TRANSCRIPT--U.S. HOUSE OF REPRESENTATIVES, GOVERNMENT REFORM COMMITTEE HOLDS A HEARING ON THE STATUS OF RESEARCH INTO VACCINE SAFETY AND AUTISM. JZSell--aa.33467.22; Fed Clearance Candidate ID 377077

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SPEAKERS:

U.S. REPRESENTATIVE DAN BURTON (R-IN) CHAIRMAN

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U.S. REPRESENTATIVE JOHN TIERNEY (D-MA)

U.S. REPRESENTATIVE JIM TURNER (D-TX)

WITNESSES:

PANEL I

DR. JEFF BRADSTREET, MD, FAAFP, MEDICAL DOCTOR AND FOUNDER OF THE INTERNATIONAL CHILD DEVELOPMENT RESOURCE CENTER AND AN AUTISM PARENT

DR. ANDREW WAKEFIELD, MD RESEARCH DIRECTOR, INTERNATIONAL CHILD DEVELOPMENT RESOURCE CENTER

DR. ARTHUR KRIGSMAN, MD PEDIATRIC GASTROINTESTINAL CONSULTANT LENOX HILL HOSPITAL, CLINICAL ASSISTANT PROFESSOR DEPARTMENT OF PEDIATRICS, NEW YORK UNIVERSITY SCHOOL OF MEDICINE

DR. VERA STEJSKAL ASSOCIATE PROFESSOR OF IMMUNOLOGY, UNIVERSITY OF STOCKHOLM AND MELISA MEDICA FOUNDATION

DR. WALTER SPITZER, MD, MPH, FRCPC EMERITUS PROFESSOR OF EPIDEMIOLOGY, MCGILL UNIVERSITY

PANEL II

DR. ROGER BERNIER ASSOCIATE DIRECTOR FOR SCIENCE, OFFICE OF THE DIRECTOR, CENTER FOR DISEASE CONTROL AND PREVENTION

DR. ROBERT CHEN CHIEF OF VACCINE SAFETY AND DEVELOPMENT, NATIONAL IMMUNIZATION PROGRAM AND ASSOCIATE DIRECTOR FOR SCIENCE AND PUBLIC HEALTH NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES CENTER FOR DISEASE CONTROL AND PREVENTION

DR. FRANK DESTEFANO MEDICAL EPIDEMIOLOGIST, NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES CENTER FOR DISEASE CONTROL AND PREVENTION

DR. STEPHEN FOOTE NATIONAL INSTITUTES OF HEALTH

DR. WILLIAM EGAN FOOD AND DRUG ADMINISTRATION

BURTON: Good afternoon. I'm sorry we're getting started just a little bit late. It's my fault and I apologize.

A quorum being present, the Committee on Government Reform will come to order. And I ask unanimous consent that all members' and witnesses' written and opening statements be included in the record. Without objection, so ordered.

I ask unanimous consent that all articles, exhibits and extraneous or tabular materials referred to be included in the record. And without objection, so ordered.

In April, the committee conducted a hearing reviewing the epidemic of autism and the Department of Health and Human Service's response. Ten years ago, autism was thought to affect one in 10,000 children in the United States. When the committee began its oversight investigation in 1999, it was thought to affect one in 500 children. Today, the National Institutes of Health estimates that autism affects one in 250 children.

Now think about that. It's gone from one in 10,000 to one in 250. We have an absolute epidemic.

In April, we looked at the investment our government has made into autism as compared to other epidemics. We showed in that hearing that the CDC and NIH have not provided adequate funding to address the issues in the manner that our public health service agencies have used to address other epidemics. And we have some charts that I think you're going to put up there on the screen to show this.

After our hearing, I joined with my colleagues on the Coalition on Autism Research and Education to request from our appropriators that at least $120 million be made available in fiscal year 2003 for autism research across the NIH and at that an additional $8 million be added to the CDC's budget for autism research.

Giving more money to research is not the only answer though. Oversight is needed to make sure that research that is funded will sufficiently answer the questions regarding the epidemic: how to treat autism and how to prevent the next 10 years from seeing the statistic of one in 250 children go to one in 25 children.

High quality clinical and laboratory research is needed now, not five or 10 years from now. Independent analysis of previous epidemiological and case control studies is needed as well.

We have learned that a majority of parents whose children have late-onset or acquired autism believe it is vaccine-related. They deserve answers. We have also learned that the parents have been our best investigators in looking for both causes of autism and for treatments.

It has been parents who have formed non-profit organizations to raise research dollars to conduct the research that the CDC, the FDA and NIH have neglected to do. We have heard from many of these parents in the

past: Elizabeth Birt, Rick Rollens, Shelley Reynolds and Jeanna Smith, just to name just a few. Each of these parents had healthy babies who became autistic after vaccination.

I might have been like many of the officials within the public health community -- denying a connection -- had I not witnessed this tragedy in my own family. I might not have believed the reports from parents like Scott and Laura Bono, Jeff Sell, Jeff and Shelly Segal and Ginger Brown, who came to me with pictures, videos and medical records. I might have been like so many pediatricians who discounted the correlation between vaccination and the onset of fever, crying and behavioral changes.

Because both of my grandchildren -- not one, but both of my grandchildren -- suffered adverse reactions to vaccines, I could not ignore the parents' plea for help. I could not ignore their evidence.

My only grandson became autistic right before my eyes, shortly after receiving his federally recommended and state-mandated vaccines. Without a full explanation of what was in the shots being given, my talkative, playful, outgoing healthy grandson Christian was subjected to very high levels of mercury through his vaccines. He also received the MMR vaccine. And within a few days -- and I'm telling you, within a few days -- he was showing signs of autism.

I won't go into the details. Those of you who have autistic children know what I'm talking about.

As a part of our investigation, the committee has reviewed ongoing concerns about vaccine safety, vaccine adverse events tracking, the Vaccine Safety Datalink (VSD) Project and the National Vaccine Injury Compensation Program. I have joined with Congressman Weldon, Congressman Waxman and 32 other members of Congress in introducing HR 3741, the National Vaccine Injury Compensation Program Improvement Act of 2002, to realign the compensation program with congressional intent.

In today's hearing, we will receive a research update from several previous witnesses, as well as new research findings that further support a connection between autism and vaccine adverse events. We will learn more about both the possible link between the use of the mercury-

containing preservative thimerosal in vaccines and autism, as well as autistic entercolitis resulting from the Measles-Mumps-Rubella vaccine, MMR vaccine.

Through a congressional mandate to review thimerosal content in medicines, the FDA learned that childhood vaccines, when given according to the CDC's recommendations, exposed over 8,000 children a day -- 8,000 a day -- in the United States to levels of mercury that exceed federal guidelines. Is there a connection between this toxic exposure to mercury and the autism epidemic? We will hear from Dr. James Bradstreet and Dr. Vera Stejskal on this issue.

We have twice received testimony from Dr. Andrew Wakefield regarding his clinical research into autistic enterocolitis. We will learn today that not only has he continued to conduct clinical research, but that this research is confirming the presence of vaccine-related measles RNA in the biopsies from autistic children.

Dr. Wakefield, like many scientists who blaze new trails, has been attacked by his own profession. He has been forced out of his position at the Royal Free Hospital in England. He and his colleagues have fought an uphill battle to continue the research that has been a lone ray of hope for parents whose children have autistic enterocolitis.

Dr. Arthur Krigsman is joining us as well today to discuss his clinical findings of inflammatory bowel disorder in autistic children. He will share with us his initial findings, as well as discuss his research plans currently with his institutional review board for approval.

Do the epidemiological and case control studies, which the CDC has attempted to use to refute Dr. Wakefield's laboratory results, answer the autism-vaccine questions honestly? Epidemiologist Dr. Walter Spitzer is back today to answer this question. What else is needed to prove or disprove a connection?

Unfortunately, rather than considering the preliminary clinical findings of Dr. Wakefield as a newly documented adverse reaction to a vaccine, the CDC attempted to refute these clinical findings through an epidemiological review. While epidemiological research is very important, it cannot be used to disprove laboratory and clinical findings. Valuable time was lost in replicating this research and determining whether the hypothesis was accurate.

Officials at HHS have aggressively denied any possible connection between vaccines and autism. They have waged an information campaign endorsing one conclusion on this issue where the science is still out. This has significantly undermined public confidence in the career public service professionals who are charged with balancing the dual roles of assuring the safety of vaccines and increasing immunization rates.

Increasingly, parents come to us with concerns that integrity and an honest public health response to a crisis have been left by the wayside in lieu of protecting the public health agenda to fully immunize children. Parents are increasingly concerned that the department may be inherently conflicted in its multiple roles of promoting immunization, regulating manufacturers, looking for adverse events, managing the vaccine injury compensation program and developing new vaccines.

Families share my concern that vaccine manufacturers have too much influence as well. And

that's something that we continue to look into.

How will HHS restore the public's trust?

One of the primary topics to be discussed at this hearing is access to the Vaccine Safety Datalink. To help fill scientific gaps, the CDC formed partnerships with eight large health maintenance organizations, through an agreement with the American Association of Health Plans, to continually evaluate vaccine safety. This project is known as the Vaccine Safety Datalink or VSD and includes medical records on millions of children and adults.

Up until this year, access to data from the VSD has been limited to researchers affiliated with the CDC and a few of their handpicked friends. This "good old boy's network" practice has predictably led to questions about the objectivity of the research and the fairness of the results.

The VSD data should be made available to all legitimate scientific researchers so that independent studies can be conducted and results verified. This database contains a wealth of data involving millions of patients over a 10-year period. If properly utilized, it can help researchers study vitally important questions about the safety of vaccines, the effects of mercury-based preservatives in childhood vaccines and many other questions.

The committee first raised this issue with the CDC two years ago. For two years, the CDC delayed. Six months ago, we were informed that the CDC was developing a plan to expand access to the database. Finally, in February of this year, after a great deal of prompting from the committee, Dr. Robert Chen, Chief of Vaccine Safety and Development at the National Immunization Program, informed our committee staff that the CDC had finalized its plan and that it was poised to put it into effect. Under this plan, any legitimate scientist could submit a proposal to the CDC to conduct research using VSD data and access to the data would be provided along with some scientific or with some basic safeguards.

In preparation for today's hearing, committee staff asked the CDC why the plan described to us in February had not been put into effect. And the staff was informed that the plan had been put into effect. However, there had been no public announcement. They put it into effect, but they didn't tell anybody.

How are researchers supposed to know about the availability of the data if there is no announcement? It took two years of prodding by this committee to get the CDC to open up access to the database. For four months, it appears that the CDC didn't inform anybody but this committee of the data's availability.

That doesn't make it appear that the CDC is making a good faith effort to open up this database. It looks to me like the CDC is trying to do the bare minimum that they have to do to get us off their backs. And that's not acceptable.

That's why I insisted that Dr. Chen be here today. I just wanted to ask him why they didn't tell anybody about the database being available. I'd like to know how he expects researchers to use this data if nobody tells them it's available.

Dr. Roger Bernier is here from the CDC to testify about these issues.

He is accompanied by both Dr. Chen, the creator of the VSD Project and Dr. Frank DeStefano, the CDC official who is also a co-author of the MMR-IBD study. They are here to address our questions on the VSD project and the vaccine-autism research. The CDC employees are accompanied by Dr. Stephen Foote from the National Institutes of Health and Dr. William Egan of the FDA.

As representatives of the people, we have a responsibility to ensure that our public health officials are adequately and honestly addressing this epidemic and its possible links to vaccine injury.

I look forward to hearing from our witnesses. And our record, the hearing record will remain open until July 3rd. And I now recognize Mr. Waxman.

WAXMAN: Mr. Chairman, today you have convened a hearing about the safety of vaccines. This is an important topic and also a familiar one to this committee.

Over the last several years, you have held a series of hearings raising questions about the safety of vaccines, questions that undoubtedly have caused real concern among some parents. These hearings have had some positive effects.

Your interest over the years has led to unprecedented attention to vaccine safety. Since your first hearing on the topic, many respected researchers have chosen to investigate whether vaccines are associated with inflammatory bowel disease, autism, diabetes and other assorted conditions among children. While rare side effects from vaccines are always possible, these studies have not found that vaccines are associated with any of these serious health problems.

Since your first vaccine safety hearing, a blue ribbon panel of scientists convened by the Institute of Medicine has reviewed many of the most widely disseminated theories alleging harm from vaccines. This esteemed panel evaluated the allegations that the MMR vaccine causes autism.

Such studies claim that thimerosal, a vaccine preservative, cause development delay. It reviewed whether the Hepatitis B vaccine causes neurological injury. It assessed the theory that multiple vaccinations cause allergies and asthma.

In each case, the Institute of Medicine panel has found that scientific evidence does not validate the theory. Expert panels in other nations have reached similar conclusions.

Mr. Chairman, you have challenged the public health system to defend itself against numerous allegations that vaccines cause a wide variety of problems. I am not aware of any allegation about the safety of vaccines that you have not pursued.

So far, the subsequent investigations and expert reviews have found vaccines to be safe. Because of your efforts in this area, Americans can have more confidence today in the safety of the vaccine supply than ever before.

But there has also been a negative consequence to your approach. You have repeatedly provided a forum for unsubstantiated allegations about vaccine safety that has alarmed and confused parents. Although the scientific evidence of vaccine safety has grown stronger, parental concerns

about vaccine safety have also increased since we started these hearings. This is a potentially dangerous development because it can lead to lower immunization rates and more disease.

I recently asked the Centers for Disease Control to describe what would happen if MMR immunization rates dropped. According to CDC, if immunization rates dropped to the levels they were in 1989, we could see over 26,000 hospitalizations from measles, 8,500 cases of pneumonia, 135 cases of encephalitis and 224 deaths.

According to the Centers for Disease Control, even a drop in immunization rates of 10 percent could result in an additional two million kids being susceptible to measles. It would also significantly increase susceptibility to rubella and congenital rubella syndrome, which can cause serious birth defects, such as blindness, deafness and stillbirth.

Congenital rubella syndrome is also a well-known cause of autism, a disease that we all want to prevent. How tragic it would be if an unjustified vaccine scare caused some children to die and others to have permanent brain deficits and still others to suffer from autism. I ask that the information from the CDC be placed in the record at the conclusion of my statement.

While I am strongly opposed to reckless allegations about vaccine risk that scare parents and are not supported by the science, I also recognize that questions about vaccines will always arise. That's why I support efforts to fund additional research on vaccine safety.

Some of the theories on the agenda for today do require additional research. And I am pleased that the government is supporting such studies.

I also support making sure that the government does not lose the ability to conduct valid vaccine safety studies. We must assure the future of initiatives like the Vaccine Safety Datalink Project.

