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 paratroopers and glider pilots invaded 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 of communication between India and protected both Palestine and Egypt.

The Nazi invasion force included the elite German paratroopers and glider pilots. Hitler felt this was to be an easy victory, yet he is quoted to have said shortly after the invasion, “France is free, Crete is free.”

The invasion of Crete took 11 days. It resulted in more than 6,000 German troopers listed as killed, wounded or missing in action. The losses to the elite 7th parachute division were felt so hard by the German military that it signified the end of large-scale airborne operations.

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

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

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

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

At Paleochora, Father Stylianos Frantzeskis, hearing of the German airborne invasion, roused his 8-year-old son, 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 prize 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.

H. RES.—

Whereas 1943 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 soil of German occupation, thus preserving democracy, freedom, and human dignity;

Whereas the Cretan Resistance Movement was organized to protect 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 in Astoria, 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 and their forebears;

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 Pan-Cretan 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 reimburse-ment formula that favors urban areas over rural areas. This formula is deeply flawed though and fails to allow our providers to even break even except 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 assist- ing 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’t wait any longer. Our rural communities are desperately in need of help and we must answer their call.

MERCURY IN MEDICINE REPORT

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

Mr. BURTON of Indiana. Mr. Speaker, I submit the following report prepared by the staff of the Subcommittee on Human Rights and Wellness, Committee on Government Reform. This report is the result of a three-year investigation initiated in the Committee on Government Reform.
Vaccines are the only medicines that American citizens are mandated to receive as a condition of birth and mandatory attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof of vaccination before their children can be immunized. While the mandate for which vaccines must be administered is a state mandate, it is the Federal Government, through the Center for Disease Control and Prevention (CDC) and its Advisory Committee for Immunization Practices that make the Universal Immunization Recommendations to which states defer in determining mandates. Since the early to mid-1990s, Congress has been concerned about the danger posed by mercury in medical applications, and in 1997, directed the Food and Drug Administration (FDA) to evaluate the human exposure to mercury through foods and drugs.

In 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 childhood vaccination. This investigation later expanded to examine the potential danger posed through exposure to mercury in dental amalgams. This full committee investigation was complemented and built upon the investigations initiated by two of its subcommittees. In January 2003, the investigation continued in the newly formed Subcommittee on Human Rights and Wellness.

A primary concern that arose early in the investigation of vaccine safety was the exposure of infants and young children 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 autism—often called “autism epidemic.” This report will address one form of mercury in medical applications, Thimerosal, as a preservative in vaccines.

In 1999, 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, and allergy 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 vaccine.

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 products that have 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 the public benefits from a product will outweigh its risks. No regulated product is totally risk-free, so these judgments are important.” FDA will allow a product to present more of a risk when its potential benefit is great—especially for products used to treat serious, life-threatening conditions.

This argument—that the known risks of infectious diseases outweigh a potential risk from neurotoxic exposure to thimerosal in vaccines, is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that the risk from thimerosal was theoretical: that no proof of harm existed. Upon a thorough review of the scientific literature and internal documents from government agencies, 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 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 used in vaccines 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 standard specific for ethylmercury, the limits for ingested methylmercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA’s methylmercury standard and determined that its limit for the compound does not protect against thimerosal. The FDA and other Federal agencies determined that in the absence of a specific standard for ethylmercury, the limits for ingested methylmercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA’s methylmercury standard and determined that its limit for the compound does not protect against thimerosal. The FDA and other Federal agencies determined that in the absence of a specific standard for ethylmercury, the limits for ingested methylmercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA’s methylmercury standard and determined that its limit for the compound does not protect against thimerosal.

The scientific evidence in this area is considered by some to still be inconclusive, in large part due to the lack of serious, effective inquiry by our health agencies. The federal government has vigorously pursued the necessary research to determine the extent of the impact of these heightened exposures to ethylmercury on our children.

A second concern that arose during the investigation was the continued use of mercury in dental amalgams. Mercury has been used as a component in dental fillings since the pre-World War II era. The American Dental Association and its member dentists have taken a position that the mercury in fillings, which is considered toxic if ingested in the tooth, and considered toxic when removed from the mouth, is completely safe while in the human mouth. This position seems counter even to the ADA-funded research that shows the daily release of small amounts of mercury vapors in the human mouth where dental amalgams are present, as well as minute chipping and swallowing of the mercury fillings over time.

Children and young children are exposed to this additional mercury. As developing fetuses, babies are exposed to mercury through the placenta. Children who have mercury amalgams, as they unknowingly excreting low levels of mercury on a daily basis to their fetuses. Additionally, children who receive dental services through Medicaid are also potentially exposed to mercury. When these children need dental fillings, because of the low cost, only mercury amalgams are available for use. This concern remains under investigation by the Subcommittee on Human Rights and Wellness.

II. FINDINGS AND RECOMMENDATIONS

A. Findings

Through this investigation of pediatric vaccine safety, the following findings are made:

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

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

3. Manufacturers of vaccines and thimerosal-encapsulated ethylmercury, have never conducted adequate testing on the safety of thimerosal.

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

5. Autism in the United States has grown at epidemic proportions during the last decade. By some estimates the number of autistic children in the United States is growing between 10 and 17 percent per year. The medical community has been unable to determine the underlying causes 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 that a relationship between the increase in neurodevelopmental disorders of autism, attention deficit hyperactive disorder, and speech or language delay, and the increased use of thimerosal in
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 cold and cough medicines. Although an advisory committee determined that ethylmercury was unsafe in these products in 1998, a rule requiring its removal was not finally published 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 immunization schedule. When CDC studies regarding exposure of infants to thimerosal were completed in 2000 and again in 2002, the CDC expressed no safety concerns.

10. The amount of ethylmercury to which children were exposed through vaccines prior to the 1999 announcement exceeded two safety thresholds established by the Federal government for a closely related substance—methylmercury. The Federal government has established no safety threshold for ethylmercury.

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

12. The CDC’s failure to state a preference for thimerosal-free vaccines in 2000 and again in 2002, as well as its failure to fulfill its responsibility. As a result, many children received vaccines containing thimerosal when thimerosal-free alternatives were available.

13. Thimerosal was allowed to remain in vaccines for six months longer than the Administration had intended to allow families who believe that their children’s autism is vaccine-induced the opportunity to be included in the program.

5. Congress needs to pass legislation to include in the National Vaccine Injury Compensation Program provisions to allow families who believe that their children’s autism is vaccine-induced the opportunity to be included in the program.

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

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

8. Thimerosal has been used in vaccines and other medical products for decades. A brief description of mercury compounds containing ethylmercury, which unlike any other metal, is a liquid at room temperature. It flows so easily and rapidly that it is sometimes called quicksilver.

9. Mercury becomes widespread in the environment. It is found in the air, soil, water, and food. Mercury can accumulate in the body over time. In the case of children, this accumulation can lead to health problems.

10. Mercury is a highly toxic substance. It can cause damage to the nervous system, the brain, and the kidneys. In children, mercury can cause delays in mental development and may lead to learning disabilities.

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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 noted with mercury exposure at levels of inorganic and organic forms of mercury. Symptoms of renal damage have been seen only at mercury exposures that also caused neurological effects.

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 reproduction of humans. 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 duration. Numbness or a 'pins and needles' sensation is the first symptom to appear at the lowest dose. This may progress to cerebellar 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, inhibition in both systolic and diastolic blood pressure in seven year olds correlated with prenatal exposure to methylmercury... indicative of later cardiopulmonary problems.

Despite the fact that ethylmercury has been widely used in common medical treatments, ranging from vaccines to nasal sprays to ointments, correlatively 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 to humans.

