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 troops began landing on Crete.

Both the allies and Nazis wanted Crete because of its strategic location. At that time the British controlled the island.

It was a very short point on the timeline to India and protected both Palestine and Egypt.

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

The invasion of Crete took 11 days. It resulted in more than 6,000 German troops listed as killed, wounded or missing in action. The losses to the elite 7th parachute division were felt so hard by the German military 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, rushed his parishioners out to war. He then went straight to war, which cost him his life.

In this struggle became an example for all Europe to follow in defying German occupation and aggression.

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

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

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

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

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

Today, the courage and fortitude of the Cretan people is seen in the members of the United Cretan Associations of New York which is located in Astoria, Queens.

I congratulate the newly elected officials and look forward to working with them.

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

H. RES. —

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

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

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

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

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

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

Whereas for 4 years, the Cretan Resistance Movement inflicted heavy casualties 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;

Whereas many of these citizens became members of the PanCretan Association of America in Astoria, a group comprising of Greek Americans with ancestry from the island of Crete and committed to preserving and promoting the rich culture and proud history of Crete.

Resolved, That the House of Representatives—

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

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

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

INTRODUCTION OF THE RURAL HEALTHCARE ACCESS IMPROVEMENT ACT OF 2003

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

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

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

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

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

As my colleagues know, the Center for Medicare and Medicaid Services uses a reimbursement formula that favors urban areas over rural areas. This formula is deeply flawed though and fails to allow our providers to even break even on many of their expenses. My legislation will directly assist our hospitals by equalizing Disproportionate Share Hospital (DSH) Payments, by equalizing urban and rural “standardized payment levels; by assisting Critical Access Hospitals, and by establishing a floor on the geographic adjustments of payments for doctors’ services. It will also improve reimbursement for home health services, ground ambulance services and hospital outpatient procedures.

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

MERCURY IN MEDICINE REPORT

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

Mr. BURTON of Indiana. Mr. Speaker, I submit the following report prepared by the staff of the Subcommittee on Human Rights and Wellness, Committee on Government Reform. This report is the result of a three-year investigation initiated in the Committee on Government Reform.
Mercury in Medicine—Taking Unnecessary Risks

I. Executive Summary

Vaccines are the only medicines that American citizens are mandated to receive as a condition for school and day care attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof of vaccinations 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 Centers for Disease Control and Prevention (CDC) and its Advisory Committee for Immunization Practices that make the Universal Immunization Recommendations to which the States then determine 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 from vaccines. This investigation later expanded to examine the potential danger posed through exposure to mercury in dental amalgams. This full committee investigation was 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 was raised as a possible underlying factor in the dramatic rise in rates of late onset- or "acquired" autism. The symptoms of autism are markedly similar to those of mercury poisoning.

Significant concern has been raised about the continued use of mercury in medical applications decades after the recognition that mercury can be harmful, especially to our most vulnerable population—the very young. This report will address one form of mercury in medical applications, Thimerosal, as a preservative in vaccines.

In 1999, CDC 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 have neurotoxicity at the fetus and at the infant level, points out that we should not have these fetuses and infants exposed to mercury. There's no need of it in the vaccines."

The Food and Drug Administration's (FDA) mission is to "promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use." However, the FDA uses a subjective barometer in determining the risks and benefits 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 benefits that 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 of mercury—has never been true for thimerosal in vaccines. One is that there has never been a scientific barometer that proof of harm existed. Upon a thorough review of the scientific literature and internal documents from government, the Committee did in fact find evidence that thimerosal posed a risk. The possible risk for harm from either low dose chronic or one time high level of 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 in vaccines received by infants in the first six months of life through their mandatory vaccinations exceeded the Environmental Protection Agency's (EPA) limit for ethylmercury in drinking water. The FDA and other Federal agencies determined that in the absence of a specific standard for ethylmercury, the limits for inorganic mercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA's methylmercury standard and determined that based upon scientific data that it, rather than the FDA's, was scientifically validated safe exposure standard.

Rather than acting aggressively to remove thimerosal from children's vaccines, the FDA and other agencies within the Department of Health and Human Services (HHS) adopted an incremental approach that allowed children to continue to be exposed to ethylmercury from vaccines for more than two additional years. In fact, in 2001, the Centers for Disease Control and Prevention (CDC) issued an advisory for children with autism. The frightening reference for thimerosal-free vaccines, despite the fact that thimerosal had been removed from almost every childhood vaccine produced for use in the United States.

On three occasions in the last 15 years, changes have been made to vaccine policies to reduce the risk of serious adverse effects. First, a transition from oral polio vaccine to injected polio was accomplished in the United States to reduce the transmission of vaccine-induced polio. Second, an acellular pertussis vaccine was developed and a transition from DTP to DTaP was accomplished to reduce the risk of pertussis-induced seizures in young children. The oral chlortetracycline vaccine for rotavirus was linked to a serious bowel condition (intussuscension), it was removed from the U.S. market. Ethylmercury has been banned from every major childhood vaccine manufactured for use in the United States, except the influenza vaccine, which continues to contain trace amounts.

This success, however, does not change the fact that millions of American children were exposed to levels of mercury through vaccines that exceeded federal guidelines. Many parents, and a growing number of scientists, believe that this mercury exposure may have contributed to the increase in the rates of autism, attention deficit hyperactivity disorder, and neurological and behavioral disorders that this country has experienced.

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 population.

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

babies and young children are exposed to this additional mercury. As developing fetuses, babies are exposed to mercury through the placenta; children and adolescents who have mercury amalgams, they are unknowingly excreting low levels of mercury on a daily basis to their fetuses. Additionally, women who receive vaccinations 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 anti-bacteriological agent.

3. Manufacturers of vaccines and thimerosal, (an ethylmercury compound used in vaccines), have never conducted adequate testing on the safety of thimerosal. The FDA has never required manufacturers to conduct adequate safety testing on thimerosal and ethylmercury compounds.

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

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

6. At the same time that the incidence of autism was growing, the number of childhood vaccines containing thimerosal was growing, increasing the amount of 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, including attention deficit hyperactivity disorder, and speech or language delay, and the increased use of thimerosal in vaccination and medical products.
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 cough syrups and cold medicines. Although an advisory committee determined that ethylmercury was unsafe in these products in 1990, a rule requiring its removal was not finalized until 1999.

9. The FDA and the CDC failed in their duty to be vigilant as new vaccines containing thimerosal were approved and added to the schedule. Although the Hepatitis B and Haemophilus Influenzae Type b vaccines were added to the recommended schedule of childhood immunizations, the cumulative amount of ethylmercury to which children were exposed nearly tripled.

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 CDC in general and the National Immunization Program in particular are duty to be vigilant as new vaccines containing thimerosal were approved and added to the schedule. Although the Hepatitis B and Haemophilus Influenzae Type b vaccines were added to the recommended schedule of childhood immunizations, the cumulative amount of ethylmercury to which children were exposed nearly tripled.

12. The amount of mercury in one dose of DTaP or Hepatitis B vaccines (25 micrograms each) exceeded this threshold many times over. Federal health officials have not conceded that the amount of thimerosal in vaccines exceeded the FDA's more relaxed threshold of 0.4 micrograms per kilogram of body weight. In most cases, however, it clearly did.

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 2001 prevented the public from exercising their responsibility. As a result, many children received vaccines containing thimerosal when thimerosal-free alternatives were available.

13. CDC's statement in 1999 that thimerosal is the sole remaining vaccine given to children in the United States on a regular basis that contains thimerosal. Two formulations recommended for children six months of age or older continue to contain trace amounts of thimerosal. Thimerosal should be removed from these vaccines. No amount of mercury is appropriate in any childhood vaccine.

14. The CDC in general and the National Immunization Program in particular are conflicted in their duties to monitor the safety of vaccines and mobilize a national effort to uncover the potential causes of the current autism epidemic.

15. 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. Two provisions are key: First, extending the statute of limitations as recommended by the Advisory Commission on Childhood Vaccines from 3 to 6 years. Second, establishing a one-year window for families, whose children were injured after 1988 but who do not fit within the statute of limitations, to have the opportunity to file under the NVICP.

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

17. 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.

