THE AUTISM EPIDEMIC--IS THE NIH AND CDC RESPONSE ADEQUATE?

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HEARING

before the

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

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APRIL 18, 2002

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Serial No. 107-74

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Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpo.gov/congress/house
http://www.house.gov/reform

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80-356 U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 2002

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C O N T E N T S

THE AUTISM EPIDEMIC--IS THE NIH AND CDC RESPONSE ADEQUATE?

THURSDAY, APRIL 18, 2002

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, Shays, Horn, Jo Ann Davis of Virginia, Weldon, Waxman, Maloney, Norton, Cummings, Kucinich, and Watson.

Staff present: James C. Wilson, chief counsel; S. Elizabeth Clay, Scott Feeney, and John Rowe, professional staff members; Jennifer Klute, counsel; Robert A. Briggs, chief clerk; Robin Butler, office manager; Elizabeth Crane, legislative assistant; Elizabeth Frigola, deputy communications director; Joshua Gillespie, deputy chief clerk; Susie Schulte, staff assistant; Leneal Scott, computer systems manager; Corinne Zaccagnini, systems administrator; Sarah Despres, minority counsel; Josh Sharfstein, minority professional staff member; Jean Gosa and Earley Green, minority assistant clerks; and Teresa Coufal, minority staff assistant.

Mr. Burton. Good afternoon. A quorum being present, the Committee on Government Reform will come to order.

I ask unanimous consent that all Members' and witnesses' written and opening statements be put in the record. Without objection, so ordered.

I ask unanimous consent that all articles, exhibits, and extraneous and tabular material referred to be included in the record. Without objection, so ordered.

Today we are here to talk about the autism epidemic. I use the word ``epidemic'' for a good reason. Typically, we think about epidemics in terms of infectious diseases. However, a condition is considered epidemic when it occurs suddenly in numbers that are clearly higher than normal.

Ten years ago only 1 in 10,000 children were thought to be autistic. When we began our investigation in 1999, that number was estimated to be 1 in 500. That is a 20 times increase. However, the number today appears to be even higher.

The Center for Disease Control [CDC], conducted two prevalence studies. The study in Brick Township, NJ, found that 1 in 181 children between the ages of 3 and 10 were diagnosed with autism, and 1 in 128 were diagnosed with autism spectrum disorders. An as yet unpublished study conducted in 1996 in Atlanta, GA, found that 1 in 294 children ages 3 to 10 had autism.

The National Institutes of Health [NIH], places the estimate at 1 in 250 children, and boys are affected four times

more often than girls. That means that about 1 in every 156 boys in this country between the ages of 1 and 10 are autistic.

Unfortunately, the unexpectedly high rates in Georgia and New Jersey are not isolated examples. This school year there are 3,789 individuals with autism in Indiana schools. This is up from 116 just 12 years ago, 116 to 3,789.

A recent news article out of Thailand indicates that there are 100,000 children in Thailand with autism. In 1999, the East Surrey Health Authority in the United Kingdom stated that the prevalence of autism in their district was 1 in every 69 boys.

In the 60 years since autism was first described, we have not yet figured out what causes it. We do not know if classical autism and late-onset autism are the same conditions or two different conditions with similar symptoms. We have come a long way in 60 years. Doctors no longer blame the condition on bad mothering. But we have a lot more work to do before we can pat ourselves on the back for our accomplishments.

Is our investment in research on autism on a comparable level with other epidemics? This is very interesting. Are the CDC and NIH funding studies that will help prevent or cure autism? Is their research adequately addressing the medical issues associated with autism such as food allergies, chemical sensitivities, and autistic enterocolitis? Is the information about autism provided by our government adequate and useful to families?

The CDC will testify today that they plan on spending $11.3 million on autism this year and $10.2 million on autism next year. We compared that to two other conditions that have been declared epidemics: diabetes and AIDS. Both of these conditions can be devastating. Both deserve sufficient research dollars to develop treatments and look for cures.

The CDC is spending over $932 million on the AIDS epidemic this fiscal year. Compare that to $11 million for autism. AIDS deserves attention--don't get me wrong--and so does diabetes, which both Secretary Thompson and the former Surgeon General declared an epidemic. CDC this year will spend just over $62 million on diabetes. The autism epidemic, just like the diabetes and AIDS epidemics, is no less deserving. Yet, the CDC's spending for autism is almost 80 times less than that for AIDS. And CDC's spending for autism is five times less than that of diabetes. CDC should be committing more research money for autism, and we are going to work on that.

Now let's look at the National Institutes of Health. We have got some charts up there on the wall which you can look at. The NIH is the premier biomedical research institution in the world. Congress has worked hard to double the NIH's budget. Their total budget this year is $27 billion. We are committed to funding research to help cure crippling diseases.

The NIH will testify today that their commitment to researching autism has grown dramatically in the last few

years. In fiscal year 1997, the NIH investment in autism research was only $22 million. Last year that number had grown to $56 million, in large part because of the Congress.

That's good, but let's put that into perspective. At the same time the NIH is spending $56 million on autism, a condition that affects 1 in every 250 children in this country, they are investing over $2.2 billion in AIDS research. The rates of diabetes increased by 49 percent between 1990 and the year 2000. Diabetes is a devastating condition in the Native American community and of increasing concern in the African American and pediatric populations. This year the NIH investment for diabetes is $688 million, and compare that to the $56 million that they are going to spend on autism, and compare that to the huge money that is being spent on the AIDS research.

I believe these numbers speak for themselves. Funding in basic and clinical research into autism needs to be expanded dramatically. We have an epidemic on our hands, and we in Congress need to make sure that the NIH and CDC treat this condition like an epidemic and put their efforts into doing several things: First, to find out the causes of the epidemic. Second, determine how to stop the epidemic in its tracks. Third, to evaluate treatment options. And, fourth, to look for a cure.

When we first began looking at this issue, we heard from thousands of families. Many told us their children were absolutely normal until they were vaccinated, and that just a few days or weeks after they became vaccinated they became autistic. We also heard about a dramatic similarity in these late-onset autism cases. Many of these children have unusually high levels of heavy metals in their systems. They have immune system irregularities. They have unresolved yeast infections. Eating foods that contain wheat or dairy may result in a rapid deterioration of behavior. Exposure to many chemicals, even perfumes, can have the same adverse effect. Many have chronic diarrhea. NIH and CDC need to fund research to get answers to all these issues.

One of the things that concerns me is that it seems that many of these children, if we tested hair samples, urine samples, blood samples, could give us an idea of whether or not they have mercury in their systems, and to what degree, and whether or not there are other toxic chemicals that may be in their systems that could be found through these tests.

Autism has personally affected my family, and many of you already know that. My grandson Christian was normal and healthy until his second year of life. He walked, he talked, he made eye contact, he enjoyed going to the mall, and all the other things that 2-year-olds do. And then suddenly, shortly after receiving his mandated immunizations, he became a different child. He no longer spoke. He would not look anyone in the eye.

He cried endlessly. He banged his head against the wall. He began running around flapping his hands, and he had chronic diarrhea and severe bowel problems. We now know that he was suffering from an adverse reaction to his vaccines. We also know that he may have received more mercury in his vaccines than is considered safe, way more than safe, by Federal standards. This mercury toxicity was contributing to the adverse reaction.

So far, the NIH and the CDC discount any potential connection. The Institute of Medicine has stated that the available research data is insufficient to prove or disprove a connection between autism and either the MMR vaccine or thimerosal, which is the preservative put in most children's vaccines. But they say the link is biologically plausible. The IOM called for more research in this area. One of the reasons we are here today is to make sure that research gets done, and gets done now rather than 10 years from now, when many more thousands of children become autistic.

When you are a parent, whether your son or daughter is autistic from birth, because of genetics, or because of some environmental exposure such as vaccines or maybe something else, you are facing a challenge more difficult than a 500-piece puzzle. You are faced with putting the puzzle of your child's life together one piece at a time.

Do you put special locks on your doors and windows and add an alarm system because you're afraid the child will wander away from your home? Do you need to put a lock on a cabinet in your kitchen to keep the foods that set your children into a spiral out of their reach? What medicines or dietary supplements will your child need? How do you find services? Does your child need to learn sign language? Do you need ABA or other behavioral therapy? Where can you find a qualified speech therapist? How are you going to pay for all of this? How are you going to get through the school services maze? How will you find time for your other children?

What happens when the child grows up? And that's something our government needs to think about. One in 250 children are becoming autistic, and we are not doing a great deal of dealing with that problem right now, but they are going to grow up and then they are going to be adults with autism. Now if you have 1 in 250 people in this society that's autistic down the road, because we haven't done our job now, how are we going to take care of it? How are we going to take care of all the health care needs besides autism at the same time as taking care of the burden they are going to be on society? And our medical and research people need to address that issue. These are all dilemmas that parents face now.

In addition to witnesses from the NIMH and CDC, I am pleased that we have several autism organizations represented here today. We were not able to have all of the organizations

testify at the table, but I hope that each will submit written statements for the record.

Mr. Lee Grossman of Hawaii is our first witness. He is the president of the Autism Society of America and has a son with autism.

Ms. Belinda Lerner of New York is a member of the Autism Coalition and has a son with autism. While having a child with autism may be her toughest battle, Ms. Lerner is not a stranger to tough battles; she is the first female attorney to work for the National Football League. Those are big guys. [Laughter.]

Mr. Stephen Shore of Brookline, MA, is a board member of Unlocking Autism. Mr. Shore, who did not speak the first 4 years of his life, has Asperger's disease, a condition on the autism spectrum. Mr. Shore is a success story. Because of his mother's drive and dedication, Mr. Shore is a doctoral candidate at Boston University. That's very commendable. He gives all families with autistic children hope.

Mr. Doug Compton is the science program director of Cure Autism Now and the father of an autistic child.

I look forward to hearing from our witnesses today. Our hearing record will remain open until May 3rd.

[The prepared statement of Hon. Dan Burton follows:]

[GRAPHIC] [TIFF OMITTED] T0356.001

[GRAPHIC] [TIFF OMITTED] T0356.002

[GRAPHIC] [TIFF OMITTED] T0356.003

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[GRAPHIC] [TIFF OMITTED] T0356.009

[GRAPHIC] [TIFF OMITTED] T0356.010

[GRAPHIC] [TIFF OMITTED] T0356.011

Mr. Burton. Mr. Waxman is not yet here.

Mr. Gilman, do you have a statement you would like to make?

Mr. Gilman. I do. Thank you, Mr. Chairman. I want to thank Chairman Burton for conducting this important hearing regarding NIH and CDC's response to the rising rate of autism in our

Nation.

I recently met in my constituency with Jeanine Conklin, a mother to Daniel, her 5-year-old autistic son. Listening to her explain the obstacles that her family must face each and every day reaffirmed by commitment to this issue. It is essential that there be continued research of and funding for learning more about how this affliction manifests itself and how it can be prevented, and how to properly educate the public. It is important to understand how we define autism, why the autism rate is increasing, and how we can support effective research that will benefit those who are already afflicted by autism.

Autism makes it difficult for an individual to interact with people and their environment. In some cases those with the illness may behave in an aggressive or self-injurious manner. It occurs in people of all races, ethnicities, and socioeconomic backgrounds. A better understanding of the origins of the disease is crucial to introducing new and effective treatments.

As Chairman Burton noted, autism has afflicted 1 in 500 children in the United States. However, the CDC shows that even higher rates occur in some specific locales such as Atlanta, GA, Brick Township, NJ, where the autism rates are 1 in 94 and 1 in 128, respectively.

These alarmingly high rates have lead to several inquiries into the contributing factor of the disease, including, but not limited to, childhood vaccines and some of the environmental factors. Many of the symptoms of autism are the same as mercury toxicity. Through an FDA review, it was learned that the amount of mercury in mandated vaccines that children were receiving in the first 6 months of their lives exceeded guidelines that were established by the Environmental Protection Agency and validated through an Institute of Medicine review.

We have convened here today to monitor whether NIH and the CDC have satisfactorily responded to the challenge of autism research. More specifically, we would like to know if they made headway into IOM's research recommendations, research to determine how children metabolize and excrete metals, particularly mercury; continued research on theoretical modeling of ethyl-mercury exposures and careful, rigorous, and scientific evaluations of chelation, when used in children with neurodevelopmental disorders, especially autism.

Our committee's oversight is an essential component to increasing communication. Autism is a disease that paralyzes communication. We cannot afford to paralyze the communication between our medical community, our government sector, and those families who have been affected by autism. We owe it to the American families like the Conklins in my area to do everything in our power to ensure that the Federal Government continues its commitment to autism, to research and discovery.

As a member of our Congressional Caucus on Autism, I am

extremely interested in the testimony that our witnesses will have to present to us today. I want to thank Chairman Burton again for his dedication to the health and safety of our Nation's children.

Mr. Burton. Thank you, Mr. Gilman.

Let's see, Dr. Weldon.

Dr. Weldon. Hi, Mr. Chairman. I do not have an opening statement, but I just want to again thank you for bringing the spotlight of congressional scrutiny onto this very critical issue of autism in America. I believe it to be a forgotten and neglected disease for too long. Thank you for your leadership on this.

Mr. Burton. Thank you, Dr. Weldon. Mr. Shays.

Mr. Shays. Thank you, Mr. Chairman. Mr. Chairman, no prepared statement other than to thank you for having this hearing and to say that, like a number of Members of Congress, I have a very sizable number of autistic young and old in my district. It is far more noticeable than in the past, and I am deeply concerned about it. I can't imagine what it must be like for a parent to hold a child and just be hungry for some type of response of recognition. So I just thank you.

I know we are all wrestling with this. I know nobody has the answers, but together I hope we are able to find some.

Mr. Burton. Thank you, Mr. Shays. Ms. Davis. Mr. Horn.

Mr. Horn. Thank you, Mr. Chairman, for this continuing effort to get at autism. I would like to have in the record a piece called ``Medicine for the Love of Zachary,'' which was Zach and Karen London, and she affected 400,000 people nationwide with her crusade. I think you would find it very inspiring.

Mr. Burton. Thank you, Mr. Horn. We will put that in the record, without objection.

[The information referred to follows:]

[GRAPHIC] [TIFF OMITTED] T0356.012

[GRAPHIC] [TIFF OMITTED] T0356.013

[GRAPHIC] [TIFF OMITTED] T0356.014

[GRAPHIC] [TIFF OMITTED] T0356.015

[GRAPHIC] [TIFF OMITTED] T0356.016

[GRAPHIC] [TIFF OMITTED] T0356.017

[GRAPHIC] [TIFF OMITTED] T0356.018

[GRAPHIC] [TIFF OMITTED] T0356.019

Mr. Burton. Are any of the minority members going to be here?

[No response.]

Mr. Burton. We will now ask the first panel to come forward. Mr. Grossman, Ms. Lerner, Mr. Shore, and Mr. Compton, would you please approach the witness table and stand up so we can swear you in?

[Witnesses sworn.]

Mr. Burton. Be seated.

We will start with you, Mr. Grossman. I guess we will just go right down the line. Do you have an opening statement?

STATEMENTS OF LEE GROSSMAN, PRESIDENT, AUTISM SOCIETY OF AMERICA, AND AN AUTISM PARENT, HONOLULU, HI; BELINDA LERNER, MEMBER, AUTISM COALITION, AND AN AUTISM PARENT, NEW YORK, NY; STEPHEN SHORE, BOARD MEMBER, UNLOCKING AUTISM, BROOKLINE, MA; AND DOUG COMPTON, SCIENTIFIC DIRECTOR, CURE AUTISM NOW FOUNDATION, NEW JERSEY

Mr. Grossman. Yes, I do, Mr. Chairman.

Mr. Burton. If we could, we would like to try to keep our opening statements to 5 minutes, if we can, so we can get through everybody and have time for questions.

Mr. Grossman. Good afternoon. My name is Lee Grossman and I am president of the Autism Society of America, chair of the Autism Society of America Foundation, a member of the Federal Government's Interagency Autism Coordinating Committee, a resident of Honolulu, HI, a small business owner for over 20 years in the medical industry, and, most importantly, a father of a child with autism whose name is Vance.

Mr. Chairman, I would like to thank you and your colleagues on the Committee on Government Reform for this opportunity to present testimony on the issue of autism, the fastest-growing disability in our country today. As President of the Autism Society of America, I can tell you that hearings such as this offer hope to hundreds of thousands of individuals and families affected by autism.

I am going to deviate from my testimony a little bit to respond to your opening statements. They're very moving to me in that it truly represents what all of the families are going through, our experiences, our frustrations in dealing with this dilemma that we're faced with.

I want to thank you very much for acknowledging for the first time, that I am aware of, that the Federal Government is now acknowledging in this country that autism is an emergency, and it is a national health crisis. It is something that has not evaded the advocates and the families to this point. It is reassuring to all of us to know that the government is finally recognizing this as an epidemic.

There are a number of factors and figures that I would like

to present here before I get into what I believe that we need to do and what ASA believes that we should do to correct this problem over the near short-term. Currently, it is easy to say that this is a national health crisis. There are as few as a half million to perhaps 1.5 million people with autism in the United States today. Estimates are as high as for every 1,000 children that are born today 6 will have autism.

