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# VACCINES--FINDING THE BALANCE BETWEEN PUBLIC SAFETY AND PERSONAL CHOICE

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HEARING

before the

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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VACCINES--FINDING THE BALANCE BETWEEN PUBLIC SAFETY AND PERSONAL CHOICE

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TUESDAY, AUGUST 3, 1999

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

The committee met, pursuant to notice, at 2 p.m., in room 2157, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Waxman, Morella, Shays, Mink, Mica, Norton, Cummings, Kucinich, Davis of Illinois, Terry, Biggert, Schakowsky, and Ose.

Also present: Representative Weldon of Florida.

Staff present: Kevin Binger, staff director; Barbara Comstock, chief counsel; Daniel R. Moll, deputy staff director; James Wilson, chief investigative counsel; David Kass, deputy counsel and parliamentarian; S. Elizabeth Clay, professional staff member; Mark Corallo, director of communications; Corinne Zaccagnini, systems administrator; Carla J. Martin, chief clerk; Lisa Smith-Arafune, deputy chief clerk; Phil Schiliro, minority staff director; Phil Barnett, minority chief counsel; Sarah Despres and David Rapallo, minority counsels; Ellen Rayner, minority chief clerk; Jean Gosa, minority staff assistant; and Andrew Su, minority research assistant.

Mr. Burton. The Committee on Government Reform will come to order. I know we have a big crowd that wants to get in, but we'll have to have the door shut, so we can hear what's going on. Officer, will you shut that door, please? Thank you.

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

[The prepared statement of Hon. Doug Ose follows:]

[GRAPHIC] [TIFF OMITTED] T2560.001

Mr. Burton. We will have more Members here shortly, but everybody is going to different hearings. This is a very, very busy week, as my colleagues all know.

I ask unanimous consent, at this point, that Representative Schakowsky be appointed to the minority vacancy on the Criminal Justice, Drug Policy, and Human Resources Subcommittee. Without objection, so ordered.

I ask for unanimous consent that Congressman Dave Weldon, who is one of the handful of physician Congressmen, join us on the stand and participate in our hearing today. Without objection, so ordered.

Mr. Waxman. Reserving the right to object.

Mr. Burton. The gentleman reserves the right to object. State his reservation.

Mr. Waxman. Mr. Chairman, we really need to establish a policy when Members, who are not on our committee, are permitted to come and join us and ask questions. When we were in the majority, the policy we applied, whether it was a Democrat or a Republican, was that if the Member from outside the committee wanted to come and sit with the Members, they were certainly welcome to; but they were not permitted to ask questions because that wouldn't have been fair to other Members. That was the rule we applied, no matter what side of the aisle the Member was from.

I don't know what the policy is now. If the policy is to let any Member who wants to come and join a hearing, join us and ask questions, it could get out of hand. So, we ought to have a policy established.

Mr. Burton. Well, I think a gentleman's agreement between you and I would probably suffice, at this point. What I would suggest is if you, Mr. Waxman, have a Member that would like to come and ask questions on a specific topic, I don't think we would have any objection on our side. The reason we have Dr. Weldon here today is because he is a physician. We're talking about issues relating to the health industry and he has some expertise and some background in this area.

Mr. Waxman. Well, Mr. Chairman, just to inquire further, and I don't--I'm not talking about this in any way personal to Mr. Weldon, but there are Members who have interest in hearings that this committee will have at one time or another. If you say you're going to let him come and you let someone on our side come, are we talking about one on each side? Or is it anybody who comes can come and--maybe what we could do, rather than work out a policy at this moment, is since we don't have

many Members here, have an agreement that we'll let Mr. Weldon ask questions. But, I do think we need to think through this whole question.

We had the issue come up recently with one of our Members who wanted to attend a hearing, and we said, look, if it were a field hearing, that's one thing, if it's in a Member's district. But, since it's a hearing in Washington, we didn't think it was proper to have a Member come and ask questions because other Members then have to wait until they take their turn, either on the first or second round. So, we need to have a policy, apply it, no matter who's involved. And this is an issue that--we had a policy when we were in the majority. I don't know what your policy is, but it sounds like for today, the question is Mr. Weldon.

Mr. Burton. Well, I think the policy generally has been as the gentleman has stated. That's why I asked for unanimous consent that there be an exception made today. I think that we would make that exception, not as a general policy, but as an exception from time to time and we could do that for the minority. But, I'd be happy to sit down with the gentleman and try to work out some kind of a policy for future hearings.

Mr. Waxman. The only thing I want to point out is that once you've made an unanimous consent exception, then others are going to say why not an unanimous consent exception for me and it gets harder to say no to people. Once you start down that road, just realize that we're sending an invitation out to anybody who wants to show up for any hearing, and it's going to be tough to control in the future.

Mr. Burton. Well, I understand. And as the chairman--and you may be chairman in the next Congress, who knows. I hope not; but, nevertheless, it could happen. [Laughter.]

But, if you're chairman in the next Congress, I will exceed to your wishes and, likewise, I hope you will mine. I will try not to make this a policy, but I will sit down with you to try to work it out, so that we can work with each other when we have exceptions like this that we'd like to have made.

The gentleman will withdraw his reservation?

Mr. Waxman. I'll withdraw my reservation.

Mr. Burton. Thank you, very much, Mr. Waxman. Then, so ordered.

We're here today to expand upon the work of two of our subcommittees. Both the Subcommittee on Criminal Justice, Drug Policy, and Human Resources and the Subcommittee on National Security, Veteran's Affairs, and International Relations have conducted hearings on vaccine issues. I'm thankful to my two subcommittee chairs, Mr. Mica and Mr. Shays, for being so diligent in pursuing issues regarding safety, efficacy, and the mandating of hepatitis B and anthrax vaccines.

In this country and around the world, we have made a decision to vaccinate the entire population against dreaded infectious diseases. Children are required to receive numerous vaccines before they enter day care centers or schools. Vaccines that we now know contain mercury. Adults in certain professions are required to receive vaccinations for employment. This policy creates an inherent conflict between the interest of the individual and the community.

The tension between the individual risks and the public benefit is a classic ethical dilemma for public health. Some have described the current mandating of an increasing number of vaccines to children to be a good intention gone too far. Many of you may remember the polio crisis earlier this century. It was through the work of brilliant scientists, like Jonas Salk and Albert Sabin, and their colleagues, that the polio vaccines were developed. It was a mad dash to the finish line of licensing for the manufacturers of these vaccines, while polio, which caused so much illness and heartache, appears to have been eradicated. But, there are still cases of polio today, cases caused by the vaccine, itself. Jonas Salk spent the last months of his life pleading with the government to stop the use of live vaccine, because of the cases of polio that it was causing.

Both the Food and Drug Administration and the Centers for Disease Control have adverse events monitoring systems. The FDA system, the Vaccine Adverse Event Monitoring System, is a passive monitoring system. Medical professionals, the pharmaceutical industry, and the public report adverse events. Over 11,000 adverse events were reported just last year. Over 5,900 adverse events have been reported so far this year, about one-sixth of those are considered serious. In all, 95,103 adverse events have been reported to this system since its inception. The former FDA Commissioner estimated that only 1 in 10 adverse events are reported, which means that we're talking about something close to 950,000.

Now, what is a serious event? It includes events that require hospitalization, events that cause disability, and events that kill. When asked about the safety of their vaccines, one pharmaceutical representative told my staff, everything has adverse events, including aspirin. To the academic or bureaucratic realm, the risk benefit ratio is numbers on a page. But to the parent of a child, who suffered a serious adverse event from a vaccine, that risk becomes a reality.

The risk was too real for the Nelson's, whose 1-month old daughter, Abbey, born healthy and hearty, died less than 1 month after coming home from the hospital. They later learned from the doctor, who performed the autopsy, that it was a death related to the hepatitis vaccine given to their daughter in the hospital when she was 2 days old.

To Rick Rollens, whose son acquired autism from a vaccine reaction, the risk was too great. The autism, vaccine linked, is very controversial. But, we have verified with current and former NIH neurologists that any injury to the brain can cause autism, including the shock to the neurological system by a vaccine. They will testify today.

To Michelle Clements, who is not able to be with us today, but who has submitted written testimony, whose son has spent at least 3 years in a coma, as a result of the DPT vaccine, the risk was too great.

We, as the government, can no longer keep our heads buried in the sand like an ostrich, pretending that there is no problem. On the flip side of this discussion is the need to protect the public at large from vaccine preventable diseases.

I am not stating or implying that we should not have vaccines, because they are crucial to public health.

We will hear today from Carola Zitzmann, whose son was born in 1964 with severe disability, after being exposed to rubella during her pregnancy. We will also hear from Rebecca Cole, whose child died from chicken pox; and from Dr. Keith Van Zandt, a pediatrician, whose child is living with hepatitis.

In 1997, President Clinton directed Secretary Shalala to work with the States to develop an integrated immunization registry system and to require that all children in federally subsidized child care centers be immunized. This mass tracking of childhood vaccinations has created State registries that are tracking children from birth to grave. With these State systems reporting back to the Federal level, we have instigated something the American people have strongly and loudly opposed, national medical tracking and invasion of the American public's privacy. One report stated that the long-term tracking strategy had three steps: first to notify families with a postcard when their child was late for a vaccine; second, if they did not comply, then a government official would call them on the telephone and remind them; and third, if they still did not comply, a government official would come and visit their home. I think that's going too far.

And what of attaching immunizations to Federal child care centers? Does this mean if your child has a medical or religious exemption, that he or she will not be allowed to access a federally subsidized facility? In our rush to vaccinate everyone, have we informed members of the public that they have choices? No, we have not. In our rush to vaccinate, do physicians and health care providers keep current in the medical literature, conscientiously reviewing medical histories, read package inserts and the Physician Desk References for contradictions, and clearly discuss these with their patients or their parents? Not very often. Have we become complacent in our protecting of our children, just so that we can meet some kind of a quota?

We will hear today also from Antonia Spaith, a Department of Defense civilian employee, who suffered serious adverse events after taking the anthrax vaccine and other vaccines. The mandating of anthrax vaccine in the military is a great concern to many in the Congress. I have joined my colleagues, Congressman Walter Jones, Ben Gilman, and others, in sponsoring legislation to stop the mandating of this vaccine.

From intense investigations, it has been learned that the decision to use this vaccine is fraught with errors. The adverse event rate is much higher than indicated and the military knows it. The research into its safety and efficacy does not provide any sense of security. We're using a vaccine that does not provide protection against strains of anthrax that would most probably be used, those that come through the air.

As we have learned at the subcommittee level, this issue is adversely affecting military readiness. We are losing a lot of members of our military, who choose to leave the military, rather than take this vaccine. Morale is low, as a result of the misinformation campaign, also on the lack of information on

adverse event reports. We learned that there is fear in the ranks about reporting. We learned that the Department of Defense filters these reports before sending them to the FDA. We, also, learned that in complete defiance of regulations, the manufacturing facility was not inspected until 1996.

