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

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

HONORING THE 62ND ANNIVERSARY OF THE BATTLE OF CRETE

HON. CAROLYN B. MALONEY

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Tuesday, May 20, 2003

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

This is a historic event with direct significance to the allies' victory of World War II. On May 20, 1941, thousands of German paratroopers and 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 lifeline to India and protected both Palestine and Egypt.

The Nazi invasion force included the elite German paratroopers and glider troops. Hitler felt this was to be an easy victory, yet he is quoted to have said shortly after the invasion, ''France fell in 8 days. Why is Crete free?''

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

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

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

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

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

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

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

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

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

The invasion was delayed from April to June of 1941. The 2-month delay in the invasion made Hitler's forces face the Russian winter.

The Russian snow storms and the sub zero temperatures eventually stalled the Nazi invasion before they could take Moscow or Leningrad. This was the beginning of the downfall of the Nazi reign of terror.

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

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

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

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

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

H. RES.—

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

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

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

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

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

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

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

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

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

Whereas many of these citizens became members of the PanCretan Association of America, an organization comprised of Greek Americans with ancestry from the island of Crete and committed to preserving and promoting the rich culture and proud history of Crete: Now, therefore, be it

Resolved, That the House of Representatives—

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

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

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

INTRODUCTION OF THE RURAL HEALTHCARE ACCESS IMPROVEMENT ACT OF 2003

HON. MAX SANDLIN

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, May 20, 2003

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

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

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

We should not waste any more time in the House of Representatives in meeting the needs of our rural providers. Today, I offer the Rural Healthcare Access Improvement Act of 2003. This bill, similar in scope to Senator GRASSLEY's amendment offers real opportunities to assist our rural health care providers. As my colleagues know, the Center for Medicare and Medicaid Services uses a reimbursement formula that favors urban areas over rural areas. This formula is deeply flawed though and fails to allow our providers to even break even on many of their expenses. My legislation will directly assist our hospitals by equalizing Disproportionate Share Hospital (DSH) Payments, by equalizing urban and rural ''standardized payment'' levels, by assisting Critical Access Hospitals, and by establishing a floor on the geographic adjustments of payments for doctors' services. It will also improve reimbursement for home health services, ground ambulance services and hospital outpatient procedures.

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

MERCURY IN MEDICINE REPORT

HON. DAN BURTON

OF INDIANA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, May 20, 2003

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

MERCURY IN MEDICINE—TAKING UNNECESSARY RISKS

I. EXECUTIVE SUMMARY

Vaccines are the only medicines that American citizens are mandated to receive as a condition for school and day care attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof that their children have been fully immunized. While the mandate for which vaccines must be administered is a state mandate, it is the Federal Government, through the Centers for Disease Control and Prevention (CDC) and its Advisory Committee for Immunization Practices that make the Universal Immunization Recommendations to which the majority of 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 through vaccination. The investigation later expanded to examine the potential danger posed through exposure to mercury in dental amalgams. This full committee investigation complemented and built upon the investigations initiated by two of its subcommittees. In January 2003, the investigation continued in the newly formed Subcommittee on Human Rights and Wellness.

A primary concern that arose early in the investigation of vaccine safety was the exposure of infants and young children to mercury, a known toxin, through mandatory childhood immunizations. This concern had been raised as a possible underlying factor in the dramatic rise in rates of late-onset or ''acquired'' autism. The symptoms of autism are markedly similar to those of mercury poisoning.

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

In July 2000, it was estimated that 8,000 children a day were being exposed to mercury in excess of Federal guidelines through their mandatory vaccines.

One leading researcher made the following statement to the Committee in July 2000:

''There's no question that mercury does not belong in vaccines.

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

The Food and Drug Administration's (FDA) mission is to ''promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.'' However, the FDA uses a subjective barometer in determining when a product that has known risks can remain on the market. According to the agency, ''at the heart of all FDA's product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great—especially for products used to treat serious, life-threatening conditions.''

This argument—that the known risks of infectious diseases outweigh a potential risk of neurological damage from exposure to thimerosal in vaccines, is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that any possible risk from thimerosal was theoretical: that no proof of harm existed. Upon a thorough review of the scientific literature and internal documents from government and industry, the Committee did in fact find evidence that thimerosal posed a risk. The possible risk for harm from either low dose chronic or one time high level (bolus dose) exposure to thimerosal is not ''theoretical,'' but very real and documented in the medical literature.

Congress has long been concerned about the human exposure to mercury through medical applications. As a result of these concerns, in 1997, Congress instructed the FDA to evaluate the human exposure to mercury through drugs and foods. Through this Congressionally mandated evaluation, the FDA realized that the amount of ethylmercury infants were exposed to in the first six months of life through their mandatory vaccinations exceeded the Environmental Protection Agency's (EPA) limit for a closely associated compound methylmercury. The FDA and other Federal agencies determined that in the absence of a specific standard for ethylmercury, the limits for ingested methylmercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA's methylmercury standard and determined that based upon scientific data that it, rather than the FDA's, was the scientifically validated safe exposure standard.

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

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

This success, however, does not change the fact that millions of American children were exposed to levels of mercury through vaccines that exceeded comparable federal guidelines. Many parents, and a growing number of scientists, believe that this mercury exposure may have contributed to the explosive growth in autism spectrum disorders, and neurological and behavioral disorders that this country has experienced. The scientific evidence in this area is considered by some to still be inconclusive, in large part due to the lack of serious, effective inquiry by our health agencies. The federal government has an obligation to vigorously pursue the necessary research to determine the extent of the impact of these heightened exposures to ethylmercury on our population.

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

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

II. FINDINGS AND RECOMMENDATIONS

A. Findings

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

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

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

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

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

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

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

7. A growing number of scientists and researchers believe that a relationship between the increase in neurodevelopmental disorders of autism, attention deficit hyperactive disorder, and speech or language delay, and the increased use of thimerosal in

vaccines is plausible and deserves more scrutiny. In 2001, the Institute of Medicine determined that such a relationship is biologically plausible, but that not enough evidence exists to support or reject this hypothesis.

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

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

10. The amount of ethylmercury to which children were exposed through vaccines prior to the 1999 announcement exceeded two safety thresholds established by the Federal government for a closely related substance—methylmercury. While the Federal Government has established no safety threshold for ethylmercury, experts agree that the methylmercury guidelines are a good substitute. Federal health officials have conceded that the amount of thimerosal in vaccines exceeded the EPA threshold of 0.1 micrograms per kilogram of bodyweight. In fact, the amount of mercury in one dose of DTaP or Hepatitis B vaccines (25 micrograms each) exceeded this threshold many times over. Federal health officials have not conceded that this amount of thimerosal in vaccines exceeded the FDA's more relaxed threshold of 0.4 micrograms per kilogram of body weight. In most cases, however, it clearly did.

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

12. The CDC's failure to state a preference for thimerosal-free vaccines in 2000 and again in 2001 was an abdication of their responsibility. As a result, many children received vaccines containing thimerosal when thimerosal-free alternatives were available.

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

14. The CDC in general and the National Immunization Program in particular are conflicted in their duties to monitor the safety of vaccines, while also charged with the 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 philosophical conflict in looking fairly at emerging theories and clinical data related to adverse reactions from vaccinations.

B. Recommendations

1. Access by independent researchers to the Vaccine Safety Datalink database is needed for independent replication and validation of CDC studies regarding exposure of infants to mercury-containing 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 bioaccumulates; the Agency for Toxic Substances and Disease Registry (ATSDR) clearly states: ''This substance may harm you.'' Studies should be conducted that pool the results of independent research that 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 the autism epidemic.

5. Congress needs to pass legislation to include in the National Vaccine Injury Compensation Program (NVICP) 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 two-year window for families, whose children were injured after 1988 but who do not fit within the statute of limitations, to have the opportunity to file under the NVICP.

6. Congress should enact 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 is a silver-colored metal, which unlike any other metal, is a liquid at room temperature. It flows so easily and rapidly that it is sometimes called quicksilver. The chemical symbol for Mercury is Hg.

Mercury has many properties that have made it popular for a number of commercial uses. For example, mercury expands and contracts evenly when heated or cooled. It also remains liquid over a wide range of temperatures and does not stick to glass. These properties have prompted its use in thermometers. Mercury conducts electricity and is used in some electric switches and relays to make them operate silently and efficiently. Industrial chemical manufacturers use mercury in electrolysis cells to charge substances with electricity. Mercury vapor, used in fluorescent lamps, gives off light when electricity passes through it. Before its health effects were well understood, mercury compounds were widely used in such common products as house paints and paper.

Various alloys (mixtures of metals) containing mercury have many uses. Mercury alloys are called amalgams. These would include silver amalgam, a mixture of silver and mercury that dentists use to fill cavities in teeth.

Mercury comes in many different forms—organic, inorganic, elemental, and metallic. As a result of its many practical uses, mercury became widespread in the environment. However, it is now widely recognized that overexposure to all forms of mercury can harm the central nervous system (brain) and the renal system (kidneys). This has led to regulatory actions to reduce the exposure of humans to mercury on many fronts. According to the Agency for Toxic Substances and Disease Registry (ATSDR): ''The nervous system is very sensitive to all forms of mercury.''

B. Thimerosal, which contains ethylmercury, has been used in medicines since the 1930's

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

Thimerosal was developed by Dr. Morris Kharasch (1895–1957; Ukraine/USA), a chemist and Eli Lilly fellow first at the University of Maryland (1922–1927) and then at the University of Chicago. He filed for a patent on June 27, 1929, for what he described as an alkyl mercuric sulfur compound (thimerosal), which he felt had potential as an antiseptic and antibacterial product. Dr. Kharasch was considered a pioneer in his field, contributing to the development of plastics and the creation of synthetic rubber. He also went on to found the Journal of Organic Chemistry.

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

Thimerosal was patented the same year that Alexander Fleming discovered penicillin. But because it took more than a decade for penicillin to be fully developed, and large-scale production to begin, thimerosal was widely used in the interim. To the medical profession, who were without antibiotics during the 1930's and 1940's, thimerosal (marketed as Merthiolate) and other antiseptic products were gladly received.

Dr. H. Vasken Aposhian, Professor of Molecular and Cellular Biology and Pharmacology, University of Arizona discussed thimerosal's history during Congressional testimony:

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

Thimerosal became the most widely used preservative in vaccines and other medical products. Its use in antiseptic products to prevent infections was common. By the time that the FDA conducted its review of mercury in 1999, more than 50 licensed vaccines contained thimerosal.

While thimerosal became widely used, there were repeated references in the scientific literature to the lack of substantial understanding of its safety. In numerous

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 inoculated into humans. It is therefore preferable to use the minimum amount of this preservative.''

Eli Lilly ceased its production of vaccines in 1974. Shortly after the FDA advisory committee determined that thimerosal in over-the-counter products was no longer ''generally recognized as safe,'' Eli Lilly and other companies chose to cease production of products such as merthiolate and mercurichrome. By the mid–1980's, Eli Lilly was completely out of the business of manufacturing or selling thimerosal-containing products. However, thimerosal continued to be used in vaccines. In the 1990's, 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 become widely accepted in the scientific and medical communities that mercury is a neurotoxin. While debate continues over what levels of exposure to mercury are safe, it is unquestioned today that overexposure 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 applications to seed grains, especially for cereal crops . . . Despite the widespread use, few cases of poisoning were reported for the first half of the twentieth century. However, in the late 1950s and 1960s serious outbreaks of alkyl mercury poisoning (methylmercury) erupted in several developing countries . . . Also in the late 1950s, evidence emerged of environmental damage from treated grain. It was observed in Sweden that predatory birds were developing neurological disorders . . . analysis . . . indicated a sharp rise in mercury levels.''

