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

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

HONORING THE 62ND ANNIVERSARY OF THE BATTLE OF CRETE

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

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

This is a historic event with direct significance to the allies’ victory of World War II. On May 20, 1941, thousands of German paratroopers and gliders began landing on Crete.

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

It was a very strong point on the line to India and protected both Palestine and Egypt.

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

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

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

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

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

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

At Paleochora, Father Stylianos Frantzkesis, hearing of the German airborne invasion, rushed in 8 days. Why is Crete free?

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 Crete heroes exemplified the courage it takes to preserve it.

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

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

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

WHEREAS—

(1) 1941 marked the 62nd anniversary of the 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;

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

(3) 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;

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

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

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

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

(8) 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;

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

(10) many of these citizens became members of the Pan-Cretan Association of America in Astoria, an organization comprised of Greek Americans with ancestry from the island of Crete and committed to preserving and promoting the rich culture and proud history of Crete;

NOW, THEREFORE, BE IT RESOLVED, That the House of Representatives—

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

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

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

INTRODUCTION OF THE RURAL HEALTHCARE ACCESS IMPROVEMENT ACT OF 2003

HON. MAX SANDLIN
OF MISSISSIPPI
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 of entry into school and day care attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof that their children have been immunized. While the mandate for which vaccines must be administered is a state mandate, it is the Federal Government, through the Centers for Disease Control and Prevention (CDC) and its Advisory Committee for Immunization Practices that make the Universal Immunization Recommendations to which states defer when determining mandates. Since the early to mid-1990s, Congress has been concerned about the danger posed by mercury in medical applications, and in 1997, directed the Food and Drug Administration (FDA) to evaluate the human exposure to mercury through foods and drugs. In 1999, following up on the FDA evaluation and pursuant to its authority, the House Committee on Government Reform initiated an investigation into the dangers of exposure to mercury in vaccines. This investigation later expanded to examine the potential danger posed through exposure to mercury in dental amalgams. This full committee investigation later expanded to examine the potential danger posed through exposure to mercury in dental amalgams. This full committee investigation, built upon the investigations initiated by two of its subcommittees. In January 2003, the investigation continued in the newly formed Subcommittee on Human Rights and Wellness.

A primary concern that arose early in the investigation of vaccine safety was the exposure of infants and young children to mercury, a known toxin, through mandatory childhood immunizations. This concern had been raised as a possible underlying factor in the dramatic rise in rates of late-onset or "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—our children. This report will address one form of mercury in medical applications, Thimerosal, as a preservative in vaccines.

In 1999, the FDA estimated that 8,000 children a day were being exposed to mercury in excess of Federal guidelines through their mandatory vaccines. One leading researcher made the following statement to the Committee in July 2000: "There's no question that mercury does pose a risk to infants and young children at the infant level, points out that we should know about childhood susceptibility, a concern remains under investigation by the Subcommittee on Human Rights and Wellness.

II. FINDINGS AND RECOMMENDATIONS

A. Findings

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

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

3. Manufacturers of vaccines and thimerosal 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.

This success, however, does not change the fact that millions of American children were exposed to levels of mercury through vaccines that have never been authorized by the Federal guidelines. Many parents, and a growing number of scientists, believe that this mercury exposure may have contributed to the rise in autism, attention deficit hyperactive disorder, and speech or language delay, and the increased use of thimerosal in...
vaccines is plausible and deserves more scrutiny. In 2001, the Institute of Medicine determined that such a relationship is biologically plausible, but that not enough evidence exists to support or reject this hypothesis.

8. The FDA acted too slowly to remove ethylmercury from over-the-counter products like cough syrups and cold preparations. Although an advisory committee determined that ethylmercury was unsafe in these products in 1980, a rule requiring its removal was not finalized until 1996.

9. The FDA and the CDC failed in their duty to be vigilant as new vaccines containing thimerosal were approved and 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 actions taken by the HHS to remove thimerosal from vaccines in 1999 were not sufficiently aggressive. As a result, thimerosal remained in some vaccines for an additional two years.

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

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

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

15. There is inadequate research regarding ethylmercury neurotoxicity and nephrotoxicity.

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

17. To date, studies conducted or funded by the CDC that purportedly dispute any correlation between autism and vaccine injury have been of poor design, under-powered, and fatally flawed. The CDC’s rush to support and promote such research is reflective of a philosophy in looking to outsource research to new theories and clinical data related to adverse reactions from vaccinations.

B. Recommendations

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

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

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

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

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

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

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

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

A. A brief description of mercury

Mercury exists in many different forms—organic, inorganic, elemental, and metallic. Only inorganic mercury is toxic. The mercury that is toxic in vivo is a metabolite called ethylmercury, which unlike any other metal, is a liquid at room temperature. It flows so easily and rapidly that it is sometimes called quicksilver. The chemical symbol for Mercury is Hg.

Mercury has many properties that have made it popular for a number of commercial uses. For example, mercury expands and contracts with temperature. It also remains liquid over a wide range of temperatures and does not stick to glass. These properties have prompted its use in thermometers and other products that measure temperature. Mercury vapor, used in fluorescent lamps, gives off light when electricity passes through it. Before its health effects were well understood, mercury compounds were used in some common products as house paints and paper. Various alloys (mixtures of metals) containing mercury are used by consumers and in hospitals. Thimerosal (mercury ethylmercury), the most commonly used form of mercury, has been used in vaccines since the 1930’s.

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publications, researchers suggested that caution be taken in human exposure. For example, a paper published in 1934 noted, “little is known about the mercuric compounds when inorganic. It is therefore extremely possible to use the minimum amount of this preservative.”

Eli Lilly&Company terminated its production of vaccines in 1974. Shortly after the FDA advisory committee determined that thimerosal in over-the-counter products was no longer generally considered unsafe, Eli Lilly & Company and other companies chose to cease production of products such as merthiolate and mercurichrome. While the mid-1980s, Eli Lilly was the only business engaged in the facturing or selling thimerosal-containing products. However, thimerosal continued to be used in vaccines. In the 1990s, thimerosal was manufactured by numerous companies, including Sigma-Aldrich, Inc.; EM Industries, Inc. (now EMD Chemicals Inc., the North American extension of Merck KGaA); Dow Chemical Company; Spectrum Laboratory Products, Inc. (formerly Spectrum Quality Products, Inc.); and GDL International, Inc.