This is a unique collaboration between CDC and several large health maintenance organizations that allows for valid and timely research on vaccine safety. Indeed, this research has led to many important policy changes over the years.

Today, we'll hear from scientists at CDC who work closely with the Vaccine Safety Datalink Project. These scientists are quite concerned about your threat to subpoena the raw data from this database to pursue a vaccine-related allegation. Because the raw data contain identifiable information from the medical reference records of more than six million Americans, a congressional subpoena would constitute a serious violation of medical privacy.

According to CDC, a subpoena could have the effect of driving health maintenance organizations from the program and destroying CDC's ability to scientifically test hypotheses relating to adverse events potentially associated with vaccines. So in other words, we're going to end up causing more harm than doing good if we pursue this subpoena approach.

You have an alternative to a subpoena, Mr. Chairman. The Centers for Disease Control has worked with HMOs to create a process for allowing independent researchers access to this data. And in continue to urge you to accept this solution and renounce your subpoena threat.

Finally, I would like to address some allegations that Dr. Wakefield makes in his written testimony. Dr. Wakefield implies that a witness who testified here last year, Dr. Michael

Gershon, either perjured himself or was guilty of sloppy science by noting problems in the lab that Dr. Wakefield used in his research. Dr. Gershon did not lie to this committee. And this portion of his testimony did not involve his scientific expertise and thus, was not sloppy.

Dr. Gershon related what he was told by Dr. Michael Oldstone of the Scripps Institute, who had performed an evaluation of this lab. Dr. Gershon continues to stand by his testimony.

Dr. Wakefield also is planning to make a needless attack on Dr. Gershon's wife, who he alleges may have a financial interest in the chickenpox vaccine. In fact, according to Dr. Gershon, while his wife did conduct research relevant to a chickenpox vaccine patent, neither he nor his wife has any financial interest in the vaccine or its manufacturer.

Dr. Wakefield's allegation is therefore groundless, as well as gratuitous.

Dr. Gershon's testimony last year was quite lengthy. And he raised many scientific issues. But Dr. Wakefield has not refuted any of them.

Instead, he is resorting to name calling, which does not move these scientific issues along and is unproductive.

I'm going to ask unanimous consent that the written testimony of Dr. Elizabeth Miller (ph) of the Public Health Laboratory Service of the United Kingdom be entered into the record. And I also alluded to other information, which I would like to also attach to this opening statement and make part of the record.

I thank the witnesses for coming today. I look forward to your testimony. And I yield back my time.

BURTON: Regarding the unanimous consents you asked to put that in the record, we'd like to review it. We'll probably have no objection to it. We'd like to take a look at it. Do we have a copy of that?

WAXMAN: Mr. Chairman, we'll make everything available to you and your staff to put into the record. I did note that the chairman asked unanimous consent at the beginning of the hearing for all submissions of materials to be part of the record. And I would hope you would come to the same conclusion with these articles.

BURTON: We probably will. We just want to review it.

WAXMAN: Well, I have no problem with that.

BURTON: Mr. Weldon?

WELDON: I thank Chairman Burton for calling this hearing. As a physician who continues to see patients, I have a very, very strong interest in maintaining the safety and integrity of our national immunization program. The response from the CDC and the NIH to the growing concerns over the safety of the Measles, Mumps, Rubella or MMR vaccine continues to baffle me.

While this vaccine may be safe for most children, there is growing clinical evidence that a subset of children may be suffering very severe reactions to the MMR. For too long, public health officials and those with a vested interest in the status quo have engaged in what I perceive to be a denial or simply viewed those who suffer severe adverse reactions as a cost of doing business.

We have a moral imperative to look at the clinical evidence to determine why some children may be suffering reactions to MMR. For nearly three years, I have been urging the CDC and NIH to more aggressively move to address these growing concerns. And I must say that I have been disappointed by the failure of the CDC and NIH, since these concerns were first raised in a study published in 1998, they have not addressed this issue.

The CDC, in conjunction with public health officials in the United Kingdom, have responded to each new clinical study raising safety concerns about the MMR with an epidemiologic study, a statistical study. They did this after the 1998 Wakefield study. They did it with the study issued in January of this year by Olman et al. (ph). And they did it again last week, in anticipation of the release of a study identifying vaccine strain measles as the strain in the affected children in the Olman (ph) study.

These statistical studies have been released with great fanfare to the media. And the media, thus far, have given the expected response of proclaiming the complete safety of the MMR vaccine.

Those who have been raising these questions and conducting clinical research in this area have grown to expect the mantra, "Our statistics say that this cannot be." I must say, if their purpose is to preserve the status quo and succeed in a public relations campaign, they have been successful; at least, to date.

However, if their purpose is to directly address the clinical findings of persistent measles inspections in seriously affected children, their efforts have been a dismal failure. They have not produced one clinical study to directly address these concerns.

My message to the NIH, but particularly to the CDC, is put away your statistics textbook and get out your microscope. The failure to do so only breeds speculation and undermines public confidence and ultimately makes the job of clinicians more difficult.

Thank you. And I yield back.

(UNKNOWN): Thank you, Mr. Chairman, for this opportunity, and to address some issues that have been of great concern to me for a while. As you know, I am cosponsoring, with Congressman Burton, a bill that would require informed consent on the part of patients at a dentist's office when the dentist is getting ready to put in a filling. That's an amalgam that contains mercury because, over the years, there has been a connection between mercury in amalgam and an effect on not only the brain cells of the mother, but going through the placenta into the fetus.

I will listen very intently, in the time that I have, to hear from CDC and to hear from the other witnesses about the connection of vaccines and autism because we're thinking now that any kind of foreign substance that is toxic that you put into any orifice of the body has an effect.

And certainly mercury in the teeth.

I've had dentists come to me and argue against our opposition, from the standpoint of they're questioning the research. Well, this morning, I put on a ring. And I can taste silver on my tongue.

This is nickel. And there is an effect that metals do have in the body from things that we apply to it and ingest or put into these orifices.

So I am hoping that CDC will support the work of Dr. Wakefield, make the connection, report back to us. Then I'm going to start looking into the use of nickel. And nickel is in most costume jewelry -- in the earrings that we wear, in the ring that I have on and so on. It does have an effect on the body.

So I want to thank the chair for having this hearing. And there have been hearings before. I'm sure there will be hearings. And I am listening very closely to see if we can, indeed, draw that linkage from vaccines to autism and other conditions that face not only children, but human beings as a whole.

Thank you, Mr. Chair. And forgive me for running out to my next hearing before I can hear all the witnesses.

BURTON: Thank you very much.

The gentleman from Tennessee, Mr. Duncan?

DUNCAN: Thank you very much, Mr. Chairman. I don't have a formal opening statement. I do want to say that I want to thank Chairman Burton for calling this hearing and continuing to pay close attention to what I think is a very, very important topic.

I mentioned at the last hearing that I've been getting interested in this because I've talked to several parents who have told me very sad, heartbreaking stories about the healthy children that they had and then just terrible problems that occurred after taking some of these vaccines.

So I think this is something that we really need to look at. I've been sitting here reading the testimony of the witnesses and looking through the outstanding notebooks that the staff has prepared for us.

And I think this is something that we need to have a hearing about and we need to continue to do some research on and look into as fully as we possibly can. And I thank you for calling this hearing.

BURTON: Thank you, Mr. Duncan.

Mr. Cummings?

CUMMINGS: Thank you very much, Mr. Chairman. And I want to thank you for holding this hearing. And I want to thank you for your tremendous interest in healthcare and for the recent hearing that you held with regard to disparities in healthcare.

Our committee has held several hearings exploring vaccine safety and the theories on the correlation between vaccinations and autism. Let me say, first off, that vaccinations have played a very significant role in this country and actually across the world. When we think of diseases like polio and smallpox and many others, vaccines have certainly allowed many people to live who probably would have died and have helped them to live the best lives that they could, as opposed to suffering.

Additionally, the committee initiated an investigation into the dramatic rise in autism rates across the country. Autism is a disorder that severely impairs development of a person's ability to communicate, interact with other people and to maintain normal contact with the outside world.

One of the most common development disabilities, autism affects two to five out of every 10,000 children. And it usually appears before the age of three.

The causes of autism are unknown. There are some effective treatments for some children. But there is no cure.

In the past, autism was considered a rare disorder. However, today, autism is being diagnosed much more frequently. There have been approximately 2,800 cases of autism reported in my state of Maryland.

Additionally, there has been a rise in the number of autism cases in California, New Jersey and other states.

Although at this time, it is unclear whether the rise in the number of autism cases is due to increased reporting or demand for services.

Emerging data appears to support the theory that changes in diagnosis explain the rise in autism cases.

Parents everywhere are anxious to learn more about the possible link between common preservative in childhood vaccinations and developmental problems whose symptoms resemble those of autism. Symptoms of mercury toxicity in young children are extremely similar to those of autism.

There is a growing awareness of the nature of autism and the kinds of approaches to diagnosis, treatment and care that are likely to be effective in meeting the needs of autistic individuals and their families. Diagnosing autism today requires specific training and experience.

I would encourage medical schools to offer specialized training to our nursing and medical students for autism. And as I have said in the past hearings, I applaud the Centers for Disease Control and Prevention, the National Institutes of Health, as well as the Kennedy Krieger Institute Center for Development and Behavior Learning at the University of Maryland School of Medicine in Baltimore and the many other organizations for their continued research on autism.

Congress should allocate more money for autism research. I offer my support to the families of autistic children who must continue to look for the cause and the cure of autism.

I am convinced that with further research, a cause and cure will be found. As such, I strongly believe that all theories for the cause of autism must be objectively researched. I look forward to hearing from today's witnesses and learning more about the Vaccine Safety Datalink, a large linked database that the Centers for Disease Control and Prevention uses to research vaccine safety.

Again, Mr. Chairman, I thank you for the hearing. And with that, I yield back.

BURTON: Thank you, Mr. Cummings.

Mr. Horn?

HORN: I commend you, Mr. Chairman. I've sat through the hearings.

And we have really looked at this situation. And I look forward later in the day -- I have to go to Transportation right now and Infrastructure. But thank you for putting all this together.

BURTON: Thank you.

Mr. Tierney?

TIERNEY: Thank you, Mr. Chairman, for having these hearings. I would like to get to our witnesses. And I'm pleased that we're going to have testifying before us here today individuals and representatives from the CDC and others who are actually conducting the research into autism and its causes.

I really believe that affected children and their families obviously can't afford to have us be complacent about this disorder. So Mr. Chairman, I'd like to enter my more complete remarks on the record, with unanimous consent, and look forward to hearing from these witnesses today.

BURTON: Thank you, Mr. Tierney.

We'd like to have Dr. Bradstreet, Dr. Wakefield, Dr. Stejskal, Dr. Krigsman and Dr. Spitzer come to the table.

And while they're coming up there, let me just say that the purpose of the Government Reform and Oversight Committee -- it's not called oversight anymore, but that's our responsibility is to conduct oversight into every agency of government where we think there's a problem.

And the minute that the Congress of the United States quits asking questions, stops asking questions about very important issues like vaccine safety, which affects every single person in this country, then we will be guilty of dereliction of our responsibilities. And as long as I'm chairman of this committee, we're going to continue to ask these questions.

And I want to make one more real brief comment and that is that we have gone from one in 10,000 children who are autistic to one in 250.

Now somebody has got to start explaining why this horrible tragedy is occurring, why we have this epidemic. And we're not getting the answers.

I mean, we have an epidemic here. And we can't just close our eyes and stick our head in the sand. We've got to find out why this is going on. And the health agencies have not yet given us an adequate answer.

Would all of you please rise so I can swear you in?

Do you swear to tell the whole truth and nothing but the truth, so help you God? Be seated.

Dr. Bradstreet, do you have an opening statement?

BRADSTREET: Unfortunately, the nature of autism is so complex that to do it in five minutes will be challenging. So I have submitted, under tab five, a more complete review of the nature of our research. I will try and get through my slides quickly, Mr. Chairman.

Thank you very much for the hearing and for an opportunity to present this. Dr. Weldon and I previously met two weeks ago in your office with the deputy secretary of health and human services, Claude Allen, to present this data to him. So he has been made aware of it. And it was a very encouraging and very positive meeting. I look forward to the outcome of that over time.

With that, the next slide.

The prevalence may be both misunderstood and underestimated. Two recent studies, one from England and one that was a CDC study with Brick Township, indicated between 57 per 10,000 and 67 per 10,000 children.

However, autism is primarily a boy-related disorder; four to eight times as many boys suffer with this disorder. That means that the prevalence is therefore in the order of one percent for boys.

Next slide.

The economic impact. We estimate that there are approximately 420,000 children with autism in this country at this time, based on those studies, greatly less than what the "Time Magazine" article set at one million. However, that puts a price tag, over the next 50 years to take care of these children, in excess of $1 trillion.

That was a lot of zeroes. I had to go through that a couple times on my calculator to make sure that that was correct. But that is the real number. The lifetime costs could be $3 trillion to $4 trillion for the families and for society, with the lost wages and other factors.

Next slide.

The biological evidence for causality is growing significantly. And for those members of the committee who may not be familiar with me, I am a physician. I am also a parent of a child with autism. And I am a clinical researcher associated with studies currently ongoing at 14 medical schools around the world.

The growing evidence is substantial that measles virus is still the front runner with the viral etiology aspects of things. And not all children suffer from measles virus-related disorders. But we'll show you today some examples that are quite, I think, impacting.

Additionally, autoimmunity continues to be published by a variety of researchers at multiple medical schools that there is a unique disorder affecting the autoimmunity in these children where they become immune to their gut and their brain. And that is a disaster for them.

Mercury -- and, to a lesser extent, lead -- remain significant toxic burdens. And we presented that data to the Institute of Medicine in July of last year.

Next slide.

The first case -- I'm going to present two cases today. I'll try and go through them briefly.

Matthew (ph), who was born in 1984 from an uncomplicated pregnancy and an easy delivery, had a normal early development, except he did develop some gait abnormalities that are very consistent with what you might expect from Mercury. We'll see that data later on.

He had a rapid decline after each of two MMRs. He did receive those in combination with other vaccines, however.

He developed autoimmunity to myelin basic protein, a critical insulator of the brain. He suffered seizures shortly after the second MMR. And he has consistent immune deficiency with protracted low mythecide (ph) counts.

Next slide.

He has inflammatory bowel disease that has been documented on an endoscopy and biopsy. He has persistent measles virus genome in that inflammatory disease. He has persistent measles virus in circulating white blood cells. He has persistent measles virus "F" gene in his cerebral spinal fluid, which is the fluid that surrounds the brain, implying it is present in the brain as well.