The FDA never required the pharmaceutical manufacturers to conduct studies to determine a safe exposure level of thimerosal. These basic issues should have been proven prior to the introduction of thimerosal into the marketplace, but more than 70 years after its introduction, these issues have still not been adequately addressed. The introduction of thimerosal into the marketplace was a single uncontrolled and poorly reported human study in the 1920s, possibly in combination with animal and laboratory studies. How- ever, the research in humans on the toxicology of thimerosal published a paper that made a brief reference to this study: "Mercury was injected into 22 persons... these large doses did not produce any anaphylactoid or shock symptoms." In the paper, the authors acknowledged that the "widespread damage... of all areas... in the brains and the kidneys." But the research in humans on the toxicology of thimerosal was published in 1985 in the Archives of Toxicology, written by researchers from the Toxicology Unit of the Medical Research Council of England. The researchers exposed rats to ethyl and methyl mercuric chloride to "compare total and inorganic mercury concentrations in selected tissues, including the brain, 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 both sexes... the concentration of toxic effects than methylmercury (the sum of inorganic and organic mercury) and organic mercury was consistently higher in the blood of ethylmercury-treated rats." The findings were: "not only did the thimerosal-induced reduction in oxidative phosphorylation was frequently present... in kidneys... both damage and mercury deposits
there is no need to have thimerosal in a vaccine. 

Dr. Weldon: "I have a couple of questions for Dr. Baskin about ethylmercury versus methylmercury. I have some people who say that data on methylmercury is fairly good, but we don't have good data on ethylmercury. I take it from your testimony there is quite a bit of data on ethylmercury and it's as toxic as methylmercury."

Dr. Baskin: "There is more data, more and more data on ethylmercury. The cells that I showed you dying in culture cell are dying from ethylmercury. Those are human frontal brain cells. You know, there has been a debate about ... ethyl versus methyl. But from a chemical point of view, most chemical compounds that are ethyl penetrate into cells and not methyl. Cells have very high affinity for them, and the membrane is made of lipids, fats. And ethyl as a chemical compound pierces fat and penetrates fat much faster. So, you know, when I began to work with some of the Ph.D.'s in my laboratory and discuss this everyone said, 'Oh, gosh, you know, we've got to adjust for the ethyl because it's going to be worse; the levels are going to be much higher in the cells.' So . . . I think at best they're equal, but it's incredibly highly likely that they are worse. And some of the results that we are seeing in cell culture would support that."

Dr. Baskin explained that according to scientific consensus and data, ethylmercury, brain tissue absorbs five times more mercury than other tissues in the body.

Dr. Weldon: "Now, you said several times in your testimony that uptake in the brain is probably much higher than in other tissues. What do you base that statement on?"

Dr. Baskin: "The Environmental Protection Agency (EPA) has developed a risk assessment protocol that uses tissue concentrations of naturally occurring mercury from the food chain and the mercury from the environment, the food chain. And it found the difference between the levels of mercury in the brain and the other tissues."

Dr. Weldon: "I'm aware that there is . . . some evidence on mercury toxicity at the July 18, 2000 hearing: "Let me just say as a final statement that this issue. And if you look at the studies, the levels are going to be much worse. And some of the results that we are seeing in cell culture would support that."

Dr. Baskin said that according to scientific consensus and data, ethylmercury, brain tissue absorbs five times more mercury than other tissues in the body.

Dr. Weldon: "So . . . I think at best they're equal, but it's incredibly highly likely that they are worse. And some of the results that we are seeing in cell culture would support that."

The testimony of Dr. Baskin builds upon the consensus that the World Health Organization (WHO) set a guideline of 0.1 micrograms of mercury per day and be considered safe. This exposure standard is a marked contrast to the 25 micrograms of mercury that was considered safe for several childhood vaccines until very recently.

The most lenient federal minimum risk level for mercury is the Acceptable Daily Intake (ADI) set by the WHO. This lower limit is a scientifically appropriate level that adequately protects the public.

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 could be expected through exposure. Dr. Roberta McKeever of Merck wrote: "A number of environmental and public health agencies have proposed a Mercury Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the US Environmental Protection Agency, the Acceptable Daily Intake of the US FDA, and the Tolerable Daily Intake of the WHO. Any exposure to the substance below the MRL is assumed 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. McKeever's explanation, many babies were exposed to levels of mercury far beyond the ADI of 7 micrograms per pound, and were exposed to amounts well over ten times the EPA's scientifically validated reference dose. For example, at a recent Committee hearing, Chairman Dan Burton (R-IN) discussed his own family's experience with vaccine injuries.

"My granddaughter 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 total level of mercury he should have been exposed to in one day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused."

To the ad lib of Dr. Baskin, based on the methylmercury ingestion guidelines, the Chairman's granddaughter would have
child, it is prudent for nursing mothers and young children not to eat these fish as well."

"In addition to the public advisories, the FDA, in January of 2001, established an aggressive public information campaign on Methyl Mercury." In January 2001, Associate FDA Commissioner Melinda Plaider, responding to Congresswoman Deborah D. Pryce's (R-OH) request for information regarding the National Academy of Sciences' report on Methylmercury, wrote:

"[I]let me reiterate, the FDA's commitment to protecting the public's health and the environment regarding mercury."

Furthermore, in their training materials for employees, the FDA reflects a slightly different understanding of the excess that they presented to the Committee:

"People are exposed every day to a tremendous number of neurotoxins in our environment. These substances include major and trace elements that may or may not be essential for sustaining life . . . Other elements are not known to be essential but are constantly found in living tissues . . . Of these elements that have no known nutritional value, some have been found to be toxic at concentrations well below those of other nonessential elements. Lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels." Other HHS entities have taken very strong mercury reduction positions. For example, the National Institutes of Health's (NIH) Division of the Health Effects of Environmental Tobacco Smoke (HEETS) program is to make the NIH mercury-free. According to the Division's own website:

"Elemental (metallic) mercury and its compounds that are exposed to excessive levels can permanently damage or fatally injure the brain and kidneys. Elemental mercury can also be absorbed through the skin, causing allergic reactions. Ingestion of inorganic mercury compounds can cause severe renal and gastrointestinal toxicity. Organic compounds of mercury such as methylmercury are considered the most toxic forms of the element. Exposures to very small amounts of these compounds can result in devastating neurological damage and death."

"For fetuses, infants, and children, the primary health effects of mercury are on neurological development. Developmental levels of mercury exposure, such as result from a mother's consumption of methylmercury in dietary sources, can adversely affect the brain and nervous system. Exposure to mercury, attention, language and other skills have been found in children exposed to moderate levels in the womb."

"The design for a Mercury Free at the NIH seeks to eliminate, as far as possible, the use of mercury in NIH facilities; to encourage the use of safer alternatives in biomedical research; to increase general awareness of mercury hazards; and to prevent mercury pollution."

This NIH program has initiated a "Hatters Pledge" program to recruit scientists to reduce the use of mercury at the NIH and to educate children on the dangers of mercury. One of the NIH Hatters Pledge I will:

- Improve my awareness of mercury hazards and how to reduce them.
- Replace mercury thermometers and other mercury-containing items with non- or low-mercury alternatives if suitable alternatives are available.
- Dispose of mercury wastes following NIH procedures.
- Report spills of mercury.

On the NIH campus, call the Fire Department (911) who are the NIH hazardous materials (Hazardous Materials) emergency responder.

Report spills of mercury.

On the NIH campus, call the Fire Department (911) who are the NIH hazardous materials (Hazardous Materials) emergency responder.

