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

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

HONORING THE 62ND ANNIVERSARY OF THE BATTLE OF CRETE

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

Mrs. MALONEY. Mr. Speaker, I rise today

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 para-
troopers and glider forces landed on Crete.

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

At a very important point on the frontline to India and protected both Palestine and Egypt.

The Nazi invasion force included the elite German paratroopers and glider forces. Hitler felt this was to be an easy victory, yet he is quoted to have said shortly after the invasion, “France is free. 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 signifies the end of large-scale airborne operations.

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

Young boys, old men and women displayed breathtaking bravery in defending their Crete.

German soldiers never got used to Cretan women fighting them. They would tear the dress from the shoulder of suspected women to find bruises from the recoil of the rifle. The penalty was death.

The Times (London) July 28, 1941 reported that “five hundred Cretan women have been deported to Germany for taking part in the de-
sense 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 out 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 signifies the end of large-scale airborne opera-
tions.

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

Young boys, old men and women displayed breathtaking bravery in defending their Crete.

German soldiers never got used to Cretan women fighting them. They would tear the dress from the shoulder of suspected women to find bruises from the recoil of the rifle. The penalty was death.

The Times (London) July 28, 1941 reported that “five hundred Cretan women have been deported to Germany for taking part in the de-
sense 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 out 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 signifies the end of large-scale airborne opera-
tions.

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

Young boys, old men and women displayed breathtaking bravery in defending their Crete.

German soldiers never got used to Cretan women fighting them. They would tear the dress from the shoulder of suspected women to find bruises from the recoil of the rifle. The penalty was death.

The Times (London) July 28, 1941 reported that “five hundred Cretan women have been deported to Germany for taking part in the de-
sense 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 out 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 signifies the end of large-scale airborne opera-
tions.

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

Young boys, old men and women displayed breathtaking bravery in defending their Crete.

German soldiers never got used to Cretan women fighting them. They would tear the dress from the shoulder of suspected women to find bruises from the recoil of the rifle. The penalty was death.

The Times (London) July 28, 1941 reported that “five hundred Cretan women have been deported to Germany for taking part in the de-
sense 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 out 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 signifies the end of large-scale airborne opera-
tions.

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

Young boys, old men and women displayed breathtaking bravery in defending their Crete.

German soldiers never got used to Cretan women fighting them. They would tear the dress from the shoulder of suspected women to find bruises from the recoil of the rifle. The penalty was death.

The Times (London) July 28, 1941 reported that “five hundred Cretan women have been deported to Germany for taking part in the de-
sense 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 out 8 days. Why is Crete free?
Vaccines are the only medicines that American citizens are mandated to receive as a condition for school and day care attendance, and in some instances, employment. Additionally, families who receive federal assistance are also required to show proof of vaccination to 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 states defer in determining mandates. Since the early to mid-1990s, Congress has been concerned about the danger posed by mercury in medical applications, and in 1997, directed the Food and Drug Administration (FDA) to evaluate the human exposure to mercury through foods and drugs. In 1999, following up on the FDA evaluation and pursuant to its authority, the House Committee on Government Reform initiated an investigation into the dangers of exposure to mercury in vaccines. 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—our children. This report will address one form of mercury in medical applications, Thimerosal, as a preservative in vaccines.

In recent years, it is estimated that 8,000 children a day were being exposed to mercury in excess of federal guidelines through their mandatory vaccines.

One leading researcher made the following statement to the Committee in July 2000: "There's no question that mercury does not belong in vaccines. There are other compounds that could be used as preservatives. And everything we know about childhood susceptibility, neurotoxicity of mercury at the fetus and at the infant level, points out that we should not have these fetuses and infants exposed to mercury. There's no need of it in the vaccines."

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

This argument—that the known risks of infectious diseases outweigh a potential risk from exposure to mercury in vaccines, is one that has continuously been presented to the Committee by government officials. FDA officials have stressed that based upon scientific data that thimerosal was theoretical: that no proof of harm existed. Upon a thorough review of the scientific literature and internal documents from government agencies, the Committee did in fact find evidence that thimerosal posed a risk. The possible risk for harm from either low dose chronic or one time exposure to thimerosal (before birth) 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 thimerosal in vaccines injected polio was accomplished in the first six months of life through their mandatory vaccinations exceeded the Environmental Protection Agency's (EPA) limit for mercury. The FDA and other federal agencies determined that in the absence of a specific standard for ethylmercury, the limits for inorganic mercury should be used for injected ethylmercury. The Institute of Medicine, in 2000, evaluated the EPA's methylmercury standard and determined that the methylmercury standard may be too protective 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 the ferrets. 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 a major component in every major childhood vaccine manufactured for use in the United States, except the influenza vaccine, which continues to contain trace amounts.

This success, however, does not change the fact that millions of American children were exposed to levels of mercury through vaccines that are greater than federal guidelines. Many parents, and a growing number of scientists, believe that this mercury exposure may have contributed to the dramatic increase in autism spectrum disorders, 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 antiseptic ointments. Although an advisory committee determined that ethylmercury was unsafe in these products in 1990, a rule requiring its removal was not finally published until 2001.

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. The cumulative amount of ethylmercury to which children were exposed nearly tripled.

10. The amount of ethylmercury to which children were exposed through vaccines prior to the 1999 announcement exceeded two safety thresholds established by the Federal government for a closely related substance—methylmercury. The Federal government had established a safety threshold of 0.1 micrograms per kilogram of body weight for methylmercury, but the amount of thimerosal in vaccines exceeded the EPA threshold of 0.1 micrograms per kilogram of body weight. In most cases, however, it exceeded this threshold many times over.

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 undermined their credibility.

13. By 1999, more than 50 licensed vaccines contained thimerosal. Thimerosal should be removed from the immunization schedule.

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 thimerosal 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 is toxic to the central nervous system. CDC studies regarding exposure of infants to thimerosal and autism should be developed to rid humans, animals, and the environment of this dangerous toxin.

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

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

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

6. Congress 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.

7. Mercury has many properties that have made it popular for a number of commercial uses. For example, mercury expands and contracts with temperature. It also remains liquid over a wide range of temperatures and does not stick to glass. These properties have prompted its use in thermometers. Mercury is also used in some electric switches and relays to make them operate silently and efficiently.