He has auto-antibodies to measles virus in his spinal fluid. He has auto-antibodies to myelin basic protein in his spinal fluid, elevated a million, a very low serum sulfur level and cysteine level and very high Mercury as a result of that.

Next slide.

And next. That is my son, who is also the, I think, inspiration for our research and the work that we do. He was a very happy, well- connected child prior to his MMR. That's about approximately at 12 months of age. And that is Matthew (ph), completely lost, about two months after his MMR vaccine.

Next slide. That is a copy of the laboratory result documenting the presence of measles virus in his terminal ileum.

Next. Copy of the laboratory result from Utah State University where Matthew (ph) had spinal fluid analyzed that showed antibodies to myelin basic protein and to measles virus in his spinal fluid.

Next slide. This shows the presence of antibodies in his RBCs. Excuse me, the presence of virus in his red blood cells. It is also present in his cerebral spinal fluid.

Next slide. And this is his first mercury titer, showing marked elevations of mercury. And if you can see for all those, essentially the only thing that is truly abnormal is a significant increase in Mercury.

Next slide. The first challenge to us to get Mercury out of his body resulted in an extremely high titer. That number of dots actually represents 24 micrograms for gram of creatne (ph). It would take it well off the slide, perhaps into the next room.

Next? This is an interesting correlation. Mark Blacksill (ph) presented this to the Institute of Medicine last year. And that shows the rising titer of cumulative Mercury in the vaccine program in California, compared to the prevalence of autism in California.

Next? And I want to superimpose on that a very interesting graphic derived from the government website on the use of methylphenidate, also known as Ritalin or Concerta. And look at the time relationship between the rise in that.

Next? It's identical. In 1990, the rise in the mercury titer started to go up. And in 1990, there is a striking and continuous rise in the use of Ritalin in this country, which I think is rather telling.

Next slide, please. This is the thimerosal versus autism relative risk that was produced in the CDC confidential study that was acquired under the Freedom of Information Act, showing that by the time approximately 37 micrograms of Mercury is administered, there is more than a doubling of the relative risk of autism.

Next. This is a copy of a transcript from the Simpson-Wood (ph) meetings. It is page 229, where Dr. Brent (ph) -- who is not employed by the CDC; he is a public health official from one of the states -- said that the medical-legal findings in the study, causal or not, are horrendous. If an allegation was made of a child's -- the behavioral findings were caused by thimerosal-containing vaccines, you will not find a scientist with any integrity who would say the reverse of the data that is available.

So we are in a bad position, from the standpoint of defending any lawsuits if they were initiated. And I am concerned.

I think that may set part of the tone for what we have seen happen in the last several years.

Next slide. Additionally, there was a very good documentary on this.

Parents are aware. And I think it's very important for Congress to be aware that the parents are receiving information from a variety of outlets.

This is not just your doing or undoing a vaccine policy. Parents are well educated. They are hungry for information. And they currently don't believe many of the reassurances that are being provided by CDC.

Next slide. Case two is very similar to my son. And I present it so that you will realize that this is not -- my son was not an isolated

case. He had, again, normal developmental milestones. He arrests

shortly after his first MMR at 15 months. He again has antibodies to many things in his brain and persistent measles virus in places that it doesn't belong, including his cerebral spinal fluid.

Next. Lab slide. This indicates that, in fact, he has antibodies to myelin basic protein and to measles virus in his spinal fluid.

Next. He has this unique antibody. And this is the presence of MMR antibody, which is actually the "H" protein or the hemogluten (ph) protein from the measles virus of a special antibody titer that was derived using MMR vaccine. And this was done in Dr. Singh's laboratory at Utah State University. Also positive in spinal fluid.

Next. We presented this data, Dr. Singh and myself, at the American Society of Microbiology last month, which indicates that 50 percent of children in our society had antibodies to this special measles, mumps, rubella-derived protein in their cerebral spinal fluid. Also, 86 percent have antibodies to myelin basic protein in their spinal fluid.

And again, a very high percentage, up to 100 percent, had antibodies to myelin basic protein in their blood.

This is not present in normal controls. This is a controlled study.

We now have significant controls. And we do not see these present.

This is not an antibody leakage phenomenon. This is real disease in these children.

Next. Again, Scott (ph) has documented measles virus in his terminal ileum in his blood, as well as the spinal fluid. These are laboratory data.

Next. And I want to include from Dr. Menkes (ph), his comments, where he concludes that, in fact -- this is related to the MMR vaccine in this particular child. Dr. Menkes (ph) wrote the textbook, "Child Neurology." He is considered to be one of the foremost experts, both on child neurology and on vaccine safety and has concluded that measles, mumps, rubella vaccine is causing this syndrome.

Next. That's the child. I think it's always important to put a face. This is impacting human lives.

Next slide. I would leave you with some questions. I think we have some important things that we need to ask. These are in the handout.

But as we work through this, I think we need to know that what if Dr. Wakefield, myself, Dr. Singh, Dr. O'Leary and Dr. Menkes (ph) and others are right. What then? What would be the reaction to public health officials if, in fact, this data is -- as we believe it is -- verifiable?

In addition to that, what is the response to treating these kids? How are we going to get this virus out of these kids and restore them to good health? And have we traded a very rare occurrence of severe side effects to natural measles infection for a very common occurrence of autism?

With that, I will end because I think I went past my time.

BURTON: That's all right. I think it was very informative.

BRADSTREET: Thank you.

BURTON: Dr. Wakefield?

WAKEFIELD: Mr. Chairman, members, it's a great pleasure to be back here again. Before bringing you up to date with the research linking MMR vaccine to regressive autism, I would like to put the record straight with respect to Dr. Gershon's testimony last year on the molecular detection of measles virus in the laboratory of Professor O'Leary.

WAKEFIELD: Dr. Gershon's testimony was false in relation to a number of assertions, whether or not his testimony constituted perjury or simply sloppy science. It is not my wish to take up valuable time in this hearing with the details of Dr. Gershon's unacceptable errors. All correspondence relating to this, all raw data have been provided to both the ranking majority and minority members.

Merely by way of illustration, he stated that tissues from experimental animals not infected with measles virus were positive in Professor O'Leary's lab. In fact, they were all entirely and consistently negative on repeat testing in blinded studies.

Scientifically, Dr. Gerson's behavior was a disgrace. And I stand by that.

I would level the same charge at anyone who relies on -- or has relied on in any way -- upon his testimony. The disgrace is that he did not check the raw data before impugning the reputation of a fellow scientist before the eyes of the world. I'm not surprised that Dr. Gershon has turned down, on two occasions, the offer to appear before this committee.

Let me turn now to the current state of the science. The association between MMR vaccine autism and intestinal inflammation was first suggested by my group on the inspiration of parents from the Royal Free Hospital Medical School in 1998 in a paper published in the "Lance" (ph). And this is well known to you.

The same research team, in collaboration with Professor John O'Leary and Dr. Simon Mertz (ph) a pediatric gastroenterologist from the Royal Free Hospital, have since shown in a comprehensive series of what were eight and now 10 peer-reviewed scientific studies, that the major findings of our original study were indeed correct. These papers are listed in the appendix. The papers are here. And I will make them available to anyone who wishes to read them.

The sum of the research of my group and our collaborators, taken together with additional work by independent physicians and scientists in the United States, has now confirmed the following facts. Children with regressive autism and intestinal symptoms have a novel and characteristic inflammatory bowel disease. This disease is not found in developmentally normal control children.

This disease is entirely consistent with a viral cause. This disease may be the source of a toxic or immune insult to the brain. Measles virus has been identified in the diseased intestine in the majority children with regressive autism studies, precisely where it would be expected if it were

the cause of the intestinal disease.

These children, who suffer the same pattern of regressive autism and intestinal inflammation, come from many countries, including the U.S. and Ireland, where they have been investigated. These barristers (?) have been nowhere near my laboratory.

Measles virus has been found in only a small minority of developmentally normal control children. The measles virus in the diseased intestine of autistic children is from the vaccine. Children with regressive autism appear to have an abnormal immune response to measles virus, as you've heard from Dr. Bradstreet.

And these findings are entirely consistent with parental reports that their normally developing child regressed into autism following exposure to the MMR vaccine. As you will hear from my colleague on my left, Dr. Stejskal, these findings are also entirely consistent with an immune-mediated damage to the developing child by thimerosal.

Confirmation of the intestinal findings. Other researchers in the U.S. have confirmed the presence of intestinal inflammation in children with regressive autism. And we will hear testimony from Dr. Krigsman to this effect and, independently, the link between measles virus in children who were given the MMR vaccine and abnormal immune responses,

Measles virus sequencing has been performed. Most significantly, a study due to be presented at the Pathological Society of Great Britain in Ireland, in Dublin at the beginning of July has confirmed that the measles vaccine virus is present in the diseased intestinal tissues of these children.

The Dublin researchers, headed by Dr. John O'Leary, professor of pathology at Trinity College-Dublin, examined viral genetic material from intestinal biopsies taken from 12 children with gastrointestinal disease and autistic spectrum disorder. The viral genetic material had already been identified as coming from measles virus in a study published in January in "Molecular Pathology."

Using state-of-the-art molecular science, the samples from these 12 children have now been characterized as from the vaccine strain virus.

This investigation continues. These data constitute a key piece of evidence in the examination of the relationship between MMR vaccine and regressive autism.

We heard last year about re-challenge phenomena, children who had received more than one dose of the vaccine. A further key piece of evidence comes from the examination of these re-challenged cases and biological gradient effects. I will explain what I mean by that.

Re-challenged refers to a situation where an exposure of an individual to an agent -- for example, a vaccine -- elicits a similar adverse reaction to that seen following the initial exposure. The secondary reaction associated with re-challenge may either reproduce the feature associated with the primary challenge or lead to worsening of the condition that was initially induced.

In other words, Mr. Chairman, I give you a drug; you develop a rash.

That could be coincidence. I give you the same drug again; you develop the same rash. That is not coincidence until proven otherwise.

During the course of our clinical investigations, we have observed some children who receive a second dose of MMR or, in the U.K., boosting with the combined measles-rubella vaccine, experience further deterioration in their physical and/or behavioral symptoms, as explained in Dr. Bradstreet's child.

In a report of April 2001, the Vaccine Safety Committee of the Institute of Medicine said that in the context of MMR vaccine as a possible cause of this syndrome, re-challenge would constitute strong evidence of an association. In the context of adverse reactions, a biological gradient refers to an increasing severity of the disease upon repeated exposure.

We have undertaken a systematic evaluation of re-challenge and biological gradient effects in children with regressive autism. We've undergone investigation at the Royal Free Hospital.

We have compared exposed children, those who have received more than one dose, with those who have only received one dose to ask: is there a sequential deterioration in their behavior and development, compared with the group who only received one dose? And is there worsening of the intestinal inflammation?

In analysis, based upon the exposed and unexposed children, we find that secondary regression on the basis of three independent analyses, including parental history alone, excluding those children whose secondary deterioration appeared after the publication of our first paper in 1998 or inclusion of only those children for whom we can find independent corroborative evidence in their records, there is a highly significant effect in terms of secondary deterioration in the children who had two doses, compared to those who only had one.

Secondary physical symptoms -- for example, deterioration in their bowel disease, their bowel symptoms -- is present. Severe lymphoid hyperplasia. You will remember the swelling of the lymph glands in the intestine is significantly worse in the children who have had two doses than one.

And to me, as a pathologist, the most significant finding is that the intestinal inflammation, a blinded observation made independently of any knowledge of the child's deterioration or their vaccination status, shows that it is much worse. It is worse in those children who have received two doses than one.

This is something that you cannot confabulate. The quality of records might not be good enough to make didactic decisions about deterioration. But you cannot fake the state of a child's intestine in terms of inflammation.

So these data identify re-challenge effects upon symptoms and the biological gradient effect upon severity of intestinal inflammation that provide evidence of a causal association between MMR and regressive autism.

What about the political aspects of this, Mr. Chairman? I have repeatedly requested a meeting with Selene Donaldson (ph), the U.K.'s chief medical officer, in order to discuss this situation.

His response has been to refuse to meet. But instead, to demand that we send him the children's samples.

He has provided absolutely no indication in terms of scientific protocol how he would proceed to analyze these samples. He may have a PCR machine in his kitchen, for all I know. I do not know how he intends to analyze them.

He has, as far as I'm aware, no ethical approval for analyzing these samples. But he may be reassured to know that independent testing is being conducted and that as part of a litigation process in the U.K., the defendants are being provided with identical samples for entirely independent analysis.

The last seven days have seen a report in the "Journal of Clinical Evidence" from the U.K. publicized as new research, disproving any links between autism and the MMR vaccines. The author specifically excluded clinical research into the bowel disease; in other words, everything that has been performed in my laboratory.

They do not cite any of our publications, beyond the initial study of 12 children in 1998. In fact, this paper does no more than review the epidemiological studies that have already been deemed irrelevant by the members of the IOM Committee.

In closing, Mr. Chairman, Dr. Bradstreet's data somewhat underestimate the size of the problem. A recent study published by the National Autistic Society in the U.K. show that in primary school children -- that is those between four and 11 -- autism now affects one in 86 children; not one in 86 boys, but one in 86 children.

This is a staggering level of a disease. It's unacceptable. And no society can afford to sustain this attrition of its children.

Something has to be done. We have to de-politicize this process and conduct the science that is necessary to answer the questions.

Thank you.

BURTON: Before we go to the next witness, I believe other scientists who differed with the prevailing opinions have suffered similar castigation as you have. And you may rest assured that eventually, the truth will out. Louis Pasteur found that out after 17 years when he was knighted.

So eventually, the truth will out. And those who criticize and continue to denigrate what you have done, they will be eating a hell of a lot of humble pie.

(LAUGHTER)

Dr. Stejskal?

STEJSKAL: Mr. Chairman, ladies and gentlemen and dear colleagues, I am honored to be here. And this is my first testimony.

STEJSKAL: And what I am going to do in this limited time is to tell you why I'm here, what are

my credentials. I have been working for 20 years in pharmaceutical industry, directing a group of clinical immunotoxicology. So I have been working with allergy to simple chemicals, like for example mercury, for 20 years.

What I am going to tell you is the fact which has not been mentioned here before, to my big surprise. And this is that thimerosal in clinical testing is a strong allergen.

You can learn about it more looking on our website, which I will show later, where I compile the studies from all over the world, telling us that thimerosal, obviously due to vaccination, is number one childhood allergen; meaning that if you are getting a special testing, which I will tell, 10, 20, 30 percent of the children are allergic.