C. Mercury is a known neurotoxin, but methylmercury has been more carefully studied than ethylmercury

After more than a century of research, it has been recognized in industrial and medical communities that mercury is a neurotoxin. While debate continues over what levels of exposure to mercury are safe, it is now clear that exposure to mercury in any form can cause neurological and renal damage. There is also a growing consensus around the theory that some individuals are more susceptible to harm from mercury than others, confounding efforts to adopt a population-level threshold for safe levels of mercury in the environment. A research paper published in 2002 summarized the scientific consensus very succinctly: “Mercury and its compounds are cumulative toxins and in small quantities are hazardous to human health. Because of its many commercial applications and its widespread presence in the environment, methylmercury received the lion's share of the attention in the scientific community during the twentieth century. A concise history of the early development of scientific knowledge about methylmercury is found in Dr. Thomas Clarkson’s, ‘The Three Modern Faces of Mercury’: ‘The first methylmercury compounds were synthesized in a chemical laboratory in London in the 1860s. Two of the laboratory technicians died of methylmercury poisoning. This so shocked the chemical community that methylmercury compounds were given a wide berth for the rest of the century ... early in the twentieth century the potent anti-fungal properties ... were discovered, leading to widespread use for food preservation and forercially for cereal crops .... Despite the widespread use, few cases of poisoning were reported for the first half of the twentieth century. Late in the 1920s and early 1930s, a number of outbreaks of alkyl mercury poisoning (methylmercury) erupted in several developing countries ... Also in the late 1950s, evidence of low environmental levels of mercury from treated grain. It was observed in Sweden in which predatory birds were developing neurological disorders, which research indicated the mercury levels .... Public health concerns about methylmercury in the edible tissue of fish suddenly erupted when fish from Lake St Clair bordering Michigan were found to have high levels. This and other findings have maintained public health concerns over this form of mercury exposure. As a result of these emerging concerns, public health officials worldwide began researching methylmercury. Today, the scientific literature is replete with evidence on toxic effects of methylmercury. In 2000, the National Academy of Sciences published a toxicological effects of Methylmercury, which concluded: Methylmercury is highly toxic. The data indicate that the adverse effects of methylmercury are expressed in multiple organ systems throughout the lifespan. The research in humans on the neurodevelopmental effects of methylmercury is extensive. Damage to renal tubules and nephron has been documented, with exposure to inorganic and organic forms of mercury. Symptoms of renal damage have been seen only at mercury exposures that also caused neurological damage. The cardiovascular system appears to be a target for methylmercury toxicity in the same dose range as neurodevelopmental effects—at very low mercury exposures. Studies in humans on the carcinogenic effects of methylmercury are inconclusive. Methylmercury may increase human susceptibility to infectious disease and autoimmune disorders by damaging the immune system. Methylmercury may adversely affect the reproductive system. The medical literature is replete with references to the dangers to methylmercury: ‘The major toxic effects of methylmercury are on the central nervous system. Its toxic action on the developing brain differs in both mechanism and outcome from its action on the mature organism ... the action of methylmercury on adults is characterized by a latent period between exposure and onset of symptoms. The period can be several weeks or even months, depending on the dose and exposure period ... paresthesia, numbness or a ‘pins and needles’ sensation is the first symptom to appear at the lowest dose. This may progress to cerebellar ataxia, dysarthria, constriction of the visual fields, and loss of hearing. ... Cardiovascular disease ... accelerated progression of carotid arteriosclerosis.’ The research is explicit that fetal brains are more sensitive than the adult brains to the adverse effects of methylmercury, which include: Severe brain damage Delayed achievement of developmental milestones Neurological abnormalities such as brisk tendon reflexes Widespread damage to all areas of the fetal brain, as opposed to focal lesions seen in adult tissue Microcephaly Purkinje [neuron] cells failed to migrate to the cerebellum Inhibition of both cell division and migration, affecting the most basic process in brain development Additionally, elevation in both systolic and diastolic blood pressure in seven year olds correlated with prenatal exposure to methylmercury ... indicative of later cardiovascular problems. Despite the fact that ethylmercury has been widely used in common medical treatments, ranging from vaccines to nasal sprays to ointments, comparably little research has been done on its health effects. The few studies that have been done tend to indicate that ethylmercury is just as toxic as methylmercury. The FDA never required the pharmaceutical industry to conduct extensive safety studies on thimerosal or ethylmercury. It was not until numerous safety concerns—such as the lack of a single uncontrolled and poorly reported human study in the 1920s, possibly in combination with animal and laboratory studies. However, the treatment was not successful and all of the patients died. The leading infectious disease specialist of the time concluded that, in his opinion, thimerosal research published a paper that made a brief reference to this study: “Merthiolate was injected into 22 persons ... these large doses did not produce any anaphylactoid or shock symptoms.” In the paper, the authors acknowledged that the 1934 paper by Drs. Powell and Jamieson who treated the meningitis patients, was not convinced of its efficacy: “beneficial effects of the drug were not definitely proven.” Drs. Powell and Jamieson published a paper from 1925 that included the statement: “A wide range of toxicity and injury tests should be done.” There is no evidence that Drs. Powell and Jamieson took their own advice and conducted studies to address these concerns.

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

One study that compared the toxicology of ethyl and methylmercury was published in 1985 in the Archives of Toxicology, written by researchers from the unit of the Medical Research Council of England. The researchers exposed rats to ethyl and methylmercury to “compare total and inorganic mercury concentrations in selected tissues, including the brain, after the daily administration of methyl or ethylmercury and to relate these findings to damage in the brain and kidneys.” This study found that both ethyl and methylmercury caused damage to the brains and the kidneys. It also found that male and female rats were affected differently: “It has been well documented that one of the first toxic effects of methylmercury in rats is depressed weight gain or even weight loss ... based on this criteria, ethylmercury proved to be more toxic than methylmercury ... in both sexes ... the concentration of total mercury in the kidneys exceeded the upper limit of the inorganic mercury) and organic mercury was consistently higher in the blood of ethylmercury-treated rats than of methylmercury-treated rats. Both ethyl and methylmercury caused damage to the brain: methylmercury caused damage to the hippocampus and ethylmercury caused damage to the frontal cortex. Ethylmercury was more toxic than methylmercury: tubular dilation was frequently present ... in kidneys ... both damage and mercury deposits
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, the understanding in the scientific community that government officials have shared with the Coalition for Mercury Awareness and Policy between Congressmen Dave Weldon (R-FL) and Dr. David Baskin during the Committee's December 10, 2002 hearing sheds a great deal of light on another true nature of ethyl versus methylmercury.

Dr. Weldon: "I have a couple of questions for Dr. Baskin about ethylmercury versus methylmercury. I am not sure what some people have 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 data on ethylmercury and it's as toxic as methylmercury."

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

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

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

Dr. Baskin: "The mercury amalgams in your mouth, the silver fillings, contain 48 to 50 percent mercury. These compounds when exposed to the bloodstream, continuously emit mercury vapor, which will go to the brain and is converted to mercuroic mercury. . . . Certain fish contain methylmercury; again, very rapidly taken up from the GI tract, transported quickly to the brain, and converted very slowly to mercuroic mercury. . . . thimerosol, which again will be taken up and quickly converted to mercuroic mercury—all three forms are neurotoxic."

"By neurotoxic, we mean it will damage nervous tissue that will damage brain tissue."

"Let me just say as a final statement that there is no need to have thimersal in a vaccine."

In making a presentation to the Institute of Medicine's Immunization Safety Review Committee, in July 2001, the former Director of the Environmental Toxicology Program at the National Institutes of Health, Dr. George Lucier, proffered the following conclusions:

"Ethylmercury is a neurotoxin. Infants may be more susceptible than adults.

"Ethylmercury should be considered equivalent to methylmercury as a developmental neurotoxin. This conclusion is clearly public health protective.

"Ethylmercury is a neurotoxin from vaccines (added to dietary exposures to thimerosal-mercury) probably caused neurotoxic responses (likely subtle) in some children.

"While the debate over whether ethyl or methylmercury is more toxic will probably not be resolved in the near future, a consensus appears to be emerging that exposure to these different types of mercury cannot be considered in isolation. Rather, witnesses before the Committee stressed that in determining safe levels of mercury exposure, the cumulative level of exposure to all types of mercury must be considered. Dr. Jeffrey Bradstreet made the following observation at the July 19, 2002 hearing:"

"More concerning to me in the Institute's treatment of mercury problems, was the almost complete absence of regard for the compounding effect of thimerosal on pre-existing mercury levels. The NHANES Study from the CDC had already established that perhaps one in ten children is born to mothers with levels which exceed the ATSDR low limit as a "scientifically appropriate level that adequately protects the public."