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

4. Over the Course of Two Decades, the FDA Slowly Removed Ethylmercury From Many Medicinal Products

In 1980, the FDA began a lengthy regulatory process to remove ethylmercury products from over-the-counter products like topical medications, dietary supplements, and contraceptives. Topical ointments are products used on the skin for either the treatment or prevention of skin infections or inflammations. They are typically divided into four categories, first-aid products to be applied to small superficial wounds to prevent infection; skin protectant to provide a barrier to minor wounds; antibiotic or antifungal creams to prevent or treat overt skin infection; and anti-inflammatory agents used to reduce inflammation and inhibit pruritis.

In 1980, the FDA asked their Over-the-Counter (OTC) Review Panel to conduct a massive review of OTC products containing ethylmercury.

As a result of the Panel's work, in 1982, the FDA issued a proposed rule to ban thimerosal from OTC topical ointments. In addition to raising questions about the general effectiveness of thimerosal for infections, the FDA found that thimerosal was too toxic for OTC use. Among the findings that they published were the following:

- The Panel reported that thimerosal had been found to be more toxic for human epithelial cells in vitro than mercric chloride, mercuric nitrate, and merbromin (mercuric bromide).
- 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 allergenic and that it is reasonable to expect humans to be equally allergic.

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

The FDA noted a Swedish study which found in healthy subjects the following levels of hypersensitivity to thimerosal: 10% of school children; 16% of military recruits; 18% of twos, and 26% of military veterans.

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

Despite this strong finding, the FDA's proposed ban on the OTC use of thimerosal was not implemented until 1999. In 1998, the FDA stated at 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. It is unclear why the FDA chose to do nothing for 18 years after a "not generally recognized as safe" finding.

Since then, the FDA has continued through that 18-year regulatory process to remove thimerosal from topical ointments, apparently no one at the FDA was prompted to review the use of thimerosal in vaccines. Action to remove thimerosal from vaccines did not begin until 1999, in response to the Congressionally mandated review. This will be discussed in much greater detail below.

At the time of the 1999 FDA review on thimerosal, it was learned that over 50 vaccines...
contained thimerosal. On July 9, 1999, the American Academy of Pediatrics joined the U.S. Public Health Service in issuing a joint statement recommending the removal of all thimerosal from vaccines. On its website, the FDA provides the following rationale for its policy on thimerosal:

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

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

E. Thimerosal is still used in some medical products

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

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

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

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

<table>
<thead>
<tr>
<th>U.S. MILITARY VACCINE SCHEDULE</th>
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<tbody>
<tr>
<td>Vaccine No. Doses Initial entry Troops in US Deployed Region or other Thimerosal content</td>
</tr>
<tr>
<td>Anthrax</td>
</tr>
<tr>
<td>Diph</td>
</tr>
<tr>
<td>Hib</td>
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<td>Hep A</td>
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<td>Hep B</td>
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<tr>
<td>Influenza A&amp;B</td>
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<tr>
<td>Jap Enceph</td>
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<tr>
<td>MMR (Live)</td>
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<tr>
<td>Meningococcus MCV</td>
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<tr>
<td>Pneumococcus 17; PCV7</td>
</tr>
<tr>
<td>Pneumococcus 123; PPV23</td>
</tr>
<tr>
<td>Polio Inactivated IPV</td>
</tr>
<tr>
<td>Rabies</td>
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<tr>
<td>Smallpox (Live)</td>
</tr>
<tr>
<td>Tet (15 mcg)</td>
</tr>
<tr>
<td>Typhoid Inactivated</td>
</tr>
<tr>
<td>Varicella (Live)</td>
</tr>
<tr>
<td>Yellow Fever (Live)</td>
</tr>
<tr>
<td>Possible Total Thimerosal Exposure</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:

<table>
<thead>
<tr>
<th>Adult weight with exposure rates according to EPA Safety Limit</th>
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<tbody>
<tr>
<td>100 pound: 0.1 mcg/45.359 kg of body weight per day</td>
</tr>
<tr>
<td>120 pound: 0.1 mcg/54.431 kg of body weight per day</td>
</tr>
<tr>
<td>150 pound: 0.1 mcg/68.039 kg of body weight per day</td>
</tr>
<tr>
<td>180 pound: 0.1 mcg/81.647 kg of body weight per day</td>
</tr>
</tbody>
</table>

It is clear from this chart that with a maximum safe limit of 8.16 micrograms in a day, individuals receiving either 110.5 micrograms or 135.5 micrograms in one day may be at risk for injury from mercury exposure. Even in keeping with the safety margin of 10 times the EPA safety limit, individuals 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 willing to have his medical issues resolved through the military or the Veterans Administration (VA) medical system, Capt. Frank Schmuck, a pilot, became so ill that he was no longer able to fly. He sought medical treatment outside the military medical system and was tested for heavy metals, and was found to have toxic levels of mercury in his system. After chelation therapy, 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 aggressively evaluating 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 2002, the National Institutes of Health had adjusted that rate to 1 in 250 children in the United States. The Autism Society of America estimates that the number of autistic children is growing by 10 to 17 percent each year.

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

Mr. Burton: “California has reported a 273 percent increase in children with autism since 1988. Florida has reported a 571 percent increase in autism. Maryland has reported a 95 percent increase between 1993 and 1999. In 1999, there were 2,462 children ages 3 to 21 in Indiana diagnosed with autism. That is one-fifth of 1 percent of all the school children in Indiana, or 1 out of every 400. This increases 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, La. I want to express my deep 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 1980’s, the CDC conducted two prevalence studies that confirmed dramatic spikes in autism cases. One was conducted in Brick Township, New Jersey, the other in Atlanta, Georgia.

In late 1997, after noticing an apparently larger than expected number of children with autism in their community, a citizen’s group in Brick Township, New Jersey, contacted the New Jersey Department of Health and Senior Services (DHSS). Because of the complexity of the disorder and the concerns that environmental factors might play a role, the New Jersey DHSS, U.S. Senator Robert Torricelli, U.S. Representative Christopher Smith contacted the CDC and the ATSDR for assistance. In response, the CDC...
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 used the word "autistic" (from the Greek word auto, meaning "self") Pointing out similarities with some behaviors exhibited by adult schizophrenics, he theorized that psychiatrists assumed autistic children were exhibiting early-onset adult-type psychoses. Kanner’s young patients came from what he called middle-class families who lived in Baltimore with mothers and fathers who were doctors, lawyers and professors. In 1954, Kanner said, “I encouraged 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 their children in turn to coldly reject contact with other people.

By 1954, Kanner began modifying his “Blame the mother” theory. The weight of evidence that brothers and sisters of autistic children were often well-adjusted, high functioning children. These findings suggested that autism was also 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 behavior of autistic children was rooted in abnormal ways in retaliation against rejecting mothers 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, that is, specifically a neurological, basis for autistic behavior. Dr. Rimland documented the similarities between brain injured children and the children of meningitis from the destructive guilt associated with having an autistic child and pointing autism research in the direction of investigating the biological mechanisms underlying the brain and immune dysfunction symptoms and their possible causes.

In 1966, Kanner established the Autism Society of America (ASA). In 1967 he established the Autism Research Institute (ARI) and began distributing a questionnaire during June of that year. The 36 years since then have seen a growing amount of research into the causes of autism.

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

After 1986, some children went from getting 25 micrograms in one day or 75 micrograms in the first six months of life to getting 62.5 micrograms of ethylmercury in a day or 187.5 micrograms in the first six months of life. This would be in addition to the amount of ethylmercury in the recommended schedule. This vaccine contained 12.5 micrograms of ethylmercury and was given within hours of birth and a total of four times in the first two years of life (37.5 micrograms of ethylmercury).

