MERCURY IN MEDICINE--ARE WE TAKING UNNECESSARY RISKS?

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HEARING

before the

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

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JULY 18, 2000

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Serial No. 106-232

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MERCURY IN MEDICINE--ARE WE TAKING UNNECESSARY RISKS?

TUESDAY, JULY 18, 2000

House of Representatives,
Committee on Government Reform,
Washington, DC.

The committee met, pursuant to notice, at 1 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Ros-Lehtinen, Chenoweth-Hage, Waxman, Maloney, Norton, Cummings,

Kucinich, Davis of Illinois, and Schakowsky.

Also present: Mr. Weldon.

Staff present: Kevin Binger, staff director; David A. Kass, deputy counsel and parliamentarian; S. Elizabeth Clay, Nicole Petrosino, and Nat Weinecke, professional staff members; Robert Briggs, clerk; Robin Butler, office manager; Michael Canty, legislative aide; Toni Lightle, legislative assistant; Leneal Scott, computer systems manager; John Sare, staff assistant; Corinne Zaccagnini, systems administrator; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Sarah Despres, minority counsel; Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerks.

Mr. Burton. A quorum being present, the Committee on Government Reform will come to order. I ask unanimous consent that all Members and witnesses' written statements be included in the record. Without objection, so ordered. I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record. Without objection, so ordered.

For the last year, the Government Reform Committee has been looking at issues regarding vaccine safety, research and policy. A few people have tried to portray this investigation as anti-vaccine. Nothing could be further from the truth. Safe, effective vaccines save lives. On the other hand, vaccines that have not been thoroughly tested and reviewed can be dangerous. The rotavirus vaccine was a good example. The government and manufacturers ignored the warning signs. A lot of babies were injured and required surgery. One baby died before the vaccine was pulled off the market.

Is it irresponsible to ask questions about why that happened? Of course not.

We have a lot of doctors who serve on Federal advisory committees who have serious conflict of interest problems. They are allowed to vote on vaccines made by companies that they get money from.

Is it irresponsible to ask questions about conflicts of interest? Of course not, especially where public health and safety are concerned.

Today we are holding a hearing about why mercury is put into vaccines that are given to children. Is that irresponsible? Of course not.

If someone holds hearings about mismanagement at the Department of Education, that does not mean they are anti-education. That means they want our educational system to be as well run as possible. That is the way that I feel about our vaccine policies. No area is so sacrosanct that the world will come to an end if we ask some sensible questions and expect to get some sensible answers.

I think this kind of oversight will make our vaccine

program stronger not weaker.

This spring we held a hearing about possible connections between autism and the MMR vaccine. We heard lots of testimony on both sides of the issue. After the hearing, I sent a letter to Secretary Shalala. So did Congressman Waxman. We both asked her to put together a panel of the best experts in the field to look at this issue. That was May 16--2 months ago. No response.

That's intolerable. If your position is that we should base our policies on good science and good research, then fine. I agree with you 100 percent. But if you are not willing to do the research, if you're not willing to ask the questions, then we have a real problem on our hands.

I believe that our primary focus on vaccine policy should always be what is best for the children. We need to insure that only vaccines that are truly needed to protect the public health are added to the childhood immunization schedule. At no time should the interests of vaccine developers be a higher priority than our children's health and well-being.

Vaccines are the only drugs that Americans are required by a government agency to take. It is thus imperative that the Federal Government ensures the safety of these mandated vaccines. Each State sets a schedule for the vaccines a child must receive in order to attend school or day care. The States rely on the Federal Government for guidance on which vaccines should be mandated. The Federal Government is also the largest purchaser of vaccines.

That brings us to today's hearing topic--mercury in medicine. This should be a no-brainer. We all know that mercury is a toxic substance. Long-term exposure to low levels of mercury has been linked to mental retardation, cerebral palsy and central nervous system disorders. We assume that the FDA will protect our children from exposure to any level of mercury through drugs. But that hasn't been the case. Thimerosal was first marketed in 1930 and has become the most widely used preservative in vaccines. It is present in over 50 licensed vaccines.

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

How much mercury are kids being exposed to at once? One would think that the FDA would have moved aggressively to remove vaccines that contain mercury from the market immediately. They did not. On July 9, 1999, the American

Academy of Pediatrics and the U.S. Public Health Service issued a joint statement recommending the removal of all thimerosal from vaccines. On May 31, 2000, the Food and Drug Administration notified vaccine manufacturers that the review of mercury compounds in drugs and foods concluded that reducing or eliminated thimerosal from vaccines is merited. However, there has been no mandatory action. These vaccines are still in use.

The FDA continues to allow the mercury containing vaccines to remain on the market. Today, over 8,000 children in America may be given a toxic dose of mercury in their vaccines.

Many parents who have contacted the committee are concerned about other ingredients as well, including formaldehyde, MSG, and aluminum. We have also been contacted by many individuals who have concerns about mercury in dental amalgams. While this is not the focus of today's hearing, it certainly warrants discussion as well.

Congress directed the Environmental Protection Agency to contract with the National Research Council to prepare recommendations on the appropriate dose for mercury exposure. That report was released on July 11. While the FDA relies on the Agency for Toxic Substances and Disease Registry's dosing level for mercury of 0.5 micrograms per kilogram of body weight per day, this is significantly higher than the EPA's dose of 0.1 microgram per kilogram of body weight. In that report it was confirmed that the EPA's reference dose is correct. We will hear from Dr. Vasken Aposhian, University of Arizona at Tucson, one of the scientists who worked on this report. Romana Trovato will testify on behalf of the Environmental Protection Agency.

Section 413 of the Food and Drug Administration Modernization Act of 1997 required the FDA to compile a list of drugs and foods that contain internally introduced mercury compounds, and provide a quantitative and qualitative analysis of the mercury compounds in this list. The act also requires the agency to compile the list and provide the analysis within 2 years after the date of its enactment on November 21, 1997. Dr. William Egan will be testifying on behalf of the FDA today.

While thimerosal has previously been ruled by the FDA to fit the ``generally recognized as safe'' standard, when the FDA conducted their over the counter drug review they changed their minds. The FDA determined that mercury compounds used as active ingredients in over the counter drug products were not found to be generally recognized as safe. Additionally, the FDA has not approved any mercury containing compounds as food additives and does not consider any mercury containing compounds to be generally recognized as safe. On their own Website, the FDA states, ``lead, cadmium, and mercury are examples of elements that are toxic when present at relatively low levels.''

How is it that mercury is not safe for food additives and over the counter drug products but it is safe in our vaccines

and dental amalgams?

Dr. Roger H. Bernier, Associate Director for Science at the National Immunization Program, Centers for Disease Control and Prevention, will testify regarding the recent discussion of the Advisory Committee on Immunization Practices regarding thimerosal.

Autism is a syndrome characterized by impairments in social relatedness and communication, repetitive behaviors, abnormal movements, and sensory dysfunction. Autism may now affect 1 in 150 U.S. children. We will hear from Dr. Marie Bristol-Power of the National Institutes of Health regarding the existing research in autism. The characteristics of autism and of mercury poisoning are strikingly similar.

Dr. Stephanie Cave, a physician from Baton Rogue, LA will be testifying about the mercury toxicity she is seeing in the 200 autistic children she has as patients.

Autism strikes families from a diverse background. We will hear from five parents today. Elizabeth Birt of Chicago, an attorney and mother of an autistic child, will be testifying about the need to remove mercury from all vaccines and a citizens petition that is being presented to the FDA making this request.

Several parents with scientific and medical backgrounds have written a report entitled ``Autism: A Unique Type of Mercury Poisoning.'' Three of these parents will be testifying today. The lead author of the report is Sallie Bernard of Cranford, NJ. Lyn Redwood of Tyrone, GA is a nurse practitioner, and Albert Enayati of Paramus, NJ is a chemist. Dr. Sharon Humiston, a doctor with an autistic child, will also be testifying.

Our children are the future of this country. As a government, we have a responsibility to do everything within our power to protect them from harm, including insuring that vaccines are safe and effective. Every day that these mercury containing vaccines remain on the market is another day we are putting 8,000 children that day at risk.

The record will remain open until August 1, 2000.

Now I will recognize my colleague, Mr. Waxman, for his opening statement.

Mr. Waxman. Today we are having another hearing to highlight allegations of the safety of vaccines.

In April this committee held a hearing to publicize the chairman's theory that certain vaccines, particularly the MMR vaccine, cause autism. This theory is based mainly on speculation. As the American Medical Association concluded recently, ``Scientific data does not support a causal association between vaccination and autism.''

Today we are going to hear testimony about a new theory, that there is a link between autism and the mercury-based vaccine preservative called thimerosal. It should be noted that

the MMR vaccine does not contain thimerosal. So this new theory is directed at childhood vaccines other than the measles, mumps and the rubella vaccine.

As I said in April, we must not get ahead of the science or raise false alarms. The best answers come from research that can withstand the rigors of the scientific method. These standards have been developed in order to find the truth. But if allegations are raised without scientific evidence, we risk scaring parents into foregoing potentially life saving childhood immunizations.

Regrettably I fear that once again we are proceeding without a sound scientific basis.

This hearing today combines two issues that I have worked on for years, autism and mercury. I have been a strong supporter of research and treatment for autism. I am a current sponsor of autism research and surveillance legislation, H.R. 997 and H.R. 274. I was also a leading supporter and sponsor of the Work Incentives Program Act of 1999, the American Disabilities Act of 1990 and the Developmental Disabilities Assistance and Bill of Rights Act of 1990, which are all laws of tremendous importance to persons with autism.

And in 1993, when I was chairman of the House Commerce Subcommittee on Health and the Environment, I was the lead sponsor of the NIH Revitalization Act, which reauthorized expanded funding for and strengthened NIH research into autism and childhood health.

I have also been very concerned about public exposure to mercury. For example, last year I introduced the Clean Smokestacks Act, H.R. 2900, to reduce methyl mercury emissions from power plants by 90 percent. As a National Academy of Sciences report confirmed only last week, these emissions pose a significant health threat and must be reduced. Methyl mercury contamination has caused 40 States to issue warnings about fish consumption. Human exposure to eating contaminated fish can cause numerous adverse health affects such as losses of sensory or cognitive ability, delays in developmental milestones, birth defects, tremors, convulsions and even death.

Currently, my legislation to reduce mercury emissions has over 100 bipartisan cosponsors, but it hasn't even been called up for a hearing, let alone movement by the leadership of the committee that has jurisdiction. For the last two Congresses, I have also introduced bipartisan legislation to require better public disclosure of mercury pollution. This legislation has over 100 bipartisan cosponsors, and I point this out to illustrate that I take the issue of mercury very seriously. Where we have a reasonable basis for taking action I believe that the Congress and agencies should expeditiously work to protect the public health from mercury exposure.

For this reason I strongly support the efforts by FDA to eliminate the use of thimerosal in vaccines. Thimerosal is a

preservative that contains ethyl mercury. Although less is known about the effects of ethyl mercury in thimerosal than about the effect of ethyl mercury from power plant emissions, ethyl mercury may pose similar health risks. It is appropriate, therefore, that thimerosal be phased out of vaccines.

This process is well underway. The maximum exposure to mercury through vaccines today is 60 percent of what it was a year ago. The entire childhood immunization schedule is currently available without thimerosal and FDA expects all vaccines to be thimerosal free by the first quarter of next year.

The question this hearing poses, however, is not whether mercury-containing thimerosal should be in vaccines in the United States. FDA decided a year ago that it should not. Rather, the purpose of this hearing appears to be to publicize the theory that thimerosal is causing autism.

The evidence to support this theory is virtually nonexistent. I fear that once again we are pursuing an anti-vaccine agenda in disregard for the scientific and medical consensus on the safety of vaccines.

The chairman has held a series of hearings on questioning vaccine safety, the public health benefits of childhood immunizations and the integrity of the scientists, health professionals and public servants working to immunize our children. The chairman has promoted allegations that MMR vaccines causes autism. He has provided a forum for allegations that vaccines can cause diabetes, and he has alleged that parents should be skeptical about vaccines because our government is beholden to the drug industry.

Well, this is a backward attitude to take at a time when vaccines promise more than ever to improve human health.

I will read and listen to the testimony of the witnesses today very attentively. I want to thank the parents who are coming here and testifying. It takes a lot of courage to share your personal experiences with Congress.

We have other things going on at the same time as this hearing, which keeps us from being able to attend the hearing in full, and I will be in and out and I want to apologize to those witnesses. The written testimony will be part of the record. I will have a chance to review it. My staff will be here and will have an opportunity to report to me on all of the testimony that is given orally that may supplement the written record as well.

Thank you, Mr. Chairman, for this chance to give an opening statement.

Mr. Burton. Before we ask any other Members if they would like to make an opening statement, we have Dr. Weldon, Congressman Weldon, who is very interested in this subject, and I would like to ask unanimous consent that he be able to participate in the hearing.

Mr. Waxman. Reserving the right to object, I am not going to object to him sitting in and being able to hear the testimony and pursue questions, but that is unusual because usually you have only members of the committee participate and if we allowed all Members to come in, it could delay many hearings to a great extent. But we want to accommodate this request and I certainly want to accommodate Dr. Weldon, for whom I have a great deal of respect.

We have 11 witnesses testifying today, and we on the minority asked for four witnesses and we were only accommodated by getting three. Now, when I say we were accommodated, we asked that the Centers for Disease Control be allowed to testify. We asked for a witness from NIH to testify. It shouldn't be a request of ours, it is no favor to us to have them testify. In any balanced hearing we certainly ought to have these people in to testify as well as those who are going to come in and express a particular point of view. We requested four witnesses and we got three. One more witness would have taken 5 minutes of testimony because that is what we allow each witness to take in giving oral testimony. Mr. Weldon will have an opportunity to ask questions at least 5 minutes one round--
--

Mr. Weldon. Would the gentleman yield.

Mr. Waxman. In a minute. I welcome that because I think he will bring out information, but it just troubles me that while we try to be accommodating, I find it incomprehensible why the majority of the committee and the chairman of this committee is not accommodating our requests.

And I yield to the gentleman, and I do not object and I welcome you because you have a special interest and expertise.

Mr. Weldon. I thank the gentleman's kindness and I just want to point out that I have another hearing to go to in 30 minutes, so I doubt that I will be able to get in any oral questions.

Mr. Waxman. I don't object to you participating and asking questions. I point out the reluctance of the majority to have a fair and full and open hearing and accommodate all of the witnesses who have something to add, even if they may have something to add on a point that the chairman may disagree with. I withdraw my reservation.

Mr. Burton. Without objection, so ordered. Do any other members have opening statements?

Representative Morella.

Mrs. Morella. Mr. Chairman, I just ask the fact that my written statement be included in the record and I just want to comment on the fact that I appreciate your efforts to hold this hearing on mercury and medicine, and I look forward to hearing the testimony of the witnesses. I really want to learn more about mercury and medicine and vaccines specifically.

In Montgomery County, the incidence of autism in our

children is alarming, and some do feel that autism may be related to vaccines, but I am concerned about the lack of information and misinformation surrounding the issue of vaccines and its possible relationship to autism, so that I hope that today we can come to a conclusion on what the appropriate steps are for this committee and the government to take.

So with your approval, the rest of my opening statement I would like to have in the record.

Mr. Burton. Without objection, so ordered.