THIMEROSAL HAS BEEN USED IN VACCINES AND OTHER MEDICAL PRODUCTS FOR DECADES

A. A brief description of mercury

Mercury is a heavy silvery-white metal, which unlike any other metal, is a liquid at room temperature. It flows so easily and rapidly that it is sometimes called quicksilver. The chemical symbol for Mercury is Hg.

Mercury has many properties that have made it popular for a number of commercial uses. For example, mercury expands and contracts as temperatures change; it also changes color. As a result, mercury has many uses, including as a thermometer. It is also used in various industrial applications, such as electrical switches and relays. Mercury is also used in some electric switches and relays to make them operate silently and efficiently. Industrial chemical manufacturers use mercury to create a variety of compounds, which are used in many different applications.

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null
were more widely spread in ethylmercury-treated rats.

While there is frequent reference to the paucity of science in understanding the harm that ethylmercury may cause, in understanding in the scientific community that government officials have shared with the Office of Safe Childhood Vaccines, that there is more data on ethylmercury and it’s as toxic as methylmercury.

Dr. Weldon: “I have a couple of questions for Dr. Baskin about ethylmercury versus methylmercury. I want to see what some of the public has been told 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 debate on ethylmercury and it’s as toxic as methylmercury.”

Dr. Weldon: “There is more data, more and more data on ethylmercury. The cells that I showed you dying in cell culture are dying from ethylmercury. Those are human frontal brain cells. You know, there has been a debate about... ethyl versus methyl. But from a chemical point of view, most chemical compounds that are ethyl penetrate into cells better than methyl. Cells have a membrane on them, and the membrane is made of lipids, fats. And ethyl as a chemical compound pieces fats and penetrates fat much better than methyl. So, you know, when I began to work with some of the Ph.D.s in my laboratory and discuss this everyone said, ‘oh gosh, you know, we’ve got to adjust for ethyl because it’s going to be worse; the levels are going to be much higher in the cells.’ So... I think at best they’re equal, but it’s likely they’re 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 understanding and data, 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. Weldon: “I take it from your testimony that the Committee repeatedly heard from government officials that merely exceeding the guideline was not cause for concern. One Merck official, in teaching a Grand Rounds session to staff in November of 1999, postulated that the minimum risk level would need to be multiplied by ten to reach a level at which harm would be expected through exposure. Dr. Roberta McCue of Merck wrote: “A number of environmental and public health agencies have established a benchmark called the Minimal Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the US Environmental Protection Agency, the Acceptable Daily Intake of the US FDA, and the Tolerable Daily Intake of the WHO. Any exposure to the substance below the MRL is assured to be safe, while exposure to ten times the MRL is assumed to place one at risk of overdose. Exposure at or near the MRL is assumed to be safe, but should trigger deliberate and careful review.”

Based on Dr. McKee’s explanation, many babies were exposed to levels of mercury that were considered safe but should trigger deliberate and careful review.
developing nervous system of the unborn 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 ag
gressive ban on Methyl Mer-
cury." In January 2001, Associate FDA Com-
missioner Melinda Plaider, responding to Congressmen's concerns regarding the National Academy of Sciences' report on Methylmercury, wrote:

"[I]f I were to reiterate, the FDA's commit-
tment to protecting the public's health and the environment regarding mercury." Furthermore, in their training materials for employees, the FDA reflects a slightly different order of priority on its list of the toxic effect of mercury or other neurotoxins than adults. "Exposures early in life are reasonably of greater health concern...because of greater brain organ suscepti-
bility."
The FDA has conceded in recent years that many children received doses of ethylmercury in their vaccines that exceeded the FDA's higher threshold. 3. Warnings Have Been Issued About Mercury in Seafood

The FDA's actions regarding the risk of medical exposures to mercury have differed greatly depending upon the number of ex-
posures to mercury. The agency has a long history of issuing warnings to the public to monitor their fish consumption due to con-
cerns about mercury exposure. During the 1990's, the FDA repeatedly issued warnings advising pregnant women and young children to avoid certain fish, or to limit their con-
sumption of these fish because of their mer-
cury content. In September of 1994, the FDA issued an advisory entitled, "Mercury in Fish: Cause for Concern?" in which they stated:"[S]wordfish and Shark taste great—espe-
cially grilled or broiled. But reports which state that these and other large predatory fish may contain mercury levels in excess of the Food and Drug Administra-
tion's 1 part per million (ppm) limit has dampened the appetites. "there is no doubt that when humans are exposed to high levels of methylmercury that poisoning and problems in the nervous system...the types of symp-
toms reflect the degree of exposure."

"During prenatal life, humans are suscepti-
to the toxic effects of high methylmer-
ccury exposure because of the sensitivity of the developing nervous system...Methyl-
mercury easily crosses the placenta, and the mercury concentration rises to 30 percent higher in fetal red blood cells than in those of the mother...none of the studies of methylmercury poisoning victims have clearly shown the level at which newborns can tolerate."

Pregnant women and children of child bearing age, who may be-
come pregnant, however, are advised by FDA experts to limit their consumption of shark and swordfish to no more than once a month."

Similarly, a March 2001 FDA advisory states:

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

In 2001, the FDA's Office of Dietary Supplements released a report on mercury in fish, stating that mercury is a neurotoxin that can cause brain damage and death. The report concluded that mercury can accumulate in the body and cause irreversible damage, especially in young children.

In 2002, the FDA issued a proposed rule to ban thimerosal from OTC topical ointments. In addition to raising concerns about the general effec-
tiveness of thimerosal in treating infections, the FDA found that thimerosal was too toxic for OTC use. Among the findings that they published were the following:

- thimerosal is highly allergic and that it is reason-
able to expect humans to be equally aller-
gic.
- thimerosal is highly toxic to human epithelial cells in vitro with mercaptide, mer-
curic, nitrate, and merbromin (mercuric thiophosphate).
- thimerosal is highly toxic to staphylococcus aureus.

Delayed hypersensitivity in 50 percent of the guinea pigs tested, indicating that thi-
merosal is highly allergenic and that it is rea-
sable to expect humans to be equally aller-
gic.

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 con-

tirmed.

In a 1996 study, 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 twins, and 26% of medics.

In 1992, the FDA advisory panel concluded that thimerosal was not generally recognized as safe. The Panel concludes that thimer-
osal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergenic property. It is not effective as a topical antiseptic because its bacteriostatic action can be re-
versed.

Despite this strong finding, the FDA's pro-
posed ban on the OTC use of thimerosal was not carried out until 1999. The agency stated at the time of the OTC review, the industry chose not to challenge the findings of the Panel relating to 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.

In the FDA advisory through that 18-year regulatory process to remove thimer-
osal from topical ointments, apparently no one at the FDA was prompted to review the thimerosal in vaccines. Action to re-
move thimerosal from vaccines did not begin until 1999, in response to the Congressional mandated review. This will be discussed in more detail later in the article."

At the time of the 1999 FDA review on thimer-
osal, it was learned that over 50 vaccines

"For fetuses, infants, and children, the pri-
mary health effects of mercury are on neuro-
logic development. Low levels of mer-
cury exposure, such as result from a mother's consumption of methylmercury in die-
tary sources, can adversely affect the brain and nervous system, attention, language and other skills have been found in children exposed to moderate levels in the womb."

"The decision for a Mercury Free at the NIH seeks to eliminate, as far as possible, the use of mercury in NIH facilities; to en-
courage the use of safer alternatives in bio-
medical research; to increase general aware-
ness of mercury hazards; and to prevent mer-
cury pollution."

This NIH program has initiated a "Hatters Pledge" program to recruit scientists to re-
duce the use of mercury at the NIH and to educate children on the dangers of mercury. One of the NIH Pledge members: 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 Depart-
ment (911) who are the NIH hazardous mate-
rial (HZMAT) emergency responder."

The Federal guidelines on mercury exposure have been included specific provisions for safe exposure limits for infants and children. It is widely accepted that infants and young chil-
dren are more sensitive than adults to the toxic effect of mercury or other neurotoxins than adults. "Exposures early in life are reasonably of greater health concern...because of greater brain organ suscepti-
bility."

The FDA has conceded in recent years that many children received doses of ethylmercury in their vaccines that exceeded the FDA's higher threshold.