8. Industrial chemical manufacturers use mercury in their products. Mercury compounds were widely used in such common products as house paints and paper.

9. Various alloys (mixtures of metals) containing mercury are used in making the various Mercury alloys are called amalgams. These would include silver amalgam, a mixture of silver and mercury that dentists use to fill cavities in teeth.

10. Mercury comes in many forms—organic, inorganic, elemental, and metallic. Mercury is toxic to the central nervous system. Mercury became widespread in the environment. However, it is now widely recognized that overexposure to all forms of mercury can cause injury to the central nervous system (CNS) and the renal system (kidneys). This has led to regulatory actions to reduce the exposure of humans to mercury on many fronts.

11. Federal health officials have not conducted epidemiological tests to determine that such a relationship is biologically plausible, but that not enough evidence exists to support or reject this hypothesis. As a result, children continued to be exposed through vaccines prior to 1999 announcements.

12. Although an advisory committee determined that ethylmercury was unsafe in these products in 1990, a rule requiring its removal was not finally published until 2001.

13. The FDA and the CDC failed in their duty to be vigilant as new vaccines containing thimerosal were approved and added to the recommended schedule of childhood immunizations. The cumulative amount of ethylmercury to which children were exposed nearly tripled.

14. The CDC in general and the National Immunization Program in particular are responsible for guarding public health in regard to heavy metals.

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

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

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

18. 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 the relationship between autism and vaccine injury is fatally flawed. The CDC’s rush to support the relationship between autism and vaccine injury is fatally flawed. The CDC’s rush to support the relationship between autism and vaccine injury is fatally flawed. The CDC’s rush to support the relationship between autism and vaccine injury is fatally flawed. The CDC’s rush to support the relationship between autism and vaccine injury is fatally flawed. The CDC’s rush to support the relationship between autism and vaccine injury is fatally flawed.

19. CDC studies regarding exposure of infants to thimerosal and autism should be conducted in a way that will allow independent replication and validation of the results.
public health officials worldwide began re-searching methylmercury. Today, the sci-entific literature is replete with evidence on toxic effects of methylmercury. In 2000, the National Academy of Sciences published a toxicological effects of Methylmercury, which concluded:

Methylmercury is highly toxic.
The data indicate that the adverse effects of methylmercury are expressed in multiple organ systems throughout the lifespan.

The research on humans on the neurodevelopmental effects of methylmercury is extensive.
Damage to renal tubules and nephron has been clearly demonstrated.

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

Methylmercury may adversely affect the reproductive system.
The medical literature is replete with ref-erences to the dangers to methylmercury:

The first methylmercury compounds were synthesized in a chemical laboratory in Lon-don in the 1960s. Two of the laboratory tech-nicians died of methylmercury poisoning. This so shocked the chemical community that methylmercury compounds were given a wide berth for the rest of the century . . .

Inhibition of both cell division and migra-tion, affecting the most basic process in brain development, is 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. Numbness or a ‘pins and needles’ sensation is the first symptom to appear at the lowest dose. This may progress to cerebella ataxia, dysarthria, constriction of the visual fields, and loss of hearing. . . . Cardiocardiovascular disease . . . accelerated progression of carotid atherosclerosis.

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.

Additional evidence both systolic and diastolic blood pressure in seven year olds correlated with prenatal exposure to methylmercury . . . indicative of later cardiovacular problems.

Despite the fact that ethylmercury has been widely used in common medical treatments, ranging from vaccines to nasal sprays to ointments, correlative 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 pharma-ceutical industry to conduct extensive safety studies on thimerosal or ethylmercury. It was not until the introduction of this mercury [8.0 mg Hg/kg/day ethylmercury and 9.6 mg Hg/kg/day ethylmercury] caused more damage than 8.0 mg Hg/kg/day methylmercury. Ethylmercury was more neurotoxic than methylmercury, as cerebral dilation was frequently present . . . in kidney . . . 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 causes, there is a growing understanding in the scientific community that government officials have shared with the Chairman's grandson, Dr. Dave Weldon (R-FL). As Dr. Weldon noted during the Committee's December 10, 2002 hearing, "many diseases may be far more common than we understand, and it's as toxic as methylmercury."

Dr. Weldon: "I have a couple of questions for Dr. Baskin about ethylmercury versus methylmercury. I don't mean to make some points that data on methylmercury is fairly good, but we don't have good data on ethylmercury. I take it from your testimony there is quite a bit of research 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 and methyl compounds don't. Cells have a mechanism to transport mercury out of the cells, and the membrane is made of lipids, fats. And ethyl as a chemical compound pieces fats and penetrates fat much better. And so, you know, it took me a while to begin to work with some of the Ph.D.s in my laboratory and discuss this everyone said, 'Oh gosh, you know, we've got to adjust for the fact because it's going to be worse; the levels are going to be much higher in the cells.' So...I think at best they're equal, but it's likely that they're more toxic. And some of the results that we are seeing in cell culture would support that."

Dr. Baskin explained that according to scientific research, one of the most vulnerable parts of the body during brain development, 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: "I don't think there is a methylmercury 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 or inhaled or exposed. So that's a five-fold preferential uptake.

The testimony of Dr. Baskin builds upon the consensus of experts in chemistry, toxicology and pharmacology. It includes the following statement from Dr. Vasken Aposthian, 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 19, 2000 hearing.

"The mercury amalgams in your mouth, the so-called silver fillings, contain 48 to 50 percent methylmercury. 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 and quickly converted to mercuric mercury—all three forms are neurotoxic.

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

"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 equivalent to methylmercury as a developmental neurotoxin. This conclusion is clearly public health protective. Ethylmercury is a neurotoxin from vaccines (added to dietary exposures to methylmercury) probably caused neurotoxic responses (likely subtle) in some children. While the relative neurotoxicity of either ethyl or methylmercury is more toxic will probably not be resolved in the near future, a consensus appeared to accept 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, 2000 hearing.

"More concerning to me in the Institute's treatment of mercury problems, was the almost complete absence of regard for ethylmercury. Cells have a membrane, have a membrane on them, and the membrane is made of lipids, fats. And ethyl as a chemical compound pieces fats and penetrates fat much better. And so, you know, it took me a while to begin to work with some of the Ph.D.s in my laboratory and discuss this..."
developing nervous system of the unborn child, it is prudent for nursing mothers and young children not to eat these fish as well."