The annual cost of treating autism in the United States is anywhere from $20 billion to $60 billion every year. Autism is growing at a rate of 10 to 17 percent each year. Based on these figures, in 10 years the annual costs associated with autism could be as much as $50 to $300 billion per year. After 60 years of dealing with this problem, the Federal Government is currently spending $75 million on research when the problem is in actuality conservatively a $20 billion problem. After 60 years of this approach, we have no identified causes of autism or any proven treatments or therapies. Something substantially greater has to be done to address this national emergency, and we have to spend substantially more money to find causes and effective treatments.

The Autism Society of America believes there are four critical areas that need to be addressed, and these four areas are in autism research, early identification intervention, secondary school education, and adult issues. Here are our immediate recommendations.

Current funding levels in biomedical research at NIH are terribly low in relation to the disorders population and economic impact. We are recommending that the Federal Government increase the funding available for research over the next 3 years to a level of $500 million per year devoted to basic science, environmental science, tissue and genetic collection, and all aspects of biomedical research related to autism. When compared to the annual growing rate of autism in our Nation, this is substantially below the funding to keep pace with the projected growth.

In the area of applied science, we must find new and innovative ways to develop and implement therapeutic and clinic interventions and effective treatments. There has been to date virtually no activity and support from Federal agencies in these vital areas. We recommend that applied research funding be increased over the next 5 years to a level of $100 million per year. This increase is needed in the case of autism because we are building from a zero base.

ASA also recommends that there is a need to increase the number of scientists involved with research and treatment grants. We request that NIH develop programs and encourage researchers to enter into fields associated with autism research and to stimulate new research protocols.

The CDC surveillance programs need to be implemented and then expanded immediately so that more exact figures on the

prevalence and population of those with autism are established. In our discussions with CDC, we recognize that data from a substantial number of State or other geographic areas will be needed to better identify those who have autism and what scope of services will be needed. We, therefore, recommend that the CDC budget in this area be increased to $8 million to expand the number of regional centers and State surveillance programs from 9 States to 20 States. These 20 States should represent a statistically significant data base to allow CDC to better identify those who have autism, and then start looking for root causes and trends.

As we must find the causes and best treatments for those with autism, there is also a need to fund areas which could identify possible causes of autism created by our society. A substantial number of families within our autism community believe some forms of autism may be caused by some use of vaccines. While we do not know this to be specifically proved at this time, we should not ignore the body of evidence that calls into question the source of many children with autism. If causation is found, those injured must be provided recourse and compensation.

This is why ASA supports and asks for early adoption by Congress of the Burton-Waxman bill, H.R. 3741, which improves the National Vaccine Injury Compensation Program by extending the statute of limitations for individuals to file claims and provides a 2-year look-back provision for the families that are presently prevented from filing under the program, through no fault of their own.

Now under early diagnosis and early intervention, ASA strongly supports the general consensus that the most effective means for a successful result in the life of an individual with autism is through early diagnosis and early intense and appropriate intervention. Therefore, we recommend that a national awareness campaign be established through the U.S. Department of Health and Human Services, national physician organizations, and community health centers to provide education and identification programs to pediatricians, child care providers, and to the population at large.

ASA has expressed its willingness to act in concert with the Department to make this happen by drawing upon its unique membership and chapter base with the entire autism community. ASA also seeks increased funds for States to Early Head Start, or zero to 3, programs administered by the Administration for Children and Families to provide.

For education for children with autism, ASA recommends to the committee that it supports and develops legislation to implement the recommendations and plans detailed in the National Research Council's report, ``Educating Children with Autism.'' This report precisely addresses the education interventional needs of secondary school age children with

autism.

ASA further recommends that Congress immediately reauthorize the Individuals with Disabilities Education Act and fulfills the long overdue commitment to the full funding of IDEA, and, last, support services for adults with autism. The current availability of services, support, employment, and residential options available to adults with autism can only be described as almost non-existent. For too long the service supports for these people has dramatically dropped once the person passes through the secondary education system. A comprehensive program must be developed and implemented to address the tremendous needs of this growing and immense population.

ASA has developed a white paper on this subject and has posted it on our Web site to help develop interest in having it implemented. We have also joined with coalitions and formed coalitions of adult service providers, and are now doing assessments of the needs of the adults with autism community to formulate initiatives and legislation to address this problem. We ask the Congress and this committee to join in supporting the development of legislation and funding that will be necessary to deal with this current and ever-growing dilemma.

In closing, Mr. Chairman, I would be terribly remiss if I did not address the relevance and significance of this hearing. As I stated, this is the first time that I am aware of that the U.S. Government has acknowledged the autism epidemic and attendant national health crisis. And with your acknowledgment, ASA stands firm and ardent in requesting that this Nation take real and measurable actions today to stop this national economic, social, and health emergency.

I have described in my testimony what needs to be done now in terms of money and autism. However, there is something just as important to be added; that is hope. The autism community has endured 60 years of unfulfilled hope.

Congressman Burton, I know you have waited with hope for your grandson over the last 5 years. I have waited and hoped for the last 14 years, and the community has waited 60 years. If we will take the actions I have offered to you today, all of our hopes can be translated into fulfillment. Please let us help each other give meaningful hope to the millions of people affected by autism.

Thank you, Mr. Chairman, and I will stand ready to answer any questions you may have.

[The prepared statement of Mr. Grossman follows:]

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[GRAPHIC] [TIFF OMITTED] T0356.021

[GRAPHIC] [TIFF OMITTED] T0356.022

[GRAPHIC] [TIFF OMITTED] T0356.023

[GRAPHIC] [TIFF OMITTED] T0356.024

[GRAPHIC] [TIFF OMITTED] T0356.025

[GRAPHIC] [TIFF OMITTED] T0356.026

Mr. Burton. Thank you for that statement, Mr. Grossman. Your recommendations, along with the others that we will hear today, will be given to the officials at NIH and CDC and the FDA. We have some of them here who are going to be testifying in a little bit, and they are, I am sure, taking all this in.

Ms. Lerner.

Ms. Lerner. Thank you, Chairman Burton and distinguished members of the committee.

I am here to speak to you today about my personal experiences with the heartbreak and frustrations of autism. By way of history, you should know, and as Chairman Burton has already said, that professionally I am an attorney with the National Football League. My job has presented me with many interesting challenges, including cross examining 6-foot 5-inch, 300-plus pound professional football players. I was the first female attorney hired in that role, and so my challenges were not limited to my interactions with football players, but in winning the confidence and respect of my male colleagues in the league and at the NFL clubs. However, those challenges, while daunting at the time, pale in comparison to the challenges I have faced, and continue to face, as a mother of an autistic son.

My son, Benjamin, was diagnosed when he was 2 years old, and when I received the news, I was relieved--yes, relieved. Prior to his diagnosis, I was the mother of a screaming, inconsolable, non-communicative little boy, who seemed to reject all my attempts to love him and was incapable of demonstrating his love for me. At a time when I should have been awash in feelings of love, I was overwhelmed by feelings of inadequacy, failure, and shame.

Now the enemy that had overtaken my son had a name--autism--and like any lawyer worth her salt, I was going to defeat my adversary by researching and understanding its characteristics. I remember bombarding the psychologist, who had diagnosed Ben, with questions: What causes autism? No one knows. How prevalent is it? Undetermined, last count, 1 in 500. What treatments are most effective? It is unclear. There have been no reliable studies. Most importantly, what are my son's chances for a normal life? Hard to say, but not particularly good.

I refused to be cowed, but little did I know at the time

the journey I was embarking on. I was able to secure a spot for Ben in a wonderful school dedicated to children with developmental disorders, where by the age of 3 he began to master basic language and other life skills. Finally, the wonderful, charming little boy hidden beneath the disorder began to emerge, and so did this incredible bond between Ben and me.

Although Ben was making progress, he, nonetheless, still had substantial and pervasive deficits. And so each time a new problem arose that required additional therapy, we needed to get permission from the school district's Committee on Pre-School Education to amend his individual education plan [IEP], to address this problem. Although I had my share of battles with the CPSE to get appropriate services for Ben, it wasn't until Ben turned 5 and was transitioned from the CPSE to the CSE, Committee on Special Education, that the hostilities elevated to an all-out war.

At that point Ben was to graduate from his special education school. So my husband and I evaluated the school district's inclusion kindergarten program, and we both agreed that the curriculum and behavioral requirements were far too advanced for Ben at that time. However, the school district refused to provide us with any alternatives. So even though the law requires that a ``free and appropriate education in the least restrictive environment'' be provided to each child, we were left with the choice of putting him in the school district's program or pay out of pocket for any alternative.

We knew that following the district's mandate would be setting Ben up for failure, in our experience a sure-fire recipe for disaster and regression. If we sued the school district, it would cost us as much as a year's tuition. So we bit the bullet and sent Ben to a private pre-kindergarten program at our expense.

This private school was initially a godsend for us, and Ben continued to make small, but steady progress. But as Ben went from pre-K to the typical kindergarten program, it was clear that his developmental problems were too severe to be handled by a well-intentioned but untrained and underequipped staff.

Because the school district would not provide additional support for Ben at his private school, his failure to get the appropriate interventions resulted in his lashing out and shutting down. Once again, the shadow of autism was eclipsing my sweet, charming little boy who had been showing so much promise.

My husband and I pulled Ben from the private school, obtained additional therapy and additional evaluations at our own expense, and put him in our only other alternative, the school district's kindergarten program, which we had rejected 2 years earlier. Ben is no longer regressing, but he is still significantly delayed in all developmental categories.

Our most recent round of evaluations have revealed that, unless Ben receives intensive interventions this summer to make up for the losses he experienced this school year, he has absolutely no chance of surviving first grade. However, because the CSE has refused to classify Ben as a child who needs year-round services, the job of securing the right therapists, as well as the financial burden of providing them, will fall to us.

Based on my unwavering love for my little boy, I am determined to do what is in his best interest so that he may have a chance for a happy, independent life. However, I and similarly situated parents are faced with many obstacles, and it is time for the Federal Government to share the burden and the shame that has dogged the parents of the autistic, and the lack of government assistance in autism to date is shameful. It is shameful that this country, the greatest nation in the world, has conducted no concerted nationwide prevalence study.

Funding Centers of Excellence, pursuant to the Children's Health Care Act, would give us a vehicle to conduct a proper nationwide tracking program. It is shameful that there has not been significant funding into biomedical research. Less than two generations ago, the disorder was thought to be a mental illness caused by cold and detached mothers. Although we now know it is a neurological disorder, we have yet to determine what causes the autism and how it impairs the brain's functioning.

It is shameful that this country has not conducted meaningful and concerted applied research to determine what therapies are most effective in countering the horrific effects of autism. Our schools have been besieged by this growing population, and while required by law to educate and treat the autistic, they lack funding and training to handle this enormous responsibility. Fully funding the IDEA statute would alleviate some of that burden.

Finally, it is shameful that our Nation, either through willful ignorance or benign neglect, has allowed this insidious and pervasive health care crisis to rise to epidemic proportions.

I began my testimony by presenting to you the challenges I have faced professionally and personally as a mother of an autistic son, and I would like to conclude by asking that you adopt these challenges and support the funding for the five Centers of Excellence and IDEA. Past generations were damned to institutionalization. Let's not condemn our present and future generations to the same fate.

I speak on behalf of the exhausted, voiceless, and desperate parents of autistic children, the children that without the proper government intervention will become adults doomed to be a financial burden rather than a contributing member of society. So please give full force and effect to the

Children's Healthcare Act and the IDEA statute. Thank you.

[The prepared statement of Ms. Lerner follows:]

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[GRAPHIC] [TIFF OMITTED] T0356.028

[GRAPHIC] [TIFF OMITTED] T0356.029

[GRAPHIC] [TIFF OMITTED] T0356.030

[GRAPHIC] [TIFF OMITTED] T0356.031

Mr. Burton. Thank you for that statement. I would urge all of you who are interested and who are leaders in the autistic community to write your Congressmen and to write the White House and to tell them that you want these changes made and that there be appropriate funding for all of these research programs that you talked about, because the squeaky wheel in this town gets the oil.

You talk about the AIDS research, and I am taking a little liberty here, so forgive me. The AIDS research moneys that are being spent are huge. I don't fault them for giving that money to AIDS research. I think it is important. But autism is equally important. Because they have been very outspoken in the AIDS community, they have gotten a great deal of results from the health officials of this country, and from the Congress, and from the administrations, $700 million; I believe it was pretty close to that. If we had that kind of money being given for autism research, we could probably get a lot more accomplished.

So write your Congressmen. Don't write me. I am already on board. [Laughter.]

But write your Congressman and write the White House and Senators and tell them that you want something done.

Dr. Weldon. Mr. Chairman.

Mr. Burton. Yes?

Dr. Weldon. Could you yield to me on this issue?

Mr. Burton. I will be glad to yield.

Dr. Weldon. Just for a minute?

Mr. Burton. Sure.

Dr. Weldon. I was going to say this in my question period. If you add up--comparing to AIDS is a good thing because the prevalence is somewhat similar. It is estimated 500,000 to a million with autism and there's 500,000 people with AIDS, about 900,000 if you add AIDS and HIV-positive status.

If you add up the money that is spent by NIH, CDC, Medicare, Medicaid, the housing money, the drug money, the Federal Government is spending $12 billion on AIDS. That is why I refer to this as a forgotten disease. You know, Mr. Grossman,

you laid out a really nice strategy. I mean it was great. I was really glad to hear you do all that.

You've got a bunch of people here that are going to be foursquare behind you, but you have got to develop a very sophisticated lobbying effort. You are a 600-pound gorilla that has been asleep for years. I can tell you, if you get your act together and start working this town aggressively--and you ought to meet with the AIDS people and just have them brief you on how they did it. I mean, we are going to double the NIH budget, and everybody is going to be out there to take a piece of it: the kidney people, the heart people, the Parkinson's people. But they've already got a big chunk, and the time is really ripe. I apologize for rambling on here.

Mr. Burton. No, that is all right.

Dr. Weldon. You brought it up, Mr. Chairman.

Mr. Burton. It adds to the discussion.

Dr. Weldon. It is a two-way street. You know, you've got to work this town, and you've got to be really slick and really sophisticated, and you've got to put money into it, too. There are a lot of people, NFL football players, businessmen with money who will write checks, and you've got to hire consultants. You've got to do a whole 9 yards, but you ought to do it because I think you can cure autism. I really do.

Mr. Burton. Thank you, Dr. Weldon.

Mr. Shore.

Mr. Shore. Chairman Burton, I thank you and your colleagues on the Committee on Government Reform for this opportunity to present testimony, this historic opportunity to present testimony on the issue of autism.

I am Stephen Shore and reside in Brookline, MA with my wife Leawee, where I am completing a doctoral degree in special education from Boston University with an emphasis on helping those with autism reach their fullest potential. I am the author of ``Beyond the Wall: Personal Experiences with Autism and Asperger's Syndrome,'' consult internationally for autism-related issues, teach college-level courses in special education at both Boston University and Lesley University, as well as work with people that have autism. I am very fortunate to be leading a fulfilling and productive life.

Most of us here today have involuntarily been inducted into this community by the autism bug. What happens? A child is born and develops typically until 18 to 24 months, suddenly hit with a bomb that spreads its shrapnel from the child to the family, to education, the community, and humanity at large. The child loses verbal ability; withdrawal from the environment occurs. We often see self-abusive and self-stimulatory behaviors, tantrums.

I was hit with that very same bomb at age 18 months with all those wonderful characteristics that we see going with it. Despite the claim of being too sick to work with and

recommendations for institutionalization by diagnosing professionals, it was my parents that were left to provide the needed early intervention, and this was at a time when that term had yet to be conceived. We are talking about the early mid-sixties. My parents had no support.

However, fortunately, my mother was able to stay home all day and provide the equivalent of what is known today, or would be known today, as a home-based early intervention with an emphasis on music, movement, sensory integration, narration, and imitation--to at first make me aware of her presence, and then to coax me out into her world. I was very lucky. Parents and educators, we need to listen to the parents. They are the experts on their children.

At this time I am before you as I continue my quest to help those with autism and Asperger's disorder lead fulfilling and productive lives. I continue to struggle with the residuals of autism. While the uniform of a suit and tie that we find in government and business may be a mere inconvenience to most people, it is a major sensory violation for me. However, helping my peers on the autism spectrum is way more important than my discomfort.

I am very lucky and the rare exception of a child with an early autism spectrum diagnosis. Here in the United States of America, the wealthiest, most powerful Nation on Earth, everyone on the autism spectrum has a right under IDEA to receive critical services throughout their lifespan tailored to their needs. This should not be a matter of luck or debate, but it is a question of how.

These are some of my observations. As board president of the Asperger's Association of New England, board member of the Autism Society of America, Unlocking Autism, and other national autism-related organizations, I see many others with autism spectrum disorder who are vastly underserved: toddlers not receiving vitally needed early intervention and school age children in need of professionals educated in how to interact with those on the autism spectrum.