That means for 20 years, this manufacturing facility that produces the anthrax vaccine was not inspected, at which time it was learned that the quality control was deplorable. After 20 years of producing this vaccine, they found that the quality control was deplorable. No vaccine has been produced and distributed since that inspection, which means that we've stockpiled vaccines that are likely adulterated and still being given to our service members, while the plant is being updated. Yesterday, a member of my staff reviewed a test video being prepared by the military to show to its members to inform them about this vaccine. It is full of intentionally misleading statements.

Now, in order to keep the pharmaceutical industry in the vaccine development business, Congress created what was supposed to be a no fault system for vaccine victims to receive compensation. There is concern that the Department of Health and Human Services has modified the injury compensation table, and in so doing, excluded those injuries that were most likely to apply to the program.

Now, we're pleased that Dr. David Satcher, the U.S. Surgeon General and Assistant Secretary for Health will be testifying on behalf of the Department of Health and Human Services. We're also pleased that Dr. Marcel Kinsbourne, Dr. Ronald Kennedy, and Dr. Samuel Katz will be testifying today, and we welcome them.

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

[GRAPHIC] [TIFF OMITTED] T2560.002

[GRAPHIC] [TIFF OMITTED] T2560.003

[GRAPHIC] [TIFF OMITTED] T2560.004

[GRAPHIC] [TIFF OMITTED] T2560.005

[GRAPHIC] [TIFF OMITTED] T2560.006

[GRAPHIC] [TIFF OMITTED] T2560.007

Mr. Burton. The hearing record will remain open until August 16th for all those who wish to make written submissions to the record.

[Note.--The information referred to is held in committee files.]

Mr. Burton. I now recognize my colleague and ranking minority member, Mr. Waxman, for his opening statement.

Mr. Waxman. Mr. Chairman, there are a few triumphs in the annals of medicine like vaccinations. Vaccines have saved more lives than any other medical intervention in history. Today, they protect us from deadly infectious diseases which spread death, disability, and misery in other less fortunate parts of

the world. Thanks to universal immunization, the United States has made tremendous progress against polio, diphtheria, whooping cough, and other diseases. According to UNICEF, these diseases kill 2\1/2\ million children and cripple 750,000 children worldwide every year. Without vaccinations, American children would also be vulnerable to similar catastrophic epidemics.

I don't think American parents would ever permit their children to be exposed to such extreme risks. But today we are becoming complacent about our success against infectious diseases. Unlike our parents and grandparents, we aren't terrorized every year by paralytic polio and whooping cough epidemics. This makes it easier to forget the value of vaccines and to focus on their potential risks. But, if children are frightened and parents discouraged about vaccines, we will quickly become vulnerable again to infectious diseases.

No one doubts that there are adverse reactions to vaccines. It is unfortunate that they happen and that children and adults suffer as a result. That is why I sponsored the National Childhood Vaccine Injury Act of 1986, which established the National Vaccine Injury Compensation Program. This program relies upon the best available science and medicine to provide an alternative to litigation for individuals who suffered specific vaccine related injuries.

Today we must continue to rely upon what science tells us about the benefits and risks of vaccines. We must continue to educate the public about vaccines, their benefits and risks. While everything we know about childhood vaccines tell us that their benefits far outweigh their risks, we must remain vigilant and continue epidemiological research into potential side effects.

There is a simple way to illustrate the importance of vaccination. Two hundred years ago, Edward Jenner developed the first small pox vaccine. I was inoculated against small pox; my children, who were born in the 1960's, were also inoculated. But those of you who were born in the 1970's do not have a small round scar that we bear on our shoulders because you didn't need the small pox vaccine. Small pox no longer threatens our children in our beds or whole communities with death. It's just a memory.

Today, we are tantalizingly close to eradicating the second communicable disease in history, polio. But until polio, meningitis, diphtheria, hepatitis, and other diseases are truly memories, our children and our families will continue to be at risk. Vaccination will remain an indispensable public health defense and it will be Congress's responsibility to continue to support and encourage universal vaccination.

Mr. Chairman, we will hear from families today who have suffered either adverse reactions to the vaccine or health problems they believe are linked to the vaccine. We will also hear from the families of those who have experienced the trauma and stigma of infectious disease. I'm sympathetic to all of our witnesses and look forward to their testimony.

Unfortunately, however, there are many witnesses that we will not hear from. The Democrats made a request for witnesses, but only half of those requests were granted. We requested to

hear from a doctor who could have talked about efforts to vaccinate worldwide and the ravages of vaccine preventable diseases on children around the globe. We asked for a doctor to testify who has been doing vaccine studies since 1967 and who is an expert on reactions to the pertussis vaccine. And we asked to hear from a member of the board of directors of the American Academy of Pediatrics. But, these requests were denied.

Many other voices are missing from this discussion. For example, there is no representative from the State health agencies who actually mandate vaccinations and administer vaccine programs. There's no representative from the vaccine manufacturers who bear a large responsibility for vaccine safety. I deeply regret that these groups are not here today to provide us with balanced and informed testimony.

That's what hearings are supposed to be all about. We hear different points of view. And in the course of hearing different points of view, we can try to find out what the truth may be. But I'm sad that at this hearing we're not getting a balanced opportunity to get input from witnesses who have something very important to say.

Now, let me just point out to everybody what that would have entailed. Witnesses are given 5 minutes to testify. The Republican majority on this committee would not let us hear from somebody from the American Academy of Pediatrics for 5 minutes. The Republicans running this committee wouldn't let us hear from a doctor that has been doing vaccine studies since 1967 and is an expert on reactions to the pertussis vaccine for 5 minutes. The Republican leadership did not allow us to hear from a doctor who could have talked about efforts to vaccinate worldwide and the ravages of vaccine preventable diseases on children around the globe for 5 minutes.

But I wouldn't object to a colleague of ours, who is not even on this committee, to be able to ask questions for 5 minutes because I think people ought to be able to have an opportunity to say what they have to say. Although when we get Members who will hear that this is a committee they can all join at any moment to ask questions, we're going to have no time for witnesses, because the Members are going to be the only ones talking.

In conclusion, I wish to submit for the record the positions of leading medical and patient organizations in support of universal vaccination. I want to submit for the record a statement from the World Health Organization and the Pan American Health Organization, the American Medical Association, the Association of State and Territorial Health Officials, the American Nurses Association, the American Public Health Association, the American Academy of Family Physicians, the Children's Defense Fund, the American Pharmaceutical Association, the Partnership for Prevention, the Bill and Melinda Gates Children's Vaccine Program, the Immunization Action Coalition, Every Child By Two, and the National Foundation for Infectious Diseases. So when we have a printed record of this hearing, we'll have a lot of different points of view in that record. It's just today, when the presentations are made to us orally, that we will not have the opportunity to

hear from all of the witnesses that we requested.

I look forward to hearing the witnesses that are here today and I hope that will help us further our understanding about vaccinations and policies that would be best suited to help improve the health and safety of the children of this country.

[The prepared statement of Hon. Henry A. Waxman and the statements referred to follow:]

[GRAPHIC] [TIFF OMITTED] T2560.008

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Mr. Burton. Well, I just like to say to my colleague, I regret that we were not able to have those additional three people testify, but we had six people on our side that wanted to testify and we have to set some limits. We try to respond and we did let you pick whomever you wanted, up to three people to testify. So, I apologize for not being able to accommodate the additional three witnesses.

Mr. Shays.

Mr. Waxman. Just to point out, there are nine witnesses----

Mr. Burton. Yes, I understand.

Mr. Waxman [continuing]. In addition to Dr. Satcher.

Mr. Burton. We gave you more than the limit.

Mr. Waxman. You gave us three out of the nine.

Mr. Burton. Yes, we gave you more than you gave us when you were in the majority. Mr. Shays.

Mr. Shays. I think some people got out of bed on the wrong side this morning. I don't think it was me. I welcome Dr. Weldon here and I look forward to others participating, as well.

The Subcommittee on National Security, Veterans Affairs, and International Relations, which I chair, held four hearings on the Department of Defense [DOD] mandatory force-wide anthrax immunization programs. Questions we consider today about improving the safety and ensuring the efficacy of all vaccines apply with special urgency to the anthrax vaccine. In one subcommittee hearing, a DOD physician stated an important standard: good medical care requires use of the least evasive, lowest risk therapy available. All vaccines should continuously be measured against that standard.

Immunization has been one of the most successful public health interventions in human history. It is undisputed vaccines have afforded remarkable, effective, and efficient protection against diseases that once sickened, disabled, or killed millions, particularly children. But as the number of mandatory vaccines climbs, great care must be taken, least the success begat complacency, or worse, arrogance about the extent of our knowledge about the human immune system. We know very little about the long-term cumulative effects of immunological challenges, both benign and toxic.

Genetic variance may play a role in each individual's immunological response. One size of immunity may not fit all. So, as we look for ways to protect the public health into the next century, today's discussion on ways to improve the safety and efficacy of vaccines is an important one. I look forward to hearing the testimony today from all of our witnesses, those chosen by our ranking member and our chairman. I look forward to other hearings on this, since I know that we can't attempt to cover everything in one hearing. I particularly look forward to Dr. Satcher's testimony. As Surgeon General, he has been outstanding and I appreciate his participation in hearings I had when I chaired the Human Resources Subcommittee. Welcome, Doctor.

[The prepared statement of Hon. Christopher Shays follows:]

[GRAPHIC] [TIFF OMITTED] T2560.084

Mr. Burton. Thank you, Mr. Shays. I just want to say you have done yeoman service with your hearings and you should be publicly acknowledged for that, and so should your staff.

Are there others, who want to make an opening statement?

Mr. Davis of Illinois. Just briefly, Mr. Chairman.

Mr. Burton. Mr. Davis.

Mr. Davis of Illinois. Thank you, very much, Mr. Chairman. I want to thank you for holding this hearing, in particular,

given the fact that I am in agreement with those, who suggest that our program of vaccination has been the greatest health achievement that we've experienced in the last two centuries. I, too, believe that it should be universal, although there are some concerns, there are some problems, there are some instances, and education must continue to be a real part of the thrust.

In addition to my own opening statement, I am also including in that statement testimony from Dr. Lawrence Frenkel, who is a physician, pediatrician, and immunologist. He's chairperson of the Committee on Infectious Disease of the Illinois Chapter of the American Academy of Pediatrics and co-chair of the Public Affairs Committee of the Greater Illinois Chapter March of Dimes and chairman of Pediatrics at the University of Illinois, College of Medicine in Rockford and has, indeed, been a health advocate for more than 30 years. So, I submit, along with my opening statement, the statement from Dr. Frenkel, and yield back the balance of my time.

Mr. Burton. Without objection, that will be included in the record.

