way.’’ Despite all his accomplishments he is a down-to-earth guy, whose company is downright 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 paras-troopers 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 parachute divisions and glider-troopers. Hitler felt this was to be an easy victory, yet he is quoted to have said shortly after the invasion, “France is one thing, Crete is 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 so hard by the German military that it signifyed 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 of the European underground 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 defying 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.

Whereas 2003 marks the 62nd anniversary of the heroic Battle of Crete, which took place on the Greek island of Crete during World War II between Nazi German forces and the people of Crete assisted by the Allied armies;

Whereas the people of Crete fought tenaciously during the Battle of Crete, delaying for two months the Nazi German invasion of Russia;

Whereas this delay forced Nazi German forces to invade Russia in the face of the brutal Russian winter, changing the final outcome of World War II and leading to the defeat of fascism;

Whereas many historians agree that the Battle of Crete was one of the most significant battles of World War II;

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

Whereas the Cretan Resistance Movement was organized and led by the Nazi German occupation of the island of Crete;

Whereas for 4 years, the Cretan Resistance Movement inflicted heavy casualties up 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, an organization 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 Representatives—

(1) observes the memory of the fallen heroes of the Battle of Crete;

(2) honors the living men and women of Crete who, during World War II, fought an oppressive invader to preserve the ideals of freedom, democracy, and the pursuit of happiness; and

(3) commends the PanCretan Association of America for preserving and promoting the history of Crete and its people.

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 patients, hurt hospitals and most of all hurt patients. My constituents in East Texas have shared their concerns with me and I know full-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 bravely 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 break even on 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.
MERCUry IN MEDICINE—TAKING UNNECESSARY RISks

1. EXECUTIVE SUMMARY

Vaccines are the only medicines that American citizens are mandated to receive as a condition of compulsory attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof that their children have been immunized. While the mandate for which vaccines must be administered is a state mandate, it is the Federal Government, through the Centers for Disease Control and Prevention (CDC) and its Advisory Committee for Immunization Practices that make the Universal Immunization Recommendations to which individual states defer when 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 1999, 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 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 to 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 "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 the most vulnerable population—our children. This report will address one form of mercury in medical applications, Thimerosal, as a preservative in vaccines.

In June 2000, the FDA 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's 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 that has known risks can remain on the market. According to the agency, "at the heart of all FDA's product evaluation decisions is a judgment about whether a product's benefits 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 to the health of newborns—posed by the agency's mission to protect the public health, has been presented to the Committee by government officials. FDA officials have stressed that the judgment that thimerosal posed a risk was theoretical: that no proof of harm existed. Upon a thorough review of the scientific literature and internal documents provided by the agency, 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 high level (bolus) exposure to thimerosal is not "theoretical," but very real and documented in the medical literature.

Congress has long been 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 mercury children were being exposed to in the first six months of life through their mandatory vaccinations exceeded the Environmental Protection Agency's (EPA) limit for methylmercury. The FDA and other Federal agencies determined that in the absence of a specific standard for ethylmercury, the limits for intake of methylmercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA's methylmercury standard and determined that based upon scientific data that it, rather than the FDA's, was the scientifically validated safe exposure standard.

Rather than acting aggressively to remove thimerosal from children's vaccines, the FDA and other agencies within the Department of Health and Human Services (HHS) adopted an incremental approach that allowed children to continue to be exposed to ethylmercury from vaccines for more than two additional years. In fact, in 2001, the Centers for Disease Control and Prevention (CDC) refused even to express a preference for thimerosal-free vaccines, despite the fact that thimerosal had been removed from almost every childhood vaccine produced for use 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 most recently, the inactivated polio vaccine for rotavirus was linked to a serious bowel condition (intussusception), it was removed from the U.S. market. Ethylmercury has been found 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 are half of the current EPA methylmercury standards. It also raises concern that the U.S. already has an established methylmercury standard and no proof of harm from this additional mercury. As developing fetuses, babies are exposed to mercury through their mother. While American women have mercury amalgams, they are unknowingly excreting low levels of mercury on a daily basis to their fetuses. Additionally, infants who receive conventional dental amalgams or who are on 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 a preservative and an anti-bacteriological agent.

3. Manufacturers of vaccines and thimerosal (ethylmercury) have existed for decades.

4. Studies and papers documenting the hyperallergenicity and toxicity of thimerosal (ethylmercury) 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 ethylmercury to which infants were exposed threefold.

7. A growing number of scientists and researchers believe the 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
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 ethylmercury from over-the-counter products like creams and cold remedies. Although an advisory committee determined that ethylmercury was unsafe in these products in 1982, a rule requiring its removal was not final until 1999. 9. The FDA and the CDC failed in their duty to be vigilant as new vaccines containing thimerosal were approved and added to the schedule. When the CDC was notified in 1999 that the amount of thimerosal in vaccines exceeded the EPA threshold of 0.1 micrograms per kilogram of body weight, the CDC's rush to support the CDC that purportedly dispute any correlation of mercury-containing vaccines.

Emerging theories and clinical data related to adverse reactions from vaccinations.

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 ethylmercury 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 levels set at the Agency for Toxic Substances and Disease Registry (ATSDR) clearly states: "This substance may harm you." Studies should be conducted that pool the results. What 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 disease.

5. Congress needs to pass legislation to include in the National Vaccine Injury Compensation Program the 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 a two-year 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 legislate 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.

III. THIMEROSAL HAS BEEN USED IN VACCINES AND OTHER MEDICAL PRODUCTS FOR DECades

A. A brief description of mercury

Mercury occurs in several common compounds, which unlike any other metal, is a liquid at room temperature. It flows so easily and rapidly that it is sometimes called quicksilver. The chemical symbol for Mercury is Hg.

Mercury has many properties that have made it popular for a number of commercial uses. For example, mercury expands and contracts with changes in temperature. It also remains liquid over a wide range of temperatures and does not stick to glass. These properties have prompted its use in thermometers. Mercury is also used in some electric switches and relays to make them operate silently and efficiently. Industrial chemical manufacturers use mercury to analyze cells to charge substances with electricity. Mercury vapor, used in fluorescent lamps, gives off light when electricity passes through it. Before its health hazards were recognized, mercury compounds were widely used in such common products as house paints and paper. Various alloys (mixtures of metals) containing mercury are used to reduce the conductivity of mercury. Mercury and mercury that dentists use to fill cavities in teeth.