In addition to the public advisories, the FDA, in January of 2001, established an ag-
gressive position on Methyl Mer-
curry."

In January 2001, Associate FDA Com-
missioner Melinda Plaisier, responding to Congresswoman Denise (D-PA) re-
garding 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 priority for mercury toxicity than what they presented to the Committee:

"People are exposed every day to a tremendous number of compounds in our environ-
ment. These substances include major and trace elements that may or may not be es-
sential for sustaining life . . . Other ele-
ments are not known to be essential but are
"constantly found in living tissues . . . Of these elements that have no known nutri-
tional value, some have been found to be toxic at concentrations well below those of
other nonessential elements. Lead, cad-
mium, and mercury are examples of ele-
ments that are toxic when present at rel-
atively low levels."

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

"[E]lemental (metallic) mercury and its compounds have the potential to cause exces-
se exposure to excessive levels ( . . . flas-
sion, ingestion of inorganic mercury com-
pounds can cause severe renal and gastro-
testinal toxicity. Organic compounds of
mercury such as methylmercury are consid-nerosal, it was learned that over 50 vaccines

In 1980, the FDA began a lengthy regu-
lar process to remove ethylmercury prod-
cts from over-the-counter products like top-
ical ointments, diaphragms, and contra-
ceptives. Topical ointments are products
used on the skin either for the treatment or
prevention of skin infections or inflam-

sions. They are typically divided into four categories, first-aid products to be
applied to small superficial wounds to pre-
vent infection; skin wound protectant to pro-
vide a protective barrier to wounds; antibi-
tic or antifungal creams to prevent or
treat overt skin infection; and anti-inflam-

atory agents used to reduce inflammation and inhibit pruritus.

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

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

"[I]n the long-term guinea pig testing, it was found to be more toxic for human epithelial
cells in vitro than mercuric chloride, merc-
curic nitrate, and merbromin (mercuric chlo-
ride). 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 thi-
merosal is highly allergenic and that it is rea-
nable to expect humans to be equally aller-
gic.

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

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

In 1982, the FDA advisory panel concluded
that thimerosal was not generally recognized
as safe. The Panel concludes that thimer-
sal is not safe for OTC topical use because of
its potential for cell damage if applied to
broken skin and its allergenic potential. It is
not effective as a topical antiseptic be-
cause its bacteriostatic action can be re-
vers."
The Committee calculated the bolus dose exposure of adult males and females below:

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

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>No. Doses</th>
<th>Initial entry</th>
<th>Troops in US</th>
<th>Deployed</th>
<th>Region or other</th>
<th>Thimerosal content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthrax</td>
<td>6 + annual</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>6 + annual</td>
<td>0</td>
</tr>
<tr>
<td>Diph</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>(People without splashes)</td>
<td>0.625 mcg/dose</td>
</tr>
<tr>
<td>Hib</td>
<td>3 + boosters</td>
<td>3 + boosters</td>
<td>3 (Korea)</td>
<td>N/A</td>
<td>N/A</td>
<td>(0.625 mcg/dose)</td>
</tr>
<tr>
<td>Hep A</td>
<td>3</td>
<td>1 Annual</td>
<td>N/A</td>
<td>N/A</td>
<td>Annual</td>
<td>25 mcg/dose</td>
</tr>
<tr>
<td>Hep B</td>
<td>3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>(Health workers)</td>
<td>25 mcg/dose</td>
</tr>
<tr>
<td>Influenza A&amp;B</td>
<td>1 Annual</td>
<td>1 Annual</td>
<td>N/A</td>
<td>N/A</td>
<td>Annual</td>
<td>25 mcg/dose</td>
</tr>
<tr>
<td>Jap Enceph</td>
<td>3 + bimodal boosters</td>
<td>3 + bimodal boosters</td>
<td>N/A</td>
<td>N/A</td>
<td>Annual</td>
<td>25 mcg/dose</td>
</tr>
<tr>
<td>MMR (Live)</td>
<td>1 every 3 years</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Meningooccal 17: PCV-7</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Meningooccal 123: PPV-23</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Polio Inactivated IPV</td>
<td>1 booster dose</td>
<td>1 booster dose</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Rabies</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Smallpox</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Td, TT (3 mcg)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Tetanus, Diphtheria, and Pertussis (DTP)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Typhoid Vaccine Activated Salmonellae</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Varicella (Live)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Yellow Fever (Live)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Possible Total Thimerosal Exposure</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

- The Committee calculated the bolus dose exposure of adult males and females below:
- Adult weight with exposure rates according to EPA Safety Limit:
  - 100 pound: 0.1 mcg/45.359 kg of body weight per day = 0.45
  - 120 pound: 0.1 mcg/54.431 kg of body weight per day = 0.54
  - 150 pound: 0.1 mcg/68.039 kg of body weight per day = 0.68
  - 180 pound: 0.1 mcg/81.647 kg of body weight per day = 0.81

It is clear from this chart that with a maximum safe limit of 0.16 mcg/dosage 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, supported by Dr. Roberta McKeel of Merck, individuals at each of these weights would be exposed to levels of mercury that would be expected to put them at risk for adverse reactions.

The Committee received documentation from one Air Force pilot who suffered from serious symptoms of Gulf War Syndrome. After failing to have his medical issues resolved through the military or the Veterans Administration (VA) medical system, Capt. Frank Schmuck, a pilot, became so ill that he was no longer able to fly. He sought medical treatment outside the military medical system and was tested for heavy metals, and was found to have toxic levels of mercury. 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 actively evaluating on behalf of Gulf War veterans.

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

**A. Autism Is Growing at Epidemic Proportions**

Autism was once considered a rare disease that affected an estimated 1 in 10,000 individuals in the United States. The Committee held its first hearing on the dramatic rise in autism in April of 2000. At the time, Federal agencies were estimating that autism affected 1 in 500 children in the United States. By 2005, 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 98 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 Cavey shared her observations about the rapid growth of autism and the pressures it is placing on families and medical professionals:

“I am in family practice in Baton Rouge, Louisiana. I have been 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, and if you have any idea what that is not, I invite you to sit in my office for 2 hours.’