Public health concerns about methylmercury in the edible tissue of fish suddenly erupted in 1969 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.''

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 Toxicological Effects of Methylmercury, which concluded:

Methylmercury is highly toxic.

The data indicate that the adverse effects of methylmercury exposure can be 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 observed following human exposure to inorganic and organic forms of mercury. Symptoms of renal damage have been seen only at mercury exposures that also caused neurological effects.

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

Studies in humans on the carcinogenic effects of methylmercury are inconclusive.

Methylmercury may increase human susceptibility to infectious disease and 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 organ . . . the action of methylmercury on adults is characterized by a latent period between exposure and onset of symptoms. The period can be several weeks or even months, depending on the dose and exposure period . . . paresthesia, numbness or a 'pins and needles' sensation is the first symptom to appear at the lowest dose. This may progress to cerebella ataxia, dysarrthia, 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, comparatively little research has been done on its health effects. The few studies that have been done tend to indicate that ethylmercury is just as toxic as methylmercury.

The FDA never required the pharmaceutical industry to conduct extensive safety studies on thimerosal or ethylmercury. It appears that our Federal regulatory framework (the FDA and its predecessor organizations) failed to require manufacturers to prove thimerosal was safe. They failed to require industry to conduct adequate testing to determine how thimerosal is metabolized. The FDA failed to require that industry conduct studies to determine the maximum safe exposure level of thimerosal. These basic issues should have been proven prior to the introduction of thimerosal into the marketplace, but more than 70 years after its introduction, these issues have still not been adequately addressed. The introduction of thimerosal appears to have been based on a single uncontrolled and poorly reported human study in the 1920s, possibly in combination with animal and laboratory studies. However, this sole human study was not a true safety study and produced a faulty foundation on which to build a robust vaccine program in which young children would be forced to be repeatedly injected with multiple doses of ethylmercury.

During the pre-antibiotic 1920's, meningitis was a killer. Out of sheer desperation, the treating physician at a hospital dealing with dozens of patients facing a sure death from meningitis, tested thimerosal on about two-dozen patients. He injected the thimerosal intravenously, without apparent side effects. However, the treatment was not successful and all of the patients died. The leading industry scientists of that era involved in thimerosal research published a paper that made a brief reference to this study: ''Merthiolate was injected intravenously into 22 persons . . . these large doses did not produce any anaphylactoid or shock symptoms.'' In the paper, the authors acknowledge that Dr. K.C. Smithburn, the clinician who treated the meningitis patients, was not convinced of its efficacy: ''beneficial effects of the drug were not definitely proven.'' Drs. Powell and Jamieson also noted in 1930 that a ''wide range of toxicity and injury tests should be done.'' There is no evidence that Drs. Powell and Jamieson took their own advice and conducted studies to address these concerns.

As a result, in 1999, 70 years after the product was first licensed, neither the FDA nor the industry had followed through on determining a safe exposure level to thimerosal or ethylmercury. Thus, when facing a policy decision on thimerosal 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 Toxicology 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 (the sum of organic and inorganic mercury) and organic mercury was consistently higher in the blood of ethylmercury-treated rats . . . both alkymercurials damaged the dorsal root ganglia and 9.6 mg Hg/kg/day ethylmercury caused more damage than 8.0 mg Hg/kg/day methylmercury. Ethylmercury was more renotoxic 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 can do, there is more understanding in the scientific community than government officials have shared with the Committee. The following dialogue between Congressman Dave Weldon (R–FL) and Dr. David Baskin during the Committee's December 10, 2002 hearing sheds a great deal of light onto the true nature of ethyl versus methylmercury.

Dr. Weldon: ''I have a couple of questions for Dr. Baskin about ethylmercury versus methylmercury. I have had some people say that data on methylmercury is fairly good, but we don't have good data on ethylmercury. I take it from your testimony there is actually 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 has been a debate about . . . ethyl versus methyl. But from a chemical point of view, most chemical compounds that are ethyl penetrate into cells better than methyl. Cells have a membrane on them, and the membrane is made of lipids, fats. And ethyl as a chemical compound pierces fat and penetrates fat much better than methyl. 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 probably 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 research in humans and animals, 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: ''Well, the literature on methylmercury is much better than ethyl on this issue. And if you look at the studies, the brain is 2 percent of the body weight but took 10 percent of the exposure. So that's a five-fold preferential uptake.''

The testimony of Dr. Baskin builds upon earlier testimony that the Committee received from recognized experts in chemistry, toxicology and pharmacology. It includes the following statement from Dr. H. Vasken Aposhian, Professor of Molecular and Cellular Biology, and Pharmacology at the University of Arizona, who provided the Committee the following information about the evidence on mercury toxicity at the July 18, 2000 hearing:

''The mercury amalgams in your mouth, the so-called silver fillings, contain 48 to 50 percent of elemental mercury. These fillings continuously emit mercury vapor, which will go to the brain and is converted to mercuric mercury . . . Certain fish contain methylmercury; again, very rapidly taken up from the GI tract, transported quickly to the brain, and converted very slowly to mercuric mercury . . . thimerosal, which again will be taken up by the brain and quickly converted to mercuric mercury—all three forms are neurotoxic.

''By neurotoxic, we mean it will damage nerves and it will damage brain tissues.

''Let me just say as a final statement that there is no need to have thimerosal 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 equipotent to methylmercury as a developmental neurotoxin. This conclusion is clearly public health protective.

Ethylmercury exposure from vaccines (added to dietary exposures to methylmercury) 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 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 elevated mercury burden.''

D. Because of its toxicity, mercury has become heavily regulated.

As the dangers of mercury have become better understood, the United States and other governments around the world have taken actions to reduce the release of mercury into the environment. In 1972, the federal government halted the use of mercury compounds for many industrial uses, such the paint used on the hulls of ships and compounds used to prevent the growth of fungi in lumber, because the mercury had leached into the environment and found its way into the human food chain.

In 1972, while certain agencies within the federal government recognized that mercury was a cumulative poison that damaged brain cells, the FDA's vaccine division seems to have ignored the issue until 1999.

1. The EPA is Regulating the Release of Mercury Into the Environment

The Environmental Protection Agency (EPA) under the Clean Air Act regulates airborne emissions of mercury. In December 2000, the EPA announced that it would issue new regulations on the emissions of mercury from coal and oil-fired power plants. That action was taken because, ''mercury has been identified as the toxic of greatest concern among all the air toxics emitted from power plants.''

More recently, President Bush announced on February 14, 2002, that mercury emissions from power plants would be reduced 69% under his Clear Skies Initiative. Under this plan, mercury emissions would be reduced from the current level of 48 tons nationally to 15 tons by 2018. The EPA also regulates mercury emissions from municipal waste combustors, medical waste incinerators, and hazardous waste incinerators.

The EPA works both domestically and internationally to reduce mercury exposures in the environment. The ''Canada-United States Strategy for the Virtual Elimination of Persistent Toxic Substances in the Great Lakes Basin'' is an example of these activities.

2. Different Limits to Exposure to Mercury Have Been Established by Different Agencies

In the course of regulating mercury, different government agencies have established different minimum risk levels for daily exposure to mercury. Exposure to less than the minimum risk level is believed to be safe, while exposure that exceeds that level is believed to increase the chances of injury. All of the levels apply specifically to ingested methylmercury.

The EPA established the most conservative level: 0.1 micrograms of mercury per kilogram of body weight per day. Under this standard, an 11–pound baby (roughly 5 kilograms) could be exposed to up to 0.5 micrograms of mercury per day and be considered safe. This exposure standard is a marked contrast to the 25 micrograms of mercury that was contained in several childhood vaccines until very recently.

The most lenient federal minimum risk level for mercury is the FDA's, which sets its limit at 0.4 micrograms per kilogram of body weight per day. (The United Nations' World Health Organization sets a slightly higher limit of 0.47 micrograms per kilogram of bodyweight per day.) Falling in between is the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) at 0.3 micrograms.

In 2000, the National Academy of Sciences issued a report titled, Toxicological Effects of Methylmercury, validating the EPA's lower limit as a ''scientifically appropriate level that adequately protects the public.''

Methylmercury guidelines

Agency	Guideline value for maximum daily consumption (µg/kg/day) (micrograms per kilogram of body-weight per day)	Guideline 'type'
EPA	0.1	Reference dose (RfD).
ATSDR	0.3	Minimal risk level.
FDA	0.4	Tolerable daily intake.
WHO	0.47	Provisional daily tolerable intake (converted from a weekly tolerable intake).

The Committee repeatedly heard from government officials that merely exceeding the guideline was not cause for concern. One Merck official, in teaching a Grand Rounds session to staff in November of 1999, postulated that the minimum risk level would need to be multiplied by ten to reach a level at which harm would be expected through exposure. Dr. Roberta McKee of Merck wrote:

''A number of environmental and public health agencies have set a Minimum Risk Level (MRL) for toxic substances. An MRL for ingestion is conceptually equivalent to the Reference Dose of the US Environmental Protection Agency, the Acceptable Daily Intake of the US FDA, and the Tolerable Daily Intake of the WHO. Any exposure to the substance below the MRL is assured to be safe, while exposure to ten times the MRL is assumed to place one at risk of overdose. Exposure at or near the MRL is assumed to be safe but should trigger deliberate and careful review.''

Based on Dr. McKee's explanation, many babies were exposed to levels of mercury that ''placed one at risk of overdose,'' and were exposed to amounts well over ten times the EPA's scientifically validated reference dose. For example, at a recent Committee hearing, Chairman Dan Burton (R–IN) discussed his own family's experience with vaccine injuries:

''My 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 his weight, the maximum safe level of mercury he should have been exposed to in one day is 1.5 micrograms, so that is 41 times the amount at which harm can be caused.''

According to the analysis of Dr. McKee, based on the methylmercury ingestion guidelines, the Chairman's grandson would have

exceeded the ''ten times the MRL'' and therefore was placed ''at risk of overdose.'' In fact, with a 62.5 microgram exposure alone, the EPA, ATSDR, and FDA levels would have been exceeded by 10 times. Because the FDA chose not to recall thimerosal-containing vaccines in 1999, in addition to all of those already injured, 8,000 children a day continued to be placed ''at risk for 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 would be five times more sensitive to the toxic effect of mercury or other neurotoxins than adults. ''Exposures early in life are reasonably of greater health concern . . . because of greater brain organ susceptibility.''

The FDA has conceded in recent years that many children received doses of ethylmercury through their vaccinations that exceeded the EPA's minimal risk level for methylmercury. 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 their actions regarding food exposures to mercury. The agency has a long history of issuing warnings to the public to monitor their fish consumption due to concerns about mercury exposure. During the 1990's, the FDA repeatedly issued warnings advising pregnant women and young children to avoid certain fish, or to limit their consumption of these fish because of their mercury content. In September of 1994, the FDA issued an advisory entitled, ''Mercury in Fish: Cause for Concern?'' in which they stated:

''Swordfish and Shark taste great—especially grilled or broiled. But reports which state that these and other large predatory fish may contain methylmercury levels in excess of the Food and Drug Administration's 1 part per million (ppm) limit has dampened some fish lover's appetites. . .'there is no doubt that when humans are exposed to high levels of methylmercury that poisoning and problems in the nervous system can occur' . . . 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 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 exposure . . . Pregnant women and women of child bearing age, who may become pregnant, however, are advised by FDA experts to limit their consumption of shark and swordfish to no more than once a month.''