The Committee repeatedly heard from government officials that merely exceeding the guideline was not cause for concern. One Merck official, in teaching a Grand Rounds session to staff in November of 1999, postulated that the minimum risk level would need to be multiplied by ten to reach a level at which harm would be expected through exposure. Dr. Roberta McKee of Merck wrote: "A number of environmental and public health agencies have set the MRL for mercury. . . . Thimerosal Toxic 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 exceeded the one microgram per kilogram body weight per day. And were exposed to amounts well over ten times the EPA's scientifically validated reference dose. For example, at a recent Committee Chairman Dan Burton (R-IN) discussed his own family's experience with vaccine injuries:

"My grandson received vaccines for nine different diseases in one day. He may have been exposed to 62.5 micrograms of mercury in one day through his vaccines. According to this weight, the tolerable dose of mercury he should have been exposed to in one day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused."

The Committee, based on the methylmercury ingestion guidelines, the Chairman's grandson would have been over 20 times above the level that adequately protects the public."

The Methymercury guidelines

- Guideline value for maximum daily consumption
- Guideline type
- EPA 0.1 Reference dose (RfD)
- MRL 0.4 Tolerable daily intake
- WHO 0.47 Provisionally tolerable intake (converted from a weekly tolerable intake)
exceeded the "ten times the MRL" and therefore was placed "at risk of overdose." In fact, with a 62.5 microgram exposure alone, the EPA, ATSQR, and FDA levels would have been exceeded by 30 times. Because the FDA chose not to recall thimerosal-containing vaccines in 1999, in addition to all those already injured, 8,000 children a day were at risk of overdose for at least an additional two years. It should also be noted that none of the Federal guidelines on mercury exposure have been included specific provisions for safe exposure limits for infants and children. It is widely accepted that infants and young children have more sensitive nervous systems because the toxic effect of mercury or other neurotoxins than adults. "Exposures early in life are reasonably of greater health concern... because of greater brain organ susceptibility."
The FDA has conceded in recent years that many children received doses of ethylmercury that exceeded greatly the upper levels of safe exposure to ethylmercury. However, it is also clear that many infants received doses of ethylmercury 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 from its position regarding seafood exposures to mercury. The agency has a long history of issuing warnings to the public to monitor their fish consumption due to concerns about mercury exposure. During the 1990's, the FDA repeatedly issued warnings advising pregnant women and young children to avoid certain fish, or to limit their consumption of fish, because of their mercury content. In September of 1994, the FDA issued an advisory entitled, "Mercury in Fish: Cause for Concern?" in which they stated:

"Swordfish and Shark taste great—especially grilled or broiled. But reports which state that these and other large predatory fish may contain high levels of mercury have increased in recent years. While the EPA has established levels that are acceptable, mercury levels in the excess of the Food and Drug Administration's (FDA) 1 part per million (ppm) limit has been found in swordfish and shark.

Moreover, there is no doubt that when humans are exposed to high levels of methylmercury that poisoning and problems in the nervous system . . . the types of symptoms reflect the degree of exposure.

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

Similarly, a March 2001 FDA advisory stated:

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

In the case of swordfish and shark, it is prudent for nursing mothers and young children not to eat these fish as well."

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

4. Over the Course of Two Decades, the FDA Slugged Reluctantly to Ban Ethylmercury From Many Medicinal Products

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

In 1980, the FDA asked their Over-the-Counter (OTC) Review Panel to conduct a massive review of OTC products containing ethylmercury. As a result of the Panel's work, in 1982, the FDA issued a proposed rule to ban thimerosal from OTC topical ointments. In addition to raising questions about the general effectiveness of thimerosal. In February 1990, the FDA found that thimerosal was too toxic for OTC use. Among the findings that they published were the following:

- The FDA's own website, "The Campaign for a Mercury Free at the End of the Nineties," was a review of OTC products containing ethylmercury.
- The FDA's Center for Veterinary Medicine has confirmed that ethylmercury has been found to be more toxic for human epithelial cells in vitro than mercuristic chloride, mercuric nitrate, and merbromin (mercuric chromate).

Delayed hypersensitivity in 50 percent of the guinea pigs tested, indicating that thimerosal is highly allergic and that it is rea-sonable to expect humans to be equally allergic.

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

A Swedish study which found in healthy subjects the following levels of hypersensitivity to thimerosal: 10% of school children; 16% of military recruits; 18% of twins, and 26% of medical students; 10% of school children; 16% of military recruits; 18% of twins, and 26% of medical students. In 1982, the FDA advisory panel concluded that thimerosal was not generally recognized as safe. The Panel concludes that thimerosal is not safe for OTC topical use because of its potential for cell damage if applied to broken skin and its allergenic potential. It is not effective as a topical antimicrobial because of its bacteriostatic action can be reversed.

Despite this strong finding, the FDA's proposed ban on the OTC use of thimerosal was not issued until 1996. The Agency noted that the time of the OTC review, the industry chose not to challenge the findings of the Panel regarding the toxicity of thimerosal in OTC products. It is unclear why the FDA chose to do nothing for 18 years after a "not generally recognized as safe" finding. The FDA's own 1999 review through that 18-year regulatory process to remove thimerosal from topical ointments, apparently no one at the FDA was prompted to review the potential for thimerosal in vaccines. Action to remove thimerosal from vaccines did not begin until 1999, in response to the Congressionally mandated review. This will be discussed in more detail later in this report. At the time of the 1999 FDA review on thimerosal, it was learned that over 50 vaccines
contained thimerosal. On July 9, 1999, the American Academy of Pediatrics joined the U.S. Public Health Service in issuing a joint statement recommending the removal of all thimerosal from vaccines. On its website, the FDA provides the following rationale for its policy on thimerosal:

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

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

E. Thimerosal is still used in some medical products

While the FDA has taken steps over the last 20 years to remove ethylmercury from topical ointments and most pediatric vaccines, a number of medical products continue to contain this preservative. Some nasal and ophthalmic products containing thimerosal remain on the market.

About 75 percent of the flu vaccines, recently recommended to be given to children as young as six months, contain at least trace amounts of thimerosal.

### 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>
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<tbody>
<tr>
<td>Anthrax</td>
<td>3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.1 mg/1 mL dose</td>
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<td>Diphtheria</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td>Hib</td>
<td>3</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Hep A</td>
<td>3</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Hep B</td>
<td>3</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Influenza A&amp;B</td>
<td>3</td>
<td>1 annual</td>
<td>1 annual</td>
<td>1 annual</td>
<td>1 annual</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>MMR (Live)</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Meningococcal</td>
<td>3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Pneumococcal 13V</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.1 mg/1 mL dose</td>
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<tr>
<td>Polio Inactivated IPV</td>
<td>1</td>
<td>Booster dose</td>
<td>Booster dose</td>
<td>Booster dose</td>
<td>Booster dose</td>
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</tr>
<tr>
<td>Rabies</td>
<td>3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Smallpox (Live)</td>
<td>3</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Tet (3 mcg)</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td>Tdap Injectable</td>
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<td>Booster dose</td>
<td>Booster dose</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Varicella (Live)</td>
<td>3</td>
<td>1 dose needed</td>
<td>1 dose needed</td>
<td>1 dose needed</td>
<td>1 dose needed</td>
<td>0.1 mg/1 mL dose</td>
</tr>
<tr>
<td>Yellow Fever</td>
<td>3</td>
<td>1 booster dose</td>
<td>1 booster dose</td>
<td>1 booster dose</td>
<td>1 booster dose</td>
<td>0.1 mg/1 mL dose</td>
</tr>
</tbody>
</table>

### Possible Total Thimerosal Exposure

- **EPA Safety Limit:** 0.1 mcg/kg of body weight per day
- **Adult dose with weight exposure rates according to EPA Safety Limit**
  - 100 pound: 0.1 mcg/45.399 kg of body weight per day = 0.45
  - 120 pound: 0.1 mcg/54.431 kg of body weight per day = 0.58
  - 150 pound: 0.1 mcg/68.039 kg of body weight per day = 0.68
  - 180 pound: 0.1 mcg/81.647 kg of body weight per day = 0.68

It is clear from this chart that with a maximum safe limit of 0.16 mcigrams in a day, individuals receiving either 110.5 micrograms or 135.5 micrograms in one day may be at risk for injury from mercury exposure. Even in keeping with the safety margin of 10 times the serum limit, supported by Dr. Robert McKee of Merck, individuals at each of these weights would be exposed to levels of mercury that would be expected to put them at risk for adverse reactions.