As was noted previously, the effects of ethylmercury have not been studied as carefully as methylmercury, and the Federal Government has not set safety thresholds for ethylmercury exposure. Because of the obvious similarities between the two, however, when the FDA reviewed the use of thimerosal in the twin, it was decided to conduct a risk assessment and set safety limits. In 1999, they compared it to the Federal limits for (ingested) methylmercury exposure.

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.

B. 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 Type 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.
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 point of fact, the potential problem was worse than the FDA suggested. Not only did the cumulative amount of ethylene mercury on the routine schedule exceed the amount of ethylene mercury in each individual shot of DTP (or DTaP) and Hepatitis B exceeded the limit. Young children were getting multiple doses of each. The EPA's threshold is 0.1 micrograms of methylmercury for each kilogram of body weight. This does not mean that injury would result above this threshold but that a cause and effect margin is built in. However, the chances of injury increase as the exposure rises above this level. For an 11-pound child, the threshold dosage would be roughly 0.5 micrograms. For a 22-pound baby (ten kilograms), the threshold would be 1 microgram. The DTP (and DTaP) vaccine contained 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 drops of thimerosal they received in vaccines in the 1990's also exceeded the EPA'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 vaccines in one visit to their 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, children 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 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 on her son's bout with mercury due to thimerosal during 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 treat my idiopathic epilepsy disease also contained mercury.

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 were regressing into autism due to thimerosal. However, the IOM physician committee charged with analyzing the medical literature for evidence of causality rejected this regression. However, a link between pertussis vaccine and autism, because 'no data were identified in the medical literature' that address the question of a relationship between vaccination with DTP or its pertussis component and autism."

Dr. Stephanie Cave, who provided testimony to the EPA during the hearing in Baton Rouge, Louisiana whose medical practice is focused on treating children with the symptoms of autism, further suggested that experts from whom the Committee received testimony that there appears to be a correlation between increased use of vaccines containing thimerosal and autism. "I believe that the introduction of the Hepatitis B vaccine in 1991 has sparked this recent epidemic because of thimerosal. When studied in isolation, but through the use of both DTP and Hib, the exposure to mercury exceeds EPA safe limits for the metal if you consider all the multiple doses at each visit. The EPA limits are usually related to ingested mercury, which is partially cleared by the liver. Injecting boluses of ethylene mercury presents an entirely different, another scenario. The 2-month dose of mercury is at least 30 times higher than the recommended maximum daily exposure set by the EPA. During the 1990's, infants received 12.5 micrograms of mercury at birth, followed by 12.5 micrograms at 1 month, 62.5 micrograms at 2 months, 50 micrograms at 4 months, 50 micrograms at 6 months, 50 micrograms at 9 months, 50 micrograms at 12 months, 50 micrograms at 15 months, and 10 micrograms at 18 months; a total of 237.5 micrograms for a child who at best weights 10 kilograms. This far exceeds the safety limits if you consider the amount of thimerosal alone. This would be more like 1 to 1.5 micrograms.

"The injection of mercury appears to affect only certain children, but I fear that we're underestimating this phenomenon by concentrating only on the autistic children. We're measuring elevated levels of mercury in other children with milder difficulties like learning disabilities, ADHD, Asperger's Syndrome and many others. We do not have any idea what the scope of this problem is at this point. And there are no safety standards for infants getting bolus doses of ethylene mercury."

V. VALID CONCERNS ABOUT MERCURY IN VACCINES WERE IGNORED BY FEDERAL POLICYMAKERS AND VACCINE MANUFACTURERS FOR DECADES

As early as 1931, scientists were noting adverse reactions to thimerosal. In fact, Dr. Kharasch filed a new patent application because he revalued the product to "stabilize merthiolate due to its tendency to acquire certain burning qualities." In 1952, Dr. Elly Lilly researchers who found Merthiolate to be a skin-disinfecting agent, it was noted that an allergist had commented that some individuals display a sensitiveness to thioc[thimerosal] compounds, which is characterized by reddenning of the treated area and the appearance of an inflamed membrane in patients who are sensitive to the drug. In view of these facts it is recommended: 1. That Merthiolate ophthalmic ointment should be used in or about the eye unless it has been previously demonstrated by patch tests that the patient is not sensitive to the drug, and that the package should be labeled to warn the consumer that such tests should be made prior to the use of merthiolate ophthalmic ointment. 2. That ointment he obtained relatively few positive reactions. Dr. D. H. Mitchell in a lecture before the American Academy of Dermatology in New York in December 1941, stated that he had observed a number of cases of severe dermatitis following the treatment of dermatophytosis with preparations of Merthiolate.

In 1943, Dr. Ellis published a case report in the Archives of Ophthalmology, which states: "The positive results of patch tests demonstrated that the patient was sensitive to tincture of merthiolate and that merthiolate is capable of producing an inflammation of the mucous membrane in patients who are sensitive to the drug. In view of these facts it is recommended: 1. That Merthiolate ophthalmic ointment should be used in or about the eye unless it has been previously demonstrated by patch tests that the patient is not sensitive to the drug, and that the package should be labeled to warn the consumer that such tests should be made prior to the use of merthiolate ophthalmic ointment. 2. That ointment he obtained relatively few positive reactions. Dr. D. H. Mitchell in a lecture before the American Academy of Dermatology in New York in December 1941, stated that he had observed a number of cases of severe dermatitis following the treatment of dermatophytosis with preparations of Merthiolate."
“There is ample evidence from the literature that thimersal (thimerosal) may cause sensitization and subsequent allergic reactions. . . . The use of thimerosal is vaccines is in accordance with safety guidelines in various national vaccine programs may in certain cases result in approximately two times higher intake of ethylmercury during the first year of life. What can be done to reduce this intake?”

In June 2000, the CDC convened a closed meeting to discuss research evidence that showed a connection between thimerosal in vaccines and local injury. According to Dr. Verstraeten, a CDC employee who has since left the agency to work in Belgium for a vaccine manufacturer, utilizing the Vaccine DataLink to evaluate any possible connection between thimerosal-preserved vaccines and neurological or renal impairment. He found, “a statistically significant positive correlation between the cumulative exposure at 2 months and unspecified developmental delay; the cumulative exposure at 3 months and tics; the cumulative exposure at 6 months and attention disorders.”

In general, the Committee and the public have been frustrated by the Department of Health and Human Services reluctance to accept that all forms of mercury are toxic and that children have likely been harmed from the FDA’s allowing the use of thimerosal in vaccines. The Committee heard testimony that many parents of developmental disabilities and autism suspect vaccines damaged their children. The recall would be like that. And we would expect you to do something now before that circus starts taking place. Denial is not proper right now.

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

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

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

“Jacob met every developmental milestone that first year, right along with J esse. They even ate the same little peas in the same bowl that were given to them together everywhere together. At only 16 months of age, Jacob and J esse received their first MMR vaccine. On this same day, they also received their fourth DTP, their fourth Hib, and their third hepatitis B. The following 24 hours, both twins slept most of the time, with over 100-degree temperatures, in spite of receiving the recommended Tylenol dosage every 6 hours. Immediately following that, Jacob began exhibiting strange behaviors. He was no longer excited or responsive when Daddy came home from the office. He no longer was interested in toys. He became preoccupied with certain toys. He would spend long periods of time studying the way their wheels would spin or whether anything else was involved. Any attempt to interrupt or distract him was met with great resistance and an eventual fit.”
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 could barely reach him."