[The prepared statement of Hon. Constance A. Morella follows:]

[GRAPHIC] [TIFF OMITTED] T2722.001

[GRAPHIC] [TIFF OMITTED] T2722.002

Mr. Burton. Ms. Schakowsky.

Ms. Schakowsky. Thank you, Mr. Chairman. I will not be able to stay for all of today's hearing. I would like unanimous consent to submit some questions for the EPA and to the FDA for the record.

Mr. Burton. Without objection, so ordered.

[The prepared statement of Ms. Schakowsky follows:]

[GRAPHIC] [TIFF OMITTED] T2722.003

Ms. Schakowsky. I also want to take a moment to welcome all of the witnesses, but particularly Ms. Birt. While not a constituent of mine, we live in neighboring towns and the two of us have exchanged letters in the past. Again, a thank you to all of the witnesses for being here, and I yield back the balance of my time.

Mr. Burton. Mrs. Maloney.

Mrs. Maloney. I would like to put my opening statement in the record so we can hear from the witnesses. Thank you.

Mr. Burton. Without objection, so ordered. We will now welcome our first panel to the witness table, Ms. Redwood, Ms. Bernard, Mr. Enayati, Ms. Birt, Dr. Cave, Dr. Aposhian and Dr. Humiston.

[Witnesses sworn.]

Mr. Burton. Ms. Redwood, if you can confine your remarks to 5 minutes. Ms. Redwood.

STATEMENTS OF LYN REDWOOD, TYRONE, GA; SALLIE BERNARD, CRANFORD, NJ; ALBERT ENAYATI, PYRAMUS, NJ; ELIZABETH BIRT, CHICAGO, IL; DR. STEPHANIE CAVE, BATON ROUGE, LA; DR. H. VASKEN APOSHIAN, PROFESSOR OF MOLECULAR AND CELLULAR BIOLOGY, AND PHARMACOLOGY, UNIVERSITY OF ARIZONA; AND DR. SHARON HUMISTON, PITTSFORD, NY

Ms. Redwood. Chairman Burton, Congressman Waxman and committee members, I want to thank you for holding this hearing today and inviting me to testify on this important issue. My name Lyn Redwood. I reside in Atlanta, GA with my husband Tommy and three children, Hanna, Drew and Will. My husband and I are both health care professionals. My husband is a physician, and I am nurse practitioner. I also hold a master's degree in community health nursing and I am a member of our county's Board of Health and Local Planning Commission.

My son Will weighed in at close to 9 pounds at birth. He was a happy baby who ate and slept well, smiled, cooed, walked and talked all by 1 year of age. Shortly after his first birthday, he experienced multiple infections, lost speech, eye contact and developed a very limited diet and suffered intermittent bouts of diarrhea. He underwent multiple evaluations and was initially diagnosed with a global receptive and expressive speech delay and later with pervasive developmental disorder, a form of autism.

I would never have made a correlation between my son's disability and vaccines until July 1999, when I read that a preservative, thimerosal, utilized in some infant vaccines actually contained 49.6 percent mercury. The report said that the FDA had determined that ``infants who received thimerosal-containing vaccines at several visits may be exposed to more mercury than recommended by Federal guidelines for total mercury exposure.'' As health care providers, my husband and I constantly receive notices that adverse events have been reported with a drug or product safety sheets have been revised, and I was wondering why no such notices were sent out notifying us that thimerosal preservative vaccines were exceeding Federal guidelines for mercury exposure in infants.

It was in light of this information that I reviewed my son's vaccine record and my worse fears were confirmed. All of his early vaccines that could have possibly contained thimerosal, had. From my research on mercury, I have found it to be a potent human toxin, which is especially damaging to the rapidly developing fetal and infant brain. While acceptable levels for exposure are published by Federal agencies, mercury is a poison at any level.

The dose thought to be safely allowed on a daily basis by EPA is 0.1 micrograms per kilogram of body weight. At 2 months of age my son had received 62.5 micrograms of mercury from three infant vaccines. According to this EPA criteria, his allowable dose was only 0.5 micrograms based upon his weight. He had received 125 times his allowable exposure on that day. These large injected bolus exposures continued at 2 months, 4 months, 12 months and 18 months to a total mercury exposure of 237.5 micrograms. I also discovered that the injections that I received during my pregnancy, the first and third trimesters,

and hours after the delivery of my son to prevent RH blood incompatibility disease also contained mercury.

Knowing that the major effect of mercury compounds is neurotoxicity, I questioned if these exposures could account for my son's regression and disability. Since he was now 5\1/2\ years old, it would be difficult for me to know what his mercury levels had been at that time. It was then that I remembered having kept a lock of hair from his first haircut at 20 months of age. Heavy metal analysis detected 4.8 parts per million mercury in his hair, the allowable levels being less than 1 part per million. The EPA action level in hair is 1 part per million as well, and 5 parts per million is considered diagnostic for mercury toxicity.

Since my son has never eaten fish nor seafood nor had dental amalgams, I had no other identifiable source for his mercury levels outside of the thimerosal exposure from his vaccines and my RhoGAM injections.

Since last fall I have spent every free moment researching this issue. As a nurse and a member of the Board of Health for our county, I felt an urgency to share my findings and concerns about thimerosal with other professionals. I did research and made phone calls, and I wrote letters and I actually went in person to Washington to meet with FDA and CDC officials to voice my concerns and present data on documented levels of mercury in many other children with developmental delays who were also exposed to thimerosal in their vaccines. All of my efforts seemed to fall on deaf ears.

On June 21, 2000 I attended the Advisory Committee for Immunization Practices meeting held in Atlanta. At that meeting a study was presented that looked at Vaccine Safety Datalink information and thimerosal exposure in over 120,000 children. The key findings of the study were significant associations between thimerosal exposure and ADD, tics, speech and language delay and neurodevelopmental delays in general. A panel of experts who were convened to review the data who concluded, ``The findings support a statistically significant, albeit weak association, but that the implications are profound.''

Unfortunately, ACIP chose not to give preference to thimerosal free vaccines, even though the vaccine manufacturers present at this meeting assured there was enough supply available to meet vaccine needs the first 6 months of life. From the comments made by ACIP committee members it was apparent that political and economic concerns for the vaccine program had taken precedence over the health, safety and welfare of the children it is charged to protect. One committee member even remarked that giving preference for thimerosal free vaccines may result in reduced public confidence in vaccine programs. From my own personal perspective, just the opposite has occurred.

You may hear today from some officials that the mercury

exposure from medicinal sources is insignificant. The fact is that neurological damage is documented to occur in infants at these levels of exposure. You may also hear that these levels of exposure only exceed EPA guidelines the first 6 months of life. That is because the data was inaccurately averaged over a 6-month period of time. As any independent toxicologist will tell you, mercury has a long half-life and its inherent pharmacokinetics you cannot legitimately calculate the effect of a bolus dose as though it were ingested in small amounts over a long period of time. To make a simple analogy, what FDA is trying to assert is that giving someone two Tylenol a day for 30 days has the same effect of giving them 60 Tylenol all at once in 1 day. This defies common sense, much less sound medical practice.

The truth is vaccines are the single largest source of mercury exposure postnatally in infants, but nowhere in the mercury literature of EPA, FDA, ATSDR are these products even identified as being a source of exposure. When I spoke with one official from EPA, he commented that my son's exposure was very high and was rather sympathetic, but since it was not an environmental exposure, his agency could not get involved. So whom do I turn to for help?

Over 1 year ago the FDA, AAP and the Public Health Service called for the immediate elimination of reduction of thimerosal from vaccines, but the sad truth is that while some progress has been made, infants continue to be injected with one of the most neurotoxic metals on Earth in excess of Federal safety guidelines as I speak here today, and the responsible agencies are unwilling to address this issue.

We are in the midst of an autism epidemic and children diagnosed with learning disabilities continue to increase daily. The statement that there is no evidence of harm does not equate with no harm not having occurred. The truth is that we have not adequately looked or we just refuse to see.

A recent national news article which addressed these concerns reported that some may say we don't have a smoking gun but the truth is the bullets are all over the floor. Millions of children have been needlessly exposed to toxic acts from federally sponsored vaccine programs and have suffered neurological damage. This problem has become so pervasive in our society that few are left untouched, as Chairman Burton well knows. It is time for someone to step forward and acknowledge these facts and provide the science to fully investigate what has happened to our children and what can be done to help them.

Thank you.

[The information referred to follows:]

[GRAPHIC] [TIFF OMITTED] T2722.005

[GRAPHIC] [TIFF OMITTED] T2722.006

[GRAPHIC] [TIFF OMITTED] T2722.007

[GRAPHIC] [TIFF OMITTED] T2722.008

Mr. Burton. Ms. Bernard.

Ms. Bernard. I have some slides.

Mr. Burton. We will put those up on the screen as you speak.

Ms. Bernard. Chairman Burton, Congressman Waxman and other distinguished members of this committee, thank you for holding this hearing to examine the possible role of mercury and thimerosal in causing neurodevelopmental disorders.

My name is Sallie Bernard. I live in New Jersey. I am the mother of triplets, age 12, Fred, Jimmy and Billy. After meeting all of his developmental milestones on schedule and receiving unremarkable pediatric reports up to age 2\1/2\, Billy began to exhibit slower word acquisition than his brothers, articulation difficulties and attentional problems. At 3\1/2\ he was diagnosed with language dysphasia and attention deficit hyperactivity disorder. At age 4\1/2\ he was diagnosed with autism.

Anyone familiar with the signs of mercury toxicity in children will recognize language difficulties and ADHD traits as common features. But in fact, research conducted by me and others has shown that the characteristics of autism itself are identical to those arising from mercury exposure.

This chart that I have up here shows only some of the similarities between autism and mercury poisoning. This shows some of the behavioral characteristics of autism and mercury poisoning. They include social withdrawal, repetitive and compulsive behaviors, language difficulties, sensory disturbance, movement disorders, cognitive deficits and unusual behaviors like head banging.

Next slide. This slide shows physiological aspects of mercury poisoning and autism. We see the same similarities, damage to the same brain areas, EEG patterns, and so forth.

The next slide. On the population characteristics, males more affected than females for both disorders and the presence of a strong genetic component. We feel that these similarities are too close to have occurred by chance. We are not alone in our thinking. The just released congressionally mandated mercury report by the National Academy of Sciences links methyl mercury and the environment to neurological deficits in children, and we know from researchers such as Suzuki and Magos that the ethyl mercury found in thimerosal is as toxic as methyl mercury. The latest issue of Environmental Health Perspectives also notes that an association has been found between exposure to toxic chemicals and various

neurodevelopmental disorders such as learning disabilities, intellectual retardation, attention deficit, hyperactivity disorder, autism and propensity to violence.

It is well-recognized by autism researchers, as reviewed by Dr. Bristol-Power and others, that autism is caused by an interaction of environmental and genetics factors. Based on epidemiological and other data we have proposed that this environmental factor is thimerosal from vaccinations acting alone or synergistically with other toxins. This is why we believe this to be true.

Next slide. This chart shows the prevalence of autism and vaccine history. Thimerosal was first introduced into vaccines in the 1930's and autism was first discovered by Leo Kanner in the early 1940's among children born in the 1930's. Studies prior to 1970 estimated autism to occur in 1 in 2,000 children while studies after 1970 showed the prevalence at about 1 in 1,000. This was also a period of increased immunization of American children. In 1996 the NIH has estimated the rate of autism to be higher at 1 in 500, and just this year the CDC has found 1 in 250 children affected with classic autism. This dramatic increase in the past decade coincides with the introduction and spread of two new thimerosal containing vaccines, the HIB and the hepatitis B.

Another observation is that autistic symptoms emerge within a short time after vaccination, generally following a period of normal development. Importantly, the amount of mercury injected with each vaccine given as a bolus or spike does greatly exceeds EPA and safety guidelines and thus is highly likely to be neurotoxic and injurious.

Last, as Lyn noted, a recent CDC study has found a statistically significant association between thimerosal and vaccines specifically, and attention deficit disorders, speech delay, motor tics and neurodevelopmental disorders in general.

Thus, we see the symptoms of autism and mercury poisoning are the same and the epidemiological and exposure data are highly supportive of a thimerosal etiology. Since thimerosal is not a necessary component of vaccines and every child can be fully immunized today with a non-thimerosal alternative, thimerosal should no longer be allowed in vaccines.

Congress, again listening to the needs of citizens, passed legislation in 1997 requiring government agencies to review thimerosal content in products. In response, the FDA investigated thimerosal in vaccines and found that no safety studies had ever been conducted on this substance.

As a parent, this is very disconcerting indeed. Vaccines are recognized as the crown jewels of the U.S. Public Health Service and their effectiveness relies on the willingness of parents to bring their children in to be immunized. By not conducting safety studies and then not taking immediate steps to ban thimerosal once its potential for harm was publicly

recognized, this program has been put at great risk. What parent will want their baby injected repeatedly with a known neurotoxin? How much confidence will parents have that our national vaccine program really cares about safety? Parents like me already have their doubts that it does.

I hope that Congress will respond once again with effective action to ensure the safety and well-being of all our children in light of the information now presented. Thank you.

[The prepared statement of Ms. Bernard follows:]

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Mr. Burton. Thank you.

Mr. Enayati.

Mr. Enayati. Good afternoon. My name is Albert Enayati. I am president of the Cure Autism Now! Foundation, New Jersey chapter. Our foundation headquarters are located in Congressman Waxman's district. My wife Sima and I are scientists who have worked for pharmaceutical companies. We have a child with autism.

Mr. Chairman, in 1971, when my wife and I were growing up in Iran, a tragic event was taking place in our neighboring country Iraq. In October of that year, Iraq imported more than 90,000 tons of grain treated with methyl mercury. Much of the grain was used as daily baked bread. The reports from Iraq were shocking. The extensive mercury poisoning caused thousands of

Iraq farmers and their families to become neurologically damaged. Hundreds died. The Iraqi episode is not unique. Similar misfortunes include mercury epidemics in Minamata, Japan, Guatemala and Russia. In the first half of the century, poisoning of infants and toddlers by mercury in teething powders led to acrodynia, or Pink Disease.

Today, another mercury tragedy is unfolding, this time among our children. As a scientist and a parent, I sadly declare that ethyl mercury in vaccines has been causing autism, attention deficit disorder and other neurodevelopmental diseases in children who, as susceptible infants and toddlers, were injected with thimerosal, a vaccine preservative which is 49.6 percent ethyl mercury by weight.

In 1982, 18 years ago, an FDA panel concluded that thimerosal is toxic, causes cell damage, can cause allergic reactions, and is not effective in killing bacteria or halting their replication. A recent hepatitis control report details how FDA, via its own Committee on Biologics, had failed, for 17 years, since the 1982 report, to follow their own organizational directives which specify ensuring product safety. Fortunately, because of the FDA Modernization Act of 1997, the CBER was forced to evaluate thimerosal in vaccines.

By 1998, the CBER's thimerosal study had run into difficulty. It is against Federal statutes to add toxic material to childhood vaccines, and thimerosal appeared to be contrary to this important law. CBER staff then searched for safety data and guidelines but found none. In fact, the CBER learned that there is very limited literature available on ethyl mercury.