The Committee received documentation from one Air Force pilot who suffered from serious symptoms of Gulf War Syndrome. After being unable to have his medical issues resolved through the military or the Veterans Administration (VA) medical system, Capt. Frank Schmuck, a pilot, became so ill that he was no longer able to fly. He sought medical treatment outside the military medical system and was tested for heavy metals, and was found to have toxic levels of mercury in his system. After chemotherapy, he returned to good health and has resumed flying. Gulf War Syndrome victims are not routinely tested for heavy metal toxicity or treated with chelation therapy by the military or the VA. Given the lack of progress in finding other successes with recovery from this condition, this is an issue that both the Department of Defense (DOD) and the VA should be working to evaluate 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 2008, the National Institutes of Health had adjusted that rate to 1 in 150 children in the United States. The Autism Society of America estimates that the number of autistic children is growing by 10 to 17 percent each year.

In that first hearing, Chairman Burton reported that according to U.S. Department of Education statistics, requests for services for school-age children with autism spectrum disorders had risen dramatically in every state. Mr. Burton: “California has reported a 273 percent increase in children with autism since 1988. . . . Florida has reported a 571 percent increase in autism. Maryland has reported a 65 percent increase 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 find the facts.”

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

“I am in family practice in Baton Rouge, Louisiana. I want to express my own appreciation to you and to the members of the committee for allowing me to testify. I am presently treating over 300 autistic children, with an additional 130 waiting to get in. . . . ‘We are treating children from all over the United States and getting calls from many places around the globe. This is truly an epidemic.’”

2. Studies Are Documenting the Incredible Growth of Autism

In the 1990’s, the CDC conducted two prevalence studies that confirmed dramatic spikes in autism cases. One was conducted in Brick Township, New Jersey, the other in Atlanta, Georgia. In late 1997, after noticing an apparently larger than expected number of children with autism in their community, a citizen’s group in Brick Township, New Jersey, contacted the New Jersey Department of Health and Senior Services (DHSS). Because of the complexity of the disorder and the concerns that environmental factors might play a role, the New Jersey DHSS, U.S. Senator Robert Torricelli, 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 10 years in metropolitan Atlantic County in 1986 as 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, concluded 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 autism is on the threshold to seeing a three-fold increase in autism with no explanation. "There's a number of things that need to be answered. We need to rethink the causes of autism." The 2002 report confirmed a 210 percent increase in the number of new professional diagnoses of autism to the most severe cases of autism entering the developmental services system between 2001 and 2002. The system added 3,577 new cases in 2002.

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

3. The Causes of the Autism Epidemic Are Not Known

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

Mr. Waxman: "Autism is a particularly frustrating disease. We still do not understand what causes it and we still do not have a cure. All we know for sure is that its impact on families can be devastating. During the hearings held in this committee, we have heard parents tell tragic stories of children who appear to be developing normally and then all of a sudden retreat into themselves, stop talking, and develop abnormally autistic behavior. Other parents have testified that their children never start to develop language skills, and instead early on manifest symptoms of autism. They also chose not to talk or walk. While 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 First Decade" by Martin Gardner, was paraphrased below:

In 1943, when child psychiatrist Leo Kanner first described 11 cases of a new mental illness in children he said was distinguished by self-absorbed detachment from other people. He described the condition he called the word "autistic" (from the Greek word auto, meaning "self"). Pointing out similarities with some behaviors exhibited by adult schizophrenics who were autistic, he concluded that psychoanalysts assumed autistic children were exhibiting early-onset adult-type psychoses. Kanner's young patients came from families with a history of middle-class families in Baltimore with mothers and fathers who were doctors, lawyers and professors. In 1954, Kanner said, "so far as I knew, the only one autistic child who came of unintelligent parents." This concentration of autistic children in educated and professionally successful families is a pattern Dr. Rimland describes in his book titled "The "Refrigerator Mom" theory as the cause of autism, theorizing that the warm maternal instincts of educated working mothers was absent or diminished. Influenced by Kanner, pediatricians for decades were persuaded to blame mothers of autistic children for being cold and emotionally rejecting, causing the children in turn to coldly reject contact with other people.

By 1954, Kanner began modifying his "Blame the Mother" position in light of evidence that brothers and sisters of autistic children were often well-adjusted, high functioning children. These findings suggested that autism was also a result of genetic or "constitutional inadequacies" as well as bad parenting. In 1971, Kanner admitted that Mothers were not to blame. However, psychoanalyst Bruno Bettelheim continued purporting the "rejecting parent" theme. Bettelheim, a Holocaust death-camp survivor, insisted that the child was "punished" in abnormal ways in retaliation against a rejecting mother who had traumatized the child by failing to provide enough love or attention.

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

In 1967, Dr. Rimland established the Autism Society of America (ASA). In 1967, he established the Autism Research Institute (ARI) and began distributing a questionnaire for parents to complete. From the 36 years of data he has since collected, his database currently contains 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 reversion 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 as autistic doubled. Today, Rimland says that the onset-at-18 months children outnumber the onset-at-birth children by 2 to 1.

Today, no one can pinpoint the exact cause or causes of autism. Nor is there any conclusive explanation for the rapid growth in cases of late-onset autism. Most experts believe that some combination of genetic and environmental factors must be at work. A leading and prominent theory is that the amount of mercury in childhood vaccines may have triggered an autistic response in children who are genetically predisposed to be vulnerable to mercury.
FDA to recommend the removal of thimerosal from most pediatric vaccines in 1999, more than a decade after the Hepatitis B vaccine was added to the schedule. In particular, the concern was that no data were identified linking between pertussis vaccine and autism, the IOM physician committee charged with evaluating the special health concerns of parents reported that their previously normal children were regressing into autism after DTP or MMR vaccination. However, the EPA’s threshold is 0.4 micrograms per kilogram of body weight. Of particular concern to many parents are those instances in which children received several vaccines during one visit to their pediatrician. This practice has become commonplace with the new vaccine schedules recommending 26 doses of vaccines before school attendance.

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

When testifying before the Committee, Mrs. Lynn Redwood made the following observation: "Some parents are beginning to wonder if there is a link between pertussis vaccine and autism because no data were identified linking thimerosal with autism." Dr. John Romano, of the Commonwealth Laboratories in Victoria, pointed out that unlike thimerosal, the Australian pertussis vaccine was linked to incertus in mice; but it was discussed that the effect of ethylmercury with Bordetella pertussis to supplement B-adrenergic blockade. Again, it was not believed that this blockade should be used in children, although it was recognized that increased motility resulted and that this could be causative. As with other chemicals of its generation, data relating to its safety and pharmacological effects in animal models are sparse.