I will tell you why this is risky to be allergic if you don't know this. And I will also tell you how it goes together, opening ways to out immunity. And at the end, to be constructive, I will tell you how to diagnose the causes, which are leading to autism, and what studies should be conducted.

So if we can have my Power Point presentation first? I have been also asked to see if it is plausible that there is a synergistic reaction between thimerosal and MMR. And yes, it is. And I will tell you why.

The next one. Again, you are well acquainted with the fact that mercury -- and I am not talking about organic mercury only; I also talk about inorganic mercury -- it will damage the brain, especially organic mercury because it's lipophelic (ph). It will easily go to brain.

There are some basically called a retrograde transport. Again, if somebody wants, it's on our website.

So, in addition to toxicity, which is very important, which of course can damage blood-brain barrier, you also have to worry about allergy.

And allergy is the thing which explains to us why not every child is affected by vaccination.

This is something which is very important as, as you know, some children cannot eat egg. Some other children cannot ride a horse because they are allergic to a horse. And some don't eat fish. People don't do either.

And then, which is also very important, the allergy affects the brain. And as you know, in spring when there is a pollen around, people become sleepy. They cannot concentrate. This is due to the chronic inflammation which is affecting the brain.

This may be part of the answer why Dr. Wakefield sees inflammation in the stomach in gut affecting the brain. This is another reason why we can see that, in certain children and especially the autistic ones, we see also other types of allergies like food allergies, atopic in general, increase disintegration of the immune system.

Next one. This is very simply showing you that we are not equal. Genetic, we're determined our detoxification capacity. These were explained to us that we have a subgroup of children and subgroup of adults which will not handle properly the overload of toxins and allergens.

Next one. Thimerosal is an allergen. It is worldwide known for years, I think, since '70s, that if you are doing special testing for a special type of allergy, which is lymphocyte-mediated allergy, so- called "delay" type hypersensitivity or cellular hypersensitivity, you do find that actually thimerosal is superceding nickel in the frequency of sensitization worldwide.

If you're looking on few studies which has been done comparing, for example, East Germany and West Germany and you see that in East Germany, the allergy was very low and it started to rise up after those two merged, you just wonder why is that so? And it may be more strict regime of vaccination couldn't do something against this.

How do you test for this quite important allergy to thimerosal and other things? You do it by so-called patch testing.

Next one, please. And in patch testing, what you do is you put this allergen, the things which you would like to see if you are allergic against, on the skin in the back.

I have to say you again, I have read some witnesses from CDC and other claiming that thimerosal is perfectly safe because the only thing we can see if it's local reaction at the skin. These people do not remember from the years at school that allergy is never a local phenomenon.

Allergy is a systemic phenomenon. It's governed by special types of white blood cells, which are circulating in the body and in the lymph.

So if somebody tells you that there is only local reaction, this is a lie or incompetence. But this is not true.

Allergy is a systemic reaction. And anywhere in the body where this foreign agent -- for example, thimerosal -- will be, the reaction will occur. And this is inflammatory reaction.

So how -- we are doing patch testing. You read on my website. There are thousands and thousands and thousands of people which we are patch testing, telling you that especially children are very strongly sensitized. And I think the data from Germany shows that children eight years or less have actually sensitization rate in those which are tested

-- that means people with skin problems -- 20 to 30 percent, which is quite amazing.

The other test which can be used and especially should be used in children because it's not so good to put the allergen on the skin because you become resensitized, is so-called "blot test," or lymphocyte proliferation test. This test has been used for years in American for detection of people which are sensitized to different occupational allergens; for example, beryllium.

This beryllium-specific stimulation test is used as a code and standard in America to detect latent sensitization to beryllium prior to clinical outcome. So pharmacological factories and those who are using beryllium have realized that you can save a lot of suffering like long-term sickness in sarcoidosis, to detect by biomarkers, because now we are looking at the markers of susceptibility that people or children which are susceptible to the agents, which other people tolerate.

And this also save the money at the end. So with MELISA, you take a blot test. MELISA stands

now for optimized lymphocyte proliferation test for memory lymphocytes. You take a blood sample and you ask if the body has or stored the information of allergy to certain substances.

If it's yes, there is a sensitization, then you can see it objectively by increase in the volume of lymphocytes and you can measure it objectively. If there is no (?), that means the person is genetically not able to respond, there is no difference.

I will, in the end, show some cases of this.

Next one. This please, if you forget everything from my hearing, you remember this. Thimerosal and autoimmunity are the two sides of the one coin. That means you can't never separate.

And why is this? Why is this?

Next one. This is because mercury -- but not only mercury; nickel, as Chairman Diana (ph) said, and other metals -- will strongly bind to certain amino acids in our bodies, which are containing SH groups, sulfhydryl groups. And these sulfhydryl groups are everywhere. They are in two amino acids which are called methionine and cysteine, for example.

And they are especially rich in fat tissue. And as you know, brain is full of fat.

So that's why mercury will go into the brain and it will bind there; for example, in so-called myelin protein. And this is the reason why this machine can measure increased antibodies -- again, myelin -- in many of those children.

So since there are physical, chemical properties which are indisputable, mercury will bind in the brain and elsewhere, where do we find these things? So it will go there, it will bind there. And then, your genetic susceptibility, if you can make it or not make it will explain why some will be ill while not other ones.

Next one. Edema (ph) and thimerosal. There is no way I can comprehend that there is a concern about synergistic adverse effects upon the immune system of susceptible children if you put those things together. So you can, by immunosuppression, which is other way how mercury works, you can lower the threshold of protection against the virus, meaning that in this time, there will be persistent viral infection instead of the limited one.

There is a fact, which you may know or may not know, and this is that in my country, in Sweden, thimerosal has been removed from vaccines in 1998. And one of the reasons for it is a report on the Pharmacovigilance Working Party of the European Agency for evaluation of medical products. And what they basically say is that alteration of the immune system due to mercury could have consequences on the ability of the host to withstand viral attack.

So Swedish people make a lecture. And since I have been working in toxicology laboratory for 20 years, I know that there is always risk assessment. And they decided they don't want to take the risk.

Next one. Next please, could you move up? Conclusion for this general part is yes. I really believe that there is a connection between synergistic effect of thimerosal and MMR and that there is a group of susceptible individuals which we may actually detect maybe even prior. And

they will be affected and they will be ill.

I will just finish up to show you a couple of cases. Some of them were published; some were not.

And just to show you how we work with this. And these are the guys, the big guys, lymphocytes, which are now stimulated. This is of course in culture outside the body. This test system is a blood test. And the big guys are lymphoblasts and the small ones are the ones which are not affected.

Next one. Since I was talking about patch testing as a device or instrument to look on the special type of hypersensitivity which is having no counterpart in the serum, I am as a start -- and we started these studies in 1992 -- we have taken people which have patched as positive and looked for their lymphocytes, just to prove that this is not only back reactions. It's a systemic reaction, driven by lymphocytes.

So this woman has a muscle inflammation. And she also --I have to look here -- she has been susceptible to infections. And she had chronic fatigue. She was patch tested in '91. And she was positive to thimerosal.

As you see now, I am looking on different mercuries because this part goes together with the dental mercury part completely. Everything I say now, it can be actually applied to dental mercury fillings. And you can look on our website again.

Since '92, she had thimerosal positive patch test. And in '92, we did MELISA test.

Next one, please. Could you put another one? This is just exposure.

We are always looking into the exposure. From this point of view, she had been occupationally exposed to inorganic mercury. She had 17 amalgam fillings.

She was exposed to ointment which was containing thimerosal. And she received gammagobulin and other vaccines at least 16 times.

And the next one? What you can see now is a diagram of her lymphocytes' reactivity to different metal sorts. And this can be difficult for you to follow, but the horizontal line shows you the line of positivity. And the rest one is very, very strongly positive.

I just show -- you can go farther on. I don't think we have time.

This is from published paper, which you can download on Internet.

Please go on. This is another patient. And this patient has been treated by mercurochrome, which is another organic mercury. And you can see showing extreme sensitization to mercurochrome, but not at all sensitization to other mercury compounds, meaning that both in patch testing and in lymphocyte testing, you can actually see no cross reactivity between inorganic and organic mercury.

But there is one cross reactivity. And this is between ethylmercury and methylmercury, meaning that we are very much afraid that any sort of sensitization to one may cross react and deteriorate

and heighten the response to other ones. And there are patch test results on this.

BURTON: Doctor, could we submit the rest of your testimony for the record?

STEJSKAL: Yes. You can do it.

BURTON: We'll get to the questions. We'll have questions for you that you can elaborate on.

STEJSKAL: I just would like to finish up with the data on autistic children, two of them?

BURTON: Okay.

STEJSKAL: And this part of study is done together with scientists from Center for Pediatric Health in Belgium, Antwerpen, from a group of Austrian researchers, from some American scientists and from some Swedish scientists. Due to that reason, I am not going into the study still continuing. So I'm just showing some case reports.

This is an Austrian girl, 14 years old, with mild form of autism, lactose-intolerance and vaccinations. And there is a causal relationship of vaccines to his deterioration.

And next one. And this shows you the non-responsiveness to inorganic mercury, strong reactivity to thimerosal, cross reaction to methylmercury and no reaction to nickel and cadmium.

Next one. And this is a Belgium boy, five years old, from John Kronenberg (ph), which is a pediatrician in Antwerpen. He was healthy at birth. He got first symptoms of autism as a baby, strong aggravation of symptoms at 15 to 18 months. He was diagnosed with autism in '96 at 11 months of age.

He has digestive problems, food sensitivity, skin lesions, eczema, rashes and irritation from metallic contact. Mother had dental work during pregnancy.

Next one. This is the schedule of vaccination in Belgium. They don't vaccinate at birth. You only one who do. At three months, four months, five months, seven months, 12; at two years, several vaccines at once.

Next one. And this is his reactivity. In this case, there is a thimerosal and methylmercury; nothing on aluminum and zinc.

At conclusion, I would like to say that credible data show that theory that thimerosal-containing vaccine may be a co-factor in the development of autism in genetically susceptible children. And I would like to tell you what I would like to have for future studies, because there is no sense if you give millions and millions of dollars to do and waste the time for nothing.

So the things what we learned about the reactivity, allergic reactivity to simple compounds -- for example, mercury, regardless it it's inorganic or if it's organic -- is that rats and mice are not suitable. One of the reasons is that they produce their own C vitamin.

So it's not a man. We don't do it. And C vitamin will protect against metals.

The second thing is that you have to do a biomarker screening for susceptible children. And there

is a notion from a paper on our website, published my daughter, which says that the increased knowledge about individual sensitivity, based on genotype and phenotype variability, together with the use of the mile markers for the diagnosis of individual susceptibility seems to be the key in elucidation of operative mechanisms of any autoimmune disease and also autism.

Thank you.

BURTON: Thank you, doctor. We'll have questions for you later.

Dr. Krigsman?

KRIGSMAN: Mr. Burton, members of the committee, thank you for having me today. The purpose of my appearance today is to report to the committee the status of my findings regarding our research into the intestinal inflammation in autistic children.

KRIGSMAN: What we have done is actually a retrospective survey. And what we have done is we have collected intestinal biopsy specimens from 43 patients. Now these 43 patients were mostly referred from private practitioners who were caring for their overall autistic medical issues; among them, their GI symptoms.

After chronic frustration and inability to control mainly symptoms of diarrhea and constipation, these patients were referred to me. Other patients came on their own, after again often years of frustration with these symptoms.

Most of the GI symptoms that these children have been seen for, mostly it's diarrhea. Many also have constipation. And a large number have both diarrhea and constipation alternating.

The stools are severely malodorous. It's one of the most common things we hear parents talk about is the entire house smelling when these children have a bowel movement in the basement.

Abdominal pain -- very, very common symptom. Most of these kids are non-communicative. And when they have pain, they either just scream and wail, fall to the floor having tantrums, unexplainable crying, could last for half an hour to an hour.

Problems sleeping at night. Waking up in the middle of the night screaming. And parents intuitively feel that these symptoms are due to pain.

Sometimes, there's an objective observation as such, holding their belly. But more often than not, it's just unexplainable crying.

Abdominal distention and poor growth. The growth is a very interesting issue. What I've seen is that most of the children with regressive autism fall in the bottom 10 percentile on the growth charts in weight for age.

And we have not found that their height for age is similarly affected. I don't have an explanation for that. But their weight for age, most of these kids are skinny kids.

The male to female ratio of these 43 patients is seven to one.

Who said that these kids are autistic? Well, the diagnosis was made either by a pediatric

neurologist, a developmental pediatrician. And, for the most part, parents have gone to both and even a third opinion.

And in no patient was the diagnosis in dispute.

Next slide. When I first meet with these patients, we do a routine evaluation for what often is diarrhea, constipation. We get a complete blood count, sedimentation rate, chemistries. To most of you, these tests are meaningless. To a gastroenterologist or parents, they're very, very meaningful.

What these tests look for are specific reasons, specific diagnoses that can cause these GI symptoms that these kids complain of. We do stool cultures. We look for parasites. We look for blood in the stool.

We go over their diet. We make major revisions in their diet. We remove carbohydrates. We remove sorbitol from their diet. We take them off gluten and casein.

And pretty much without exception, none of these interventions help.

And none of these tests show anything that would explain why these kids have chronic diarrhea, constipation and pain.

At that point, I perform a colonoscopy, along with biopsy. We look at the entire colon -- and not just the colon, but more importantly, the very end of the small bowel, which is the terminal ileum, which is the area that Dr. Wakefield had described as involved in these diseases.

And by the way, I should mention that, as recently as two years ago, I would never have put a colonoscope in any of these children. I didn't

feel it was justified or appropriate. I didn't know what I'd be

looking for. And I wouldn't do it, even though I had seen quite a number of them.

And it wasn't until I read Dr. Wakefield's article in September 2000, "American Journal of Gastroenterology," where he described the biopsy findings in over 60 patients. And he described a pattern of colonic inflammation that could explain their symptoms.

It wasn't until I read that article -- I read it about seven times, actually, in one night, because I just couldn't believe it. And after reading it over and over, I decided that I could not find any valid criticism to the article. And I felt justified, at that point, to perform these colonoscopies myself.

And at the outset, I will say that our findings, which are independent of Dr. Wakefield's findings, completely support his explanation and his observations of the abnormalities that are found in the bowels of these children.

I also performed an upper endoscopy, looking up the esophagus and stomach. I performed that task in those children who, based upon the histories as related by the parents, sounded as if the -- if those histories contained abdominal pain, a story of pain, then we needed to rule out any esophageal or esophagus problems, stomach problems, intestinal inflammation, infection, et

cetera.

Next slide. I'm going to be showing now a series of slides, actual photographs that are taken during the colonoscopies, to give you a

visual idea of the extent of abnormality that we find. As you'll see,

these are not normal.