The CBER team then compared ethyl mercury intake with Federal guidelines for safe mercury intake, but again the CBER ran into difficulty. Thimerosal is injected in bolus doses and metabolized in humans to ethyl mercury but all theoretical guidelines for safe mercury intake were based upon ingested methyl mercury. Left with no choice, the CBER team assumed that the toxicity of thimerosal injected in bolus doses was equivalent to that of methyl mercury ingested gradually.

Armed with this assumption, they compared the vaccinal ethyl mercury intake in children 6 months old to the suggested safe limits by EPA. It was then that they made a remarkable discovery: Even without considering infants and toddlers' susceptibility to neurotoxic effects, the mercury intake from vaccinations in the first 6 months of life far exceeded the limit set by EPA.

I believe that the FDA record justifies concluding that the U.S. immunization program has been in violation of Federal statutes. Presumptions about safety have superseded safety guidelines and appropriate testing. Dangerous substances in vaccines remain untested. This negligence is inexcusable. Thousands of children and their families have been

neurologically impaired by physician-injected ethyl mercury and while this has happened, the responsible supervisory agency, the FDA, was asleep at the wheel.

Mr. Chairman, despite the FDA warning in 1982 and the known toxicity of thimerosal, the FDA allowed the continued injection of cell damaging neurotoxic product into our children. Furthermore, since 1990, the FDA and CDC increased the likelihood of neurological damage by allowing thimerosal to be injected into day-old and 2-month-old infants. I am here because of my son Payam. For more than a year, he passed his developmental milestones, but after his DPT and MMR shots, Payam began not responding to his name, no longer ran to greet me when I returned from work. His spoken language disappeared and he no longer responded to his parent's words. Within a few months he had begun biting himself, hitting his head against the wall, flapping hands, toe walking and running aimlessly around the house. Even sleep patterns had deteriorated. All these traits appear in medical literature about mercury poisoning. Mr. Chairman, every symptom of my son's autism parallels traits known in mercury poisoning.

Many experts would have us believe that my son's regression was coincident with his vaccination. However, as a trained scientist, my reading of mercury literature indicates that every trait that defines autism can be induced by organic mercury. Not surprisingly, the FDA and CDC have asked vaccine producers to initiate a gradual discontinuance of using vaccines containing thimerosal. However, no family needs a neurologically impaired child. Injecting ethyl mercury in infants and toddlers ought to be discontinued immediately and clinical research to be initiated regarding mechanisms of treatment.

Thank you, Mr. Chairman.

Mr. Burton. Thank you. Ms. Birt.

Ms. Birt. Thank you. My name is Liz Birt. I live in Wilmette, IL with my husband and children, Sarah age 8, Matthew age 6 and Andrew age 4. I would like to thank you for holding this hearing today and allowing me to testify.

I have sat in this room before as a member of the audience. On April 6 of this year I listened as the chairman's opening statement detailed in part the story of my son Matthew. Matthew is classified as autistic, a diagnosis made entirely on behavioral observations. However, he has physical problems, including antibodies to myelin basic protein, abnormal EEG, inflammatory bowel disease and live measles virus in his terminal ileum. Matthew's immunologist at a teaching hospital believes that the thimerosal contained in the vaccines contributed to the development of these medical conditions and they have led to his contraction of the live measles virus by priming this immune symptom for an adverse reaction.

I am also here testifying as an advocate for not only the

immediate recall of thimerosal containing vaccines but for fundamental change. This is unfortunately a failure to assign responsibility for vaccines which are mandatory for all children. The manufacturers, the FDA and the CDC, NIH and the AAP all share responsibility for allowing this neurotoxin to remain in vaccines. This is the mandate of the FDA. The American public relies on this agency with its scientific experts to protect us. Yet for some unknown reason this issue was ignored. Why are American children today being exposed to vaccines which on a conservative basis subject them to 30 times the allowable amount of mercury for an adult? Why weren't the most basic calculations done to ensure that these products are safe? It is the children like my son who were injured in the name of the greater good who, just like the soldiers returning from the Vietnam War, are now being ignored.

I am here today to let the members of the committee know that these children have voices, and the voices of their parents and the grandparents, some of which are in this room today, will be heard however unpleasant the message. We want these products off the market immediately. Not one more child should be vaccinated with these vaccines.

Members of the committee may ask how does a member of the public speak with such conviction. Everything that is an official governmental publication paints a picture of complete safety. However, it does not take a genius to be able to discern the truth from the spin, deliberate material misrepresentations and even fraud contained in some of these publications.

The CDC's fact sheet on thimerosal states ``thimerosal is a mercury containing preservative that has been used since the 1930's. It is used to ensure the medical products stay potent and sterile. It has been used in medicines as well as medical products such as throat sprays and contact lens solutions.'' This I submit would leave the average American parent to conclude that thimerosal is not a toxic substance.

What is missing is since 1977 clinicians have recognized thimerosal as being potentially dangerous. For nearly 20 years the U.S. Government has singled out thimerosal as a potential toxin. My question to the committee members and to the FDA is: Why is thimerosal even in these vaccines if it was determined in 1982 by the FDA that it was not even safe or effective as a bacteriostatic agent: Why has this product not been recalled?

This fact sheet states mercury exposures from vaccines containing thimerosal are within the safety margins included in exposure guidelines established by Federal agencies. The reality is there are no established safety margins published by any Federal agency for thimerosal exposure in infants and toddlers, and American children today are receiving many multiples of the EPA daily exposure guidelines for mercury for adults.

Why aren't the parents being told the truth by the CDC? If these statements were held to the same standards that we have for SEC rules, all of these people would be subject to prosecution. The CDC's own Vaccine Safety and Development Officer is on record as stating that

Part of our problem is, unlike efficacy doses where there was a real effort on the part of the World Health Organization case definition ahead of time, similar efforts were not done for safety.

The CDC is currently working with several large HMOs and a large link data base to study adverse events. The data base will study single validation, new vaccines and new schedules. Future topics could include examining communication of vaccine risk and defining the biological basis of groups at risk for adverse events.

Finally, of all of the positive things that were done by the Vaccine Compensation Act of 1986, one thing that they more or less neglected was research. They found a mechanism to fund an injury compensation program after the injury has already happened, but there is no way at this point to fund the research to try to prevent such injuries.

Why wasn't a safety definition developed? Why isn't it important to identify those at risk for adverse vaccine events? Why isn't research funded?

We must have accountability today. Conflicts of interest on vaccine committees at the FDA and CDC must be eliminated. The stakes are too high. We as parents need information on which to base informed consent. When my son was vaccinated at 2 days of life, I was only told after the vaccine was given. How can this type of process allow parents to receive the type of information that they need to make their decisions regarding the care of their children? We are the caregivers of our children, not these agencies.

Members of the committee, I urge you to support a petition to be filed this week by the Coalition for Safe Minds. This petition calls for the immediate recall of all vaccines containing thimerosal. These vaccines should never be used. Our country is experiencing an epidemic of neurodevelopmental disorders. These conditions cause not only heartbreak to the affected families, but the financial ramifications are immense to our entire country.

Thank you.

[The prepared statement of Ms. Birt follows:]

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Mr. Burton. Thank you.

Dr. Cave.

Dr. Cave. My name is Stephanie Cave. I am in family practice in Baton Rouge, LA. I want to express my deep appreciation to you and to the members of the committee for allowing me to testify. I am presently treating over 300 autistic children, with an additional 150 waiting to get in. Dr. Amy Holmes, the physician-parent of an autistic child, joined in February to help with the overwhelming numbers of children with this problem. We are treating children from all over the United States and getting calls from many places around the globe. This is truly an epidemic. If you have any idea that it is not, I invite you to sit in my office for 2 hours.

Mercury can exist as a pure element or in various forms of organic and inorganic mercury and it affects the immune system and neurological systems at a very basic level. The timing of infant vaccines with mercury corresponds to critical periods of neuronal development. The blood brain barrier is not fully developed in the infant or toddler. The fetus is at risk of exposure to toxins during gestation, including methyl mercury from seafood eaten by the mother or other sources, Rhogam, which we have already mentioned, given at 28 weeks gestation, and the influenza vaccine given during pregnancy. These metals can be passed not only transplacentally, but also through breast milk to the infant at a time when the liver detoxification process is not perfected to the point of removing the metals.

We have measured this detoxification process, and we have

found it to be woefully inadequate in the developmentally delayed children. The organic ethylmercury injected in bolus through vaccines enters the brain and converts to inorganic mercury, which cannot cross back over the blood brain barrier. This form is more likely to cause autoimmune antibodies to brain tissue, and this is what we are seeing in these children.

I believe that the introduction of the hepatitis B vaccine in 1991 has sparked this recent epidemic because of thimerosal. When added to the mercury imparted through the DPT and HIB, the exposure to mercury exceeds EPA safe limits for the metal if you consider a bolus dose on a single day. The EPA limits are usually related to ingested mercury, which is partially cleared by the liver. Injecting boluses of ethyl mercury presents an entirely different, another scenario. The 2-month dose of mercury is at least 30 times higher than the recommended daily maximum exposure set by the EPA.

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

In establishing normal safety limits, if there is such a thing for a metal as toxic as mercury, bolus injections were not considered. Consider a nurse giving an injection who is not shaking the vial according to directions before drawing out the vaccine dose. This would give a chance that child receiving the last dose could get as much as 10 times the usual amount in one dose.

There was an article in the Journal of Pediatrics in May 2000 that showed mercury in the blood of infants at birth prior to the hepatitis B injection. After the vaccine, the levels rose in the blood of the infants tested. In some preterm infants, there were levels that measured 10 times that seen in term infants. The bile production is minimal in infancy, making it more difficult for metals to be cleared from the body. When added to a vaccine, the metals are even more dangerous because the vaccines trigger immune reactions that increase the permeability of the GI tract and the blood/brain barrier.

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

daily dose in an adult. There are no parameters for comparison.

We have simplified the problem in our practice. We test all developmentally delayed children for the presence of heavy metals. Hair is screened, followed by a determination in urine after a challenge of an oral chelator, DMSA, and it is rare that we find any child with a developmental problem who does not have increased levels of mercury in the urine after a chelator challenge. An interesting phenomenon is that we are finding many more lead-intoxicated children than blood screens would indicate. And lead amplifies the toxicity of ethylmercury in the brain.

We performed a number of tests on blood, urine, hair, and stool in the autistic children. The abnormal findings that we see in autism involving the immune system, GI tract, and central nervous system are also seen in mercury poisoning. These include but are not limited to changes in T lymphocytes, low levels of glutathione, low sulfate levels, IgA deficiency, and the presence of myelin basic protein antibodies in the brain. The children are responding well to the use of oral chelators and supplements which take out heavy metals. We are measuring levels in the urine as we treat. The changes in the children are remarkable with each dose of a chelator. This treatment may take months to complete but the chance for recovery is evident on a daily basis.

Because mercury has such far-reaching effects in the destruction of function in many systems of the body, our treatment also involves nutritional repletion of cellular chemistry, normalization of gastrointestinal bacteria, dietary programs and restoration of liver detoxification systems.

Our medical training did not adequately prepare us for this challenge. We have learned little about testing heavy metals and even less about treating. The word ``chelation'' is not in the vocabulary of most physicians. A few physicians who are treating these children are inundated with them in their practices now. The good news is that they're responding well to the therapy. The changes in neurological functioning are remarkable with each day of treatment.

It is imperative that we stop giving heavy metals to children through vaccines when their bodies can least handle such an insult. We're seeing the link on a daily basis. The children are recovering steadily but the treatment is expensive and tedious. It would make more sense for us to eliminate the cause of the problem by deleting thimerosal from the vaccines now and by withdrawing current lots containing thimerosal from pediatric offices and health units. We also need to channel funds for research into the clinical trials needed to explore the link between mercury and developmental problems in children.

I brought some slides of just a couple of the children before and after treatment. It's kind of hard to see. The child

on the left has a blank stare, he has no speech. On the right he's smiling. He is now speaking. He's speaking in sentences. And this is following the nutritional treatment and the removal of metals.

Second slide. This is a child before treatment on the left: bleary-eyed, no speech at all, irritable, self-injurious, hands flapping. And on the right, I think you can see the change. And this child had a lot of metal. He had lead, he had mercury, he had aluminum. We're finding a lot of aluminum in these children. I think aluminum is going to end up being as big a problem as mercury if we keep putting it into the vaccines.

On the left, again no speech, blank eyes, blank stare, little frowning look; and on the right, I think you can see the mother's smile as well as you can see the child's smile. This was a twin, by the way. And she now has two speaking twins.

One more? OK. I think we're back to the start. Thank you.

[The prepared statement of Ms. Cave follows:]

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Mr. Burton. Thank you, Dr. Cave. Sounds like you're doing real good work down there. We'll check all the references that you used as well as your statement.

Doctor.

Mr. Aposhian. May I have the first slide, please?

Mr. Chairman, members of the committee, I have been asked to review mercury toxicity with you for a short period of 5 minutes. And with your permission, I'll dispense with the usual introductory remarks and get to the point.

May I have the next slide, please? The next slide, please.

The next slide will tell you about the different forms of mercury. We have elemental mercury, we have organic mercury, and we have mercuric mercury that we usually call inorganic. The elemental mercury you're probably familiar with as far as the silvery liquid that most children play with at some time in their lives. It is dangerous because it emits mercury vapor at room temperature or when it's in our mouth, as we will talk about in a moment. It's a very dangerous poison.

The organic mercury, methylmercury, comes from fish--the fish that you eat, certain kinds of fish. And thimerosal comes from the vaccines and other medical preparations. A recent FDA list pointed out there are 217 medical preparations listed with the FDA that contain organic mercurials; 217.

And finally, the slide mentions mercuric mercury that we'll speak about in a moment. As far as the sources and forms of brain mercury, this is shown in the next slide. You may not be able to see that, but on the left is a tooth, underneath is thimerosal, and over to the right hand side is a fish. The greatest exposure to mercury of the American population comes from the amalgams in their mouths. This has been clearly established. The mercury amalgams in your mouth, the so-called silver fillings, contain 48 to 50 percent of elemental mercury. These fillings continuously emit mercury vapor which will go to the brain and is converted to mercuric mercury, as is pointed out there.

On the far right-hand side, you'll see a picture of a fish. 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. And then on the bottom left-hand side, you'll see thimerosal, which again will be taken up by the brain and quickly converted to mercuric mercury.

Now, one of the findings of the recent National Academy of

Sciences report is that you really cannot consider any form of mercury alone. Let me just read you the one statement from the prepublication form of this report. It says: Prospective data on all sources of mercury exposure such as vaccines and dental amalgams and dietary intakes of methylmercury are essential to understanding the effects of environmental mercury exposure on any outcomes.

May I have the next slide, please? This will show you the target organs of various forms of mercury: mercury vapor of the brain, methylmercury of the brain, thimerosal of the brain, and mercuric mercury if it's taken up from outside of the body, the kidney. What's important to find out is all three of the first three forms are neurotoxic, neurotoxic in particular in the brain. By neurotoxic, we mean it will damage nerves and it will damage brain tissues.

The next slide, please. Neurotoxicity of mercury. I think the first statement is that the mercury stays in the brain. I can't quite see the slide myself from here. The mercury remains in the brain. My colleague, Mary Aposhian, has looked for the last 10 years for compounds that would bring mercury out of the brain. There is no such therapeutic agent that we know of. Most of the research in this country, as far as getting mercury out of the brain, is supported by the family of a former Vice President of the United States. It is believed that that Vice President died of mercury toxicity. That family has done more for studying basic mercury toxicity than probably any other foundation or government in our country.