Chairman Burton made the following observation: "In 1992, Dr. Ellis published a case report in the Archives of Ophthalmology, which states: 'The positive results of patch tests demonstrated that the patient was sensitive to tincture of merthiolate and that merthiolate is capable of causing an inflammatory reaction of the mucous membrane in patients who are sensitive to the drug.' In view of these facts, it is recommended: 1. That merthiolate be labeled with the words 'for external use only'; and 2. That the package should be labeled to warn the consumer that this product should not be used in or about the eyes unless it has been previously demonstrated by patch tests that the patient is sensitive to the merthiolate ointment. If the patient may become sensitized to merthiolate while using the ophthalmic ointment, it may be advisable to withdraw this product from the market before a case of permanent ocular damage occurs, in spite of the fact that no cases of ocular injury due to merthiolate have been reported."

In 1943, Dr. Ellis further explained his hypothesis. "I believe that the introduction of the hepatitis B vaccine in 1991 has sparked this recent epidemic because of thimerosal. When you combine this with the exposure through the DTP and Hib, the exposure to mercury exceeds EPA safe limits for the metal if you consider a child's exposure to silicates. "The EPA limits are usually related to ingested mercury, which is partially cleared by the liver. Injecting boluses of ethylmercury presents an entirely different, another scenario. The 2-month dose of mercury is at least 30 times higher than the recommended daily maximum exposure set by the EPA. During the 1960s, infants received 12.5 micrograms of mercury at birth, followed by 12.5 micrograms at 1 month, 62.5 micrograms at 2 months, 50 micrograms at 4 months, 50 micrograms at 8 months, 125 micrograms at 15 months, and 125 micrograms at 24 months; a total of 237.5 micrograms for a child who at worst weights 10 kilograms. This far exceeds the safety limits if you consider bolus dosing. The limits would be more like 1 to 1.5 micrograms.

"The bile production is minimal in infancy, making the metals more likely to be cleared from the body. When added to a vaccine, the metals are even more dangerous because the vaccines trigger immune reactions that increase the permeability of the GI tract and the blood-brain barrier. The injection of mercury appears to affect only certain children, but I fear that we're underestimating the problem by concentrating only on the autistic children. We're measuring elevated levels of mercury in other children with milder difficulties like learning disabilities, ADHD, Asperger's Syndrome and many others. We do not have any idea what the scope of this problem is at this point. And there are no safety standards for infants getting bolus doses of ethylmercury."

V. VALID CONCERNS ABOUT MERCURY IN VACCINES WERE IGNORED BY FEDERAL POLICYM Aker and vaccine manufacturers for decades

As early as 1931, scientists were noting adverse reactions to thimerosal. In fact, Dr. Kharasch filed a new patent application because he reformulated the product to stabilize meurhosal due to its tendency to acquire certain burning qualities."

In 1932, Dr. Lilly researchers who found Merthiolate to be a skin-disinfecting agent, it was noted that an additional 25 micrograms of ethylmercury were also sensitive to tincture of merthiolate and that merthiolate is capable of causing an inflammatory reaction of the mucous membrane in patients who are sensitive to the drug. In view of these facts, it is recommended: 1. That merthiolate be labeled with the words 'for external use only'; and 2. That the package should be labeled to warn the consumer that this product should not be used in or about the eyes unless it has been previously demonstrated by patch tests that the patient is sensitive to the merthiolate ointment. If the patient may become sensitized to merthiolate while using the ophthalmic ointment, it may be advisable to withdraw this product from the market before a case of permanent ocular damage occurs, in spite of the fact that no cases of ocular injury due to merthiolate have been reported."
There is ample evidence from the literature that thimerosal (thimerosal) may cause sensitization and subsequent allergic reactions. The use of thimerosal is vaccines at low levels in accordance with various national vaccine programs may in certain cases result in approximately two times higher intake of ethylmercury during the first 6 months of life, which can be considered reasonably safe. Given the great uncertainty of the estimations of safe levels in young children, it is suggested to restrict the use of thimerosal in vaccines.

In June 2000, the CDC convened a closed meeting to discuss research evidence that showed a connection between thimerosal in vaccines and autism. The case of Verstraeten, a CDC employee who has since left the agency to work in Belgium for a vaccine manufacturer, utilized the Vaccine Safety Datalink to evaluate any possible connection between thimerosal-preserved vaccines and neurological or renal impairment. He found, "a statistically significant positive correlation between the cumulative exposure at 2 months and unspeciﬁed developmental delay; the cumulative exposure at 3 months and tics; the cumulative exposure at 6 months and autism." He concluded, "This analysis suggests that all forms of mercury are toxic and that children who have been exposed to mercury in general may be increased by exposures to mercury from thimerosal-containing vaccines during the first six months of life."

This issue will be discussed in more detail in another section of this report. The Committee and the public have been frustrated by the lack of a department of health and human services’ stance to accept that all forms of mercury are toxic and that children who have been exposed to mercury in general may not be receiving the increased exposure to mercury through vaccines.

During the July of 2000 hearing on mercury, Congresswoman Helen Chenoweth-Hage (R-ID) eloquently expressed the views of many parents. Mrs. Chenoweth-Hage said, "I have a staff who are in the Navy Reserve right now, but he used to be active with the airborne divisions, and he was in for a test at a hospital military hospital, and upon taking his temperature, he broke a thermometer, and mercury splattered all over his clothes and shoes. He took the first thing he did was cut off his clothes. The second thing was call OSHA to clean up the mercury. And then they worked on him to make sure his eyes were not affected. You know, they were not affected, absolutely amaze me. I wonder where the disconnect is, for Pete’s sake.

"You had a testimony just as I did, and you are willing to, with a straight face, tell us that you are eventually going to phase this out after we know that a small baby’s body is slathered with 62 times the amount of mercury that it is supposed to have, and OSHA reacts like they did in the case of this accident of this naval man. It doesn’t make sense. No wonder people are losing faith in their government. And to have one of the witnesses tell us it is because mothers eat too much fish? Come on. We expect better. We heard devastating testimony in this hearing today, and we heard it last April. And this is the kind of response we get from our government agencies?"

I am sorry. When I was a little girl, my daddy talked to me about something about a duck test. I would ask each one of you to read this very excellent work by Sallie Bernard and Albert Enayati, who testified here today. My daddy used to say if it walks like a duck and looks like a duck and sounds like a duck, for Pete’s sake it is a duck.

"I recommend that you read this, side-by-side, page after page of analysis of the symptoms of thimerosal exposed with a mere 0.1 parts per million of the ethylmercury compared to autism, this is the duck test, and you folks are trying to tell us that you can’t take this off the market. What if there was a vaccine that was inj ected tomorrow; 80 children may be coming down, beginning tomorrow, with autism? What if there was an E. coli scare? What if there was a recall of the automobile? The recall would be like that.

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

"You know, I still go back to the fact—I still still have a duck test. Mr. Egan, [FDA] I will address you to this. You know, it was shown in the last panel that autistic symptoms emerge after vaccination. It was shown that there was a toxic dose of mercury. It was shown that autism and mercury poisoning, the physiological comparison is striking. There are altered neuronal development, a number of classic abnormalities, abnormal neuronal organization, immune system disturbances, EEG abnormalities. It goes on and on and on, the comparisons. That is why I say, I believe that the Chairman and the ranking member are all asking you that, we cannot wait until 2001 to have this pulled off.