Mercury comes in many different forms—organic, inorganic, elemental, and metallic. The oral route is the most common manner in which mercury became widespread in the environment. However, it is now widely recognized that overexposure to all forms of mercury can cause health problems including central nervous system (brain) and the renal system (kidneys). This has led to regulatory actions to reduce the exposure of mercury on many fronts. According to the Agency for Toxic Substances and Disease Registry (ATSDR): "The nervous system is very sensitive to all forms of mercury.

B. Thimerosal, which contains ethylmercury, has been used in medicines since the 1930's. In addition to its many commercial applications, mercury has been used in a number of medical applications. One such product that came into frequent use during the twentieth century was thimerosal. Thimerosal is an organic compound made up of equal parts of thiosalicylic acid and ethylmercury. It is 49.6 percent ethylmercury by weight.

Thimerosal was developed by Dr. Morris Kharasch (1895-1957, Ukraine/USA), a chemist and Eli Lilly fellow first at the University of Maryland and then at the University of Chicago. He filed for a patent on June 27, 1929, for what he described as an alkyl mercuric sulfonate compound (thimerosal) that he felt bore the potential to be an anti-septic and antibacterial product. Dr. Kharasch was considered a pioneer in his field, contributing to the development of plastics and the creation of synthetic rubber. He also went on to find the Journal of Organic Chemistry.

In October 1929, Eli Lilly and Company registered thimerosal under the trade name Merthiolate. Merthiolate was used to kill bacteria and prevent contamination in anti-septic ointments, creams, jellies, and sprays used by consumers and in hospitals. Thimerosal was also used in nasal sprays, eye drops, contact lens solutions, immunoglobulins, and most importantly here—vaccines.

Thimerosal was patented the same year that Alexander Fleming discovered penicillin. But because it took more than a decade for penicillin to be fully developed, and because the product of thimerosal was widely used in the interim. To the medical profession, who were without antibiotics during the 1930's, thimerosal (marketed as Merthiolate) and other antiseptic products were gladly received.

Dr. H. Vasken Aposhian, Professor of Molecular and Cellular Pathology and Professor of Chemistry at the University of Arizona discussed thimerosal’s history during Congressional testimony.

“In the early thirties, in fact the 1940’s and up until the mid-1950’s, mercurials were used in medicine . . .” The medical community . . . had nothing better to use. They had no better to use as a preservative at that time than thimerosal. And I would venture the opinion that it has just been going on because no one has objected to it. And there’s no evidence that I don’t know any medical community or scientific community that would agree to the need for having thimerosal in any vaccine.”

Mercury is not widely used preservative in vaccines and other medical products. Its use in antiseptic products to prevent infections was common. By the time the FDA conducted its review of mercury in 1999, more than 50 licensed vaccines contained thimerosal.

While thimerosal became widely used, the public did not realize the potential for scientific literature to the lack of substantial understanding of its safety.
Methylmercury is highly toxic. The data indicate that the adverse effects of methylmercury are expressed in multiple organ systems throughout the lifespan.

The research in humans on the neurodevelopmental effects of methylmercury is extensive. Damage to renal tubules and nephron has been found to be related to pressure on inorganic and organic forms of mercury. Symptoms of renal damage have been seen only at mercury exposures that also caused neurological damage.

The cardiovascular system appears to be a target for methylmercury toxicity in the same dose range as neurodevelopmental effects—at very low mercury exposures.

Studies in humans on the carcinogenic effects of methylmercury are inconclusive. Methylmercury may increase human susceptibility to infectious disease and auto-immune disorders by damaging the immune system.

Methylmercury may adversely affect the reproductive system.

The medical literature is replete with references to the dangers to methylmercury: "The major toxic effects of methylmercury are on the central nervous system. Its toxic action on the developing brain differs in both mechanism and outcome from its action on the mature organ. . . . the action of methylmercury on adults is characterized by a latent period between exposure and onset of symptoms. The period can be several weeks or even months, depending on the dose and exposure period. Paresthesia, numbness or a 'pins and needles' sensation is the first symptom to appear at the lowest dose. This may progress to cerebella ataxia, dysarthria, constriction of the visual fields, and loss of hearing. . . . Cardiovascular disease. . . . accelerated progression of carotid arteriosclerosis." The research is explicit that fetal brains are more sensitive than the adult brains to the adverse effects of methylmercury, which include:

Severe brain damage

Delayed achievement of developmental milestones

Neurological abnormalities such as brisk tendon reflexes

Widespread damage to all areas of the fetal brain, as opposed to focal lesions seen in adult tissue

Microcephaly

Purkinje [neuron] cells failed to migrate to the cerebellum

Inhibition of both cell division and migration, affecting the most basic process in brain development

Additionally, dilatation in both systolic and diastolic blood pressure in seven year olds correlated with prenatal exposure to methylmercury . . . indicative of later cardiovascular problems.

Despite the fact that ethylmercury has been widely used in common medical treatments, ranging from vaccines to nasal sprays to ointments, comparatively little research has been done on its health effects. The few studies that have been done tend to indicate that ethylmercury is just as toxic as methylmercury.

The FDA never required the pharmaceutical industry to conduct extensive safety studies on thimerosal or ethylmercury. It was left to the manufacturers of vaccines to try to determine if thimerosal 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 extensive safety studies to determine the safe exposure level of thimerosal. These basic issues should have been proven prior to the widespread use of thimerosal in vaccine formulations.

Additionally, elevation in both systolic and diastolic blood pressure was frequently present. . . . in kidney patients. Both damage and mercury deposits were consistently higher in the blood of patients with hypertension. The rate of blood pressure dilatation was frequently present . . . in kidney patients . . . these large doses did not produce any anaphylactoid or shock symptoms. . . . In the authors' own conclusion they go on to say that a "wide range of toxicity and injury tests should be done." There is no evidence that Drs. Powell and Jamieson took their own advice and conducted studies to address these concerns.