The most sensitive organs: brain of fetus, brain of children, brain of adults. Again, the brain of the fetus is uniquely susceptible to mercury toxicity, as are the brains of children and the brains of adults. We're mature. What I would like you to remember is a child is not a small adult. The metabolism, the biology of the child, is quite different. The child has developing organs. The fetus has developing organs. And we know that mercury will stunt certain metabolic reactions involved in development.

The next slide, please. The final slide points out that which damages the brain. Again, the recent National Academy of Science report really introduced something quite novel as far as the thinking of the scientific community. And that is, as you look at all this--these slides, the central compound, the central form of mercury here is mercuric mercury. Mercuric mercury vapor converts into mercuric mercury, thimerosal converts to mercuric mercury, as does methylmercury. So this is probably the culprit, mercuric mercury. The report points out that we must consider methylmercury and mercuric mercury as well as thimerosal in order to understand the neurotoxicity of mercury.

Let me just say as a final statement that there is no need to have thimerosal in a vaccine. There are other agents that

can be used that are known to be safe.
Thank you for your attention.
Mr. Burton. Thank you, Doctor.
[The prepared statement of Mr. Aposhian follows:]
[GRAPHIC] [TIFF OMITTED] T2722.180

[GRAPHIC] [TIFF OMITTED] T2722.181

[GRAPHIC] [TIFF OMITTED] T2722.182

[GRAPHIC] [TIFF OMITTED] T2722.183

[GRAPHIC] [TIFF OMITTED] T2722.184

[GRAPHIC] [TIFF OMITTED] T2722.185

Mr. Burton. Dr. Humiston.
Dr. Humiston. Mr. Chairman and members of the committee, I applaud your efforts to bring parents, scientists, and policymakers together around the issue of autism. I am grateful for the opportunity to share my perspective as a parent, pediatrician, and public health researcher.
Last week, my baby Quinn demonstrated developmental skills that thrilled my husband and me. He pulled his father's hand toward a pile of rocks, used his other hand to point toward a puddle, and said, ``dad ock bla-bla,'' which meant, ``Daddy, throw this rock in the water.'' Unfortunately, Quinny is 7\1/2\ years old.
The worst day of my life was not the day the developmental pediatrician told me, almost apologetically, that my son was autistic. The worst day came later when the specialists told me that Quinn's progress was minimal after a year and a half of intense therapy, and that this made his prognosis grave. My family's response was very typical. We reached out and embraced a succession of therapies, each touted as a lifesaver. We heard that gluten allergy was the cause, and we changed Quinn's diet. Later we tried, for example, a phenol-free diet, megavitamins, anti-yeast medications, and cranio-sacral massage. Each therapy was supposed to get at the cause of Quinn's autism. Each therapy was expensive, and each for my son was a failure.
You may wonder what would make a reasonable person pursue such an array of untested and unproven approaches. Well, I am a desperate mother. I am desperate to help my son quickly during his early years when we'd expect rapid brain development. I am desperate because the science lags so far behind my son's needs. My family has been blown by every wind, every theory, to explain this pervasive developmental disorder, and we are tired. We are physically tired, financially tired, emotionally tired. So I am here today to encourage you to nurture the science that will help, if not my son, then at least my little

girl's future children.

Funding, of course, is a very good way to show support. I appreciate the significant increases in NIH funding for autism research. I am grateful for CDC's investment in vaccine research. Generous and sustained funding for short-term and long-term studies is the most powerful help the government can offer my family. Please do more.

I have also a list of please don'ts. Please don't overemphasize the investigation of some factors because they seem so risky, while ignoring other potentially important factors. We know, for example, that because vaccination is unpleasantly memorable, we tend to perceive it as riskier than, say, exposure to mercury in fish, which is not very memorable. Please don't exhaust your investigation on the mercury in vaccines and ignore the subtler and potentially more significant sources of neurotoxicants. Please don't ignore factors because they are complex or seemingly unalterable. I would prefer answers that are correct to answers that are quick and expedient.

Please don't imagine that shaking public confidence in vaccines won't lead to the death of some children. We know that previous pronouncements on thimerosal led some U.S. birthing centers to discontinue the use of hepatitis B vaccine and this in turn led to cases of chronic infection in newborns. These babies have had about a 9 percent chance of going on to die of liver cancer or cirrhosis, neither of which are enviable deaths.

We know that in the UK and Japan, pertussis vaccines scares led to decreases in vaccination and consequent increases in whooping cough, a disease that wracks a baby's body. We cannot forget that just 10 years ago, we saw a measles epidemic in this country that killed 123 children. That's not theoretical. We can count the death certificates. Though Hib disease essentially vanished once the vaccine was out, I will never forget it--fathers carrying limp, lethargic toddlers into the emergency department. Your actions have consequences. Please don't forget.

Please don't miss the opportunity to study the results of removing thimerosal from vaccines. As the manufacturers change to mercury-free formulations, I hope someone is doing a definitive study to see if autism rates plummet.

And finally, please don't ever frame this as a battle of parents against scientists. Generating hypotheses is a first step to finding causes and cures, and this committee has heard many conflicting hypotheses. The next step, testing these hypotheses, is painfully slow and costly, but I hope you will commit yourself to this scientific process. I believe it holds the greatest hope for my son and the many children like him. Thank you.

[The prepared statement of Dr. Humiston follows:]

[GRAPHIC] [TIFF OMITTED] T2722.186

[GRAPHIC] [TIFF OMITTED] T2722.187

[GRAPHIC] [TIFF OMITTED] T2722.188

Mr. Burton. Thank you for your comments. I'd just like to say at the outset that nothing that this committee has ever said would indicate, at least from the Chair, that we are opposed to vaccines. We are very much in favor of vaccinations. What we are concerned about is whether or not the contents of those vaccinations are safe and whether or not they're being properly followed and looked into by the agencies of jurisdiction, the FDA and the CDC. And we're also very concerned about whether or not there are conflicts of interest between the people on the advisory panels that are making recommendations to FDA and the CDC and the pharmaceutical manufacturers.

I'd like to ask you, Dr.--how do you pronounce your name--Aposhian. They started using thimerosal in 1930.

Mr. Aposhian. About that time.

Mr. Burton. I was just wondering, I know this is pure speculation, we have a tremendous increase in Alzheimer's and, because of the neurological problems that many people are seeing from thimerosal being used in the vaccinations, where this could be a contributing factor in the Alzheimer's increase.

Mr. Aposhian. There are some scientific papers that speculate about that. But at the present time, it cannot be said that Alzheimer's disease has been caused by mercury.

Mr. Burton. You think that, along with the aluminum and formaldehyde and other things that have been in vaccinations for a long time, should be looked into by the health agencies as possible contributing factors?

Mr. Aposhian. 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.

I think the Academy of Pediatrics has also quite firmly stated there is no need of thimerosal in vaccines.

Mr. Burton. Why--and this is a question for any of you--why was thimerosal put in vaccines in the first place? Does anybody know? Why did they put that in there? It was supposed to be a preservative. As I read the statements that you made today, it was supposed to be something that kept bacteria out of the vaccinations, out of the vaccines.

Mr. Aposhian. That's correct, sir.

Mr. Burton. And yet the information that I see here is that it really doesn't.

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

Mr. Burton. Dr. Enayati said in his statement in 1982, 18 years ago--and it's in the Federal Register--an FDA panel concluded that thimerosal is toxic, causes cell damage, can cause allergic reactions, and is not effective in killing bacteria or halting their replication.

That was 18 years ago. Why, if we knew that 18 years ago, did they continue to let that be put into these vaccines? Does anybody know the answer to that?

Mr. Aposhian. I think that's what you should ask the FDA representative.

Mr. Burton. Oh, I plan to. Now, the hepatitis B vaccine has thimerosal in it, and that's given to infants. As I understand it, infants don't really have a great deal of exposure to hepatitis B because it's--you can contract it through blood, through sex, or through, I guess, needles. Unless the parent has it. So why are we giving hepatitis B vaccines to infants? Does anybody know that? Unless the parent has it. Would you like to comment, Dr. Humiston? I see you started to move forward.

Dr. Cave. One of the main areas that we need it is when we have a mother who tests positive for hepatitis B.

Mr. Burton. I understand that. Aside from that, why the need to have it?

Dr. Cave. I agree with you. I don't find the need for it on the day of birth in children who don't have mothers who are positive.

Mr. Burton. OK. Doctor.

Dr. Humiston. The day of birth is different than some time during infancy. We know that in 1990, before universal vaccination with hepatitis B, that by age 10 there were 19,000 children in the United States that had contracted hepatitis B, even though their mothers were hepatitis B surface antigen negative. So they have--it's possible to have exposure to hepatitis B in ways other than perinatally. It's a small number overall. You know, if you look at the entire population of the United States less than 10 years of age, but 19,000--and, of course, when you are exposed to hepatitis B during your early life, you're more likely to go on and be a chronic carrier.

Mr. Burton. Have there been studies--and I'll yield to Danny--or, excuse me, to Mr. Davis in just a minute--but have there been studies showing the various ages at which children contract hepatitis B? Because it seems to me inconceivable before the age of 6, or 5, that children would really have much exposure to it. I mean, you said below age 10. How about the various age increments? You don't know?

Dr. Humiston. I don't know how it's divided out.

Mr. Burton. Could we check that out and find out what ages we start to see----

Dr. Cave. It's very rare if the mother is not hepatitis B-positive that an infant shows hepatitis B.

Mr. Burton. Up until what age, you say 5 or 6?

Dr. Cave. I think it's far beyond that.

Mr. Burton. Mr. Davis, you're recognized.

Mr. Davis of Illinois. Thank you very much, Mr. Chairman. I missed a part of the testimony from some of the witnesses, but that which I heard I found to be quite intriguing.

Dr. Aposhian, how long has the scientific community been aware of the alternatives to the use of mercury?

Mr. Aposhian. Sir, it depends how you define the scientific community. The academic community, I would say since 1955, has been concerned about the use of mercurials in medicine. The use of mercurials in medicine has had a long history. It used to be used as a treatment of syphilis. It used to be used for the treatment of many, many infectious diseases before we had antibiotics.

Mr. Davis of Illinois. I know that there's often resistance to change, even when something comes along that we can assume or we might even know to perhaps be more effective, more efficient, less dangerous, less costly or whatever. Can you think of any reasons why, if we are aware of the alternatives and if they are safer, why we have not moved assiduously in that direction?

Mr. Aposhian. Congressman Davis, there are three groups involved here, I think. We have an academic group, we have a government group, and we have an industrial or pharmaceutical group. Because of our society, most industrial groups, most pharmaceutical companies, are very reluctant to change anything because of the tremendous cost of getting that change through the FDA. And the other concern by pharmaceutical companies is just how dangerous is dangerous? And that, I think, is where the greatest argument comes in and that's where the FDA should be acting as a judge.

Dr. Humiston. I don't mean to be cynical about the pharmaceutical companies, but I don't think that they're going to take to moving toward thimerosal-free vaccines, I don't think they will be taking financial losses, because one of the things that happens is we won't be able to have vaccines in multidose vials. Multidose vials are much less expensive than

single-dose vials. So going to all single-dose vials will actually bring more profits to the pharmaceutical companies. And I don't--you know, I am not saying that that's their motive, I'm simply saying that they have nothing to lose.

Mr. Davis of Illinois. But it is in fact, I guess, sometimes difficult to feel that certain kinds of self-interests don't creep into the ultimacy of decisionmaking. And I guess that's where it takes----

Dr. Humiston. Again I don't mean to be cynical, but I think that the pharmaceutical companies have moved quite quickly, and partly, probably, because they don't have a great deal to lose.

Mr. Davis of Illinois. I guess what you're saying is no matter how you cut it, you can't get around the whole concept of ultimate involvement of all of us in arriving at public policy, and that if there is enough action and activity, then one part balances out or one side balances out the other and we arrive at the public interest.

I assume--I also listened to your testimony in terms of your own personal experience, and I was obviously moved, as anybody would be by it. Given your own training as well as the experiences, do you feel or would you have reason to believe that there might be any connection between immunization and autism?

Dr. Humiston. What Mr. Davis is referring to is that I was formerly with the National Immunization Program. Now I'm a pediatrician at the University of Rochester. I have to say that I try very hard to keep an open mind scientifically, and I think that that is the most important stance that we can take now. What I am advocating for is good science. And again, I was present during the ACIP meeting, the Advisory Committee on Immunization Practices. I was happy to see that the science is going forward quickly. I hope that the science can go forward quickly. We've--this committee has heard other theories as well. And I hope that we come to better understanding--also the genetics. I mean, there's so many factors here. I think that immunization is just a tiny part, but it sticks in our mind because it's so memorable.

Mr. Davis of Illinois. I thank you very much. Plus, Mr. Chairman, I must say I was pleased to hear your comment in terms of the position of the committee relative to the fact that there are no conclusions having been determined or reached, but what the committee is really hoping to do is to try and probe as deeply, as widely as it can, to try and find out as much as we possibly can about the issue. And I appreciate that comment that you made.

Mr. Burton. Thank you, Mr. Davis. Ms. Chenoweth.

Mrs. Chenoweth-Hage. Thank you, Mr. Chairman. As a grandparent of an autistic child, I've been fascinated with your testimony. I want to thank all of you for the method of your delivery. I know it's difficult. In the last hearing I had

difficulty even giving my own opening statement, and I'm not a patient, I'm a grandparent. But they're precious, precious little children. And my heart goes out to you. But also I thank you very much for your courage in being here today.

I wanted to begin my questioning with a question to Dr. Cave. I've been fascinated with your treatment procedure. And your procedure involves nutritional repletion of cellular chemistry and normalization of gastrointestinal bacterial balance, dietary problems, restoration of liver detoxification systems. What do you think about chelation also as a treatment? Have you considered that?

[The prepared statement of Hon. Helen Chenoweth-Hage follows:]

[GRAPHIC] [TIFF OMITTED] T2722.004

Dr. Cave. We are using oral chelation with a sustained release DMSA. The DMSA is a drug approved by the FDA for lead intoxication in children. We've used a sustained release form which has given us a totally different picture. We're pulling on a 24-hour basis now, and we're seeing the metal come out. And the children are changing in the first week that we start treating.

We have another layer of treatment in which we add alphallipoic acid which does take it to the central nervous system. When we start pulling it from the central nervous system, we get sentences and speech in children who have not spoken. It's been phenomenal.

Mrs. Chenoweth-Hage. That was going to be my next question. Can you pull it from the central nervous system?

Dr. Cave. Yes, we can.

Mrs. Chenoweth-Hage. Is chelation the best method of doing that, have you found?

Dr. Cave. It's the only method. You have to pull the metal with something that will hook on to the metal. And these have--sulf-hydryl groups, which will hook on to mercury.

Mrs. Chenoweth-Hage. Dr. Cave, I was also interested in knowing what your thoughts were about why some children are affected this way while others perhaps have a physiologic system that's developed to the point that the toxins don't reside in the brain. What happens there?

Dr. Cave. We are measuring the detoxification systems in the children's livers and we're finding variability. In the children that we're seeing that are developmentally delayed, there is very little--they're not able to detoxify very well. There's very little ability. The normal child has a better system. And we can measure that. There are some genetic factors. We have some ideas about that, too. And we're looking at several lipoproteins; that's very early right now. But it can be explained--it can't be fully explained, but it can be partially explained at this point, and there are genetic

factors for sure.