Similarly, a March 2001 FDA advisory states:

''Some fish contain high levels of a form of mercury called methylmercury that can harm an unborn child's developing nervous system if eaten regularly. By being informed about methylmercury and knowing the kinds of fish that are safe to eat, you can prevent any harm to your unborn child and still enjoy the health benefits of eating seafood.. . . While it is true that the primary danger from methylmercury in fish is to the developing nervous system of the unborn child, it is prudent for nursing mothers and young children not to eat these fish as well.''

In addition to the public advisories, the FDA, in January of 2001, established an aggressive ''Education Plan on Methyl Mercury.'' In January 2001, Associate FDA Commissioner Melinda Plaiser, responding to Congressman William J. Coyne (D–PA) regarding the National Academy of Sciences' report on Methylmercury, wrote:

''[L]et me reiterate, the FDA's commitment to protecting the public's health and the environment regarding mercury.''

Furthermore, in their training materials for employees, the FDA reflects a slightly different emphasis on mercury's toxicity than what they presented to the Committee:

''People are exposed every day to a tremendous number of substances in our environment. These substances include major and trace elements that may or may not be essential for sustaining life . . . Other elements are not known to be essential but are constantly found in living tissues . . . Of these elements that have no known nutritional value, some have been found to be toxic at concentrations well below those of other nonessential elements. Lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels.''

Other HHS entities have taken very strong mercury reduction positions. For example, the National Institutes of Health's (NIH) Division of Safety has initiated a program to make the NIH mercury-free. According to the Division's own website:

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

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

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

This NIH program has initiated a ''Hatters Pledge'' program to recruit scientists to reduce the use of mercury at the NIH and to educate children on the dangers of mercury.

The NIH Hatters Pledge:

I will:

Improve my awareness of mercury hazards and how to reduce them.

Replace mercury thermometers and other mercury-containing items with non- or low-mercury alternatives if suitable alternatives are available.

Dispose of mercury wastes following NIH procedures.

Report spills of mercury.

On the NIH campus, call the Fire Department (911) who are the NIH hazardous material (HAZMAT) emergency responder.

Off campus, call the local fire department or facility's hazardous material (HAZMAT) emergency responder.

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

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

In 1980, the FDA began a lengthy regulatory process to remove ethylmercury products from over-the counter products like topical ointments, diaper rash creams, and contraceptives. Topical ointments are products used on the skin either for the treatment or prevention of skin infections or inflammatory processes. 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 to small wounds; antibiotic or antifungal creams to prevent or treat overt skin infection; and anti-inflammatory agents used to reduce inflammation and inhibit pruritis.

In 1980, the FDA asked their Over-the-Counter (OTC) Review Panel to conduct a massive review of OTC products. The panel opted to divide the task into categories, one of which was a review of OTC products containing ethylmercury.

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

At the cellular level, thimerosal has been found to be more toxic for human epithelial cells in vitro than mercuric chloride, mercuric nitrate, and merbromim (mercurichrome).

It was found to be 35.3 times more toxic for embryonic chick heart tissue than for staphylococcus aureus.

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

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

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

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

Despite this strong finding, the FDA's proposed ban on the OTC use of thimerosal was not finalized until 1998, 18 years later. At the time of the OTC review, the industry chose not to challenge the findings of the Panel regarding the toxicity of thimerosal in OTC products. It is unclear why the FDA chose to do nothing for 18 years after a ''not generally recognized as safe'' finding.

Although the FDA went through that 18–year regulatory process to remove thimerosal from topical ointments, apparently no one at the FDA was prompted to review the use of thimerosal in vaccines. Action to remove thimerosal from vaccines did not begin until 1999, in response to the Congressionally mandated review. This will be discussed in 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 increasing awareness of the theoretical potential for neurotoxicity of even low levels of organomercurials, and because of the increased number of thimerosal-containing vaccines that have been added to the infant immunization schedule, concerns about the use of thimerosal in vaccines and other products have been raised. Indeed, because of these concerns, the Food and Drug Administration has worked with, and continues to work with, vaccine manufacturers to reduce or eliminate thimerosal from vaccines.''

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

E. Thimerosal is still used in some medical products

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

Some nasal and ophthalmic products containing thimerosal remain on the market.

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

Many adult vaccines contain thimerosal.

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

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

U.S. MILITARY VACCINE SCHEDULE

Vaccine	No. Doses	Initial entry	Troops in US	Deployed	Region or other	Thimerosal content
Anthrax	6 + annual	N/A	N/A	6 + annual	6 + annual	0
DtaP	N/A	N/A	N/A			0 (or 0.5 mcg/dose)
Hib	N/A	N/A	N/A		(People without spleens)	0
Hep A	3 + boosters	N/A	3 + boosters	3 + boosters	3 + boosters	0
Hep B	3	3	3	3 (Korea)	3 (Korea), Health Care Workers, STDs.	0 (or 0.5 mcg/dose)
Influenza A&B	1 Annual	1	1 annual	1 Annual	1 Annual (Health workers)	25 mcg/dose or 24.5, mcg/dose or 1, mcg/dose or .98 mcg/dose
Jap Enceph	3 + biannual boosters	N/A	N/A	3 + biannual boosters	3 + biannual boosters (Travel Rural Asia).	35 mcg per 1 mL dose or 17.5 mcg/0.5 mL dose
MMR (Live)	1	1	N/A	Seldom needed	NA (Health workers)	0
Meningococcal MGC	1 every 3 years	1	N/A	Within 3 years	Travel to mid-Africa, Arabia	25 mcg/dose
Pneumococcal 17; PCBV–7	N/A	N/A	N/A	N/A	N/A	0
Pneumococcal 123; PPV–23	1	1 (Pendleton)	N/A	N/A	(No spleen, other chronic diseases).	0 or 25 mcg/dose
Polio Inactivated IPV	1 booster dose	1	N/A		(Travel Africa Asia)	0
Rabies	Pre:(3 doses + booster)	N/A	N/A		(Veterinary bites)	0
Smallpox (Live)	1 every 10 years	N/A	1	1	1	0
Td; TT (25 mcg)	1 every 10 years	1	1 every 10 years	1 every 10 years	1 every 10 years	8 mcg/dose or 25 mcg/dose.
Typhoid Injectable	1 every 2 years	N/A	1 every 2 days	Every 2 years	Every 2 years (travel)	0
Varicella (Live)	2 doses if needed	Screen, 2 doses	N/A	N/A	N/A	0
Yellow Fever (Live)	1 every 10 years	(N, MC) 1	1 every 10 years	1 every 10 years	1 every 10 years (travel Africa, Pacific, South Am).	0
Possible Total Thimerosal Exposure.				110.5 mcg per shot day	135.5 mcg per shot day	

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

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

Adult weight with exposure rates according to EPA Safety Limit

100 pound: 0.1 mcg/45.359 kg of body weight per day = 4.54

120 pound: 0.1 mcg/54.431 kg of body weight per day = 5.44

150 pound: 0.1 mcg/68.039 kg of body weight per day = 6.8

180 pound: 0.1 mcg/81.647 kg of body weight per day = 8.16

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

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

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

A. Autism Is Growing at Epidemic Proportions

1. Introduction

Autism was once considered a rare disease that affected an estimated 1 in 10,000 individuals in the United States. The Committee held its first hearing on the dramatic rise in autism in April of 2000. At the time, Federal agencies were estimating that autism affected 1 in 500 children in the United States. By 2002, the National Institutes of Health had adjusted that rate to 1 in 250 children in the United States. The Autism Society of America estimates that the number of autistic children is growing by 10 to 17 percent each year.

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

Mr. Burton: ''California has reported a 273 percent increase in children with autism since 1988 . . . Florida has reported a 571 percent increase in autism. Maryland has reported a 513 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 first look to the cause.''

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

''I am in family practice in Baton Rouge, LA. I want to express my deep appreciation to you and to the members of the committee for allowing me to testify. I am presently treating over 300 autistic children, with an additional 150 waiting to get in.

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

2. Studies Are Documenting the Incredible Growth of Autism

In the 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 250) children aged 3 through 10 years. The prevalence of the more broadly defined autism spectrum disorder was 6.7 per 1,000 (1 in 150) children. It is important to note that even though the families of Brick Township requested that the CDC include an evaluation of a possible link between autism and their children's immunization, the CDC chose not to do so. Their evaluation of the cause of the cluster of autism in Brick Township was inconclusive.

The CDC's Atlanta study confirmed the dramatic results of the Brick Township study. The CDC found that 1,987 of the 289,456 children aged 3 to 10 years in metropolitan Atlanta in 1996 were autistic (1 in 146). These numbers were 10 times higher than studies conducted in the 1980s and early 1990s.

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

The main author of the study, Dr. Robert Byrd, said, ''It is astounding to see a threefold increase in autism with no explanation . . . there's a number of things that need to be answered. We need to rethink the causes of autism.''

The 2002 report confirmed a 210 percent increase in the number of new children professionally diagnosed with the most severe cases of autism entering the developmental services system between 2001 and 2002. The system added 3,577 new cases in 2002.

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

3. The Causes of the Autism Epidemic Are Not Known

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

Mr. Waxman: ''Autism is a particularly frustrating disease. We still do not understand what causes it and we still do not have a cure. All we know for sure is that its impact on families can be devastating. During the hearings held in this committee, we have heard parents tell tragic stories of children who appear to be developing normally and then all of a sudden retreat into themselves, stop communicating, and develop autistic behavior. Other parents have testified that their children never start to develop language skills, and instead early on manifest symptoms of autism. I can only imagine how 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 & Vaccines: A New Look At An Old Story'' by Barbara Loe Fisher is paraphrased below:

In 1943, when child psychiatrist Leo Kanner first described 11 cases of a new mental illness in children he said was distinguished by self-absorbed detachment from other people and repetitive and bizarre behavior, he used the word ''autistic'' (from the Greek word auto, meaning ''self.'') Pointing out similarities with some behaviors exhibited by adult schizophrenics, Kanner and other psychiatrists assumed autistic children were exhibiting early-onset adult-type psychoses. Kanner's young patients came from well-educated middle and upper class families in Baltimore with mothers and fathers who were doctors, lawyers and professors. In 1954, Kanner said, ''We have not encountered any one autistic child who came of unintelligent parents.'' This concentration of autistic children in educated and professionally successful families led Kanner to develop the ''refrigerator Mom'' theory as the cause of autism, theorizing that the warm maternal instincts of educated working mothers was absent or diminished. Influenced by Kanner, pediatricians for decades were persuaded to blame mothers of autistic children for being cold and emotionally rejecting, causing the children in turn to coldly reject contact with other people.