2. Studies Are Documenting the Incredible Growth of Autism

In the 1980’s, the CDC conducted two prevalence studies that confirmed dramatic spikes in autism cases. One was conducted in Brick Township, New Jersey, the other in Atlanta, Georgia.

In late 1997, after noticing an apparently larger than expected number of children with autism in their community, a citizen’s group in Brick Township, New Jersey, contacted the New Jersey Department of Health and Senior Services (DHSS). Because of the complexity of the disorder and the concerns that environmental factors might play a role, the New Jersey DHSS, U.S. Senator Robert Torricelli, and U.S. Representative Christopher Smith contacted the CDC and the ATSDR for assistance. In response, the CDC...
In 1943, when child psychiatrist Leo Kanner first described 11 cases of a new mental illness in children he said was distinguished by self-absorbed detachment from other people and a few not doing the word “autistic” (from the Greek word auto, meaning “self”) Pointing out similarities with some behaviors exhibited by adult schizophrenics. Psychiatrists assumed autistic children were exhibiting early-onset adult-type psychoses. Kanner’s young patients came from what he called middle-and-upper-class families in Baltimore with mothers and fathers who were doctors, lawyers and professors. In 1954, Kanner admitted, “I encountered one autistic child who came of unintelligent parents.” This concentration of autistic children in educated and professionally successful families later led to the “refrigerator mother” 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” theory, stating that autism was also a result of genetic or “constitutional inadequacies” as well as bad parenting. In 1971, Kanner admitted that Mothers were not to blame. However, psychoanalyst Bruno Bettelheim continued purporting the “rejecting parent” theme. Bettelheim, a Holocaust death-camp survivor, insisted that the concentration of autistic children in abnormal ways in retaliation against a rejecting mother who had traumatized the child by failing to provide enough love or attention. However, a California psychologist and father of an autistic child, Bernard Rimland, Ph.D., in 1964 disproved Dr. Bettelheim’s theories through the publication of his landmark book Infantile Autism: The Syndrome and its Implications for a Neural Theory of Behavior. In this book, Dr. Rimland methodically dismantled the psychoanalytical biological and sociological theories, specifically a neurological, basis for autistic behavior. Dr. Rimland documented the similarities between brain injured children and autistic children, differentiating 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 on childhood autism to parents. In 36 years, his database has grown to include more than 30,000 cases of autism from around the world. In analyzing the data for age of onset of autism, he discovered that before the early 1980’s, most of the parents reported their children first showed signs of abnormal behavior from birth or in the first year of life. But after the mid-1980’s, there was a re-awakening of this pattern. The numbers of parents reporting that their children developed normally in the first year and a half of life and then later demonstrated autistic traits doubled. Today, Rimland says that the onset-at-18 months children outnumber the onset-at-birth children by 2 to 1. Today, it is not clear what the exact cause of autism is. 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 number of vaccines given in infancy, and in particular the thimerosal in vaccines may have triggered an autistic response in children who are genetically predisposed to being vulnerable to mercury damage.

The alarms growing in autism coincided with an increase in the number of childhood vaccines containing thimerosal on the recommended schedule. Through most of the twenty 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 calls for more research into the relationship between ethylmercury in vaccines and autism. A number of vaccines never contained thimerosal. These classes of vaccines are generally live-virus vaccines. The ethylmercury (ethylmercury) compound making them unsuitable for vaccines.

Prior to the approval of the recombinant Haemophilus Influenzae Type B (Hib) vaccine in 1985, the only vaccine containing thimerosal routinely given to infants was the DTaP vaccine. DTaP contains 25 micrograms of ethylmercury and was given 3 times in the first 6 months of life and a total of 4 times in two years (100 micrograms of ethylmercury).

Today, the polysaccharide Haemophilus Influenzae B (Hib) vaccine was first licensed in 1985. It had 25 micrograms of ethylmercury and was given 3 times in the first 6 months of life and 7 times in the second 6 months of life, for a total of 4 times in the first two years of life. The approval of the Hep B vaccine in 1986 added another thimerosal-containing vaccine 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 6 months of life (37.5 micrograms of ethylmercury).

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 calls for more research into the relationship between ethylmercury in vaccines and autism. A number of vaccines never contained thimerosal. These classes of vaccines are generally live-virus vaccines. The ethylmercury (ethylmercury) compound making them unsuitable for vaccines.

Prior to the approval of the recombinant Haemophilus Influenzae Type B (Hib) vaccine in 1985, the only vaccine containing thimerosal routinely given to infants was the DTaP vaccine. DTaP contains 25 micrograms of ethylmercury and was given 3 times in the first 6 months of life and a total of 4 times in the first two years of life. The approval of the Hep B vaccine in 1986 added another thimerosal-containing vaccine 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 6 months of life (37.5 micrograms of ethylmercury).

After 1986, some children went from getting 25 micrograms in one day or 75 micrograms in the first six months of life to getting 62.5 micrograms of ethylmercury in a day or 187.5 micrograms in the first six months of life. This would be in addition to the 12.5 micrograms of ethylmercury in the Hep B vaccine given in the same month. 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 determined safety thresholds for ethylmercury exposure. Because of the obvious similarities between the two, however, when the FDA reviewed the reports of adverse reactions to injected ethylmercury in 1999, they compared it to the Federal limits for (ingested) methylmercury exposure. They were compelled to admit at that point that there was no cumulative uptake 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 particular, the current 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 dose of DTP (or DTaP) and Hepatitis B exceeded the limit. You children were getting many vaccinations containing thimerosal. The EPA’s threshold is 0.1 micrograms of methylmercury for each kilogram of body weight. This does not mean that injury would not occur above this limit, but it does cause a significant safety margin is built in. However, the chances of injury increase as the exposure rises above this level. For an 11-pound baby (five kilograms), the threshold old 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 the youngest children, the highest levels of thimerosal they received in vaccines in the 1990’s also exceeded the EPA’s higher threshold of 0.4 micrograms per kilogram of body weight.

Of particular concern to many parents are those instances in which children received several vaccines in one visit to a 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, infants get more ethylmercury 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 on her son’s belief with respect 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 tested positive for ethylmercury if I was exposed to it before birth. I also tested positive for ethylmercury in the amniotic fluid.”