Mrs. Chenoweth-Hage. I see. Mrs. Birt, I found it very interesting in your testimony that you testified to the fact that there were some questions back in 1988 and then finally--about thimerosal--and then finally in 1997 they issued a final rule, the FDA did, that disallowed thimerosal or indicated that products containing thimerosal were neither effective and may not be safe for over-the-counter----

Ms. Birt. Correct.

Mrs. Chenoweth-Hage [continuing]. Treatments. And also in your testimony, you talked--you testified to the fact that the FDA asked the vaccine companies to give them information on this. And could you elaborate more on that? I found that section of your testimony fascinating.

Ms. Birt. I think the problem is that the manufacturers aren't held accountable, so nobody is responsible in the ultimate product. It's like a big circle. It goes from the manufacturer to the FDA to the CDC to the public. But nowhere in there is anybody legally or financially accountable if there's a problem. And the way our society is geared is that profitability is the highest thing.

And I think that in order for the vaccine manufacturers to make the product thimerosal-free, they had to change their methods of production. And this is only speculation--they may have known there was a problem earlier and just didn't want to say anything. Nobody knows that for sure.

But I think this whole process of finding out the truth will lead us to the truth eventually. But I think the fundamental problem is that we don't have accountability in the system, so the people who have the most to lose really aren't protected, which is basically the job of the government, to protect people who are at risk. And that has not been done in this process.

Mrs. Chenoweth-Hage. Mr. Chairman, I see my time is up. I just wish I had about 3 hours to engage with these witnesses. My congratulations to you and your staff for the outstanding information we've received.

Mr. Burton. Thank you, Congresswoman Chenoweth. We'll have one more round, if you would like to ask some more. Mr. Gilman, Chairman Gilman.

Mr. Gilman. Thank you, Mr. Chairman. I regret that I was tied up on the floor with legislation that we're involved in. And I want to thank you, Mr. Chairman and the committee, for conducting this series of hearings on vaccine safety, and I want to thank our panelists for coming to voice their concerns and to give us their information. As we examine the various additives that are present in vaccines, it's extremely important that we note the role that they play and what, if any, other compounds may be available to fulfill their roles as appropriate substitutes.

Today's hearing focuses on thimerosal, the preservative that contains small amounts of mercury. And that's the first that I've been made aware of how mercury is part of these vaccine substances and what they can do to our youngsters. I've been informed that these preservatives are used to inhibit the growth of bacteria fungus that might contaminate a multidose vial of vaccine where a physician reenters the same vial several times to inoculate several children. Apparently, without preservatives, there is a risk that a vial of vaccine could become contaminated and a physician could inadvertently inject a living organism into a child. Since 1968, I've been informed preservatives have been required by law in multidose vials.

Thimerosal has been used for more than 60 years in a variety of vaccines. The fact that it's been used that long, of course, does not attest to its safety. It's been effective as a preservative in very low doses and highly stable--it is highly stable throughout the shelf life of that vaccine, and works across a broad spectrum of microbial agents. As such, it's been considered the best preservative that was available. And while its value in keeping vaccines free of contamination has been unchallenged, serious questions have now arisen as to the possible side effects in infants from exposure to mercury, the mercury that's available in thimerosal.

It's my understanding that aside from 60 years experience in the field, there has been little directly applicable data on this concern until very recently. CDC has now looked at the level of exposure to mercury of immunized infants in three HMOs versus the appearance of symptoms such as renal failure, a hallmark of mercury poisoning, and various neurological deficits, including autism. This data has indicated what there is no association between the amount of mercury an infant is exposed to from vaccines in the development of any neurologic or renal problem. And that's why it's so important we're examining this issue today.

And another type of additive to vaccines is the adjuvant. Adjuvants in vaccines help boost the child's immune response to bacteria or virus that is a poor stimulant of its own accord. Adjuvants therefore provide the ability to decrease the amount of bacteria or virus needed in a vaccine and/or to decrease the number of doses needed in an immunization series. Aluminum salts, I've been informed, are the only licensed adjuvant in our Nation. They've been safely used in vaccines for a number of years.

Today, taking testimony from our panelists who are before us now regarding adjuvants and additives in vaccines and alleged associations between these additives and various illnesses, is extremely important to us. We must be vigilant in matters of vaccine safety. We've just gone through extensive hearings on anthrax and trying to make certain that any

utilization of anthrax by the military is not going to affect their well-being. At the same time, it's important we focus our attention on scientific evidence. We must be careful we don't jump to conclusions based on anecdotes and speculations, but that's why it's good you're here to present specific cases to us. We must not lose sight of the fact that vaccines have saved millions of people from debilitating and deadly diseases, but we don't want the vaccine itself to cause side effects that are just as deadly.

The effect of needlessly scaring parents away from immunizing their children is a real concern, and that's why we must tread very carefully as we go through this maze of trying to find out just what has affected our children by the substances that are present in the vaccine.

So again I thank Mr. Chairman, thank you for being here, and I want to thank our panelists who are here today to give us the benefit of their thinking.

[The prepared statement of Hon. Benjamin A. Gilman follows:]

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[GRAPHIC] [TIFF OMITTED] T2722.190

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[GRAPHIC] [TIFF OMITTED] T2722.192

Mr. Burton. Thank you, Chairman Gilman.

Ms. Ros-Lehtinen.

Ms. Ros-Lehtinen. Thank you so much, Mr. Burton, for this hearing and for your constant leadership on this terrible issue of autism. I don't have autistic children, but I have a very good friend who has, as you may remember, because I've spoken about them before in this committee, two autistic children. Because of them, these hearings are of great importance to me personally and to many constituents in my district. Due to my association with her and her family I have come to know so much about autism and how many families are affected and indeed devastated by this problem.

I'm always delighted to go back home with all of your material--and I want to commend your staff for preparing such fine materials for us at each hearing--how happy the parents of autistic children are with the literature, and then when I have the meeting with the so-called experts, how alarmed they are with the papers.

I find that there's a great disconnect in the scientific community about what parents have come to know and understand through their own research and through their own set of circumstance. And I hope that both sides come closer together because I know that I will have that same reaction when I come

back to Miami this weekend; that parents will be very happy with this information and the experts won't.

And we do have some very good centers for autism in south Florida. I don't know if there's a geographical connection, but certainly south Florida has been very impacted by the effects of autism. We have the Card Center at the University of Miami, Center for Autism and Related Disabilities, a great center, and the Dan Marino Institute in Broward County. So my community has been blessed with good information. Yet I find that scientists and many within the medical community, the people with whom I deal with, they are not satisfied with the information that we give them. I find that disturbing, because I would think that these experts would be happy to see others doing research and promising information.

I wanted to followup with a view of the great information that was given to us today. You were saying that in one of the publications, I'm not sure which one, that mercury levels can be detected in urine, hair, and blood.

I'm interested in knowing how many autistic children you believe have been tested for mercury levels? As I said. I have two children of my own, they're 14 and 13 now. I don't recall whether that was a normal set of tests, but whatever it was, it was at a normal range. Is testing for mercury something that is usually done by pediatricians? Do you think that that is something that they should be looking at? Would it involve a more intrusive examination than is already given to children? Are you advocating that parents should have their children tested for mercury levels?

That's my first question. Let me just throw them all out and whoever wants to, answer. Also, chelation--is that how you say it? Chelation methods, do they come in pill form or a shot or liquid that the child swallows, and how many children have undergone this chelation therapy or method? Finally, what was it formulated originally to treat? I'm interested in understanding more about that therapy.

Thank you, whoever would like to answer those questions about mercury testing and chelation therapy and address the disconnect between parents and so-called medical authorities.

Dr. Cave. Mercury is not something that is usually tested, and we were not really taught to test hair samples or to give chelation doses and test urine samples. If you look at some of the material I've provided in the handout on the hair samples that I have, you cannot find mercury in these children. We find mercury in the hair of children who are receiving the vaccines, but these children are beyond the first dose of vaccine. So the mercury has moved beyond this level. It stays in hair only a certain period of time. It doesn't actually stay in blood.

But when we give the dose of a chelator, it brings it into blood and then into the urine, and then we can measure it in urine. This is something that we started doing 4 or 5 years ago

when we started treating the children. And I noticed that we were finding metals in the small children and in children who were receiving the--well, a vaccine like hepatitis B later on in life. I found it in the hair sample of a young man who had the hepatitis B series in college. He was left with severe depression, and his brother was left with seizure disorder. And I found it in the hair of both of these young men.

But you have to be able to look for something. You have to know how to look for it in order to find it. When we were using the drug as it's given in the regular drugstore, without technology-sustained release, we were not even finding very much in the urine. Now that we're using a sustained release, we're bringing it out into the urine.

If you notice on the handout that I have there, it's very high in the urine as submitted, even though it was negative in the hair. In the hair, we look for aluminum and we find aluminum and we find antimony in the hair. And we are treating that--we're not treating that with the same medication. We're using an over-the-counter to treat the aluminum and it's working well, with no toxicity that we can see.

Mr. Burton. Anyone want to comment briefly on the chelation she was talking about, the various forms of chelation?

Mr. Aposhian. Let me say that our laboratory for the last 18 years has been the primary laboratory dealing with the use of DMSA, the development of DMSA, the approval of DMSA by the FDA. It's a chelating agent. That means it competes with other materials in the body for a particular metal or group of metals, makes that metal more soluble, and therefore excretes it.

The controversy has always been, just because you get rid of a metal does not necessarily mean you improve the clinical position of--the clinical condition of the patient. This is always controversial.

Chelation therapy is certainly not accepted by the vast majority of established medicine. It is accepted quite greatly by alternative medicine people. I think it's just a subject of controversy at the present time. There is no question at all that it helps children that have been exposed to lead. It gets rid of the lead and decreases their chances of getting any worse.

The National Institutes of Environmental Health Sciences at the present time have a $35 million program to see whether giving DMSA to children who have been adversely affected by lead will improve their condition. As yet there is no solid information that their condition has been improved, but all the information is not present yet.

Chelation therapy has always been a method of getting rid of toxic metals. There are various chelating agents that can be given by mouth, like DMSA. There are other ones that can be given by mouth or injection. And there are also very toxic

ones. I also want to point out, the problem is that you can't take an autistic child, give him any kind of an agent, and then test his brain to see whether that particular toxic metal has been removed. We can do that in animal studies; we cannot do it in human studies, of course.

Does that answer your question, Congresswoman?

Ms. Ros-Lehtinen. Yes.

Dr. Cave. But clinically they're improving. We're bringing them back 80 percent, 90 percent, in terms of social interaction with speech, with eye contact, and that's proof that the central nervous system is functioning at a higher level. We can't go in and biopsy the brain, but we can certainly look at the child.

Mr. Burton. Mr. Cummings, you have questions?

Well, we have a number of questions I would like to submit for the record to each one of you. You have been very, very informative in your statements and I really appreciate that. I would like to ask you a whole host of questions, but the hour is getting late, and I know we're going to have votes on the floor and we're going to be down there for awhile. So would you all be willing to answer questions for the record that we submit to you? We'll put those in the record as soon as we get them.

I want to thank you all for being here. I hope you can stay around to hear the testimony from the agencies of the government. Thank you very much.

We will now have panel No. 2. Ms. E. Ramona Trovato, Director of the Office of Children's Health Protection, Environmental Protection Agency; Dr. William Egan, Acting Office Director, Office of Vaccine Research and Review, the Center for Biologics Evaluation and Research; Dr. Roger H. Bernier, Associate Director for Science at the National Immunization Program, Centers for Disease Control and Prevention; and Dr. Marie Bristol-Power, National Institute of Health and Human Development, the National Institute of Health.

Could I have you all stand so we could have you sworn, please?

[Witnesses sworn.]

Mr. Burton. Be seated. We'll start with Ms. Travato. Did I pronounce your name right?

Ms. Trovato. You sure did. May I begin?

Mr. Burton. Yes.

STATEMENTS OF E. RAMONA TROVATO, DIRECTOR, OFFICE OF CHILDREN'S HEALTH PROTECTION, U.S. ENVIRONMENTAL PROTECTION AGENCY; DR. WILLIAM EGAN, ACTING OFFICE DIRECTOR, OFFICE OF VACCINE RESEARCH AND REVIEW, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH [CBER], FDA; DR. ROGER H. BERNIER, ASSOCIATE DIRECTOR FOR SCIENCE, NATIONAL IMMUNIZATION PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND DR. MARIE BRISTOL-POWER, NATIONAL

INSTITUTE OF HEALTH AND HUMAN DEVELOPMENT, NATIONAL INSTITUTE OF HEALTH

Ms. Trovato. Good afternoon. I am Ramona Trovato, Director of the Office of Children's Health Protection at the U.S. Environmental Protection Agency. I appreciate the opportunity to appear before you today to talk about the problem of mercury, particularly as it affects fetuses and very young children.

Mr. Chairman, while I appreciate the primary interest of this committee today is the role that mercury may play in causing health effects in children when used as preservatives in vaccines, EPA does not have regulatory authority to address vaccines and their preservatives. EPA does have authority to address releases of mercury to our air, land, and water, and is actively addressing such releases through both regulatory and nonregulatory actions.

Mercury is a naturally occurring metal which persists in the environment and has long been known to have toxic effects on the nervous systems of humans and wildlife. The most significant releases of mercury to the environment in the United States are man-made emissions to the atmosphere from combustion sources, including waste and fossil fuel combustion. Mercury from such emissions as well as naturally occurring mercury and mercury from past uses, such as in fungicides on crops, is deposited into the soil and water. Concentrations of mercury in air and water are usually low and of little direct health concern. Once mercury enters water, however, it may be converted to methylmercury which can then accumulate in fish and marine animal tissue. Methylmercury levels in fish at the top of the food chain are, an average, 7 million times higher than the concentrations of dissolved methylmercury found in the surrounding waters. As a result, human exposure to methylmercury occurs primarily through eating contaminated fish. The amount of methylmercury that people are exposed to depends on the species of fish consumed, the concentration of methylmercury in the fish, and how much and how often fish are consumed.

While most U.S. consumers need not be concerned about their exposure to methylmercury, some exposures may be of concern. Those who frequently consume large amounts of fish or who eat fish from water contaminated with mercury may be more highly exposed. Populations such as pregnant women and their fetuses may be at risk if they consume large amounts of contaminated fish or fish with relatively high levels of methylmercury.

Because the developing fetus is the most sensitive to the effects of methylmercury, women of childbearing age may be at particular risk. These women should pay attention to the fish advisories issued by their States that suggest limiting the consumption of fish containing higher levels of methylmercury.

Methylmercury is toxic to adults, children, and the fetus but prenatal and postnatal exposure can adversely affect the nervous system. Dietary methylmercury is almost completely absorbed into the blood and distributed to all tissues, including the brain. It also readily passes through the placenta to the fetus and fetal brain. Effects on the fetal nervous system occur at lower exposures than do effects on the adult nervous system. Mercury interferes with the development and function of the central nervous system, with health consequences ranging from subtle to severe, depending on the amount and timing of exposure.

In 1995, EPA published a reference dose of 0.1 micrograms per kilogram of body weight per day, based on the effects seen in children following methylmercury consumption by the mother during pregnancy.