"For us, there is no denying that in Jacob's case of autism, the answer does not lie in genetics, but in a catalyst. The thousands of hours of research that we have spent searching and retracing his regression continue to point to the fact that the road to Jacob's autism began when his immune system was damaged by Hepatitis B vaccine that he received when he was ill. The final blow was the adverse reaction to the host of vaccines he received 16 months later. We are certain that for Jacob, the catalyst was his vaccine."

Testifying two years later, on April 18, 2002, Autism Society of America President Lee Grossman testified about the strongly held views of many of the Society's members:

"A substantial number of families within our autism community believe some forms of autism may be caused by some use of vaccines. While we do not know this to be specifically proved at this time, we should not ignore evidence that calls into question the source of many children with autism. If causation is found, those injured must be provided recourse and compensation."

"I think the stories I have heard that many of our members tell, that many of these people in the audience will tell you, is that they believe that there is evidence that there is a direct linkage, a direct causation of vaccines causing their child's autism. I think it is imperative for us, the advocates in the room, for ASA, and for Congress, for the lay public, to stand together to get this question answered, answered immediately."
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 several types of developmental disorders, including attention deficit disorder, speech and language delay, tics, and general neurodevelopmental delays. Phase I of the study, which was performed with data from the CDC's Vaccine Safety Datalink (VSD) uncovered the aforementioned associations. Phase II of the study, which provided enough data to analyze only speech delays and attention deficit disorder, did not detect an association between those disorders and thimerosal-containing vaccines. Phase II of the study also briefly described one possible genetic risk factor. He 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, and it is a risk factor 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 our children.''

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

"Our results are very consistent with the report that thimerosal not been removed from all vaccines and medicines given to children and pregnant women. The report specifically cited the influenza vaccine, the diphtheria-tetanus toxoid vaccine, and some nasal sprays. I fully concur that, 'full consideration of the potential toxicity of thimerosal in vaccines not containing thimerosal as a preservative' versus those vaccines not containing thimerosal. The results were very dramatic as shown in the accompanying table attached to this document. In our preliminary studies, vaccines containing thimerosal as a preservative consistently demonstrated in-vitro toxicity that was dramatically greater than the non-thimerosal or low-thimerosal containing vaccines."
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 live for a week. We infuse these cells with thimerosal at various doses, and we use a number of very sophisticated techniques to detect cell death and cell damage."

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

"Here is a slide where you see a lot of blue cells. This is a control sample, one without thimerosal. The beads don't take up. In order for something to turn blue, the cell has to have holes punched in their membranes. And guess what? At an extracellular concentration of thimerosal, the cells are blue. It means that this stuff grabs a hold of the membrane and punches holes into it, so that the dye can penetrate, not only into the cytoplasm but into the very center of the cell, the nucleus, where all the DNA exists.''

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

Dr. Baskin testified that other researchers in his field were coming to 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. These microglia, and most of the conclusions that have been made by the National Institutes of Health and the FDA have been wrong.

D. Public health officials continue to defend the use of thimerosal in vaccines

Public health officials continue to resist the idea that thimerosal may have contributed to the rise in autism spectrum disorders. In public statements as recently as December of 2002, Federal officials have continued to defend the use of thimerosal, despite the fact that:

- They asked vaccine manufacturers to remove thimerosal from childhood vaccines more than three years ago.
- In tests they acknowledged that many children received a cumulative amount of ethylmercury in vaccines that exceeded the FDA's safe limits for ethylmercury.
- One Federal study showed an association between thimerosal in vaccines and some developmental disorders.
- On April 18, 2002, the Committee heard testimony at Baylor College of Medicine. Dr. Baskin of the Epidemiology and Surveillance Division of the CDC's National Immunization Program, her response to a question about mercury and thimerosal at the hearing indicated that the damage may be more extensive than the CDC and the FDA believe.

"As far as the thimerosal issue is concerned, the evidence is too incomplete and fragmentary for the government to make a decision about its role in causing autism. Of course, many substances are known to be dangerous when administered in high concentrations, but the additives that are included in vaccines are present in trace amounts, and even when multiple vaccines are given, these are still very small amounts of potential toxins. It is not established that thimerosal is associated with any harm as a vaccine additive.

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

She further stated:

"There are no data to there are no established harms associated with this. I know that this is a very sensitive issue, and a number of studies are underway, but we do not have data that support known hazards associated with thimerosal contained in vaccines at this point."

Later in 2002, Dr. Karen Midthun, Director of the FDA's Office of Vaccines Research and Review, expressed the following views:

"Our review showed no evidence of harm caused by thimerosal used as a preservative in vaccines except for local hypersensitivity reactions."

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

In her testimony, Dr. Midthun attempted to downplay the extent to which the exposure to thimerosal from vaccines in the 1990s exceeded the FDA's threshold for ethylmercury exposure:

"During the first two months of life, cumulative exposure to mercury could have exceeded the more conservative limits of the FDA in some cases, depending on the specific vaccine formulations used and the weight of the infant."

There is no question that the cumulative amount of ethylmercury on the recognized retail schedule of childhood vaccines exceeded the FDA's threshold for ethylmercury exposure:

"During the first two months of life, cumulative exposure to mercury could have exceeded the more conservative limits of the FDA in some cases, depending on the specific vaccine formulations used and the weight of the infant."

"There is no question that the cumulative amount of ethylmercury in individual vaccines exceeds the threshold. The FDA's threshold is 0.1 micrograms per kilogram of body weight. For an eleven-pound baby, the FDA's safe threshold would be 0.5 micrograms. At the time thimerosal was removed from these vaccines today in the United States, in the 1990s, Aventis Pasteur's DTaP vaccine contained 25 micrograms of thimerosal. GlaxoSmithKline's Hepatitis B vaccine contained 12.5 micrograms of thimerosal. Wyeth Lederle's Hib vaccine contained 25 micrograms of thimerosal."

Dr. Midthun's carefully couched statement was the reaction of almost everybody in the audience.

"My first concern was that it would harm the credibility of the immunization program. But gradually it came home to me that there was some real risk to the children."

In a statement released by Johns Hopkins University after the publication of the profile in the New York Times, Dr. Baskin clarified that he still does not believe that there is a connection between thimerosal and autism.

"Neil Halsey, M.D., does not and has not supported the belief that thimerosal or vaccines themselves cause autism in children, saying scientific evidence does not suggest any causal association between any vaccine and autism."

However, Dr. Halsey's statement made it equally clear that he believes that there may be an association between exposures to low levels of mercury and other neurological immaturity.

His statements specifically to the Faerois Islands studies and the calculation that the cumulative amount of thimerosal in childhood vaccines exceeded the FDA's limits for ethylmercury:

"In 1999, Dr. Halsey became concerned that the use of thimerosal as a preservative in many vaccines led to some children being exposed to more ethylmercury than was recommended, based on guidelines from the Environmental Protection Agency for exposure to methylmercury, a related product. Recent studies have determined that fetuses who as fetuses were exposed to low to moderate amounts of methylmercury through fish consumption later on had increased risk for having mild neurological learning deficiencies. The findings from the studies did not show an association between thimerosal exposure and autism.

E. Research on the effects of thimerosal has been limited to draw conclusions

To date, very little epidemiological or clinical research has been done on the neurodevelopmental effects of thimerosal, and particularly its ethyl-mercury component. As the IOM noted in its report on thimerosal, "the data regarding toxicity of low doses of thimerosal and ethylmercury are very limited," and most of the conclusions that have been drawn about ethylmercury are based on analogies to methylmercury, which has been studied extensively. Few or none of the studies that have been performed on ethylmercury have been of limited value, for several reasons.
Perhaps Dr. Thomas Verstraeten conducted the broadest review of a possible relationship between thimerosal and neurological disorders in 2003. This study reviewed several thousand medical records from the Vaccine Safety Datalink maintained by the CDC. As noted earlier, Phase I of this study purported to find a statistically significant association between thimerosal and some neurological disorders. However, this study has never been published. Moreover, because the data used in the study came 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. Readers interested in learning more on the importance of a random sample size:

...it remain in the blood longer or be more sensitive to it. So if a child had some different tendency in weight, premature infants."