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 literature that addressed the question of a relation between vaccination with DTP or its pertussis component and autism. Dr. Stephanie Cave, who provided testimony to the EPA earlier this year in Baton Rouge, Louisiana whose medical practice is focused on treating children with the symp- toms of autism, said that experts from whom the Committee received testimony that there appears to be a correlation between increased use of vaccines containing thimerosal and autism.

“I believe that the introduction of the hepatitis B vaccine in 1991 has sparked this recent epidemic because of thimerosal. When thimerosal is included through the Hepatitis B and Hib, the exposure to mercury exceeds EPA safe limits for the metal if you consider children detoxification.”

“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, 25 micrograms at 12 months, and 25 micrograms at 18 months; a total of 237.5 micrograms for a child who weighs 10 kilograms. This far exceeds the safety limits if you consider bolus detoxification would be more like 1 to 1.5 micrograms.”

“The bile production is minimal in infancy, making the metals more difficult to be cleared from the body. When added to a vaccine, the metals are even more dangerous because the vaccines trigger immune reactions that increase the permeability of the GI tract and the blood/brain barrier.”

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

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 methylthioacetate due to its tendency to acquire ‘certain burning qualities.’”

In 1932, in a paper published by Lilly researchers found Merthiolate to be a skin-disinfecting agent. It was noted that another researcher has seen adverse reactions.

In 1942, Dr. William R. Gibson to Dr. Alan Baskett, of the Biological Services, of the Pittman-Moore Company to Dr. Jamieson of Eli Lilly, “we re-examined the effect of mercury with Bordetella pertussis to supplement B-adrenergic blockade. Again, it was not believed that this blockade should be used in infants 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 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 effects of mercury exposure, and consideration of cumulative doses of this component in early infancy . . .”

In 1992, 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 iodine, they may be sensitive to any compound containing mercury. We have investigated 5 patients with a history of thimerosal sensitivity, and four were sensitive to thimerosal and not to any other organic or inorganic mercury compounds with which they were tested. . . .”

In 1992, Dr. Ellis published a case report in the Archives of Ophthalmology, which states: “The positive results of patch tests demonstrate that the patient is sensitive to tincture of merthiolate were also sensitive to 1:5000 merthiolate ophthalmic ointment and that merthiolate is capable of causing an inflammatory response in the conjunctiva in patients who are sensitive to the drug. In view of these facts it is recommended: 1. That Merthiolate ophthalmic ointment should be used in children for the eye unless it has been previously demonstrated by patch tests that the patient is not sensitive to the product. 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. 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 the use of thimerosal in the Australian pertussis vaccine was linked to intussusception in mice:

“Tinouye discussed the effect of ethylmercury with Bordetella pertussis to supplement B-adrenergic blockade. Again, it was not believed that this blockade should be used in infants 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.”

There is ample evidence from the literature that thimerosal (thimerosal) may cause sensitization and subsequent allergic reactions. The use of thimerosal is vaccines is declining in accordance with various national vaccine programs may differ. In certain cases, it is the kind of re-misconfidence in their government. And to a large extent, it doesn't make sense. No wonder people are losing faith in their government. 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 2003, her autistic son, Liam, was four years old. Her testimony left no doubt as to her views:

"I recommend that you read this, side-by-side, page after page of analysis of the symp-toms that one might observe in children who have suffered from the 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 mar-ket because we are not going to be in-jected tomorrow. 80 children may be coming down, beginning tomorrow, with autism? What if there was an E. coli scare? What if VAERS forms, (3) pediatricians are not reporting to VAERS either, (4) and despite efforts by policymakers at CDC, FDA, AAP, and many others, efforts to enhance the safety of vaccines, they remain uncon-vincing.

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

"You know, I still go back to the fact--I still think the duck test. Mr. Egan, [FDA] I will address this to you. You know, it was shown in the last panel that aut-is tic symptoms emerge after vaccination. It was shown in this panel that toxic doses of mercury. It was shown that autism and mercury poisoning, the physiological compar-ison is striking. There's altered neurotransmitter activity, abnormal brain neuronal organization, immune system dis-turbance, EEG abnormalities. It goes on and on and on, the comparisons. That is why I say, I am upset. I think 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 over-whelming. Let's do something before we see it in the courts."

In 2003, thimerosal remains in some vac-cines.

A. Many parents of autistic children believe that adverse reactions to vaccines are respon-sible for their children's condition. Based on personal experiences, many parents view the condition of their children is related to an adverse reac-tion to a childhood vaccine, or a series of vaccinations. This is particularly true of parents whose child 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 be-fore the Committee in 2003, made the fol-lowing statement:

"At a recent autism conference in Chicago, and prior to either my own presentation or that of Vaccines. A survey of 500 parents if they felt their child re-gressed following a vaccine. In that obvi-ously 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 to VAERS, the 35 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 others around the world with similar findings. Yes, media attention creates bias. But despite the infor-mal nature of this survey, it does tell us something about this debate we are cur-rently engaged in: (1) parents of children with autism suspect vaccines damaged their child, (2) parents are not repeating this using VAERS forms, (3) pediatricians are not re-porting to VAERS either, (4) and despite ef-forts by policymakers at CDC, FDA, AAP, and many others, efforts to enhance the safety of vaccines, they remain uncon-vincing.

"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 and running off. If I dressed him 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 be-cause autism often coincides with the time of vaccination, and state that there is no sci-entific evidence to back this up. My question to experts: How long do you have to have evidence to surface time and time and time again, case after case after case, before it can become a viable hypothesis, especially when the solution to solving the problem seems so apparent?"

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

"Jacob met every developmental milestone that first year, right along with J esse. They were like peas in a pod. They were everywhere together. At only 16 months of age, Jacob and J esse received their first MMR vaccine. On this same day, they also received their fourth DTP, their fourth Hib, and their third hepatitis B. The following 24 hours, both twins slept most of the time, with over 100-degree temperatures, in spite of receiving the recommended Tylenol dosage every 6 hours. Immediately following that, Jacob began exhibiting strange behaviors. He was no longer excited or responsive when Daddy would spend long periods of time studying, 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 believed he 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 we have spent searching and retracing his regression continue to point to the fact that the road to Jacob's autism began when his immune system was damaged by Hepatitis B, which was 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 Gut drank: "...we think it is imperative for us, the advocates 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 Vaccine Injury Compensation Program (VICP), alleging that receipt of 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 1986 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 spectrum disorders under various circumstances. The two-year schedule for completing this omnibus proceeding includes a discovery period for establishing an evidentiary hearing on the deaths, an evidentiary hearing, and a ruling on general causation issues by July of 2003.