Just last week, the National Academy of Sciences released their findings on the health effects of methylmercury based on its evaluation of recent epidemiological studies. The NAS affirmed EPA's reference dose is a scientifically justifiable level for public health protection for the most sensitive subpopulation--mothers and their unborn fetuses. The NAS has also indicated that the majority of U.S. population has low risk of adverse effects from current methylmercury exposures. However, the NAS also estimated that more than 60,000 children are born each year at risk of adverse neurodevelopmental effects such as overall cognitive ability, language development, spatial perceptual skills, and motor skills due to in utero methylmercury exposure.

EPA is taking action to reduce mercury in the environment. EPA has issued standards that limit air emissions of mercury. The agency has developed regulations for boilers, process heaters, solid waste combustors and chlor-alkali plants. The remaining largest identified source of mercury emissions are coal-fired utility boilers.

In summary, it is clear that women of childbearing age should take steps to minimize their exposure to methylmercury from eating contaminated fish. People who regularly eat fish should be aware of any State fish advisories. Because of the beneficial effects of fish consumption, the long-term goal needs to be reduction of the concentration of methylmercury in fish rather than the replacement of fish in the diet by other foods. EPA will continue to take steps to further improve public health, especially to protect children and fetuses, our most susceptible population.

Thank you very much, and I'll be happy to answer questions.

Mr. Burton. Thank you, Ms. Trovato.

[The prepared statement of Ms. Trovato follows:]

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[GRAPHIC] [TIFF OMITTED] T2722.194

[GRAPHIC] [TIFF OMITTED] T2722.195

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Mr. Burton. Dr. Egan.

Mr. Egan. Thank you, Mr. Chairman and members of the committee. I am William Egan, the Acting Director for FDA's Office of Vaccine Research and Review. I appreciate this opportunity to discuss additives in childhood vaccines. I will focus my current remarks on thimerosal. I ask that my full written statement be entered into the record.

Mr. Burton. Without objection, so ordered.

Mr. Egan. Let me say that I am sympathetic to the concerns of the parents expressed by the previous panel. FDA will continue to work with parents and other public health agencies to foster the research and data necessary to determine the causes, treatment and hopefully prevention of autism.

Vaccines licensed by FDA have been protecting children in the United States from deadly infections for well over 50 years and have been credited for saving more lives and preventing more illnesses than any other medical treatment. The risk of childhood diseases from failure to vaccinate far outweighs exposure to thimerosal in vaccines. Prior to licensure each vaccine undergoes a thorough review, and FDA considers all vaccines currently available to be both safe and effective.

Preservatives are added to vaccines to help minimize the consequences of inadvertent microbial contamination, and with certain exceptions the use of preservatives is required by regulation for all multidose formulations. Thimerosal is an effective preservative which has been used in vaccines and other products since the 1930's.

Requirements for preservatives in multidose vaccine formulations exist in many countries, not just in the United States, and have arisen as a result of tragic experience when bacterially contaminated vaccines were inadvertently administered to children. While the use of thimerosal does not absolutely eliminate the possibility of bacterial contamination, it markedly reduces its likelihood.

The FDA has been actively addressing the issue of thimerosal as a preservative in vaccines. A review of thimerosal by FDA and other Public Health Service agencies last year found no evidence of harm from its use in vaccines. Nevertheless, because of concerns about the potential exposure of infants to mercury from all sources, in July 1999 the Public Health Service, in concert with the American Academy of Pediatrics, urged vaccine manufacturers to reduce or eliminate thimerosal in vaccines. Much progress has been made to this end

over this past year.

Let me focus on the routine recommended immunizations given to children in their first 6 months of life. Last year at this time thimerosal was present in both of the licensed hepatitis B vaccines; in some, type B Haemophilus influenza, DTaP vaccine, and that is the vaccine for diptheria, tetanus and pertussis. Since last summer, thimerosal has been eliminated or reduced by more than 96 percent in the pediatric hepatitis B vaccines. With regard to the Haemophilus vaccines, Wyeth-Lederle has announced that they will be manufacturing only their thimerosal-free single-dose Haemophilus formulation. The other Haemophilus vaccines are already thimerosal-free as is a combination vaccine for Haemophilus and hepatitis B. All of the Haemophilus vaccines now being manufactured are thimerosal-free.

Let me now turn to the four DTaP vaccines. The DTaP vaccine from SmithKline Beecham does not contain thimerosal as a preservative, and both Wyeth-Lederle and Aventis Pasteur have announced that they will be submitting license supplements to FDA for thimerosal-reduced vaccines either this month, later this month, or in August. North American Vaccines has begun discussions with the agency on a thimerosal-free formulation. FDA is committed to the expedited review of these applications, and hopefully in early 2001 will have additional thimerosal-reduced DTaP vaccines.

Various Federal agencies, including FDA, the Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry, have been addressing the health risks of mercury, particularly methyl mercury. Thimerosal is a derivative of ethyl mercury, a closely related compound. It is important to note that there are no convincing data or evidence of any harm caused by the level of exposure that some children may have encountered following the existing immunization schedule. FDA's Office of Vaccines continues to urge manufacturers to develop new vaccines without thimerosal as a preservative and to remove or reduce thimerosal content in existing license vaccines.

Based in part on the substantial progress that has been made in the reduction of thimerosal for vaccines in this past year, the American Academy of Family Physicians, the American Academy of Pediatrics and the Public Health Service in consultation with its Advisory Committee on Immunization Practices recently reaffirmed its goal set last year to greatly reduce or remove thimerosal from vaccines as rapidly as possible. The group also stated that the risk of not vaccinating children with DTaP or the remaining HIB vaccine is believed to far outweigh the risk, if any, of the thimerosal in them.

Childhood vaccines have been a success story. Without vaccinations, children would be at a high risk of contracting

many serious preventable childhood diseases. It makes good sense to remove thimerosal from vaccines, and we are committed to that goal, and we are rapidly reaching that goal. While we are continuing to work to remove thimerosal from childhood vaccines, we need to do this safely.

Thank you for the opportunity to testify, and I will be glad to answer any questions.

[The prepared statement of Mr. Egan follows:]

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[GRAPHIC] [TIFF OMITTED] T2722.200

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Mr. Burton. We have some votes on the floor. How many votes are there? Three. We have three votes on the floor, and I really apologize, but we will probably have to run down there for those votes. Rather than have you start your testimony, Dr. Bernier, I think we will go ahead and recess now, and we will be back in 25 minutes. We stand in recess.

[Recess.]

Mr. Burton. If we can get the doors closed, please, and get everyone to return to the hearing. I apologize for being away for so long.

Dr. Bernier.

Dr. Bernier. Good afternoon, Mr. Chairman and members of the committee. I am Dr. Roger Bernier, Associate Director for Science of the National Immunization Program at the Centers in

Disease Control and Prevention.

In opening, I would like to emphasize that we in the National Immunization Program have deep empathy for all of the parents who have experienced the devastating disorder that is autism. It is impossible for us who have devoted their lives to the health and well-being of children not to be affected and touched by the personal stories and hardships that lie behind every child and family affected by autism.

Because of their enormous contributions to the health and well-being of children, vaccines have been frequently cited as one of the greatest public health achievements in the 20th century. The introduction and widespread use of vaccines have prevented millions of cases of childhood diseases and millions of premature deaths. Thanks to vaccines, there are few visible reminders of how serious and deadly vaccine-preventable diseases can be. The graphic impact of pertussis, another disease that was quite prevalent prior to the development and use of an effective vaccine, is detailed in my written testimony, and I would like if my written testimony can be part of the record.

As a world leader in the licensing of new vaccines, the United States places a high priority on safety and efficacy. The steps that we have taken with respect to thimerosal illustrate how much we value vaccine safety. The Public Health Service in collaboration with the American Academy of Pediatrics and the American Academy of Family Physicians set a goal for the removal or significant reduction of thimerosal as a preservative for all vaccines routinely administered to children in the first year of life. We took this action even though there was no scientific data showing such exposure caused any harm.

The risk of harm from thimerosal in vaccines remains largely theoretical. However, because it is feasible to produce vaccines that don't need thimerosal-based preservatives, we set the goal of moving as swiftly as possible to a thimerosal-preservative-free childhood immunization schedule while ensuring that children continue to receive the immunizations necessary to prevent disease. Since last June we have made significant progress toward achieving that goal. Six of the seven vaccines recommended for routine use do not contain thimerosal as a preservative, including the four vaccines that never did. By early 2001 we expect to have an adequate thimerosal-preservative-free vaccine supply for all of the routinely recommended childhood vaccines.

Since last July, the CDC has also undertaken a number of studies to understand the potential human health effects, if any, from exposure to thimerosal in vaccines. Using medical histories from the Vaccine Safety Datalink, investigators screened more than 100,000 children. They wanted to see if any statistical associations could be found between exposure to

ethyl mercury in thimerosal-containing vaccines and those conditions most likely to be related to this type of exposure, that is kidney or neurologic conditions found in the medical records. The researchers looked at 17 different diagnostic codes. They found five inconclusive correlations between thimerosal exposure and the codes for language delays, speech delays, attention deficit disorder, unspecified developmental delays and tics. Importantly, however, this screening study did not find any evidence of any increased association between these conditions among premature infants, nor did it find any associations between thimerosal exposure and autism.

An independent expert review of the screening study with the five inconclusive correlations was also undertaken. Twelve experts from outside the CDC evaluated the methods used and the results obtained. The consultants were unanimous in agreeing that the available evidence taken as a whole failed to meet the set of criteria necessary to establish that thimerosal caused the adverse health effects examined in these studies.

We did not stop here, however. Good science involves trying to reproduce findings. We thus arranged to analyze information from another managed care organization to see if the five inconclusive correlations in the initial screening study could be duplicated in a similar yet completely separate data base. The second study found no statistically significant positive correlation between speech, language and attention deficit disorders and exposure to mercury from thimerosal-containing vaccines. The direction of the findings is reassuring as it does not confirm the earlier observations.

To help us continue to address concerns about vaccine safety, CDC and NIH are contracting with the Institute of Medicine to establish a standing committee on vaccine safety. And I believe, Mr. Chairman, this is partly in response to the request that you had made with Congressman Waxman from the last hearing. There are steps very far along to move toward working with IOM to look at these vaccine safety concerns. This IOM committee will meet several times each year to assess any new evidence about possible adverse health effects from vaccines and to determine which vaccine safety concerns are a priority for further followup. The first issue we will seek to be taken up by the committee will be to review the available information about vaccines, including thimerosal and autism.

Mr. Chairman, I recognize that a call for more research can be discouraging for parents with autistic children who feel that they cannot wait another day before doing something about this illness, but information which is not the right information only sends parents and families down the wrong paths. The history of science is replete with hypotheses and touted cures that have not panned out. If we hope to accurately identify and effectively address the causes of diseases and disorders, we must continue to trust the tools that have served

us well, in this case the most rigorous scientific methods possible.

In summary, I would like to reiterate three key points from my testimony. First, the introduction and widespread use in the United States of vaccines against many childhood diseases have prevented hundreds of millions of cases of disease and millions of deaths.

Second, vaccine safety has been and is a high priority at the CDC and other Federal agencies. The vaccines produced and licensed in the United States meet the highest standards of safety and efficacy in the world.

Third, there is currently no persuasive scientific evidence which establishes a causal link between vaccines and autism or vaccines and any neurodevelopmental outcome. It is imperative that children continue to receive all of the recommended vaccines in the most timely manner possible. Doing so will assure the greatest possible level of protection from the still circulating viruses and bacteria that cause serious and potentially deadly childhood diseases.

Mr. Chairman, I would be happy to answer any further questions that you or the other Members may have.

Mr. Burton. Thank you.

[The prepared statement of Mr. Bernier follows:]

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Mr. Burton. Dr. Bristol-Power.

Ms. Bristol-Power. Mr. Chairman, members of the committee, I am Dr. Marie Bristol-Power, coordinator of the Network on the Neurobiology and Genetics of Autism at the National Institute of Child Health and Human Development at the NIH. I am pleased to address the committee on the topic on NIH autism research and vaccines.

Autism is a complex disease, and a variety of influences, genetic, infectious, immunological, metabolic and possibly environmental, have been implicated as causes or triggers for autism. We believe that no single cause can account for all cases of autism, nor that any one treatment or cure will prevent or treat effectively all of its manifestations. Autism might be better understood as a class of disorders. Solving the puzzle of autism will be like peeling an onion, one layer at a time.

Current consensus is that autism probably involves multiple genes interacting in some complex way that makes individuals susceptible to autism or autism spectrum disorders. The scientific challenge is to identify both the genetic basis underlying the disorder and the environmental influences that might precipitate autism in a genetically susceptible individual.

Autism has two modes of presentation: One, the symptoms are apparent from birth. In the second the child apparently develops normally and then loses functional speech and socialization somewhere between 18 and 24 months of age. At this time there is no proven explanation for why children who develop normally lose speech and communication or speech and socialization. However, like the overall etiology of autism, there is likely to be a variety of causes for autistic regression.

Recent reports both in the literature and testimony from this committee have raised the possibility of a link between autism and vaccinations, particularly the MMR vaccine, and between autism and vaccine additives. Since it is clear that vaccines are safe and effective for the vast majority of children, such reports raise the question of whether or not some children may suffer adverse events from vaccines which are helpful to the vast majority of children who receive them.

The results of current study are inadequate to draw conclusions which would have far-reaching effects on children vaccination programs so important to the health of America's children. NIH is taking a number of different approaches to get information as soon as possible that will determine the merit of these recent concerns.

In addition to pursuing our ongoing research on a variety

of different causes for autism, NICHD, with cofunding from the CDC, is beginning a study of regression in autism. A thousand persons with autism will be evaluated through the Network on the Neurobiology and Genetics of Autism of the Collaborative Programs of Excellence in Autism which are supported by Child Health and the Institute on Deafness and Other Communication Disorders. We will identify a number of--200 children with documented regressive autism, and they will be compared with matched groups of children with early onset autism and with normally developing children. We will then compare across these groups early onset autism, regressive autism, and normal development; the presence, absence, duration of normal development; age of regression; vaccination history of children and of mothers over the course of the pregnancy; measles antibody levels and any association of vaccine additives and autism. The assessments will be done independently with blind assessments, and we will reexamine the hypotheses raised by investigators such as Drs. Singh, Wakefield and O'Leary. No one study can be definitive.

Recent work by CDC is important and informative. We are also eagerly awaiting reports from the American Academy of Pediatrics and a report from the group founded by the National Academy of Sciences and the National Institute of Medicine, which is important because it will be an ongoing committee. This retrospective research and the reviews will provide valuable information. However, what is really needed is a prospective longitudinal study that will follow a minimum of 100,000 to 150,000 children and youth from pregnancy through at least 21 years of age so we can find out what the interaction of genes and environment are that result in autism.

We stand ready to work with you, with Congress, with parent advocacy groups, scientists and individual families so that no stone is left unturned for us to uncover the causes of autism, including the causes of autistic regression.

I am pleased to answer any questions you might have.

Mr. Burton. Thank you.

[The prepared statement of Ms. Bristol-Power follows:]

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[GRAPHIC] [TIFF OMITTED] T2722.233

Mr. Burton. Would you put that slide up there, please.