If anything, the limitations of this study's inability to measure the effects of thimerosal in routine vaccines poses very little risk to full-term infants, but that thimerosal in topical ointments was not a factor in children's bodies at various times beyond peak levels, it did not attempt to determine the effects of the mercury from the injection. It was clearly brought out in an exchange between Congressman Burton and Dr. Christopher Portier, Director of the Environmental Protection Agency:

"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—" doesn't make sense."

The authors went on to conclude:

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

Skepticism of a vaccine-autism connection halted this study. However, its value is limited by a number of criticisms that have been raised since its publication. Some of the most common cited shortcomings were discussed in testimony at the Committee's December 10, 2002, hearing by Baylor University's Dr. Baskin.

1. The sample size was very small:
   - Only 40 children who received thimerosal were examined. By contrast, almost all number of children were genetically predisposed to injury by mercury, the chances of a sample of 40 children detecting such a trend would be very low. In his testimony, Dr. Baskin stated:
     "The sample size, as you said, Dr. Weldon, was small. Autism occurs in one in 150 kids. So if this child had some random tendency 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, they might have found one child 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 after being injected, the authors drew blood from their subjects at varying times between three and 28 days after shots were administered. However, as Dr. Baskin notes, peak levels of mercury in the blood are expected to appear within 24 hours:
     "We know the stool levels were high, but if you actually measured the blood levels, they said it was somewhere between 3 and 27 days later. The peak mercury levels after injection occur within 24 hours... So if they were drawing blood later than that, and much later than that, of course the levels weren't going to be high. But the mercury may stump from the injection to the stool; it goes through the blood. At some point it was high because it was high in the stool."

For decades, ethylmercury was used as a preservative or anti-bacterial agent in a range of products, including antiseptic ointments for treating burns, and many vaccines and other medicines. However, it now appears that the presence of mercury in some vaccines can raise doubts about the entire system of vaccine safety. In fact, the FDA has never acted to remove thimerosal and other mercury compounds from vaccines and other medicines. It is clear that the guiding principal for FDA policymakers has been to avoid shaking the public's confidence in vaccination. For this reason, many FDA officials have stubbornly denied that thimerosal may cause adverse reactions. Ironically, the FDA's willingness to address this issue more forcefully, and remove thimerosal from vaccines earlier, may have done more long-term damage to the public's trust in vaccines than confronting the problem head-on.

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

B. Thimerosal manufacturers accumulated evidence of the toxicity of thimerosal

Eli Lilly and Company of Indianapolis licensed thimerosal in 1930. It was marketed under several brand names. It was used extensively both in topical ointments to prevent infections and as a preservative in a variety of medicines. However, it now appears that the safety or effectiveness of thimerosal was ever done.

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

In 1996, a review of internal Eli Lilly documents dating back 70 years suggests that the only study of thimerosal involving human subjects was done prior to 1930. For the next seven decades, Lilly spokespeople would refer to that original study as evidence of thimerosal's safety. However, it is now clear that this uncontrolled study was woefully inadequate.

As previously discussed in this study, an intravenous solution containing thimerosal was tried as an experimental treatment for individuals suffering from 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 that the intent of the study was "merely to throw a bone to the researcher." Considering the type of patient involved, one might question these observations (the appearance of no deleterious action) as providing little indication of any harmful effects of high doses of Merthiolate in humans, in particular, more long term effects.

In 1973, the FDA requested additional data on Merthiolate from Eli Lilly. Lilly's Director of Regulatory Affairs, E.A. Burrows, responded with a ringing defense of Lilly's product. February 1, 1973. "Due to the length of time this product has been on the market, its efficacy and safety have been proven by over forty years of usage throughout the world. Because of this long period of use, it would be difficult to get recognized researchers to conduct new studies for efficacy or safety. They believe that over forty years of wide usage has proven efficacy and safety beyond that which could be done in special studies."

Despite Mr. Burrows's contention, numerous independent observers have recognized the lack of data on thimerosal and suggested the need for more research:

An April 24, 1973, intra-office memo stated: "If we have any experience with the merthiolate solution, we have to know pretty definitely what to expect from merthiolate products before we put them on the market. . . . Can we expect to have the stronger ointment and jelly used without complaint which awaited the use of the solution in the same strengths? . . . Our experience with the solution ought to serve as a warning and certainly in the face of that warning we ought not to advocate the use of the solution without some clear, definite evidence that we will not repeat our solution experience."

A September 1973, paper from Lilly's files stated: "[l]ittle is known about the effect of mercuric compounds when inoculated into humans. It is therefore preferable to use the minimum amount of this preservative necessary to maintain the sterility of the product."

An April 1969, memo regarding the possible use of thimerosal in contact lens solution states:

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

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

A December 1972, memo states: "A review of some data being generated by the current concern for mercury in the environment would be advisable in order to obtain data on the metabolic deposition of Merthiolate."

An August 1973, memo entitled, "Merthiolate Ticity", acknowledged: "The effects of long-term, intravenous use in man is not known, no long-term toxicity tests have been performed."

Perhaps more disturbing is that Lilly's files contained numerous papers and reports documenting the toxicity and hyper-sensitivity of Merthiolate. Although these papers and case reports strongly suggested the need for much more research, there apparently was little follow-up.

A July 1970 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 dem- onstrated conclusively that there is no con- nection between the lot of serum and the re- action. In other words, Merthiolate is unsat- isfactory as a preservative for serum in- oculated into dogs. . . . The data indicate that there is no marked local reaction than does phenol or tricresol."

A 1967 paper published by an Army physician in Baltimore reported that Merthiolate was causing contact dermatitis in his pa- tients. He concluded:

"No eruption or reactions have been ob- served or reported to Merthiolate internally, but it may be dangerous to inject a serum containing Merthiolate into a patient sen- sitive to Merthiolate."

A 1946 paper from an Arizona doctor re- ported the case of a woman who suffered re- peated multiple reactions to Merthiolate ap- plied to a burn. She reportedly suffered chills and fever and had small vesicles and erythema in the area of her Merthiolate application. After her recov- ery, the patient began using Merthiolate in the crease for which she was being surgically treated ap- peared after repeated application of a tinc- ture of Merthiolate. She continued using the Merthiolate for a year, and noted that the burn scar became too raw and painful to continue use, and then sought medical care.

A 1930 New York Academy of Sciences article entitled, "Antiseptics," found that Merthiolate "is toxic when in- jected parenterally and therefore cannot be used in chemotherapy."

A 1973 article entitled, "Dangers of Skin Burns from Thimerosal," reported the case of a woman who received severe burns result- ing from a chemical interaction between thi- merosal and aluminum. The article sug- gested 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 submission of the committee's report in 1982, 1990, 1991, 1994, and 1995. This sequence of these proceedings all the more mystifying is that there appears to have been no opposition to this action throughout the process. No individual sought to appear before the advisory committee in defense of mercury-containing products, and when the FDA sought public comment along the way on proposed rules to remove mercury from immunizations, it re- ceived none. At the time of the FDA's final action, there were 20 over-the-counter prod- ucts containing mercury being marketed by eight different manufacturers. Their silence on this point is telling.

D. The FDA's actions to remove mercury from over-the-counter products should have prompted a review of mercury in vaccines.