By 1954, Kanner began modifying his ''Blame the Mother'' position in light of evidence that brothers and sisters of autistic children were often well-adjusted, high functioning children. These findings suggested that the development of 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 Bettleheim continued purporting the ''rejecting parent'' theme. Bettleheim, a holocaust death-camp survivor, insisted that the autistic child was behaving 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. Bettleheim's theories through the publication of his landmark book Infantile Autism: The Syndrome and Its Implications for a Neural Theory of Behavior. In this book, Dr. Rimland methodically dismantled the psychoanalytic theory of autism and argued for a biological, specifically a neurological, basis for autistic behavior. Dr. Rimland documented the similarities between brain injured children and autistic children, liberating parents 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 1965, Dr. Rimland established the Autism Society of America (ASA). In 1967 he established the Autism Research Institute (ARI) and began distributing a questionnaire to parents of autistic children. Some 36 years later, his databank includes information on more than 30,000 cases of autism from around the world. In analyzing the data for age of onset of autism, he discovered that before the early 1980's, most of the parents reported their children first showed signs of abnormal behavior from birth or in the first year of life. But after the mid-1980's, there was a reversal of this pattern. The numbers of parents reporting that their children developed normally in the first year and a half of life and then suddenly became autistic doubled. Today, Rimland says that the onset-at-18-months children outnumber the onset-at-birth children by 2 to 1.

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

B. The alarming growth in autism coincided with an increase in the number of childhood vaccines containing thimerosal on the recommended schedule

Through most of the twentieth century, individuals were required to receive very few vaccines. However, with the licensing of the Hepatitis B (Hep B) vaccine and the Haemophilus Influenzae Type b (Hib) vaccine starting in the mid-to-late 1980's, and their subsequent recommendation for universal use in 1991, the amount of mercury to which infants were exposed rose dramatically. It was during this period of increased exposure to thimerosal and its ethylmercury component that the growing wave of late-onset autism became apparent. This confluence of events led many to suspect a correlation between the two and call for more research into the relationship between ethylmercury in vaccines and autism spectrum disorders.

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

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

The polysaccaride Haemophulus Influenzae B (Hib) vaccine was first licensed in 1985. It had 25 micrograms of ethylmercury and was given 3 times in the first six months of life (75 micrograms of ethylmercury) and a total of four times in the first two years of life.

The approval of the Hep B vaccine in 1986 added another thimerosal-containing shot to the recommended schedule. This vaccine contained 12.5 micrograms of ethylmercury and was given within hours of birth and a total of 3 times in the first six months of life (37.5 micrograms of ethylmercury).

After 1986, some children went from getting 25 micrograms in one day or 75 micrograms in the first six months of life to getting 62.5 micrograms of ethylmercury in a day or 187.5 micrograms in the first six months of life. This would be in addition to any fetal exposure to mercury from the mother. In 1991, the CDC recommended that both Hib and Hep B be added to the universal recommendations for childhood immunization.

As was noted previously, the effects of ethylmercury have not been studied as carefully as methylmercury, and the Federal Government has not established safety thresholds for ethylmercury exposure. Because of the obvious similarities between the two, however, when the FDA reviewed the amount of injected ethylmercury in vaccines in 1999, they compared it to the Federal limits for (ingested) methylmercury exposure. They were compelled to admit at that point that the cumulative amount of ethylmercury in vaccines exceeded the EPA's threshold for exposure to methylmercury. This led the

FDA to recommend the removal of thimerosal from most pediatric vaccines in 1999, more than a decade after the Hepatitis B vaccine was added to the schedule.

In point of fact, the potential problem was worse than the FDA suggested. Not only did the cumulative amount of ethylmercury on the routine schedule exceed the EPA's limit, the amount of ethylmercury in each individual shot of DTP (or DTaP) and Hepatitis B exceeded the limit. Young children were getting three boosters of each shot. The EPA's threshold is 0.1 micrograms of methylmercury for each kilogram of body weight. This does not mean that injury would definitely occur above this level because a significant safety margin is built in. However, the chances of injury increase as the exposure rises above this level. For an 11–pound baby (five kilograms), the threshold would be roughly 0.5 micrograms. For a 22–pound baby (ten kilograms), the threshold would be 1 microgram. The DTP (and DTaP) vaccine contained 25 micrograms of thimerosal per dose, as does the Hepatitis B vaccine. The Hib vaccine contained 12.5 micrograms per dose. In addition, it is clear that for many, many children, the amount of thimerosal they received in vaccines in the 1990's also exceeded the FDA's higher threshold of 0.4 micrograms per kilogram of body weight.

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

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

When testifying before the Committee, Mrs. Lynn Redwood made the following observation regarding her son's bolus exposure to mercury through vaccinations: ''According to the EPA criteria, his allowable dose was only 0.5 micrograms based on his weight. He had received 125 times his allowable exposure on that day. The large injected bolus exposures continued at two months, four months, 12 months, and 18 months to a total mercury exposure of 237.5 micrograms. I also discovered that the injections that I received during my pregnancy, the first and third trimesters, and hours after the delivery of my son to prevent RH blood incompatibility disease also contained mercury.''

Concern that autism may be linked to vaccines is not a new debate. Twelve years ago, the Institute of Medicine was asked to evaluate the science on a possible connection. The Institute of Medicine published Adverse Effects of Pertussis and Rubella Vaccines and confirmed that pertussis and rubella vaccines can cause brain and immune system damage. At the time, an increasing number of parents reported that their previously normal children were regressing into autism after DTP or MMR vaccination. However, the IOM physician committee charged with analyzing the medical literature for evidence of cause and effect, rejected the reported link between pertussis vaccine and autism, because 'no data were identified [in the medical literature] that address the question of a relation between vaccination with DTP or its pertussis component and autism.'

Dr. Stephanie Cave, who provided testimony to the Committee, is a doctor in Baton Rouge, Louisiana whose medical practice is focused on treating children with the symptoms of autism. She concurs with other experts from whom the Committee received testimony that there appears to be a correlation between increased use of vaccines containing thimerosal and a rise in autism:

''I believe that the introduction of the hepatitis B vaccine in 1991 has sparked this recent epidemic because of thimerosal. When added to the mercury imparted through the DTP and HIB, the exposure to mercury exceeds EPA safe limits for the metal if you consider a bolus dose on a single day.

''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 1990's, infants received 12.5 micrograms of mercury at birth, followed by 12.5 micrograms at 1 month, 62.5 micrograms at 2 months, 50 micrograms at 4 months, 50 micrograms at 6 months, 50 micrograms at 15 to 18 months; a total of 237.5 micrograms for a child who at best weighs 10 kilograms. This far exceeds the safety limits if you consider bolus dosing. Safety limits would be more like 1 to 1.5 micrograms.

''The bile production is minimal in infancy, making it more difficult for metals 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've underestimated the devastation 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 POLICYMAKERS AND VACCINE MANUFACTURERS FOR DECADES

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

In 1932, in a paper published by Lilly researchers who found Merthiolate to be a skin-disinfecting agent, it was noted that another researcher has seen adverse reactions. ''Reimann has reported that some individuals display a sensitiveness to thio [thimerosal] compounds, which is characterized by reddening of the treated area and the appearance of small papules and vesicles.''

In 1935, in a letter from the Director of Biological Services, of the Pittman-Moore Company to Dr. Jamieson of Eli Lilly, ''we have obtained marked local reaction in about 50 percent of the dogs injected with serum containing dilutions of Merthiolate varying from 1 in 40,000 to 1 in 5,000 . . . no connection between the lot of serum and the reaction. In other words, Merthiolate is unsatisfactory as a preservative for serum intended for use on dogs . . . I might say that we have tested Merthiolate on humans and find that it gives a more marked local reaction than does phenol and tricresol.''

In 1942, an Army doctor in Baltimore, Maryland published a journal paper in which he raised concerns about thimerosal: ''Some investigators claim that if a patient's skin is sensitive to one of the mercurials he may be sensitive to any compound containing mercury. We have investigated 5 patients with dermatitis due to Merthiolate and found that four were sensitive to Merthiolate and not to any other organic or inorganic mercury compounds with which they were tested . . . Sulzberger found that in performing routine patch tests with 10 percent ammoniated mercury ointment and 10 percent salicylic acid ointment he obtained relatively few positive reactions; but if the two ointments were combined so that the concentration was five percent of each, then 50 percent of all patients tested gave positive reactions.'' Dr. Elliss further explained in his paper, ''Dr. J. H. Mitchell in a lecture before the American Academy of Dermatology in New York in December 1941, stated that he had observed a number of cases of severe dermatitis following the treatment of dermatophytosis with preparations of Merthiolate.''

In 1943, Dr. Elliss published a case report in the Archives of Opthalmology, which states:

''The positive results of patch tests demonstrated that the two patients were sensitive to tincture of merthiolate were also sensitive to 1:5000 merthiolate ophthalmic ointment and that merthiolate is capable of causing an inflammation of the mucous membrane in patients who are sensitive to the drug. In view of these facts it is recommended: 1. That Merthiolate ophthalmic ointment should not be used in or about the eye unless it has been previously demonstrated by patch tests that the patient is not sensitive to the ointment. 2. That the package should be labeled to warn the consumer that such tests should be made previous to the use of merthiolate ophthalmic ointment in or about the eye. Since a patient may become sensitized to Merthiolate while using the ophthalmic ointment, it may be advisable to withdraw this product from the market before a case of permanent ocular damage occurs, in spite of the fact that no cases of ocular injury due to merthiolate have been reported.''

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

''I discussed the possible effect of ethylmercury with Bordetella pertussis to supplement B-adrenergic blockade. Again, it was not believed that this blockade should predispose toward intessusception, 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.''

In August of 1998, an FDA internal ''Point Paper'' was prepared for the Maternal Immunization Working Group. This document, prepared almost a full year before the Public Health Service—American Academy of Pediatrics joint statement made the following recommendation:

''For investigational vaccines indicated for maternal immunization, the use of single dose vials should be required to avoid the need of preservative in multi-dose vials . . . Of concern here is the potential neurotoxic effect of mercury especially when considering cumulative doses of this component in early infancy . . .''

On September 8, 1998, the Safety Working Party of the European Agency for the Evaluation of Medicinal Products issued its working paper, ''Assessment of the Toxicity of Thimerosal in Relation to Its Use in Medicinal Products.'' The Working Party concluded:

''There is ample evidence from the literature that thiomersal (thimerosal) may cause sensitization and subsequent allergic reactions . . . the use of thimerosal is vaccines given to infants in accordance with various national vaccine programs may in certain cases result in approximately two times higher intake of ethylmercury during the first year of life than what can be considered reasonably safe. Given the great uncertainty of the estimations of safe levels in young children, it is suggested to restrict the use of thimerosal in vaccines.''

In June of 2000, the CDC convened a closed meeting to discuss research evidence that showed a connection between thimerosal in vaccines and neurological injury. Dr. Thomas 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 attention deficit disorder . . . 1, 3 and 6 months and language and speech delay . . . 1, 3, and 6 months of age and neurodevelopmental delays in general.''

He concludes:

''This analysis suggests that in our study population, the risks of tics, ADD, language and speech delays, and developmental delays in general may be increased by exposures to mercury from thimerosal-containing vaccines during the first six months of life.''

This issue will be discussed in more detail in another section of this report.

The Committee and the public have been frustrated by the Department of Health and Human Services reluctance to accept that all forms of mercury are toxic and that children have likely been harmed from the FDA's negligence in assuring the safety of thimerosal and in not monitoring the increased exposure to mercury through vaccines.

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

Mrs. Chenoweth-Hage:

''. . . I have a staffer who is in the Navy Reserve right now, but he used to be active with the airborne divisions, and he was in for a test in one of the medical military hospitals, and upon taking his temperature, they broke a thermometer, and mercury splattered across his glasses and some got in his eye. Well, the first thing they did was cutoff his clothes. The second thing was call in OSHA to clean up the mercury. And then they worked on him to make sure his eyes were irrigated, and you guys, you witnesses, absolutely amaze me. I wonder where the disconnect is, for Pete's sake.