3. Warnings Have Been Issued About Mercury in Seafood

The FDA’s actions regarding the risk of medical exposures to mercury have differed greatly depending upon the number of ex-
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cially grilled or broiled. But reports which state that these and other large predatory fish may contain mercury levels in excess of the EPA’s minimal risk level for methyl-
mercury. However, it is also clear that many infants received doses of mercury that exceeded a safe FDA’s higher threshold.

In 2001, the FDA’s Office of Dietary Supplements released a report on mercury in fish, stating that mercury is a neurotoxin that can cause brain damage and death. The report concluded that mercury can accumulate in the body and cause irreversible damage, especially in young children.

In 2002, the FDA issued a proposed rule to ban thimerosal from OTC topical ointments. In addition to raising concerns about the general effec-
tiveness of thimerosal in treating infections, the FDA found that thimerosal was too toxic for OTC use. Among the findings that they published were the following:

- thimerosal is highly allergic and that it is reason-
able to expect humans to be equally aller-
gic.
- thimerosal is highly toxic to human epithelial cells in vitro with mercaptide, mer-
curic, nitrate, and merbromin (mercuric thiophosphate).
- thimerosal is highly toxic to staphylococcus aureus.

Delayed hypersensitivity in 50 percent of the guinea pigs tested, indicating that thi-
merosal is highly allergenic and that it is rea-
sable to expect humans to be equally aller-
gic.

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 con-

tirmed.

In a 1996 study, 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 twins, and 26% of medics.

In 1992, the FDA advisory panel concluded that thimerosal was not generally recognized as safe. The Panel concludes that thimer-
osal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergenic property. It is not effective as a topical antiseptic because its bacteriostatic action can be re-
versed.

Despite this strong finding, the FDA’s pro-
posed ban on the OTC use of thimerosal was not carried out until 1999. The agency stated at the time of the OTC review, the industry chose not to challenge the findings of the Panel relating to 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.

In the FDA advisory through that 18-year regulatory process to remove thimer-
osal from topical ointments, apparently no one at the FDA was prompted to review the thimerosal in vaccines. Action to re-
move thimerosal from vaccines did not begin until 1999, in response to the Congressional mandated review. This will be discussed in more detail later in the article."

At the time of the 1999 FDA review on thimer-
osal, 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 recommended 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.

U.S. MILITARY VACCINE SCHEDULE

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>No. Doses</th>
<th>Initial entry</th>
<th>Troops in US</th>
<th>Deployed</th>
<th>Region or other</th>
<th>Thimerosal content</th>
</tr>
</thead>
</table>

[Table with details of vaccine schedule]

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

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

Adult weight with exposure rates according to EPA Safety Limit

100 pound: 0.1 mcg/45.359 kg of body weight per day = 0.16
120 pound: 0.1 mcg/54.431 kg of body weight per day = 0.28
150 pound: 0.1 mcg/68.039 kg of body weight per day = 0.45
180 pound: 0.1 mcg/76.467 kg of body weight per day = 0.58

It is clear from this chart that with a maximum safe limit of 0.16 micrograms in a day, individuals receiving either 100, 200, 150, or 135 micrograms in one day may be at risk for injury from mercury exposure. Even in keeping with the safety margin of 10 times the safety limit, recommended by Dr. Robert W. McKee of Merck, individuals at each of these weights would be exposed to levels of mercury that would be expected to put them at risk for adverse reactions.

The Committee received documentation from one Air Force pilot who suffered from serious symptoms of Gulf War Syndrome. After failing to have his medical issues resolved through the military or the Veterans Administration (VA) medical system, Capt. Frank Schmuck, a pilot, became so ill that he was no longer able to fly. He sought medical treatment outside the military medical system and was tested for heavy metals, and was found to have toxic levels of mercury in his system. 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 consider in their evaluations 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 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 increases between 1993 and 1998... In 1999, there were 2,462 children ages 3 to 21 in Indiana diagnosed with autism. That is one-fourth of 1 percent of all the school children in Indiana, or 1 out of every 400. This increase is not just better counting. If we want to find a cure, we must first look to the cause."

In July 2000, Dr. Stephanie Cave shared her observations about the rapid growth of autism and the pressures it is placing on families and medical professionals:

"I am in family practice in Baton Rouge, 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 350 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 that I have seen. 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, and U.S. Representative Christopher Smith contacted the CDC and the ATSDR for assistance. In response, the CDC...
conducted an extensive prevalence investigation.

The rate of autism among children in Brick Township was 4 per 1,000 (1 in 258) children aged 3 to 5 years old in 1986. The prevalence of the more broadly defined autism spectrum disorder was 6.7 per 1,000 (1 in 150) children. It is important to note that even though the families of Brick Township requested that the CDC include an evaluation of a possible link between autism and their children’s immunizations, it was not done. Their evaluation of the cause of the cluster of autism in Brick Township was inconclusive.

The CDC’s Atlanta study confirmed the dramatic results of the Brick Township study. The CDC found that 1,987 of the 289,456 children aged 3 to 10 years in metropolitan Atlanta in 1992 were autistic (1 in 146). These numbers were 10 times higher than studies conducted in the 1940s and early 1950s.

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

The main author of the study, Dr. Robert Byrd, said: “I am not intending to suggest a specific explanation for the rapid growth in autism with no explanation . . . there’s a number of things that need to be answered. We need to rethink the causes of autism.”

The 2002 report confirmed a 210 percent increase in the number of new children professionally diagnosed with the broader definition of autism in the United States in 1992 compared to 1987.

It is important to note that the figures reported in California do not include persons with Pervasive Developmental Disorder (PDD), PDD-Not Otherwise Specified (PDD-NOS), Asperger’s Syndrome, or any of the other milder autism spectrum disorders. The California data reflect only those children who have received a professional diagnosis of level 1 DSM-IV autism—the most severe form of autism.

3. The Causes of the Autism Epidemic Are Not Known

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

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

A summary of the developing theories on the causes of autism, as described in “Autism: The Story” by Barbara Loe Fisher is paraphrased below:

In 1943, when child psychiatrist Leo Kanner first described 11 cases of a new mental illness in children he said was distinguished by self-absorbed detachment from other people and strange behavior. He used the word “autistic” (from the Greek word, meaning “self”) Pointing out similarities with some behaviors exhibited by adult schizophrenics, those psychiatrists assumed autistic children were exhibiting early-onset adult-type psychoses. Kanner’s young patients came from well-to-do middle and upper class families in Baltimore with mothers and fathers who were doctors, lawyers and professors. In 1954, Kanner admitted that one autistic child was the 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 “refrigerator Mom” theory as the cause of autism, theorizing that the warm maternal instincts of educated working mothers was absent or diminished. Influenced by Kanner, pediatricians for decades were persuaded to blame mothers of autistic children for being cold and emotionally rejecting, causing the children in turn to coldly reject contact with other people.

By 1954, Kanner began modifying his “Blame the Mother” claim with a new hypothesis that brain injury is 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 “rejection parent” theme. Bettelheim, a holocaust death-camp survivor, insisted that the childhood autism in his relatives was caused by the warm maternal instincts of educated working 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 explanation of autistic behavior. He specifically challenged the notion that autistic behavior was a result of genetic or “constitutional inadequacies” or bad parenting. He instead pointed to the destructive guilt associated with having an autistic child and linking autism research in the direction of investigating the biological mechanisms underlying the brain and immune dysfunction symptoms and their possible causes.

In 1964, Dr. Rimland established the Autism Society of America (ASA). In 1967 he established the Autism Research Institute (ARI) and began distributing a questionnaire that 10,000 parents completed. In 1986, his databank includes information on more than 30,000 cases of autism from around the world. In analyzing the data for age of onset of autism, he discovered that before the early 1980’s, most of the parents reported their children first showed signs of abnormal behavior from birth or in the first year of life. But after the mid-1980’s, there was a re-awakening of this pattern. The numbers of parents reporting that their children developed normally in the first year and a half of life and were then diagnosed autistic doubled. Today, Rimland says that the onset-at-18-months children outnumber the onset-at-first year of life and are at least twice as frequent. According to Rimland, “the growth 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 and autism.”

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

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

The polysaccharide Haemophilus Influenzae B (Hib) vaccine was first licensed in 1985. It had 25 micrograms of ethylmercury and was given three times in the first six months of life (75 micrograms of ethylmercury) and a total of four times in the first two years of life.