[The prepared statements of Hon. Danny K. Davis and Dr. Frenkel follow:]

[GRAPHIC] [TIFF OMITTED] T2560.085

[GRAPHIC] [TIFF OMITTED] T2560.086

[GRAPHIC] [TIFF OMITTED] T2560.087

[GRAPHIC] [TIFF OMITTED] T2560.088

[GRAPHIC] [TIFF OMITTED] T2560.089

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[GRAPHIC] [TIFF OMITTED] T2560.093

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Mr. Burton. Mrs. Morella.

Mrs. Morella. Thank you, Mr. Chairman. I want to thank you for holding this hearing today, to examine the role and necessary risks of vaccines and immunization. As we listen to the compelling testimony of our witnesses today, I would hope that we keep in mind the remarkable benefits society enjoys because of widespread vaccination. In fact, Mr. Chairman, vaccines and immunization programs have been so remarkably successful in eliminating or controlling many of the more common infectious diseases of childhood, that their use is often taken for granted. It's precisely because of this

widespread success that the risks from vaccination, and there are risks, are causing such alarm today. However, we must not forget that vaccinations have been so successful that cases of diphtheria, whooping cough, tetanus, measles, mumps, and German measles is so unusual in the United States, that these infections and their consequences are unknown to most Americans.

To get a clear understanding of the great contributions widespread vaccination has made, we need only listen to the stories from people like Barbara Hahn. In an earlier hearing on the subject, Mrs. Hahn testified about the effects of infectious diseases on millions of American families. I'd like to just read a short excerpt from her testimony to make the point.

She said,

I would like to tell you about my mother and all mothers like her, who suffered through the loss of a child from an infectious disease. Raising a family in the hills of Kentucky, where most people were too poor to pay for the little, if any, medical help available, my mother struggled to keep her family healthy. When one of her babies became serious ill, my mother and her parents did everything they could to try to help her. Despite their efforts, my mother watched her child, Patsy Lynne, die from whooping cough. While making arrangements for Patsy's funeral, my mother learned that another one of her children was gravely ill. Both children were buried on the same day, in the same casket, in the same grave, next to my mother's church.

Mr. Chairman, childhood diseases like whooping cough and polio have been largely eradicated. As Mrs. Hahn's testimony shows, just a generation ago, the coming of summer brought fears of epidemics of polio. And now, iron lungs can be seen only in museums and dusty hospital storerooms. This has been accomplished through the development and use of safe and effective vaccines in national immunization programs around the world. Small pox was eradicated from the planet in 1977. Polio eradication was defined as a goal for the year 2000. And remarkably, Americans were declared to be free of wild polio myelitis on September 29, 1994.

As we prepare for the 21st century, the promise of vaccines has never been greater. But, a great challenge still remains. I understand representatives of PKIDS, the Parents of Kids with Infectious Diseases, will testify about their children's continuing battle with vaccine preventable diseases. And while vaccines have virtually eradicated the childhood diseases of the last generation, other diseases, such as hepatitis B, baracella, tetanus, and meningitis, are still common and have caused serious illness or the deaths of thousands of children. It's astounding that approximately 1 million preschool American children are not adequately protected against potentially fatal diseases that can be prevented with a vaccine. Therefore, Mr. Chairman, we have to continue to work to increase the awareness of the benefits of disease prevention through vaccination.

Furthermore, if the promise of vaccines is to be fully

realized, vaccines must not only be effective in the prevention of disease, they have to be safe. Unfortunately, recent reviews by the Institute for Medicine have identified many gaps and limitations in current knowledge of vaccine safety. Given new technologies for the development, production, manufacture, regulation, and administration of vaccines, the vaccine safety network for the United States must be enhanced to provide appropriate evaluation of new candidates. To ensure continued public acceptance of vaccines, close monitoring of potential adverse effects and adverse reactions, adequate scientific evaluation of associates, and appropriate responses to newly identified risks of vaccines, including research in targeted development of new technologies and vaccines, are critical. So, I guess I'm saying we need to look at a balance, Mr. Chairman.

I certainly look forward to hearing the testimony from today's witnesses. I welcome them all, beginning with the distinguished Surgeon General, Dr. Satcher. Thank you, Mr. Chairman, for indulging me.

Mr. Burton. Thank you, Mrs. Morella. Are there further opening comments? If not, Dr. Satcher, Mr. Surgeon General, would you and the people who will be testifying with you from your office, stand, so you can be sworn. Oh, you've brought a lot of people with you.

[Witnesses sworn.]

Mr. Burton. Let the record reflect the witnesses responded in the affirmative. Dr. Satcher, we recognize you for 10 minutes for your opening statement, sir.

## STATEMENT OF DAVID SATCHER, M.D., SURGEON GENERAL OF THE UNITED STATES

Dr. Satcher. Thank you, Mr. Chairman. I am Dr. David Satcher, Assistant Secretary for Health in the Department of Health and Human Services, and Surgeon General of the United States. I thank you, Mr. Chairman and distinguished members of the committee for your invitation to testify at this important hearing on vaccines. With me today are technical experts from our department and the agencies especially involved in vaccines and immunizations activities. They are: Mr. David Benoir, Office of the General Counsel; Dr. Robert Breiman, who heads the National Vaccine Program Office; Dr. Walter Orenstein from the Centers for Disease Control, where he heads the National Immunization Program; Dr. Kathy Zoon and Dr. William Egan from the Food and Drug Administration; Mr. Thomas Balbier from the Health Resources and Services Administration; and Dr. Regina Rabenovitch from the National Institutes of Health.

As Assistant Secretary for Health and the Surgeon General, I'm called upon to use the best available science to protect and advance the Nation's health. For over 200 years now, the Public Health Service has operated with the understanding that in so much as we care for the needs of the most vulnerable among us, especially our children, we do most to protect the health of the Nation. Throughout our history, the most vulnerable have often been those attacked by various forms of diseases. Thanks to advances in medicine and public health, vaccines have served as a way to offer protection to

individuals and communities.

Vaccines represent a remarkable public health success story. They are perhaps the 20th century's most important medical interventions, having prevented millions of diseases, disabilities, pain, suffering, and death. And from a risk benefit perspective, they are considered by many to perhaps be the safest and most efficacious medical interventions of our time.

During my tenure as Director of the Centers for Disease Control and Prevention, from 1993 to 1998, we made a commitment and were successful at increasing the Nation's immunizations by the age of 2, from 55 percent to 78 percent in 1996. Determined not to allow the barriers of access, cost, lack of insurance, and others to impede us from boosting immunization rates, we went into the community, partnered with organizations, such as the National Council of LaRaza, the Congress of National Black Churches, and others, to help us overcome the barriers to immunization. Today, immunization rates are approaching 90 percent and we're working still to increase that level. But despite our success, disparities in immunization rates still exist for some racial and ethnic groups in this country. Minority children still lag behind their white counterparts, when overall vaccination rates are compared.

However, we in medicine and public health continue to be concerned that some recipients of vaccines suffer injuries, as a result of the vaccine. We recognize how important it is to acknowledge the significance of the problem of vaccine injury.

This administration has made immunizations a priority. Today, immunization coverage among children in the United States is higher than ever before for most vaccines. These high immunization coverage levels translate into record--or near record low levels of vaccine preventable diseases. So, this afternoon, I will briefly discuss issues related to the benefits of vaccines, our concerns for injuries because of vaccines, our progress through the years, what we're doing to ensure that vaccines are as safe as possible, and what we must do to continue to enhance vaccine safety.

Vaccines offer many benefits to individuals and their communities. When we vaccinate a child, for example, that child becomes protected against a series of illnesses and diseases. But not only does the vaccinated child receive protection from developing a potentially serious disease, the community also benefits when comprehensive vaccination programs are in place. Those programs provide what we call community or herd immunity, which helps to indirectly protect those individuals who cannot be vaccinated, such as those who may be too young for certain vaccinations or who have other health problems that prevent them from being immunized; yet, they're still susceptible to the disease.

For example, babies that are under 1 year of age are too young to receive the measles vaccine, but receive some protection from the vaccination of other individuals. Also protected are children and adults, who cannot be vaccinated with some vaccines for medical reasons, such as children with leukemia. So, the entire community benefits from the reduction of the spread of infectious agents, and healthier communities

mean a healthier Nation.

Vaccines not only save lives and eliminate disability, pain, and suffering, they are also cost effective. Immunizations are one of the most cost effective medical and public health interventions we know.

Let me give you an overview of our experience with immunizations and treatment of vaccine preventable diseases. Today, there are far fewer visible reminders of the suffering, injuries, and premature deaths caused by diseases that can now be prevented with vaccines. By now, many Americans have heard my story. When I was 2 years old in Anniston, AL, I came down with a severe case of whooping cough, which led to pneumonia, and a family physician, who came out to the farm to visit me, predicted that I would not live out the week. I was fortunate. I survived. That year, 1943, in the United States over 190,000 children suffered from whooping cough and 3,500 died; 1995, in this country, there were 5,000 cases of whooping cough and 5 deaths. And that's not our best story. In fact, that's one of our worst stories, in terms of where we are today.

A physician entering practice today may never see a case of meningitis, due to haemophilus influenza type B. Before the introduction of effective vaccines in 1988, approximately 1 in 200 children under the age of 5 developed invasive haemophilus influenza B disease. It was the leading cause of bacterial meningitis in children under 5, accounting for about 60 percent of all such cases. Today, most residents in pediatrics will not see a child with haemophilus influenza meningitis. In fact, whereas in 1988, there were 20,000 cases, today, there are only about 100; and whereas there were almost 500 deaths a year, today, there are very few, if any. By 1998, vaccination of preschool children reduced the number of cases by more than 99 percent.

Finally, in the 1960's, many people witnessed firsthand the terrible effects of rubella, commonly known as German measles. During an epidemic between 1964 and 1965, about 20,000 infants were born with deafness, blindness, heart disease, mental retardation, and other birth defects, because rubella virus infected their pregnant mothers. Today, thanks to nearly universal use of effective vaccines, the rubella virus poses virtually no threat to the children of expecting mothers. So, we can see from our track record that vaccines offer a great many reasons for placing our trust and hope in them, in protecting the health of individuals, communities, and the Nation.

But, we are concerned about vaccine safety. As gratifying and as efficacious as the benefits of immunizations are, we still have serious concerns. Vaccines are not 100 percent safe. They have risk. A small percentage of children still suffer adverse consequences, as a result of vaccines. And as long as there is a risk of injury or illness in even one child, we should not, we will not be satisfied. Our concern for children injured because of vaccines is not without tangible expression. We've developed a compensation system to provide families with financial restitution for vaccine related injuries.

So, how are we dealing with the problem of vaccine injuries today? We're committed to vaccine safety through enhanced

surveillance systems, vaccine safety research, adopting safe vaccine administration policies, and educating and providing information to parents, the health care providers, and to the general public. We have a draft proposal for a comprehensive vaccine safety program built upon the cornerstones of surveillance, research, communication, and education. This updated proposal has been reviewed and approved by the National Vaccine Advisory Committee and is now undergoing review within the Department. We're working diligently to ensure that vaccines licensed in the United States are safe and effective as they can be, and we have one of the toughest vaccine approval systems in the world.