''You listened to the 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 slammed 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 you to get real. 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 talks 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 people who are affected with mercury poisoning compared to autism, this is the duck test, and you folks are trying to tell us that you can't take this off the market when 8,000 children are going to be injected tomorrow; 80 children may be coming down, beginning tomorrow, with autism? What if there was an E. coli scare? What if there was a problem with an 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 inconclusive. 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? 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 circus starts taking place. Denial is not proper right now.

''You know, I still go back to the fact—I still want to talk about the duck test. Mr. Egan, [FDA] I will address this to you. You know, it was shown in the last panel that autistic symptoms emerge after vaccination. It was shown that vaccines contain toxic doses of mercury. It was shown that autism and mercury poisoning, the physiological comparison is striking. There is altered neurotransmitter activity, abnormal brain neuronal organization, immune system disturbance, EEG abnormalities. It goes on and on and on, the comparisons. That is why I say, I back up what 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 autistic condition of their children is related to an adverse reaction to a childhood vaccine, or a series of vaccinations. This is particularly true of parents of children who have developed ''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 that of Dr. Wakefield, I asked the audience of 500 parents if they felt their child regressed following a vaccine. In that obviously non-scientific survey, approximately 90 percent 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 under the VAERS system, fewer than 15 said they had. Then I asked if their pediatrician had offered to report this, they just laughed. I have now conducted this simple survey with over 5000 parents at conferences around the world with similar findings. Yes, media attention creates bias. But despite the informal nature of this survey, it does tell us something about this debate we are currently engaged in: (1) parents of children with autism suspect vaccines damaged their child, (2) parents are not reporting this using VAERS forms, (3) pediatricians are not reporting to VAERS either, (4) and despite efforts by policymakers at CDC, FDA, AAP, IOM and elsewhere to reassure parents of the safety of vaccines, they remain unconvinced.''

The Committee has heard moving testimony from parents in support of this belief, as well as from parent-advocates. Shelley Reynolds is a mother of two from Baton Rouge, Louisiana. When she testified before the Committee in April of 2000, her autistic son, Liam, was four years old. Her testimony left no doubt as to her views:

''Liam was a normally developing baby until June 27, 1997, when he received his MMR and Hib vaccines. He did everything he was supposed to do. He cooed, rolled over, crept, crawled, pulled up and walked on time. He said 'Mama,' he said 'Daddy,' he said 'Love you.' He learned how to sing 'Itsy Bitsy Spider.' He played finger games with us. He loved to interact, and he especially loved to show off for his grandparents.''

* * * * *

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

* * * * *

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

* * * * *

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

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

''Jacob met every developmental milestone that first year, right along with Jesse. They were two little peas in a pod and went everywhere together. At only 16 months of age, Jacob and Jesse received their first MMR vaccine. On this same day, they also received their fourth DTP, their fourth Hib, and their third hepatitis B. The following 24 hours, both twins slept most of the time, with over 100-degree temperatures, in spite of receiving the recommended Tylenol dosage every 6 hours. Immediately following that, Jacob began exhibiting strange behaviors. He was no longer excited or responsive when Daddy would come home from work. He began to become preoccupied with certain toys. He would spend long periods of time studying the way their wheels would spin or whether or not they were lined up just right. Any attempt to interrupt or distract him was met with great resistance and an eventual fit.

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

* * * * *

''At times, Jacob was so withdrawn that we could absolutely not reach him.''

* * * * *

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

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

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

* * * * *

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

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

Not surprisingly, suspicions that there may be a causal relationship between some vaccines and autism have spawned a significant amount of litigation.

As of October 2002, more than 875 families had filed petitions for compensation under the Federal Vaccine Injury Compensation Program (VICP), alleging that a vaccine or a series of vaccines caused their child's autism. It has been estimated that as many as 3,000 to 5,000 such petitions may be filed in the near future.

Congress established the VICP in 1987 to provide compensation to families of individuals who suffer vaccine injuries. The Federal government maintains a trust fund out of which awards are paid and which is funded by an excise tax on vaccines. Petitions for compensation are adjudicated before a team of special masters, with the Justice Department representing the Federal government.

With the knowledge that the growing number of petitions seeking compensation for autism spectrum disorders poses a difficult challenge for the VICP, the Chief Special Master laid out a special two-part procedure for resolving these claims. First, a general causation inquiry known as the ''Omnibus Autism Proceeding'' will be conducted to determine generally if vaccines can cause autism disorders, and if so, under what circumstances. The two-year schedule for completing this omnibus proceeding includes a discovery period for establishing an evidentiary record, testimony of expert witnesses, an evidentiary hearing, and a ruling on general causation issues by July of 2004. In the second part of the two-part procedure, the Special Master's determination in the omnibus proceeding will be applied to individual cases.

Thus far, there are two primary contentions underlying all of the autism cases filed in the VICP. The first is that the MMR vaccine has caused autism in some children. The second alleges that the mercury contained in several other vaccines caused neurological damage, resulting in autism spectrum disorders. These contentions are summarized in the 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 vaccine in question has developed a neurodevelopmental disorder, consisting of an 'Autism Spectrum Disorder' or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the 'thimerosal' ingredient in certain Diptheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two [vaccine administrations].''

In addition to petitions filed under the VICP, many parents have filed lawsuits against vaccine manufacturers and manufacturers of thimerosal. The first such lawsuit was filed in Texas in May of 2001 on behalf of five-year-old Joseph Alexander Counter (Counter v. American Home Products). According to his parents and attorneys, he was diagnosed with autism and then was found to have high levels of mercury exposure. Later that year, a group of law firms calling themselves the ''Mercury Vaccine Alliance'' filed class action lawsuits in nine different states.

While dozens of lawsuits have been filed, they generally fall into three different categories:

1. Actions claiming that thimerosal is an adulterant or a contaminant in a vaccine;

2. Actions seeking compensation for loss of consortium (love and companionship) on behalf of parents of autistic children; and

3. Class actions seeking compensation for autistic children and medical monitoring for broad populations of children who were exposed to mercury in vaccines.

Under the National Childhood Vaccine Injury Act, which created the Vaccine Injury Compensation Program, victims of vaccine injuries are not allowed to file lawsuits against vaccine manufacturers unless they have first sought compensation through the VICP. However, one exception allows lawsuits for vaccine injuries allegedly caused by an ''adulterant'' or a ''contaminant'' intentionally added to the vaccine. In twin decisions in May of 2002, a Federal judge ruled that thimerosal could not be considered an adulterant or a contaminant, and claims filed on that basis were dismissed. However, in those same decisions, the court ruled that parents of vaccine-injured children are entitled to seek damages in court for loss of consortium without going through the VICP.

As these cases work their way through the courts, procedural rulings in different jurisdictions will have a great influence on whether potentially thousands of families seek compensation through the courts or through the VICP.

VI. A GROWING NUMBER OF SCIENTISTS AND DOCTORS BELIEVE THAT A RELATIONSHIP BETWEEN THIMEROSAL IN VACCINES AND AUTISM SPECTRUM DISORDERS IS PLAUSIBLE

A. Introduction

A growing number of respected scientists and researchers are convinced that there is a relationship between the use of thimerosal in childhood vaccines and the growing incidence of autism. A number of these scientists have testified before the Committee. At the same time, senior officials from Federal health care agencies and other public health experts continue to insist that there is no evidence of such a relationship.

Two things appear to be clear in this debate. First, concerns about the use of thimerosal in vaccines existed in public health agencies for more than two decades before action was taken to remove them from vaccines. The lethargic response to these legitimate concerns will be discussed in the following section of this report. Second, much more research needs to be done before any conclusive determinations can be made about vaccines and autism spectrum disorders. Developing more and better research data will be critically important to resolving the legal disputes over compensation for children with autism, and restoring the confidence of the American public in vaccines.

This section will review the current state of the scientific debate over vaccines and autism.

B. Institute of Medicine reports call for more research

In 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 dealt with 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 autistic disorders among a small number of 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 establishing causality. Studies may not have sufficient precision to detect very rare occurrences on a population level. A poor understanding of the risk factors and failure to use a standard case definition may also hamper the ability of epidemiological studies to detect rare adverse events.''

The IOM recommended further research to determine if exposure to the MMR vaccine is a risk factor for autism disorders in a small number of children. They also called for targeted studies to follow up on a groundbreaking series of case studies by Dr. Andrew Wakefield of Great Britain, who determined that 12 British children who suffered from autism spectrum disorders and chronic bowel inflammation also had vaccine-strain measles virus in their tissues. Although the parents of eight of the twelve children traced the onset of autistic symptoms to the time period when the MMR vaccination was given, the IOM stated that the study was of limited utility because of its small sample size.''

Six months later, the IOM issued its second report, entitled, ''Immunization Safety Review—Thimerosal-Containing Vaccines

and Neurodevelopmental Disorders.'' They found insufficient evidence to accept or reject a connection between thimerosal in vaccines and autism. They did, however, state that such a connection is ''biologically plausible,'' and recommended much more research on the issue.

The report summarized:

''The committee concludes that although the hypothesis that exposure to thimerosal-containing vaccines could be associated with neurodevelopmental disorders is not established and rests on indirect and incomplete information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given in children, the hypothesis is biologically plausible.''

* * * * *

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

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

Phase II of the study, which provided enough data to analyze only speech delays and attention deficit disorder, did not detect an association between those disorders and thimerosal, as had Phase I. After being briefed on both phases of the study, the IOM's Immunization Safety Review Committee agreed that they were inconclusive. The ''VSD Study'' is discussed at greater length in Section VII.

The IOM also noted with some discomfort that thimerosal had not been removed from all vaccines and medicines given to children and pregnant women. The report specifically cited the influenza vaccine, the diphtheria-tetanus toxoid vaccine, and some nasal sprays. They urged that, ''full consideration be given by appropriate professional societies and government agencies to removing thimerosal from vaccines administered to infants, children or pregnant women in the United States.'' It was also recommended that any remaining stocks of childhood vaccines containing mercury be removed from doctor's offices and replaced with mercury-free alternatives.

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

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

Further analysis of cohorts of 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 excrete metals;

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

Research in appropriate animal models on neurodevelopmental effects of ethylmercury;

Rigorous scientific investigations of chelation as a treatment for neurodevelopmental disorders; and

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 terminate its use in vaccines.

C. A growing number of researchers believe that there may be a relationship between vaccines and autism spectrum disorders

A growing number of researchers and medical professionals believe that there may be a link between the mercury preservative used 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 based on work they have done to-date. They believe that this is a promising field of research that may yield breakthroughs on the question of the underlying causes of the growing incidence of autism and other neurodevelopmental disorders.

On April 25, 2001, the Committee heard testimony from Dr. Boyd E. Haley, who is the Chairman of the Chemistry Department at the University of Kentucky. Dr. Haley has spent many years studying the effects of mercury on the human body. Dr. Haley summarized his views in this way:

''I cannot say, nor would I say, that vaccinations cause autism. However, if the data holds up that I have been seeing with the relationship, I think it is an awfully good suspect, at least one of the co-factors that might aid in the onset of this disease. So I would really recommend and encourage you to put some pressure on the National Institutes of Health (NIH) to look at the contribution of different forms of mercury we put in our medicines and in our dentistry to see what effect they have on the neurological health of Americans.''