The approval of the Hep B vaccine in 1986 made further thimerosal use not to be done in accordance with the recommended schedule. This vaccine contained 12.5 micrograms of ethylmercury and was given within hours of birth and a total of three times in the first six months of life (37.5 micrograms of ethylmercury). After 1986, some children went from getting 25 micrograms in one day or 75 micrograms in the first six months of life to getting 62.5 micrograms of ethylmercury in a day or 187.5 micrograms in the first six months of life. This would be in addition to the thimerosal exposure in the Hep B vaccine. In 1991, the CDC recommended that both Hib and Hep B be added to the universal recommendations for childhood immunization.

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 safety of ethylmercury, they concluded it was no different than methylmercury. As late as 1999, they compared it to the Federal limits for (ingested) methylmercury exposure. They were compelled to admit at that point that cumulative and cumulative ethylmercury in vaccines exceeded the EPA’s threshold for exposure to methylmercury. This led the
F.D.A. to recommend the removal of thimerosal from most pediatric vaccines in 1999, more than a decade after the Hepatitis B vaccine was added to the schedule.

In particular, the original problem was worse than the F.D.A. suggested. Not only did the cumulative amount of ethylmercury on the routine schedule exceed the EPA's threshold for the amount of ethylmercury in each individual shot of D.T.P. (or D.T.a.P.) and Hepatitis B exceeded the limit. Young children were getting many more doses of each. The F.D.A.'s threshold is 0.1 micrograms of methylmercury for each kilogram of body weight. This does not mean that injury would occur above this threshold because a significant safety margin is built in. However, the chances of injury increase as the exposure rises above this level. For an 11-pound infant (5 kilograms), the threshold would be roughly 0.5 micrograms. For a 22-pound baby (ten kilograms), the threshold would be 1 microgram. The D.T.P. (and D.T.a.P.) 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 amount of thimerosal they received in vaccines in the 1990's also exceeded the F.D.A.'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 doses of vaccines within a short period of time. This is an issue that pediatricians and other health care providers are faced with daily, and they have become used to giving multiple doses of vaccines in a short period of time. The practice has become commonplace with the new vaccine schedules recommending 26 doses of vaccines before school attendance.

Chairman Burton spoke about one such incident in a recent hearing: "The F.D.A. 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 his vaccines. According to his weight, the maximum safe level of mercury he should have been exposed to in 1 day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused.

When testifying before the Committee, Mrs. Lynn Redwood made the following observations: "It is true that the thimerosal contained in vaccines is a skin-disinfecting agent. In the past, the Merthiolate ointment was used to disinfect the skin in patients who are sensitive to any compound containing mercury. Merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to the drug. In view of these facts it is recommended that the package should be labeled to warn the consumer that the package may have been contaminated with mercury ointment and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to it. We should also inform the consumer that the skin in patients who are sensitive to one of the mercurials he may be sensitive to all of them."" In 1941, stated that he had observed a series of ocular injuries due to merthiolate and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to the drug. In view of these facts it is recommended that the package should be labeled to warn the customer that the package may have been contaminated with merthiolate ointment and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to it. We should also inform the consumer that the skin in patients who are sensitive to one of the mercurials he may be sensitive to all of them."

"Reimann has reported that some individuals display a sensitiveness to thio [thimerosal] compounds, which is characterized by reddening of the treated area and the appearance of a mucous membrane reaction."

In 1943, Dr. Elliss published a case report in the Archives of Ophthalmology, which states: "The positive results of patch tests demonstrated that the two individuals sensitive to tincture of merthiolate were also sensitive to 1:5000 merthiolate ophthalmic ointment and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to the drug. In view of these facts it is recommended that the package should be labeled to warn the consumer that the package may have been contaminated with merthiolate ointment and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to it. We should also inform the consumer that the skin in patients who are sensitive to one of the mercurials he may be sensitive to all of them."" In 1941, stated that he had observed a series of ocular injuries due to merthiolate and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to the drug. In view of these facts it is recommended that the package should be labeled to warn the customer that the package may have been contaminated with merthiolate ointment and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to it. We should also inform the consumer that the skin in patients who are sensitive to one of the mercurials he may be sensitive to all of them."

"For investigational vaccines indicated for multiple immunization, the use of single dose vials should be avoided to the extent possible in multi-dose vials. Of concern here is the potential neurotoxic effect of mercury on the developing central nervous system. By considering cumulative doses of this component in early infancy..."
“There is ample evidence from the literature that thimerosal (thimerosal) may cause sensitization and subsequent allergic reactions . . . the use of thimerosal is vaccines of thimerosal in accordance with various national vaccine programs may in certain cases result in approximately two times higher intake of ethylmercury during the first year of life. What can we do to ensure that exposure is reduced reasonably safe. Given the great uncertainty of the estimates of safe levels in young children, it is suggested to restrict the use of thimerosal in vaccines.”

In June of 2000, the CDC convened a closed meeting to discuss research evidence that showed a connection between thimerosal in vaccines and autism. This is the kind of respect you have to get real. We heard devastating medical evidence that children with autism suspect vaccines damaged their child. The parents are not reporting this using VAERS forms, (3) pediatricians are not reporting to VAERS either, (4) and despite efforts by policymakers at CDC, FDA, AAP, and VFC, families like Reynolds are all asking you, that we have seen in the courts. This is a test in one of the medical military hospitals.

The Committee has heard moving testimony from parents in support of this belief, as well as from parent-advocates. Shelley Reynolds is a mother of two from Baton Rouge, Louisiana. When she testified before the Committee in April of 2000, her autistic son, Liam, was four years old. Her testimony left no doubt as to her views: “Liam was a normally developing baby until June 27, 1997, when he received his MMR and Hib vaccines. He did everything he was supposed to do. He cooed, rolled over, crawled, pulled up and walked on time. He said ‘Mama,’ he said ‘Daddy,’ he said ‘Love you.’” He learned how to sing ‘It’sy Bitsy Spider.’ He played finger games with us. He loved to interact, and he especially loved to show off for his grandparents.”

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

At the same hearing, the Committee heard testimony from Jenea Smith of Denham Springs, Louisiana. At one 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.

“Liam was a normally developing baby until June 27, 1997, when he received his MMR and Hib vaccines. He did everything he was supposed to do. He cooed, rolled over, crawled, pulled up and walked on time. He said ‘Mama,’ he said ‘Daddy,’ he said ‘Love you.’” He learned how to sing ‘It’sy Bitsy Spider.’ He played finger games with us. He loved to interact, and he especially loved to show off for his grandparents.”
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 it was hard to tell if he could actually hear what was being said."

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

"We also believe that there is strong evidence that the adverse reaction to the host of vaccines that he received caused his autism."

"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 hide the 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 that 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 a direct linkage, a direct causation between vaccines and autism. I think it is imperative for us, the advocates for these people in the audience will tell you, is that they believe that there is a direct causal relationship, a direct causation between vaccines and autism."

"It is important to recognize the inherent methodological limitations of such studies in establishing causality. Studies may not have sufficient precision to detect very rare occurrences on a population level. A poor understanding of the risk factors and failure to understand of a causal relationship at the population level between MMIR vaccine and autism spectrum disorders."

"The IOM stated that the epidemiological evidence available at the time showed no association at a population level between the MMIR vaccine and autism. However, the authors cautioned that if the vaccine triggered autism in a small number of children who were predisposed to an adverse reaction, the population studies that had not shown a correlation to date would be too imprecise to detect that:"
and Neurodevelopmental Disorders." They found insufficient evidence to accept or reject a connection between thimerosal in vaccines and autism. They did, however, state that such a connection is "biologically plausible," and recommended much more research on the issue.

The report summarized:

"The committee concludes that although the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders is not established by current evidence, it is not inconsistent with available information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given in children, the hypothesis is biologically plausible."

"* * * * *

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

The IOM noted that it had reviewed the results of one unpublished epidemiological study that detected a "statistically significant but weak association" between exposure to thimerosal and several types of developmental disorders, including attention deficit disorder, speech and language delay, tics, and general neurodevelopmental disorders. 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. Dr. Haley, who was a member of the committee that reviewed the study, recommended that the CDC perform research of this type throughout the country. To help the scientific community better determine whether such a connection is "biologically plausible," and recommended much more research on the issue.