I don't know if you can see that slide or not, but it shows the growth of autism in America, and if you can look at that real closely, you will see that in the 1940's up through the 1970's, there was a gradual growth, and then it started to climb. The HIV vaccine was introduced in the late 1980's, and the hepatitis B vaccine was introduced, and we used to have somewhere between 1 child in 2,000 was autistic, and now it is close to 1 in 150. Some people would say that is darn near an epidemic.

What I would like to ask is if this thimerosal is not a problem, why are you phasing it out of the vaccines?

Mr. Egan. Although I am not aware of any convincing data on harm from the thimerosal that is in vaccines----

Mr. Burton. Mercury.

Mr. Egan [continuing]. From mercury in vaccines, we are nonetheless committed to removing mercury, all sources of mercury, from children. And we are also concerned about potential risks and I guess some of the data that are making people more concerned in recent years about the effect of low levels of mercury.

Mr. Burton. My grandson in 1 day got 62 times what was an acceptable level. In 1 day.

Let me ask you about this quote. In 1982, 18 years ago, as detailed in the Federal Register, and you can look this up, Federal Register volume No. 42, an FDA panel concluded that thimerosal is toxic, causes cell damage, can cause allergic reactions and is not effective in killing bacteria or halting their replication. That was 18 years ago, and yet you keep saying there is no conclusive evidence. Why is that?

Mr. Egan. That report in the Federal Register was referring to the use of thimerosal, these organicmercurics, in topical materials.

Mr. Burton. Not given internally?

Mr. Egan. Like mercurochrome.

Mr. Burton. It is bad on the outside, so you give it on the inside?

Mr. Egan. In high concentrations. Yet it is effective as a preservative in biologics. It has continued to be used as a preservative in some of the eye drops.

Mr. Burton. You know, one of the things that concerns me, Doctor, is that--you say that mercury in vaccines has not been proven to be a problem. How do you account for this dramatic rise? Do you think that is all genetics?

Mr. Egan. I don't know the causes of the rise.

Mr. Burton. You will admit it is a dramatic rise?

Mr. Egan. It is dramatic, and I would agree with your assessment as epidemic.

Mr. Burton. And mercury is a poison?

Mr. Egan. Yes, it is. It is neurotoxic.

Mr. Burton. And the FDA and the CDC are committed to phasing it out. Why not take it out today; 8,000 children are going to be immunized today. We understand that there is a supply for every child in America of nonmercury-oriented drugs. Why is it that we are not phasing it out today?

Mr. Egan. There are a couple of things. If I can first address its use as a preservative, it is an effective preservative, and it is demonstrated to be an effective preservative. All of the preservatives that are used in vaccines are required to meet the USP definition of a preservative, meaning that the test article, the vaccine with the preservative in it, is taken. There are five challenge organisms that are added, there are three bacteria and two fungi, and these are added at 0.1 milliliter of each of the bacteria and fungi in a concentration between 100,000 and a million organisms, and within 14 days the preservative is required to reduce the bacterial count by 99.9 percent.

Mr. Burton. Let me interrupt you there. As I understand it, if you take a vaccine that is a single vaccine, not a multiple vaccine, in one shot, that the preservative that you are talking about either isn't necessary, or you don't have to use something like mercury; is that correct?

Mr. Egan. That's correct.

Mr. Burton. It is a single shot.

Mr. Enayati. A single-dose vial.

Mr. Burton. Why don't we do that?

Mr. Egan. That is primarily what is being done. Most of the changes that have been brought about since last summer have been the conversion of vaccines from multidose vials or even single-dose that did contain----

Mr. Burton. If we have a supply on hand to take care of the needs of the American people and the children, why are we continuing to put mercury in their bodies? Why don't we stop now? Dr. Bernier.

Dr. Bernier. I would like to try to answer that question, Mr. Chairman.

Mr. Burton. Sure.

Dr. Bernier. It is a good question, and it is one that we believe we would answer in the following way. We have set a goal to remove thimerosal from vaccines. We do not disagree with anyone who believes that this material should be taken out as rapidly as possible. We have set that goal. And I think we are pleased by the substantial progress that has been made and documented here today. Last year at this time a child could receive 187.5 micrograms of ethyl mercury from vaccines. Today that maximum is down to 75 micrograms. We have, since last summer, now reached a point where six of the seven vaccines are free of thimerosal as a preservative, and we believe the seventh one will be as soon as 6 to 9 months now, which is in

early 2001.

Mr. Burton. Seventy-five micrograms, 1.5 is considered safe.

Dr. Bernier. I am not sure where you get that value, Mr. Chairman.

Mr. Burton. For a 33-pound child, according to what we have found through our research, 1.5 micrograms is what is acceptable.

Dr. Bernier. I need to emphasize that there is no data, there is no compelling evidence at this time of any harm that has come to any child from vaccines that contain thimerosal as a preservative.

Mr. Burton. How do you account for that graph over there? Do you think that is a coincidence?

Dr. Bernier. I would like to defer that to Dr. Bristol-Power. I think this is a question about autism and the increasing rates of autism, and she is best qualified to comment on that.

Mr. Burton. Let me make one more comment. Of the 11 members on the Advisory Committee on Immunization Practices, of the 11 members, 6 of them have financial interests of one kind or another in the pharmaceutical companies that manufacture these vaccines. That doesn't look good to the public. Now, it may or may not be something that we should be concerned about, but it does concern a lot of people that we are keeping mercury that isn't necessary in vaccines when we have a supply that doesn't have to have those--that mercury in there. At the same time, the committee that is making the advisory panel that makes recommendations to CDC, over half of them have financial interests in the pharmaceutical companies. We checked for the past 10 years, and every one of the recommendations by the advisory panels has been accepted by FDA and CDC; so what they say is pretty much law. Now, how do you account for that?

Dr. Bernier. I think there are several questions in your last statement. Let me tackle the issue about conflict of interest which I think you are raising.

I am not responsible primarily for the management of that committee or have any direct responsibilities. The only thing I can say to you is, as I understand it, there are laws and regulations about who can serve on committees, and CDC is currently, as I understand it, following those procedures and has gotten a vote of confidence about how they are doing on that. I am not qualified to comment about that. In our society it is possible under the law to have conflicts of interest, and there are procedures for dealing with those.

On the issue of whether or not we could move more quickly, we believe substantial progress has been made. We have set the goal, and we think that we have the right goal. We think that we have made substantial progress. If we were to move too precipitously, there would be consequences to pay. We know from

the hepatitis B experience that occurred last summer that children fall through the cracks and that there is disease that is resulting as a consequence. So we don't want to move to this transition in a way that in some way jeopardizes the health of children, because we are confident that that will happen if we move too precipitously.

So we are on the right course. We have made tremendous progress, and we are going to get there in the foreseeable future. We should stay the course.

Mr. Burton. Ms. Chenoweth, and could you yield to me for about 10 seconds?

Mrs. Chenoweth-Hage. Yes.

Mr. Burton. Let me just say that 8,000 children are immunized today. You are phasing out thimerosal. You know there is a problem. You are not saying it, but you know there is a problem. You have a supply on hand that does not require having mercury in it, and yet you continue to use mercury, mercury-oriented vaccines. It makes no sense. You have a supply to do it, and the FDA is not stopping this immediately, I submit, because there is a financial interest by a lot of pharmaceutical companies that have a large supply of this mercury-oriented vaccine still in stock.

Mrs. Chenoweth-Hage. Thank you, Mr. Chairman, and I may ask you for a second and maybe a third round of questions. I have a lot of questions to ask these witnesses.

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

You listened to the testimony just as I did, and you are willing to, with a straight face, tell us that you are eventually going to phase this out after we know that a small baby's body is slammed with 62 times the amount of mercury that it is supposed to have, and OSHA reacts like they did in the case of this accident of this naval man. It doesn't make sense. No wonder people are losing faith in their government. And to have one of the witnesses tell us it is because mothers eat too much fish? Come on. We expect you to get real.

We heard devastating testimony in this hearing today, and we heard it last April. And this is the kind of response we get from our government agencies?

I am sorry.

When I was a little girl, my daddy talked to me about

something about a duck test. I would ask each one of you to read this very excellent work by Sallie Bernard and Albert Enayati, who testified here today. My daddy used to say if it walks like a duck and talks like a duck and sounds like a duck, for Pete's sake it is a duck.

I recommend that you read this. Side by side, page after page of analysis of the symptoms of people who are affected with mercury poisoning compared to autism, this is the duck test, and you folks are trying to tell us that you can't take this off the market when 8,000 children are going to be injected tomorrow; 80 children may be coming down, beginning tomorrow, with autism? What if there was an E. coli scare? What if there was a problem with an automobile? The recall would be like that.

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

I yield back the balance of my time, Mr. Chairman.

Mr. Burton. Mr. Waxman.

Mr. Waxman. Dr. Bristol-Power, you are an expert on autism, someone well versed on the literature of autism. Can you tell us your position on the possible connection between vaccines and autism?

Ms. Bristol-Power. Based on the evidence right now, we are looking at any evidence linking vaccines and autism, particularly the MMR vaccine and autism and additives in autism. Some very serious concerns have been raised both in recent literature reports and in evidence and testimony before this committee. So we are beginning a study right now to look very seriously at whether or not there is a link that should be--that can be substantiated in a large group of 1,000 patients with well-documented autism. We will be collecting behavioral measures and biological measures that will be tested in an independent laboratory that will reexamine the hypotheses that have been raised here. We are taking seriously the testimony of this committee and are reacting, we hope, with most haste to get answers to the questions that you have raised.

Mr. Waxman. I think that is worthwhile because we want to make sure that we have checked everything out and evaluate whether this hypothesis is accurate or not that there is some connection, but up to now haven't you and other scientists looked at the connection between vaccines and autism, and have you found evidence to connect the two? Or are the reports

accurate that say that autism might occur very early on in fetal development and that the connection appears because the time of autism manifesting itself in the child is pretty close to the time that immunizations are given?

Ms. Bristol-Power. There are a couple of aspects. Historically, the vast majority of children have symptoms of autism from birth, so for that group certainly the later onset associated with any vaccines would not be compatible.

We have a group of children that do regress that we know develop normally and lose speech and social interaction. At this point we don't have a satisfactory answer why they regress. But there are a variety of developmental disorders which are characterized by a period of normal development and regression. For example, there is a disorder called glutaricacidemia. It is a metabolic disorder. The children develop normally, and without treatment essentially it blows out their basal ganglia, and they become very disabled, and that is a metabolic cause.

There are genetic disorders. Rett syndrome, those children develop normally, and then only gradually develop autistic characteristics. We now know there is a genetic basis for that. We have to be careful in assuming that because the onset is later, it necessarily is associated with something that happened later.

Mr. Waxman. I appreciate that, but I want to ask another question of Dr. Bernier. On this issue of mercury, mercury is being taken out of vaccines, and I think that is a good thing because we should always err on the side of safety. The question that I would like to ask, and I am sure parents want to know, is this being done because there are known adverse related events or as a precautionary measure? CDC convened an expert panel to examine data that showed a possible weak link between thimerosal and certain developmental delays. The panel presented its findings to CDC's Advisory Committee on Immunization Practices and concluded that data were insufficient to show a causal connection between thimerosal and certain developmental delays. Is that true? Is that the position that CDC has taken?

Dr. Bernier. That's correct, Mr. Waxman. At the present time CDC has no evidence of harm to any children from thimerosal in vaccines. We have constantly acted to look at the safety. Following the episode last summer, CDC did begin to look at the data in the Vaccine Safety Datalink, and one of the outcomes that we looked at was autism, and there was no suggestion of any association between thimerosal exposure and autism in the Vaccine Safety Datalink study.

Mr. Waxman. Dr. Egan, is the FDA removing thimerosal from vaccines in response to evidence of actual harm or as a precautionary measure?

Mr. Egan. It is done as a precautionary measure and to

reduce mercury exposure from all sources, vaccines included.

Mr. Waxman. I see my time has expired.

Mr. Burton. You say that you are doing it as a precautionary measure. When did FDA and CDC first start being concerned about mercury in vaccines?

Mr. Egan. I guess the major concern started somewhere around May 1999.

Mr. Burton. May 1999. When you look back at the statement, and you were talking about a topical mercury a while ago, but in 1982, the FDA panel concluded that thimerosal is toxic, causes cell damage, can cause allergic reactions and is not effective in killing bacteria or halting their replication. If that was true for a topical mercury substance, why would you not be concerned about that if it was ingested?

Mr. Egan. Those topicals refer to high concentrations.

Mr. Burton. I understand, but we are talking about pretty high concentrations; are we not?

Mr. Egan. I will have to look up and get back to you exactly what the concentrations were.

Mr. Burton. I wish you would, because it doesn't say what the concentrations were. Like I said, we had testimony today from people that said that their children were getting 125 times, 75 times what EPA and others say is--and CDC says is a safe amount of mercury into their bodies. If in 1982 you knew there was a problem and you didn't know the amounts for a topical, why would you continue to allow vaccinations to be given to children by the millions when there was a concern? I mean, I just don't understand. You say in 1999 you became concerned about it, but in 1982 in the Federal Register you had an FDA panel that said, hey, this is a problem. They said it is toxic. It causes cell damage and can cause allergic reactions. This was a topical. Why would you allow it to be inside a vaccination?

Mr. Egan. It was allowed because it is effective as a preservative for those vaccines, and the dose was markedly reduced relative to those topicals.

Mr. Burton. But you knew mercury was toxic, and there had been an FDA panel that said it was a problem, yet nobody over there said, we ought to take a look at this as far as vaccinations are concerned?

Mr. Egan. I don't know. I don't know what people said.

Mr. Burton. When this panel reached its conclusions and put it in the Federal Register, did anybody say, hey, if it is bad for the outside, why are we giving it to them on the inside? Or was maybe the pharmaceutical companies that made it as a preservative and it was in the vaccines saying that they had to keep it in there. Can you do some research and find out what happened during this timeframe? I can't imagine in 1982, 18 years ago, realizing that this was a real problem, continuing to keep it in vaccinations.

Mr. Egan. It was kept in other materials at that time as a preservative, not as an active ingredient.

Mr. Burton. When did they start taking it out of over-the-counter stuff?

Mr. Egan. I will have to get back to you on all of those. I believe it is still in ophthalmics----

Mr. Burton. Many of the over-the-counter----

Mr. Egan [continuing]. As preservatives.

Mr. Burton. Many of the over-the-counter drugs they have taken it out of at FDA request. In 1998, they said that it was no longer generally recognized as safe, and yet here we are 2 years later, and you are phasing it out. You are phasing it out.

This is the thing that Mr. Waxman and I may not agree, but I cannot understand, maybe you can explain, if there is any question about mercury in vaccine, if there is even a question, you are phasing it out because there is a question. You have a supply of all the vaccines that are necessary to immunize children of this country. You have that. You have them now. Why in the world are you continuing to immunize kids with something that is questionable? Give me an answer. I don't understand it.

Mr. Egan. To date there is no--we have no evidence, convincing evidence, of harm from the thimerosal in vaccines.

Mr. Burton. Doctor, I understand you have said that. The point is that you have a supply that you don't have to worry about, and you have a supply that you are phasing the mercury out of because there is concern. You don't agree that there is scientific evidence. If you are phasing it out, why in the world not use what you know to be safe so that the kids of this country can be safe?