As a result, in 1999, 70 years after the product was first licensed, neither the FDA nor the industry had followed through on determining a safe exposure level to thimerosal or ethylmercury. The FDA has, however, subsequently conducted research 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 1920's, 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 laboratory chemists of the time wrote in thimerosal research published a paper that made a brief reference to this study: "Mercury poisoning was injected into 22 persons . . . these large doses did not produce any anaphylactoid or shock symptoms." In the authors' own words they go on to say that a "wide range of toxicity and injury tests should be done." There is no evidence that Drs. Powell and Jamieson took their own advice and conducted studies to address these concerns.

As a result, in 1999, 70 years after the product was first licensed, neither the FDA nor the industry had followed through on determining a safe exposure level to thimerosal or ethylmercury. Thus, when facing a policy decision on the safety of vaccines and thimerosal, the FDA had to work from an assumption that the toxicity of ingested methylmercury was the same as injected ethylmercury.

This study that completed the toxicology of ethyl and methylmercury was published in 1955 in the Archives of Toxicology, written by two others from the same Unit 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 brains and the kidneys. It also found that male and female rats were affected differently.

"It has been well documented that one of the first toxic 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 in rats . . . in both sexes . . . the concentration of toxic effects is higher for thimerosal than for methylmercury (and inorganic mercury) and organic mercury was consistently higher in the blood of ethylmercury-treated rats than both materials damaged the dorsal root ganglia and 9.6 mg Hg/kg/day ethylmercury caused more damage than 8.0 mg Hg/kg/day methylmercury. Ethylmercury was more toxic than methylmercury but this toxicity was not demonstrated in humans treated with thimerosal (at a single daily dose of 0.05 mg/kg). The research is explicit that fetal brains are more sensitive than the adult brains to the adverse effects of methylmercury, which include:

Severe brain damage

Delayed achievement of developmental milestones

Neurological abnormalities such as brisk tendon reflexes

Widespread damage to all areas of the fetal brain, as opposed to focal lesions seen in adult tissue

Microcephaly

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were more widely spread in ethylmercury-treated rats."

While there is frequent reference to the paucity of science in understanding the harm that ethylmercury compounds can cause, understanding in the scientific community that government officials have shared with the public has come in fits and starts. At a December 10, 2002 hearing, a member of the Institute of Medicine noted, "There is a paucity of science in understanding the harm that ethylmercury compounds can cause. Understanding in the scientific community that government officials have shared with the public has come in fits and starts."

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 established a Minimum Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the U.S. Environmental Protection Agency, the Acceptable Daily Intake of the U.S. 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 believed to be safe, and were exposed to amounts well over ten times the EPA's scientifically validated reference dose. 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's 41 times the amount at which harm can be caused."

In making a presentation to the Institute of Medicine's Immunization Safety Review Committee, in July 2001, the former Director of the Environmental Toxicology Program at the National Institutes of Health, Dr. George Lucier, offered the following conclusions: "Ethylmercury is a neurotoxin. Infants may be more susceptible than adults. Ethylmercury should be considered equivalent to methylmercury as a developmental neurotoxin. This conclusion is clearly public health protective. Ethylmercury is a neurotoxin from vaccines (added to dietary exposures to methylmercury) probably caused neurotoxic responses (likely subtle) in some children. While the evidence that either ethyl or methylmercury is more toxic will probably not be resolved in the near future, a consensus appears to have formed that exposure to these different types of mercury cannot be considered in isolation. Rather, witnesses before the Committee stated that in determining safe levels of mercury exposure, the cumulative level of exposure to all types of mercury must be considered. Dr. Jeffrey Bradstreet made the following observation at the July 19, 2002 hearing: "More concerning to me in the Institute's treatment of mercury problems, was the almost complete absence of regard for the comparative neurotoxicity of methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury. Those fillings contain methylmercury."
exceeded the “ten times the MRL” and therefore was placed “at risk of overdose.” In fact, with a 62.5 microgram exposure alone, the EPA, ATSDR, 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 continued to be placed “at risk of overdose” for at least an additional two years.

It should also be noted that none of the Federal guidelines on mercury exposure have included specific provisions for safe exposure limits for infants and children. It is widely accepted that infants and young children are more susceptible 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 that may have been toxic to infants and women of child bearing age, who may be pregnant. In 1980, the FDA issued a proposed ban on the OTC use of thimerosal in Seafood. The FDA’s actions regarding the risk of mercury exposure to infants and children were prompted to review the toxicity of thimerosal when 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 from its actions regarding seafood 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:

“Mercury levels in predatory fish may contain methylmercury. This type of mercury is of the EPA’s minimal risk level for methylmercury. However, it is also clear that many infants receive substantial doses of mercury that exceed a FDA higher threshold.

Some fish contain high levels of ethylmercury. For fetuses, infants, and children, the primary health effects of mercury are on neurologic development. In excess of the Food and Drug Administration’s (FDA) 1 part per million (ppm) limit has demonstrated a toxic effect on human health when present at relatively low levels.

Wash hands and go to the local fire department for hazardous material (HAZMAT) emergency responder. Dispose of mercury waste following NIH guidelines.

Replace mercury thermometers and other mercury-containing items with non- or low-mercury alternatives. Mercury is highly toxic and it is reasonable to expect humans to be equally allergic. It was found to be 35.3 times more toxic for embryonic chick heart tissue than for staphylococcus aureus.

Delayed hypersensitivity in 50 percent of the guinea pigs tested, indicating that thimerosal is highly allergic 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 1980, the FDA advisory panel considered 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 allergenic potential. It is not effective as a topical antiseptic because its bacteriostatic action can be reversed.

The FDA’s proposed ban on the OTC use of thimerosal was not implemented until 1996. The FDA has stated that the time of the OTC review, the industry chose not to challenge the findings of the Panel regarding the toxicity of thimerosal in OTC products.

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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:

"Of 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 ophthalmics 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.