We desperately need more educational research. Today we know very little about the interventions that are effective with individuals with high-functioning autism and Asperger's syndrome. The implications are enormous. So many of my peers living far below their potential, homelessness, other substandard living conditions, unemployment, and serious underemployment are all too common.

People with high-functioning autism and Asperger's syndrome need to be taught more how to interact successfully with the environment and people around them. Until medical terminology can answer the questions it is pursuing, we have thousands of individuals who are exposed to educational interventions that are not validated or, perhaps even more tragic, not exposed at all because the educational community doesn't know what to do.

We have some literature that supports best practice for people with moderate to severe autism spectrum disorders, but the same cannot be said for individuals with high-functioning autism and Asperger's syndrome. We need to look at the academic, cognitive, developmental, behavioral, social, sensory, and other interventions.

As was mentioned before, the CDC estimates that 1 out of 250 children have autism right now. What are we going to do in 10 to 15 years when they become adults? This number, 1 in 250, is actually much greater if we look at the people that are affected by autism. What do I mean by that? We are talking about the family. One child has autism. We have other siblings. We have parents, grandparents, other relations, friends. Funds devoted to research and early intervention now will pay huge dividends later.

But what about the adults? There is very little literature on this population also. What happens in the Commonwealth of Massachusetts where I live is we see people with high-functioning autism not being served by the Department of Mental Retardation because they have an IQ over 70; thus, they are not considered as having retardation. The Department of Mental Health says autism is not a psychiatric disorder, so they don't get services from the Department of Mental Health. As a result, they fall in the crack, a big crack, and don't receive services at all, and similar situations exist in many other States also.

What I have described, and what has been talked about by you, by Lee, by Ms. Lerner, is a national emergency. They were talking about up to 1.5 million individuals in the United States having autism, and the numbers are rising. The U.S. Department of Education, the California Department of Developmental Services, and others, ASA, estimates autism is growing at a rate of 10 to 17 percent annually. We are talking about a rate of 100 to 400 percent over the next 10 years.

If we look at the Mind Institute, they estimate that the conservative cost of a lifetime of care, and here we are talking only transportation, day services, and residential care, for every person with autism is $2 million. Multiply that by 1 million and 1.5 million, and that doesn't even begin to express the opportunity cost of lost wages and other contributions to society such as charitable work and even playing in musical ensembles. Every one of these persons must be given the same chance that only a select few, often due to luck, have had to succeed in life.

I would like to close with several concrete recommendations. One is let's work with the Autism Society of America by supporting their funding request and in developing legislation regarding the autism spectrum, including implementation of the National Research Council's Educating Children with Autism Report recommendations.

Two, immediate and abundant funding for research and

education of those who work with people having autism.

Three, fund fellowships to increase the number of skilled medical doctors, teachers, and other professionals in working with people in the autism spectrum.

Four, mainstream autism as it relates to insurance payments. We are dealing with a medical neurobiological condition, and not a psychiatric one, and, thus, should not be constrained by policy limits that we see on mental health coverage.

Five, standardized payments for recognized methods of interventions across the country. It is unfair that some families are placed on long waiting lists, perhaps a year or two, to access coverage.

No one particular approach can be required because different children respond to different methodologies. According to IDEA, we have to provide the child what they need in order to get the education they need. Some sound approaches include, but are not limited to, the Miller Method, Floor Time, Hagashi, Teach, and applied behavioral analysis.

In summary, it is clear that we have some good interventions and treatments for autism in place at this time, but it is a travesty that the quantity and quality of these services are lacking. The NIH needs to work with organizations such as the Autism Society of America in developing national policy for people within the autism community, so that all those having autism have a fair shot at leading fulfilling, productive, and independent lives to the limits of their capacities.

Mr. Chairman and members of the Committee on Government Reform, your providing this historic opportunity to present testimony on this issue of autism today is very much appreciated. I know you will do the right thing. Thank you, and I am here to serve you.

[The prepared statement of Mr. Shore follows:]

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Mr. Burton. Thank you, Mr. Shore. Mr. Compton.

Mr. Compton. Good afternoon, Chairman Burton and members of the committee. My name is Doug Compton, and I have been an

advocate for the autism community for 6 years while I was a career scientist studying heart disease. I have recently become the science program director for the Cure Autism Now Foundation. My son, Daniel, who is now 9 years old, has autism.

I won't restate the prevalence estimates. As we all know, they are high, and scientists are debating why these numbers are changing, the extent to which the environmental factors are playing, whether diagnosis is playing a role in the rise, or whether genetics are playing a role in the rise with its interaction with environmental factors.

What I will say is that we still do have hope. Four years ago my family and I came from New Jersey to the Capital to help introduce the Children's Health Act. We came with enthusiasm, and it was a bright day. My son stood at a microphone such as this and repeated his favorite script over and over, and he is still doing that to this day.

During the years between the introduction of the bill and its passage, groups such as Cure Autism Now, the National Alliance for Autism Research, and the ASA formed partnerships to establish genetic resources, brain resources, and alliances with the NIH and other organizations studying autism. Together, we funded research to try to identify the causes from genetics to environment. We have funded brain imaging studies. We have funded animal models and treatment trials. We have closed no doors, as there is still no conclusive evidence as to what causes this thing we call autism, nor are there any universally effective treatments.

We continue to push the research agenda from the private sector, but we need our government to push harder. While there has been a large increase in funding from the Federal Government from $5 million to $30 million a year, this is far from sufficient. It is not commensurate with or ambitious enough to address the depth of the human suffering and of the economic hardship which the disorder is placing on affected individuals.

The formula by which specific funding is allocated by the NIH is a mystery to us. Far more money is spent on diseases, as you said, which affect fewer people. We understand that the NIH has to follow the scientific opportunity, but we ask that decisions be linked directly to the real costs to society. We invest vastly more money in Alzheimer's research, for example, which has a much shorter course between diagnosis and death than autism.

Autism is a lifelong disorder which has no apparent inherent impact on longevity. Children diagnosed today with autism will be an economic and emotional burden to the country for the next 70 years.

Nearly 2 years after the passage of the Children's Health Act, its conditions and goals are far from being met. A recent report prepared by the National Institute of Mental Health in

February of this year contains what we consider to be several inaccuracies. It reports that $56 million is spent each year on autism, and we believe that these numbers are slightly exaggerated due to accounting numbers of dollars that are spent from related activities. We would like to see those numbers put specifically toward direct research dollars that are focused on autism.

We would also ask our friends at the NIH, when they put out these reports, to show us where the numbers are coming from, so that we continue to maintain a relationship of trust and accountability between the public and the Federal Government. We have been told by the NIH to anticipate the designation of two of the five clinical centers mandated by the act this year. Even this small step took a lot of effort on the advocacy groups' part. The casual attitude of the NIH toward autism does not reflect sufficient urgency in our minds. While it was stated in an NIH report to Congress that there would be an increase to $15 million per year for these centers, it became clear that is not going to be happening in the near-term.

We would like to request that more than two Centers of Excellence be designated in this cycle of funding and three to four more in the next cycle, as the law provides for a minimum of five centers. Time is of the essence. We realize that scientific and medical research moves forward slowly, and I know that from my own experience at the bench. We could double or triple the pace if the NIH were to designate more centers in this cycle now and then an additional number in the next cycle.

I know that there are qualified applicants and centers who are anxious to get started. There have been minor activities by the Federal Government in brain and gene banking, as required by the act, but we expect a larger concerted effort, as described in the legislation.

These brain and gene repositories are vital resources to be able to understand all aspects of the disorder, including the environmental interactions with these factors. The advocacy groups have invested substantial dollars in these resources, and we expect a larger effort from the government.

The NIH also needs to increase its intramural programs in autism. We have been trying, since the beginning at CAN, to develop field-building in which we recruit heavily at major national neuroscience meetings to try to bring people to the field of autism. I know that the NIH recognizes this and is supporting intramural programs, but we believe that it is very important that be one of the goals of the NIH, to develop scientists who are maybe working in labs alongside with the NIH, who are actually working on autism and don't realize that they are because this is a complex disorder that affects many biological systems in the body, including the GI tract and the immune systems.

The Children's Health Act mandated that physician and

public education programs be developed to allow for earlier diagnosis and intervention. It is well established that this is currently the most effective means of changing a child's course on the catastrophic course and possibly creating a productive, independent person. The Department of Health and Human Services has failed to move these programs forward.

In New Jersey the advocate groups came together and funded a program called First Signs, which we launched last year at the Autism Caucus. It has been piloted in New Jersey and seems to be successful in training doctors.

It is unacceptable that 49 States do not have a formal mandated training and education program for doctors and the public. People are losing precious time. We lost lots of time with my son because no one knew what he had.

Finally, we have heard that the CDC, also as part of the Children's Health Act, has been prevented from fulfilling its prevalence research studies due to the Family Education Rights and Privacy Act. They have been working with the Department of Education for over a year to allow access to the education records that hold diagnostic information. We think that should be able to be resolved so that the CDC can be allowed to do their job.

The passage of the Children's Health Act was an incredible first step in changing the course of this disease, and the parents want to thank Congress for this. There is great momentum, but it will take much more effort and money than the not-for-profit advocacy groups could ever hope to sustain. We ask Congress to continue to lead us forward and for the NIH and CDC to show leadership in autism.

My son still has autism, of course, and so do hundreds of thousands of other Americans. They need our government agencies to be responsive.

I would like to close by thanking the members of the committee for listening to us and for acting on our requests.

[The prepared statement of Mr. Compton follows:]

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Mr. Burton. Members of the committee, we are going to have a vote in about 10 minutes. So what I will do is I will yield to you right now for questions, and then I will stay here. Then I guess, Dr. Weldon, if you can come back and take the Chair, so I can rush over and vote, and then we will keep the hearing going, if that's all right with the vice chair.

So let's start with you, Mrs. Morella. Do you have any questions? I will ask my questions while you guys are running

over to vote.

Mrs. Morella. I was not the first to arrive here, if you want me to yield to Mr. Horn.

Mr. Burton. Let's see, I think Dr. Weldon was the first to arrive. So we will start with Dr. Weldon then. Then we will go to you, Mr. Horn. Is that all right?

Dr. Weldon. Thank you, Mr. Chairman.

Mr. Grossman, the agenda that you put together, could you just tell me a little bit about how you came to those recommendations? You had some figures in there. Did you have a committee that helped you work on that?

Mr. Grossman. These figures were actually put together in-house at ASA. We have been inundated recently by numerous media in the United States, as well as in Europe, to support the data about explosion in the prevalence of autism. We were challenged to find any good studies or any information out there. We reviewed extensively all the literature that we had available. We put it out to many people that are on our panel of professional advisors, other consultants that we know, professionals in the field, to provide us with information that would support the data, show some meaning to the statistics that we feel we need to support showing this increase.

Frankly, there is nothing out there. There are no good studies. This is all anecdotal evidence. So basing what we know on the ranges that exist that are commonly being bantered about and accepted, we put together a formula of approximately what it would take to fund at this point the research.

If you are specifically addressing the research and like the $500 million, for example, we are looking at the cost of autism, which is, we conservatively say, $20 billion annually. That is based on what we figure is the prevailing--the numbers, conservative numbers, of a half million times about $40,000 per person for treatments per year, which is actually a low figure.

Dr. Weldon. Did you have any professionals help you put this together? Tell me a little bit about ASA. How many members do you have and how many staff?

Mr. Grossman. There's 200 chapters throughout the United States. We have approximately 25,000 members throughout the United States. We have a panel of professional advisors made up of about 20 experts in the field. Our membership extends beyond the 24,000. We don't exclude anybody that has an interest in it. Our office here is located in Bethesda, MD. We have a staff of, I believe, seven people.

The committee was made up of staff and people on our board, as well as professionals that we were consulting with. We would gather the information, extend it out through conversations, and then come back to put that information together.

The $500 million, it is, to be frank with you, a drop in the bucket compared to really what needs to be done to address this. It is what we felt was a conservative number to approach

the government with.

We feel also that much has to be done. That is why there is a 3-year ramping up of those figures, because the infrastructure of what is available today in America to support autism research is not there. It needs to be developed to get us to that point.

Dr. Weldon. I am glad you raised that point because this is one of the issues I have gotten into with the NIH. I was very pleased that Mr.--is it ``Mr.'' or ``Dr.'' Compton--Mr. Compton, he alluded to this issue, that if we were somehow able to get an appropriation through this year for $500 million, the NIH would be really hard-pressed to find a way to spend that much money. There are not a lot of people prepared to do the research studies.

I don't recall, did you say anything in your recommendations about behavioral treatment at all? I know we need to do a lot of basic science treatments in terms of the pathophysiology and preventions, but dealing with all of these older kids and adults, it seems to me there is really not a good body of knowledge. Some of it seems to be emerging.

Mr. Grossman. Yes, I mentioned in my testimony that virtually it is nonexistent today, the research that is going on on the therapeutic aspect or the treatment aspect of autism, and we specifically ask for a ramping-up over the next 5 years to a level of about $100 million, based specifically on the behavioral treatment, therapeutic, clinical aspects of autism.

Dr. Weldon. I am running out of time. I have one more question. Your health insurance policies cover virtually nothing, correct? You get a diagnosis of autism. Your typical Blue Cross/Blue Shield, whatever, they will not cover any types of therapies, treatments whatsoever, correct? So these families are literally on their own? It is all out of pocket?

Mr. Grossman. Yes, essentially, it is all out of pocket. The only avenue that is available to us is services provided to us by the educational system.

It is funny that you brought this up because that is an important issue that we are grappling with on the insurance that would require a full hearing on its own. Recently, California was able to pass legislation mandating that developmental disabilities, and specifically autism, be covered under the medical insurance plans in that State.

Dr. Weldon. Thank you, Mr. Chairman.

Mr. Burton. Mr. Horn.

Mr. Horn. Thank you, Mr. Chairman.

I have been very interested in what you had to say, and there is a few simple things I need to know. Is it Asperger's? What is this disease?

Mr. Shore. Asperger's syndrome.

Mr. Horn. Asperger's. Could you tell me the difference between autism and that? I see in our lists here that, after

Mr. Shore's bit, that he is a doctoral candidate at Boston and also has Asperger's disease, sometimes known as high-functioning autism. I would like to just get a feel for what is that particular part of this.

Mr. Shore. Well, the major difference between autism and Asperger's syndrome, we talked about the autism spectrum, ranging from severe to light. At the severe end that is what we consider the classical canner's autism. That is what most of society thinks of children with autism. These are the children that we see being nonverbal, having tantrums whenever there is a change in the environment, perhaps being self-abusive, a strong, you might say, or severe lack of body-to-environmental awareness.

As we move to, say, the moderate part of the spectrum, we have more environmental awareness. These children have more receptive language abilities. So they understand more than they can speak. They may be considered being limited verbal, perhaps having one or two-word phrases and not very many of them.

At the high-functioning end, and Asperger portion of the spectrum, that is the lightest end of the spectrum, and we actually see more people over there than at the severe end. These children, particularly with Asperger's syndrome, according to the DSM-4 revised, they don't have any delay in communication, but the issues of socialization--I should say verbal ability. There are still difficulties in communication. So we see major issues in communication, socialization, restricted interests, and repetitive motions.

Now when we move to Asperger's syndrome, these are the children that strictly, according to the DSM-4, have never lost their verbal ability. Applied a little bit more loosely, these are children, to need to be specific, who had have verbal ability until 18 months, the bomb hits; we lost verbal ability and we get it back. So usually by around the age of 4 or 5 or so, maybe 6, the verbal ability is back. It is pretty much at the level of most other people, but the language is used, you might say, in a unique way and there is often difficulties with dealing with abstract subjects, you might say reading between the lines, which translates to difficulties in being able to determine what other people's intents are, if it is not spoken in a very concrete, clear way.

The important thing to keep in mind, though, is that with both autism and Asperger's syndrome the issues are coming from the same place. You are still dealing with the communication issues in one way or another. The most severe end, lack of verbal ability; the lighter end, Asperger end, verbal ability, but difficulties in dealing with pragmatics or what is between the words, you might say.

You still have restricted interests, special interests they are called, as Tony Oustwich talks about them, interests that are so strong that they actually interfere with daily

functioning. What the current educational--what people are beginning to learn in education is to use these special interests in order to facilitate learning.

Repetitive motions, that is often the self-stimulatory behavior that we see, and an issue that the DSM-4 doesn't cover that I find present throughout the autism spectrum, sensory integration issues. In that case what we are talking about is some of the senses are turned up too high, way too high. I know people on the spectrum that if they were in a room like this, I would see their eyes vibrating like this, and they would say, ``We've got to get out of here.'' Because they actually see the cycling of the fluorescent lights above that screen there. Some senses are up too high, some are too low, and other senses, information that comes in from the senses is distorted or unable to use the information, you might say, in a typical manner that other people would.

Mr. Horn. Mr. Compton, is there anything you want to add to this definition?

Mr. Compton. No, I think that Stephen described it fairly well.