This first slide is normal. This is a terminal ileum, the area at the end of the small bowel, in a normal patient. And what you can see -- my laser pointer is not showing up.

In the photo on the right, if you look carefully, you'll see very small bumps. They're almost indiscernible. Those are enlarged lymph nodes. But those are normally enlarged lymph nodes. Those are the kind of lymph node enlargement in normal small bowel.

Next slide. In contrast, the upper row of photographs -- could we dim the lights here? Is that possible?

BURTON: You can't dim the lights with the cameras? She said it would not be . . .

KRIGSMAN: Pity, because I think the effect would be greater. The photographs would be . . .

BURTON: Just one second. You say we cannot dim the lights? The TV cameras then can't pick up what you're doing. And I think that's important that the American people get a chance to review all this.

KRIGSMAN: Absolutely.

The upper row, three across, show marked nodularity, marked abnormality because of those numerous small lumps and bumps.

Next slide. Another patient, same exact finding.

Next slide. Another patient. You're looking down the tube of the small bowel. On your right side, along the wall, those large nodular bumps. This is not normal.

Next slide. I call your attention to the upper left. And those large, bumpy nodules are the ileal tissue that Dr. Wakefield had first described. On the right slide, same patient, a view from a different way, upper right corner.

Next slide. Another patient, same finding.

Next slide. Same finding, upper right corner on both those pictures.

Next slide. Upper right corner on both the pictures, those large, nodular bumps.

Next slide. Same thing, lower left half of the slide.

Next slide. Same thing from another patient, all over the --mucosa of the ileum, there's nodularity.

Next slide. This particular patient didn't have as much nodularity as they have swelling. The medical term is edema and it's one of the byproducts of ongoing inflammation.

Next slide. Same thing.

Next slide. There's a very dramatic photograph. If you look in the middle, downwards in both of those pictures, it's actually normal mucosa. But on both sides of the midline, you see marked nodularity.

Next slide. Same thing.

Next slide. Again.

Next slide. These are all different patients.

Next slide. Same thing once again.

Next slide. And again.

Next slide. Next slide. This patient I included because the lower two photographs show the same nodularity. The upper two photographs are of the colon.

And if you look carefully, you'll see very small, minute nodules scattered around the mucosa. So not only are these nodules present in the ileum of these patients, they are also present, scattered throughout the colon.

Next slide. Same thing.

Next slide. Same thing.

Next slide. Same thing.

Next slide. This patient, the inflammation was so bad in the colon that he formed what's called a pseudo-polyp. And the polyp is recognizable to all.

It's actually not really a polyp. What's happened in this patient is that the surrounding tissue is so inflamed and eroded that what's left is the polyp. Everything else has eroded around it.

Next slide. This patient I just saw yesterday. And I included this

-- this is the final patient I'll be showing you. This is the oldest patient that I have done a colonoscopy on.

He's 13 years old, autistic. The regression history is not clear.

It's been many years. Chronic history of one to two bowel movements a day, always very loose, dismissed by the pediatrician.

Over the last three months, this child's diarrhea has become uncontrollable, 10, 15 times per day. He's incontinent all of a sudden. He never was incontinent. And his behavior has been intolerable -- aggressive, throwing tables over. And his parents are at the verge of institutionalizing him

because of this recent worsening over the last three or four months.

His mother found me out. And I do the colonoscopy just yesterday.

And this child has the absolute worst colitis I've ever seen.

Most of these kids, when you put the scope up the colon, the colon appears normal. It's only in biopsy that you find the abnormalities.

In this particular child, the inflammation was so bad that it has attained the characteristics of classic inflammatory bowel disease. If you saw this colon, you'd think this patient had ulcerative colitis or Crohn's Disease.

Next slide. What's interesting about this patient -- and Dr. Wakefield might be interested particularly in this slide -- is that this is -- the photo on the left is the bottom of the esophagus. And in the area at about 3:00, you see a wide little nodule. That is an abscess ulcer, which is something you see in class inflammatory bowel disease.

And you find those ulcers anywhere in the GI tract.

The photo on the right is the upper esophagus, the upper esophageal sphincter. And you can see, there are two nodules there are well, two more abscess ulcerations as well.

And I'm wondering if this patient doesn't have just autistic enterocolitis, but actual inflammatory bowel disease. And the biopsies are still pending.

Next slide. I'm going to bypass these slides because -- but I just want to point out that the areas, that big round ball on the right is the microscopic view of those big nodules that you saw grossly.

Next slide. Next slide. Okay, what you're seeing over here, that circle in the middle is a crypt. And the intestine on the left side of that crypt, you see what seems to be small, little black dots infiltrating it.

This is a cryptitis. This is one of the classic findings of bowel inflammation, which we have seen over and over and over again in these patients, exactly as described by Dr. Wakefield.

Next slide. Same view, but the crypts are -- the crypt in the middle in particular is being invaded by inflammatory cells. There's a very heavy inflammatory exiting throughout the mucosa.

Next slide. Same thing over here.

One more slide.

Okay. So looking at our 43 patients, what are our cumulative results? Well, the percent of patients who have colitis, 65 percent. And by colitis, I mean either active colitis or chronic colitis. There is a difference.

Active colitis, 51 percent of the patients have that; chronic colitis, 40 percent. Most patients have both, which is why the overall colitis indicator is 65 percent.

A third type of colitis is the osinofilla (ph) colitis, also described by Dr. Wakefield. We have that a seven percent number, very similar to his number.

The percentage of patients who had those large nodularities of the ileum, we found to be 90 percent; also very similar to Dr. Wakefield's.

Thirty-five percent of our patients had no form of colitis. However, even though they did not have colitis or inflammation on biopsy, all of them, without exception, had abnormal lymph nodes. So they are not normal, even though there is no colitis.

Next slide. And this is my last slide. I'd just like to conclude that our study is ongoing. We have a control group in place. We are waiting for formal IRB approval to sit down with one designated pathologist, a gastrointestinal pathology specialist, on pre-agreed- upon pro forma to define the exact grade of colitis, types of colitis. And with one definition, to review all the slides that we've done from all 43 patients, plus our control group and publish our results and make them known.

The question I would like to explore in our publication is: if you compare regressive autistic children with non-regressive autistic children, is the incidence of colitis the same? Or will it be different?

I would like to go over the growth of these children and compare the growth of children, both in regressive groups and non-regressive groups and see if we find a weight percentile difference when we compare the two groups.

And finally, I would like -- because it is our hypothesis that children with regressive autism will be those who are most likely to exhibit growth failure. And it is our hypothesis also that if we trace back their growth charts to early infancy, I suspect that we will find that for the first year of life, they were growing normally at closer to the median and that, somewhere near the onset of their autistic symptoms, I suspect we're going to find that they began to show evidence of growth failure, along with their autism, which suggests that their autistic symptoms and their GI symptoms are related.

Thank you very much for having me.

WELDON: Thank you very much, Dr. Krigsman. You essentially did what I've been asking the NIH to do for several years.

Dr. Spitzer, you're recognized for five minutes to make the presentation.

SPITZER: Thank you, Dr. Weldon. I'd like to start by saying my presentation will attempt to be as objective and as neutral as I can. I would like in particular to say that despite disagreement on a narrow set of issues, he CDC, in my experience of 35 years in epidemiology, has been a great institution. I'm honored that some of my students have been hired by them, that we've been able to recruit their colleagues, graduates and people with work experience.

And it is not adhominim (ph). I do not know Dr. Davis (ph) or any of the colleagues. I'm looking at the paper and what I find. And I'd like that accepted.

Next slide, please.

So the focus of what I'm going to talk about is measles-containing vaccines and the risk of inflammatory bowel disease, as published by Dr. Robert Davis (ph) and others in the publications cited in the slide.

The purpose of the study published was to examine the risk of inflammatory bowel disease following exposure to a measles-containing vaccine. Unfortunately, as implied by other of my colleagues at the table, the use of the results to demonstrate no link between MMR and autism is what I respectfully consider to be a misuse of the study. And I shall try to explain why.

Next. The fatal flaw of the study is that it is grossly underpowered. With conventional programs of power calculation, the calculation of power is somewhat complex but not controversial. And we all do it similarly in various institutions.

The power we calculate is 12 percent. But normally accepted power is on the order of 80 percent. And when you're looking at trying to demonstrate no difference, you want the power to be higher to avoid what is called a Type II error, as opposed to a Type I error, which is what we worry about in clinical research.

Next, please. And as I say there in what I try to make non-jargon English, a power of 12 percent means that one has a chance of 88 percent of declaring no increase in risk if, indeed, there was a twofold increase.

Now just to explain that in a somewhat different way to a non- statistical, non-epidemiologic audience and to colleagues in the world of politics. If you mandate a poll as you're facing reelection and so on and you get a poll back with a figure, a point estimate, that 55 percent in your jurisdiction are in favor of reelection. In the published newspapers, "Time Magazine" and so on and so forth, you'll see that the error is about three percent. So whether you're on the low side -- 52 percent or 58 percent -- you'll probably get elected.

But if it were 40 percent, your estimates go down to the 20's and up to the 80's and 90's. And you have no way, from that poll which had insufficient numbers, to predict whether you're going to get elected or not. It's an underpowered poll, as I'm giving the example from this paper.

So the low power results in the wide confidence intervals you see in almost every -- if not every -- estimate of the paper we're talking about. And in this case, six percent of the exposed to needles containing vaccines, in the population from which the sample was drawn, were among the controls they picked. I think their choice of controls was reasonable,

And that's what determines a low power. It's an imbalance, a maldistribution with exposed and non-exposed in the controls. That low six percent is what demonstrates the low power.

Next, please. Let me turn then to another issue. We can expand with questions, Mr. Chairman.

A hallmark of science, as I've always taught and my colleagues teach, is replication and/or verification. I think the replication that Dr. Krigsman has done of the British work is an enormous contribution to our understanding the validity of what went on before. And it must be

part of the practice in an evolving challenge like this and other challenges.

And these temples of secrecy, it's more in academia in fact, I would say, than in organizations like the CDC where, "this is our data," and false issues such as confidentiality are brought up. We worked that out decades ago.

Ten years ago, I went through the database in Saskatchewan. And in four months, we sorted out the controversy of beta argones (ph) and death in children due to asthma. It took four months; it took $4 million. It would have taken five years and $25 million to do it out in the field.

And you can protect the identity of the patients easily in our state of science today and computer skills and so on.

We should avoid adversarial challenges. There were those who didn't believe this. We worked together in that.

And you know, I just hope we can get bast that in these controversies. And as I say, temples of secrecy and adversarial approaches have no room in population science and most other clinical and related sciences.

Next slide, please. I would agree with what the chairman said earlier, that the Datalink database should be opened to train scientists with reasonable safeguards. I don't believe in fishing expeditions. I'm sure colleagues in the CAT (ph) worry about that. Advanced research plans . . .

BURTON: Can you speak into the microphone because we . . .

SPITZER: I'm sorry, sir.

BURTON: Pull the microphone a little closer to you.

SPITZER: Like I say, these occasional searches -- random searches -- to see if you can find some dirt, if you wish, didn't have no place.

This is done seriously, in a scientific way. But access must be given to the legitimate concerned academic population governmental organization that needs to look, especially if they're funded through public funds like the Saskatchewan database in Canada.

Next. So I conclude, the Davis (ph) case control study from the Vaccine Safety Datalink Project, cannot determine whether measles- containing vaccines do or not increase the risk that we are concerned about. And in the three years that I've been looking at epidemiologic literature from the entire world, scarcely any of it allows you to rule out MMR; nor can it rule it in.

And part of the reason is in most jurisdictions where this is being done, you can't get high power. That's why, in a case control study that my colleagues and I have designed to sort out this problem. And we can't do it in the U.S. and in the U.K.

The population has been penetrated to too much of a degree. It has to be done in eight other countries. Just like the NIH supported the WHO studies on oral contraceptives for exactly the same reasons --and appropriately so.

And lastly, this study does not contribute to our understanding of the relationships between MMR and MCV and autism.

Thank you for your attention.

BURTON: Thank you.

Do you want to start the questions? I'm going to yield to Dr. Weldon because he is a physician and has some scientific background. And I thought I'd let him start off the questions. And then I'll chime in as we go through this.

WELDON: Thank you, Mr. Chairman. And I want to thank all of our witnesses. You have provided us with a tremendous amount of information. I wanted to focus on a couple of important points initially.

If I understand you correctly, Dr. Bradstreet, you have two cases where you have identified the measles virus in the cerebral spinal fluid in two children with regressive autism?

BRADSTREET: We presented two cases out of the ongoing investigation.

WELDON: So you have other cases?

BRADSTREET: Yes, sir. We do.

WELDON: Have you submitted this for peer review and publication?

BRADSTREET: No. At this point in time, the data is preliminary. We are in the process of developing a control base and replicating the science, at which time we will submit it for peer review.

We intend to have, based on the current rate of acquisition of cases, at least 30 cases to submit.

WELDON: This is fairly significant, what you presented. And has anybody done this type of research where they've looked at kids with regressive autism and done a spinal tap on them and checked their spinal fluid for evidence of the antibodies to myelin basic protein, as you've described, but more importantly, the viral particles in their cerebral spinal fluid?

BRADSTREET: I believe we're the only people so far who have done that research.

WELDON: So you did a research of the medical literature. And you didn't find any evidence that this has been looked at previously?

BRADSTREET: Not at any point in time in the creation of the vaccine, the introduction of the vaccine, development of the safety issues of the vaccine or subsequent to that has anyone looked for persistence of the measles virus from the vaccine or autoimmunity in the sensors to the brain, as it relates to the vaccine strain. I'm not aware of any data to that effect.

WELDON: Now my understanding of pathophysiology, for them to have measles particles in their cerebral spinal fluid, that suggests an ongoing encephalitis, basically, in these kids. Is that what you're implying to the committee?

BRADSTREET: I think it's very early, in terms of drawing conclusions. There is clearly a persistence of a detectable viral genome in the brain in these children. There is the autoimmunity to myelin basic protein and the presence of abnormal antibodies to measles virus only in the children with autism. We do not see that in controls.

Before we draw further conclusions, we would love to have those controlled spinal fluid looking at the virus. We should have that within two months.

WELDON: Now one of these children is your own child.

BRADSTREET: Correct.

WELDON: Have you tried antiviral therapy in treating these kids?

BRADSTREET: We have. And I would say, at this point in time, it's unpredictable. And we clearly need a lot more research.

There is a risk of developing hemolytic anemia. In autism, it seems to greatly exceed the risk of hemolytic anemia from antivirals that's published in the literature. And I've been in contact with the manufacturers of various antivirals.