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 Special Master's 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 petitioners ask that the [question] has developed a neurodevelopmental disorder, consisting of an 'Autism Spectrum Disorder' or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the 'thimerosal' ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTPa), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two vaccinations!"

In addition to petitions filed under the VICP, many parents have filed lawsuits against vaccine manufacturers and manufacturers of thimerosal. Such lawsuits were filed in Texas in May of 2001 on behalf of five-year-old Joseph Alexander Counter (Counter v. American Home Products). According to 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 autism children and medical monitoring for broad populations of children who were exposed to mercury in vaccines.

Under the National Childhood Vaccine Injury Act, the Vaccine Injury Compensation Program, victims of vaccine injuries are not allowed to file lawsuits against vaccine manufacturers unless they have first filed a claim 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 recourse to the VICP.

As these cases work their way through the courts, procedural rulings in different jurisdictions will have a great influence on whether peti
tioners who file compensation through the courts or through the VICP.

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

A. Introduction

A growing number of respected scientists and researchers are convinced that there is a relationship between 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 since the mid-1990s, before any indication was made that thimerosal action was taken to remove them from vaccines. The le
thargic 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.

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

In 2001, the Institute of Medicine (IOM) released two reports after reviewing the evidence they received related to possible correlations between vaccines and the growing incidence of 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 reported on the MMR vaccine. The second dealt with vaccines containing thimerosal.

The IOM stated that the epidemiological evidence available at the time showed no association at a population level between the MMR vaccine and autism. However, the authors cautioned that if the vaccine triggered autism 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, as they do not have sufficient precision to detect very rare occurrences on a population level. A poor understanding of the risk factors and failure to use appropriate 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 thimerosal 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 32 British children who suffered from autism spectrum disorders and chronic bowel inflammation also had vaccine-strain measles viruses in their tissues. Although the parents of eight of the twelve children traced the onset of autistic symptoms to the time of their MMR vaccination was given, the IOM stated that the study was of limited utility because of its small sample size.

Three years 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, further research is needed. Information, primarily from analogies with methylmercury and levels of maximum mercury exposure from vaccines given in children, the hypothesis is biologically plausible."

* * * * *

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

The IOM noted that it had reviewed the results of one unpublished epidemiological study that detected a "statistically significant but weak association" between exposure to thimerosal and several types of developmental disorders, including attention deficit disorder, speech and language delay, tics, and general neurodevelopmental delays. Phase II 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.

In his testimony the previous year, Dr. Boyd E. Haley, who is the director of the Vaccine Safety and Autism Program 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 suspicion, and that is one of the co-factors that might contribute to 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 adults."

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 II. In our preliminary studies, vaccines containing thimerosal as a preservative consistently demonstrated in-vitro toxicity that was dramatically greater than the non-thimerosal or low-thimerosal containing vaccines."
to detoxify the cerebral spinal fluid may be at least part of the neurological aspect of this disease."

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

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

* * * * *

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

"Here is a slide where you see a lot of blue cells. This is a model of the brain, and the blue color represents the cells that are blue. It means that this stuff grabs a hold of the membrane and punches holes into it, so that the dye can penetrate, not only the plasma but into the very center of the cell, the nucleus, where all the DNA exists."

* * * * *

"Don't forget, we did this in adult brain cells. These are the same brain cells that we see 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 reporting very similar findings. At the Columbia University, there's now a model in mice who were injected with low doses of thimerosal at various doses, and we use a number of very sophisticated techniques to detect cell death and cell 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 turn, they acknowledged that many children received a cumulative amount of ethylmercury in vaccines that exceeded the EPA's safe limits for mercury.
- One study showed an association between thimerosal in vaccines and some developmental disorders.

On April 18, 2002, the Committee heard testimony at Bayley Memorial on the Federal Interagency Committee on the Epidemiology and Surveillance Division of the CDC's National Immunization Program. Her response to a question about mercury and autism included the following statement:

""As far as the thimerosal issue is concerned, the evidence is too incomplete and fragmentary to make a decision and establish 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 potential exposure. We have not established 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 address these issues."

She further stated:

"There are not data to—there are no established harms associated with this. I know this is a radiation, and there's a number of studies 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 Midtun, Director of the FDA's Office of Vaccines Research and Review, expressed the following views:

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

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

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

"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 the Faroe Islands studies and the calculation that the cumulative amount of thimerosal in childhood vaccines exceeded the EPA's limits for methymercury:"

* * * * *

""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 imbalances. His statement is specific to the Faroe Islands studies and the calculation that the cumulative amount of thimerosal in childhood vaccines exceeded the EPA's limits for methymercury:"

"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 methymercury, a related product. Recent studies have determined that the Faroe Islands studies and the calculation that the cumulative amount of thimerosal in childhood vaccines exceeded the EPA's limits for methymercury:"

* * * * *

"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 of its forms, for infants and children, and to discontinue using thimerosal as a preservative wherever 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 neurodevelopmental effects of thimerosal, and particularly its ethyl-mercury component. As the IOM noted in its report on thimerosal, "the data regarding toxicity of low doses of thimerosal and ethylmercury are very limited, and most of the conclusions that have been drawn about ethylmercury are based on analogies to methylmercury, which has been studied extensively."

Particularly, studies that have been performed on ethylmercury have been of limited value, for several reasons.
kids, they may well not have found even one.

In his testimony, Dr. Baskin stated:

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

"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 any sense."

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

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

Dr. Portier: "No."

Given the small sample size, the failure to measure mercury at peak levels, and the study's inability to measure the effects of the ethylmercury present in the bodies of the subjects, it is difficult to understand how the authors could come to 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 a starting point, it's a start, but the interpretation is inaccurate."

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

Evidence of ethylmercury's toxicity was available to Federal regulators and the private sector almost from the product's inception. For far too long, both neglected this evidence. Despite evidence dating to the 1930s that ethylmercury in medicines was potentially hazardous, little was done to remove it from a number of products until 1980. For the next several decades, Lilly's track record in ensuring the safety and reliability of this product was notably poor. Internal Eli Lilly documents dating back 70 years suggest that the only study of thimerosal involving human subjects was done prior to 1930. For the next seven decades, Lilly's track record would refer to that original study as evidence of thimerosal's safety. However, it is now clear that this uncontrolled study was woefully inadequate.

