades, after determining that thimerosal was "generally recognized as safe" for topical ointments, the agency did not extend their evaluation to other applications of thimerosal, in particular as a vaccine preservative.

One leading researcher made the following statement to the Committee in July of 2002:

"The question that mercury does not belong in vaccines. . . . There are other compounds that could be used as preservatives. And everything we know now indicates that neurotoxicity of mercury at the fetus and at the infant level, points out that we should not have these fetuses and infants exposed to mercury. There’s no need of it in the vaccines.""
Mr. UDALL of Colorado. Mr. Speaker, today, I am introducing legislation titled the “National War Permanent Tribute Historical Database Act,” that will help the Department of Interior and the Department of Veterans’ Affairs keep track of the many important war memorials on public lands throughout our country. It would also provide a report to Congress to determine if there should be a permanent fund within the Treasury for the upkeep of these memorials.

The freedom we enjoy in the United States has not just been given to us. Men and women have made great sacrifices, some with their lives, to protect our way of life. We have erected memorials to honor these soldiers, sailors, and aviators and their valiant deeds. Unfortunately, many of these memorials don’t receive the care they deserve and have fallen into disrepair. These memorials may not be as large as those on the National Mall or Arlington National Cemetery but they are just as important and should be taken care of.

In 2000, Congress agreed to a resolution expressing the need for cataloging and maintaining public memorials. The National War Permanent Tribute Historical Database Act would follow through with this sense of Congress and take a first step by cataloging our public war memorials.

Mr. Speaker, as we honor America’s men and women in uniform this Memorial Day, many of us will be thinking these soldiers who have recently been fighting in Iraq and Afghanistan. But the other conflicts America’s service men and women have fought in should not be forgotten. These memorials remind people what their local men and women did to protect our country. By cataloging and reporting to Congress on the condition of all of our war memorials on public lands and by considering how to maintain them we make sure that our veterans are not forgotten. Passage of this bill would be a step toward renewing our commitment to honor our nation’s veterans.

HON. FORTNEY P. STARK OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, May 21, 2003

Mr. STARK. Mr. Speaker, I rise today to introduce the Medicare Out-of-Pocket Spending Limit Act of 2003. This legislation protects Medicare beneficiaries from potentially ruinous medical bills by ensuring they will never have to pay more than $2,000 out-of-pocket for Medicare services. It does so without limiting seniors’ choice of physician and without forcing seniors to leave Medicare and join a private plan. In short, it is real Medicare reform, the kind of reform that seniors and people with disabilities want and need.

President Bush and many of my Republican colleagues portray Medicare as a disastrous program that is broken, bankrupt, and dumb. They think private insurers—the same ones who refused to cover seniors back in 1965 when Medicare was created—can do a better job than Medicare has done for the last 38 years.

More than 40 million seniors and individuals with disabilities know that President Bush and Congressional Republicans are wrong. They know that Medicare is a vitally important program that successfully protects some of the most vulnerable among us. They want us to strengthen Medicare, not undermine it. That is why I am introducing the Medicare Out-of-Pocket Spending Limit Act.

The bill I am introducing today provides an essential Medicare improvement for all Medicare beneficiaries. Today Medicare covers about 52% of seniors’ health costs, leaving many to pay significant medical bills out of their own pockets. Medicare beneficiaries with chronic conditions or catastrophic illnesses face the greatest risk of potentially unlimited health costs. Most Medicare beneficiaries have incomes below $20,000 per year and cannot afford to spend a large share of their income on health care.

The Medicare Out-of-Pocket Spending Limit Act will offer seniors the security of knowing that they will never have to pay more than $2,000 out-of-pocket on Medicare services per year. Current and future Medicare beneficiaries will have the option of enrolling in this new, voluntary benefit at an affordable premium. Beneficiaries with incomes below 175 percent of the federal poverty level would pay reduced or zero premiums.

The benefits provided by the Medicare Out-of-Pocket Spending Limit Act are long overdue. In testimony before the Ways and Means Committee this month, the Chairman of the Medicare Payment Advisory Commission identified the lack of a spending limit as a “serious limitation of the Medicare benefit package.” In January 2003, the National Academy of Social Insurance’s Study Panel on Medicare and Chronic Care in the 21st Century recommended that Congress “limit cost-sharing requirements by adding an annual cap on out-of-pocket expenditures for covered services.” The Medicare Out-of-Pocket Spending Limit Act follows through on these expert recommendations.

Importantly, the Medicare Out-of-Pocket Spending Limit Act provides these improvements in traditional Medicare. Unlike the President’s and the Congressional Republicans’ plan to “reform” Medicare by ending it as a defined benefit for all beneficiaries, my bill will guarantee that elderly and disabled Americans will never be forced to give up traditional Medicare in order to get crucial benefits. Beneficiaries will be free to choose between the traditional Medicare program and private plans. But it will be a real choice, not coerced through the lure of more generous coverage. Seniors should never have to choose between the doctors they know and trust and the coverage they need.

This legislation is supported by beneficiary advocacy groups including: Families USA, the Center for Medicare Advocacy, the Alliance for Retired Americans, and the Medicare Rights Center. I urge my colleagues to join us in support of strengthening Medicare for all seniors and disabled Americans by cosponsoring the Medicare Out-of-Pocket Spending Limit Act.

Below is a more detailed summary of the legislation:

**Medicare Out-of-Pocket Spending Limit Act of 2003—Summary**

This bill would improve Medicare for all beneficiaries by adding a new voluntary benefit to the traditional Medicare program. Seniors and disabled Americans electing this coverage would be protected from extraordinary out-of-pocket costs when they need medical care. The additional benefit—created under a new Medicare Part D—would have the following features:

- **Out-of-pocket limit.** Beneficiaries enrolled in the new benefit would never pay more than $2,000 out-of-pocket per year for services covered under the traditional Medicare program. The out-of-pocket spending limit would be adjusted each year by the growth in average per capita spending under this new benefit.

- **Eligibility and enrollment.** Beneficiaries entitled to Medicare Part A and enrolled in Part B would be eligible for the new benefit. Costs of Medicare benefits would stay extra-

- **Premiums.** Premiums for the new benefit would be calculated in the same manner as Medicare Part B premiums (25 percent of estimated program costs), with a late enrollment penalty for beneficiaries who choose not to enroll during the open enrollment period.

- **Low-income beneficiaries.** Beneficiaries with incomes up to 150 percent of poverty would be eligible for the new benefit with no additional premiums. Beneficiaries with incomes between 150 percent and 175 percent of poverty would be eligible for the new benefit with a sliding scale premium. No assets test would be used in determining eligibility for these additional low-income protections. These low-income benefits would be administered by the States but 100 percent federally funded.

**Medicare+Choice.** All Medicare+Choice plans would have to provide the out-of-pocket spending limit benefit. Plans would be...