Mr. Horn. So I would be curious about what type of either biochemical, chemical, or whatever, to work on some of these things. Would you work with autism as well as Asperger's approach or are there certain other ways that would call for a different type of scientific approach?

Mr. Compton. Well, I would like to address one of the aspects that Stephen brought up, which would be that, obviously, people with Asperger's who have more communication are more readily, I believe, have their symptoms remediated by behavioral teaching and interventions.

In the area of I think what you are referring to as pharmacotherapy, I would say that we are in the infancy of that. I just returned from an autism clinical trial task force that our foundation held in Los Angeles last week, and I believe to this day there have only been seven well-controlled, double-blind, placebo-control clinical trials in autism. Because we don't know what the underlying neuroanatomical substrates are that are aberrant or the biochemical pathways that are aberrant across the spectrum, it is very difficult at this point to design targeted therapeutics for the disease.

We are still not certain how many disorders are represented under the umbrella of the autism spectrum. I would be certain from the data that I heard last week that certain treatments will actually give serious adverse effects to some patients, increase their hyperactivity and motor stereotypies, cause restlessness, decreased sleep, whereas in another subset of patients we may see improvements with these types of therapies. So I would say that it is too early in the field to generalize about any of this.

When we think about treatments that go beyond the brain to

the GI tract or to immune dysfunction, they we have opened up an even wider area that we need to study. All of this reflects back on the fact that we need to cast a wide net and we need more money, and we need more intramural programs, because despite the fact that we have made tremendous progress in the past 5 years through a lot of the advocacy groups funding research and the NIH's efforts with the CPEA programs and the newly funded research, we are far from having any clue as to how to develop effective therapies.

Mr. Horn. Do you feel like the report to Congress is an accurate representation of what is happening in autism research?

Mr. Compton. Well, I would say, I was talking with Dr. Foote before this, and we don't have a line-by-line itemization of each dollar that is spent, but when we look at the directed programs, which we are very happy that money is being spent there, we don't see it add up to $56 million. Now that can be due to something that as a scientist I firmly agree that we need to field-build and we need to fund research in other areas, but in the autism community I believe that we need to focus on autism. When there are basic research questions being addressed which could include development of brain imaging techniques or genetic techniques, or what have you, for those to be lumped under the category of spending on autism, if in fact that is being done, I'm not certain if that is being done, but we do see an inconsistency that could be explained by this phenomenon. That is acceptable in the sense that the intramural researcher, if it is being claimed as being money spent on autism, that the intramural researcher is actually doing autism research or at least collaborating with a researcher who is doing autism.

I would suggest, if possible, that there be a detailed report from the Public Information Officers, so that we would feel as a community that there was an open dialog on this issue.

Mr. Burton. Mr. Horn, can we go to Mrs. Morella, and we'll come back to you in just a moment? We are going to have a vote here, and I want to make sure she has an opportunity.

Mr. Horn. I have got to dump some stuff off for later things, so I will try to come back.

Mr. Burton. That would be fine.

Mr. Horn. OK.

Mr. Burton. Mrs. Morella.

Mrs. Morella. Thank you, Mr. Chairman.

I think as people who are here assembled probably know, you have had a real commitment to try to unlock those secrets of autism. Had I thought about it earlier today, I would have worn my autism ribbon, which is puzzle pieces, you know, seeking to come together, but they have yet to do that. But we on this committee have been seeking the data, wanting to know more

about what studies are being conducted, and are rather frustrated about the fact that so much needs to be done and has not been done yet. That is the purpose of the meeting. So I thank you for this hearing, Mr. Chairman, and for your commitment.

Mr. Grossman, you probably know that I represent Bethesda, MD, where ASA is located, very proud of the fact that is your national headquarters.

Mr. Shore, I am a graduate, as is my husband and a couple of my kids, of Boston University. I congratulate you on pursuing doctoral studies, and I thank Mr. Compton and Ms. Lerner for being here.

Also, I represent the National Institutes of Health, and I am very proud of the work that they do, and I am very proud of the fact that in the budget that we approved on the House side, and the President submitted, there is like a 16 percent increase for NIH, which is going to bring it to that 5-year plan of having doubled the budget of NIH during that 5 years, by 2003.

Now the question I want to ask all of you, or however time will allow, is: NIH is going to be at the table right after you. If you had a chance to ask them a question or if you had a chance to say to them, ``How do we work together''--I mean, are they providing information? Is there a partnership? Does there need to be more of
a partnership? I know their intent is very good. So it could be that you want to say something for the record and that you would like to ask them something or make a suggestion.

I would like to start off with you, Mr. Grossman.

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

[GRAPHIC] [TIFF OMITTED] T0356.041

[GRAPHIC] [TIFF OMITTED] T0356.042

[GRAPHIC] [TIFF OMITTED] T0356.043

[GRAPHIC] [TIFF OMITTED] T0356.044

[GRAPHIC] [TIFF OMITTED] T0356.045

[GRAPHIC] [TIFF OMITTED] T0356.046

Mr. Grossman. The relationship that ASA has developed with NIH over the last year has been very, very positive. The communication has been----

Mrs. Morella. I would add CDC, too.

Mr. Grossman. Right, and the CDC has been very, very positive. There's been much communication between us in terms

of us addressing our concerns with them, and them providing us answers to those issues.

I am the representative on the Interagency Autism Coordinating Committee also, which is a forum which started, our first meeting was in November, which summarizes at that first meeting all the activities of the Federal agencies and will be an organization or committee going forward that, hopefully, will be coming forward with more suggestions.

In looking at the report to Congress, for example, which describes in detail what NIH and CDC is doing, it is pretty much I believe they have been mandated at this point to do. What we would need to do, and I don't have any specific suggestions for them at this point, is that we need collectively, the autism community, as well as the legislative branch and the administration, needs to provide them with the resources that they need specified for autism to expand their research efforts, to expand the service delivery.

This incorporates a much broader base than just those two agencies, NIH and CDC. This is a national emergency. It has reached epidemic proportions. It is not only a two-Federal agency issue. It is a national issue, and we need to bring it forward as such.

Mrs. Morella. Would any of the other panelists like to respond to that? Yes, Mr. Compton?

Mr. Compton. Yes, I would like to respond. Despite the fact that I may have sounded critical about the NIH, I am absolutely thrilled with what has been going on since my son was diagnosed. When I first went to my first meeting and I saw Dr. Bristol Powers speak, I was very impressed, and I still maintain tremendous hope.

I think that the NIH and its subdivisions, the NIMH and NICHD, etc., and the CDC need more money. It may sound ridiculous, but $56 million is not very much money when you look at the vast number of systems that are affected in autistic individuals.

Beyond the medical research, at a biological level, there is a need, for instance, to develop protocols, to measure outcomes in clinical trials, and it does not just mean clinical trials of pharmaceuticals or interventions. It means clinical trials of educational interventions, which need to be held to the same degree of scrutiny. A lot of families are wasting money on therapies that are not biologically based, which are probably also not helping their children.

I would like the NIH to break down any of the barriers among the agencies and try to promote as much collaboration as possible. When it comes down to it, I think it is all about money and the prioritization and, as we talked about earlier, the way that decisions are made to weigh the cost of the disease to society versus the cost of investment. I think that needs to be looked at critically, and to develop the intramural

programs such that there is true focus of related fields to this disease. It not only gets you more bang for your buck, but creates the cross-talk and the collaborative environment that I think is going to be necessary to correct the situation.

Mr. Shore. I have something to add. I think it is a great start. We need more. We need more work on collaborating, and I see a lot of in-fighting between the autistic community. If we just look at educational interventions, like some of the ones that I have named, there is no--I haven't found any study where anyone who has taken a serious look at comparative methodology. What I find in looking at the different methodologies such as the ones I have listed, a lot of them are doing similar things, but they are calling them different names.

Also, because of such wide differences in people with autism, it is a wide spectrum. There are some children where a particular method works much better than another method. I would like more research. Actually, that is going to be part of my doctoral dissertation, but that is just a start. I am just going to validate the instrument.

What I am talking about is something that will be able to allow us to match the child to the method, because at this time it is a bit like the Keystone Cops: ``Oh, this method is the greatest; that's all there is. The other methods aren't worth even thinking about.'' We should be kind of ashamed of that. We should all be working together and corroborating.

Mr. Compton's suggestion of outcome studies, they are very, very important, longitudinal studies, hard to do, but we need them.

Mrs. Morella. Thank you. You have all been very helpful in responding to that question. Thank you, Mr. Chairman.

Mr. Burton. Thank you, Mrs. Morella.

One of the things that has concerned me has been the large incidence of autism being created, I believe, by things like thimerosal, which includes mercury in that preservative. In Russia, in the 1980's, they recognized problems. As a matter of fact, we just got a letter that we received this week from a professor of medicine at the Academy of Medical-Social Management in Russia, and this letter details the history of concern about thimerosal in vaccines and injury. This is a concern, as I said, that reaches back to the eighties.

I would like to specifically note that Dr. Krashenyuk states, ``starting vaccination against hepatitis B of premature infants at age 2 months . . . when they reach a weight of 4 kilograms is recommended in the U.S. From our point of view, this practice is undoubtedly harmful, since it does not take elementary notions of the infant's immunity into account--up to 1.5 years of age the infant does not have its own immune protection, and is protected only by the mother's passive immunity.'' And then he goes on to say, ``It is impossible today to deny the fact that this preservative,'' thimerosal,

``can cause severe post-vaccination complications in children.''

[The information referred to follows:]

[GRAPHIC] [TIFF OMITTED] T0356.047

[GRAPHIC] [TIFF OMITTED] T0356.048

Mr. Burton. That same conclusion has been reached in countries like Norway, Sweden, and Denmark has not allowed any thimerosal in any of their vaccinations since 1990.

Was there any connection when your children became vaccinated and the onset of the autism? Did you notice it in close proximity? Any of you at the table?

Ms. Lerner. Not me personally, but I can tell you that, because of the controversies surrounding the MMR, I was very concerned when my son had to get his second round of vaccinations. So in New York State they allow you to get a titers test to determine what the immunization level is for the child and whether or not it necessitates a second vaccination. As a result of that blood test, it showed my son still had very high levels of the immunity in his system, which led me to believe that, for whatever reason, based on his neurology, he was not able to properly metabolize the original vaccination that he got. Now Ben's symptoms date back to, I think, infancy, but there is demonstration that obviously, based on their compromised neurology, that they can't process these vaccinations in the same way.

Mr. Burton. In the audience, how many have noticed a change in your child after the vaccinations?

[Significant show of hands.]

Mr. Burton. OK, I just wanted to know that from the audience.

Mr. Grossman. Mr. Chairman, if I can comment on that?

Mr. Burton. Yes, sure.

Mr. Grossman. Personally, I didn't recognize any change in my son. We knew something was wrong, and it was about at the time that he would have received his vaccination, but it took us a while before we figured things out. It actually was my sister, who is a practicing psychologist in Philadelphia, that took a trip with him to the mainland, and she noticed that I had to get some interventions for him, something was terribly wrong, and she threatened to take my son away from me unless I did.

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

lay public, to stand together to get this question answered, answered immediately.

We are perhaps creating generations of children that are severely getting injured through vaccinations. We don't know that, but there is a growing body of evidence such as what you are reporting from Europe that really draws into question what is going on. So whatever is necessary from you to give us direction on what we need to do, we will support that.

Mr. Burton. How many members? You said you had 25,000 members in your organization?

Mr. Grossman. 25,000 members, and we have an extended membership of people that are signed up as advocates that actually don't pay a membership. Our reach, we believe, extends into certainly 50,000 to 60,000 people at any one time.

Mr. Burton. Now the organization that you are connected with, Ms. Lerner, how many members do you have? Do you know?

Ms. Lerner. It is hard to actually quantify that because we are an umbrella organization, and organizations like ASA, CAN, NAR, they are all part of our group. So we would be collectively whatever their membership----

Mr. Burton. So it would be kind of included in the same?

Ms. Lerner. Yes.

Mr. Burton. How about you, Mr. Shore?

Mr. Shore. Yes, the Asperger's Syndrome Coalition of the United States, I believe we have a reach of probably 2,000 to 3,000 by the time the mailing that is rebound all over the place.

Mr. Burton. OK, and your organization?

Mr. Compton. CAN's membership, I am not sure if the membership is completely autistic, for autistic families, runs at about 35,000.

Mr. Burton. Around 35,000? Well, somewhere between 60,000 and 100,000 people can be reached by your organizations, and I am sure there are other organizations here that I am familiar with. I would like to just restate one more time what I said earlier. That is that the squeaky wheel gets the oil in this town.

I cited the amount of money that is being spent for the various research projects including AIDS and diabetes, and so forth, and the comparison of that with the money that is being used for autism research. We are going to be funding at a much higher level research at NIH in the coming years, and this is the time for you to be proactive.

I cannot stress enough how important it is, and I will be doing my part here as well, and other Members will, to contact your Congressman, your Senators. Don't just write to one; write to them all, if you can, in your State, and make sure and tell your members, make sure to tell them how important it is that there be an increase and an adequate amount of funding and the proper research into rehabilitation for children and

prevention, to make sure that we find out what is causing this, not just possibly things like mercury in vaccines, but other things, maybe other toxic substances that may be in the vaccines, maybe mixing too many at one time. The immune system might not be able to handle that much. Maybe it is the MMR vaccine. I don't know what all the circumstances are, but that research needs to be done, and it is going to cost money. It is going to take pressure to be exerted from folks like you folks.

Yes, go ahead.

Mr. Waxman. I want to join you in supporting more research because there is still so much we don't know about autism. We do not know how prevalent it is. We need to do the research in order to understand what the actual prevalence of autism is and whether the increases in cases is due to better diagnosis or to environmental causes that can be prevented, or some combination of factors.

We also don't understand the causes of autism, nor do we have a cure. That is why Congress enacted the Children's Health Act of 2000. This act, which I strongly supported, increased funding for autism research. But we need to do more than wait for the research. The National Academy of Sciences has made it very clear in a report last year that early intervention is critical for educating and treating autistic children. It is incumbent on the medical and educational communities to identify children in need of services as early as possible, and it must be a high priority for Congress to assure that all children with developmental delays, including autism, have access to scientifically proven treatment and educational services that can maximize their potential.

I appreciate the contribution of all the witnesses who have testified at these hearings and educated us about what it is like to live with a child with autism or to live with autism themselves. I want you to know that the experiences you have recounted are part of the record. They will be shared with our colleagues, and they are going to have a genuine impact.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Henry A. Waxman follows:]

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[GRAPHIC] [TIFF OMITTED] T0356.050

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Mr. Burton. Thank you, Mr. Waxman. We do appreciate what you have done in the past to help in this area.

Let me just say to this panel that we really appreciate your testimony. We hope you stick around to hear what the NIH

people have to say and the people from our health agencies.

We are going to take a brief recess here. Dr. Weldon will start the hearing, and I will be back as soon as I get a chance to vote on the floor.

We stand in recess at the fall of the gavel.

[Recess.]

Dr. Weldon [assuming Chair]. Chairman Burton asked me to reconvene the hearing.

So I would like to again convey his thanks to the first panel, and I would like to ask our next panel to come forward and take their seats.

The committee will now resume. On the second panel we have Dr. Steven Foote, Director, Division of Neuroscience and Basic Behavioral Science, National Institute of Mental Health, at the National Institute of Health, and Dr. Coleen Boyle, Associate Director of Science and Public Health, National Center on Birth Defects and Developmental Disabilities. And we have a third panelist, is that right? You are going to accompany Dr. Boyle, OK. And your name is?

Ms. Wharton. Melinda Wharton.

Dr. Weldon. OK, could you all please rise?

[Witnesses sworn.]

Dr. Weldon. Let the record indicate that the witnesses indicated in the affirmative.

I want to thank the panelists for being here. I would ask you to try your best to summarize your comments to approximately 5 minutes, and we will begin with you, Dr. Boyle. Please proceed.

STATEMENTS OF COLEEN BOYLE, ASSOCIATE DIRECTOR FOR SCIENCE AND PUBLIC HEALTH, NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY MELINDA WHARTON, DIRECTOR, EPIDEMIOLOGY AND SURVEILLANCE DIVISION, NATIONAL IMMUNIZATION PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION; STEPHEN FOOTE, DIRECTOR, DIVISION OF NEUROSCIENCE AND BASIC BEHAVIORAL SCIENCE, NATIONAL INSTITUTE OF MENTAL HEALTH, NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ANN WILLOUGHBY, DIRECTOR, CENTER FOR RESEARCH FOR MOTHERS AND CHILDREN, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Dr. Boyle. Good afternoon, Congressman Weldon and members of the committee. I am Dr. Coleen Boyle, Associate Director for Science at the National Center on Birth Defects and Developmental Disabilities at the CDC, and I am accompanied by Dr. Melinda Wharton, who is the Director of the Epidemiology and Surveillance Division at the National Immunization Program at CDC.

First, I would like to thank you for the opportunity to

update you today on CDC's activities related to autism that have occurred during the year since your last hearing. I would also like to thank the parents, the autism advocacy groups, and Mr. Shore for sharing their concerns with us about autism.