As previously discussed in this study, an intravenous solution containing thimerosal was tried as an experimental treatment for meningitis. While the treatment was found to be ineffective, the doctor who conducted the study concluded that the solution caused no harm and with few side effects. It is clear today that such a limited number of subjects, all suffering from the same serious illness, would
hardly qualify as a sufficiently sized random sample, and a study such as this one would be of very little value by today's standards. In fact, an internal Eli Lilly memo from 1972 candidly admitted that, medically, it is difficult to understand why the expert panel's conclusion that thimerosal is "toxic when injected parenterally and therefore cannot be used in chemotherapy." A 1973 article, "Dangers of Skin Burns from Thimerosal," reported the case of a woman who suffered 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.

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 Exemptions prompted a review of mercury in vaccines. 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 effectiveness 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 issued a Federal Register Notice of Proposed Rules or Notice of Proposed Rules regarding these products in 1980, 1982, 1990, 1991, 1994 and 1995.

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 review mercury content in over-the-counter products. It is equally difficult to understand why the expert panel's 1980 findings on thimerosal's safety 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 thimerosal 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 have never understood, the fact that we know that ethylmercury is a skin sensitizer when it's put on the skin, and now we're injecting this IM (intramuscularly) at a time when the immune system is just developing, the functionality of the immune system is just being set at this age. So now we're injecting a sensitizer severally times a day, 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?"

Different branches of the FDA regulate over-the-counter products and vaccines. Vaccines are regulated by the Center for Biologics and Evaluation and Research (CDER). Vaccines are regulated by the Center for Biologics Evaluation and Research (CDER).
Evaluation and Research (CBER). This, however, is little justification for the lack of coordination. The FDA’s determination that mercury was unsafe and should be removed from vaccines was not reenacted in the Federal Register no fewer than five times prior to the FDA’s belated review of mercury in vaccines.

What caused the FDA to review mercury in vaccines was not its own regulatory process, but rather an act of Congress. In 1997, Congress passed and the President signed into law the Homeland Security and Transportation Modernization Act (FDAMA). Among other things, this law required the FDA to compile a list of foods and drugs that contained mercury and determined that thimerosal was unsafe in toptimal 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 counterbalanced by the growing realization that there was more methylmercury in childhood vaccines than previously thought, and that nobody had thought to calculate the cumulative amount of mercury in infant vaccines. 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 existing regulations and recommendations for use. (We must keep in mind that the dose of ethylmercury was not generated by ‘rocket science’. Conversion of the ethylmerosal to methylmercury by internal enzymes was internal resistance to such an action."

An exchange of e-mails in October of 1998 makes clear that Dr. Leslie Ball was already raising the issue of removing thimerosal from vaccines. It also makes clear that there was internal resistance to such an action. Dr. Marion Gruber of the Office of Vaccine Studies and the National Institute of Allergy and Infectious Diseases wrote an internal FDA memo to Dr. Ball, which concluded that:

"I disagree about the conclusion regarding no basis for removal of thimerosal. On a strictly scientific basis, yes, there are no data that have looked at the specific issue of thimerosal in vaccines. However, there are fact/data that would argue for the reevaluation of the exposure recommended for methylmercury 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 other regulatory agencies. This comparison led the consultant to the FDA, Dr. Barry Rumack, to develop a pharmacokinetic model to analyze the amount of mercury to which infants and children were being exposed. The results were presented to the Committee two charts developed from the model dated June 28, 1999. Both charts demonstrate what has now become widely acknowledged: 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 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 limits for ethylmercury were exceeded. Simple math makes clear that most infants also breached the FDA’s higher limit of 0.4 micrograms per kilogram. "We must follow the three basic rules: (1) be aware of all potential ramifications; (2) be open with consumers about why products have more mercury than we realize; (2) be open with consumers about why
we didn't catch this earlier; (3) show contribution. As you know, the Public Health Service informed us yesterday that they were planning to conduct business as usual, and would probably make a decision as to whether to place these products in the market. While the Public Health Service may think that their 'product' is immunizations, I think their 'product' is their recommendations on polio and well-baby vaccination.

The fact that the 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 accept, is the fact that the CDC, on two separate occasions, refused to publicly state a preference for thimerosal-free vaccines.

In June of 2000, the CDC's Advisory Committee on Immunization Practice met in Atlanta. Among other things, the Advisory Committee was asked to consider what guidance the Public Health Service (PHS) should issue a public statement of preference for thimerosal-free vaccines. At the time, the industry was in the midst of introducing thimerosal-free childhood vaccines, and several vaccines containing thimerosal were still on the market. 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 and contained trace amounts of thimerosal, older versions of these vaccines containing thimerosal were still in inventories and being used around the country.

As a statement of 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. Although the CDC would have been able to provide clear guidance to pediatricians on how to safely administer DTaP vaccines, the Advisory Committee's vote effectively eliminated the maximum exposure to ethylmercury for many infants. In the absence of a statement of preference by the CDC, 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 Polio or Hepatitis B. As a result of the Advisory Committee's decision, 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."

Later in the discussion, Dr. Neal Halsey 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 what you said is that the future vaccines that are presented from the manufacturers is that there really still is some Hib out there in the market, but that's not the case at the end of the third month."

"We think that having this type of a more logical policy is 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, some manufacturers continued to produce vaccines containing ethylmercury at a time when there were serious doubts about its safety.
What makes the CDC's decision even more vexing is that just prior to the Advisory Committee meeting in 2000, a study conducted by the CDC suggested that there was at least a correlation between 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 thousands of patients belonging to seven major health maintenance organizations. Phase I of the study was designed to screen data for potential abnormalities among children receiving thimerosal-containing vaccines and selected neurological disorders. Phase II was designed to test the hypotheses generated in the first phase.

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

The findings of Dr. Verstraeten, the primary author of the study, set off a firestorm of debate within the Federal health agencies when they were released in June of 2000. Enough concern was generated that a conference was arranged 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 just a few days old, 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 increase in the number 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 that are excluded because of their age. Clearly there is a gross underreporting—1.4% of the kids diagnosed with a speech and language problem versus 4-5% reported in National Immunization Surveys, less than 3% with ADHD versus 3-10% reported previously, etc."