The "VSD Study" is discussed at greater length in Section VII. The IOM also noted with some discomfort that thimerosal had not been removed from all vaccines and medications given to children and pregnant women. The report specifically cited the influenza vaccine, the diphtheria-tetanus toxoid vaccine, and some nasal-spray influenza vaccines. Dr. Haley urged that "full consideration be given by appropriate professional societies and government agencies to removing thimerosal from vaccines and from those vaccines given to infants, children or pregnant women in the United States." It was also recommended that any remaining stocks of childhood vaccines containing thimerosal be removed from doctor's offices and replaced with mercury-free alternatives.

Finally, the report recommended that numerous types of research be conducted to help the scientific community better determine if there is a causal relationship between thimerosal and autism or other disorders.

Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines;

Epidemiological studies comparing the prevalence of autism in children not receiving thimerosal-containing vaccines versus children who did not receive thimerosal-containing vaccines during clinical trials;

Clinical research on how children metabolize and excrete mercury;

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

Research in appropriate animal models on neurodevelopmental effects of ethylmercury;

Rigorous scientific inquiry into any similarities of thimerosal for countries that decide they want to follow the example of Europe and the United States and terminate its use in vaccines.

A growing number of researchers believe that there may be a link between the mercury preservative in vaccines and autism spectrum disorders and other neurodevelopmental disorders. Few, if any, would make such a statement categorically until more research is done. However, judging by testimony received by the Committee, many researchers believe that this hypothesis is plausible and that work should move forward. They believe that this is a promising field of research that may yield breakthroughs on the question of the underlying causes of the growing incidence of autism and other neurodevelopmental disorders.

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

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

"I was requested to do an evaluation of the potential toxicity of the thimerosal-containing thimerosal as a "preservative" versus those vaccines containing thimerosal. The results were very dramatic as shown in the accompanying Table 1. I 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 reports that thimerosal-containing vaccines versus non-thimerosal containing vaccines as observed in cell culture studies reported in 1986. The chemical rationale for these results is that thimerosal-containing vaccines would release ethyl-mercury as one of its breakdown products. Ethyl-mercury is a well-known neurotoxin. Further, the alternative to thimerosal levels of aluminum cation plus significant levels of formaldehyde, also found in these vaccines, would make the vaccine mixture of even greater risk than thimerosal."

"Dr. Haley went on to state that infants are more susceptible to damage from mercury, because the defense mechanisms in their bodies are immature and so there must be something specific or contributory factor to the cases of autism we see in this country?"

"* * * * *

"Using this vaccine mixture on infants, who do not have fully developed bile acid synthesis in the renal (kidney) and dramatically increase the toxic effects, especially if they are spuriously ill. The toxic effects of exposure to thimerosal in infants cannot be reasonably extrapolated from those observed in adults made toxic by exposure to similar ethyl-mercury containing compounds. Mercury is primarily removed from the body through the bile system and is removed by the renal system. Inability to rid the body of these toxics would greatly increase the damage they are capable of doing in infants."

Dr. Haley's concerns about the inability of infants to fend off the adverse effects of mercury were echoed by Dr. David Baskin. Dr. Baskin is a neurosurgeon and a professor of neurosurgery and anesthesiology at Baylor College of Medicine. He has been involved in extensive research on the central nervous system and serves on scientific advisory boards of the National Institutes of Health. Testifying before the Committee in December of 2002, Dr. Baskin said:

"Dr. Haley's concerns about infants' brains are more sensitive. We know the blood-brain barrier, the barrier to drugs between the blood and the brain, is virtually gone in infants."

"At all regulatory agencies, tests performed by the Committee have hypothesized that some children must have had a genetic pre-disposition that makes them more vulnerable to neurological damage from those vaccines. An exchange between Congressman Burton and Dr. Baskin at the December 10, 2002, hearing reflected this emerging consensus:"

"I think you're right. Do you think that you believe from your studies that the mercury is a contributing factor to the cases of autism we see in this country?"

"* * * * *

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

"* * * * *

Dr. Baskin: "I think it's hard to look at a particular individual like that. I think the problem is, on one hand, there is probably an environment-genetic interaction. In other words, a lot of children get the injection and don't become autistic, others do. But the specific factors or the way the way a certain subgroup of children are able to handle toxins. . . . I don't think we yet know the answer to that."

"* * * * *

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

"If you have APO–E4, you can carry out mercury for every atom of APO–E that goes through the barrier to drugs between the blood and the brain. Dr. Haley's concerns about the inability of infants to fend off the adverse effects of mercury were echoed by Dr. David Baskin. Dr. Baskin is a neurosurgeon and a professor of neurosurgery and anesthesiology at Baylor College of Medicine. He has been involved in extensive research on the central nervous system and serves on scientific advisory boards of the National Institutes of Health. Testifying before the Committee in December of 2002, Dr. Baskin said:

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to detoxify the cerebral spinal fluid may be at least part of the neurological aspect of this disease.

Dr. Baskin described research he is conducting which demonstrates what the effects of mercury are when it is not removed from brain tissue: "Let me turn to some studies that we're doing in our 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 develop when infants ingest these cells with thimerosal at various doses, and we use a number of very sophisticated techniques to detect cell death and cell damage."

* * * * *

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

"Here is a slide where you see a lot of blue cells. These microglia and macrophage cells don't take up. In order for something to turn blue, the cell has to have holes punched in its membranes. And guess what: At an extraordinary low dose of thimerosal, most of these holes 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 the plaques 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, and I remember that infant brain cells are much more sensitive, so there's a real cause for concern.

Dr. Baskin testified that other researchers in his field have come 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 macrophage cells grab a hold of the membrane and punch holes into it, so that the dye can penetrate, not only the plaques but into the very center of the cell, the nucleus, where all the DNA exists."

* * * * *

"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 FDA continues 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 EPA's threshold for methylmercury exposure: "During the first months of life, cumulative exposure to mercury could have exceeded the more conservative limits of the EPA 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 recommended schedule of childhood vaccinations exceeded the EPA's threshold for methylmercury exposure:

"During the first months of life, cumulative exposure to mercury could have exceeded the more conservative limits of the EPA 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 vaccines exceeded the EPA's threshold for methylmercury exposure:

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

Dr. Midthun's careful couched statement suggested that there were many instances in which U.S. infants were exposed to cumulative amounts of ethylmercury from their vaccines that were significantly lower than the EPA's threshold for methylmercury. In the 1990s, at least, this does not appear to have been the case. It is clear that the DTaP, Hepatitis A and B vaccines exceeded the EPA's threshold individually for almost all infants, without even considering cumulative amounts, in fact, as will be discussed in the next section of this report, the amount of ethylmercury in these vaccines also exceeded the FDA's higher threshold of 0.4 micrograms per kilogram. It is clear that the DTaP, Hepatitis A and B vaccines exceeded the EPA's threshold individually for almost all infants, without even considering cumulative amounts, in fact, as will be discussed in the next section of this report, the amount of ethylmercury in these vaccines also exceeded the FDA's higher threshold of 0.4 micrograms per kilogram.

One vaccine policymaker, who was at least partially swayed by the Faroe Islands studies and other evidence, was Dr. Neal Halsey, director of the Center for Vaccine Safety at Johns Hopkins University. Dr. Halsey was an influential member of Federal advisory committees that oversaw the expansion of the Federally recommended schedule of childhood vaccines in the 1990s. By all accounts, Dr. Halsey was instrumental in the study that led to the removal of thimerosal from childhood vaccines in 1999.

In contrast to Dr. Midthun's statements, Dr. Halsey's testimony to the Senate Finance Committee in 2002 claimed that he was astonished when he reviewed an FDA analysis of how much mercury was in vaccines being given to children:

"My first reaction was simply disbelief, which was the reaction of almost everybody involved in vaccines. In most vaccine containers, thimerosal is listed as a mercury derivative. It is a hundredth of a percent of what I believed, and what everybody else believed, was that it was truly a trace, a biologically-insignificant amount. My honest belief is that if the labels had the mercury content in micrograms, this would have been uncovered years ago. But the fact is, no one did the calculation."