The committee requested that CDC testify about the problems of autism and what we know about the apparent increase in rates. We were also asked to discuss the timeline for implementation of the research recommendations from the IOM evaluation of the autism vaccine-related issues as well as CDC's funding for autism research. We are prepared to discuss these issues.

The committee also requested that we address research efforts conducted by the CDC into treatments for autism spectrum disorder. CDC has not conducted research into the treatment of autism spectrum disorders since the NIH is the agency responsible for such clinical research.

Last year I told you about the report of a prevalence study that has already been mentioned today in Brick Township, NJ. That investigation found rates of 6.7 and 4.0 per thousand children for autism spectrum disorder and for autistic disorder, respectively.

This year we can report on the prevalence of autism spectrum disorder in the metropolitan Atlanta Disabilities Program. This report shows a prevalence of autism spectrum disorder of 3.4 per thousand children, as you have already heard. We believe this to be a minimum prevalence and that most of the cases that we have included are actually autistic disorder. In general, the Atlanta rate is similar to that which we found in Brick Township. We cannot determine whether the rates are increasing or not because we don't have comparable data from earlier years, but we will continue to monitor the current rate closely.

We can also not yet generalize for a prevalence for the U.S. population. The population in Brick Township was very small, about 9,000 children, and the population monitored in metropolitan Atlanta is much larger, close to 300,000 children, but we cannot assume that is representative of the U.S. population. Determining if there are regional differences in autism prevalence really requires data from other regions of the country.

To address this need, we have implemented a State autism monitoring program. In fiscal year 2000 we funded five States to track autism. In fiscal year 2001 we funded four Centers on Autism and Developmental Disabilities Research and Epidemiology for the purpose of not only collecting prevalence data, but for conducting collaborative epidemiologic studies to try to begin to identify causes and preventable risk factors for autism.

With these programs, plus the one that CDC runs in Atlanta, we have now nine States involved in monitoring the prevalence of autism. With the new funding that we have received in fiscal

year 2002, we expect to add at least three programs, bringing the total up to 12 States that will be tracking autism prevalence.

Monitoring the prevalence of developmental disabilities such as autism provides a number of challenges, including identifying proper sources for case information. Unlike birth defects that are more easily identified in the first year of life, developmental disabilities are diagnosed later in childhood and may require nontraditional sources for public health monitoring.

Collecting data from these sources has proved challenging. CDC will continue to work with colleagues in other agencies to try to address this important issue.

In 2000, CDC and NIH contracted with the Institute of Medicine to establish an independent expert committee to review the hypotheses about existing and emerging immunization safety concerns. Some researchers have suggested that the receipt of either the MMR vaccine or thimerosal-containing vaccines has been associated with various neurodevelopmental disabilities, including autism.

The IOM was asked to review the available information on these issues. In the March 2001 IOM report regarding the association between MMR vaccine and autism spectrum disorder, the committee concluded that the evidence favors rejection of a causal relationship at the population level between the MMR vaccine and ASD.

In October 2001 the IOM Immunization Safety Committee published a report on the possible association between thimerosal-containing vaccines and neurodevelopmental disorders. In this report the IOM concluded that the evidence is inadequate to accept or reject a causal relationship between exposure to thimerosal vaccines and the neurodevelopmental disorders of autism, ADHD, and speech and language delay.

In these reports IOM also made specific recommendations for a number of epidemiologic studies. The CDC has initiated a broad range of studies to better assess these findings as well as to address recommendations by the IOM Immunization Safety Review Committee. These studies are discussed and detailed in my written summary.

CDC remains committed to collecting accurate data on the prevalence of autism and to conducting studies to find its causes. We want every child to be born healthy and to grow and develop normally, so that they are able to lead productive lives. We are dedicated to continuing our work to identify what causes autism and how it can be prevented.

We appreciate your attention to this problem and we look forward to working with you, Dr. Weldon, and other members of the committee.

[The prepared statement of Dr. Boyle follows:]

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Dr. Weldon. Thank you very much, Dr. Boyle. We will now hear from Dr. Foote. You may proceed.

Dr. Foote. Dr. Weldon, members of the committee, I am Dr. Steve Foote, Director of the National Institute of Mental Health's Division of Neuroscience and Basic Behavioral Science. Entering on cue is Dr. Ann Willoughby, Director of the Center for Research for Mothers and Children at the National Institute of Child Health and Human Development, who is accompanying me today.

The sustained attention that this committee has directed to the issue of autism research has helped to focus and accelerate our efforts at NIH. I appreciate the opportunity to talk with you about NIH support of research on autism. I am a neuroscientist who has been interested in the brain and its disorders throughout my career. Like others, I have found autism to be a particularly challenging mystery.

My view of this disorder has been broadened and deepened recently by my continuing interactions with family members of children and adults with autism. I feel their urgency. An affected child cannot wait for research before growing up. Each day, each potential improvement is crucial.

I would like to acknowledge the important role of family and advocacy groups in our efforts. They have not only raised the visibility of autism and challenged assumptions, they have

pushed for accelerated and expanded research activities.

Today I would like to report on progress that has been made at NIH. Only a few years ago research on pervasive developmental disorders, the autism spectrum disorders, was fragmented and distributed across NIH institutes and other agencies with little coordination. Today a more integrated, but still appropriately specialized approach is in place.

The basic research on autism that is sorely needed is moving forward at an accelerated pace, as is continued genetic research and studies of the etiology of various symptoms, such as communication disorders. I am a witness today because I play several roles in this integration and overall comprehensive planning. I am the Interim Executive Secretary of the Department of Health and Human Services' Interagency Autism Coordinating Committee that was created under a provision of the Children's Health Act of 2000. In addition, I serve as a scientific program staff member of the NIH Autism Coordinating Committee, a longstanding body that serves to coordinate research efforts within the NIH.

We have made much progress in implementing the provisions of the Children's Health Act of 2000 that focused on NIH research activities. The act authorized augmentation of autism research activities at the National Institutes of Health and the CDC.

First, with regard to the Interagency Autism Coordinating Committee, the Secretary of the Department of Health and Human Services delegated to NIH the authority to organize the IACC, and NIMH was asked to lead this effort. The IACC has already begun to enhance communication and effective interaction among the several agencies that support or conduct autism-related research, service, or educational activities, and it will engage family and advocacy groups.

The NIH Autism Coordinating Committee has continued to act within NIH to allow program scientists and directors of the relevant institutes to come together to plan and conduct research, and it communicates closely with the IACC. The inaugural meeting of the IACC was held in November 2001 on the NIH campus, and it included the public members selected by the Secretary. Lee Grossman, for example, was one of the founding public members of that committee. The date of the second meeting has been set for next month, and we are on schedule, as stipulated in the Children's Health Act, to have twice-a-year meetings of that committee.

In terms of accelerated and expanded research activities, NIH issued a Request for Applications to implement on a fast track the requirement for new Centers of Excellence Programs for autism research as specified in the Children's Health Act. An RFA is a clear statement to the field, setting aside funds, that NIH invites research applications in a particular area. These comprehensive centers are to be called STAART Centers,

which stands for Studies to Advance Autism Research and Treatment.

A number of applications were received in response to this initial RFA. They were reviewed last month, and the successful applicants will be funded this summer. A second round of competition has already been posted. It will close in August of this year, and those successful applicants will be funded in 2003. At that time the full network of at least five centers stipulated by the law will be in place. The five participating NIH institutes have established a funding pool of $12 million per year.

This past year the NIH ACC also endorsed two other RFAs, one for groups planning to submit center applications this year in order to allow them to undertake planning activities, and one for innovative research into treatments for autism.

In addition to these activities, NICHD and NIDCD will competitively renew their longstanding Cooperative Program for Excellence in Autism. This program will expand to be essentially the same size as the STAART program. And in yet another enhancement of the NIH autism research portfolio, NIEHS, in collaboration with the EPA, has funded two new centers focused on autism research.

We at NIH are in a heightened state of awareness concerning the need for more research on autism, due to the clear magnitude of this major public health problem and due to the work of many people within and outside this room, and we have been making progress. As mentioned earlier, our budget for autism research has expanded rapidly over the past few years, more than doubling. The research now in this portfolio, and to be included in the near future, holds the promise of answers not only for children with autism, but also for unlocking the secrets of brain development, what its possibilities are, how it goes wrong, and when to intervene, which will help all children realize their potential.

In summary, NIH is on schedule in terms of implementing the letter and the spirit of all aspects of Title I of the Children's Health Act, including a broadly based increase in autism research support,
the initiation of a new Centers of Excellence Program, the extension of the CPEA Program, the enhancement of genetic and other resources, and the establishment of the Interagency Autism Coordinating Committee.

I would be happy to answer any questions.

[The prepared statement of Dr. Foote follows:]

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Mr. Burton. Thank you, Dr. Foote. Dr. Willoughby, does she have any comments?

Dr. Willoughby. No, sir.

Mr. Burton. You are just there to hold him up if he falls down. [Laughter.]

Dr. Willoughby. He doesn't need it.

Mr. Burton. OK. I would like to put a chart up there. Maybe you can explain this to me. The chart on the comparisons, please, the NIH one. Yes.

I don't know if you can see that. Do you have a slide that you can put it on the slide machine, so that they can maybe see it clearly?

What that says is that, for diabetes, the yellow line on diabetes shows for fiscal year 2003 there's $845 million; in fiscal year 2002, the blue line, it is $781.3 million, and in fiscal year 2001, it is $688.1 million.

If you look at the middle set of lines, that concerns HIV and AIDS. There is $2,770,000,000 in fiscal year 2003; $2,000,515,000 in fiscal year 2002, and $2,247,000,000 in fiscal year 2001.

Then that very last part that is very difficult to see, that shows autism. In 2003 it will be $70 million, and in 2002 it will be $65 million, and in fiscal year 2001 it is $56

million.

Now, according to the statistical data we have, there is about the same number of people who are autistic estimated as there are HIV, and yet the amount of money that is projected to be spent for HIV is going to be almost $3 billion as opposed to $70 million for research. Can you explain that to me? Any of you?

Dr. Foote. Well, I think you know better than I do that these budget figures result from a complex state of affairs that involves not only NIH, but Congress, public health issues, and history. I don't think that I could adequately explain exactly how those numbers came about.

Mr. Burton. Well, NIH, as I understand, they come up to the Hill and they propose to the appropriators, the Appropriations subcommittees, ``The College of Cardinals'' we call them up here, they propose various amounts of spending or spending levels for various things. Can you tell me, in the last 2 or 3 years, how much money has been requested for AIDS research or for diabetes research or for autism research?

Dr. Foote. The short answer is no.

Mr. Burton. Well, could you get that for me?

Dr. Foote. Yes.

Mr. Burton. I would like to know what NIH is asking for.

Dr. Foote. We can obtain that information for you.

Mr. Burton. Now NIH receives unprogrammed, unallocated funds for research, and I don't, how much is that? Do you know how much money that is? Well, it is in the billions of dollars. Can you tell us how the research spending levels are decided over there, the unspecified, unprogrammed moneys?

Dr. Foote. Yes. NIH has several approaches to funding research. One of the largest is to accept investigator-initiated grant proposals, which are subjected to peer review. Priority scores are assigned, and then program officials like myself make final funding decisions and budgetary decisions.

There's a distribution of funds among basic research funding pools, basic research that is applicable to biomedical research. This issue has come up earlier today. For example, as one of the earlier witnesses pointed out, in an area that is relevant to autism, we support a number of studies of brain development, imaging the brain in children, activities that are relevant to understanding childhood disorders like autism or attention deficit hyperactivity disorder. A certain fraction of our funds goes into those basic research efforts. There are other funds that are dedicated, in the case of clinical neuroscience, to efforts to understand specifically brain development in individuals affected with autism, and so forth.

Mr. Burton. Let me interrupt just a minute here. The NIH estimates that now 1 in 250 children born will become autistic between the ages of 3 and 8, I believe. Now that is your estimate. That is NIH's estimate. That is an epidemic. That is

a major, major problem, and yet only $70 million is going to be allocated for research in this area in 2003, and only--what did I say--$65 million this fiscal year. I would suggest that it might be wise to take a look at those unallocated funds and see if more of that couldn't be appropriated or utilized for autism research.

The other thing I want to point out to you, and you were here, you have been here for the whole hearing. I am sorry you had to wait so long, but they always take longer than we anticipate, especially when we have votes.

I want you to look around. Everybody that has a child who became autistic shortly after being vaccinated, hold your hands up, please. I want you to look at that. Do you see that? I didn't put them up to that. But every time we have a hearing--and, incidentally, I will hold my hand up, too, because my grandson was a perfectly normal child, was going to be 6-foot 10. I was planning on him in the NBA to take care of me in my old age. Within just days after getting nine shots in 1 day he was banging his head against the wall and running around the wall.

And all these people tell you pretty much the same thing. Yet, when we have people from NIH and CDC up here, they continue to tell us, well, we don't have any information or evidence that these vaccines have anything to do with it. Hold your hands up again, will you, please?

[Significant show of hands.]

Mr. Burton. I want you to look at that. Now I don't know what you want for evidence, but that ought to be enough to make sure that there is very comprehensive studies done on thimerosal, which has mercury in it, that is going into so many children's vaccines. Now, granted, you are taking it out.

You have been up here before, I believe, but I have also mentioned that every Congressman who gets a flu shot gets thimerosal, too. I told the doctor today, Dr. Eisold, the physician here on Capitol Hill, that I am going to inform every single Congressman and Congresswoman and Senator before the next shots are given for flu vaccine that they have mercury being injected into their bodies. Now we all want to get the flu shot, obviously, because we don't want to have that confused with anthrax and maybe die or something, because the anthrax scare was a real one, and the symptoms are similar. But we want to make sure that everybody is informed about it.

I tell you, most people who had their children vaccinated did not know that they were being injected with mercury. I mentioned earlier I think five or six countries that have stopped using thimerosal in their vaccines, and I read a letter from this Russian doctor who says there is no doubt that it has a bad effect on children who are being vaccinated. Yet, we continue to put mercury into these children, not in one vaccine, but in my grandson's case, I think it was seven or

eight of the nine in 1 day.

So I would urge you, and you will be getting a letter from me and the head of the Autism Conference. We will be sending you letters signed by probably 50 or 100 Congressman urging you to do more extensive research into the vaccines and into the causes of autism in the coming years. We're also going to be contacting the members of the Appropriations Committee to try to earmark funds for that, and the people in the audience are going to be contacting everybody they know that lives and breathes to write to their Congressmen and Senators about it as well.

[Applause.]

Mr. Burton. Thank you. Thank you. I didn't request that, either.

Dr. Weldon, do you have any questions you would like to ask?

Dr. Weldon. Yes, thank you, Mr. Chairman. I have some questions for Dr. Boyle.

Dr. Boyle, you mentioned several studies that the CDC is undertaking in response to the recommendations of the recent IOM. I have several questions regarding those studies.

First of all, as you know, many Americans are suspect over the ability of the CDC to conduct an unbiased study. Rightly or wrongly, these are legitimate concerns. Well, they are concerns, whether you feel it is right or wrong. I certainly hope that those concerns are being taken into account.

If the research you are doing is to have any real effect on public perceptions, you must make every effort to ensure independence. Otherwise, the CDC will have not achieved its desired goal of restoring public confidence in the vaccine program.

Specifically, to get to my questions, the first study you mentioned using the MADDSP data appears to be an epidemiologic study. Is that right? There are no biopsies done as part of that study to look at the presence of measles in the intestinal tracts of these children, correct?

Dr. Boyle. That is correct.

Dr. Weldon. The second study you mentioned is designed to determine whether or not the timing of the MMR has any association with the onset of regressive autism. Again, this is another epidemiologic study, correct?

Dr. Boyle. Yes, and, actually, that one is being conducted in conjunction with NIH.

Dr. Weldon. It is? OK. So, again, no biopsy specimens, no tend to look at the gastrointestinal tract.

Dr. Foote. There are blood samples to examine questions of excretion and blood levels of mercury and immune parameters.

Dr. Weldon. The third study, I think it is a study out of Denmark, again, an epidemiologic study, but then you mentioned a fourth study?

Dr. Boyle. Actually, that one also has biological markers in it as well.

Dr. Weldon. The third one?

Dr. Boyle. The Denmark study.

Dr. Weldon. The Denmark study? Is it serum specimens?

Dr. Boyle. This is done in collaboration with the Danish National Research Study, and it actually looks at some particular biomarkers.

Dr. Weldon. What are those biomarkers?

Dr. Boyle. Various neurotropins. There is a study that was reported last year at the hearing by Dr. Cary Nelson at the NIH that looked at some specific neurotropins that may, in fact, be predictors of autism. So what we're trying to do with that study is essentially look at whether or not these particular children may be more vulnerable.

Dr. Weldon. What I really wanted to get though is in the fourth study, you say you are in the early stages of planning this study to investigate whether or not measles vaccine strain virus is present in the intestines of some children with ASD. So is that the one where you are going to try to look at the issues raised by Dr. Wakefield in his reports and Dr. O'Leary?