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

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

* * * * *

''Our results are very consistent with the reported toxicity of thimerosal-containing vaccines versus non-thimerosal containing vaccines as observed in cell culture studies reported in 1986. The chemical rationale for the neurotoxicity of thimerosal is that this compound would release ethyl-mercury as one of its breakdown products. Ethyl-mercury is a well-known neurotoxin. Further, combining thimerosal with millimolar levels of aluminum cation plus significant levels of formaldehyde, also found in these vaccines, would make the vaccine mixture of even greater risk as a neurotoxic mixture.''

Dr. Haley went on to state that infants are more susceptible to damage from mercury, because the defense mechanisms in their bodies are less well developed:

''Infants, with their immature physiology and metabolism, would not be expected to handle mercury as efficiently as mature adults.''

* * * * *

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

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

''We clearly know infants' brains are more sensitive. We know the blood-brain barrier, the barrier to drugs between the blood and the brain, is virtually gone in infants.''

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

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

Dr. Baskin: ''Yes.''

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

Dr. Baskin: ''I think it's hard to look at a percentage. I think that, as NIH is focusing on, there is probably an environment-gene interaction. In other words, a lot of children get the injection and don't become autistic, and so there must be something specific or different about the way a certain subgroup of children are able to handle toxins. . . . I don't think we yet know the answer to that.''

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

''If you look at the chemistry of the APO–E proteins, this can be reflected in the fact that it is a housekeeping protein that clears the brain of waste materials. If you have APO–E2, you can carry out two atoms of mercury for every atom of APO–E that goes out. If you have APO–E4, you can carry out none.

''He [Dr. Mike Godfrey of New Zealand] took this and looked at autistic children. When he did the screen of autistic children, there was a huge preponderance of them that had APO–E4, indicating that there is a genetic risk factor, which deserves further study. And it does imply that the inability

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

Dr. Baskin described research he is conducting which demonstrates what the effects of mercury are when it is not removed from brain tissue:

''Let me turn to some studies that we're doing at Baylor College of Medicine. We have the opportunity to actually grow human frontal cortex cells in cell culture. So these are cells from the front part of the brain that grow in culture. We incubate these cells with thimerosal at various doses, and we use a number of very sophisticated techniques to detect cell death and cell damage.''

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''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 blue dye that normal cells don't take up. In order for something to turn blue, the cell has to have holes punched in their membranes. And guess what: At an extraordinarily low dose of thimerosal, most of the cells are blue. It means that this stuff grabs a hold of the membrane and punches holes into it, so that the dye can penetrate, not only into the cytoplasm but into the very center of the cell, the nucleus, where all the DNA exists.''

* * * * *

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

Dr. Baskin testified that other researchers in his field are finding similar results:

''At the recent International Meeting for Autism Research at the Society for Neuroscience, a number of investigators around the world are finding similar things. At Columbia University, there's now a model in mice who were injected with low doses of thimerosal very similar to what's given in human vaccines. These mice develop neurological deficits that look like autism, and when you take their brains out and you analyze them, they have the same type of brain damage.''

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

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

They asked vaccine manufacturers to remove thimerosal from childhood vaccines more than three years ago;

In the 1990's, they acknowledged that many children received a cumulative amount of ethylmercury in vaccines that exceeded the EPA's safe limits for methylmercury;

One Federally sponsored study showed an association between thimerosal in vaccines and some developmental disorders.

On April 18, 2002, the Committee heard testimony from Melinda Wharton, Director of the Epidemiology and Surveillance Division of the CDC's National Immunization Program. Her response to a question about mercury in vaccines hinted at the skeptical attitude that prevails at the CDC and the FDA:

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

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

She further stated:

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

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

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

* * * * *

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

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

''During the first 6 months of life, cumulative exposure to mercury could have exceeded the more conservative limits of the EPA in some cases, depending on the specific vaccine formulations used and the weight of the infant.''

There is no question that the cumulative amount of ethylmercury on the recommended schedule of childhood vaccinations exceeded the EPA's threshold for methylmercury. In fact, there is little doubt that the amount of ethylmercury in individual vaccines exceeded the threshold. The EPA's threshold is 0.1 micrograms per kilogram of body weight. For an eleven-pound baby, the EPA's safe threshold would be 0.5 micrograms. Although thimerosal has been removed from these vaccines today in the United States, in the 1990's, Aventis Pasteur's DTaP vaccine contained 25 micrograms of thimerosal. GlaxoSmithKline's Hepatitis B vaccine contained 12.5 micrograms of thimerosal. Wyeth Lederle's Hib vaccine contained 25 micrograms of thimerosal.

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

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

In contrast to Dr. Midthun's statements, Dr. Halsey told the New York Times that he was astonished when he reviewed an FDA analysis of how much mercury was in vaccines being given to children:

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

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

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

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

However, Dr. Halsey's statement made it equally clear that he believes that there may be an association between exposures to low levels of mercury and other neurological impairments. His statement referred specifically to the Faroe Islands studies and the calculation that the cumulative amount of thimerosal in childhood vaccines exceeded the EPA's limits for methylmercury:

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

* * * * *

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

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

To date, very little epidemiological or clinical research has been done on the neurological effects of thimerosal, and particularly its ethyl-mercury component. As the IOM noted in its report on thimerosal, ''the data regarding toxicity of low doses of thimerosal and ethylmercury are very limited,'' and most of the conclusions that have been drawn about ethylmercury are based on analogies to methylmercury, which has been more widely studied. The few studies that have been performed on ethylmercury have been of limited value, for several reasons.

Perhaps Dr. Thomas Verstraeten conducted the broadest review of a possible relationship between thimerosal and neurological disorders in 2000. This study reviewed several years of 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 exposure to 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. It is discussed at greater length in the next section of this report.

In November of 2002, a study on thimerosal conducted at the University of Rochester was published in The Lancet, 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 infants exposed to thimerosal, and high levels of mercury in their stools, indicating to them that ethylmercury has a shorter half life then methylmercury, and that most of the mercury was excreted through the gastro-intestinal tract. According to the authors:

''We have shown that very low concentrations of blood mercury can be detected in infants aged 2–6 months who have been given vaccines containing thiomersal [sic]. However, no children had a concentration of blood mercury exceeding 29 . . . parts per billion, which is the concentration thought to be safe in cord blood.''

The authors went on to conclude:

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

Skeptics 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's Dr. Baskin.

1. The sample size was very small:

Only 40 children who received thimerosal were studied. If 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 a child had some different tendency in their blood to absorb more mercury or have it remain in the blood longer or be more sensitive in their brain, if they only checked 40 kids, they may well not have found even one kid with a predisposition to autism.''

2. The sample was not random:

In his testimony, Dr. Baskin commented on the importance of a random sample size:

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

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

In an effort to determine how long it takes ethylmercury to be expelled from an infant's body, and what the expected 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, as Dr. Baskin notes, peak levels of mercury in the blood are expected to appear within 24 hours:

''We know the stool levels were high, but if you look at when they actually measured the blood levels, they said it was somewhere between 3 and 27 days later. The peak mercury levels after injection occur within hours or at least within the first 24 hours. So if they were drawing blood later than that, and much later than that, of course the levels weren't going to be high. But the mercury doesn't jump from the injection to the stool; it goes through the blood. At some point it was high because it was high in the stool.''

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''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 their bodies. This limitation was clearly brought out in an exchange between Congressman Burton and Dr. Christopher Portier, Director of the Environmental Toxicology Program at the National Institute of Environmental Health Sciences:

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

Dr. Portier: ''No.''

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

''They described this as a descriptive study, and that's exactly what it was. It provides some interesting information, it's a start, but the interpretation is inaccurate.''

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

A. Introduction

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 1980's. Even then, regulatory actions to remove thimerosal and other mercury compounds from medical products proceeded at a glacial pace. The decision to remove thimerosal from topical ointments 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.

For decades, ethylmercury was used as a preservative or anti-bacterial agent in a range of products, including antiseptic ointments for treating cuts, nasal sprays, eye solutions, diaper rash treatments, contraceptive products, and perhaps most importantly, vaccines. Several years after an FDA advisory committee found that thimerosal wasn't safe for use in topical ointments, new childhood vaccines containing thimerosal were being approved and added to the recommended schedule. It appears that nobody analyzed the potential impact of the increased cumulative amount of mercury to which young children were being exposed. In fact, if Congress had not enacted legislation in 1997 requiring the FDA to study the amounts of mercury being used in FDA-approved products, it is questionable that the FDA would have analyzed mercury in vaccines at all.

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

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

It is clear that the guiding principal for FDA policymakers has been to avoid shaking the public's confidence in the safety of vaccines. For this reason, many FDA officials have stubbornly denied that thimerosal may cause adverse reactions. Ironically, the FDA's unwillingness to address this issue more forcefully, and remove thimerosal from vaccines earlier, may have done more long-term damage to the public's trust in vaccines than confronting the problem head-on. Given the serious concerns about the safety of thimerosal, the FDA should have acted years earlier to remove this preservative from vaccines and other medicines.

B. Thimerosal manufacturers accumulated evidence of the toxicity of thimerosal

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

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

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

As previously discussed in this study, an intravenous solution containing thimerosal was tried as an experimental treatment for 22 men who were seriously ill with Meningitis. While the treatment was found to be ineffective, the doctor who conducted the study concluded that the solution caused no harmful side effects. It is clear today that such a limited number of subjects, all suffering from the same serious illness, would

hardly qualify as a sufficiently sized random sample, and a study such as this one would be of very little value by today's standards. In fact, an internal Eli Lilly memo from 1972 candidly notes the study's shortcomings:

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

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

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

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

An April 24, 1930, intra-office memo stated:

''. . . in view of our experience with the merthiolate solution, we have to know pretty definitely what to expect from merthiolate ointment and jelly before they are put on the market . . . Can we expect to have the stronger ointment and jelly used without complaint which attended the use of the solution in the same strengths? . . . Our experience with the solution ought to serve as a warning and certainly in the face of that warning we ought not to advocate the use of the stronger products without some pretty definite evidence that we will not repeat our solution experience.''

A September 1934, paper from Lilly's files states:

''[L]ittle is known about the effect of mercuric compounds when inoculated into humans. It is therefore preferable to use the minimum amount of this preservative necessary to maintain the sterility of the product.''

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

''When Merthiolate breaks down, are the degradation products toxic or irritating? Our files yield no test information on the irritancy of degraded merthiolate.''

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''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 would not be hazardous.''

A December 1972, memo states:

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

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

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

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 1935, letter from the Pittman-Moore Company indicated that Merthiolate was not appropriate for use in dogs:

''We have obtained marked local reaction in about 50% of the dogs injected with serum containing dilutions of Merthiolate, varying in 1 in 40,000 to 1 in 5,000, and we have demonstrated conclusively that there is no connection between the lot of serum and the reaction. In other words, Merthiolate is unsatisfactory as a preservative for serum intended for use on dogs. Occasional dogs do not show the local reaction, but in some instances, the reaction is extremely severe. I might say that we have tested Merthiolate on humans and find that it gives 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 1948 paper from an Arizona doctor reported the case of a woman who suffered repeated multiple reactions to Merthiolate applied to her skin prior to surgery. She reportedly suffered chills and fevers and had small vesicles and erythema in the area of her Merthiolate application. After her recovery, the patient indicated that the ulcer for which she was being surgically treated appeared after repeated application of a tincture of Merthiolate. She continued applying the Merthiolate until her skin became too raw and painful to continue use, and then sought medical care.

A 1950 New York Academy of Sciences article entitled, ''Mercurials as Antiseptics,'' found that Merthiolate ''is toxic when injected parenterally and therefore cannot be used in chemotherapy.''