### U.S. MILITARY VACCINE SCHEDULE

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Initial entry</th>
<th>Troops in US</th>
<th>Deployed</th>
<th>Region or Other</th>
<th>Thimerosal content</th>
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<td>N/A</td>
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<td>(Health workers)</td>
<td>25 mcg/dose or 34.5 mcg/dose or 0.5 mcg/dose or 0.3 mcg/dose</td>
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<tr>
<td>Possible Total Thimerosal Expos-</td>
<td></td>
<td></td>
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</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 pounds: 0.1 mcg/45.359 kg of body weight per day = 4.54
  - 120 pounds: 0.1 mcg/54.431 kg of body weight per day = 5.44
  - 150 pounds: 0.1 mcg/66.39 kg of body weight per day = 6.8
  - 180 pounds: 0.1 mcg/86.647 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 10.5 micrograms or 13.5 micrograms in one day may be at risk for injury from mercury exposure. Even in keeping with the safety margin of 10 times the EPA, the estimates by Dr. Robert 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, Captain 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 being treated, he returned to good health and has resumed flying. Gulf War Syndrome victims are not routinely tested for heavy metal toxicity or treated with 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 examining on behalf of Gulf War veterans.

### IV. THERE ARE GROWING QUESTIONS ABOUT WHETHER MERCURY IN CHILDHOOD VACCINES IS RELATED TO AUTISM SPECTRUM DISORDERS

A. Autism is Growing at Epidemic Proportions

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 2012, the National Institutes of Health had adjusted that rate to 1 in 50 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 the 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 increases between 1993 and 1998... 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. I am here to express my own appreciation 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 150 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 1980s, 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, and U.S. Representative Chris 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 aged 3 to 5 years. The prevalence of the more broadly defined autism spectrum disorder was 6.7 per 1,000 (1 in 150) children. It is clear that even though families of Brick Township requested that the CDC include an evaluation of a possible link between autism and their children's immunizations, the investigation did not do so. 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 299,456 children aged 3 to 10 years in metropolitan Atlanta in 1996 were autistic (1 in 146). These numbers were 10 times higher than studies conducted in the 1990s 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, said, "It is astounding to see a three-fold increase in autism with no explanation . . . there's a number of things that need to be answered. We need to rethink the causes of autism."

The 2002 report confirmed a 210 percent increase in the number of new children professionally diagnosed with the most severe cases of autism entering the developmental services system between 2001 and 2002. The system added 3,577 new cases in 2002. It is noteworthy that the figures reported in California do not include persons with Pervasive Developmental Disorder (PDD), PDD-Not Otherwise Specified (PDD-NOS), Asperger's Syndrome, or any of the other milder autism spectrum disorders. The California data reflect only those children who have received a professional diagnosis of level one, DSM IV autism—the most severe form of autism.

3. The Causes of the Autism Epidemic Are Not Known

The underlying causes of the explosion in autism remains a mystery. While the medical community has made many advances over the years in developing treatments and better diagnostic tools, little progress has been made in understanding why some children become autistic.

Mr. Waxman: "Autism is a particularly frustrating disease. We still do not understand what causes it and we still do not have a cure. All we know for sure is that its impact on families can be devastating. During the hearings held in this committee, we have heard parents tell tragic stories of children who appear to be developing normally and then all of a sudden retreat into themselves, stop talking, and develop autistic behavior. Other parents have testified that their children never start to develop language skills, and instead early on manifest symptoms incongruent with that even though they do not have autistic behavior. Other parents have testified that their children never start to develop language skills, and instead early on manifest symptoms incongruent with those of autistic behavior. We should note that even though it may be frustrating and difficult this must be for families. And I appreciate how urgently we need to understand what causes autism, how to treat it, and if possible, how to prevent it."

A summary of the developing theories on the causes of autism, as described in "Autism: The Silent Epidemic" by Barbara Lee Fisher is paraphrased below:

In 1943, when child psychiatrist Leo Kanner first described 11 cases of a new mental illness in children he said was distinguished by self-absorbed detachment from other people. He named the condition autism, from the Greek word "autistic," meaning "self." Pointing out similarities with some behaviors exhibited by adult schizophrenics, Dr. Kanner hypothesized that psychiatrists assumed autistic children were exhibiting external-onset adult-type psychoses. Kanner's young patients came from wealthy middle and upper-class families alienated in Baltimore with mothers and fathers who were doctors, lawyers and professors. In 1954, Kanner identified "one autistic child who came of unintelligent parents." This concentration of autistic children in educated and professionally successful families led Kanner to develop the "refrigerator Mom" theory as the cause of autism, theorizing that the warm maternal instincts of educated working mothers was absent or diminished. Influenced by Kanner, pediatricians for decades were persuaded to blame mothers of autistic children for being cold and emotionally rejecting, causing the children in turn to coldly reject contact with other people.

By 1954, Kanner began modifying his "Blame 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 "constitutional 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 autistic child was a result of maternal coldness. He theorized that autistic children were in abnormal ways in retaliation against a rejecting mother who 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 autism by showing that autism is specifically a neurological, basis for autistic behavior. Dr. Rimland documented the similarities between brain injured children and autistic children. He suggested that 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 1964, Dr. Rimland established the Autism Society of America (ASA). In 1967 he established the Autism Research Institute (ARI) and began distributing a questionnaire to pediatricians for 36 years. Awaiting the results, his database includes information on more than 30,000 cases of autism from around the world. In analyzing the data for age of onset of autism, he discovered that before the early 1980's, most of the parents reported their children first showed signs of abnormal behavior from birth or in the first year of life. But after the mid-1980's, there was a re-emergence of this pattern. The numbers of parents reporting that their children developed normally in the first year and a half of life and then suddenly became autistic doubled. Today, Rimland says that the onset-at-18-months children outnumber the onset-at birth children by 2 to 1.

Today, no one can pinpoint the exact cause or causes of autism. Nor is there any conclusive explanation for the rapid growth in cases of late-onset autism. Most experts believe that some combination of genetic and environmental factors must be at work. A leading and prominent theory is that the nature of the genetic contribution to autism may be in the way vaccines may have triggered an autistic response in children who are genetically predisposed to being vulnerable to mercury toxicity.