Ms. Wharton. There is a study that is still in development. No word has made yet to an investigator to do the study, but, yes, there is a plan to look for the presence of measles virus geno-meno-testinal tissue.

Dr. Weldon. One of the concerns that I have is that the biological markers is a competent lab. As I understand it, the standards and the techniques that Dr. O'Leary uses are not in common use in most labs. They are relatively unique and there are only a small handful of labs that are capable of duplicating that work. Is that correct?

Ms. Wharton. Yes, similar methods to what Dr. O'Leary used were being put in the study, and laboratory work will be done simultaneously on blinded specimens by a number of different independent laboratories.

Dr. Weldon. OK. The question I have for you, are you making every effort to make sure that the virology sampling and analysis is of the same quality and caliber as the work that is done by Dr. O'Leary? I am saying this because, if you publish something and if other scientists can nitpick it and say they didn't use this technique and didn't use that technique, and the techniques were faulty, then we are not going to restore public confidence in the system and we are going to be back to square one.

Ms. Wharton. Yes, I appreciate that, Dr. Weldon, and thank you for making that point. There will be an effort made in this study to use the best virologic techniques available, as well as having specimens obtained from patients whose clinical systems are well-characterized, whose vaccinations and disease histories are ascertained with appropriate blinding of the

specimens.

Dr. Weldon. Thank you very much. I would like to be notified as soon as possible when you are ready to--I guess you do Request for Proposals associated with that study?

Ms. Wharton. Yes, as far as I know, no specific funding mechanism has yet been identified, but we hope to be able to make an award this fiscal year.

Dr. Weldon. Thank you. Well, please keep my office informed.

Dr. Boyle, the epidemiologic study on thimerosal, the preliminary data, as you know, did not show any link with autism, but did show a statistically significant link with speech development disorder, and then the final analysis that statistically significant link disappeared.

There have been a number of people who have wanted to look at that data, and the CDC has not released the datasets. Could you explain to me why the CDC has not released the datasets on that information? There is some concern that the sampling techniques used may have diluted down the information.

Ms. Wharton. With your permission, Dr. Weldon, I will respond to that question. There has been a lot of discussion about the differences in the preliminary analyses of the screening data from the Vaccine Safety Data Link with the subsequent studies done.

The major differences between the preliminary analyses were that they included followup through 1997. Because of the way the Vaccine Safety Data Link works, we receive additional information each year regarding subsequent followup on patients. So what has happened since then is we now have several years of additional followup on the children who were initially part of the study cohort, which actually should greatly enhance our ability to detect neurodevelopmental problems which may not be diagnosed until the children are older.

With extension of the study 2 years, from 1997 through 1999, there is an average increase in followup of 23 months. So it is not that we have diluted it out by including younger children, but we have extended followup, and that accounts primarily for the differences in findings between the preliminary analyses and the subsequent analyses.

Regarding your question about access to the information, as you know, the Vaccine Safety Data Link essentially is electronic medical information of a large number of individuals. There is a strong obligation to maintain the confidentiality of those data. That need has greatly complicated the ability to make the information, the dataset, available for independent review.

However, we appreciate this request and have worked very hard with the individual health maintenance organizations that participate in the Vaccine Safety Link Data Project to identify

mechanisms through which independent researchers can repeat analyses from these sorts of vaccine safety studies while maintaining the confidential nature of these private medical records, as well as the proprietary interests of the health maintenance organizations that participate in the project.

We have been able to develop a process that is quite comparable to that used by the National Center for Health Statistics, using their Research Data Center, so that a dataset can be made available for re-analysis using a protocol that could be developed by independent researchers. We have shared this plan with Chairman Burton's staff. So, in fact, we have been able to solve, I think, the most serious problems related to re-analysis and will be prepared to receive protocols to----

Dr. Weldon. To release the data?

Ms. Wharton. It is making the data available for analysis using a protocol that has been written. We can't release the data because these are confidential medical records, but the data can be made available in a secure setting, so that analyses can be performed by independent researchers.

Dr. Boyle. I just may add as well, this is a prototype that the National Center on Health Statistics has developed for other types of confidential information, allowing people access, allowing them to have availability of the resources to actually analyze the data.

Dr. Weldon. Well, what I would like to see is the data made available as soon as possible, so that an independent review--so that the committee can look at the data. Certainly, I understand the need to maintain patient confidentiality.

One other question I have: Dr. Boyle, you were in my office about 2 years ago. We talked about incidence, and you talked about the Atlanta study. It was just getting underway. So, based on the information you have recently released, the incidence rates that were being spoken of, 1 in 250, 1 in 500, and many scientists were questioning that 2 years ago and 3 years ago, you are saying now, yea, verily, at least in Atlanta that it is that high, and it is reasonable to speculate it may be that high throughout the Nation? I know you are scientists and you are going to say we have no proof of that, but I have been in Atlanta and I have been to lots of other cities. I find it hard to believe that this would be exclusive to Brick Township and Atlanta. So the rates are really high?

Dr. Boyle. Based on what we found in Atlanta, they are very comparable to what we found in New Jersey. The important part of what we found in Atlanta is that most of, even though we call it autism spectrum disorder, the way we find cases is through access to school records, and we know that most of those children are children who are in special education. Higher-functioning children, children with Asperger's disorder, or children with higher-functioning autism may not be captured by those methods. So, in fact, the rate, if you look at the

whole spectrum, might be a little higher.

Dr. Weldon. Well, I know you are scientists and you won't believe it is going to rain unless the weather balloons go up and measure the humidity in the clouds and the barometric pressure, etc., but, and I think I have said this before at previous hearings, when I started medical school in the seventies, I didn't know anybody with autism. I never saw any kids with autism. I didn't know anybody on the faculty with autism. I didn't know, I never saw a case as I went through all the rotations. The thing that has really dramatically struck me is I am starting to hear everywhere so-and-so's got a child with autism. I think it is one of these things where the scientists are the last to find out what is going on.

I am certainly glad your data verified what everybody has been saying, that we've got a crisis, and I certainly would encourage you to duplicate the analysis in other locations and try to refine the data as much as possible, and then continue to track it to see if the rate is increasing even further. I certainly appreciate all the work you are doing.

I yield back to the gentleman from Connecticut.

Thank you very much. Thank you for your testimony.

Mr. Shays [assuming Chair]. I thank the gentleman.

I want to apologize. I don't usually take the Chair when I haven't heard the testimony, but Mr. Burton is on the floor of the House on an issue that he also cares deeply about, and as we know, he is a very passionate person, thank goodness.

I want to ask you a question, Mr. Foote. ``Doctor,'' I'm sorry. I just want to ask you, do you think the title of this hearing is appropriate in terms of its being an epidemic or would you qualify it in a certain way, and if you would qualify it, how would you qualify it? It is not a trick question. It sounds like it, but, honestly, it isn't.

Dr. Foote. I think it is clear, as Dr. Weldon was saying, that there has been a change. It has been a change that has involved a substantial increase, as in Chairman Burton's definition of an epidemic as an unexpected large increase in the prevalence of a disorder. Given that definition, I think it is fair for him to use that term. I would call it a large increase, and our response, I believe, has been appropriate; that is, that we are mobilizing and we are assembling the structure, and putting it in place, that will provide resources for investigators to undertake large-scale studies that would not previously have been possible that are necessary to address a disorder that is occurring this commonly. That is our goal, and that is what our actions have been: to establish centers where young investigators who are interested in autism can be trained to go on and develop the science that is going to be necessary to have rational treatments for this disorder.

There is only so much we can do in a short period of time. Science is an endeavor that takes a lot of training and a

certain amount of ramping-up to be able to use funding in an appropriate and very high-quality way. So we are hoping that we are putting in place the infrastructure that will allow that to happen.

Mr. Shays. Thank you. That is a very helpful answer.

Dr. Boyle, how would you respond to that question?

Dr. Boyle. Well, I guess, rather than sort of fooling with the semantics of it, I feel, based on the work that we have done, the work that many other people have done, that the prevalence of autism is clearly much higher than what we previously thought, and that we need to have a concerted response to that issue.

I think at CDC we have strived over the last 5 years to do that, both in terms of trying to understand the magnitude of the problem, who's affected, and then by actually setting up sort of the research, epidemiologic capacity, to begin to address why this is happening.

It is clearly hard to look retrospectively and say, what was the rate 30 years ago, what was the rate 15 years ago. We don't have that data assembled. But I think it really shows us that in this country we need to understand that developmental disabilities, including autism, are extremely important conditions, and conditions that we all must take seriously.

Mr. Shays. Let me understand. It is my understanding that CDC is going to actually be reducing its spending next year on autism. Is this accurate, and if so, why would that be happening?

Dr. Boyle. Well, actually, we were appropriated $9.7 million for autism in 2002. We also included additional funding for autism-related activities from the Vaccine Safety Program. I can actually let Melinda talk. We are still going to be expending the $9.7 million for autism that is specifically appropriated by Congress for those activities.

Mr. Shays. Let me just say something, just so I can put this on the record. I don't fault administrators when we in Congress don't appropriate the money, but where administrators become responsible is when they see a need and they can fill a need, they don't request the money, and then we in Congress don't respond.

I am getting the sense that in the last years this has been mostly generated by Congress kind of pushing NIH and others to treat this as a more important effort. I may be wrong, and I am happy to be corrected.

But, I'm sorry, you wanted to make your response?

Ms. Wharton. Well, I was going to elaborate on what Dr. Boyle just said----

Mr. Shays. Sure.

Ms. Wharton [continuing]. About the small reduction that you see in the projected CDC numbers for fiscal year 2003. As Dr. Boyle said, there has been a certain amount of money

appropriated for autism activities, and that has been supplemented by vaccine safety appropriations. There have been a number of studies launched in response to different issues that have come up related to autism that have been initiated in the last couple of years. Some of those studies, the final funding cycle is in fiscal year 2002. So that accounts for the apparent reduction. In the fiscal year 2003 spending we have only reported to you what we currently anticipate spending based on the President's budget, but, of course, if additional issues arise that require additional studies, those might very well be the studies we would end up doing in fiscal year 2003, in response to new concerns or problems that arise.

Mr. Shays. When a President submits a budget, and I don't pretend to be a big spender, and I voted against spending, so I am not suggesting where blame lies here, but what I am interested in knowing, though, is if the President and the Budget Director are not suggesting enough funds for either of your agencies as it relates to this effort, have you gone on record as saying you need more money, not just with Congress? Let me start with the Budget Director, or are you basically just accepting whatever has been allocated?

Dr. Boyle. This is really not done at my level. I clearly feel like this is an important issue, but it is really done at levels above me.

Mr. Shays. OK, Dr. Foote.

Dr. Foote. Well, the same is true for me, but, once again, to point out the way NIH does business, we have to have scientists who have the skills and the motivation to propose to us, even if we publicize an RFA, the kind of science that is necessary to address the issues. So we need to cultivate fields and we need to develop the competence and the expertise and the people and the resources to make the research possible. More often, that is a matter of sustained investment over a period of at least a few years to get fields really ready to take advantage of opportunities. So, yes, we have consistently, I think, advocated for that approach to biomedical research.

Mr. Shays. I used to chair the Human Resources Subcommittee of Government Reform and for 4 years had oversight of NIH and CDC, and so on, and FDA as well, and HHS. I am very familiar with the point you are mentioning. I think it is important to put on the record.

But would it be fair to say that you have a pretty good comfort level that if the field was hearing your testimony, that we wouldn't be flooded with people who say, ``I've come in with proposals and I've been told there isn't the money''? Are you pretty comfortable in suggesting to this committee that there aren't a lot of people out there looking to do research in this area, and that you have to cultivate this group? Is this kind of what you are suggesting?

Dr. Foote. I think if there is appropriate training offered

and if the structure that we are establishing and that other institutes at NIH have long supported, such as NICHD and NIDCD with their CPEA Program, the field expands because this is an interesting problem. This is a problem that scientists are motivated to get into and to try to help. There will be growth. As you know, once the seed is there, then sometimes growth can be quite rapid. So I think that is the scenario we are looking at, that in a few years, over the next few years, there will be investigators coming in with applications, and so on, and we will need to plan for some sustained growth in this area, so that people don't get disappointed. So that is the scenario we will be trying to plan for, sustained growth.

Mr. Shays. In our public life, just in our private life, we may come in contact with families and friends who have children that have different challenges, and autism being one of them, but in our public life, we're obviously exposed to more families. I find myself thinking, what if I was the parent? I would find myself somewhat frustrated with traditional medicine, given that it sometimes does seem to prod, traditional research. I would be very fearful that there weren't things that I was doing to my child, or had done, that may have contributed; in other words, if they were allergic to certain things, and so on.

So I have tremendous empathy as to why people don't want to wait too long, because wouldn't it be amazing to think that, when we discover something 5 or 10 years from now, we will learn that there were things we were doing for our kids, thinking we were helping them, when we were actually hurting them, and there were things that we could have done at a younger age that would have made them well, but at an older age may not have the same impact. I know you all have to have that sense as well.

I want to ask a few questions that the staff has prepared. So I will be reading a few of these, but I would like to put them on the record, and I would like the synergy of both of you responding and making comment.

But, Dr. Foote, this is to you. It relates to Dr. Ruth Kirchstein of NIH. I guess she is the Deputy Director, is that correct?

Dr. Foote. She is currently the Acting Director of NIH.

Mr. Shays. She published research she conducted in the 1960's on thermara----

Dr. Foote. Thimerosal.

Mr. Shays [continuing]. Thimerosal, yes.

Dr. Foote. Yes.

Mr. Shays. Our staff has been seeking to speak to her about this research and what other research she conducted relative to this. I am interested if you or anyone else at NIH is looking at this issue, and whether she will be getting back in touch with our staff. We need some cooperation from her, frankly.

Dr. Foote. I can carry that message back.

[Applause.]

Mr. Shays. Let me just say something to our guests. In this hearing it is truly a hearing, and so I want to respect your interests, but it is important that we have decorum.

Dr. Foote. My understanding is that was an FDA research effort. So I think probably it is also appropriate to request of FDA whatever documentation they have.

Mr. Shays. Can we, given that you are before our committee, can we anticipate that you will certainly try to help us in this regard?

Dr. Foote. You can anticipate that we have heard what you have said, and that we will carry the message back, yes. Thank you, Mr. Chairman.

Mr. Shays. Isn't it going to be important to evaluate the real-world treatment approach in autism and not just one therapy at a time? Let me just repeat the whole question. And don't you think it would be important to find a practice-based research center that is providing care for individuals with autism, so that we can track cutting-edge treatments in real-world situations?

Dr. Foote. Well, the issue of treatment, obviously is a primary one for families faced with an affected individual. As we were just discussing, it may be some time before there is a treatment founded and based on the pathophysiology of the disorder and derived in some rational way that really has a silver bullet approach to this disorder. In the meantime, people, of course, need to be trying to help their children, and doing it in as timely a way as possible, and in a way that is guided as much as possible by reliable information.

So NIH has in place several research programs focused on treatment. The CPEA networks have strong treatment components utilizing treatments that families are making use of right now, aimed at evaluation of their effectiveness and, as has been mentioned many times, which subset of affected individuals that treatment might be most appropriate for.

When we issued the RFA for the new STAART centers, the one requirement, absolute requirement, we had was that each application had to include a treatment component, a treatment study, and for a center to be considered to be fundable it had to have at least one treatment study that got strong ratings from the Peer Review Committee. So it has been our intention all the way along that in this major new effort treatment would be an inherent and major part of the overall effort.

Then I might note, finally, that this past year the NIH Autism Coordinating Committee issued an RFA as the result of which we funded seven applications having to do with new approaches to treatment, and we have funded those seven grants to get them going. So we are trying to undertake an effort where we are developing basic science for long-term treatment,

but we are also doing these very much more immediate efforts where people have to find treatments; they have to use treatments now. People look for evidence. They say, ``I want to use the kind of treatment that has the best evidence supporting it,'' and they often find that they go and look and the evidence base is very fragmentary, anecdotal, highly variable. It is not clear to them what to do when faced with this entire array of possible treatments. So we have undertaken efforts to try to help to deal with that as well.

Mr. Shays. Thank you. I am going to have the staff ask these questions, and ask as many as you want. I am going to listen to them. I might jump in, but I think that we might cover this more quickly to do it that way, given that they are going to be a little more familiar with your responses as well.

Ms. Clay. Dr. Foote, when can we expect the NIH intramural program to replicate Dr. Wakefield's research?

Dr. Foote. I'm sorry, there was a distraction. When can we expect the intramural research program? I'm sorry, is that what you said?

Ms. Clay. Yes. When can we expect children to be able to be seen at the NIH Clinical Center who have autism and who also have gastrointestinal issues to be investigated in the same manner that Dr. Wakefield did?

Dr. Foote. I don't know the answer to that. I would be glad to find out the answer to that and furnish it to you.

Mr. Shays. That would be helpful. Thank you.

Ms. Clay. Yes.

Isn't it going to be important for the program at the NIH Clinical Center to be expanded for autism?