However, even after the extensive studies required for licensure, post marketing research and surveillance are necessary to identify safety issues, which may only be detected following vaccination of a much larger population. This is because very rare events may not even be detected and if noted, not shown to be due to a vaccine. The National Childhood Vaccine Injury Act of 1986, which Congressman Waxman authored and mentioned earlier, led to the creation of a unified national system to collect, manage, and evaluate the reports of possible adverse events. This system, which was initiated in 1990 and jointly managed by CDC and FDA, is a vaccine adverse event reporting system. And recently, the CDC has added to that the Vaccine Safety Datalink to really pursue these cases, to understand the relationship between them and vaccines.

In 1997, we had to make the very tough decision, when I was director of CDC, to switch our polio immunization strategy from primary reliance on oral polio vaccine [OPV], to an inactivated polio vaccine [IPV]. We made the switch to IPV, which never causes polio, even though OPV only very rarely caused it, 1 in 2.4 million doses. So, we estimate that we spend $3 million per injury or a case of polio from oral polio vaccine; i.e., we spend $3 million to prevent one case. And, yet, we think that's well spent. If we can save a single child, we feel that it is worth it.

A good example of how the vaccine safety monitoring system works is in alerting us to and helping address the recent concern about rotavirus vaccines and a type of obstruction, which we call intersusception. Between September 1998 and June 1999, 15 cases of intersusception following rotavirus vaccine were reported to our reporting system. The cases tended to be younger than most cases of intersusception normally occurring in the absence of vaccination. This signal led to special studies, to evaluate whether there is truly causal roles of rotavirus vaccines in intersusception. On July 16th, CDC recommended that vaccination of children scheduled to receive the rotavirus vaccine before November 1999 be postponed, until the studies are completed and findings are available.

I've adopted, as one of my priorities as Surgeon General, to move this Nation toward a more balanced community health system, which balances health promotion, disease prevention, early detection, and universal access to health care. One of the goals of that health system is to ensure that every child has the opportunity for a healthy start in life. A very definite part of that healthy start is ensuring that children

are immunized against vaccine preventable diseases. And we're making great progress.

So, Mr. Chairman, in conclusion, vaccines have given us much for which we can be grateful. They've eradicated small pox. They've eliminated polio myelitis in the Americas and controlled measles, rubella, tetanus, diphtheria, haemophilus influenza type B, and other infectious diseases. And they have saved millions of lives and avoided disease, disability, pain, and suffering, in many people.

The public has a right to and should expect safe vaccines. Although no system is perfect and no medicine or vaccine can ever be guaranteed to be 100 percent free of possible side effects or adverse events, particularly when administered to millions of people, we are still committed to improving the safety of vaccines. The Department and its constituent agencies, who are represented here today, and the scientific community and industry strive to continuous improvement in vaccine safety. As we enter the 21st century, promoting optimum health of people through the development and administration of safe and effective vaccines will continue to be a priority for our department.

Mr. Chairman and committee members, I assure you, in the interest of protecting and promoting public health, we will continue to make policy decisions and recommendations based on the best available science. Vaccines are very safe and effective. They are not perfect and will require continuing vigilance and research. Thank you for this opportunity to testify.

[The prepared statement of Dr. Satcher follows:]

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[GRAPHIC] [TIFF OMITTED] T2560.097

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[GRAPHIC] [TIFF OMITTED] T2560.107

[GRAPHIC] [TIFF OMITTED] T2560.108

[GRAPHIC] [TIFF OMITTED] T2560.109

[GRAPHIC] [TIFF OMITTED] T2560.110

[GRAPHIC] [TIFF OMITTED] T2560.111

Mr. Burton. Thank you, Dr. Satcher. We have to go and vote. It will take about 10 minutes.

[Recess.]

Mr. Burton. Would everyone please take their seats. We have other Members who will be drifting back in. We had two votes on the floor of the House. I apologize for the delay, but this is a very hectic week. In order to make sure that we keep the hearing moving, I will go ahead and start the first round of questioning. I'm sure Mr. Waxman will be back here shortly.

Dr. Satcher, first of all, I would like to preface my questions by saying we think the Department of Health and the National Institutes of Health, the National Cancer Institute, and the Food and Drug Administration do a great deal of very, very good work. I don't think anybody on this committee or probably in the entire country believes that vaccinations should be done away with. We all believe that vaccinations have provided a quality of life and health in this country that is unparalleled in the annals of world history.

However, there have been some disturbing things that we have been told over the past couple of years. I, myself, have experienced some things that have been of concern to me. My granddaughter, whom I told you about before the hearing, when she was very, very young--she's 5 years old now and doing very well, I might add--she got a hepatitis B shot and within 12 hours, she was in the hospital and not breathing. It was a direct result of a reaction to the hepatitis B shot. She came out of it and the doctors did a good job, but that was of great concern to us.

My grandson--I only have two grandchildren--my grandson got a DPT shot, and he's now been adjudged to be somewhat autistic. We've talked to other people who have had similar problems.

So, what we want to find out, if we can, if not today, at some point in the future, whether or not these are problems that emanate from these shots, because there are a number of cases like that across the country. We're going to hear from some witnesses today who will talk about that.

So, let me start off with hepatitis B cases. Can you tell us what percentage of hepatitis cases are not from sexual transmission or from blood or needle exchange properties? What percentage is caused by either needle exchanges or blood transmissions or from sexual transmission?

Dr. Satcher. You want to know what percentage are not from one of those causes?

Mr. Burton. Yes.

Dr. Satcher. OK. Well, let me ask Dr. Orenstein to respond.

Dr. Orenstein. Thank you, very much. About 25 to 30 percent of cases have no identified risk factors that are reported.

Mr. Burton. About 25 to 30 percent have no identified risk factors, that's correct?

Dr. Orenstein. Yes.

Mr. Burton. When I talk to some other physicians, who are in the Congress, and they thought the percentage was much lower than that. But, is that a scientific fact?

Dr. Orenstein. Those are data collected from both Sentinel Surveillance System, is the main area that information comes from. These are people, who are interviewed and do not admit to any risk factors. And you will hear about cases--or have seen cases in prior hearings that have had no identified risk factors.

Mr. Burton. How many children under the age of 5 have been infected with hepatitis B from things other than needle exchanges, blood products, or from sexual transmission?

Dr. Orenstein. I don't have the data broken down by under 5. But under 9, the CDC estimates that about 19,000 infections with hepatitis B virus occur----

Mr. Burton. What percentage would that be, Doctor?

Dr. Orenstein. Overall, it would be, in the absence of vaccination, about 350,000 infections. So, I'd have to do the math, but it's about----

Mr. Burton. So, 350,000 infections about. And how many did you say from under the age of 9?

Dr. Orenstein. Under the age of 9, with no known risk factors, there are about 19,000.

Mr. Burton. So, 20,000 out of--so, it's about one-twentieth?

Dr. Satcher. For that age group, it would be much higher than that.

Dr. Orenstein. For that age group, it would be----

Mr. Burton. No, but I mean overall cases.

Dr. Orenstein [continuing]. Higher. But for all cases, it would be, I guess, 6 percent, isn't it--about 6 percent.

Mr. Burton. OK. But under the age of 5, it would be much, much less than that?

Dr. Orenstein. According to some of our data on serology, the incidence occurs between--often between age 2 and age 5. And so, it's not clear that there is like a continuous level increase up through age 9.

Mr. Burton. If you keep statistical data, for the record, I'd like to have you submit, the number of cases and the percentage of hepatitis B cases under the age of 5. When do we require children to get the hepatitis B shot, at what age?

Dr. Orenstein. It depends on the State, because it----

Mr. Burton. Well, most States.

Dr. Orenstein. Most States would be school entry, age 5 to 6.

Mr. Burton. I think it's very significant, because like I said, my granddaughter had to get it at a very, very young age and there were very severe side effects. I'm sure other parents have that same problem.

Dr. Satcher. Well, I think the question here is when is it recommended----

Mr. Burton. Right.

Dr. Satcher [continuing]. As opposed to when is it required.

Mr. Burton. It's recommended at what age?

Dr. Satcher. Well, now--at birth for most children. As you

know now, we've at least relaxed that for children of mothers, who have not shown any evidence of exposure. But the requirement relates to day care or school entry.

Mr. Burton. That's usually 5 to 6 years old?

Dr. Satcher. Right.

Mr. Burton. We talked a while ago about the filing deadline of August 6th for hepatitis claims to the National Vaccine Injury Compensation Program. As I understand it, that is statutorily set for August 6th, which is about 3 days from now; is that correct?

Dr. Satcher. Well, I will ask the person who heads that program, to respond.

Mr. Balbier. Mr. Chairman, you are correct. August 6th is the deadline for filing claims that are----

Mr. Burton. Well, there are a number of people, I'm sure, across the country that were unaware of that. I was wondering, would you work with us to try to get that extended for, say, 3 or 4 months, so that people across the country, who may be paying attention to what we're talking about today, would have a chance to file a claim, if they need to?

Mr. Balbier. It would require legislation to extend the deadline. I would point out that that did happen once before in the history of the program for claims arising prior to 1988.

Mr. Burton. Well, what method has been employed to make the public aware of that?

Mr. Balbier. We have several ways of doing that. We have vaccine information statements that are provided routinely. Every time a child is immunized, it provides information on the Vaccine Injury Compensation Program, including our 800 number and our website, where they can get more information.

Mr. Burton. Well, unfortunately, we had a problem in our family and I didn't know about it and I'm chairman of this committee. So, I know that it must not have been as far reaching or as effective as it could have been. So, I wish we would work together to try to get an extension and try to inform the public, because I'm sure there are a lot of people who would like to at least make that kind of a claim.

Mrs. Mink. Would the chairman yield?

Mr. Burton. I'd be happy to yield to my colleague.

Mrs. Mink. I wanted to inquire why we have a statutory deadline? Why did Congress set a deadline?

Mr. Balbier. The deadline that we're going to reach at the end of this week is the deadline for filing claims that occurred for the 8 years prior to the coverage of the hepatitis B vaccination. Hepatitis B vaccination was covered under the National Vaccine Injury Compensation Program on August 6, 1997, when the excise tax went into effect to cover that vaccine. At that time, the vaccine was covered for any injury that was thought to be related to the vaccine, and people had 2 years to file a claim, for any vaccine administered during the 8 years prior to 1997, and they had 2 years to do so. So, we are now reaching the August 6, 1999 deadline for filing those 8 year retroactive claims. So, it's only for those claims that occurred prior to the coverage of hepatitis B vaccine under the compensation program.

Mrs. Mink. So, subsequent to 1988, there are no statutory

deadlines. Is that what I'm to understand?