And there is something unusual going on in autism that makes them more susceptible to side effects to antivirals. So it would not be a way to proceed, generally speaking, at this time, without some very carefully observed research.

WELDON: Now are you making any attempt -- I understand the strain of measles that is in the vaccine has certain genetic markers that enable researchers to distinguish it from so-called "wild" type measles. Are you making an attempt to do the genetic mapping to see whether this is wild type measles or the vaccine strain?

BRADSTREET: Certainly, that would be place. But the collaborators for us that are at the various laboratories that are analyzing the spinal fluid are going to be looking at strain specificity. The history is consistent -- very consistent -- with this being vaccine in onset, as opposed to a vaccine failure, where wild virus is getting in and causing these persistent symptoms. Again, we should know that within one to two months.

WELDON: And do these kids have seizures also?

BRADSTREET: A very high percentage have seizures. And again, this is a select group of children with autism. I am not trying to extend these conclusions to the entire population. These are children that have a very well established history that's very consistent with looking at measles virus or MMR as a cause of their symptoms.

WELDON: Thank you, Dr. Bradstreet.

Dr. Krigsman, Dr. Wakefield came under a lot of criticism when he published his findings. A lot of professional derogatory statements were made. I believe his credentials as a research professor have been threatened.

Have you encountered anything like this in your research at all? You're at Mount Sinai, is that correct?

KRIGSMAN: Lenox Hill Hospital.

WELDON: Lenox Hill. By the way, what is your background? Where did you do your training?

KRIGSMAN: I trained at Mount Sinai. I did my pediatric residency at Down State (ph) in Brooklyn and my fellowship in pediatric gastroenterology at Mount Sinai in Manhattan.

WELDON: And you have published research articles previously?

KRIGSMAN: Yeah.

WELDON: And you're a professor of medicine?

KRIGSMAN: No. I have a position at NYU, which is the academic affiliate of Lenox Hill Hospital.

WELDON: Okay. And have you come under any of the criticism encountered . . .

KRIGSMAN: Not yet.

(LAUGHTER)

WELDON: Okay.

Dr. Wakefield, I'm curious about just this issue of Dr. Gershon. The ranking member brought it up. And I just want to clarify my understanding of this issue because I was here when Dr. Gershon testified. And according to Dr. Gershon's statement that measles virus particles were detectable in the controls in Dr. O'Leary's lab -- do I have that correct?

WAKEFIELD: That's correct.

WELDON: And you're contending that there was no evidence to support the statement made by Dr. Gershon, that Dr. Gershon didn't look at the data. He made that statement based on essentially hearsay, what he had heard from somebody else. Is that correct?

WAKEFIELD: That is my understanding. And in fact, the written data show quite the opposite, that there is substantial evidence that there was no contamination or no presence of measles virus in those tissues.

WELDON: Well, the reason I'm bringing this issue up -- and I don't want to get too bogged down in the controversies between you and Dr. Gershon. But as I understand it, Dr. O'Leary, who is a very well respected viral pathologist -- I think he was the gentleman who first identified herpes simplex type A as the causative agent for Kaposi's Sarcoma -- that he came under a certain amount of criticism within -- he's in Dublin, correct? -- within the British Isles, Great Britain, England, Ireland? And he actually lost some credibility and some research grants. Is that correct, based on that testimony?

WAKEFIELD: Yes, within a week of that testimony, he had lost five grants from the Irish Cancer Society.

WELDON: From the Irish Cancer Society? And I would assume that was very costly to him and his research lab. Is that correct?

WAKEFIELD: Sorry, could you say that again?

WELDON: Was that very costly to him and his research lab?

WAKEFIELD: Extremely, both in terms of staff, research and professional reputation.

WELDON: Is Dr. O'Leary litigating this issue?

WAKEFIELD: No. I think that what I simply want to do here is put the record straight. And we do not wish to pursue it beyond that. Let's get on with the science.

WELDON: Mr. Chairman, I yield back.

BURTON: I just wanted to add, I talked to Dr. O'Leary on the phone.

And he would have been here today to testify, but he's having some health problems of his own. And he couldn't be with us.

But he, I think, stands by what Dr. Wakefield said.

WELDON: If you could just indulge me for another minute?

Dr. Spitzer, I get the "Archives of Internal Medicine." And I, like a lot of busy doctors, I just read the abstracts and I move on. In the case of the Davis (ph) study, I just want to make sure I understand this correctly.

I took medical statistics in medical school. And I also took it in college. And I've looked at this study. And I'd like to -- do you have the study?

SPITZER: Yes, I have it right in front of me, Dr. Weldon.

WELDON: I want to get at this issue of the power. Table three, which is on page 357 in the study, they report all inflammatory bowel disease. And they have the -- it's the fourth column -- and they have it broken down by age. And they have these ranges for children who receive the MMR before age 12 months. it's a .61 with a range of .15 to 2.45. And then they have all the different.

As I understand it, one basically means it's neutral. Correct?

SPITZER: Yeah.

WELDON: And then the range is -- let's take the less than 12 months.

What they're saying is .61. So they're saying, I guess there's a suggestion there's a reduction in risk of inflammatory bowel disease.

But the range is as low as .15, which would be a dramatic reduction in risk, up to almost a two-and-a-half-fold increase?

SPITZER: Yes.

WELDON: That tells me this is garbage. I hate to say that. But that's like my pollster telling me your chance of being reelected is 55 percent, with a range of 10 percent to 90 percent.

SPITZER: Well, I prefer not to use that word. But it just makes it difficult. You can't rule a failure to reelect versus reelection in or out on the basis of the poll.

WELDON: Well, I think my time has expired. And I'm sure the co- authors of the study will take issue with some of this when they have their opportunity to testify. So I yield back.

Thank you very much.

BURTON: If the gentleman would like, we'll come back for some more questions for this panel.

Mr. Waxman?

WAXMAN: Thank you very much, Mr. Chairman.

I want to point out to the witnesses and the audience that I have a conflict in the schedule because at the same time as this hearing, there's a Commerce Committee markup, a vote on Medicare and Medicaid. So I'm trying to go back and forth.

But I wanted to get on the record some points about Dr. Wakefield's testimony because Dr. Wakefield today testified about an upcoming scientific presentation in Ireland by Dr. O'Leary. And in this presentation, which is going to take place in July, scientists are presumably going to claim to have found vaccine-strain measles in the intestines of children with developmental disorder.

And I hope to have a copy of that abstract. Do I have a copy of that? I do have a copy of the abstract. And I want to make it a part of the record.

In the abstract, it states that the conclusion that the virus was vaccine-strain, which means caused by the vaccine, is based on one nucleic acid, position number 7901. Now according to the abstract, if the chemical at position 7901 is adenine, then the strain is natural measles virus. But if the chemical is guanine, then the strain is from the vaccine.

According to this abstract, this difference can perfectly distinguish between natural and vaccine strains of the measles. However, according to the Gene Bank website run by the National Institutes of Health, this isn't true. So what we see in this abstract, from what we hear from Dr. Wakefield, there's a real question.

Measles experts have told us that more than 10 natural measles strains have a guanine at position 7901, even though the abstract says that only happens in the vaccine strain. Well, if there are 10 natural measles strains that have that particular chemical positioning, then this theory doesn't hold up. And I have the names of some of those strains. And I expect to even receive other

names, which I want to add to the record later on.

I want to ask Dr. Wakefield, are you aware if Dr. O'Leary has checked the NIH website thoroughly before writing his abstract? And if it is true that position 7901 does not distinguish between natural and vaccine strain measles, would it be fair to say that the conclusion of the abstract remains unproven?

WAKEFIELD: The work was based upon a recent publication by Parks (ph) and colleagues, which may well supercede what is published on the website. And in that study, they make a clear distinction between vaccine and wild types of strains based upon that mutation.

Other questions on this will have to be referred to Professor O'Leary himself, who can't be here.

WAXMAN: Well, I want to ask you whether you know if Dr. O'Leary checked the NIH website thoroughly before writing his abstract?

WAKEFIELD: I know for sure that he has checked the Gene Bank website.

WAXMAN: Well, if it's true that this position 7901 does not distinguish between natural and vaccine strain measles, if that's true, would it be fair to say that the conclusion of the abstract remains unproven?

WAKEFIELD: Yes, it would.

WAXMAN: I want to point out that we have been in contact with Dr. David W.G. Brown (ph), the laboratory director, and Dr. L. Gin (ph), clinical scientist. They are the head of the World Health Organization Collaborating Center for Measles in the United Kingdom.

And according to Dr. Brown (ph), he says the data presented suggesting the presence of fragments of measles vaccine in these tissue samples is not scientifically valid. The authors should have reviewed the measles database fully. And there are a number of questions that he believes should have been evaluated.

Now I guess we'll have to hear from Dr. O'Leary whether he did the work that was required in order to come up with the conclusion that would be beyond doubt the conclusion. Or whether it's simply a conclusion that remains to be unproven.

But Dr. Brown (ph) says the approach described is scientifically flawed and will not reliably discriminate between wild and vaccine strains. He didn't know why the authors did not review available data or discuss with other measles groups with experience in this field.

Sequencing is the definitive technique to discriminate between wild and vaccine strains of measles. And he doesn't know why that wasn't used.

So I want to just make the point here in the time that I have available to me that what we have now presented to us is another conclusion that's made, but it's based on some unproved information from an abstract. And I'm looking at the abstract.

Based on the abstract that Dr. O'Leary is going to be submitting and which Dr. Wakefield

submits to us as establishing the point he wants to make, according to the World Health Organization Collaborating Center head, Dr. Brown (ph), it's another unproven theory. And we need to have a lot more questions answered about that particular scientific evaluation.

BURTON: Before you leave, Mr. Waxman, I think we have some later information on that. And I'll yield to Mr. Weldon. Maybe he can bring us up to date.

WELDON: I just want to clarify this issue here that Dr. Waxman -- I almost promoted you, sorry.

WAXMAN: Well, I have a juris doctor.

WELDON: You do? I'm glad you shared that with me. I'll refer to you as doctor.

The abstract that we're talking about is 12 biopsies. Is that correct? Or you haven't seen it. It's not your publication, right? So you're being asked to identify something that -- well, let me just say for the record, I know a little bit about this issue of single mutation of a single amino acid using it as a discriminator in determining whether a population -- in this case, it was 12 biopsies -- are wild type versus their vaccine type.

And you get into the statistics of this -- and maybe Dr. Spitzer may want to comment on this -- the statistical probability of all 12 of these being they happen to get wild type is extremely low. Whereas, if that is indeed a marker that is used for the vaccine type, then the statistical probability is much, much higher.

Now yes, you could say that some in that sample may have acquired it through a wild type. But nonetheless, the statistically higher probability is that this is vaccine-related measles.

BURTON: Would any of the witnesses care to comment on that?

SPITZER: Thank you. I would really have to look at the specifics of the study, would have to look at comparison groups, especially with a low sample of 12 of that sort, and have a bit better understanding than you obviously have, Dr. Weldon, of the biology under that.

So off the top of my head, I prefer not to give an opinion. I'll have to look at the basic data and the design and some of the biological issues before giving an opinion.

WELDON: Just for the record, so the ranking member understands, when I was an undergraduate, I did molecular genetics research. And specifically, we were looking at these kinds of issues in the research that I did. So I'm somewhat familiar with the issue that they're publishing on.

WAXMAN: Would the gentleman yield to me?

WELDON: Yeah, I'd be very happy to yield.

WAXMAN: It just seems to me that the question is either the test reliably distinguishes vaccine and natural strain or it doesn't. And that really goes to the very heart of this abstract because if the test does establish that the measles in the gut or the bowel came from a natural strain or it came from the vaccine strain, we want to know whether that's established.

And I think what Dr. David W.G. Brown (ph), who is the head of the World Health Organization Collaborating Center for Measles in the United Kingdom is pointing out to us is that he thinks the conclusion that they can distinguish the strain that was from the vaccine from other natural sources of strain is not proved by this abstract because that position of those genes can be the result of strains not from the vaccine itself.

So that is the essential point that I think remains unsettled. Either it is or it isn't. And Dr. Brown (ph) believes it hasn't been established. Whether it's 12 or more, if in fact the chemical at position 7901 is from a natural measles virus or from a strain from the vaccine is the question that I think needs to be established and addressed.

And I think we have enough question here to really feel that we don't have the conclusion in place.

BURTON: We have to leave for a vote. But we're not through with this panel yet. But I'd just like to say that we've gone from one in 10,000 children who are autistic and have all these kinds of variables and complications to one in 250; in some cases, more than that.

Something is causing it. And we've got to find out what it is. And CDC and FDA and HHS had better get on the ball or else in 10 years, it may be one in 25.

I mean, something has to be done. We've got to get to the bottom of this. And to sit here and just argue back and forth about one case study or another begs the issue.

The issue is there is a problem and it has to be solved.

We stand in recess at the fall of the gavel. We'll be back in about 15 or 20 minutes.

(RECESS)

BURTON: Is Dr. Krigsman coming back? While we're waiting, let me talk to Dr. Stejskal.

How many people do you estimate are allergic to mercury?

STEJSKAL: Mr. Burton, what sort of mercury you mean? Because there is a distinction when you talk about allergy, if you talk about thimerosal or other mercury.

BURTON: Something like thimerosal.

STEJSKAL: Something like thimerosal?

BURTON: Right.

STEJSKAL: Then we have to go for patch testing, which is the things that has been mostly looked at.

BURTON: I understand. But what . . .

STEJSKAL: And I can tell you the numbers are not insignificant. In children, it seems to be especially often they do react to thimerosal.

BURTON: Ten percent? Twenty percent? Thirty percent?

STEJSKAL: No. Twenty to 30 percent of those which are tested. In unselected population, that means adolescents which are healthy, not coming to dermatology clinics, the number which I remember from Howard Miller (ph) in Sweden, it's about 15 percent.

BURTON: Fifteen percent?

STEJSKAL: Yes.

BURTON: So anywhere from 15 to 30 percent of the children are allergic to thimerosal.

STEJSKAL: Yes.

BURTON: Dr. Krigsman, you did how many endoscopies or colonoscopies on those children?

KRIGSMAN: We have 43 results back from 43 patients. One patient had to do a colonoscope twice because of unexplainable worsening symptoms.

In addition to the 43 patients that we've seen, five have been scoped already. And those biopsy results are still pending.

BURTON: I know that you can't make a categorical statement about this. But in your opinion, do you think this was caused by just a regular measles virus? Or do you think it was caused by the vaccines? What's your theory on this?

KRIGSMAN: Well, I read the same papers that everyone else has read.