Dr. Foote. It sounds to me like that is addressing basically the same issue of what is happening on the NIH campus in terms of the ability of people to access that facility and get advice and potentially care, or enter into clinical trials, through that particular facility. I am afraid I don't know the answer to that. I will have to find out, but we will try to provide an answer that encompasses both of those questions.

Ms. Clay. Dr. Boyle, we have talked about the CDC's Vaccine Safety Data Link project today. You have been tracking for 10 years vaccine adverse events through several HMOs. The committee asked for the raw data a couple of years ago, and we were told we could not have it because the HMOs were threatening to pull out of the project. We have learned that at least one pharmaceutical company has had access to the data through one of the HMOs and that other individuals have tried to receive this data through Freedom of Information Act and been denied.

Why has the pharmaceutical industry been given preferential treatment?

Ms. Wharton. The study in question was actually done by one of the participating HMOs and was not a Vaccine Safety Data

Link project. These individual HMOs each have their own research organizations which make their own arrangements with outside entities, including universities, pharmaceutical companies, vaccine manufacturers, and others, to do research using their patient population.

The particular study you are referring to, which I believe was initially on the list of VSD studies actually shouldn't have been on that list because it wasn't a VSD study. It was a study engaged in by one of the individual organizations in corroboration with a manufacturer, which they do many studies in terms of post-licensure safety studies, for example, these individual organizations.

Ms. Clay. So your position is that no pharmaceutical company has had access to the Vaccine Safety Data Link project tapes at all?

Ms. Wharton. That is my understanding.

Mr. Shays. Could you verify that? In other words, would you check that out?

Ms. Wharton. Yes, we can get back to you on that, but that is my understanding.

Mr. Shays. And would you, in getting back, confirm yes or no? In other words, if your answer is the same, don't not get back to us; say that you have confirmed your answers.

Ms. Wharton. Yes, I will do that. Thank you.

Mr. Shays. Thank you very much.

Ms. Clay. In reviewing the publications that were provided to us from the CDC from this project, it appeared that an equal or more number of these projects were not looking at vaccine safety issues, but were looking at ways to increase immunization rates. Is that an accurate assessment?

Ms. Wharton. I'm sorry, I can't answer your specific question.

Ms. Clay. We were given about 45 published studies. Fourteen of them were looking at potential adverse event correlations doing vaccines. Another 14 or more were specific studies looking at how to improve immunization rates. So, in other words, how we were going to have increased uptake of vaccine usage within the HMOs, not at all about vaccine safety.

Ms. Wharton. Well, the Vaccine Safety Data Link is used by the participating investigators to answer a variety of questions, including disease incidence, other issues beyond those related to vaccine safety, but it is still done within the same constraints of the system; that is, maintaining confidentiality of the patient records.

Ms. Clay. Well, given the need to find out the issues of vaccine safety and the lack of research looking at adverse events, and that the creation of this project was specifically to look at adverse events, wouldn't it be important to put our focus there first?

Ms. Wharton. Well, I appreciate your comments, and I can

assure you that the people who are directly involved with the VSD project share your concern that the primary focus of the project has to be vaccine safety. The other projects that have been done through the system have really been, in general, smaller projects that have not required use of substantial resources. This system was created for vaccine safety, and vaccine safety continues to be its primary focus.

Ms. Clay. And who at the CDC makes the decision of what projects can and cannot be conducted with the access to this data?

Ms. Wharton. It actually is not CDC's decision. It is a collaborative project involving a number of health maintenance organizations, which, as I noted earlier, have their own research structures and their own principal investigators. This group collaboratively reviews protocols and makes decisions about what are appropriate uses of VSD resources.

Ms. Clay. And as we move forward in having protocol established for outside experts to have access to this data, can we be assured that the data will be available fairly, and that there will be no reduction of access to the projects that they are requesting the data for?

Ms. Wharton. Well, clearly, it is our intent to make the dataset available for re-analysis. A protocol will need to be developed and will need to be approved by the institutional review boards of the participating health maintenance organizations, but, yes, the dataset will be made available, the appropriate dataset will be made available for the re-analysis.

Ms. Clay. Can we be assured then that if a researcher wants to conduct an independent analysis of Dr. Verstraeten's study, that can be done without bias?

Ms. Wharton. You have asked a difficult question, and I may not be giving you quite the answer you are anticipating. Actually, I think there are some real issues with Dr. Verstraeten's study, and the epidemiological term for that is ``bias.'' But, yes, what needs to be done is a protocol developed that will specify what data are needed for analysis, and those data will be provided in this confidential, in this secure setting of the Research Data Center at the National Center for Health Statistics using the existing model, following IRB approval.

Mr. Shays. Does the gentlelady, Ms. Watson, have questions that she would like to ask? We are having staff just pursue some questions, but if you have some questions or comments, I would love to recognize you.

Ms. Watson. Let me just first thank the committee for holding this hearing. Since I am so late, I am wondering if there was a connection made between the fumes and the toxicity from mercury in the amalgams and autism. All right, we had kind of reached and bridged a gap. We thought there was some kind of

connection.

Mr. Shays. If you would like to just ask a question or two about that, we would be happy to have you do that.

Ms. Watson. Yes. Let me ask those from CDC, I'm carrying a piece of legislation that will prohibit the use of mercury in dental fillings. Fifty percent of that silver that they call silver is really mercury. The bill will outlaw eventually the use of it at all, but we want people very well informed when they go in to have fillings.

Can someone comment on whether there has been a connection made between mercury fillings and autism? Does that ring a bell with anyone?

Dr. Boyle. I'm Dr. Boyle from CDC.

Ms. Watson. Yes.

Dr. Boyle. As far as I know, there has been no study that specifically addressed that issue in terms of dental fillings and autism.

Ms. Watson. Yes.

Dr. Boyle. No, there has not been a connection, but also there has not been specific studies.

Ms. Watson. In my literature that we have collected around the bill, there has been some reference to not only autism, but serious conditions of brain deterioration suspected coming from that toxic substance that is emanating from the fillings. So I would like to let you know that my door and mail is open. If there is anything that you find in the literature that you could share with our office, it would certainly help us.

My staff is just handing me a note that is saying in some of the vaccines thimerosal contains mercury, and it is a kind of preservative, and it goes into the filling. So what we are looking for is any research, evidence, that would indicate a connection. Thank you.

Mr. Shays. Does the gentlelady from California have any other questions she would like to make?

Ms. Watson. No, Mr. Chairman.

Mr. Shays. I am going to have the staff continue to ask questions. If you are still here and want to jump in, you could do that.

Ms. Watson. Let me just ask one more question.

Mr. Shays. Sure. No, you have the floor.

Ms. Watson. In your research, is it true that autism continues throughout a lifetime or can autism come to some point where the person comes back to very normal growth? Can someone comment on that?

Dr. Foote. Well, I think the observations are that it is a lifetime disorder with sometimes quite striking remission in certain symptom domains. The communication disorder, the communication problems, for example, can improve substantially. People have striking luck with certain kinds of treatments for parts of the disorder in certain children. But these tend to be

sporadic, partial alleviation of the disorder rather than a sustained and total remission.

Ms. Watson. Can the disorder be affected, say, for the good through a change in nutrition? Is there any evidence?

Dr. Foote. There have been reports--we were just talking a little bit earlier about the fact that the number of appropriately blinded, placebo-controlled studies in autism are several, literally several studies in the entire literature that have been very well done. Nutritional changes haven't been one of the domains in which there have been really careful studies.

So there are examples of alleviation of symptoms with dietary changes or nutritional supplements, but those tend to be anecdotal; that is, stories about a few to several people rather than carefully controlled clinical trials.

Ms. Watson. Are autism patients treated individually? The condition can change for the better, but it still stays with them for the rest of their life? So my question is, can they be treated individually or is there a protocol?

Dr. Foote. Well, because we do not have broadly effective, standardized, rigorously demonstrated treatments, and people are confronted with serious difficulties in day-to-day life with an autistic child, people search for treatments. So, given that the typical story is that a given child will be exposed to several different treatment regimes over a period of time, the most broadly used treatments tend to be behavioral treatments rather than drug or other kinds of treatments. There are certain behavioral treatments, educational treatments, that with sustained large investments of time and effort can show substantial improvement in a large fraction of children. I think that is a fair statement.

Ms. Watson. Institutionalization is one way to deal with this disorder. What percentage of those identified during their school years go into institutions, or do you have that information?

Dr. Foote. I don't have that information.

Ms. Watson. Anyone?

Dr. Boyle. From our work in Atlanta and Brick, there were no children who were currently institutionalized.

Ms. Watson. There are no children in Atlanta or no children in your studies in the children that you know of?

Dr. Boyle. In our studies of trying to establish the prevalence of autism, there are no children who were institutionalized. However, the whole issue of institutionalization in children, I mean there is clearly very few children who are currently institutionalized.

Ms. Watson. Throughout the country?

Dr. Boyle. Again, this is just in Atlanta and New Jersey.

Ms. Watson. Just in Atlanta. So you don't have any information countrywise? That is something I would like to

know. I know in California they do institutionalize. I know in Massachusetts they institutionalize. I am just wondering how prevalent it is across the country. Thank you.

Mr. Shays. Dr. Foote and Dr. Boyle, let me just say it is our intention to let you get out pretty soon. You haven't had a break or anything. Do you have 20 more minutes in you? Are you OK?

I am going to do something that may seem a little unusual, and I may have to just cut it off if it is not a good idea. But, Dr. Foote and Dr. Boyle, if you can trust me in terms of my ability to control a meeting, it is not lost on me that we have a lot of people in the audience who have a keen direct interest. There may be a question or two that none of us on the panel here have asked that we should have. I am going to ask if there is someone in the audience who may have a question that says we should have addressed this. I will allow you to stand up and tell the committee, and then we may choose, our committee may choose to ask that question.

My motivation is that it would be a shame to have people leave without you having the opportunity to respond and maybe clear something up. Both of you have such a nice, friendly smile. I figured I could get away with it. So we are going to try it out, but I have the counsel--excuse me, the minority counsel would like to ask you a few questions, the majority professional staff would just like to ask a few more, and then I am going to just throw it out to the audience, pick two or three of you and ask you to stand and tell me if there is a question you think we should have asked, loud enough so I can repeat it to our witnesses.

There you go. So I will recognize the minority counsel. Yes? Mrs. Morella, I had asked if there was any question, and I had been told you didn't have any. Would you like the floor?

Mrs. Morella. I would love it.

Mr. Shays. You have the floor as long as you would like.

Mrs. Morella. Particularly because I represent the National Institutes of Health, and, Dr. Foote, I am glad you are here, and I work very closely with CDC, and I am glad you are here, Dr. Boyle, too.

I was here for the first panel and heard the kinds of questions or the points that they brought out. I think one of the notes that I had jotted down was they felt there was a need to develop a national policy, that we needed more collaboration, that we needed to match the child to the method.

We pointed out the fact that there are just so many questions that are still unanswered. Funding was stressed by I think every member of that first panel. I am not sure--if you would kind of comment on whether you see, what do you see is really necessary? Is it the need for further collaboration? Will funding alone do it? How do we get some of these questions answered, particularly also with regard to vaccines and what

their connection is to autism? If any of you would like to comment on that just general area? Dr. Boyle.

Dr. Boyle. I will start. I took some notes, too, during the last panel. I would applaud the issue of collaboration. I think we have made a good start across not just NIH and CDC, but all the agencies involved. The Department of Education, the Health Services and Resources Administration, all of these agencies need to work together to address this issue.

Mrs. Morella. Should we do something about that? I mean, is there direction we should be offering?

Dr. Boyle. I think the direction from Congress from the Child Health Act clearly directed collaborations. It directed, I think, to CDC and NIH, but other partners have clearly been pulled into that. I think that we need to continue to make that happen, as well as work with all of the parent groups that are seated behind us here.

I applaud the effort of hearing from the parents at the end of the committee hearing today. So I would definitely second that notion.

The other thing I heard about was, though, the issue of training.

Mrs. Morella. Yes.

Dr. Boyle. And this is training across the board. I think a lot has happened in the last 5 years in terms of both epidemiology researchers, diagnosticians, treatment issues. I think that we have made clear progress, but I do think this is an area that we need to put concerted energies into.

There is a lot of interest in autism and other neurodevelopmental disorders, and we want to continue to have that momentum happening it and growth in positive ways.

Mrs. Morella. Dr. Foote, I would love to give you an opportunity to respond to any of those facets.

Dr. Foote. Well, the Children's Health Act called for the establishment of an Interagency Autism Coordinating Committee. We now have that up and running. There is, of course, always a big distance between sitting down in the same room and talking and converting that into something that resembles a national policy or even a coherent picture of what it is that is being done, which, of course, helps you identify what isn't being done.

But I think at our first meeting, and I think on the agenda for our second meeting of that committee, those are exactly the jobs that we are taking on. I think we have the appropriate representation on the committee to be able to do that in a realistic way. So I think if there is going to be a national agenda about autism, I think that there is a kernel for starting that with the Interagency Autism Coordinating Committee.

Mrs. Morella. Maybe this committee hearing will help to spur that on.

Thank you, Mr. Chairman. I am pleased also to note your new concept of involving the audience, involving the parents.

Mr. Shays. Well, we have done it before and it has worked, but it does take cooperation.

Mrs. Morella. Right.

Mr. Shays. We will give it a try in a second. Excuse me for not calling on you; I apologize. I think it was the nervousness of thinking how we were going to do the latter. [Laughter.]

I recognize minority counsel.

Ms. Despres. Thank you. I have just a couple of questions regarding that request for the Vaccine Safety Data Link data. I was wondering if you could explain to us why the privacy concerns are so important. I am particularly interested in what could happen to the VSD if the participating HMOs didn't believe that there was adequate control over patient confidentiality.

Ms. Wharton. Well, in fact, I think just the fact that this discussion has been ongoing for so long has convinced all of them that there is no longer assurance that the data can be maintained in a private way at CDC. The individual participating organizations are no longer sending master datasets to CDC. I think that unless these issues can be resolved, the project is likely to no longer be possible to continue.

What we have tried to do is develop a new way of doing studies where, in fact, the data won't reside at CDC, but the analyses will be done in a distributed way among the participating organizations. This is something which is theoretically possible to do, but operationally would clearly require much more in the way of data management and statistical support of the individual sites, as well as at CDC. So I think, in effect, it will reduce the amount of work that will be possible for us to accomplish within the VSD with existing resources.

Ms. Despres. Can you explain to us, if the VSD is not able to continue, what would be the implications for vaccine safety research in the future? I am also curious about the implications of the fact that the data currently is not at CDC. What present implications on vaccine safety research has that had and what implications could it have in the future.

Ms. Wharton. Well, at the moment we, as I understand it, have not yet received any of the year 2000 data because none of the organizations are currently willing to send it to us. So we are not currently able to perform any studies easily in terms of screening analysis that requires access to the year 2000 data. Now, again, the data do reside at the individual sites and can be accessed in this distributed way, but it is far more laborious.

Should the project cease to exist, I think it would dramatically change--it would be a great loss for us. The VSD

has provided a mechanism through which vaccine safety concerns could be rapidly addressed, and often reassurance provided in a very prompt way when something comes up. Now many issues are complex and do require more detailed investigation beyond what can get from analyzing the automated data tape, and do require chart review, and so forth. Those studies are more complicated and take longer to perform, but the VSD has really been one of the bedrocks of our vaccine safety system. I think its loss would be a great one.

Dr. Boyle. Can I add a comment to that as well? I think that this actually has had a ripple effect with the HMOs. We are dealing with other issues where we would like to have a rapid response and work with the HMOs because they are a wealth of information and data, and they are reluctant to participate because of these privacy issues.

Ms. Despres. So without having VSD data now and the possibility that you won't have it at all in the future, would that mean that it could take longer to detect vaccine adverse effects?

Ms. Wharton. It clearly would take longer. It would clearly be more laborious. It clearly would be more resource intensive, and we would be unable to accomplish as much.

Ms. Despres. I don't have any more questions. Thank you.

Mr. Shays. I thank you very much. It is important to get on the record. I appreciate it.

I recognize the majority professional staff.

Ms. Clay. Aren't some of the privacy concerns as a result of the HIPAA regulations that are about to be implemented?

Ms. Wharton. Some of the privacy concerns do overlap with HIPAA issues. There are additional State requirements in some of the States in which these organizations persist. But it is a general issue that we have to assure the confidentiality of these data.

Ms. Clay. And is their not providing the tapes to you a violation of the contract that you have with the association that oversees these HMOs?

Ms. Wharton. We are in the process of trying to develop a new procurement mechanism that will allow development of this distributed model.

Ms. Clay. One of the correlations that we have looked at between the issue of mercury in medicine and exposure for our children is the same process that we went through in the 20th century looking at lead in paint and its effect on children. How does this issue correlate, the CDC and the NIH response correlate for mercury as it did to lead in the paint 50 years ago?