Mr. Balbier. There are deadlines of 3 years for filing an injury claim from the onset of injury and 2 years from the date of death, if a death is thought to be related to the vaccine, or 4 years from the onset of the injury that led to the death from an injury thought to be----

Dr. Satcher. We wish to point out, Mr. Chairman, that the Secretary has submitted proposed legislation that would extend some of those times.

Mr. Burton. Well, I would like to work with you and the Secretary, then, to get that extension passed through the Congress, because, like I said, I'm not sure the American people have really been well informed about that.

Dr. Satcher. I believe it would extend it to 6 years, right?

Mr. Balbier. That's correct.

Mr. Burton. Oh, to 6 years?

Mr. Balbier. It would double the statute of limitations to 6 years for injury requirements.

Mr. Burton. That would be even better.

Mr. Balbier. We have already proposed legislation to do that, and we would like very much to see that happen.

Mr. Burton. We'll work on that. Would you make sure we do that?

The other things that I wanted to ask you about, do you keep records on people's concerns about the side effects of certain vaccines, like hepatitis B and the DTP shot?

Mr. Balbier. With the compensation program, itself?

Mr. Burton. Not necessarily the compensation, but where people are making claims that their child or have been making inquiries about their child being affected, they believe, by the shot.

Mr. Balbier. We have several ways of tracking that. We have what we call a passive surveillance system, called the Vaccine Adverse Event Reporting System, whereby any provider of the vaccine can report any injury thought to be related to vaccine.

Mr. Burton. Wait a minute, any provider of the vaccine? You're talking about the pharmaceutical company?

Mr. Balbier. No, the administrator of the vaccine. That's one way.

Mr. Burton. Which would be the doctor?

Dr. Satcher. But, it also could be--it's not limited to the doctor.

Mr. Balbier. Right. In fact, one of the advantages of the system that was developed, the Vaccine Adverse Event Reporting System, is that it allows anybody to report. The law also requires that physicians give out vaccine information statements to parents before their child is immunized. And on that statement, it gives the parent the number that they can report a case. And that was put in purposely, because some parents were concerned, in the 1980's, that their doctors weren't reporting cases. So, we offer the opportunity for parents to report, as well.

Mr. Burton. Could we get the statistical data on at least two of those: hepatitis B and the DTP shot?

Dr. Satcher. There's another point that I think we should

probably make and that is the reporting system is one thing. And as you know, there are about 12,000 incidents reported a year. Recently, CDC has initiated what is called the vaccine survey data link. So, we are actually aggressively studying the relationship between the vaccine and adverse events, in about 2 percent of the population?

Dr. Orenstein. It covers about 2 percent of the U.S. population of children. And it allows us to look at when a given illness occurs, how often it's occurring without vaccination, so that we can compare the two.

Mr. Burton. If you could provide that information, we would really appreciate it.

Now, regarding anthrax and the anthrax vaccine, we have been told by the General Accounting Office [GAO], in two separate hearings that my colleague, Mr. Shays, held as chairman of that subcommittee----

Mr. Shays. Four hearings.

Mr. Burton. Four hearings, that for 20 years, the person, who was producing this, really wasn't checked thoroughly, as far as the quality control at their facility, I believe it was in Michigan. And when they found out about it, they went up there and checked, and they found that it was way below par and that the serum that was being used, and is still being used, might be, in many cases, tainted. Now, we've had 300,000 people vaccinated in the military with this serum and I just don't understand how we could allow that to happen, if there's some question about the cleanliness of the product, whether or not it might cause side effects simply because it might be tainted and why that product was not inspected more thoroughly over that 20-year period and why the producer of that product is still producing it, to the best of my knowledge.

Dr. Satcher. I'm going to ask Dr. Kathy Zoon, who is head of the Center for Biologic Evaluation and Research at FDA, to respond. You know that the anthrax program is a DOD program, but your question is still relevant.

Mr. Burton. I understand. But, I understand that they're talking about expanding the anthrax vaccination program to children. And that troubles me a great deal, because we have had a number of service people, who are not only getting out of the service, but have had severe side effects.

Dr. Satcher. We have not made that recommendation and that kind of recommendation would come through the Advisory Committee on Immunization Practices.

Mr. Burton. Well, maybe it was just for military children; I don't know. But, that's what I've been told.

Dr. Zoon. Thank you, Mr. Chairman. I would like to, one, say that vaccine safety to the FDA is extremely important and with any vaccine, including anthrax, there are four levels, in which we oversee the safety. One is through the review of the data that comes in during the development of a vaccine and then data that comes into the agency, as part of the licensure procedure. That is the beginning of the vaccine and the surveillance that FDA does. Subsequently to that, we do inspections of facilities that produce vaccines. And we, also, are involved in release of lot material and review of protocols for lot release before any product can be distributed. And

finally, that we are involved with surveillance, which includes the VAER system and work with the CDC very closely on followup.

With respect to your question regarding the facility producing anthrax vaccine, there have been many inspections of that particular facility over the years. On each inspection, not every part of the facility may be inspected completely at each time. However, many of the records are inspected on each of the inspections. And, in fact, there have been multiple FDA inspectors in the course of the past 10 years in the facility at which you're speaking. So, there has been followup. In addition, FDA reviews all the lot release protocols for this. And right now, the company is not manufacturing and distributing vaccines.

Mr. Burton. Thank you. I'll followup on that later. Mr. Waxman.

Mr. Waxman. Dr. Satcher, you're the head of the Public Health Service, and that Public Health Service in the United States, as I recall, was set up in the last part of the 18th century, 1798. I also recall the reason that we have the Public Health Service in the United States was because of the yellow fever epidemic, which was transmitted by merchant sailors who had wiped out 10 percent of the population of Philadelphia. As a result, we set up the Public Health Service. Isn't that right?

Dr. Satcher. Yes, an act of Congress, because at that time, as you know, Congress was located in Philadelphia. President John Adams signed the act of Congress in 1798, giving rise to what we then called the Marine Hospital Service to take care of merchant seamen. But, you're absolutely right, it was in 1793 that this yellow fever outbreak hit Philadelphia and it was felt to have been related to merchant seamen, who were going in and out of the country. It was a devastating experience. As you said, it wiped out over 10 percent of the population; 50 percent of the population of Philadelphia fled because of that epidemic.

We were back there last year, in fact, to begin the 200th anniversary celebration of the Public Health Service, because, later, the Marine Hospital Service became the Public Health Service. So, we went back there in July to begin our celebration. And we retraced the trail of the yellow fever epidemic and it was really quite an experience. But, it was this outbreak that gave rise to the Marine Hospital Service, which would later on become the Public Health Service.

Mr. Waxman. I think we shouldn't forget history.

Dr. Satcher. I agree.

Mr. Waxman. And I worry sometimes that the successes that the immunization program has brought to this country and to the world might be a victim of the--the program might be a victim of its own success, when people forget about these dreaded diseases----

Dr. Satcher. Right.

Mr. Waxman [continuing]. That still occur. Right now, as a matter of fact, in certain parts of the world, mainly Russia, according to press accounts, there are over 2,000 reported cases of diphtheria since January 1 of this year. Can you explain how existence of a disease in a foreign country, such

as diphtheria in Russia, can threaten unvaccinated children in the United States?

Dr. Satcher. Let me give another example, measles. Virtually all of the cases of measles that we have seen in recent years have been imported. They've come in from other countries and they've led to, in some cases, outbreaks in this country, when they got into a population that was not vaccinated. The risk to the population of people, who take exemptions for vaccinations, the risk of measles is 35 times what it is in the rest of the population and you know less than 1 percent of the population takes advantage of religious or philosophical exemptions. We're talking 0.64 percent. But even with that small number, there's a 35 time full risk of measles. And most of the measles comes from other countries.

Mr. Waxman. So, in the United States, some people don't get vaccinated?

Dr. Satcher. They take exemption because of religious reasons there are 48 States that allow for religious exemptions, every State except Mississippi and West Virginia.

Mr. Waxman. Now, as I understand the chairman's statement, I don't want to attach any policy to it because he has to speak for himself, but it sounds like he and others are saying maybe we ought to leave a choice to everybody, whether they want their kids to be immunized or not. I don't know if that--let me not attribute it to him. Would that make sense as a policy for public health, if we just let people make that choice for themselves?

Dr. Satcher. I think by definition in public health, we're concerned about the health of the individual; but, we're also concerned about the health of the community, the population. And we make rules to protect the community. In fact, you can't even protect the health of the individual, unless there is a community approach to things like immunization. So, it is true that when we make decisions and recommendations about immunization, we're concerned about the population. That's very basic to public health.

Mr. Waxman. What if I say it's my child and I'm willing to take the chance because I heard that there are some adverse reactions. I heard about a congressional hearing that seemed to put a spotlight on those adverse reactions and I don't want to take a chance for my child. My child might be at risk, but am I putting other children at risk?

Dr. Satcher. Well, no question about it. I mean, when a child is not immunized--and many States, as I said, allow exceptions--exemptions for religious, and then 15 States, I believe, allow philosophical exemptions. But, we know from much of our experience, and certainly Dr. Orenstein can give more details about outbreaks that have occurred in population for religious reason and others that took exception--I respect people's religion if they decide to take an exemption. But, clearly, if States did not have any rules about what it takes to get into school, many more children would be affected by infectious disease outbreaks.

Mr. Waxman. Now that means we've got to be sure that these vaccines are as safe as possible. What mechanisms are in place to assure the vaccines are safe?

Dr. Satcher. Well, there are quite a few of them, and I'll just give an overview. We have a very tight surveillance system. And I believe the most important thing, of course, is what Dr. Zoon said. We take new vaccines through at least four phases. I mean after the animal studies, there's the phase one study, looking at safety in a small number of individuals. Then there's the phase two studies, which look at dose ranges for vaccines. Phase three studies, like the one that they're beginning now in Thailand for HIV vaccine, really implements the vaccines in a larger population of people, who are at great risk for an infectious disease like HIV. And it evaluates what happens, in terms of safety and efficacy. And only after you've been through that does FDA then approve implementation of that program. And even after that, there's a so-called post marketing phase, in which you really look at what happens when you make this vaccine available to a broader population.

Mr. Waxman. That's the Vaccine Adverse Event Reporting System?

Dr. Satcher. That's right.

Mr. Waxman. That's the post-marketing surveillance?

Dr. Satcher. Post-marketing surveillance is the Vaccine Adverse Event Reporting System, and, in some cases, even some more detail followup. As I mentioned, the Vaccine Safety Datalink, which is primarily with managed care programs, but involves more than 2 percent of the population, looks at these events and sees to what extent they relate to the vaccine.

Mr. Waxman. Mr. Chairman, I appreciate getting a little extra time because I want to ask some questions about the Vaccine Compensation Program, which I am proud to have authored, and I also have a conflict because I'm supposed to be at a conference on another piece of legislation. It has nothing to do with anything we're discussing today.