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

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 Injury Act at this time. I deal with causality, it seems pretty clear to me that the data are not sufficient one way or the other. My gut feeling is that we have a very strong correlation, but I don't want that grandstand to get a Thimerosal-containing vaccine until we know better what is going on. It will probably take a long time to resolve."

Dr. Zoon 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 study findings are not sufficiently significant, although weak, association, that the implications—for obvious reasons—are profound. Therefore, the consultants were unanimous in the 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."

VIII. FOCUSED, INTENSIVE RESEARCH EFFORT IS BADLY NEEDED

One of the most consistent refinements heard by the Committee throughout its three-year investigation is that more research has been done. The Committee has heard testimony from parents, scientists and government officials that much more research is needed and that needed 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
- Possibilities relationships between vaccine ingredients like the 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 recommended the following research recommendations:

- Use accepted and consistent case definition assessment and injury outcomes (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
- Deeply 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

One of the most consistent refinements heard by the Committee throughout its three-year investigation is that more research has been done. The Committee has heard testimony from parents, scientists and government officials that much more research is needed and that needed 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
- Possibilities relationships between vaccine ingredients like the 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 recommended the following research recommendations:

- Use accepted and consistent case definition assessment and injury outcomes (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
- Deeply 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.

For information on the review of the effects of thimerosal-containing vaccine and ASD, rechallenge refers to children who appeared to have experienced some form of neurological regression after a thimerosal-containing vaccine and who appeared to have experienced another regression following a second dose of MMR or other vaccines containing thimerosal.
The Centers for Disease Control and Prevention has also been negligent in addressing the research needs regarding vaccine injury and autism. The CDC's funding for autism research has lagged behind funding for other serious diseases. The NIH, with a budget of $2.2 Billion per year, invested just $5.6 Million towards autism research. Much of that research has been focused on looking for genetic causes of autism, which is important, but does not address the possible connection to vaccine injury. To put the spending on autism in perspective, the Committee compared it to the spending on two other serious epidemics—HIV/AIDS and diabetes. At the same time that the NIH was spending $56 Million on autism research, they spent $588 Million on diabetes research and over $2.2 Billion on HIV/AIDS research.

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

1. Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines.
2. Case series of children who did not receive thimerosal-containing doses of vaccines during clinical trials.
3. Epidemiological studies comparing the prevalence of neurodevelopmental disorders in children who received vaccines before thimerosal was removed to children who received vaccines after it was removed.
4. An increased effort to identify the primary sources and levels of prenatal and postnatal exposure to thimerosal.
5. Clinical research on how children metabolize and excrete thimerosal.
6. Theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal on background mercury exposures from other sources.
7. Research in appropriate animal models on neurodevelopmental effects of ethylmercury.
8. Rigorous investigations of thimerosal as a treatment for neurodevelopmental disorders; and
9. Research to identify a safe, effective and inexpensive alternative to thimerosal for countries that decide they want to follow the example of Europe and the United States and discontinue its use.

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

Another concern is the lack of a sufficient investment into research on autism and its causes. Autism is growing at epidemic proportions and nobody knows why. The rates of autism have quadrupled during the Committee's investigation, yet funding for research on autism lags badly behind funding for other serious diseases. The NIH, with a budget of $2.7 Billion per 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 $588 Million on diabetes research and over $2.2 Billion on HIV/AIDS research.

The Centers for Disease Control and Prevention has also been negligent in addressing the research needs regarding vaccine injury and autism. The CDC's funding for autism research has lagged behind funding for other serious diseases. The NIH, with a budget of $2.2 Billion per year, invested just $5.6 Million towards autism research. Much of that research has been focused on looking for genetic causes of autism, which is important, but does not address the possible connection to vaccine injury. To put the spending on autism in perspective, the Committee compared it to the spending on two other serious epidemics—HIV/AIDS and diabetes. At the same time that the NIH was spending $56 Million on autism research, they spent $588 Million on diabetes research and over $2.2 Billion on HIV/AIDS research.

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

1. Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines.
2. Case series of children who did not receive thimerosal-containing doses of vaccines during clinical trials.
3. Epidemiological studies comparing the prevalence of neurodevelopmental disorders in children who received vaccines before thimerosal was removed to children who received vaccines after it was removed.
4. An increased effort to identify the primary sources and levels of prenatal and postnatal exposure to thimerosal.
5. Clinical research on how children metabolize and excrete thimerosal.
6. Theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal on background mercury exposures from other sources.
7. Research in appropriate animal models on neurodevelopmental effects of ethylmercury.
8. Rigorous investigations of thimerosal as a treatment for neurodevelopmental disorders; and
9. Research to identify a safe, effective and inexpensive alternative to thimerosal for countries that decide they want to follow the example of Europe and the United States and discontinue its use.

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

Another concern is the lack of a sufficient investment into research on autism and its causes. Autism is growing at epidemic proportions and nobody knows why. The rates of autism have quadrupled during the Committee's investigation, yet funding for research on autism lags badly behind funding for other serious diseases. The NIH, with a budget of $2.7 Billion per 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 $588 Million on diabetes research and over $2.2 Billion on HIV/AIDS research.

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

1. Case-control studies examining the potential link between neurodevelopmental disorders and thimerosal-containing vaccines.
2. Case series of children who did not receive thimerosal-containing doses of vaccines during clinical trials.
3. Epidemiological studies comparing the prevalence of neurodevelopmental disorders in children who received vaccines before thimerosal was removed to children who received vaccines after it was removed.
4. An increased effort to identify the primary sources and levels of prenatal and postnatal exposure to thimerosal.
5. Clinical research on how children metabolize and excrete thimerosal.
6. Theoretical modeling of ethylmercury exposures, including the incremental burden of thimerosal on background mercury exposures from other sources.
7. Research in appropriate animal models on neurodevelopmental effects of ethylmercury.
8. Rigorous investigations of thimerosal as a treatment for neurodevelopmental disorders; and
9. 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.
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. FORNTYE 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 physicians 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 may 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 for Medicare services. It does so without limiting seniors' choice of physicians and without forcing seniors to leave Medicare and join a private plan. The out-of-pocket spending limit 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.

Eligibility and enrollment. Benefits 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