"You know, if a jury were to look at this, the circumstantial evidence would be overwhelming. Let’s do something before we see it in the courts."

In 2003, thimerosal remains in some vaccines. A. Many parents of autistic children believe that adverse reactions to vaccines are responsible for their children’s condition. Based on their personal experiences, many parents believe that the significant increase of their children is related to an adverse reaction to a childhood vaccine, or a series of vaccinations. This is particularly true of parents who believe in the “late onset autism,” in which symptoms do not begin to emerge until the child is between one and two years old. This time period coincides with a number of vaccinations on the childhood schedule. While this belief is not universal, many parents hold it passionately. Dr. Jeffrey Bradstreet, when testifying before the Committee in 2001, made the following statement:

"At a recent autism conference in Chicago, and prior to either my own presentation or the VAERS report of 500 parents if they felt their child regressed following a vaccine, in that obviously non-scientific survey, approximately 90 percent of the parents raised their hands to affirm vaccines were what they suspected had caused their child’s symptoms. When I asked for how many had reported the event within three hours of the shot, 13 said they had. Then I asked if their pediatrician had offered to report this, they just laughed. I have now conducted this same survey over and over again at events around the world with similar findings. Yes, medical attention creates bias. But despite the infor-
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 you could not even reach him."

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

"The two-year schedule for completing this exhaustive search and retracing his regression continues to point to the fact that the road of Jacob's autism began when his immune system was challenged due to the thimerosal B injection he received when he was ill. The final blow was the adverse reaction to the host of vaccines he received 16 months later. We are certain that for Jacob, the catalyst was his vaccine."

"Testifying two years later, on April 18, 2002, Autism Society of America President Lee Grossman laid out a special two-part procedure which awards are paid and which is funded by the Federal government maintains a trust fund out of the tobacco settlement money. This fund is used to compensate to families of individuals who suffer vaccine injuries. The Federal Master Autism Petition For Vaccine Compensation filed by the families:"

"As a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the child in this question has developed a neuromuscular disorder, consisting of an 'Autism Spectrum Disorder' or a similar disorder. This disorder was caused by a mercury-containing vaccine. The thimerosal is 50% Merck's and 50% of the DTP vaccines."

"The common thread linking both reports was the conclusion that much more research needed to be done before firm conclusions could be drawn."

"In April of 2001, the Institute of Medicine (IOM) released two reports after reviewing the evidence they received related to possible connections between vaccines and autism."

"The IOM was created by the National Academy of Sciences in 1970 to conduct independent analyses of public policy matters related to health care. The first report was on the MMR vaccine. The second dealt with vaccines containing thimerosal. The common thread linking both reports was the conclusion that much more research needed to be done before firm conclusions could be drawn."

"In April of 2001, the IOM issued its report on the MMR vaccine, entitled, "Immunization Safety Review—Measles-Mumps-Rubella Vaccine and Autism." After reviewing the available scientific studies, the IOM determined that: 'The evidence favors rejection of a causal relationship at the population level between MMR 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 MMR vaccine and autism. However, the authors cautioned that if the vaccine triggered autism, the disorders among many children who were predisposed to an adverse reaction, the population studies that had been done to date would be too imprecise to detect them."

"It is important to recognize the inherent methodological limitations of such studies in that capturing causality 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 cause and case definition may also hamper the ability of epidemiological studies to detect rare adverse events."
Thimerosal was removed, to children who received vaccines before thimerosal-containing doses 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 enough to put some pressure on the National Institute of Health to fund research on vaccines as observed in cell culture studies and epidemiological studies comparing the prevalence of autism to those who have received thimerosal-containing vaccines versus those who have not. The results are very consistent with the potential toxicity of vaccines containing thimerosal as a "preservative" versus those vaccines not containing thimerosal. The results were very clear in the accompanying Table 4.1 attached to this document. In our preliminary studies, vaccines containing thimerosal as a preservative consistently demonstrated in-vitro toxicity that was dramatically greater than the non-thimerosal or low-thimerosal containing vaccines.

"Our results are very consistent with the report of Dr. Baskin regarding the potential toxicity of vaccines containing thimerosal on background exposure from other sources; Research in appropriate animal models on neurodevelopmental effects of ethylmercury; Rigorous science in well designed clinical trials as a treatment for neurodevelopmental disorders; and Research to identify a safe, effective and inexpensive thimerosal-free alternative 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 thimerosal 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 enough to put some pressure on the National Institute of Health to fund research on vaccines as observed in cell culture studies and epidemiological studies comparing the prevalence of autism to those who have received thimerosal-containing vaccines versus those who have not. The results are very consistent with the potential toxicity of vaccines containing thimerosal as a "preservative" versus those vaccines not containing thimerosal. The results were very clear in the accompanying Table 4.1 attached to this document. In our preliminary studies, vaccines containing thimerosal as a preservative consistently demonstrated in-vitro toxicity that was dramatically greater than the non-thimerosal or low-thimerosal containing vaccines."
to detoxify the cerebral spinal fluid may be at least part of the neurological aspect of this disease.

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

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

"Here is a slide where you see a lot of blue cells. This is a mouse. These mice develop neurologic deficits that look like autism, and when you take their brains out and you analyze them, they have the same type of brain damage."

"The idea that thimerosal may have contributed to the growth in autism spectrum disorders is strongly supported by the notion that growth in children's autism is the only reason why we've seen such an increase in autism."

"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 where autism can be treated with rhDNase, and when treated with rhDNase, the cells are blue. It means that this stuff grabs a hold of the membrane and punches holes into it, so that the dye can penetrate, not through the plasma but into the very center of the cell, the nucleus, where all the DNA exists."

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

"Dr. Baskin testified that other researchers in this field have noted 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 where autism can be treated with rhDNase, and when treated with rhDNase, the cells are blue. It means that this stuff grabs a hold of the membrane and punches holes into it, so that the dye can penetrate, not through the plasma but into the very center of the cell, the nucleus, where all the DNA exists."

"We incubate these cells in cell culture. So these are cells from the front part of the brain called frontal cortex cells in cell culture. So these are cells that grow in culture. We incubate these cells."

"The DNA exists."

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"The DNA exists."
Perhaps Dr. Thomas Verstraeten conducted the broadest review of a possible relationship between thimerosal and neurological disorders in 2003. 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 comes from the Vaccine Safety Datalink, and because the medical records in this database are jealously guarded by the CDC, the data used in this study has never been made public. The data could not be analyzed until later in the next section of this report.