"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. Halsey clarified that he still does not believe that there is a connection between thimerosal and autism:

"Neal 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 impairments. His statement specifically referred to the Faroe Islands studies and the calculation that the cumulative amount of thimerosal in childhood vaccines exceeded the EPA's limits for methylmercury:

"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 adults who as fetuses were exposed to low to moderate amounts of methylmercury through fish consumption, instead of mother's increased risk for having mild neurological learning deficiencies. The findings from the studies did not show an association between methylmercury exposure and autism."

"As a precaution and in an effort to make vaccines as safe as possible, Dr. Halsey worked with the American Academy of Pediatrics and the Public Health Service in 1999 to urge reductions in exposure to mercury, in all its forms, for infants and children, and to discontinue using thimerosal as a preservative whenever possible.

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

To date, very little epidemiological or clinical research has been done on the neuro-developmental 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 more extensively. There have been many 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 2000. This study reviewed several 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 and the results are now generally out of date.

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

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

- "We have shown that very low concentrations of ethylmercury can be detected in children aged 2-6 months who have been given vaccines containing thimerosal [sic]. However, no children had a concentration of blood greater than 29 parts per billion, which is the concentration thought to be safe in cord blood."

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

Skepticism of a vaccine-autism connection hailed this study. However, its value is limited by a number of criticisms that have been raised since its publication. Some of the most commonly cited shortcomings were discussed in testimony at the Committee's December 4, 2002 hearing by Baylor University's Dr. Baskin.

1. The sample size was very small:
- "Only 40 children who received thimerosal were included. A much larger 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 one child had some condition, yet another had a similar condition in their blood to absorb more mercury or little it remain in the blood longer or be more sensitive in their brain, if they only checked 40 kids, you would have found in one kid with a predisposition to autism.""

2. The sample was not random:
- "In his testimony, Dr. Baskin commented on this point. In the study's inability to measure the effects of ethylmercury in the bodies of infants at various times beyond peak levels, it did not attempt to determine the effects of the mercury on their bodies. This limitation was clearly brought out in an exchange between Congressman Burton and Dr. Christopher Portier, Director of the Environmental Toxicology Program at the National Institute of Environmental Health Sciences:
  
  "Mr. Burton: "Does the study recently published in The Lancet identify the effects of mercury on infants who are vaccinated with thimerosal?"

  "Dr. Portier: "No."

  "Given the small sample size, the failure to measure mercury at peak levels, and the study's inability to measure the effects of ethylmercury in the bodies of infants, it is difficult to understand how they came to their conclusion that "the thimerosal in routine vaccines poses little risk to full-term infants." If anything, the limitations of this study point out the need for much more research to be done. As Dr. Baskin pointed out: "They described this as a descriptive study, and that's exactly what it was. It provides a starting point, it's a start, but the interpretation is inaccurate.""

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

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

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

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

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

It is clear that the guiding principal for FDA policymakers has been to avoid shaking the public's confidence in vaccines. For this reason, many FDA officials have stubbornly denied that thimerosal may cause adverse reactions. Ironically, the FDA's diluting its guidance in response to public concern on thimerosal product by product, and removing thimerosal from vaccines earlier, may have done more long-term damage to the public's trust in vaccines than confronting the issue head on.

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

B. Thimerosal manufacturers accumulated evidence of the toxicity of thimerosal

Eli Lilly And Company of Indianapolis licensed thimerosal in 1930. It was marketed under a number of trade names, but it was used extensively both in topical ointments to prevent infections and as a preservative in a variety of medicines. However, it now appears the issue was 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 issue head on.

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

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 spokespersons would refer to that original study as evidence of thimerosal's safety. However, it is now clear that this uncontrolled study was woefully inadequate.

As previously discussed in this study, an intravenous solution containing thimerosal was tried as an experimental treatment for meningitis. While the treatment was found to be ineffective, the doctor who conducted the study concluded that the solution caused no harmful side effects. It is clear today that such a limited number of subjects, all suffering from the same serious illness, would
hardly qualify as a sufficiently sized random sample, and a study such as this one would be of very little value by today's standards. In fact, an internal Eli Lilly memo from 1972 candidly admitted that dog safety was not a concern. The company indicated that Merthiolate was not appropriate for use in dogs: "Considering the type of patient involved, one might question these observations (the appearance of no deleterious action) as providing no 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. "Due to the length of time this product has been on the market, its efficacy and safety have been proven by over forty years of use throughout the world. Because of this long period of use, it would be difficult to get recognized researchers to conduct new studies for safety or efficacy. They believe that over forty years of wide usage has proven efficacy and safety beyond that which could be done in special studies." Despite Mr. Burrow's contention, numerous independent researchers recognized the lack of data on thimerosal and suggested the need for more research:

A 1947 paper published by an Army physician in Baltimore reported that Merthiolate was causing contact dermatitis in his patients. He concluded: "No eruptions or reactions have been observed or reported to Merthiolate internally, but it may be dangerous to inject a serum containing Merthiolate into a patient sensitive to Merthiolate." A 1948 paper from an Arizona doctor reported that Merthiolate was toxic when injected intradermally and that a "more marked local reaction than does phenol or trichrosol." A 1949 article in the Journal of the American Medical Association stated: "Perhaps more disturbing is that Lilly's experience with the solution ought to serve as a warning we ought not to advocate the use of it in situations where it is not indicated. The problem is that Lilly's use of thimerosal was not meant to protect than the bacteria it was meant to protect. It was a toxoid, a vaccine to cause an immune response.

The FDA was painfully slow to require the removal of mercury from over-the-counter products. No individual submitted a petition to the FDA to do this, and the agency itself acted without any public review. The FDA 18 years to remove mercury from over-the-counter products, the FDA would not formally require the removal of mercury from these products for another 18 years. The submission of the committee's report in 1980 set in motion a tortuous bureaucratic process that would not result in the banning of mercury from over-the-counter products until 1996. The agency published Advanced Notice of Proposed Rules or Notice of Proposed Rules regarding these products in 1980, 1982, 1990, 1991, 1994 and 1995. The most recent 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 ban mercury-containing products it received none. At the time of the FDA's final action, there were 20 over-the-counter products 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 remove mercury from over-the-counter products. It is equally difficult to understand why the expert panel's 1980 findings on thimerosal's safety led top officials at the FDA to further and immediately review the use of thimerosal in vaccines. Surely there must have been concern that if it was not safe for OTC topical use because of its allergic nature, thimerosal in vaccines might be even more hazardous. Perhaps the concern for mercury in the environment would be addressed, and we could finally get to obtaining data on the metabolic deposition of Merthiolate.

A 1972 letter from the Pittman-Moore Company indicated that Merthiolate was not appropriate for use in dogs:

"We have obtained marked local reaction in about 50% of the dogs injected with serum containing dilutions of Merthiolate, varying in 1 in 40,000 to 1 in 5,000, and we have demonstrated that there is no connection between the lot of serum and the reaction. In other words, Merthiolate is unsatisfactory as a preservative for serum in intradermally injected dogs do not show the local reaction, but in some instances, the reaction is extremely severe. I might say that we have tested Merthiolate intradermally and it gives a more marked local reaction than does phenol or trichrosol." A 1973 article in the Journal of the American Medical Association stated: "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 use is not effective as a topical antimicrobial because its bacteriostatic action can be reversed." Despite the fact that the expert committee found thimerosal and other ethyl-mercury compounds unsafe and ineffective for over-the-counter products, the FDA would not formally require the removal of mercury from these products for another 18 years. The submission of the committee's report in 1980 set in motion a tortuous bureaucratic process that would not result in the banning of mercury from over-the-counter products until 1996. The agency published Advanced Notice of Proposed Rules or Notice of Proposed Rules regarding these products in 1980, 1982, 1990, 1991, 1994 and 1995. The most recent 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 ban mercury-containing products it received none. At the time of the FDA's final action, there were 20 over-the-counter products containing mercury being marketed by eight different manufacturers. Their silence on this point is telling.
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 made until 2001, after it had been publicly debated缠困 in the Federal Register no fewer than five times prior to the FDA’s belated review of mercury in vaccines.

What caused 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 Vaccine Modernization Act. Among other things, this law required the FDA to compile a list of foods and drugs that contained mercury. This list was introduced into Congress by the CDC’s Center for Disease Control to study its effects on the human body, and restrict its use if found to be harmful.