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

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

In 1974, the FDA undertook a comprehensive review of the safety and effectiveness of over-the-counter medicines. As one facet of this review, a panel of experts was assembled to review the safety and efficacy of over-the-counter drugs containing mercury. The Advisory Review Panel on OTC Miscellaneous External Drug Products began this review in 1975. In 1980, the panel delivered its report to the FDA. It reviewed 18 products containing mercury, and found them all either unsafe or ineffective for their stated purpose of killing bacteria to prevent infections.

In terms of effectiveness, the panel stated that, ''mercury compounds as a class are of dubious value for anti-microbial use.'' They stated that, ''mercury inhibits the growth of bacteria, but does not act swiftly to kill them.'' In fact, the panel cited a 1935 study of the effectiveness of thimerosal in killing staphylococcus bacteria on chick heart tissue. The study determined that thimerosal was 35 times more toxic to the heart tissue it was meant to protect than the bacteria it was meant to kill.

In terms of safety, the panel cited a number of studies demonstrating the highly allergenic nature of thimerosal and related organic mercury products. For instance, they cited a Swedish study that showed that 10 percent of school children, 16 percent of military recruits, 18 percent of twins, and 26 percent of medical students had hypersensitivity to thimerosal. They stated that while organic mercury compounds like thimerosal were initially developed to decrease the toxicity of the mercury ion, thimerosal was actually found to be more toxic than bichloride of mercury for certain human cells.

By way of summary, they stated the following:

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

Despite the fact that the expert committee found thimerosal and other ethyl-mercury compounds unsafe and ineffective for over-the-counter products, the FDA would not formally require the removal of mercury from these products for another 18 years. The submission of the committee's report in 1980 set in motion a tortuous bureaucratic process that would not result in the banning of mercury from over-the-counter products until 1998. The agency published Advanced Notice of Proposed Rules or Notice of Proposed Rules regarding these products in 1980, 1982, 1990, 1991, 1994 and 1995.

What makes the glacial pace 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-based 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 in topical ointments did not 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 Schwetz, who went on to serve as the Acting Director of the FDA for nearly a year:

''One thing I haven't heard discussed, the fact that we know that ethylmercury is a skin sensitizer when it's put on the skin, and now we're injecting this IM (intramuscularly) at a time when the immune system is just developing, the functionality of the immune system is just being set at this age. So now we're injecting a sensitizer several times. During that period of time, what's the impact of a sensitizer—of something that is known to be a skin sensitizer, what is the effect on the functional development of the immune system when you give a chemical of that kind repeatedly IM?''

Different branches of the FDA regulate over-the-counter products and vaccines. OTCs are regulated by the Center for Drug Evaluation and Research (CDER). Vaccines are regulated by the Center for Biologics

Evaluation and Research (CBER). This, however, is little justification for the lack of coordination. The FDA's determination that mercury was unsafe and should be removed from over-the-counter medications was published in the Federal Register no fewer than five times prior to the FDA's belated review of mercury in vaccines.

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

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

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

There was tremendous reluctance on the part of some officials to admit that a mistake had been made in allowing ethylmercury to be used in vaccines. There was great uncertainty in others caused by the lack of data specifically on ethylmercury. However, the institutional resistance to change was counter-balanced by the growing realization that there was more ethylmercury in childhood vaccines than previously thought, and that nobody had thought to calculate the cumulative amounts. The essence of the debate was captured in a 1999 e-mail from a former FDA official weighing the pros and cons of taking action. He opined that hastening the removal of thimerosal from vaccines would:

''. . . raise questions about FDA being 'asleep at the switch' for decades by allowing a potentially hazardous compound to remain in many childhood vaccines, and not forcing manufacturers to exclude it from new products. It will also raise questions about various advisory bodies regarding aggressive recommendations for use. (We must keep in mind that the dose of ethylmercury was not generated by 'rocket science'. Conversion of the percentage thimerosal to actual micrograms of mercury involves ninth grade algebra. What took the FDA so long to do the calculations? Why didn't CDC and the advisory bodies do these calculations when they rapidly expanded the childhood immunization schedule?)''

It is clear that each time an important decision had to be made, the factions that were skeptical of thimerosal's dangers and favored a ''go-slow'' approach, were able to water down the actions. In 1999, when the Federal government could have ordered thimerosal removed from vaccines by a specific date, or stated a preference for thimerosal-free vaccines, a statement was instead issued asking for a commitment from vaccine manufacturers to eliminate or reduce mercury in vaccines as expeditiously as possible. As a result, almost two years passed before the three major thimerosal-containing vaccines—DTaP, Hib and Hepatitis B—were being manufactured in thimerosal-free formulations. In 2001, when the CDC and its influential advisory committee could have stated a preference for thimerosal-free vaccines, they chose not to do so. As a result, thimerosal-containing vaccines that remained in stock in doctors' offices continued to be used. In point of fact, we have no proof that in 2003, some children in the United States are not still receiving thimerosal-preserved vaccines that have lingered in medical offices or clinics.

The CDC's decision not to endorse thimerosal-free vaccines in 2001 is particularly troubling. With the exception of the influenza vaccine, all major childhood vaccines were being manufactured without thimerosal at that time, so there was little threat of shortages. Their failure to state a preference was an abdication of their responsibility.

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

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

An exchange of e-mails in October of 1998 makes clear that Dr. Leslie Ball was already leaning toward the removal of thimerosal from vaccines. It also makes clear that there was internal resistance to such an action. Dr. Marion Gruber of the Office of Vaccine Research and Review forwarded an internal FDA memo to Dr. Ball, which concluded that:

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

Dr. Ball's response on October 15, 1998, to Dr. Hasting's conclusion was sharp:

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

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

An important part of the FDA's review was a comparison of the amount of ethylmercury in vaccines to the recommended safe levels for exposure to methylmercury established by the EPA and the FDA. In 1999, a consultant to the FDA, Dr. Barry Rumack, developed a pharmacokinetic model to analyze the amount of mercury to which infants were being exposed. The FDA produced to the Committee two charts developed from that model dated June 28, 1999. Both charts demonstrate what has now become widely acknowledged, that most children in the 1990s received doses of ethylmercury in their vaccines that exceeded the EPA's limits for exposure to methylmercury (0.1 micrograms per kilogram) for at least the first six months of their lives. Even more significantly, the charts also indicate that most children received doses of ethylmercury that exceeded the FDA's less-restrictive limits (0.4 micrograms per kilogram) for at least the first two months of their lives.

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

Dr. Neal Halsey, Director of the Institute of Vaccine Safety at Johns Hopkins University, acknowledged this important fact, however. As previously mentioned, Dr. Halsey became convinced that thimerosal should be removed from vaccines. On June 22, 1999, Dr. Ball presented the results of her research to the Medical Policy Coordinating Committee of the FDA's Center for Biologics Evaluation and Review (CBER). Dr. Halsey attended that meeting. The next day, on June 23, 1999, Dr. Halsey wrote a letter to the members of the American Academy of Pediatricians' Committee on Infectious Diseases, which he chaired. He stated:

''In the past few days, I have become aware that the amount of thimerosal in most hepatitis B, DTaP and Hib vaccines that we administer to infants results in a total dose of mercury that exceeds the maximum exposure recommended by the EPA, the FDA, CDC and WHO . . .''

Dr. Halsey's admission that more than just the EPA's more conservative guideline was exceeded is a significant departure from the public statements of most Federal officials. Dr. Halsey acknowledges that the guidelines of the EPA, the CDC, the FDA and the World Health Organization were all exceeded.

Another noteworthy fact is that the charts produced by Dr. Rumack, and the FDA's analysis in general, failed to take into consideration the background levels of mercury to which children are exposed from other sources. Dr. Ball pointed out this weakness in her June 1999 e-mail:

''These calculations do not account for other sources of Hg [mercury] in the environment. Even infants can have additional exposures, e.g., breast milk.''

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

The issue of what to do with thimerosal in vaccines came to a head in the summer of 1999. In June and July, a series of meetings were held involving the FDA, the CDC, the Public Health Service, the American Association of Pediatricians, and other agencies. Documents reviewed by the Committee indicate that the Public Health Service opposed a public effort to remove thimerosal from vaccines. One FDA document stated that the Public Health Service was concerned that stating a preference for thimerosal-free vaccines could ''result in unwarranted loss of confidence in immunization programs in the US and internationally, shortages of childhood vaccines might ensue, and other potential far-reaching ramifications are envisioned.''

In a July 2, 1999, e-mail, Dr. Ruth Etzel of the Department of Agriculture also noted the Public Health Service's resistance:

''We must follow the three basic rules: (1) act quickly to inform pediatricians that the products have more mercury than we realized; (2) be open with consumers about why

we didn't catch this earlier; (3) show contrition. As you know, the Public Health Service informed us yesterday that they were planning to conduct business as usual, and would probably indicate no preference for either product. While the Public Health Service may think that their 'product' is immunizations, I think their 'product' is their recommendations. If the public loses faith in the PHS recommendations, then the immunization battle will falter. To keep faith, we must be open and honest now and move forward quickly to replace these products.''

Adding to the pressure on the Federal government to act was the fact that steps were being taken in Europe to remove thimerosal from vaccines. On April 19, 1999, the European Agency for Medicinal Evaluation (EMEA) met in London. The EMEA is responsible for establishing guidelines for the use of drugs and biologics in the European Union. The FDA's Dr. Norman Baylor attended this meeting. Following this meeting, on June 29, 1999, the EMEA issued a document encouraging the removal of thimerosal from childhood vaccines:

''Vaccines: The fact that the target population for vaccines in primary immunization schedules is a healthy one, and in view of the demonstrated risks of thiomersal (sic) and other mercurial containing preservatives, precautionary measures (as outlined below) could be considered.

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

By early July, a compromise on a course of action was reached in the U.S. between the competing factions. A joint statement was released by the American Academy of Pediatrics and the U.S. Public Health Service. The statement included the following points:

Acknowledged that some children may have been exposed to levels of mercury that exceed one Federal guideline on methylmercury during the first six months of life;

Asserted that there is no evidence of any harm caused by thimerosal in vaccines;

Called on vaccine manufacturers to make a clear commitment to reduce as expeditiously as possible, the mercury content of their vaccines;

Urged doctors and parents to immunize all children, even if thimerosal-free vaccines are not available; and

Encouraged doctors and parents to postpone the Hepatitis B vaccine (which contained thimerosal at the time, and was generally given immediately after birth) until the child is two to six months old, unless the mother tested positive for Hepatitis B.

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

As a result of the limited steps taken in 1999, vaccines containing thimerosal remained on the market for nearly two years. GlaxoSmithKline's Hepatitis B vaccine did not become thimerosal-free until March of 2000, and Aventis Pasteur's DTaP vaccine did not become thimerosal-free until March 2001. In addition, thimerosal-containing vaccines on the shelves in doctor's offices around the country continued to be used in spite of the fact that thimerosal-free versions were available.

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

In June of 2000, the CDC's Advisory Committee on Immunization Practice met in Atlanta. Among other things, the Advisory Committee was called upon to recommend whether the CDC should issue a public statement of preference for thimerosal-free vaccines. At the time, the industry was in the midst of its transition to thimerosal-free childhood vaccines, and several vaccines containing thimerosal were still on the market. Of particular concern was the DTaP vaccine. In June of 2000, three of the four DTaP manufacturers (Aventis Pasteur, North American Vaccine and Wyeth) were still producing DTaP with thimerosal. Only SmithKline Beecham produced a thimerosal-free DTaP. In addition, because manufacturers of the Hib and Hepatitis B vaccines had just recently converted to formulas that were thimerosal-free or contained trace amounts of thimerosal, older versions of these vaccines containing thimerosal were still in inventories and being used around the country.