The Vaccine Compensation System was set up to try to make sure that people didn't have to go to court and go through all the expense of litigation in order to be compensated when they had an adverse reaction from vaccines. And I think it's well worthwhile, Mr. Chairman, for us to use our oversight authority to be sure that program is working.

Now, the administration is proposing that there be a lifting of the time limits for people to come in with their claims. Could you tell us about that?

Dr. Satcher. We have--and I'm going to ask--where is----

Mr. Balbier. I'm right here.

Dr. Satcher [continuing]. In terms of how the litigation process has worked and how well it's worked. But, I think what we're concerned about is making it as easy as possible for people to file claims and to report adverse events. So, the Secretary made some proposals--legislative proposals that would make that process much easier than it is now. And I, also, want to say that when in doubt, we try to give the benefit of the doubt to the petitioner.

Mr. Waxman. I sure hope so.

Dr. Satcher. We do. Without question, we do it in this program.

Mr. Waxman. Well, we're going to hear testimony contrary to that and I'm concerned about it, because I think we ought to

give the benefit of the doubt.

Dr. Satcher. I think we can demonstrate that. I can give some specific examples, where the Advisory Committee on Childhood Vaccines, made up, in addition to experts, parents of children, who have suffered events, are members of that committee. And there have been times when that committee has used its authority to override other committees, to make sure that we give the benefit of the doubt to the petitioner.

Mr. Waxman. I want to get more detail on that and I want to get more for the record. The administration is going to propose some legislation. And if Congress is going to deal with legislation, I think we can recognize the fact that there is a lot of money in that vaccine fund at the present time. Mr. Chairman, maybe one area where we can work together is to make sure that if there are excess funds, we devote those excess moneys for more vaccine safety research and surveillance.

I don't know if you're in a position to comment on that, because the administration would have to take its position. But do you think that might make some sense?

Dr. Satcher. Well, obviously, Congress is going to have to make that decision. I believe there is about $1.4 billion in that trust fund now and there have been various proposals suggested. One proposal would reduce the excise tax from 75 cents to 25 cents. Another proposal would be to use money from that fund to fund safety research. And, you know, obviously, I would--I favor vaccine safety research, because I think, as I said in my testimony, we should do everything we can to make vaccines as safe as possible. But, using the trust fund for that purpose is something the Congress must decide.

Mr. Waxman. Yes. Now, you get these reports about adverse reactions. What do you do with them? Do you have any examples of where you've gotten the information and have been able to do something to make vaccines safer?

Dr. Satcher. Tom, I believe that you----

Mr. Waxman. Rotavirus is one issue that I've heard about. Can you tell us----

Dr. Satcher. Oh, yes, no, that's the one, OK.

Dr. Orenstein. I think there are a number of things to evaluate the reports and to take action when action is indicated and to do further research when signals are generated that there may be a problem with vaccine safety. Vaccine safety is absolutely critical to the immunization program.

Rotavirus is probably a very good example, because it's a recent example, in which a signal was generated about potential intestinal blockage in children younger than the usual age at which the blockage would have occurred in the absence of vaccine. Because of that, we did two things. It was such a strong signal, and combined with other data we had, that we recommended a postponement to vaccination, at least until November, so we could clarify whether, indeed, rotavirus is causing intestinal obstruction or not. And we are in the process of undertaking a major national study to evaluate that.

There are other signals that have been suggested in the Vaccine Adverse Event Reporting System, such as the relationship of Guillian-Barre Syndrome, a paralytic illness with influenza vaccine. We undertook research to look at that,

which suggested that about once in a million doses of influenza vaccine, there could be a problem. There is continuous monitoring. The FDA looks at death reports. It looks at clinical reports. There are meetings regularly with FDA and CDC in order to try to take a comprehensive look at vaccine safety.

Mr. Waxman. Let me say if in rare cases there is an adverse reaction, we ought to compensate the victim as best we can for that adverse reaction. But I don't want this country to become lax in the area of vaccinating our kids, because I don't want these diseases to come back and I don't want people looking at a hearing like this and thinking, oh my gosh, more people are hurt than helped when the child's immunized.

Because that isn't any cost benefit evaluation--we always hear we ought to have cost benefit evaluation--but the benefits outweigh the costs enormously to have our children immunized. Do you agree with that?

Dr. Satcher. Well, a good example is just the followup on what Dr. Orenstein just said about the one in a million risk of Guillian-Barre Syndrome for influenza. The risk of hospitalization from getting the disease influenza ranges from 200 to 1,000 times that. That's the risk of not just having influenza but having to be hospitalized with influenza. It's 1,000 times greater than the risk of getting Guillian-Barre Syndrome.

Mr. Burton. Thank you again, and let me just apologize to you for trying to impute some views. I don't know what your views are on the subject so I should not have asked the question in that way.

Mr. Shays. Thank you.

Mr. Burton. But I appreciated the witnesses answering the question.

Mr. Shays. Thank you, Dr. Satcher, and your staff for being here. We are not looking at the issue of vaccines for children right now, but my subcommittee is looking at the issue of whether we should have a mandatory program for our military personnel to protect against various biological agents; one is anthrax. But there are many others, and there are questions of different types of anthrax and which you should be protected from. I'm going to focus more on that, and I'm just going to accept as a fact that besides just teaching general cleanliness, which has probably done a world of difference to society, vaccines have been second only to that in terms of their benefit to society.

And so I don't know if this would be Dr. Zoon or anyone else, but I will ask you and you can defer. How long might it take to review and approve a new recombinant vaccine against anthrax? How long would it take, or should it take?

Dr. Zoon. If a biologic license application came in and it was evaluated that a new recombinant anthrax vaccine would presumably be a priority for the FDA, which would probably mean we would review the application within 6 months.

Mr. Shays. But overall, from start to the end, review an application, so much more, would have to go in before they could make that application.

Dr. Zoon. Yes.

Mr. Shays. What's the sense of the total--it would just

take you 6 months, or it would take the Government 6 months, but in addition----

Dr. Zoon. I think you're asking about the development time?

Mr. Shays. Right.

Dr. Zoon. Is that correct?

Mr. Shays. Yes, ma'am.

Dr. Zoon. Yes. It varies for a product how long it can take under development. And presumably, once you've discovered it through the time it has all the pre-clinical information, manufacturing information, and clinical information can vary in the timeframe. Generally, the shortest timeframe to collect all that information is 2 years, and sometimes it can take much longer.

Mr. Shays. What kind of data would FDA require to demonstrate efficacy of a new anthrax vaccine against aerosol challenges in humans?

Dr. Zoon. At this point in time, there are a number of different opportunities and models that we would look at for both pre-clinical data and data in humans. Because of the seriousness and the ethics involved with doing a challenge study with anthrax, clearly that would not be possible. Also, the incidence of anthrax in the United States is very, very low and therefore a natural history could not be done. What could be, what we would have to look at would be several things, and this is not all-inclusive, but just to give you some sense is, we'd look at pre-clinical data, animal model data, looking at challenge data in good animal models. We'd also look at safety data in humans and we'd look at immunogenicity data in humans as a start.

Mr. Shays. Which leads to the question, what is the status of the FDA regulations on correlating the data on animal immune response to the likely response in humans?

Dr. Zoon. My understanding, there is a proposed regulation that has been drafted. I am not certain as to the status of it right now.

Mr. Shays. And finally, of the most widely discussed biological warfare agents, one is smallpox, another is anthrax, another is the plague. Now there's botulism, glanders and others. How many do we have vaccines against?

Dr. Zoon. Currently there is a licensed smallpox vaccine, of which there is limited quantity. There's one licensed anthrax vaccine.

I thought they--I'd have to get back to you on the rest, sir, because I'm not 100 percent sure.

Mr. Shays. But clearly one of the challenges we have is developing vaccines. The military is talking about ultimately vaccinating for a good number of perceived potential attacks against our military. The challenge that we are going to have, it seems to me, is developing a vaccine that we think will do the job given the challenge of how you test it. And it will be interesting to see how you all weigh in on this, because that's the direction our military's going in and it raises gigantic questions. Thank you.

Mr. Burton. If the gentleman would yield. I think a lot of people who are paying attention to this discussion right now might not understand what kind of questions you're asking, in

layman's terms. So I'd just like to clarify a couple of things. As I understand it right now, the anthrax vaccine has been proven effective to a degree against the kind of anthrax that is communicated through the skin and through touching. As far as anthrax being communicated through an aerosol or through a missile that would explode and spray anthrax into the atmosphere where people would breathe it, it has not been proven effective in that. As a matter of fact there was one test, as I understand it, or one case where they had given people the anthrax vaccine in a farm environment, where five people died who inhaled the anthrax bacteria. The thing that a lot of people in the military would like to know is, does the anthrax vaccine work against an aerosol or an aerosol-type dispensing of this, this dread disease? And along with that, if it doesn't--because the most likely way that an enemy would try to attack the U.S. military operation would be through an aerosol-spread bacteria--why are we using this vaccine? If it's not effective against that, and that's the most likely way that an enemy would attack us with it, why are we using that vaccine and mandating it right now?

Dr. Satcher. I don't think we're going to try to answer that because--I think it's a very good question, but I think--
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Mr. Burton. It needs to be answered because 300,000 of our troops have been vaccinated, and right now, according to what I've been able to understand, it isn't going to protect them if an aerosol attack with anthrax ensues.

Dr. Satcher. I just mentioned the question of why because the Department of Defense obviously has risk information that we don't have in terms of terrorism. We can answer the other question you raised. But if you say, why, the Department of Defense made the decision; they certainly have security information that we don't have about the risk that we're facing. And they make decisions based on that. We can answer the question about the relative risk.

Dr. Zoon. Yes, Mr. Chairman----

Mr. Burton. Would the gentleman yield? Just to clarify the information being provided. If you could, and National Security, Veteran's Affairs, and International Relations Subcommittee would love the answer to the question that you said you would get back to us on. I'm going to have my staff followup on that, so it would be helpful. You may answer, then I'll yield to Mr. Davis. Thank you, Mr. Davis.

Dr. Zoon. Thank you, Mr. Chairman. There is, while be it limited data looking at the ability of the current anthrax, licensed anthrax vaccine to be protective of inhalation anthrax, you are very right, sir, that the primary incidence of the disease in the mills where the study was done on the original anthrax was cutaneous, or skin. However, there were five cases of inhalation anthrax. And when the data was looked at, four of these five cases were fatal cases. When the data was looked at this single-blinded control study, it was discovered that of those deaths from inhalation anthrax, two were in the placebo group and three were in the unvaccinated group, and zero were in the vaccinated group.

Mr. Burton. So you have none that were vaccinated, that you

can tell one way or the other about the aerosol.

Dr. Zoon. Well, in fact, those people that were vaccinated did not have any cases of inhalation anthrax.

Mr. Burton. So using deductive reasoning, you say it was effective against that?