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

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

There was tremendous reluctance on the part of some officials to admit that a mistake had been made in allowing ethylmercury to be used in vaccines. There was great uncertainty in others caused by the lack of data specifically on ethylmercury. However, the institutional resistance to change was counter-balanced by the growing realization that there was no ethylmercury in childhood vaccines than previously thought, and that nobody had thought to calculate the cumulative amounts of ethylmercury in vaccines. Some of the debate was captured in a 1999 e-mail from a former FDA official weighing the pros and cons of taking action. He opined that hastening the removal of thimerosal from vaccines would “…raise questions about FDA being ‘asleep at the switch’ for decades by allowing a potentially dangerous component to continue in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various federal actions regarding the review of recommendations for use. (We must keep in mind that the dose of ethylmercury was not generated by ‘rocket science’. Conversion of the thimerosal to ethylmercury involves simple micrograms of mercury involves ninth grade algebra. What took the FDA so long to do the calculations? Why didn’t CDC and the Advisory Committee do these calculations when they rapidly expanded the childhood immunization schedule?”

It is clear that each time an important decision moved forward, the fact that thimerosal’s dangers and favored a “go-slow” approach, were able to water down the actions. In 1999, when the Federal government could have ordered thimerosal removed from vaccines by a specific date, or stated a preference for thimerosal-free vaccines, a statement was instead issued asking families to refrain from vaccine manufacturers to eliminate or reduce mercury in vaccines as expeditiously as possible. As a result, almost two years passed before the three thimerosal-containing vaccines—DTaP, Hib and Hepatitis B—were being manufactured in thimerosal-free formulas. In 2001, when the CDC and its influential 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 vaccinated with expired-preparing vaccines that have lingered in medical offices or clinics.

The CDC’s decision not to endorse thimerosal-free vaccines in 2001 is particularly troubling. With the exception of the influenza vaccine, all major childhood vaccines are thimerosal-containing, but there being a debate about 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 removing mercury from 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 FDA’s CBER. Despite the general lack of scientific research on the toxicity of ethylmercury, 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 to thimerosal.

An exchange of e-mails in October of 1998 makes clear that Dr. Leslie Ball was already leaning toward thimerosal-free vaccines. It also makes clear that there was internal resistance to such an action.

Dr. Marion Gruber of the Office of Vaccine Safety, a former oncologist and internal FDA memo to Dr. Ball, which concluded that:

- no scientific database to take regulatory actions and to recommend to take thimerosal either out of vaccines or to leave it in. In fact, somebody should perform the adequate studies on the toxicity of thimerosal or its metabolized forms.

Dr. Ball’s response on October 15, 1998, to Dr. Hastings’s conclusion was sharp:

“I disagree about the conclusion regarding no basis for removal of thimerosal. On a strictly scientific basis, yes, there are no data that have looked at the specific issue of thimerosal in vaccines. However, there are facts/data that would argue for the removal of thimerosal in vaccines on methylmercury exposure in infants and the knowledge that thimerosal is not an essential component to vaccines. In addition, the European community is moving to ban thimerosal.”

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

An important part of the FDA’s review was a comparison of the amount of ethylmercury in vaccines to the recommended safe levels for exposure to methylmercury established by the EPA. The result was a comparison of the amount of ethylmercury in infants and proved to be much lower than the amount of ethylmercury in infants and the knowledge that thimerosal is not an essential component to vaccines. In addition, the European community is moving to ban thimerosal.

The amount of ethylmercury in children’s vaccines exceeded the EPA’s limits for exposure to methylmercury. (0.1 micrograms per kilogram for the first six months of their lives. Even more significant, the charts also indicate that most children received doses of ethylmercury that exceeded the EPA’s limits for exposure to methylmercury. (0.1 micrograms per kilogram for the first six months of their lives. Even more significant, the charts also indicate that most children received doses of ethylmercury that exceeded the EPA’s limits for exposure to methylmercury. (0.1 micrograms per kilogram for the first six months of their lives. Even more significant, the charts also indicate that most children received doses of ethylmercury that exceeded the EPA’s limits for exposure to methylmercury. (0.1 micrograms per kilogram for the first six months of their lives.

Federal officials have never publicly acknowledged this second fact. In public statements and Congressional testimony, they have acknowledged only that the EPA’s exposure guidelines do not apply to thimerosal.

In a July 2, 1999, e-mail, Dr. Ruth Etzel of the Public Health Service’s resistance: “We must follow the three basic rules: (1) expose as few infants as possible to inactivated vaccines that have more mercury than we realize; (2) be open with consumers about why
As a result of the limited steps taken in 1999, the public loss of thimerosal re- mained on the market for nearly two years. GlaxoSmithKline’s Hepatitis B vaccine did not become thimerosal-free until March of 2000, and Merck’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 were still being used in situations where the fact that thimerosal-free versions were available.

"It could entail financial losses for all ex- isting stocks of vaccines that contain thimerosal."

The financial health of the industry should not have been a factor in this decision. The financial health of vaccine manufacturers certainly should never have been more im- portant to the Federal health officials than the health and well being nation’s children. The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neuro- logical consequences of mercury in vaccines on children—and there were substantial doubts—the prevailing consideration should have been how best to protect children from harm. However, that protecting the industry’s profits took prece- dence over protecting children from mercury damage.

"As I said, the policy seems to be working. So this indicates that on this particular fac- tor, this policy is moving us in an upward di- rection towards something."

In rejecting a statement of preference for thimerosal-free vaccines, the Advisory Com- mittee 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 for Hepatitis B. One of the factors that were all considered was the fi- nancial health of the vaccine industry. In de- scribing the pros and cons of each option, Dr. Bernier returned several times to financial issues: "We think that having this type of a more stage transition reduces the potential for fi- nancial losses in the short-term, and is somewhat akin to what was done in the tran- sition from oral polio to inactivated polio..."

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

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

The financial health of the industry should not have been a factor in this decision. The financial health of vaccine manufacturers certainly should never have been more im- portant to the Federal health officials than the health and well being nation’s children. The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neuro- logical consequences of mercury in vaccines on children—and there were substantial doubts—the prevailing consideration should have been how best to protect children from harm. However, that protecting the industry’s profits took prece- dence over protecting children from mercury damage.

"Roger, you said that after july, the maxi- mum exposure will be 75 micrograms. My understanding from when the develop- ing 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 sub-committee was passed over without any com- ment."

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

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Again, it appears that this seemingly sen- sible proposal received no serious consider- ation.

One year later, in June of 2001, the Advi- sory Committee again rejected the idea of expressing a preference for thimerosal-free vaccines, despite the fact that the manufac- turers of Hib, Hepatitis B and DTaP had shifted to thimerosal-free products at that point. The CDC’s decision not to express a preference for thimerosal-free vaccines, and the Advisory Committee’s concurrence in this policy, was an abdication of their re- sponsibility. As a result of their inaction, children continued to receive vaccines containing ethylmercury at a time when there were serious doubts about its safety.
What makes the CDC’s decision even more vexing is that just prior to the Advisory Committee meeting in 2000, a study conducted by the CDC suggested that there was at least a correlation between levels of 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 adverse events following thimerosal-containing vaccines and selected neurological disorders. Phase II was designed to test the hypotheses generated in the first phase.

Phase I indicated 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 intellectual delays. The study did not find a correlation between thimerosal and autism because the sample size of children diagnosed with the disorder was too small to draw a statistically significant conclusion.

The findings of Dr. Verstraeten, the primary author of the study, set off a fire alarm within the Federal health agencies when they were released in June of 2000. Enough concern was generated that a conference was called at the Simpsonwood Retreat Center near Atlanta. At this conference, Dr. Verstraeten explained that the study underestimated the numbers of children with developmental disorders, including autism. This occurred because the youngest subjects in the study were just one year old; such disorders were likely to be diagnosed. He commented:

"But one thing that is for sure, there is certainly an under-representation of some of these [disorders] because some of the children are just not old enough to be diagnosed. So the crude incidence rates are probably much lower than what you would expect because the cohort is still very young."

Dr. Colleen Boyle of the CDC raised this point at the meeting of the National Vaccine Advisory Committee in the summer of 2000. FDA officials spoke passionately about this issue at the conference, branding the scientific consensus on the safety of the vaccine “miseducated.”