8. The alarming growth in autism coincided with an increase in the number of childhood vaccines containing thimerosal on the recommended schedule. Through most of the twentieth century, individuals were required to receive very few vaccines. However, with the licensing of the Hepatitis B (Hep B) vaccine and the Haemophilus Influenzae B (Hib) vaccine starting in the mid-to-late 1980's, and their subsequent recommendation for universal use in 1993, the amount of mercury to which infants were exposed rose dramatically. It was during this period of increased exposure to thimerosal and its ethylmercury component that the growing wave of late-onset autism became apparent. This confluence of events led many to suspect a correlation between the two and call for more research into the relationship between ethylmercury in vaccines and autism.

A number of vaccines never contained thimerosal. These classes of vaccines are generally live-virus vaccines. The ethylmercury in these vaccines was considered to be making it unsuitable for such vaccines. These shots include the Measles-Mumps-Rubella (MMR) vaccine, the oral polio vaccines (which are no longer recommended for use in the United States), and the chicken pox (varicella zoster) vaccines.

Prior to the approval of the recombinant Hep B vaccine in 1986, all the only vaccine containing thimerosal routinely given to infants was the DTP vaccine. DTP contained 25 micrograms of ethylmercury and was given 3 times in the first six months of life (75 micrograms of ethylmercury) and a total of four times in two years (100 micrograms of ethylmercury).

The polysaccharide Haemophilus Influenzae B (Hib) vaccine was first licensed in 1985. It had 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 the first two years of life.

The approval of the Hep B vaccine in 1986 added the growing amount of mercury to the recommended schedule. This vaccine contained 12.5 micrograms of ethylmercury and was given within hours of birth and a total of 3 times in first 6 months of life (37.5 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 25 micrograms of ethylmercury in the Hep B and Hib vaccines. It is not known what the impacts of the thimerosal exposure to children.

As was noted previously, the effects of ethylmercury have not been studied as carefully as methylmercury, and the Federal government does not set safety thresholds for ethylmercury exposure. Because of the obvious similarities between the two, however, when the FDA reviewed the data on the thimerosal and injected ethanol in 1999, they compared it to the Federal limits for (ingested) methylmercury exposure.

They were compelled to admit at that point that the cumulative and total amount of ethylmercury in vaccines exceeded the EPA's threshold for exposure to methyl mercury. 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 particular, the problem was worse than the FDA suggested. Not only did the cumulative amount of ethylmercury on the receiving end exceed the EPA's threshold level of ethylmercury in each individual shot of DTP (or DTaP) and Hepatitis B exceeded the limit. Young children were getting doses of mercury weighing hundreds of micrograms each time. The EPA's threshold is 0.1 micrograms of methylmercury for each kilogram of body weight. This does not mean that injury would happen above this level but cause a significant safety margin is built in. However, the chances of injury increase as the exposure rises above this level. For an 11-pound (5-kilogram) infant, the EPA threshold would be roughly 0.5 micrograms. For a 22-pound baby (ten kilograms), the threshold would be 1 microgram. The DTP (and DTaP) vaccine contains 25 micrograms of thimerosal per dose, as does the Hepatitis B vaccine. The Hib vaccine contained 12.5 micrograms per dose. In addition, it is clear that for young children, the amount of thimerosal they received in vaccines in the 1990's also exceeded the FDA's higher threshold of 0.4 micrograms per kilogram of body weight.

Of particular concern to many parents are those instances in which children received several vaccinations at one visit to the pediatrician. This practice has become commonplace with the new vaccine schedules recommending 26 doses of vaccines before school attendance.

Chairman Burton spoke about one such incident at a recent hearing: “The FDA recently acknowledged that in the first 6 months of life a child can get more thimerosal than is considered safe by the EPA. The truth is that sometimes kids go to their doctor's office and get four or five vaccines at the same time. My grandson received vaccines for nine different diseases in 1 day. He may have been exposed to 62.5 micrograms of mercury in 1 day through his vaccines. According to his weight, the maximum safe level of mercury he should have been exposed to in 1 day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused.

When testifying before the Committee, Mrs. Lynn Redwood made the following observation in her son’s behalf due to mercury through vaccinations: “According to the EPA criteria, his allowable dose was only 0.5 micrograms based on his weight. He had received 125 times his allowable exposure on that day. The large injected bolus exposures continued at two months, four months, 12 months, and 18 months to a total mercury exposure of 237.5 micrograms. I also discovered that the injections that I received during my pregnancy, the first and third trimesters, and hours after the delivery of my son to protect my infant from its own white matter injury of the brain may be permanent.”

Concern that autism may be linked to vaccines is not a new debate. Twelve years ago, the Institute of Medicine published Adverse Effects of Pertussis and Rubella Vaccines and confirmed that pertussis and rubella vaccines can cause brain and immune system damage. At the time, an increasing number of parents reported that their previously normal children, who had rejected the MMR, reacted to this new vaccine with a heightened sensitivity to the vaccine and the disease. In 1992, in a letter from the Director of Biological Services, of the Pittman-Moore Company to Dr. Jimison of Eli Lilly, “we observed a distinct reaction of about 50 percent of the dogs injected with serum containing dilutions of Merthiolate varying from 1 in 40,000 to 1 in 5,000 . . . no deaths or convulsions were noted by any other researcher.” In other words, Merthiolate is not satisfactorily as a preservative for some individuals displaying a sensitiveness to thio[merthiolate] compounds, which is characterized by reddening of the treated area and the appearance of a white papule and erythema.

In 1932, an Army doctor in Baltimore, Reimann has reported that some individuals display a sensitivity to thio[merthiolate] compounds, which is characterized by reddening of the treated area and the appearance of a white papule and erythema. Dr. Kharasch filed a new patent application because of increased motility resembling that of the Gl tract and the bloodbrain barrier. For example, injecting mercury into the eye unless it has been previously demonstrated by patch tests that the patient is not sensitive to the ophthalmic ointment, it 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.