And what I'd like to do and what we plan on doing is to attempt to replicate what Dr. Wakefield's group has published. And we have everything in place.

We have our lab. We have been in contact with other laboratories that have performed this test. We have the details of the ASA (ph). We have the patients. All we're waiting for now is the hospital approval. The day after we get that, we've started.

BURTON: So you prefer not to theorize until you get the actual study?

KRIGSMAN: If I do it myself, I don't know.

BURTON: Okay. We would like to have that. If you would send that to me for the record when you get it because we think that will be not insignificant.

I think what you've done today by showing your results so far is very significant. And I think finding the measles virus in the spinal fluid is also a very significant finding. And I don't if I were over to CDC or FDA, I think I'd want to start replicating those studies right away over there before the private sector does it and they're proven wrong.

It seems to me that our health agencies ought to be ahead of the game instead of standing around waiting for the basketball game to be over and then say, "Oh well, we better do something about that."

I think -- I don't think Dr. Weldon had any more questions for this panel, did he? Do you know?

I think we've pretty much covered everything with you. You've been a very good panel. You've been very patient. And we really appreciate you being with us.

We have one more question. Let me get this real quick.

Do you believe -- and I'll address this to the whole panel -- do you believe that the CDC statistical studies can dismiss the clinical findings? That's what the Associated Press has said and what Reuters News Service has said. Do you believe that the CDC statistical studies can dismiss the clinical findings?

BRADSTREET: If I might take that up, as a clinician treating about 1,500 children with autism between myself and my partner, Dr. Jerry Kartzenow (ph) who is a pediatrician. One of the disturbing things for me in the way this has been handled by the media is that I have a patient -- and I only take care of one patient at a time, even though I may have 1,500 in my practice -- who has a definable, biological problem I can measure.

I can get a laboratory test and measure autoimmunity to brain. I can find excessive amounts of mercury. And I can send off biopsies and find measles virus.

Now we could debate whether that's the vaccine strain or the wild strain. But we don't seem to be debating the fact that it's measles virus that is persistent in these children. So we have a definable biological problem that must be addressed as a clinician.

The problem is that medicine has not yet given me, as a clinician, the tools to deal with most of these problems. So we need a lot more data that would allow me to treat.

Does it dismiss -- does the statistics somehow magically erase the laboratory results and the clinical findings and the abdominal pain and the history and the chronic diarrhea like my patients are experiencing?

Absolutely not.

BURTON: Anyone else want to comment? Dr. Wakefield?

WAKEFIELD: Just to say, Mr. Chairman, that the statistical studies of the CDC and others have actually tested the wrong hypothesis. And this point was made in the paper that was commissioned by the Institute of Medicine for the review on MMR last year. Until they set about testing the correct hypothesis for a relationship between vaccines, be that thimerosal or MMR or both, and autism, then they will continue to come up with ambiguous or negative conclusions.

BURTON: Anyone else?

STEJSKAL: I would like you to put the overhead. And I would like to stress again that I am sure that case control studies, when you just pull up all autistic children against all controls, which may be asymptomatic but still sensitized, will have a power to tell you anything. So unfortunately -- no, not this one. The last one, which I gave to you with quotations for reference.

Yes, that's it.

BURTON: Okay.

STEJSKAL: And just please read it, sir, carefully. The effect of risk factor may be diluted. So if we are now talking about mercury sensitization or mercury -- weak mercury detoxification as a factor in these which develop the disease, normal case control study will not catch this.

So this is what this paper saying, the effect of risk factor may be diluted if evaluated in heterogeneous population. So how you have to study is that analysis has to be based on the clinical markers of susceptibility either for toxicity or for allergy, but on the biomarkers. These biomarkers can be enzymed for detoxification.

We have different methionines. And you have to select patients, autistic children, for this. And then you have to do average to do the studies.

So analysis based on clinical markers of susceptibility which are phenyldicate (ph) markers, but also genetic markers, if they are available. And this may be one way how to elucidate separate causes best ways and identify specific environmental risk factors.

So I think this is very important that the new studies which should be set up would be done so we can really measure and find the causes.

Thank you.

BURTON: Go ahead.

WELDON: I just have one quick follow-up question. And I'll just offer it out to the whole committee. One of the issues that I've had a little bit of a problem with over the years we've been looking at this issue is we hear about mercury and we hear about MMR . . .

(AUDIO BREAK)

(UNKNOWN): . . . I believe that are thimerosal-related. There is going to be an effort, led by CDC, to try to create a multi-centered laboratory study that will examine, I believe, some of the same questions that Dr. Wakefield and others have looked at.

So yes, that effort is underway. And good progress has been made in trying to organize this kind of multi-centered study. But we're trying to do this in such a way that we can overcome some of the shortcomings or limitations that may have existed on some of the earlier work.

BURTON: So what you're saying is you're in the process of doing it now, but you have not yet done it?

(UNKNOWN): Specifically relating to the work that Dr. Wakefield and his colleagues have done, that's correct. But there is a lot of other work that has been done and that has been reviewed by the IOM and these other committees that I've talked about.

So I wouldn't want to leave the impression that there is a big void of information. I wouldn't want

to leave the impression that we know everything we should know. But I certainly don't want to leave the impression that there is a void either.

BURTON: How long have we been talking about this? How many times have I had people from HHS and FDA up here? It's been, what? Couple of years, hasn't it?

(UNKNOWN): It's been often.

BURTON: Two to three years. Yeah, it's been often.

(UNKNOWN): Yes.

BURTON: And now you're staring to look into it. And I want to tell you, we appreciate that. And I'm sorry it took so much prodding to get it started.

We were talking about the Vaccine Safety Datalink. For two years now, we've tried to get that information so that other doctors and scientists who are not connected to our health agencies who have credentials could start using that information to do studies on their own.

We were told in -- when was it? January or February? In January or February that that was going to be made public. Before this hearing, we asked why it had not yet been made available to responsible people in the scientific community. And we were told, "Oh, it has been made available."

I didn't know it. Did you make any kind of report to the public? Did you announce this in a press release or anything?

CHEN: Off-mike.

BURTON: We can't hear you. Can you pull the microphone closer, Dr. Chen? Have you got it turned on? There you go.

CHEN: I think several members of the audience were present at the meeting. And we discussed several issues. The VSD Project is a very important and unusual project that contains about 7.5 million persons in the United States and their personal medical records.

And so with all the public concern in terms of data privacy, it is very important to work out a process in which we could balance the privacy of these individuals' medical records on the one hand, as well as secondly, the desire for us to be able to look at independent data.

Now the two years that it has taken us to develop a process, in fact I think we, number one, when we first approached the HMOs, there were severe concerns on all of them that, in fact, they would not agree to this and that they would, in fact, withdraw from the project. And so we've had to take the time to work out a compromise in which they would still be willing to participate in this partnership with the government with our ability to look at data safety issues, as well as meet the needs of the HMOs, in terms of protecting their privacy.

So I think that's the question in terms of why it has taken time. And so we have, in fact, come from where each of the HMOs, not only the principal investigators, but also their governing

bodies, were opposed to this idea. And we've kind of gone through each of them and, in fact, convinced them to come around to the other way, to this research data center.

So that's what has taken considerable amount of time and convincing.

Now in terms . . .

BURTON: Let me pursue this. So in February, you had a meeting and other CDC employees were involved, with committee staff. And they discussed the release of the Vaccine Safety Datalink raw data to researchers. That was in February.

And at that meeting, CDC provided a draft proposal. Have we got that exhibit? Exhibit number one is -- can we put that up on the screen?

Well, never mind. It's in your file there, exhibit number one for researchers to access to the VSD data. At that time, the staff was told that the project was ready to go.

Isn't that what we were told? It was ready to go at that time in February?

CHEN: That's correct.

BURTON: And we did not receive, up to this meeting today, a press release or an advertisement in any medical journal was seen or on any CDC website regarding this new program. Now if you're going to make an announcement, how do you propose to let anybody know unless you tell us?

CHEN: As I mentioned at the meeting to the people that were present, that this in fact is the first time that we have tried to develop this mechanism with the National Center for Health Statistics. It's a pilot project, using their research data center, which historically have not put this type of personal medical records available for public use.

It's really for kind of national health interview survey, where people over the telephone are willing to answer those type of questions about their health status. Those are the type of things that are put on there.

So this is in fact a pilot process. And so until we work out all the potential concerns through the first couple of test projects, if you will, it is our sense that it will be premature to widely advertise it.

BURTON: But I think, with the quantum leaps that we've seen in technology, there's not any real risk if you don't want the researchers from the outside to know who the individuals are that is on the data.

You can do that. You can protect the privacy of those individuals. You can make sure that there is no public announcement about that.

CHEN: Unfortunately, that turns out not to be really feasible in this database. If you could imagine that for any vaccine safety study, you need several parameters that are key to be able to make the analysis.

You need to know the date of birth of that individual. You need to know the date of vaccination of that person and any medical visits and what diagnoses they had.

So you need all of those three elements in order to be able to do your analysis. And it turns out that with the key variable on date of birth

-- so for example, this was actually one of the major concerns expressed by one of HMOs in Colorado, the principal investigators, his daughter in fact recently had a sprained ankle.

So he kind of posed hypothetically to his analyst that if you attended a birthday party and knew my daughter's date of birth and you also happened to find out that the child had a sprained ankle the previous day or the previous week, can you find this child? And in fact, he was very easily able to find that.

BURTON: I see where you're going. We're talking about how many people? Six million?

CHEN: 7.5 million.

BURTON: 7.5 million. And you're concerned because there is a sprained ankle and somebody goes to a party that they might be able to tell by using the birth date who this person was.

BERNIER: Mr. Chairman, may I interject if I may? I want to put on the record very clearly that CDC does support sharing information and trying to work transparently, which I think is where you've been trying to get us to go. So let me make clear . . .

BURTON: What I'm trying to find out right now is why, when we were told in February they were going to release this -- you know, every day is important to people who are going through these problems. My grandson, my granddaughter, all these people out here who have kids who are autistic, the people whose kids are becoming autistic today. Every day is important to them.

And when we're told in February we're going to get information and the information -- here we are, at the end of June, and we haven't received it. And yet, it was supposed -- we've been told that, "Oh yeah, it was made public a long time ago." But nobody knew it. That's important.

And that's what I'm trying to get at here. Why if you made a decision, why didn't you tell us? Why didn't we know about it? Why didn't all these people in the scientific community that wanted to get started on this, why weren't they told about it?

BERNIER: Well, first of all, we have been trying to strike the right balance between the interests of all of the concerned parties, so that's part of the reason. The other thing is that this is new for us. We're not interested in highly publicizing something where it is a pilot type of project.

When we can iron out the wrinkles, we potentially will be in a position to make this more available. So part of this is that this is a new pilot project and there have been efforts to try, as Dr. Chen alluded to, we have to try to protect the cooperation of the HMOs. We have the proprietary interest of the HMOs and the privacy rights of the patients.

So we are trying to strike a balance. And we are trying to make this work as smoothly as possible. We don't know all of the issues that we will confront when we do bring in these

researchers to reanalyze some of the studies that we have done.

So we are trying to move cautiously so that we can do so. But we will get to where you're going for people who want to reanalyze studies that CDC has done in the VSD.

BURTON: I have more questions. But I'll yield to my colleagues. As I said before, as I yield to Dr. Weldon, we all want you to be cautious.

We don't want to make mistakes. We all support vaccinations that's done in a responsible way because it has protected the health of this country.

But you've got people every day that are starting to suffer. There's huge quantities of people who have children now that are suffering from these diseases.

And the quicker we move, the better. And the more people that get involved in the research, the better. So having outside responsible scientists having this data so they can get started on it quickly is very, very important.

Mr. Weldon? Dr. Weldon?

WELDON: Thank you, Mr. Chairman.

Let me just start out by saying to you, Dr. Bernier, we . . .

BERNIER: Sorry, I'm getting a lot of notes.

WELDON: Yeah, this is very technical and complicated. We all support the vaccine program, okay? I'm a physician. And I vaccinated hundreds and hundreds of people every year in my practice. And we all recognize the tremendous accomplishment of the vaccine program in preventing death and morbidity in the United States, world over. Okay?

And I'm just saying that because we've had a lot of hearings on this issue over the years. And a lot of people from the vaccine community come forward and they point out all of that over and over again.

And we don't really question any of that. Our concern is that there has been clinical evidence that there are some very serious problems with our vaccine program and that officials in the United States and officials in Great Britain have been trying to avoid addressing them straight up.

I mean, just to cite one teeny, little example. This doctor over here, Bradstreet, did a culation on his kid and culated out a mountain of mercury from this kid. We had, in other panels, we had physicians with autistic kids who did hair analysis on their kids and discovered they had toxic mercury levels.

Now I'm very glad you're getting around to the studies now. And I'm very, very pleased. You said you have six studies going on.

But I just want to underscore that we all support the vaccine program. We all know it saves millions of lives. We all want to see it continue.

But credibility is also one of the other issues at stake here. It's not just the science of the matter. It's the credibility of our vaccine program. The last thing I personally want to see is that public confidence get undermined -- like it has been undermined in Great Britain -- and you've got thousands of families refusing to vaccine now.

And as I understand it, you have outbreaks of measles going on over there. And I would like to see us handle it better.

And let me just say -- and you can take this back to your bosses -- one of the things I continue to be very, very disappointed about is the amount of money that's being thrown at this issue. We have, I think, about a million people with HIV/AIDS. The CDC budget for HIV/AIDS is $932 million, almost $1 billion for HIV/AIDS for a million people.

We have about a half a million people -- kids mainly -- with autism.

And the CDC budget is about $10 million or $11 million. And we have to start putting the resources to this problem to address this issue.

And the access to the data, you guys have to work through that problem and you have to allow skeptical people to look at the data. Because the impression is being generated that there is a cover up going on. And I want to say that this study lends credence to the concern of their being a cover up.

This archive study -- and Dr. Chen, I'd love for you to respond to my question. You have got a claim in here in your conclusions, "Vaccinations with MMR and other measles-containing viruses or the timing of the vaccination early in life does not increase the risk of inflammatory bowel disease."

Now you weren't the principal author. It was Robert Davis (ph). And there is 10 different authors here, so maybe you didn't write that conclusion.

But the statisticians are telling us that you don't have the power in this study to make that sort of a claim. And what's really disturbing to me is now in clinical evidence, which this is sort of the Bible in medicine, this study is being quoted in clinical evidence that there is no relationship. But the statisticians that I've talked to tell me that the data doesn't support the claim at all.

And this suggests again that you guys are -- it's like you're circling the wagons and you're not really addressing the issue straight on, straight up, honestly.