A statement of preference by the CDC would have been a clear signal to pediatricians not to use vaccines containing thimerosal, when thimerosal-free versions were available. This action would have substantially reduced the exposure to ethylmercury for many infants. Despite this knowledge, the advisory committee voted unanimously not to state a preference.

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

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

* * * * *

''As I said, the policy seems to be working. So this indicates that on this particular factor, this policy is moving us in an upward direction towards—it's a positive thing.''

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

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

* * * * *

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

* * * * *

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

The financial health of the industry should never have been a factor in this decision. The financial health of vaccine manufacturers certainly should never have been more important to the Federal health officials than the health and well being and the nation's children. The CDC has a responsibility to protect the health of the American public. If there were any doubts about the neurological effects of ethylmercury in vaccines on children—and there were substantial doubts—the prevailing consideration should have been how best to protect children from potential harm. However, it appears that protecting the industry's profits took precedent over protecting children from mercury damage.

In opting not to state a preference for thimerosal-free vaccines, the Advisory Committee shrugged off two sensible proposals that were presented during the meeting. A representative of SmithKline Beecham (now GlaxoSmithKline) stated that her company could supply sufficient amounts of thimerosal-free DTaP vaccine to ensure that the youngest infants receiving the initial doses of DTaP could receive thimerosal-free doses:

''I think it's important that you know that, although we cannot supply the entire U.S. market right now for all five doses immediately, we would be able to supply the vast majority of the U.S. market for the primary series, that is with targeting of the first three doses.''

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

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

''Roger, you said that after July, the maximum exposure will be 75 micrograms. My understanding from the information presented from the manufacturers is that there really still is some Hib out there in the market that is being used, but does contain thimerosal as a preservative. There also is hepatitis B out there that does contain it. So there's no guarantee the maximum exposure would be 75 micrograms. What I proposed last October was that they put a limit of one thimerosal-containing vaccine as a preservative per visit, which would then guarantee what you're looking for. And I think that that's the right policy because that allows for the continued use, though very limited. It eliminates the maximum exposure, but you do have the problem of what's in the 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 continued to receive vaccinations 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 exposure to 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 hundreds of thousands of patients belonging to seven major health maintenance organizations. Phase I of the study was designed to screen data for potential associations between thimerosal-containing vaccines and selected neurological disorders. Phase II was designed to test the hypotheses generated in the first phase.

Phase I produced a statistically-significant association between exposure to thimerosal during the first three months of life, and tics, attention deficit disorder, language and speech delays, and general neurodevelopmental delays. The study did not find a correlation between thimerosal and autism because the sample size of children diagnosed with autism was in all probability not large enough.

The findings of Dr. Verstraeten, the primary author of the study, set off a fierce debate within the Federal health agencies when they were released in June of 2000. Enough concern was generated that a conference 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 an under-ascertainment of all of these [disorders] because some of the children are just not old enough to be diagnosed. So the crude incidence rates are probably much lower than what you would expect because the cohort is still very young.''

Dr. Colleen Boyle of the CDC raised this issue a few months earlier. She states 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 missed cases—and how this relates to exposure. Clearly there is a gross underreporting—1.4% of the kids dignosed with a speech and language problem versus 4–5% reported in National surveys; less than 1% 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, largely because of the small sample size employed (16,000, as opposed to 110,000 in Phase I). The Institute of Medicine determined that, ''the small sample size limited the power of the study to detect a small effect, if it exists. The committee concludes that the Phase I and II VSD analyses are inconclusive with respect to causality.''

Although the panel assembled at the Simpsonwood Retreat Center had many unanswered questions about the VSD study, some members found the evidence compelling. Dr. David 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 Compensation Program 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 enough. Forgive this personal 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 male in the line of the next generation, and I do not want that grandson to get a Thimerosal-containing vaccine until we know better what is going on. It will probably take a long time. In the meantime, 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 causal relationship between thimerosal and neurological disorders, it did indicate the need for much more research:

''So what were the responses of the consultants? With regard to the first question, a need for further investigation. Overall the group expressed unanimous feeling that the findings supported a statistically significant, although weak, association, but that the implications—for obvious reasons—are profound. Therefore, the consultants were unanimous in their opinion 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 conference, 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. Phillippe 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 entire thimerosal debate, as I think they are as comparable as apples and pears at the best. Unfortunately I have witnessed how many experts, looking at this thimerosal issue, do not seem bothered to compare apples to pears and insist if nothing is happening in these studies, then nothing should be feared of thimerosal. I do not wish to be the advocate of the anti-vaccine lobby and sound as if I am convinced that thimerosal is or was harmful; but at least I feel we should use sound scientific argumentation, and not let our standards be dictated by our desire to disprove an unpleasant theory.''

It appears that many who 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 we have recognized that there really is 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 that knowledge is very important.''

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

''. . . the sensitivity of the fetus versus the neonate is very important, and for some of you who have forgotten about the sensitive windows during fetal development, the nervous system develops post-natally. So it isn't unreasonable to expect that there would be particular windows of sensitivity. So it isn't the matter of averaging the dose over the whole neonatal period—it's what's the week or what's the day or what's the series of hours that represent a particular event in the development of the nervous system when this whole thing might be dangerous. There may be weeks surrounding that when there isn't a major problem. We don't have that information.''

VIII. FOCUSED, INTENSIVE RESEARCH EFFORT IS BADLY NEEDED

One of the most consistent refrains heard by the Committee throughout its three-year investigation is that not enough 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 unbiased 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 made the following research recommendations:

Use accepted and consistent case definitions and assessment protocols for ASD (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.

Develop 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. (In the context of MMR vaccine and ASD, rechallenge refers to children who appeared to have experienced some form of neurological regression after a first dose of MMR or other measles-containing vaccine and who appeared to have experienced another regression following a second dose of MMR or other measles-containing vaccine.)

Study the possible effects of different MMR immunization exposures.

Conduct further clinical and epidemiological studies of sufficient rigor to identify risk factors and biological markers of ASD in order to better understand genetic or environmental causes.

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:

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

Further analysis of cohorts of 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 excrete metals;

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

Research in appropriate animal models on neurodevelopmental effects of ethylmercury;

Rigorous scientific investigations of chelation as a treatment for neurodevelopmental disorders; and

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

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

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

The Centers for Disease Control and Prevention has also been negligent in addressing the research needs regarding vaccine injury and a connection to the autism epidemic. In FY 2002, the CDC invested $11.3 Million on autism, while spending $62 Million on diabetes, and $932 Million on HIV/AIDS. With spending for autism 80 times less than that for AIDS, it is obvious that CDC is not addressing the autism epidemic with enough rigor. Instead, at the time of the Committee's April 2002 hearing, the CDC actually planned to cut autism research spending to $10.2 Million.

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

Chairman Burton expressed some of these concerns at the June of 2002 hearing:

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

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

IX. CONCLUSIONS

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

In a further attempt to raise the level of awareness of the autism epidemic, in November of 2002, Chairman Burton called upon the President to announce a White House Conference on autism to ''galvanize a national effort to determine why autism has reached epidemic proportions in this country.'' Chairman Burton suggested this would be a valuable opportunity to ''bring together the best minds from across the country to chart a course of scientific research to uncover the underlying causes of this epidemic. . . Mr. President, you are in a unique position to provide the leadership that is necessary to organize a national effort to resolve these problems.'' In January of 2003, the response from Bradley A. Blakeman, Deputy Assistant to the President and Director of Appointments and Scheduling was, ''I do not foresee an opportunity to add this event to the calendar.'' It is unfortunate that the request of the Chairman, and the hundreds of families who personally appealed to the White House for this Conference did not appear to have been brought to the personal attention of the President, who has stated that ''no child shall be left behind.''

Vaccines are the only medicines that American citizens are mandated to receive as a condition for school and day care attendance, and in some instances for employment. Additionally, families who receive Federal assistance are required to show proof that their children have been fully immunized. While the mandate for which vaccines must be administered is a State mandate, it is the Federal Government, through the Centers for Disease Control and Prevention (CDC) and its Advisory Committee for Immunization Practices that make the Universal Immunization Recommendations to which the States refer for determining mandates. Federal programs and funding to State programs provide immunizations free-of-charge to many children. In July of 2000, it was estimated that 8,000 children a day were being exposed to mercury in excess of Federal guidelines through their mandatory vaccines. Given the importance of vaccination in our overall public health strategy, it is imperative that the Department of Health and Human Services adequately addresses the concerns of families of whose children have possible vaccine-induced autism. The continued response from agency officials that ''there is no proof of harm'' is a disingenuous response. The lack of conclusive proof does not mean that there is no connection between thimerosal and vaccine-induced autism. What the lack of conclusive proof indicates is that the agency has failed in its duties to assure that adequate safety studies were conducted prior to marketing. Furthermore, in the last two decades, after determining that thimerosal was no longer ''generally recognized as safe'' for topical ointments, the agency did not extend their evaluation to other applications of thimerosal, in particular as a vaccine preservative.

One leading researcher made the following statement to the Committee in July of 2000: ''There's no question that mercury does not belong in vaccines.

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

The Food and Drug Administration's (FDA) mission is to ''promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.'' However, the FDA uses a subjective barometer in determining when a product that has known risks can remain on the market. According to the agency, ''at the heart of all FDA's product evaluation decisions is a judgment about whether a new product's benefits to users will outweigh its risks. No regulated product is totally risk-free, so these judgments are important. FDA will allow a product to present more of a risk when its potential benefit is great—especially for products used to treat serious, life-threatening conditions.''

This argument—that the known risks of infectious diseases outweigh a potential risk of neurological damage from exposure to thimerosal in vaccines—is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that any possible risk from thimerosal was theoretical, that no proof of harm

existed. However, the Committee, upon a thorough review of the scientific literature and internal documents from government and industry, did find evidence that thimerosal did pose a risk.

Thimerosal used as a preservative in vaccines in likely related to the autism epidemic. This epidemic in all probability may have been prevented or curtailed had the FDA not been asleep at the switch regarding the lack of safety data regarding injected thimerosal and the sharp rise of infant exposure to this known neurotoxin. Our public health agencies' failure to act is indicative of institutional malfeasance for self-protection and misplaced protectionism of the pharmaceutical industry.

NATIONAL WAR PERMANENT TRIBUTE HISTORICAL DATABASE ACT

HON. MARK UDALL

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, May 21, 2003

Mr. UDALL of Colorado. Mr. Speaker, today, I am introducing legislation titled the ''National War Permanent Tribute Historical Database Act,'' that will help the Department of Interior and the Department of Veterans' Affairs keep track of the many important war memorials on public lands throughout our country. It would also provide a report to Congress to determine if there should be a permanent fund within the Treasury for the upkeep of these memorials.

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

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

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

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

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Wednesday, May 21, 2003

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

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

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

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

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

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

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

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

Below is a more detailed summary of the legislation:

MEDICARE OUT-OF-POCKET SPENDING LIMIT ACT OF 2003—SUMMARY

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

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

Eligibility and enrollment. Beneficiaries entitled to Medicare Part A and enrolled in Part B would be eligible for the new benefit. Current Medicare beneficiaries would have a one-time six-month open enrollment period to elect this coverage. Otherwise, normal Medicare enrollment rules would apply.

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

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

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