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Taken from an October 1978, letter from William R. Gibson to Dr. Alan Baskett, of the Commonwealth Laboratories in Victoria Australia regarding the use of thimerosal in the Australian pertussis vaccine was linked to intercurrence in mice:

The effect of thimerosal on the immune response of newborn mice was studied. The mice were injected daily for 7 days with either thimerosal or thimerosal plus Bordetella pertussis. The mice were then injected with Bordetella pertussis and the antibody response was measured. The results showed that the mice receiving thimerosal plus Bordetella pertussis had a significantly lower antibody response than the mice receiving Bordetella pertussis alone.

In August of 1998, an FDA internal “Point Paper” was prepared for the FDA 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 marketing approval, immunization, the use of single dose vials should be required to avoid the need of preservative in multi-dose vials... Of concern here is the potential neurotoxic effect of dietary mercury and the need to consider cumulative doses of this component in early infancy...”

"There is ample evidence from the literature that thimerosal (thimerosal) may cause sensitization and subsequent allergic reactions..."
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 would absolutely reach our limit."

"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 damaged after Hepatitis B vaccine."

"As a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the question has developed a neurodevelopmental disorder, consisting of an 'Autism Spectrum Disorder' or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the 'thimerosal' ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTPa), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two inventions."
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 as a causal hypothesis and is not supported by direct and inconclusive 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 thimerosal and autism spectrum disorders and other neurodevelopmental disorders. Few, if any, would make such a statement categorically until more research is done. However, judging by testimony received by the Committee, many researchers believe that this hypothesis is plausible and worthy of more study to date. They believe that this is a promising field of research that may yield breakthroughs on the question of the underlying causes of the growing incidence of autism and other neurodevelopmental disorders.

On April 25, 2001, the Committee heard testimony from Dr. Boyd E. Haley, who is the Dean of The College of Medicine at the University of Kentucky. Dr. Haley has spent many years studying the effects of mercury on the human body. Dr. Haley summarized his views in this way: “I cannot say, nor would I say, that vaccinations cause autism. However, if the data holds up that I have been seeing with the relationship, I think it is an awful good suspect, at least one of the co-factors that might aid in the onset of this disease. So I would really recommend and encourage you to put some pressure on the National Institutes of Health (NIH) to look at the contribution of different forms of mercury we put in our medicines and in our dentistry to see what effect they have on the neurological health of Americans.”

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

“I was requested to do an evaluation of the potential toxicity of thimerosal-containing thimerosal as a “preservative” versus those vaccines not containing thimerosal. The results were very striking. I decided to prepare a 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 that thimerosal-containing vaccines versus non-thimerosal containing vaccines as observed in cell culture studies reported in 1986. The chemical rationale for the pairing of thimerosal-containing thimerosal is that this compound would release ethyl-mercury as one of its breakdown products. Ethyl-mercury is a well-known neurotoxin. Further, the alternative to thimerosal is formaldehyde, also found in these vaccines, which, according to the approved labeling, is present in the thimerosal and not the formaldehyde-containing vaccine. Our understanding of aluminum is that it is a housekeeping protein that clears the body of these toxicants would greatly increase the damage they are capable 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 pediatrician 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:

“Newborns’ 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. We believe that all research that has been testified 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 personally 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 person infected with a virus, think that using mercury, there, is probably an environment-genetic interaction. In other words, a lot of children get the infection and don’t become autistic. In fact, there probably must be specific or genetic factors that somehow influence the way a certain subgroup of children are able to handle toxins. . . . I don’t think we yet know the answer to this, but . . .”

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 inefficient at removing mercury:

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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 that 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 only the cortex of the brain incites these 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 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. The nucleus of those blue cells don't take up. In order for something to turn blue, the cell has to have holes punched in its membranes. And you guess what: At an extracellular concentration of thimerosal, the cells are blue. It means that this stuff grabs a hold of the membrane and punches holes into it, so that the dye can penetrate, not through glass 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. The reason that infant brain cells are much more sensitive, so there's a real cause for concern."

Dr. Baskin testified that other researchers in his lab and elsewhere have arrived at 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 things. 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."

"Neal Halsey, MD, . . . does not and has not supported the belief that thimerosal or vaccines themselves cause autism in children. We've been very consistent in our views."
Perhaps Dr. Thomas Verstraeten conducted the broadest review of a possible relationship between thimerosal and neurological disorders in 2000. This study reviewed several reports 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. The study's methodology and length is described 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, Great Britain's premier medical journal. 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 of children exposed to thimerosal, and high levels of mercury in their stools, indicating to them that ethylmercury has a shorter half-life than methylmercury, and that mercury was expelled through the gastro-intestinal tract. According to the authors:

"We have shown that very low concentrations of thimerosal can be detected in infants aged 2-6 months who have been given vaccines containing thimerosal (sic). 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 [sic] 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 is a safe preservative and possesses little risk to full-term infants, but that thimerosal-containing vaccines should not be administered to very low birth weight, premature infants."

Skepticists 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 12, 2002 hearing by Baylor University’s Dr. Baskin.

1. The sample size was very small:

   Only 40 children who received thimerosal were studied. A small 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 100 kids. So if a child had some predisposition to thimerosal 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, you wouldn’t have found one kid with a predisposition to autism."

2. The sample was not random:

   In his testimony, Dr. Baskin commented on this:

   "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 ethylmercury to be expelled from an infant’s body, thimerosal containing vaccines were given to infants at one and two months of age. After four weeks, the authors noted that peak levels of mercury in the blood are expected to appear within 24 hours.

   "We know the stool levels were high, but if you draw the blood samples at 24 hours or at least within the first 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 was on its way to the stool; it goes through the blood. At some point it was high because it was high in the stool."

4. You can’t do a pharmacokinetic study if you don’t have the peak level:

   "You can’t do a pharmacokinetic study if you don’t have the peak level. They clearly didn’t have the peak level because they have high stool mercury, and they have low blood mercury— it doesn’t make sense."

5. 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 on the infants. This limitation was clearly brought out in an exchange between Congressman Burton and Dr. Christopher Porter, Director of the Environmental Toxicology 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. Porter: “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 authors can come to the broad 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 data for the future, it’s a start, but the interpretation is inaccurate."

E. VI. 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 ignored this evidence despite their profound implications for human health.