It is difficult to understand why it took the FDA 18 years to address mercury from over-the-counter products. It is equally dif- ficult to understand why the expert panel's 1980 findings on thimerosal's safety and top- ics, the FDA to further and immediately remove 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 indi- vidual's skin, it might not be safe to inject ethylmercury deep into an infant's tissue. The Director of the FDA's National Center expressed such a concern at a 1999 meeting for Toxicological Research, Dr. Bernard Schwartz, who went on to serve as the Acting Director of the FDA for nearly a year.

"One thing I 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 (intra- muscularly) at a time when the immune sys- tem is just developing, the functionality of the immune system is just being set at this age. So now we're injecting a sensitizer sev- eral times a week in the surface of an infant's skin. We don't know what the impact of a sensitizer—of some- thing that is known to be a skin sensitizer, what is the effect on the functional develop- ment of the immune system? What do we give a chemical of that kind repeatedly IM?"

Different branches of the FDA regulate over-the-counter products and vaccines, which are regulated by the Center for Drug Evaluation and Research (CDER). Vaccines are regulated by the Center for Biologics
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 vaccines was not authorized in the Federal Register no fewer than five times prior to the FDA's belated review of mercury in vaccines.

What provoked 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 Food and Drug Administration Modernization Act (FDAMA). Among other things, this law required the FDA to compile a list of foods and drugs that contained regulated levels of mercury. If background levels were included in all calculations, one scientific expert at the FDA was convinced that thimerosal should be removed. On June 22, 1999, Dr. Ball presented the results of her research to the Medical Policy Coordinating Committee (MPCC) of the Centers for Disease Control and Prevention (CDC) at the CDC's Biennial Review and Evaluation (CBER). Dr. Halsey attended that meeting. The next day, on June 23, 1999, Dr. Halsey wrote a letter to the members of the American Academy of Pediatrics' Committee on Infectious Diseases, which he chaired.

“...raise questions about FDA being 'asleep at the switch' for decades by allowing a potential toxin to be consumed by infants in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about..."... raise questions about FDA being asleep at the switch for decades by allowing a potential toxin to be consumed by infants in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various other sources of Hg [mercury] in the environment, e.g., breast milk."

One point needs to be made about thimerosal-free vaccines. In 2001, when the CDC and its manufacturers to eliminate or reduce mercury in vaccines as expeditiously as possible. As a result, almost two years passed before the thimerosal-containing vaccines—DTaP, Hib and Hepatitis B—were being manufactured in thimerosal-free formulations. In 2002, when the CDC and its influenza committee continued to state a preference for thimerosal-free vaccines, they chose not to do so. As a result, thimerosal-containing vaccines that remained in stock in doctors' offices continued to be used. In point of fact, we have no proof that in 2003, some children in the United States were being vaccinated with thimerosal-pre- served vaccines that had lingered in medical offices or clinics.

The CDC's hesitation to endorse thimerosal-free vaccines in 2001 is particularly troubling. With the exception of the influenza vaccine, all major childhood vaccines were being manufactured without thimerosal at that time, so there was little threat of shortages. Their failure to state a preference was an abdication of their responsibility.

The task of assessing the amount of mercury in vaccines and its ramifications was assigned to Dr. Leslie Ball, a pediatrician employed at the FDA and her husband and colleague Dr. Robert Ball, a medical officer at the FDA's CBER. Despite the general lack of scientific research on the toxicity of thimerosal, their review of the available literature led to two working conclusions:

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

An exchange of e-mails in October of 1998 makes clear that Dr. Leslie Ball was already concerned about thimerosal from vaccines. It also makes clear that there was internal resistance to such an action. Dr. Marion Gruber of the Office of Vaccine Safety, the FDA's CBER, and an internal FDA memo to Dr. Ball, which concluded that:

"In the past few days, I have become aware..."... raise questions about FDA being 'asleep at the switch' for decades by allowing a potential toxin to be consumed by infants in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various other sources of Hg [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 roughly 80 to 100 micrograms per year. Background levels were included in all calculations prepared by the European Medical Evaluation Agency, which was at the time reviewing thimerosal in vaccines in Europe. If background levels of mercury had been incorporated into the FDA's and CDC's calculations, the results would have been even more pronounced, possibly even leading to more aggressive measures to remove thimerosal. It is unfortunate that this simple, and scientifically expected result was not taken.

The issue of what to do with thimerosal in vaccines came to a head in the summer of 1999. In June and July, a series of meetings were held involving theFDA, the Public Health Service, the American Academy of Pediatrics, and other agencies. These meetings revealed 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 US and internationally, shortages of childhood vaccines might ensue, and the potential far-reaching ramifications are envisaged."

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) act quickly to inform pediatricians that the public effort to remove thimerosal in vaccines has been made..."... raise questions about FDA being asleep at the switch for decades by allowing a potential toxin to be consumed by infants in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various other sources of Hg [mercury] in the environment, e.g., breast milk."

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May 21, 2003

CONGRESSIONAL RECORD — Extensions of Remarks

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we didn't catch this earlier; (3) show contribution. As you know, the Public Health Service informed us yesterday that they were planning to conduct business as usual, and would probably seek to preserve the fact that the CDC, on two separate occasions, refused to publicly state a preference for thimerosal-free vaccines.

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 asked to recommend what the CDC should issue a public statement of preference for thimerosal-free vaccines. At the time, the industry was in the midst of implementing thimerosal-free childhood vaccines, and several vaccines containing thimerosal were still on the market. Of particular concern was the DTaP vaccine. In June of 2000, three of the four DTaP manufacturers (Aventis Pasteur, North American Vaccine and Wyeth) were still producing DTaP with thimerosal. Only SmithKline Beecham produced a thimerosal-free DTaP. In addition, because manufacturers of the Hib and Hepatitis B vaccines had just recently converted to formulas that were thimerosal-free, trace amounts of thimerosal, older versions of these vaccines containing thimerosal were still in inventories and being used around the country.

As a statement of no preference by the CDC would have been a clear signal to pediatricians not to use vaccines containing thimerosal, when thimerosal-free versions were available, this action would have substantially reduced the exposure to ethylmercury for many infants. Despite this knowledge, the advisory committee voted unanimously not to state a preference.

CDC officials guided the Advisory Committee toward this conclusion. For example, while three different options were presented to the Advisory Committee, a detailed policy statement to be issued to the public had been prepared for only one of these options—a statement of no preference. In describing the three options, Dr. Roger Berner of the CDC clearly indicated the CDC's desire not to state a preference for thimerosal-free vaccines. He said:

"We believe that such a policy would be consistent with the evidence that we have at this time. ... The policy seems to be working..."

"As I said, the policy seems to be working. So this indicates that on this particular factor, this policy is moving us in an upward direction towards the goal..."

In rejecting a statement of preference for thimerosal-free vaccines, the Advisory Committee considered a number of factors. These included a desire to avoid confusion, and a concern that immunization rates might fall, allowing for an outbreak of diseases such as Pertussis or Hepatitis B. However, one of the factors that was at the top of the CDC's consideration was the financial health of the vaccine industry. In discussing the pros and cons of each option, Dr. Berner returned several times to financial issues.

"We think that having this type of a more staged transition reduces the potential for financial losses to the manufacturers, and is somewhat akin to what was done in the transition from oral polio to inactivated polio..."

"It could entail financial losses of inventory if current vaccine inventory is wasted. It could harm one or more manufacturers and may then decrease the number of suppliers..."

"The evidence justifying this kind of abrupt policy change does not appear to exist, and it could entail financial losses for all existing stocks of vaccines that contain thimerosal..."