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

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

*We have shown that very low concentrations of thimerosal can be detected in infants aged 2–6 months who have been given vaccines containing thimerosal [sic]. However, no children had a concentration of blood mercury of 20 parts per million, 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 the administration of thimerosal-containing vaccines, we conclude that thimerosal-containing vaccines pose little risk to full-term, but that thimerosal-containing vaccines should not be administered to very low birth weight, premature infants.*

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

1. The sample size was very small:

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

*The sample size, as you said, Dr. Weldon, was small. Autism occurs in one in 150 kids. So if you have 40 kids, that's only one autistic kid in their blood to absorb more mercury or make it remain in the blood longer or be more sensitive in their brain, if they only checked 40 kids, you might have found one kid with a predisposition to autism.*

2. The sample was not random:

In his testimony, Dr. Baskin commented on this issue:

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

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

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

"We know the stool levels were high, but if you waited until you actually measured the blood levels, they said it was somewhere between 2 and 27 days later. The peak mercury levels after injection occur within about 24 hours. So if they were drawing blood later than that, and much later than that, of course the levels weren't going to be high. But the mercury just kind of fell into the stool; it goes through the blood. At some point it was high because it was high in the stool.*

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

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

While the University of Rochester study measured the levels of mercury in infants' bodies at various times beyond peak levels, it did not attempt to determine the effects of the mercury on the children. 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 the ethylmercury present in the bodies of the subjects, it is difficult to understand how the authors could come to such a very little risk to full-term infants. If anything, the limitations of this study point out the need for much more research to be done. As Dr. Baskin pointed out:*"You described this as a descriptive study, and that's exactly what it was. It provides some data, but it's not the start, but the interpretation is inaccurate."*VII. EVIDENCE OF ETHYL MERCURY'S TOXICITY WAS NEGLECTED BY MANUFACTURERS AND FEDERAL REGULATORS FOR YEARS*

Evidence of ethylmercury's toxicity was available to Federal regulators and the private sector almost from the product's inception. For far too long, both neglected this evidence. Despite evidence dating to the 1930s that ethylmercury in medicines was potentially hazardous, little was done to remove it from a number of products until the 1990s. Even then, regulatory actions to remove thimerosal and other mercury compounds from medical products proceeded at a glacial pace. The decision to remove thimerosal 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. "They described this as a descriptive study, and that's exactly what it was. It provides some data, but it's not the start, but the interpretation is inaccurate."
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 chides the study's shortcomings: "Considering the type of patient involved, one might question these observations (the appearance of no deleterious action) as providing any indication of any harmful effects of high doses of Merthiolate in humans, in particular, more long term effects."

In 1973, the FDA requested additional data on Merthiolate from Eli Lilly. Lilly's Director of Regulatory Affairs, E.A. Burrows, responded with a ringing defense of Lilly's product on February 15, 1973: "Due to the length of time this product has been on the market, its efficacy and safety have been proven by over forty years of use throughout the world. Because of this period of use, it would be difficult to get recognized researchers to conduct studies for efficacy or safety. They believe that over forty years of wide usage has proven efficacy and safety beyond that which could be done in special studies."

Despite Mr. Burrows' contention, numerous internal documents at Lilly recognized the lack of data on thimerosal and suggested the need for more research:

- An April 24, 1973, intra-office memo stated: "Most of our experience with the thimerosal solution, we have to know pretty definitely what to expect from thimerosal and why before they get on the market . . . Can we expect to have the stronger ointment and jelly used without complaint which avoided the use of the stronger solution without some very definite evidence that we will not repeat our solution experience."

- A September 1974, paper from Lilly's files stated: "[L]ittle is known about the effect of mercuric compounds when inculated into humans. It is therefore preferable to use the minimum amount of this preservative necessary to maintain the sterility of the product."

- An April 1969, memo regarding the possible use of thimerosal in contact lens solution states: "When Merthiolate breaks down, are the effects toxic or irritant? Our files yield no test information on the irritancy of degraded merthiolate."

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

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

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

Perhaps more disturbing is that Lilly's files contained numerous papers and reports documenting the toxicity and hypersensitivity of Merthiolate. Although these papers and case reports strongly suggested the need for much more research, there apparently was little follow-up. A July 1970 letter from the Pittman-Moore Company indicated that Merthiolate was not appropriate for use in dogs:

"We have obtained marked local reaction in about 50% of the dogs injected with serum containing dilutions of Merthiolate, varying in 1 in 40,000 to 1 in 5,000, and we have demonstrated no connection between the lot of serum and the reaction. In other words, Merthiolate is unsatisfactory as a preservative for serum injected intradermally. The dogs do not show the local reaction, but in some instances, the reaction is extremely severe. I might say that we have tested Merthiolate and observed a more marked local reaction than does phenol or tricresol."

A 1947 paper published by an Army physician in Baltimore reported that Merthiolate was causing contact dermatitis in his patients. He concluded: "No eruptions or reactions have been observed or reported to Merthiolate internally, but it may be dangerous to inject a serum containing Merthiolate into a patient sensitive to Merthiolate."

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

"A 1950 New York Academy of Sciences article entitled, "Antiseptics," stated that "mercury inhibits the growth of staphylococcus bacteria on chick heart tissue. Ineffective for their stated purpose of killing bacteria to prevent infections."

The panel's 1999 review of the safety of thimerosal in vaccines is known to be a skin sensitizer, especially if it is injected. Indeed, the immune system is just being set at this age. So now we're injecting a sensitizer into the immune system when you give a child a vaccine."

"One thing I haven't heard discussed, the fact that we know that thimerosal is a skin sensitizer when it's put on the skin, and now we're injecting this IM (intramuscular) at a time when the immune system is just developing, the functionality of the immune system is just being set at this age. So now we're injecting a sensitizer severely toxic to the surface of an individual's skin, it might not be safe to inject ethylmercury deep into an infant's tissue. The Director of the FDA's National Center expressed such a concern at a 1999 meeting for Toxicological Research, Dr. Bernard Schwartz, who went on to serve as the Acting Director of the FDA for nearly a year. ""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 safety is not effective as a topical antimicrobial because its bacteriostatic action can be reversed."


The process of these proceedings all the more mystifying is that there appears to have been no opposition to this action throughout the process. No individuals 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 certain 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 at topically used products failed to prompt the FDA to further and immediately review the use of thimerosal in vaccines. Surely there must have been concern that if it was not safe to apply ethylmercury to the surface of an individual's skin, it might not be safe to inject ethylmercury deep into an infant's tissue. The Director of the FDA's National Center expressed such a concern at a 1999 meeting for Toxicological Research, Dr. Bernard Schwartz, who went on to serve as the Acting Director of the FDA for nearly a year. ""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 safety is not effective as a topical antimicrobial because its bacteriostatic action can be reversed."

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Different branches of the FDA regulate over-the-counter products and vaccines. Vaccines are regulated by the Center for Biologics Evaluation and Research (CDER). Vaccines are regulated by the Center for Biologics Evaluation and Research (CDER).
Evaluation and Research (CBER). This, however, is little justification for the lack of coordination. The FDA’s determination that mercury was unsafe and should be removed from childhood vaccines in 1999 breached the Federal Register no fewer than five times prior to the FDA’s belated review of mercury in vaccines.

What prompted the FDA to review mercury in vaccines was not its own regulatory process, but rather an act of Congress. In 1997, Congress passed and the President signed the Food and Drug Administration Modernization Act (FDAMA). Among other things, this law required the FDA to compile a list of foods and drugs that contain mercury and to determine if thimerosal was unsafe in topically applied products. 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 thimerosal to be used in vaccines. There was great uncertainty in others caused by the lack of data specifically on thimerosal. However, the institutional resistance to change was counter-balanced by the general feeling that there was no mercury in childhood vaccines than previously thought, and that nobody had thought to calculate the cumulative amount of thimerosal in vaccines. The essence of the debate was captured in a 1999 e-mail from a former FDA official meaning the pros and cons of taking action. He opined that: ‘‘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 factors/data that would argue for the removal of thimerosal in vaccines. I also makes clear that there was internal resistance to such an action. Dr. Marion Gruber of the Office of Vaccine Science Research and Internal FDA memo to Dr. Ball, which concluded that:

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

Dr. Ball’s response on October 15, 1998, to Dr. Hastings’ conclusion was sharp. ‘‘I disagree about the conclusion regarding no basis for removal of thimerosal. On a strictly scientific basis, yes, there are no data that have looked at the specific issue of thimerosal in vaccines. However, there are factors/data that would argue for the removal of thimerosal in vaccines. I also makes clear that there was internal resistance to such an action. Dr. Marion Gruber of the Office of Vaccine Science Research and Internal FDA memo to Dr. Ball, which concluded that:

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 FDA’s review of thimerosal in vaccines was not able to come to a conclusion on the toxicity of thimerosal or its metabolized forms.