Dr. Zoon. Within that limited data base, for that study, we have that information, which would suggest some protection against inhalation anthrax. Subsequently, studies were done in a primate model looking at protection challenge studies that were done by Dr. Ivens. And this was a study where they used a spore challenge in rhesus monkeys. And it was shown to protect against the aerosol challenge.

Mr. Burton. Mr. Davis.

Mr. Davis. Thank you very much, Mr. Chairman. Dr. Satcher, let me thank you for your testimony, and also the advances that I think we're making in public health under your leadership and with the assistance of your team. I agree that the greatest weapon we have, the greatest defense that we have against childhood diseases are vaccinations. According to Evan, Rachel, Brian, David, Katie, Tim, Catherine and Natalie, these are all children who live in Illinois, whose vaccinations produced terribly devastating results for them. They are children who cannot walk, children who cannot play, and they're children whose parents believe that their conditions were caused by their vaccinations. In addition to that, there is a group in my community headed by a woman named Barbara Mallarky, who is the spokesperson for the Illinois Coalition for Vaccine Awareness and a health activist who lives in my community. I see her quite frequently. She believes that strong anecdotal evidence suggests that children are being adversely affected by vaccinations, especially hepatitis B. My question is, what can we tell the parents of these children, and what can I tell Ms. Mallarky and her group?

Dr. Satcher. Thank you, Congressman Davis. And I appreciate your background in public health, too, so I know I don't have to tell you how we go about making decisions and the struggles that we go through. There are a few issues involved here. And the first one, of course, is that there are adverse events that occur from vaccines. They are very rare. They don't compare with the benefits, but--they are very rare, but they are very significant for the people who are affected. That's the first thing, and we are determined to reduce adverse events to as near zero as possible. The other thing, of course, is that it is sometimes difficult for us to determine when an event occurs temporally related to vaccines, that the vaccine caused the event. And the only way we can determine that to the best of our ability is to investigate. That's why we have a system that allows those kinds of investigations to take place. People can petition, and in many cases it has been found--I believe there have been 1,400 families who have received a little over $1 billion from the system, because they filed complaints about injuries that occurred. I don't believe it is possible to compensate people adequately for the kind of thing that we're talking about. But there is a system set up to investigate and to determine the likelihood that an adverse event was due to the vaccine. And if it is determined that it was, we have a

system to attempt to provide some compensation. So the system, I think, is there. The most important system is the one in which we are working night and day to continue to improve safety.

Mr. Davis. So I can assure them that the Public Health Service is doing everything in its power to continue with the research, to investigate, to try and reduce as near to zero as we can, these situations that may occur.

The other question that, that I'd like to ask--we have the injury compensation program, which is publicly funded. Are there any liabilities for the manufacturers of the vaccinations that we use?

Mr. Balbier. If a petitioner under the program chooses to reject an award or is unsuccessful in obtaining an award, that individual may then sue the manufacturer. So the program is not an absolute protection of the manufacturers by any means.

Mr. Davis. So it is the first line of defense for the consumer. Then if people are not satisfied, they can go beyond that in terms of seeking redress.

Dr. Satcher. That is correct. But there is a very important point here, and I don't know if we've made it yet. Part of the value of this program--sort of a no-fault, where the Government takes responsibility--is that we have been concerned and are concerned that manufacturers are willing to continue to take the risk to develop vaccines. We have been successful in developing effective vaccines because there is a program like this available in which we share the risk of vaccines.

Mr. Benor. Absolutely.

Dr. Satcher. I think one of the major benefits of this program is that manufacturers are encouraged to continue to do research. And as Dr. Zoon described, it's an odious process of bringing a vaccine to market.

Mr. Davis. So you're really saying that we are co-partners in a way, in trying to make sure that we have available to us the, the medicines or the pharmaceuticals that are needed to address some of the problems. Well, I appreciate that. And let me, Mr. Chairman, thank you, and also just say that, I have studied the public health system for a long time and I can tell you it is so refreshing to see that we are moving toward a public health modality in terms of really trying to move beyond just the individual protections, to the point of protecting our communities, our cities, our States, and indeed our Nation. I thank you very much.

Mr. Burton. Before I yield to my colleague, let me just say that we should be concerned about the public health and public welfare. But our country was set up in such a way as to try to maximize the protection of the individual as well. And that's why, one of the reasons we're having this hearing today, because we want to make absolutely sure that people are getting as much information as possible about these vaccines and the possible side affects. Now I don't want to prolong this because I want to yield to my colleague. But my granddaughter had a hepatitis B shot, and within 12 hours, she was in intensive care; she couldn't breathe. One of my daughter's best friends is in the audience, and her child had a hepatitis B shot and died. Now that's 2 people that I know personally. Now this may

just be a coincidence, but if those kinds of side-effects occur, then we need to know why. We need to be able to inform people across this country of the risk. Maybe we're giving too many shots in too short a period of time. Maybe, unlike Japan, we're not checking the immune systems of children before we give the shots. Do we check the number of the antibodies? Do we check these really thoroughly before we give our children shots, or do we just indiscriminately give them shots? Twenty-one shots before they're 6 years old. Can their little immune systems stand that much onslaught? Those are the questions that need to be answered. But I know that in my family, I've got an autistic grandchild--out of two grandchildren, one's autistic, the other almost died from the hepatitis B shot, and one of her best friend's child did die from a hepatitis B shot. Now you can call that coincidence if you want to. I kind of think it's more than coincidence. That's why we're having this hearing--not that we don't want to vaccinate, but we need to have an informed population to make sure that parents, while conforming to the rules of society to make sure that the whole population is safe, protects their family and their children as well.

Dr. Satcher. Chairman Burton, let me just say I agree with you. I think this is a very important hearing. I can't think of any hearing that could be more important. So there's no question in my mind about the importance of this hearing and the importance of this issue.

Mr. Burton. I look forward to working with you, Doctor.

Dr. Satcher. We want safe vaccines.

Mr. Burton. I think you're a sincere fellow, and from what I can tell, you've done a good job. Of course, I'm a layman; I'm not a doctor. [Laughter.]

Mr. Mica. Thank you, Mr. Chairman, Dr. Satcher. I have a couple of questions. In January I took over a subcommittee that deals with the oversight of HHS and was immediately deluged by people contacting our subcommittee about the need for oversight of some of the vaccine programs, particularly hepatitis B. We did some studies and investigation, and we conducted a hearing on May 18. I'm pleased that you, and the administration, shortly thereafter have taken some actions. You told us today that you have several actions which you are recommending. One is lifting of the time limits; two, I heard about dollars for research--two items that were raised at our hearing. Could you tell me about the specifics of lifting the time limits, what this involves? And then, we now have $1.3 billion in the fund. Are we talking about taking money out of that for additional research purposes?

Dr. Satcher. To respond to your last question, we don't have the authority to do that. Any use of those funds other than----

Mr. Mica. Oh, I know. But you're recommending to Congress that we change the law to give you the authority, but to what degree?

Dr. Satcher. Well, I'm not sure we have made that specific legislative recommendation.

Mr. Mica. You don't have a specific legislative proposal.

Dr. Satcher. No, we don't.

Mr. Mica. When can we expect that?

Dr. Satcher. I hate to try to make predictions--because it's been discussed between the administration and Congress.

Mr. Mica. Can we get a recommendation from you, say by September since we're well into the 106th session? We're going to do a hearing on the compensation fund because it's been brought to light that there were problems, and this is the first time that I've heard of the administration's proposal in this regard. Maybe sometime in September, could we get that?

Dr. Satcher. Let me say there exists now a set of legislative recommendations from Secretary Shalala to Congress about how to improve this system to improve the benefits to people who are adversely affected by vaccines. Those are in place now. I don't want to say exactly when the administration will submit other proposals because I don't know.

Mr. Mica. Well, maybe we can work with you.

Dr. Satcher. Yes.

Mr. Mica. One of the things that also came out in the hearing is the frustration with the compensation and that the average length of time to go through the process is 2 years. That's average length, and many of these take more time. Do you know if you have any recommendation about how to deal with speeding up that process for compensation?

Dr. Satcher. I'm going to ask the attorney but--let me just say, there are times when we compare this system to the regular tort system. As you know, it's been much more efficient, but still we're not satisfied with it--but it's much more efficient than the----

Mr. Mica. Then that would be one area too we'd like to--if we don't have a recommendation. I have a press account that says, that relates to a surprise announcement. It says, a surprise announcement late yesterday. And this was a change in policy relating to mandatory vaccination of children with hepatitis B vaccine. It says, the surprise announcement came late yesterday afternoon, just 7 weeks after a May 18th hearing on the safety of hepatitis B vaccine. The vaccine policies in the U.S. House--our subcommittee conducted--brought out problems with that. And I guess the announcement related to eliminating mercury content in hepatitis B vaccine. It was a joint announcement by the Public Health Service, your folks, and the Academy of Pediatrics. OK. Our hearing was May 18th. When did you have the first information that there might have been a problem relating to the mercury content? Was that after our May 18th hearing and before your announcement, or before our hearing?

Dr. Satcher. I can speak to that from the Public Health Service. I was involved in that announcement with the American Academy of Pediatrics, and the announcement was to give pediatricians and parents more flexibility in terms of implementing the hepatitis B vaccine.

Mr. Mica. What I'm interested in, I want to know when you had the information. When did you know----

Dr. Satcher. I'm going to get to--Dr. Zoon----

Mr. Mica. And was that in your possession before the hearing that we held, or did they come to you after the hearing that we held?

Dr. Satcher. It was after the hearing that you held.

Mr. Mica. It was.

Dr. Satcher. In fact, it came to my attention, it came, I believe, less than a week before we made the decision. We--and this included the American Academy of Pediatrics. Now there have been some studies in other countries about thimerasol and its effect. But in terms of FDA looking and getting reports from manufacturers in this country, and the information coming to us, it was a few days or weeks before--Dr. Zoon, do you want to comment?

Mr. Mica. Would you supply the committee and the subcommittee with any communications you had, all communications you had, relating to this particular matter, say, in the last year? Would that be possible?

Dr. Zoon. Yes. Certainly we can provide you--would you like me to give you some background, sir, or would you just like it for the record?

Mr. Mica. I'd just, I'd like to have the information for the record.

Dr. Satcher. We can say more about that if you'd like.

Mr. Mica. The last thing--and my time is about up. You are the Surgeon General, the Chief Health Officer of the United States, and I noticed an article that was included here. I don't know if you gave it to us or if it was provided in our packet. But you talk quite a bit about some health issues, particularly smoking, excess, not eating enough vegetables, and not exercising. I chair the Criminal Justice, Drug Policy, and Human Resources Subcommittee, and our concern is, of 14,000 young people and others die every year in drug related deaths.

Dr. Satcher. Would you like for me to read the Surgeon General's prescription?

Mr. Mica. No. But I just----

Dr. Satcher. It, includes advice against the use of drugs.

Mr. Mica. Yes, but again, I noticed this. I think you threw away your pipe to set an example.