Mr. Waxman. Mr. Chairman, I ask unanimous consent that you be given an additional minute, because I think you have asked a key question. Why not take it off now?

Dr. Bernier. I think a couple of things need to be pointed out. First of all, we have concerns about reliance on a single manufacturer. There are issues about whether or not that single manufacturer could gear up rapidly enough to move from being a partial provider of our national need to being the exclusive provider for the entire country. We have concerns about wether or not they can really do what they say they can do. That is No. 1.

No. 2, we have concerns when we rely on a single manufacturer about problems that can occur in production, in meeting the requirements of the FDA. There have been episodes where there have been a fire in a plant. There have been episodes where there has been disruptions in the manufacture, and there have been shortages. So we have concerns that if we transition our vaccine supply too abruptly, we are taking a gamble. We are afraid we might lose and risk the health of children.

There is also an issue about public policy, and we believe that whenever possible we should try to promote a situation where we have several manufacturers. In the long run that serves the interest of children best if we can have multiple producers of vaccines and not have to rely on a single one.

So, Mr. Chairman, I think we are exaggerating the disagreement here this afternoon. We agree that we do not need to have thimerosal in vaccines. If it doesn't need to be there, we should take it out. And we should take it out as rapidly as possible. We have agreed to that. The Public Health Service, the vaccine manufacturers, and the academies are all in agreement. We have two, in my career, historic documents which are joint statements by the American Academy of Family Physicians, the American Academy of Pediatrics, and the Public Health Service, which includes NIH, FDA, HRSA and CDC all signing one statement. That is not easy to accomplish, believe me. We have all said that this material should come out as soon as possible. We don't disagree.

There has been substantial progress made in just the last 12 months for hepatitis B. As Dr. Egan has said, there are two vaccines that are free. There is no more hepatitis B with thimerosal for pediatric use. Children can have an entire supply free of thimerosal. For HIB, there are four vaccines. Three always were free, and now the fourth one is going to be free this month. So now we can say the entire supply of HIB vaccine is going to be thimerosal free.

That leaves DTaP. There are four companies, one of which has already achieved thimerosal-free status. Three others are working on it. Two of them have told us publicly that they will have the supplements into Dr. Egan this summer, and we have gone on the record publicly stating this. We discussed this, during this last month. We put in writing that we anticipate that we are going to get there by early 2001. Some argued don't put the date in there. That will force us to be accountable in a way that we may regret, but people agree to do that because they agreed that it is a priority, and they saw the light at the end of the tunnel, and they were confident about it.

In summary, No. 1, we agree with you that thimersol should come out. No. 2, it is coming out rapidly. And the third point is we have to do it in a way that we feel will not jeopardize the health of children, and we have seen their health jeopardized in the case of hepatitis B. We don't want to jeopardize their health this way.

Some may think that is a gamble worth taking because there is not disease right now, but I can say this. When the three options were given at the ACIP meeting in June, the ACIP was not willing to take that gamble. The American Academy of Family Physicians would not take that gamble. NIH would not take that gamble. HRSA would not take that gamble. CDC would not take that gamble, and FDA would not. They all signed the joint

statement.

Mr. Burton. You have made your point.

Mrs. Chenoweth, would you yield to me for just a minute?

Mrs. Chenoweth-Hage. Yes, Mr. Chairman.

Mr. Burton. The point is today you have a supply of vaccine that could be used to vaccinate every child in America that does not contain mercury.

Now, the 8,000 children that are going to be vaccinated today, tomorrow and the next day are going to have mercury in the vaccine. Now, if you are wrong, if you are wrong, those kids could become autistic as a result of that. Like my grandson, they could become autistic and be ruined for life. And no matter how much hyperbole you use, if you have a safe supply of vaccine over here, why are you using the other?

You said we only want to have one supplier. Well, you know, get the others up to speed as quickly as possible. You have a supply now. You have people supplying it now, and this hypothesis begs the question if you don't have a supply, then you still have a supply of the mercury-oriented vaccine as a backup if you have to use it, but why not use the safe stuff right now?

Mrs. Chenoweth.

Mrs. Chenoweth-Hage. Thank you, Mr. Chairman.

You know, I still go back to the fact--I still want to talk about the duck test. Mr. Egan, I will address this to you. You know, it was shown in the last panel that autistic symptoms emerge after vaccination. It was shown that vaccines contain toxic doses of mercury. It was shown that autism and mercury poisoning, the physiological comparison is striking. There is altered neurotransmitter activity, abnormal brain neuronal organization, immune system disturbance, EEG abnormalities. It goes on and on and on, the comparisons. That is why I say, I back up what the chairman and the ranking member are all asking you, that we cannot wait until 2001 to have this pulled off.

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

Mr. Egan, you stated it is very important to remember that safety margins are incorporated in all acceptable mercury exposure limits, right? Could you tell me what those exposure limits are for a 1-month-old, a 3-month-old, a 6-month-old, a 9-month-old and a 1-year-old?

Mr. Egan. Various government agencies have arrived at different guidelines for mercury exposure.

Mrs. Chenoweth-Hage. I am asking you, representing your agency, Doctor. Can you tell me based on your testimony what those exposure limits are that you referred to for a 1-month, 3-month, 9-month, 6-month and 1-year-old?

Mr. Egan. Well, last summer when this was discussed within the Public Health Service, all of the agencies of the Public

Health Service concurred on the ATSDR recommendation, guidelines, which is 0.3 micrograms of mercury per kilogram body weight per day.

Mrs. Chenoweth-Hage. Well, would you provide that in detail to the committee in a report?

Mr. Egan. Yes, I will, ma'am.

Mrs. Chenoweth-Hage. How were those exposure limits arrived at? Could you also provide that in the report? I'd also like to know what the demographics of the population was that were tested. And could you forward that data to support your claim that you made in your testimony?

Mr. Egan. Yes, ma'am.

Mrs. Chenoweth-Hage. OK. And all the background data. What studies, Dr. Egan, were submitted to the FDA to prove that thimerosal was safe?

Mr. Egan. When--OK. When thimerosal was, you know, was first used in vaccines in the--I guess starting around the 1930's when vaccines were not regulated by FDA but by other organizations, there were some toxicology studies, you know, acute toxicology studies in animals and very, very limited amount of data in people that there was no acute toxic effect.

Mrs. Chenoweth-Hage. And these were studies that were done in 1930, that were submitted to----

Mr. Egan. They were also done in, I guess, the late 1920's and reported by researchers at Eli Lilly in 1930.

Mrs. Chenoweth-Hage. OK. With regards to the induction of HIB vaccine and hepatitis B vaccine, could you advise the committee on what studies were done with regards to these new vaccines that would prove that thimerosal was safe? These were done, introduced, in the eighties and nineties.

Mr. Egan. I believe it was in 1990. There was a long history of the use, safe use of thimerosal, you know, in vaccines since they were--since it was first introduced. And at that time, there was no data to suggest that the added mercury from the introduction of those new vaccines would be harmful.

Mr. Burton. The gentlelady's time has expired. I'm sorry. Mr. Waxman.

Mrs. Chenoweth-Hage. I do have other questions that I would like to submit in writing.

Mr. Burton. Yes. We'll give you some questions we'd like for you to answer if you wouldn't mind after the hearing is over.

Mr. Egan. Yes, sir.

Mr. Burton. Mr. Waxman.

Mr. Waxman. As I understand your testimony, you're not sure there's a problem from thimerosal, but you're taking the prudent course of getting it out of the vaccines. Dr. Bernier, as I understand your statement before in answer to the question why we're not taking it out of all vaccines immediately, you worry about the supply of vaccines that will be available,

although the chairman made the statement that we have enough supply now to immunize every child in the country with vaccines without the thimerosal. Is that an accurate statement?

Dr. Bernier. I would have to refer that to the manufacturer. We have been told publicly that yes, they do have an adequate supply of vaccine, but we're concerned--I wouldn't want to--I guess my first answer was perhaps a little too long; I didn't get to the second part. We have concerns about the supply. But the second thing is we have concerns about the harm that might come from an overly abrupt change. To answer the question it's a harm we believe is more real than the harm that we think would be associated with thimerosal.

Mr. Waxman. What is that harm?

Dr. Bernier. We know the harm from pertussis, we know the harm from hepatitis B. We know the harm from Haemophilus influenza B. We can, for example, just look at USA Today. Two days ago, there was this story of a mother who made a decision not to immunize her child against Haemophilus influenza B because it was a new vaccine. It sounded scary to her. And when asked by her pediatrician, should I take this Haemophilus B influenza vaccine, or do you want this Haemophilus B vaccine for your child, the mother made a decision ``no.'' The child is now deaf, the child has mental difficulties that requires Ritalin every day, and obviously this mother has deep regret about that. We believe----

Mr. Waxman. I'm going to have to interrupt you because it sounds like you've answered the question and you're going on, but I only have a limited time. That would take up all my time.

Dr. Bernier. I understand. I have that tendency.

Mr. Waxman. I understand. I have the same tendency. But just so I can frame the issue: Nobody wants to have thimerosal, because it has mercury, in the vaccines, whether we think it does harm or whether we're sure it does harm or whether we just think maybe it does and let's be safe about it, so we ought to get it out of the vaccines as quickly as possible. But what I hear you saying is that if we move too precipitously, we might not have a full supply of all the immunizations available of all these illnesses that we know can be prevented, and we know we're going to get all these diseases back and we don't know, if we have the use of the vaccines that still have thimerosal in them, that there's ever going to be any harm for sure about the mercury. Is that your position?

Dr. Bernier. That's right. We would be trading a harm that we know for one we don't know. We know the harm will come if children are not immunized, and we know that it happened just in the last 12 months. So we're facing a harm we know versus a theoretical harm--which at this time is still only theoretical from the best evidence that we have.

Mr. Waxman. I think that's a good on-point statement, answer to my question. I think all of us would like to have

this thimerosal out as quickly as possible. But on the other hand, I must agree with you. I don't want the supply upset, because I believe in immunizations, and I worry that people are going to be frightened because of the theory that has not yet been established of a connection to autism, that they might not get their kids vaccinated. We know for sure when that happens, we're going to get a whole long list of terrible diseases that I can feel as passionate about as anybody else.

But the chairman showed a graph that showed an increase in autism. The chart showed a steep rise in the number of cases of autism. Ms. Bristol-Power, the chairman says there's a dramatic increase in autism, but some experts have told us that this could be due to better detection. I wonder if you have a view about that and if there really is an epidemic, a sudden increase, because Dr. Egan seemed to agree there was an epidemic, but you're the expert on whether there was.

Mr. Egan. I'm sorry, but what I meant was apparently there's a very large number of cases.

Mr. Waxman. Being detected.

So my question, Dr. Bristol-Power: Are there more cases being detected because there's a dramatic increase in cases or better detection mechanism?

Ms. Bristol-Power. We don't have the information to answer that question. We know that part of the increase is better diagnosis, more public awareness, and better services, frankly, so more children are being presented at service locations.

In the United States right at the moment, we don't have adequate studies that would let us know about whether there is an increase in prevalence. We do know worldwide epidemiological studies show that--any studies done since 1987--there's about a double the rate of previous results from previous studies. But again it's not clear how much of that increase is from better diagnosis and greater public awareness, where these children have been diagnosed in other categories before.

Mr. Waxman. Do you agree with that position, or do you agree with that position of Dr. Bristol-Power?

Mr. Egan. Dr. Bristol-Power is the expert on autism, not I.

Mr. Waxman. So you would have no disagreement with her.

Mr. Egan. I would have absolutely no reason to disagree with her.

Mr. Waxman. Thank you, Mr. Chairman.

Mr. Burton. I think we're reaching the end of the hearing. I do have a couple final questions I'd like to ask here. How long will children continue to receive mercury vaccines if there's not a recall? How many years will they continue to receive those?

You know, you mentioned the DTaP vaccination, but you have not mentioned the DPT vaccination which is still in use, which does use thimerosal. And the DPT shot, there's a lot of concern about that vaccination. That's why they went to the DTaP shot.

Yet the FDA has not recalled the DTP vaccination and it's still being used. So how long will mercury vaccines containing mercury be used if there's no recall?

Mr. Egan. For the routine immunization schedule that's recommended by ACIP and AIP, the recommendation is for DTaP.

Mr. Burton. I know, but they still use the DTP shot. We had people from CDC and Health and Human Services testify that they still are using it. It's still being used.

Mr. Egan. Again I'll have to get back to you on some of that. There have been some lots of DTP, primarily I believe Tetramune which is the DTP-HIB combination vaccine, but I believe that the few lots of that that have been released are for sale overseas.

Mr. Burton. Well, in any event----

Mr. Egan. It's not being used the United States.

Mr. Burton. You're saying you don't believe there's use in this country?

Mr. Egan. I'll have to check on it.

Mr. Burton. But in any event, the question I'm asking is mercury containing vaccines, how long will they be in use if there's not a recall?

Mr. Egan. Well, the majority of the vaccines, the Haemophilus vaccine and the hepatitis B vaccines are already thimerosal free. This has been accomplished since last summer.

Mr. Burton. My question is--those vaccines that contain mercury, even though you're phasing it out. How long will they be used if you do not recall them?

Mr. Egan. The--in their public statement, Pasteur and Wyeth, who are the other major manufacturers, two other major manufacturers of DTaP, said that they will be submitting supplements to their license for thimerosal-reduced vaccines either the end of July or the beginning of August.

Mr. Burton. But the existing supply will be used until it runs out, and you don't know how long that would be?

Mr. Egan. No. Perhaps my colleague from CDC can, you know, comment on the----

Mr. Burton. I'd just like to know, because even though you're transferring over to vaccines containing no mercury, if there's a supply out there, if it's not recalled they're going to continue to be given to children. And that's a concern. Yes, sir.

Dr. Bernier. May I try to answer that question? I don't think I can be definitive about it, because you're right that there is a pipeline, there is a supply, and it doesn't disappear overnight. But I think the handwriting is on the wall for vaccines that contain thimerosal in the United States, Mr. Chairman, I think we all agree with that. And as soon as the supply is considered adequate and secure, I believe you will find committees and others beginning to recommend many preferences for these vaccines. How quickly will all of this

take place? The recommendation--it will depend on how the recommendation is stated. If you'll go back to the July 1999 statement of--joint statement--it said that this goal was to be achieved as rapidly as possible. And we're now publicly on record as predicting that it will occur early next year. But--
--

Mr. Burton. OK. This is my last question, and if Mr. Waxman has any questions he can ask them as well. The FDA seems to be saying that vaccines that were licensed from 1970 to the year 2000 were not required to do testing on thimerosal. Is that correct? None of those--I mean, because thimerosal was used from the 1930's on, they really haven't done any testing since the seventies on whether or not there's a side effect from that; is that correct?

Mr. Egan. I'm not sure if any--what test was or wasn't done on those specific vaccines, but I will get back to the committee on that.

Mr. Burton. We'd like to know if there was any testing done on thimerosal. So anything you can give us on that we would appreciate.

Henry, do you have any last questions? If not, I want to thank you very much for being here. We'll submit some more questions to you for the record.

We appreciate you being here. We hope that you'll carry back to the agencies which you represent, the concerns of these parents that were here today regarding vaccines. We're for vaccinations, Henry and I agree on that, but we want to make sure they're completely tested and they're safe. Thanks a lot.

[Whereupon, at 5 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

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