For decades, ethylmercury was used extensively both in topical ointments to prevent infections and as a preservative in a variety of medicines. However, it now appears it was used more forcefully, and remove thimerosal from vaccines earlier, may have done more long-term damage to the public’s trust in vaccines overall and confronted a vulnerable public.

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.

Fully 24 years after the FDA recommended the removal of thimerosal from childhood vaccines, 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, 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 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 acknowledged the shortcomings of the study: "Considering the type of patient involved, one might question these observations (the appearance of no deleterious action) as providing no justification for 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. Burrow, responded with a ringing defense of Lilly's product: "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 safety or efficacy. 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 conclusion, numerous investigators have recognized the lack of data on thimerosal and suggested the need for more research:

An April 24, 1980, intra-office memo stated: "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 safety or efficacy. They believe that over forty years of wide usage has proven efficacy and safety beyond that which could be done in special studies."

A 1980 resolution of the American Medical Association's House of Delegates stated: "A July 1935, 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 1 in 40,000 to 1 in 5,000, and we have demonstrated no connection between the lot of serum and the reaction. In other words, Merthiolate is unsatisfactory as a preservative for serum injected into dogs. The dogs do not show the local reaction, but in some instances, the reaction is extremely severe. I might say that we have tested Merthiolate for the toxic effect given here is more of a 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 eruptions 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 1966 paper from an Arizona doctor reported the case of a woman who suffered repeated multiple reactions to Merthiolate applied to the skin to prevent infection. She reportedly suffered chills and fever and had small vesicles and erythema in the area of her Merthiolate application. After her recovery, the patient noted a vesicle for which she was being surgically treated appeared after repeated application of a tincture of Merthiolate. She continued the Merthiolate treatment until the vesicle became too raw and painful to continue use, and then sought medical care.

A 1965 New York Academy of Sciences article entitled, "Antiseptics," stated that, "The Panel concludes that thimerosal is 'toxic when injected parenterally and therefore cannot be used in chemotherapy.'" A 1973 article stated, "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.

The FDA's actions to remove mercury from over-the-counter products have prompted a review of mercury in vaccines. It is difficult to understand why it took the FDA 18 years to remove mercury from over-the-counter products. It is equally difficult to understand why the expert panel's 1980 findings on thimerosal's safety in topically applied vaccines led the FDA to further and immediately review 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 for Toxicological Research, Dr. Bernard Schwartz, who went on to serve as the Acting Director of the FDA for nearly a year, stated: "One thing I have never understood, 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 severally. The toxicity of the mercury ion, at this time, what's the impact of a sensitizer—of something that is known to be a skin sensitizer, what is the effect on the functional development of the immune system? Will we give a chemical of that kind repeatedly?"

Different branches of the FDA regulate over-the-counter products and vaccines. The FDA is regulated by the Center for Biologics
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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 childhood vaccines was belated and established in the Federal Register no fewer than five times prior to the FDA’s belated review of mercury in vaccines.

What happened to 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 the Public Health Security and Bioterrorism Modernization Act (FDAMA). Among other things, this law required the FDA to compile a list of foods and drugs that contained mercury. The Centers for Disease Control and Prevention started studying its effects on the human body, and restricted 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 the FDA had determined that thimerosal was unsafe in topical ointments, 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 uncertainty in others caused by the lack of data specifically on ethylmercury. However, the institutional resistance to change was counter-balanced by the growing realization that there was no ethylmercury in childhood vaccines than previously thought, and that nobody had thought to calculate the cumulative amount of thimerosal from vaccines.

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 Environmental Protection Agency’s (EPA) Exposure Assessment, which was at the time reviewing thimerosal in vaccines. From background levels were included in all calculations prepared by the European Medical Evaluation Agency. The results were exceeded in the European Community is moving to ban thimerosal.

Dr. Ball presented the results of her research to the American Academy of Pediatrics’ Committee on Infectious Diseases, which he chaired. He stated: “In the past few days, I have become aware that the amount of thimerosal in most hepatitis B, DTaP and Hib vaccines that we administer to infants results in a total dose of mercury that exceeds the amount of mercury recommended by the EPA, the FDA, CDC and WHO.”

Dr. Halsey’s admission that more than just the three vaccines with the most concerns was exceeded is a significant and clear indication of Pediatricians, and other agencies. Dr. Halsey’s admission that more than just the three vaccines with the most concerns was exceeded is a significant and clear indication of Pediatricians, and other agencies.

“These calculations do not account for other sources of mercury in the environment, e.g., breast milk.”

One document written by Dr. Ball estimated that exposure to mercury from sources other than vaccines could total 80 to 100 micrograms per year. Background levels were included in all calculations prepared by the European Medical Evaluation Agency. The results were exceeded in the European Community is moving to ban thimerosal.

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 were held involving the Department of Agriculture, the Public Health Service, the American Association of Pediatrics, and other agencies. These meetings revealed for the first time that the Public Health Service opposed a public effort to remove thimerosal from vaccines. One FDA document stated that the Public Health Service was concerned that stating a preference for thimerosal-free vaccines could “result in unwarranted loss of confidence in immunization programs in the United States and internationally, shortages of childhood vaccines might ensue, and other potential far-reaching ramifications are envisioned.”

On July 2, 1999, e-mail, Dr. Ruth Etzel of the Department of Agriculture also noted the Public Health Service’s resistance: “We must follow the three basic rules: (1) avoid any actions that could make parents think that all products have more mercury than we realized; (2) be open with consumers about why
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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 expressing 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.

During the meeting, members of the Advisory Committee again rejected the idea of expressing a preference for thimerosal-free vaccines. However, just days later 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 Hib and Hepatitis B vaccines had just recently converted to formulas that were thimerosal-free, the Advisory Committee members had witnessed the transition from oral polio to inactivated polio vaccines. As a result of their inaction, was an abdication of their responsibility. As a result of their inaction, was an abdication of their responsibility. As a result of their inaction, was an abdication of their responsibility. As a result of their inaction, was an abdication of their responsibility.