The financial health of the industry should never have been a factor in this decision. The financial health of vaccine manufacturers certainly should never have been more important to the Federal health officials than the health and well being of America's children. The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neurologic safety of thimerosal, that information should have been made clear to the parents of our children—and there were substantial doubts—the prevailing consideration should have been how best to protect children from potential harm. However, that protecting the industry's profits took precedence over protecting children from mercury damage.

In opting not to state a preference for thimerosal-free vaccines, the Advisory Committee shrugged off two sensible proposals that were presented during the meeting. A representative of SmithKline Beecham (now GlaxoSmithKline) stated that her company could supply sufficient amounts of thimerosal-free DTaP vaccines to the youngest infants receiving the initial doses of DTaP could receive thimerosal-free doses: "I think it's important that you know that there is a company, GlaxoSmithKline, that U.S. market right now for all five doses immediately, we would be able to supply the vast majority of the U.S. market for the primary series, that is with targeting of the first three doses."

Given the repeated concerns expressed about the effects of thimerosal on the developing central nervous system in very young babies, ensuring thimerosal-free doses for the first three boosters of DTaP would seem to merit serious consideration. However, this sensible submission was passed over without any comment.

Later in the discussion, Dr. Neal Halsey asserted that there is no evidence of any harm caused by thimerosal in vaccines; called on vaccine manufacturers to make a clear commitment to reduce as expeditiously as possible, the mercury content of their vaccines; urged doctors and parents to immunize all children receiving thimerosal-free vaccines are not available; and encouraged doctors and parents to postpone the Hepatitis B vaccine (which contains a thimerosal-containing preservative, ethylmercury) until after the child is two to six months old, unless the mother tested positive for Hepatitis B.

Given the information that the Federal agencies had at the time, the plan of action laid out in the joint statement was inadequate. They could have, but did not acknowledge that the amount of thimerosal in vaccines exceeded every Federal guideline for exposure to methylmercury for the majority of American children. They could have, but did not recommend that vaccine manufacturers remove thimerosal from vaccines by a specific date. They could have, but did not urge pediatricians to choose thimerosal-free vaccines when both thimerosal-containing and thimerosal-free vaccines were available.

As a result of the limited steps taken in 1999, public loss of confidence remained on the market for nearly two years. GlaxoSmithKline's Hepatitis B vaccine did not become thimerosal-free until March of 2000, and SmithKline's DTaP vaccine did not become thimerosal-free until March 2001. In addition, thimerosal-containing vaccines on the shelves in doctor's offices around the country could continue to be used in situations where the fact that thimerosal-free versions were available.
What makes the CDC’s decision even more vexing is that just prior to the Advisory Committee meeting in 2000, a study conducted by the CDC suggested that there was at least a weak correlation between thimerosal and several types of neurological disorders. 

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

Methodologically, a significant association between exposure to thimerosal during the first three months of life, and tics, attention deficit disorder, language and speech delays, and general developmental delays. The study did not find a correlation between thimerosal and autism because the sample size of children diagnosed with autism was too small to be statistically meaningful.

The findings of Dr. Verstraeten, the primary author of the study, set off a firestorm in the scientific community. The CDC, which had monitored the safety of thimerosal in vaccines for many years, had not previously linked thimerosal to any neurological disorder.

The CDC was forced to admit that the study was underpowered — the small sample size limited the study’s ability to detect a statistically significant association between thimerosal and autism. The CDC issued a statement acknowledging the study’s limitations and saying that further research was needed.

In 1999, Dr. Katherine Zoon stated: “When I saw this, and I went back through the literature, I was actually stunned by what I saw—because I thought it was plausible.”

A month later, he sent an e-mail to Dr. Phillippe Grandjean, the author of several studies on the effects of mercury on the nervous system, looking at the developing nervous system, at the developing immune systems, and the effects of these agents on that at critical times of development, hasn’t been—hasn’t been done—and I think that knowledge is very important.”

At the same meeting, Dr. Bernard Schwetz, the Director of the FDA’s toxicology center, stated: “The sensitivity of the fetus versus the neonate is very important, and for some of you who have forgotten about the sensitive windows during fetal development, the nervous system develops post-natally. So it isn’t unreasonable to expect that there would be particular windows of sensitivity. So it isn’t a matter of averaging the whole neonatal period—it’s what’s the week or what’s the day or what’s the series of hours that represent a particular event in the development of the nervous system system when this whole thing might be dangerous. There may be weeks surrounding that when there isn’t a major problem. We don’t have that information.”

VIII. FOCUSED, INTENSIVE RESEARCH EFFORT IS BADLY NEEDED

One of the most consistent refrains heard by the Committee throughout its three-year investigation is that more research has been done. The Committee has heard testimony from parents, scientists and government officials that much more research is needed. And that well-constructed research that addresses the specific issues of vaccine-injury must be conducted. Areas in which research is urgently needed include:

The causes of autism

Treatments for those suffering from autism spectrum disorders

Possible relationships between vaccine ingredients like thimerosal and autism

The neurotoxicity of thimerosal

The neurotoxicity of dental amalgams containing mercury

Immune system and gastrointestinal system dysfunction after vaccination

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

Use accepted and consistent case definitions when assessing mercury exposure (autism spectrum disorder) in order to enhance the precision and comparability of results from surveillance, epidemiological, biological investigations.

Explore whether exposure to MMR vaccine is a risk factor for ASD in a small number of children.

Deep targeted investigations of whether or not measles vaccine-strain virus is present in the intestines of some children with ASD.

Encourage all who submit reports to VAERS of any diagnosis of ASD thought to be related to MMR vaccine to provide as much detail and as much documentation as possible.

Case Reports in VAERS or elsewhere of “rechallenge” should be identified, documented, and followed up. One case of MMR vaccine and ASD, rechallenge refers to children who appeared to have experienced some form of neurological regression after a subsequent exposure to the thimerosal-containing vaccine and who appeared to have experienced another regression following a second dose of MMR or other measles-containing vaccines.

Study the possible effects of different MMR immunization exposures.
The research needs regarding vaccine injury have also been negligent in addressing serious epidemics—HIV/AIDS and diabetes. At $10.2 Million. The IOM called for the following recommendations. The States refer for determining man-
Mr. UDALL of Colorado. Mr. Speaker, today, I am introducing legislation titled the “National War Permanent Tribute Historical Database Act,” that will help the Department of Interior and the Department of Veterans’ Affairs keep track of the many important war memorials on public lands throughout our country. It would also provide a report to Congress to determine if there should be a permanent fund within the Treasury for the upkeep of these memorials.

The freedom we enjoy in the United States has not just been given to us. Men and women have made great sacrifices, some with their lives, to protect our way of life. We have erected memorials to honor these soldiers, sailors, and aviators and their valiant deeds. Unfortunately many of these memorials don’t receive the care they deserve and have fallen into disrepair. These memorials may not be as large as those on the National Mall or Arlington National Cemetery but they are just as important and should be taken care of. In 2000, Congress agreed to a resolution expressing the need for cataloging and maintaining public memorials. The National War Permanent Tribute Historical Database Act would follow through with this sense of Congress and take a first step by cataloging our public war memorials.

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

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

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

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

The benefits provided by the Medicare Out-of-Pocket Spending Limit Act are long overdue. In testimony before the Ways and Means 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 entitled to 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 this 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 150 percent of poverty would be eligible for the new benefit with no additional premiums. Beneficiaries with incomes between 150 percent and 175 percent of poverty would be eligible for the new benefit with a sliding scale premium. No assets test would be used in determining eligibility for these additional low-income protections. These low-income benefits would be administered by the States but 100 percent federally funded.

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