Dr. Boyle. Well, I will start first. One of the things that we are hoping to be able to do with our State-based program is to be able to monitor, and we call it, from an ecological standpoint. The implications you have had were in terms of

looking at lead. But we are hoping to be able to look over time at the prevalence of autism based on our State-based monitoring program and how that prevalence may have been impacted based on the removal of thimerosal from vaccines.

Dr. Foote. I think the NIH response to the thimerosal issues has been to undertake a series of research projects looking at metabolism, and distribution of ethyl-mercury in the body, rates of clearance, and potential toxic effects. There are several such research efforts now underway, some of which, as we discussed earlier, and in collaboration with CDC. So I think this is a serious and appropriate response to those issues.

Ms. Clay. And, Dr. Foote, if a parent, when they have a newly diagnosed child, goes to the NIH Web site and looks for information on therapies for the child, will they find adequate information?

Dr. Foote. Well, we have a joint linkage with the National Library of Medicine in which there are large amounts of data available. The real problem is one of the underlying science and the underlying science not being adequately developed. Anybody would be daunted right now in attempting to sift through that information. I don't think it is as much a matter of organizing the information as it is of literally developing the information, and that is the effort that we have underway. So, yes, we have taken seriously the task of having an interface with the public that makes information accessible to them, but our real job and the real effort that is going to solve this problem is to have better information available.

Mr. Shays. Now let me state what I would like to do. I would like to let our witnesses leave soon. I would like to just say that this is a hearing of the House of Representatives, of Congress, so the decorum needs to be done well.

I am going to first ask how many people would like to ask the question. I am going to invite five people to take each of those five seats. I am going to invite you, Ma'am, in the front row to come up to that seat up there, yes. I am going to invite you in the very back to come up, the very back there. I am going to invite you, sir, to come up. I am going to invite you, Ma'am, in the middle, and I am going to invite you in the very back there.

I am going to have you each take a seat. What I am going to invite each of you to do, the committee is going to invite each of you, you are just going to go down and you are going to identify your name, as you ask the question, where you live. If you have a loved one who is impacted, we are happy to have you share the name of your child, but this is primarily for an opportunity to ask a question. We will just see how it goes. OK?

You all are nice--thank you--to let us do this.

Just turn the mic on, start at the very end, and ask your question.

Ms. Mintz. Hi. My name is Sandy Mintz. I am from Anchorage, AK. I am lucky enough not to have a child who has been injured by a vaccine.

My question is, is NIH ever planning on doing a study using the only proper control group, that is, never vaccinated children?

Dr. Foote. I am not aware of--but note carefully what I said, that I am not aware of--a proposed study to use a suitably constructed group of never vaccinated children. Now CDC would be more likely perhaps to be aware of such an opportunity.

Dr. Boyle. The study that I mentioned earlier that we are doing in collaboration with Denmark compares children who received the MMR vaccine versus children who did not receive MMR.

Ms. Mintz. But I am saying never vaccinated with any vaccine. That assumes that other vaccines don't cause autism, which is what needs to be studied, not assumed.

Mr. Shays. Let me just say that if you would turn off your mic, I am happy to have you do the followup, if you would respond to it.

Ms. Mintz. I'm sorry.

Mr. Shays. No, you don't need to apologize. And we will go to the next. Do you have any other comment based on that? The point that is being made, any vaccination. Could we just suggest that you take this under advisement?

Ms. Wharton. The difficulty with doing such a study in the United States, of course, is that a very small portion of children have never received any vaccines, and these children probably differ in other ways from vaccinated children. So performing such a study would, in fact, be quite difficult.

The Denmark study was a study that, in fact, could not have been done in the United States, although, of course, these children did potentially receive some other vaccines, but simply hadn't received MMR.

Mr. Shays. I will invite anyone who is here to speak to staff or me afterwards if they want to augment a comment.

Let's go to the second person. I am sorry, I don't know your name. So I can't call you by name. So you are going to be a number to me.

Ms. Stewart. OK.

Mr. Shays. You are No. 2.

Ms. Stewart. OK. My name is Dr. Linda Stewart. I am from New York. I am coming from Switzerland. I have been working in Switzerland for 30 years in the political and internal affairs international arena. I am also a mother of a son, my No. 2 son, who has been recently diagnosed with autism spectrum disorder.

Mr. Shays. How old is your son now?

Ms. Stewart. He is 8.

Mr. Shays. OK.

Ms. Stewart. We returned to the United States, as he was born and vaccinated in Florida. We had been to four or five neurologists in Europe, the highest doctors we could find in France, Switzerland, Italy, and we came to the United States to find out if we could find any help for the boy since he was born and vaccinated here.

All the tests, MRIs----

Mr. Shays. Let me ask you, can you do your question, if you could, yes?

Ms. Stewart. Yes. All our tests showed normal, and we were able to find a program by residents from NASA that showed the child was full of mercury. My question to you, respectfully, as scientists and researchers, what results, with all the millions that I hear you mention back and forth today, what have been your results in a pragmatic and functional level for the millions of research that you have received in biological autism?

Dr. Foote. The types of studies that happened and are underway are studies about the levels of mercury that result from vaccination and are about the timing of the onset of autism symptoms in regressive and/or non-regressive autism and how those may be or may not be systematically related to the time of vaccination.

Some of those data are in; some of those studies are currently being conducted, and some of those studies are still being organized. The data are not yet in. But the money is on the table. The studies have been funded and they are underway.

Ms. Stewart. Thank you.

Mr. Shays. No. 3.

Ms. Wedewer. Hi. My name is L.D. Wedewer. I am the U.S. Autism Ambassador, and I have more titles than my arms, so I will leave it at that.

But I have a two-part question actually. My daughter received a hepatitis B shot at 2 days old, which I truly feel was too young, but I was never given any information on the cause and effect, what could happen to her. Do you feel that there is a need to ensure that parents have the knowledge of what the mercury could do to the individual, and how would we assure that?

Ms. Wharton. Well, clearly, we do try to inform parents of the known risks and benefits of vaccination through vaccine information statements, which are required by the National Vaccine Injury Compensation Act passed by Congress some time ago.

The mercury is no longer contained in any of the hepatitis B vaccines administered to infants or thimerosal is not, and thimerosal--the vaccines now being routinely administered to children, in fact, none of them contain thimerosal at this

point.

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

Ms. Wedewer. OK, and my second part to the question is I have, as the U.S. Ambassador, I have been receiving over the last year numerous information and different amounts of proof on the thimerosal connection, Ma'am, as my daughter is one of them. I had found a recent CDC report that had never been released that had birth to 6 months, and yet the release that you released to the public and congressional hearings omitted birth to 6 months. Is there a reason why the original report and the second report do not match?

Ms. Wharton. Well, this is an issue that was addressed earlier. I believe the study you are referring to is Dr. Thomas Verstraeten's analysis of the VSD screening data.

Ms. Wedewer. I actually have it here today, if you would like to have it in front of you, so you know----

Mr. Shays. No, but she is on target, right? She got the study.

Ms. Wedewer. OK, go ahead.

Mr. Shays. Yes.

Ms. Wharton. And as I mentioned earlier, the initial studies focused on a limited followup period. Since that time, there has been more extensive followup which should actually enhance the finding of children whose subsequent developmental abnormalities were diagnosed later in life. So more extensive followup should help us do a better study.

Ms. Wedewer. OK, my final, this is the final part to it, and I promise I will let Mr. Horowitz go on. My last concern--and, remember, I receive e-mails from many, many parents; I was inducted by more than 245,000 people, so I----

Mr. Shays. Ask your question. Why don't you ask it.

Ms. Wedewer. I have U.S. knowledge. May I ask, why, then, if you are so worried about releasing the statistics from the parents to a congressional hearing, as I do work with Democrats, etc., in Iowa, do you really think--as a parent of a child with autism, I don't think that I would have a problem with you releasing the information for someone else to look at. Do you really think that other parents would have problem with that, when everybody they see----

Mr. Shays. OK, you have asked your question. Now I am going to have you move the mic, so I know you are not going to have a fourth followup.

Ms. Wedewer. OK. [Laughter.]

Mr. Shays. OK.

Ms. Wharton. Well, it is not just parents of children who have neurodevelopmental abnormalities. It is all the patients

participating in these health maintenance organizations, which is a measurable proportion of the U.S. population, have data on every medical encounter and every diagnosis they have received. I think these are data which have to be maintained confidentially. We have no choice about that.

Mr. Shays. Thank you. We have two more to go, and you all have been wonderful. Yes, sir, you are No. 4. Turn the mic on, if you would.

Mr. Horowitz. Thank you. My name is Dr. Len Horowitz. I am here representing an organization nationwide called Vaccination Liberation, as well as I am an Honorary Autism Ambassador, and I appreciate this opportunity.

My question is not simply for the good representatives here, but also for all of us to consider. We have currently in the last several years particularly become very aware of the tobacco industry and its infusion into what amounts to cancer sticks, a variety of ingredients that the industry itself knew was totally toxic. The evidence before this committee, I understand, including the Verstraeten report, indicates clearly the Centers for Disease Control and other industry officials knew well in advance that mercury, as well as potentially aluminum, formaldehyde, formalin derivatives, as well as foreign species DNA, RNA, proteins, cause a horrific number of injuries.

The question that I have is, how, as we begin to spend millions of dollars and give to these same organizations who have this knowledge, how can we assure that putting virtually the fox in charge of the hen house do we expect this autism pandemic or epidemic here in the United States to stop without a full housecleaning within the NIH, CDC, NAID, NIMH, and FDA, freeing this bureaucracy from special pharmaceutical industry biases and influences, especially since the lives of our children, our Nation's future is at great and grave risk?

Mr. Shays. OK, let me say, you are not going to have a followup on that one because that was such a long question, and it did have a sense of bias as well as a statement, but it is an important question to put on the record.

I don't know if you all want to address it. It was thrown out to all of us. Do you want to just make any response? I mean, Dr. Foote, can you--let me try to narrow it down a little bit.

Given that we did know that there are a lot of things that we have allowed to happen where we knew they shouldn't, how do we sort that out? In other words, in Congress, in the private sector as well, I mean we could say with hindsight we know it shouldn't have happened. We can say, well, some people in a company may have known, but maybe not everyone. Just he deserves some type of response.

Ms. Wharton. Well, I would call into question the initial statement that we know that all these additives are in vaccines

and we know that they cause harm.

Mr. Shays. Right.

Ms. Wharton. In fact, that is not known. The Institute of Medicine has reviewed the data regarding IOM and autism and has found that the evidence favors rejection of a connection between MMR vaccine and autism. As far as the thimerosal issue is concerned, the evidence is too incomplete and fragmentary to make any decisions about causation.

Of course, many substances are known to be dangerous when administered in high concentrations, but the additives that are included in vaccines are present in trace amounts, and even when multiple vaccines are given, these are still very small amounts of products. It is not established even that thimerosal is associated with any harm as a vaccine additive.

That said, we have committed a large amount of staff time and funding to try to further elaborate these issues and have designed a whole series of studies that have been described in our written testimony that we believe will help address these issues and are responsive to the specific research recommendations made to us by the Institute of Medicine.

Mr. Shays. Thank you. I am going to respond and say that some of our most dedicated employees are in the very institutions you have mentioned. So I would dispute that we need a cleaning of the house, but I do think----

Mr. Horowitz. Just in terms of those biases by special interests, currently, the waivers bother me, the fact that we have CDC officials and ASIP officials in the vaccine----

Mr. Shays. You know what we are going to do----

Mr. Horowitz [continuing]. That get these waivers----

Mr. Shays [continuing]. We are going to allow you to have dialog directly with the staff about this afterwards, and the staff will stay.

Let me just go to No. 5, and then you all have been very trustworthy, and I thank you, and I know it is tempting to jump in, but you won't be given an opportunity. We are going to five, and then you all are going to get home.

Ms. Bigelow. Hi. I am Rita Bigelow. I have an 11-year-old boy with autism. I just want to say thank you to the Congressmen and women who are here helping us with this cause, and also to the people from the NIH. Thank you for listening to us, answering our questions.

Mr. Shays. And CDC.

Ms. Bigelow. And CDC. Sorry.

Mr. Shays. Yes.

Ms. Bigelow. I am with the Autism Coalition and with other groups. I see many of my friends who are here, too. So thanks to all of them for making the trip down.

I have a question that is a little bit taking a different tack, but I worked with several researchers in autism, tried to raise money for them, and worked with them. It seems that most

scientists believe that autism is caused by a combination of genetic and environmental triggers.

My specific question, and I don't have a part B, but, what types of steps has the NIH taken to promote genetic studies? You know, the genes may perhaps interact with environmental triggers, with psycho-pharmacologic agents, things like that.

Dr. Foote. So the CPEA network that has been funded for the past several years by NICHD and NIDCD has a coordinated genetics program, their Centers of Excellence in Neurobiologic and Genetics of Autism, where they have multiple sites at which they collect genetic data from subjects. The advantage of having multiple sites being that you can collect from them a much larger cohort than you could ever do having individual investigators operating just within their own spheres. So it provides power to genetic analyses that couldn't otherwise be obtained.

In the new STAART Centers Program, we will be doing the same kind of thing, where there will be standardized diagnostic protocols across all of the sites, standardized instruments, so that then you can collect genetic data from a large number of subjects distributed at various sites and have the numerical power to do genetic analyses that wouldn't otherwise be possible.

We have at NIMH a genetics repository where we collect large amounts of genetic data and make it available to any responsible investigator who applies to us to receive genetic materials from rigorously diagnosed subjects about whom we have large amounts of information.

So this is the future. This is what we are actively implementing. We recently just gave a multimillion dollar grant to the AGRE data base, which you may have heard of, which has originated from advocacy groups, and really the grassroots, generating genetic samples. So now we feel like we are in the position where we can have a very large data base of genetic information combined with very detailed behavioral and clinical information from subjects, so that we can do powerful genetic analyses.

Then just one final note, and then I will be quiet, because you hit one of my buttons here, obviously. The other issue is that some of these questions that come up, ``Why did my child respond so dramatically to a particular vaccine when all the other kids on the block didn't respond the same way?'' Well, the genetics may well be a clue to that. The way we are going to get the answer eventually is through these combined genetics efforts where we have a large number of subjects, thorough clinical histories, standardized genetic information, freely available to a number of investigators who may well want to look at exactly this question. So that is where we are going. We are getting there.

Mr. Shays. Dr. Boyle.

Dr. Boyle. I was just going to be very brief. In our centers' studies, these are epidemiologic studies that are done collaboratively, sort of what we call gene environment interaction. This is a very important issue, and it is clearly one that is the basis for the studies, and that is what we are addressing.

Mr. Shays. I thank all five of our----

Mrs. Morella. Mr. Chairman, may I just add something to that?

Mr. Shays. Sure.

Mrs. Morella. That is where you are going to need the passage of the Genetic Non-Discrimination in Employment and Health Act, which has about 260 co-sponsors here on the House side.

Mr. Shays. I hope I am on that bill. Good grief.

Mrs. Morella. I think you are, yes. [Laughter.]

Mr. Shays. Ms. Watson, do you have any last comments you would like to make?

Ms. Watson. No, I don't except to thank the panel.

Mr. Shays. Yes. I am going to ask this question. I have one other question.

Mrs. Morella, any comments?

Mrs. Morella. No, Mr. Chairman.

Mr. Shays. I had a question that I was asked to give, and I think by the response to one that we are doing this. But the question was, do the CDC and NIH recommend that the removal of thimerosal from childhood vaccines--it appears that is the case, that we are removing them from childhood vaccines? Is that the case?

Ms. Wharton. That recommendation was actually made in 1999.

Mr. Shays. Great.

Ms. Wharton. And the vaccine manufacturers moved very quickly to reformulate and relicensed all the routinely administered childhood vaccines, so that they are now available only in thimerosal--they are now marketed only in thimerosal--in formulations that do not contain thimerosal as a preservative.

Mr. Shays. Got you. Let me ask you this now: Is there any question that you had prepared to answer that we never thought to ask that you want to answer? [Laughter.]

[No response.]

Mr. Shays. I think that our guests would recognize that you all have been very patient, and I think our witnesses would recognize that you all, those of us who are our guests at this hearing are dealing with some really tough issues. We want to be helpful to you and want you to stay in touch with our committee. Our committee record will be open until the 3rd, and you are invited to submit anything in writing to the committee that you would like to submit.

But I do thank all of you for participating here, and I

thank No. 1, 2, 3, 4, and 5 for being here and your patience in not having the sixth or seventh followup.

This hearing is now adjourned. Thank you.

[Whereupon, at 5:10 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[The prepared statements of Hon. Thomas M. Davis, Hon. Wm. Lacy Clay, Hon. Christopher H. Smith, and additional information submitted for the hearing record follow:]

[GRAPHIC] [TIFF OMITTED] T0356.148

[GRAPHIC] [TIFF OMITTED] T0356.149

[GRAPHIC] [TIFF OMITTED] T0356.150

[GRAPHIC] [TIFF OMITTED] T0356.151

[GRAPHIC] [TIFF OMITTED] T0356.152

[GRAPHIC] [TIFF OMITTED] T0356.082

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[GRAPHIC] [TIFF OMITTED] T0356.107

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