Later in the discussion, Dr. Neal Halsey, a vaccines expert at the University of Maryland, made a suggestion that could have had far-reaching implications for protecting childhood vaccines. Dr. Halsey suggested that the Advisory Committee adopt a policy that no child should receive any thimerosal-containing vaccine per day:

"Roger, you said that after july, the maximum exposure will be 75 micrograms. My understanding of what we have presented from the manufacturers is that there is actually some Hib out there in the market that is being used, but does contain thimerosal. The manufacturer is saying that the Hepatitis B out there that does contain it. So there's no guarantee the maximum exposure would be 75 micrograms. What I proposed last October was that they put a limit of one thimerosal-containing vaccine as a preservative per visit, which would then guarantee what you're looking for. And I think that's the right policy because that allows for the continued use, though very limited. It eliminates the maximum exposure, but you do have the problem of what's in the clinic."

Dr. Bernier returned several times to financial health of the industry should be a priority over protecting children from mercury exposure. The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neurotoxicity of ethylmercury, Vacines: The fact that the target population for vaccines in primary immunization schedules is a healthy one, and in view of the demonstrated risks of thimerosal (sic) and other mercury containing preservatives, precautionary measures (as outlined below) could be considered.

For vaccination of infants and toddlers, the use of vaccines without thimerosal [emphasis added] and other mercurial preservatives should be encouraged.

By the time Dr. Neal Halsey's suggestion was put forward, it was clear that the Advisory Committee would reject the idea of expressing a preference for thimerosal-free vaccines. 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.

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After the Advisory Committee's concurrence in the CDC's decision not to state a preference for thimerosal-free vaccines, the Advisory Committee pushed for the DTaP manufacturers to continue the transition from thimerosal-containing vaccine to thimerosal-free vaccine. The Advisory Committee's suggestion was passed over without any comment.

It eliminates the maximum exposure, but you do have the problem of what's in the clinic."

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

One year later, in June of 2001, the Advisory Committee again rejected the idea of expressing a preference for thimerosal-free vaccines. Despite the fact that all manufacturers of Hib, Hepatitis B and DTaP had shifted to thimerosal-free products at that point, the CDC's decision not to express a preference for thimerosal-free vaccines, and the Advisory Committee's concurrence in this policy, was an abdication of their responsibility. As a result of their inaction, children could continue to receive thimerosal-containing vaccines at a time when there were serious doubts about its safety.
old not be immunized with Thimerosal- containing vaccines if suitable alternative preparations are available. I do not believe that the diagnoses justifies compensation in any of the VSD cases at this point. I deal with causality, it seems pretty clear to me that the data are not sufficient one way or the other. My gut feeling? It worries me a lot more that the [VSD] comment, but I got called out at eight o'clock for an emergency call and my daughter-in-law delivered a son by C-Section. Our first child male in the line of the next generation, and I do not want that grandson to get a Thimerosal-containing vaccine until we know better what is going on. It will probably take a long time for us to get the data right. I know that there are probably implications for this internationally, but in the meantime I think I want that grandson to only be given Thimerosal-free vaccines.

One participant in the Simpsonwood panel later stated that, while there was general agreement that the VSD study did not prove a strong association relationship between thimerosal and neurological disorders, it did indicate the need for much more research:

"So what do the consultants? With regard to the first question, a need for further investigation. Overall the group expressed unanimous feeling that the VSD study underreported the merosa issue, do not seem bothered to compare how many experts, looking at this thimerosal issue, do not seem bothered to compare the number of [disorders] because some of the children are just not old enough to be diagnosed. So the crude incidence rates are probably apples to pears and insist if nothing is happening in these studies into this entire thimerosal debate, as I think they are as comparable as apples and pears at the best. Unfortunately I have witnessed this more than once or twice more than 1%. If we had done a WMHC versus 3-10% reported previously, etc.

Had the study been extended until these children were older, a stronger correlation between thimerosal and neurological disorders might have been detected, as more children were diagnosed. However, this was not done. Ultimately, the majority of the Simpsonwood panel determined that the VSD study was not conclusive. Phase II of the VSD study failed to confirm the findings of Phase I of the study. The sample size employed (16,000, as opposed to 110,000 in Phase I). The Institute of Medicine determined that, "the small sample size limited ability to determine a causal effect, if it exists. The committee concludes that the Phase I and II VSD analyses are inconclusive with respect to causality."

Although the panel assembled at the Simpsonwood Retreat Center had many unanswered questions about the VSD study, some members found the evidence convincing. Dr. David J. Johnson, Public Health Officer for the state of Michigan and a member of the Advisory Committee on Immunization Practices, stated:

"This association leads me to favor a recommendation that infants up to two years..."
May 21, 2003

CONGRESSIONAL RECORD — Extensions of Remarks

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Continued.

...and reiterated the importance of research on the causes of autism and its potential link to vaccine injury. He noted that, while the CDC has invested $62 Million on diabetes research and over $2.2 Billion on HIV/AIDS research, they spent $688 Million on autism research, while the NIH was spending $56 Million on diabetes and over $700 Million on HIV/AIDS research. The CDC has also been criticized for its failure to investigate the potential link between thimerosal and autism, as the IOM stated that there was not enough evidence to reach any conclusions on this relationship. The CDC has also been criticized for its reliance on observational data, which may not be as robust as randomized controlled trials.

The report also highlighted the critical need for a coordinated national strategy on autism research, which would bring together the diverse activities of various agencies and organizations. The report called for a strategic plan on autism research to be developed, which would establish a timeline for the research process, and would be shared with the public. The report also called for increased funding for autism research, as the current levels of funding are not adequate to address the pressing research needs.

The report also discussed the need for increased funding for the National Institute of Mental Health Sciences, and the need for greater overall coordination among various agencies and organizations. The report noted that the current fragmented system of responsibility for research into autism and related issues is not working, and that there is a need for a coordinated national effort to resolve these problems.

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INTRODUCTION OF THE MEDICARE OUT-OF-POCKET SPENDING LIMIT ACT

HON. FORTNEY PETE 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% 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 Health Subcommittee 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. Current Medicare beneficiaries would have a one-time six-month open enrollment period to elect this coverage. Otherwise, normal Medicare enrollment rules would apply.

**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 135 percent of poverty would be eligible for the new benefit with no additional premiums. Beneficiaries with incomes between 135 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...