At this conference, Dr. Verstraeten declared his study was not conclusive. He said: "I do not want that grandson to get a Thimerosal-containing vaccine until we know better what is going on. It will probably take a long time before I can tell you that. In the meantime, I know that there are probably implications for this internationally, but in the meantime I think I want that grandson to only be given Thimerosal-free vaccines."

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

"So what were the responses of the consultants? With regard to the first question, a need for further investigation. Overall the group expressed unanimous feeling that the findings were supplanted by significance, although weak, association, but that the implications—for obvious reasons—are profound. Therefore, the consultants were unanimous in their further investigation should be pursued with a degree of urgency and, parenthetically, not only for public health policy in this country, but for public health policy in the world."

Simpsonwood Retreat Center had many unexplained case reports of autism. The knowledge about this vaccine was not at this point. Dr. Verstraeten went on to say:

"I know that much of this is very hypothetical and, personally, I would rather not engage in that argument. This study debunks this entire thimerosal debate, as I think they are as comparable as apples and pears at the best. Unfortunately I have witnessed the small number of children who are diagnosed with this issue, do not seem bothered to compare apples to pears and insist if nothing is happening in these studies, then nothing should be done. I do not wish to be the advocate of the anti-vaccine lobby and sound as if I am convinced that thimerosal is or was harmful; but at least I feel we should use sound scientific argumentation, and not let our standards be dictated by our desire to disprove an unpleasant theory."

It appears that Dr. Verstraeten participated in the thimerosal debates allowed their standards to be dictated by their desire to disprove an unpleasant theory. The decision by the CDC not to state a preference for mercury-free vaccines is especially difficult to understand, given the deep-seated concerns many policy-makers had about the potential impact of ethylmercury on the fragile central nervous systems of developing babies. The FDA officials spoke passionately about this problem at a meeting of the National Vaccine Advisory Committee this summer of 1999. Dr. Katherine Zoon stated:

"We need to understand more about thimerosal because in the past two days, I have seen this clinically a paucity of data, And I think some of the points made about looking at the developing nervous system, looking 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 we need to study this issue more carefully.

At the same meeting, Dr. Bernard Schwetz, the Director of the FDA’s toxicology center, stated:

"We need to understand more about 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 unreasonable to expect that there would be particular windows of sensitivity during 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 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 refrainthe Committee throughout its three-year investigation is that much research has been done. The Committee has heard testimony from parents, scientists and government officials that much more research is needed and that well-designed 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.
- Possibility relationships between vaccine ingredients like thimerosal and autism.
- The neurotoxicity of ethylmercury.
- The neurotoxicity of dental amalgams containing mercury.
- Immune system and gastrointestinal system dysfunction after vaccination.
- In 2002, 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 made the following research recommendations:

Use accepted and consistent case definition assessment tools for autism spectrum disorders.

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. Case reports of MMR vaccine and ASD, rechallenge refers to children who appeared to have experienced some form of neurological regression after a prior MMR vaccine-containing vaccine and who appeared to have experienced another regression following a second dose of MMR or other measles-containing vaccine.

Study the possible effects of different MMR immunization exposures.
Conduct further clinical and epidemiological studies of sufficient rigor to identify risk factors and biological markers of ASD in order to better understand genetic or environmental factors.

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

Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines;

Further study of children who did not receive thimerosal-containing doses of vaccines during clinical trials;

Epidemiological studies comparing the prevalence of neurodevelopmental disorders in children who received vaccines before thimerosal was removed to children who received vaccines after it was removed;

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

Clinical research on how children metabolize and excrete thimerosal.

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

Research in appropriate animal models on neurodevelopmental effects of ethylmercury;

Rigorous investigations of thimerosal as a treatment for neurodevelopmental disorders;

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

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

Another concern is the lack of a sufficient investment into research on autism and its causes. Autism is growing at epidemic proportions and nobody knows why. The rates of autism doubled during the Committee’s investigation, yet funding for research on autism lags badly behind funding for other serious diseases. The NIH, with a budget of $2 billion per year, invested just $5.6 million towards autism research. Much of that research has been focused on looking for genetic causes of autism, which is important, but does not address the possible connection to vaccine injury. To put the spending on autism in perspective, the Committee compared it to the spending on two other serious epidemics—HIV/AIDS and diabetes. At the same time that the NIH was spending $5.6 million on autism research, they spent $168 million on diabetes research and over $2.2 billion on HIV/AIDS research.

The Centers for Disease Control and Prevention has also been negligent in addressing the research needs regarding vaccine injury and autism. In FY 2002, the CDC invested $11.3 million on autism, while spending $62 million on diabetes, and $922 million on HIV/AIDS. With spending on vaccines three times less than spending on AIDS, it is obvious that CDC is not addressing the autism epidemic with enough rigor. Instead, at the time of the Committee’s April 2002 hearing, the CDC actually planned to cut autism research spending to $10.2 million.

Of additional concern has been the CDC’s bias against theories regarding vaccine-induced autism. Rather than aggressively work to replicate clinical findings with laboratory experiments, the CDC has exaggerated the supposed relationship between vaccines and autism, (the Wakefield autism entercolitis studies), the CDC funded researchers who also worked for vaccine manufacturers, and in uncontrolled, population-based epidemiological studies to look at the possible correlation between vaccine injury and a subset of the population that might be injured. The CDC’s funding is too heavy on epidemiological findings. While epidemiological studies are important, they are not a substitute for focused, clinical research.

Chairman Burton expressed some of these concerns at the June of 2002 hearing: “Officials at HHS have aggressively denied any possible connection between vaccines and autism. They have waged an information campaign endorsing one conclusion on an issue where the science is still out. This has significantly undermined public confidence in the safety of vaccines and is increasing immunization rates. Parents come to us with concerns that integrity and an honest public health response to a crisis have been left by the wayside in lieu of protecting and promoting a health agenda to fully immunize children. Parents are increasingly concerned that the Department may be inherently conflicted in its multiple roles of promoting immunization, regulating vaccine manufacturers, looking for adverse events, managing the vaccine injury compensation program, and developing new vaccines. Families share my concern that vaccine manufacturers have too much influence as well. How will HHS restore the public’s trust?”

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

IX. CONCLUSIONS

It is obvious from all accounts that there is a crisis in the United States regarding the dramatic rise in autism rates and the resulting strain placed on families, the education system, and State Medicaid and disability programs. A further crisis will ensue in the next two decades when we see an explosion of these fetuses and infants who were not exposed to thimerosal. The question that mercury does not belong in vaccines.

There are other compounds that could be used as preservatives. And everything we know about the neurotoxicity of mercury at the fetus at and the infant level, points out that we should not have these fetuses and infants exposed to mercury. There’s no need of it in the vaccines.”

The Food and Drug Administration’s (FDA) mission is to “protect and promote the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety.” However, the FDA uses a subjective barometer in determining when a product has that known risks can remain on the market. According to the agency, the harm that the FDA product evaluation decisions is a judgment about whether a new product’s benefits to users will outweigh its risks. No regulated product is risk-free. But in some cases, the FDA’s judgment on risk-free products is 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 the risk of neurological damage from exposure to thimerosal in vaccines—is one that has continuously been presented to the Committee by vaccine manufacturers. FDA has affirmed that any possible risk from thimerosal was theoretical, that no proof of harm...
Thimerosal used as a preservative in vaccines is related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies’ failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry.

NATIONAL WAR PERMANENT TRIBUTE HISTORICAL DATABASE ACT

HON. MARK UDALL
OF COLORADO
IN THE HOUSE OF REPRESENTATIVES
Wednesday, May 21, 2003

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.

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

HON. FORTNEY PETE STARK
OF CALIFORNIA
IN THE HOUSE OF REPRESENTATIVES
Wednesday, May 21, 2003

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

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

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

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

The Medicare Out-of-Pocket Spending Limit Act will offer seniors the security of knowing that they will never have to pay more than $2,000 out-of-pocket on Medicare services per year. Current and future Medicare beneficiaries will have the option of enrolling in this new, voluntary benefit at an affordable premium. Beneficiaries with incomes below 175 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 new benefit would be protected from extraordinary out-of-pocket costs when they need medical care. The additional benefit—created under a new Medicare Part D—would have the following features:

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

Cost. 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. Benefits 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