CHEN: Dr. Weldon, let me address some of the points that you addressed. I think if you take a look at my record over the years, I've done everything I can to build the infrastructure that's needed for us to address some of these issues. I started the Vaccine Adverse Event Reporting System. I started the Vaccine Safety Datalink project.

And I think part, in retrospect, part of our challenge, if you will, in the field of vaccinology is that, in fact, there is one additional missing piece of the infrastructure which, in part, has created an unnecessary gulf, if you will, between the clinicians and the population scientists. And if you think about it, adverse events obviously occur rarely, so that any particular doctor reporting to

VAERS will be pretty much doing so for the very first time.

And so our difficulty has been finding a way in which these type of cases can be assessed in a standardized way. The analogy would be that, for example, we do not expect the average primary care physician to be able to diagnose and treat a rare type of leukemia on their own. We create, in fact, a sub-specialty, a hematology oncology, which over time then as a sub-specialty, is able to make progress on these rare outcomes.

And now this situation with vaccine safety is that, by and large, these events are rare. And so we, in fact, need a tertiary infrastructure to be able to study them. And we have just started the Clinical Immunization Safety Assessment Centers in this current fiscal year. So I think we will have a mechanism, I think, to bridge the type of research between population and the individual level.

WELDON: Well, let's talk technical stuff here. The issue is power.

And the problem with the power in this study, the power calculation renders this study invalid because you do not have enough people in your control group who were not vaccinated. And the only way that we can get a statistically valid study, because the penetration of this vaccine is so extremely high, is that we would literally have to have a multi-national effort to try to address the question that you attempted to answer in this study, which you really didn't answer.

CHEN: And I agree that more studies -- this is one study. And with all evidence, the more studies the better that are replicated.

(UNKNOWN): If I may?

WELDON: Yeah.

(UNKNOWN): I'm a co-author of this paper.

WELDON: You're on this too. Please.

(UNKNOWN): . . . strongly criticized. I just want to put my viewpoints and put it into context.

WELDON: Can you move the microphone up a little bit closer, please?

(UNKNOWN): I think this paper and the low power that was alluded to earlier, I think kind of missed the main point of this paper. It combined all measles vaccine into one group. And therefore, we found that 94 percent were vaccinated.

By the time of this study, the hypothesis with IDD and measles vaccine had shifted to the MMR vaccine as the culprit. Before that, there have been studies done looking at single antigen measles vaccine, one done by Montgomery (ph), which Dr. Wakefield is a co-author; the cohort study of a 1970 British birth cohort. They did not find any association with single antigen measles vaccine.

Similarly, a case control study by FINI (ph) could not find association with single antigen measles vaccine. Subsequently, the study by Montgomery was the one in which there were two

cases in which the individuals -- again, this long-term follow up. They were followed up to about age 26. It think it was about two cases that the individuals had wild type measles disease and mumps disease in the same year. And I think it was part of that. And those two cases had a high relative risk.

I think it was their finding that the sort of theory, the hypothesis that having the two antigens exposure at the same time may be more detrimental. From there, I think they have part of the evidence that it's combined measles-mumps-rubella vaccine that's really the more dangerous combination and calls for a single antigen vaccine.

So by the time of this study, really the main new information to address or issue to address is MMR vaccine. And if you'll look in this study, the proportion vaccinated with MMR was 66 percent. I think the relevant table is table two, where we're looking at ever vaccinated with MMR vaccine. And you'll see that the upper end of the 95 percent confidence interval for inflammatory bowel disease is 1.69.

We can be fairly confident. We can be over 95 percent confident that the relative risk for inflammatory bowel disease in this population associated with MMR is well below two.

WELDON: We've got a range of .21 to 1.69.

(UNKNOWN): This is a range. But this isn't a flat range. You have to look at the odds ratio. That .59 says that's our best estimate.

It's almost like if you would repeat this study, it would be statistically like a bell-shaped curve. Most of the results would be around .69.

You may have a few out there around 1.6, maybe a few down by .2. But they're more mainly going to cluster around. So this is our best estimate is .6. And it's for MMR. It's a lot better than focusing --I mean, I'll agree that we were much more limited at looking at table three with specific ages of vaccination. They were more limited in looking specifically at Crohn's Disease or ulcerative colitis.

But I don't think our power -- I'd say our power was reasonable or at least, as the confidence intervals would suggest, address the main issue that was expended at the time.

WELDON: Well, let me just reclaim my time here. The issue is this is a relatively low probability event. I mean, the data suggests that the vast majority of girls can take this vaccine and it's probably less than one percent are having -- this hypothesis is correct, that MMR alone or MMR somehow interacting with mercury is causing regressive autism associated with inflammatory bowel disease or autistic enterocolitis.

The data is that it's maybe one percent of boys and it's well below one percent of girls. It may be on the order of .2 percent or less of girls. So even an odds ratio that you're putting forward here in table two, I'll give you credit, of 1.69 doesn't answer the question.

And you cannot, on the basis of the data that you've provided here, substantiate the conclusion. And frankly, I've been reading the annals

-- or excuse me, the archives for years, not the "Archives of Pediatric and Adolescent Medicine," the "Archives of Internal Medicine." But it's published by the same publisher, AMA.

And I'm surprised this would be accepted for publication. And I'm even more disturbed that the data is being cited in other publications as further evidence that there is no relationship.

Meanwhile, we have more and more clinical studies. We heard from another researcher here, totally unaffiliated with Dr. Wakefield, basically substantiating Dr. Wakefield's findings. And now we have even the more disturbing development of a researcher telling us he's finding measles in the cerebral spinal fluid in these kids.

Now perhaps maybe the CDC is the wrong agency to be addressing these questions. None of you are with NIH, correct? You're with NIH? I mean, the NIH budget, I think is even more disturbing.

You've got in '03, $2.7 billion on AIDS-related research, HIV/AIDS, which I don't quibble with. It's a terrible problem. But $70 million?

You've got 500,000 people with autism and a million people with AIDS.

Why don't we just apply the dollars now?

Now I've heard you say you've got to get quality research and that you just can't throw money out. You want quality.

But I know enough about research. If you dangle the money in front of them, the quality research will start coming forward. There's a lot of researchers who will say, "I can do that." Why don't we get answers to some of these questions?

(UNKNOWN): As we discussed several weeks ago when I last testified before this committee, but I think even in that time, for example, we've made strides toward funding our first large autism research centers.

And there will be a formal announcement about that in several weeks.

And in those centers, for example, is where a there's kind of training will occur that will allow young investigators to develop skills, to develop quality grant applications, to design very rigorous experiments to undertake these issues.

Your message is well taken that there is a need for biomarkers for this disorder. There is a need for more clinical investigation. And we have put the money on the table.

We are working with investigators with a great deal of technical assistance to them about how to prepare grant applications and so on.

WELDON: I want to just underscore a very, very important point in all this. And I don't mean to keep picking on AIDS. But you know, you're going to have another dramatic increase in the funding. The president wants it. The House and the Senate all want it.

You're going to get hundreds of millions of dollars more. Keeping this kind of a ratio, you have to start applying disproportionately more money to autism so we can get answers to some of these questions. And one of the reasons I feel so strongly about this is, unlike AIDS, where it's clearly a behaviorally-related disease, these kids may be getting this from a government-mandated vaccination.

And that if we get answers to some of these questions, we may be able to prevent it; whereas, in the case of AIDS, we can't really prevent it because it's behaviorally related. It's not something mandated by the government that has caused it.

So a shift in priorities can have a dramatic impact.

I'm going to yield back. I just want an answer for the record.

The issue brought up by the ranking member on using various coding regions in the RNA and in the proteins as biomarkers to determine whether or not there is a wild type version of the vaccine strain, I want to introduce into the record a research article published by a Dr. Christopher L. Parks (ph). And it's entitled "Analysis of Non-Coding Regents of Measles Virus Strains in the Edmonton (ph) Vaccine Lineage."

I yield back.

BURTON: Without objection, we'll submit that for the record. We also have an article which we'll also put those in the record.

Ms. Morella, do you have some questions?

MORELLA: Thank you, Mr. Chairman. I thank you for this hearing and continuation of the series.

Dr. Weldon made some exceedingly great points, by virtue of his experience and knowledge. I also, I agree with him that we should not be acquainting HIV and AIDS with the money that's going into this research either. Let's just contribute the money to all of the research. I know he doesn't mean to say we take away from one or the other.

But I'm going to ask a series of questions to Dr. Chen.

Dr. Chen, sir, in the U.S. medical community, studies that have been done by CDC researchers are given a great deal of credence, aren't they?

CHEN: I hope so.

MORELLA: Right. And internationally, such studies tend to be viewed as the opinion of the government, correct?

CHEN: You have to ask those people. Again, we try to do the best science possible.

MORELLA: Right. Generally, medical authorities, particularly those in the international community, tend not to distinguish between CDC employees publishing research and the CDC's

official position. Correct?

CHEN: Again, you have to ask -- I have not done a survey to look at that.

MORELLA: Generally, you would agree with this? Isn't it true then that HHS requires or perhaps should require that CDC ensure that its research regarding vaccines, for example, is of the highest caliber, is not misleading and that a published study actually answers the question being asked.

CHEN: I think all studies have their strengths and weaknesses, as has been seen by the discussion this morning. And all we can do is, for any particular study, do our best to see what we can answer with the particular study design and address the kind of the strengths and weaknesses in the discussion.

MORELLA: So if a given CDC study can't reach a conclusion, the CDC in the article needs to explicitly say so. Correct?

CHEN: Again, in any particular discussion, hopefully we discuss both the strengths and the weaknesses. And in the weaknesses, obviously that would be -- no single study on its own, very rarely, is able to definitively arrive at a single conclusion. What you do is you add to the weight of the evidence on a particular issue.

MORELLA: Right. It's also our understanding that the Vaccine Safety Datalink project was your idea, your concept. Is that true?

CHEN: Well, I don't know if it's unique. I think there were several other predecessors who actually did smaller projects, versions of these large linked databases. In fact, the drug safety folks actually came up with the early versions of these linking up automated pharmacy files, if you will, with automated outcome files.

MORELLA: But you were a critical part of that process.

CHEN: So we were building on those other -- like science, we're always building on others' ideas.

MORELLA: Yeah, you're being pretty modest about it. Was the project originally designed for a specific length of time? Or was it designed to go into perpetuity?

CHEN: Well, I think the thought would be that we will continue to vaccinate. And presumably, there will continue to be vaccine safety issues.

Our initial contract, I think, was for five years because that's the extent of how long government contracts could be. So I don't know if we actually ever thought about it in terms of how long it would run. But it was definitely ran for at least five years.

MORELLA: So about five years was the original intent.

Why was the project extended past the original five-year plan? Who made the decision?

CHEN: Well, I think the main reason is there continued to be new vaccines added. And there are

continuing new vaccine safety issues that arose. The main impetus, back in around early 1990 when we got started, the Institute of Medicine reviewed the evidence available on the safety issues as part of the Vaccine Injury Compensation Act.

And for about two-thirds of the issue that they looked at, they had to take the agnostic position that there was inadequate events to accept or reject a causal relationship. So there was a large number of research issues that, in fact, was a backlog, if you will, from even before.

MORELLA: But who was it who made the decision? And as a matter of fact, who at CDC determines what studies will be conducted?

CHEN: Well, it's actually a decision like any multi-center research project. It's done collaboratively through the principal investigators, so we have a monthly conference call among the PIs to kind of look at potential new study ideas.

We take into account a whole variety of potential study ideas, be it from the Institute of Medicine, be it from VAERS, be it from case reports in the literature. And then on an annual meeting, face-to-face meeting, we try to even do further prioritization among our ongoing studies.

MORELLA: So it's collaborative?

CHEN: It's very much unusual. It really is a partnership. It's the largest collaborative project between CDC and managed care organizations. And so we have the public health interest to do the vaccine safety monitoring.

The HMOs -- and I should mention that this is perhaps an aspect that is different than Canada and Saskatchewa, where there is national health insurance -- the HMOs kind of have their own internal administrative databases as part of their regular internal insurance organization, if you will. And so we piggyback the VSD project onto data that's really collected for routine medical care.

MORELLA: May I just ask one more question related to that, Mr. Chairman? In February of this year, I understand that you and other CDC employees met with committee staff to discuss the release of the Vaccine Safety Datalink raw data to researchers. Is that correct?

CHEN: It was not the raw data. I think there is some confusion here. What we had talked about is that in terms of the completed studies of the VSD, in which individuals would wish to do independent validation of our findings, we would make that available through the research data center.

MORELLA: And at this meeting, CDC provided a draft proposal for researchers to access the VSD data. And at the time, again I understand that the staff was told that the project was ready to go.

Is this project now up and running?

CHEN: In fact, I think someone contacted me yesterday in terms of the proposal process and we're in discussions with him.

MORELLA: And so again, I understand that no one has seen a press release. Have you released a press release or an advertisement in any of the medical journals or on the CDC website?

CHEN: Generally, we do not publicize or issue a press release on matters like this. That is really handled by the department.

We pursued this issue at the urging of the committee and made your staff aware of the availability of this new policy, so that other researchers who may wish to replicate the findings, we make it available.

MORELLA: You can see what I'm getting at. I mean, the idea that I think it's important that you make the announcement; otherwise, how do you propose that people are going to even know that the program does exist?

The committee was sent an email message last week saying that applicants could send their applications to you? Do you have the procedures and the timeline for people to respond?

CHEN: Again, as I mentioned earlier to an earlier question, this is a pilot process that we're working out. And we are going to accept those requests. And we'll just work it through and see how it goes. Because I think this is very much an experiment in terms of seeing whether, in fact, we are able to maintain this very valuable infrastructure for vaccine safety monitoring to the extent that the HMOs are still willing to continue to participate.

We cannot mandate them to participate. It's really their patients, their database and their institutional review boards who have oversight over the access to these data.

MORELLA: Can outside researchers contact the HMOs who participate in the VSD directly with specific research proposals?

CHEN: If they wish, sure. In fact, currently for example, the infrastructure that the VSD has built has permitted a number of other folks who are interested in research, predominantly folks interested in doing vaccine-related research, to work directly with the HMOs. Yes.

MORELLA: My time has expired. I would yield back. I thank you for your response, Dr. Chen. And you can see we're looking at what that streamlined procedure will be -- the openness timeline.

Thank you, Mr. Chairman.

BURTON: Thank you, Ms. Morella. We certainly want to see this opened up as quickly as possible so that other researchers can check on all these things that we're talking about today.

Dr. Egan, one thing that's bothered me for a long, long time, do you know when thimerosal was checked for its safety initially?

EGAN: I guess the first study that I'm aware of, I guess, was in the late 1920s when some researchers from Eli Lilly first evaluated the . .