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 FDA’s review of thimerosal in vaccines was not able to come to a conclusion on the toxicity of thimerosal or its metabolized forms.
The fact that more forceful action to remove thimerosal from the vaccine marketplace was not taken in 1999 is disappointing, just as disappointing, and even more difficult to understand, is the fact that the CDC, on two separate occasions, refused to publicly state a preference for thimerosal-free vaccines.

In June of 2000, the CDC’s Advisory Committee on Immunization Practice met in Atlanta. Among other things, the Advisory Committee was asked to consider a recommendation to have the PHS and industry state a preference for thimerosal-free vaccines. As I said, the policy seems to be working. As you know, the Public Health Service and its advisory committees have concluded that the available data are not sufficient to warrant a change from thimerosal-containing vaccines. This is not to say, however, that the pharmaceutical industry has a carte blanche to continue to use thimerosal, or to continue to manufacture vaccines containing thimerosal.

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

Later in the discussion, Dr. Neal Halsey made another suggestion that would limit the exposure of infants to ethylmercury. He suggested that the Advisory Committee adopt a policy that no child should receive more than one thimerosal-containing vaccine per day:

"Rogers, you said that after July, the maximum exposure will be 75 micrograms. My understanding is that if the one thimerosal-containing vaccine presented from the manufacturers is that there really still is some Hep B out there in the market that is being used, does that mean that with one Hepatitis B out there that does contain it, there’s no guarantee the maximum exposure would be 75 micrograms. What I proposed last October was that they put a limit of one thimerosal-containing vaccine as a preservative per visit, which would then guarantee that you’re looking for. And I think that the right policy because that allows for the continued use, though very limited. It eliminates the maximum exposure, but you do have the problem of what’s in the pipeline."

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

One year later, in June of 2001, the Advisory Committee again rejected the idea of expressing a preference for thimerosal-free vaccines. Despite the fact that all manufacturers of Hib, Hepatitis B and DTaP had shifted to thimerosal-free products at that point, the CDC’s decision not to express a preference for thimerosal-free vaccines, and the Advisory Committee’s concurrence in this policy, was an abdication of their responsibility. As a result of their inaction, children continue to receive thimerosal-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 weak correlation between thimerosal and several types of neurological disorders.

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

Phase I produced a statistically-significant association between exposure to thimerosal during the first three months of life, and tics, attention deficit disorder, language problem versus 4–5% reported in National surveys; less than 1% with ADHD versus 3–10% reported previously, etc.‘’

However, enough concern was generated that a consensus of medical experts was assembled at the Simpsonwood Retreat Center near Atlanta. At this conference, Dr. Verstraeten explained that the study underreported the numbers of children with developmental disorders, including autism. This occurred because the youngest subjects in the study were not yet at an age at which such disorders were likely to be diagnosed. He commented:

‘‘But one thing that is for sure, there is certainly a paucity of data, And I think 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 issue a few months earlier. She stated in an April 25, 2000, e-mail to Dr. Frank DeStefano, one of the study’s co-authors:

‘‘For me, the big issue is the missing cases of autism in this study. Clearly there is a gross underreporting—1.4% of the kids diagnosed with a speech and language problem versus 4.5% reported in National studies; less than 3% with ADHD versus 3–10% reported previously, etc.’’

Had the study been extended until these children were older, a stronger correlation between thimerosal and neurological disorders might have been detected, as more children were diagnosed. However, this was not done. Ultimately, the majority of the Simpsonwood panel determined that the VSD study was not conclusive. Phase II of the VSD study failed to confirm the findings of Phase I. The Institute of Medicine determined that, ‘‘the small sample size limited the ability to detect a significant effect, if it exists. The committee concludes that the Phase I and II VSD analyses are inconclusive with regard to causality between thimerosal and ASD.’’

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

‘‘This association leads me to favor a recommendation that infants up to two years old not be immunized with Thimerosal-containing vaccines if suitable alternative preparations are available. I do not believe that the diagnoses justifies compensation in the Vaccine Injury Act at this point. I deal with causality, it seems pretty clear to me that the data are not sufficient one way or the other. My gut feeling? It worries me. I would have preferred a second comment, but I got called out at eight o’clock for an emergency call and my daughter-in-law delivered a son by C-Section. Our first child! In the line of the next generation, and in the long run, I do not want that grandson to get a Thimerosal-containing vaccine unless we know better what is going on. It will probably take a long time for us to get to the bottom line, and 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 ground-breaking 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 not significative although weak, association, but that the implications—for obvious reasons—are profound. Therefore, the consultants were unanimous in the view that further investigation should be pursued with a degree of urgency and, parenthetically, not only for public health policy in this country, but for public health policy around the world.’’

Documents reviewed by the Committee indicate that Dr. Verstraeten was not pleased with the response to his study. During the Simpsonwood meeting, he stated:

‘‘When I saw this, and I went back through the literature, I was actually stunned by what I saw—because I thought it was plausible.’’

A month later, he sent an e-mail to Dr. Philippe Grandjean, the author of several groundbreaking studies on the toxicity of mercury. Dr. Verstraeten wrote:

‘‘I know that much of this is very hypothetical and, personally, I would rather not drag the Faroe and Seychelles studies into this whole thing might be dangerous. There is no consensus in the scientific community that this has been proven—there is a risk. I do not want 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 the best possible evidence 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. FDA officials spoke passionately about this problem at a meeting of the National Vaccine Advisory Committee in the summer of 1999. Dr. Katherine Zoon stated:

‘‘We need to understand more about thimerosal because in the past two days, I think it’s almost 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 it’s knowledge that we need.’’

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

‘‘The sensitivity of the fetus versus the neonate is very important, and for some of you who have forgotten about the sensitive windows during fetal development, the nervous system develops post-natally. So it isn’t unreasonable to expect that there would be particular windows of sensitivity. So it isn’t a lot of average for the whole neonatal period—it’s what 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. ’’

One of the most consistent refrains heard by the Committee throughout its three-year investigation is that 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.

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

Use accepted and consistent case definition and outcome assessment tools in future studies (autism spectrum disorder) in order to enhance the precision and comparability of results from surveillance, epidemiological, biological investigations.

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

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

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

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

Study the possible effects of different MMR immunization exposures.
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 about a possible relationship between thimerosal and autism spectrum disorders. The IOM called for the following types of research:

- Clinical research on how children metabolize and excreted mercury.
- Theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal-containing vaccines.
- 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 shared among the National Institute of Mental Health, the National Institute of Neurological Disorders 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 into a strategy and timeline, and focus research on the most pressing research needs.

Another concern is the lack of a sufficient investment into research on autism and its causes. Autism is growing at epidemic proportions and nobody knows why. The rates of autism and other neurological disorders in children who did not receive thimerosal-containing doses of vaccines during clinical trials;

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

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

- Clinical research on how children metabolize and excreted mercury.

The theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal-containing vaccines 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.

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

HON. FORTUNE PETE STARK
OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, May 21, 2003

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

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

More than 40 million 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. Current Medicare beneficiaries would have a one-time six-month open enrollment period to elect this coverage. Otherwise, normal Medicare enrollment rules would apply.

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

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