Dr. Satcher. That's a good article.

Mr. Mica. My concern is, having survived one of your predecessors, the infamous Jocelyn Elders, that she sent the wrong message out on drugs. And that, to me, is our biggest social and societal problem, with 2 million Americans behind bars, 70 percent of them because of drug-related offenses, and with skyrocketing teen addiction rates and usage rates. Since this administration has taken office--again, people have to look up to folks. And you, as the Chief Health Officer, I would hope, would give us every bit of support relating to hard narcotics--heroin, cocaine, and the methamphetamine addiction that we're facing. I count on you for that.

Dr. Satcher. Yes, you can. But I would also like to just say that I believe that the program that General McCaffrey is running, dealing with the use of illicit drugs, is the most aggressive in the history of this country, and we're seeing results.

Mr. Mica. That's only as a result of the predecessor to Mr. Shays' subcommittee, Mr. Hatcher, who came forward to lead the subcommittee and restore the funds and----

Dr. Satcher. I will be willing to give credit to as many people as possible.

Mr. Mica. Thank you.

Dr. Satcher. I'm just happy to see that the program is working.

Mr. Mica. But we need you; you're our chief health spokesperson.

Mr. Burton. The gentleman's time has expired. Ms. Schakowsky.

Ms. Schakowsky. Thank you, Mr. Chairman and Dr. Satcher. It's a pleasure to meet you. As a new Member of Congress, and someone who comes from a State legislature where we have had to make decisions about mandatory vaccination programs, I've been a supporter of those because I think, as we look around at the chief reasons that we've been able to extend life expectancy and improve the general health of our population, that one of the chief public health strategies has been these vaccination programs for polio and rubella and smallpox, et cetera. But I am concerned because under the strong leadership of my subcommittee chairman, Mr. Shays, I have been hearing a lot about the anthrax vaccine. And one of the things that came up is that there was very little research done on the different reactions that women may have to vaccines, that there's a different kind of immune system. And I'm wondering if there are gender-difference studies that are required, and if you're aware of this?

Dr. Satcher. Let's ask Dr. Zoon from FDA.

Dr. Zoon. The original anthrax vaccine, which is the licensed vaccine we have today, was licensed back in 1970. And at that time there were not guidance documents available in general on inclusion of different populations. Subsequent to that though, there are guidances now that the FDA issues in drug development on the inclusion of different populations, of which women are a significant population. So I think that I cannot give you the breakdown of male and female that were in the original trial, and in fact, we had tried to go back and find some of those data, and they're not as easy to find in terms of the way they were recorded, based on the participants in those studies. But I think I would like to assure that right now, the information we do gather on vaccines do include different populations.

Ms. Schakowsky. Well, let me ask you then about another population, which is hyper-reactors. That came up also in the anthrax discussions. And it may refer back to what the chairman was asking, that there are individuals whose bodies do produce adequate immune response with a lower dosage, for whom a higher dosage may pose a real problem. Is there any way to identify these individuals and provide alternative vaccination schedules or lower doses, et cetera, so that in the future we may be able to avoid some of these adverse reactions?

Dr. Zoon. In vaccine and other product development that is done today, there are--as Dr. Satcher alluded to in phase II studies of clinical development, these are generally dose ranging studies, where they look at the immune response, immunogenicity, as well as safety. I would have to go back to look at those original data, and I'm not sure that all that data would be available from the old studies, because those were done in the 1950's.

Ms. Schakowsky. Well, it seems to me that might be a direction that we need to go in.

Dr. Satcher. Let me just say that's a very important question, and it is a very important subject of research. We need to be able to better predict how individuals will react to a vaccine much better than we can now. Now in the other medications too, I think you're right--Chairman Burton's example sounded like an anaphylactic-type reaction. I wouldn't know, unless I had the records, but that's what it sounded like. A very dangerous reaction; they can occur with any medication. I've seen them occur with the dye used for renal tests, and people can go into anaphylactic reaction soon after being exposed. We need better ways to predict who will respond in different ways to vaccines and different medications than we have now. That research has to continue.

Ms. Schakowsky. One other line of questions--let me just ask them, and then you can respond. The VAERS system, which is really a rather passive system of reporting adverse reactions--there were a lot of reasons again, in hearing the anthrax debate and testimony, to doubt the system, not the least of which was, it seemed some people from the Department of Defense were discouraged, some of the people in the Armed Services were discouraged from making those reports. But in a broader sense, how satisfied do you feel that we're getting an adequate representation? Some have projected maybe we only hear about 1 in 10 adverse reactions. And I wonder if you have thought about ways that we can improve the VAERS system so it's more useful to us in making these important decisions.

Dr. Satcher. Dr. Orenstein of CDC is here.

Dr. Orenstein. Thank you very much. The VAERS system is really our warning system for problems. It generally can be very helpful, particularly at finding serious problems. The reporting efficiency of VAERS, which is what you're getting at, is how often are events reported. This varies with the severity of the reports. We find, for example, with regard to vaccine-associated polio that about 70 percent or so of the cases that are known get reported to VAERS. With regard to other serious events like seizures, we generally see about 25 to 40 percent of what we would expect to be reported. When we deal with more mild events, or events that require, let's say, a laboratory test to document an abnormality, the reporting efficiency goes down substantially. But it's very difficult with any passive system to get a feel for how much is out there and whether it's causing something, because many of the illnesses that occur after vaccination also occur in the absence of vaccination. For example, in 1990, there were over 5,000 deaths from Sudden Infant Death Syndrome--children who died from Sudden Infant Death Syndrome, children who were well, most of them, and then were found as crib deaths, or may have had some mild illness beforehand. We would expect when we vaccinate large numbers of children--and we're talking about a birth cohort of 4 million children--that you're going to get deaths after vaccination. The real issue is, is the clinical syndrome different, or is it occurring more frequently than expected? And that's when we use our Vaccine Safety Datalink. The Vaccine Safety Datalink is a project where we fund independent researchers in 4 large

managed-care organizations, in the Western United States, who have access to all of the medical records, so they can determine the expected incidence in the absence of vaccination to compare with the incidence in the presence of vaccination. We need to do more with VAERS. And I think that we are not satisfied with where VAERS is. Each year we send out a letter to 200,000 individuals to encourage reporting to VAERS. We've put in our standards for pediatric immunization practices that we want reported to VAERS, serious events even if you don't think that it's related to vaccination. We've done a lot; we need to do more. And I think that what you're pointing out is some of the weaknesses to VAERS.

Mr. Burton. The gentlelady's time's expired.

Mr. Weldon. Thank you, Mr. Chairman. I want to thank you for extending an invitation to me, and I want to thank the ranking member for withdrawing his objection.

[The prepared statement of Hon. Dave Weldon follows:]

[GRAPHIC] [TIFF OMITTED] T2560.112

Mr. Weldon. I certainly want to thank you, Mr. Surgeon General, for your testimony. I know some of the people who are joining you there have been in my office to talk about these issues. And I want the record to reflect that I am a strong supporter of vaccination; that I vaccinated my patients according to CDC recommendations when I was practicing. But I'd like the record also to reflect that there is an increasingly growing level of public concern about the safety of our vaccines, and therefore I think it's extremely important that this issue be aired before the Congress. And if the light of scrutiny makes a determination that the system is safe, then we have the ability to broadcast that information to the public. And as well, if there are areas that need to be investigated further, we have the ability to appropriate the funds necessary to make sure the appropriate studies are done. I'd just like to start off with a couple of questions I have about the hepatitis B vaccine, the decision to recommend that for all newborns. My understanding of the transmission of hepatitis B is obviously it can be done through blood-borne contamination, through transfusions or infected needles, but as well through the route of sexual transmission. And indeed it's the sexually transmitted route that's deemed to be the most rapidly increasing segment of that problem. Am I correct in my understanding of this disease?

Dr. Orenstein. The known modes of transmission are the ones that you have mentioned. Clearly, there has been much greater recognition of transmission among heterosexuals because, with regard to multiple sex partners. And that has accounted for a substantial proportion of hepatitis B cases. On the other hand, there are cases that we are not getting any, any history of any of these known risk factors for transmission. We presume in some way that they've been exposed, to either blood on abraded skin, a bite, or some other means. But there are these 25 to 30 percent of cases in which, at least, there is no admitted risk factor for transmission.

Mr. Weldon. How did hepatitis B compare to some of the other diseases where decisions were made to inoculate the whole

population in terms of its incidence, as compared to polio, pertussis--I realize hepatitis B is a very serious illness and it costs a tremendous amount of money. But did the cost benefit analysis of this disease include the consideration that it's obviously different? The point I really am curious about is, being that a major mode of transmission is sexual transmission, we have never proposed inoculating the whole population for a sexually transmitted disease, am I correct?

Dr. Orenstein. I'm not aware of anything where we've recommended the whole population be vaccinated for a sexually transmitted disease. But clearly this has more--sexual transmission is very important and I don't want to minimize that, but it's not the sole way of transmitting it.

Mr. Weldon. Do you know what percentage is through sexual transmission, or could you speculate?

Dr. Orenstein. I could get that data for you, for the record--a substantial proportion.

Dr. Satcher. Let me just say one other thing. The process by which we decide to initiate an immunization program for any given agent is a very interesting and open process, as you probably know. The Advisory Committee on Immunization Practices is widely publicized. It includes experts from clinical practice, research----

Mr. Weldon. I assume the American Academy of Pediatrics as well.

Dr. Satcher. Yes. Very important representation from AAP and the American Academy of Family Physicians. But it's a very good question. They debated extensively before recommending.

Mr. Weldon. I'm running out of time. The context of my concern is, it's three more shots, and one of the complaints is, it's getting to be a lot of shots. I think we have to address those issues.

Dr. Satcher. Right.

Mr. Weldon. I have a couple of other questions that maybe you can, you may just need to supply for the record. One is, if you can supply for the record the studies that are currently being done through CDC and NIH on vaccine-related side effects. I know there's--and as I said, some of you have come in the office and talked to me and there's a lot going on. But I think it would be important for us to have that for the record. And the other question I had was, is a legislative fix going to be needed if you're going to use the vaccination compensation fund to fund research studies? Because I know there's some discussion of that. And is that allowed under current law?

Dr. Satcher. My understanding is that it would require an act----

Mr. Weldon. An act of Congress.

Mr. Benor. Yes, I can confirm that.

Dr. Orenstein. Can I answer your other question that we never answered, and that is to put hepatitis B in perspective with some of the other vaccine-preventable diseases? We estimate that about 4,000 to 5,000 persons die each year from hepatitis B related liver cancer and hepatitis B related cirrhosis. If we compare that to measles in the pre-vaccine era, there were about 400 to 500 deaths from measles. If we compare it with haemophilus influenza type B, which is a severe

cause of meningitis, we estimated that it was about 400 to 500 deaths. So hepatitis B, when you look at the long-term consequences, was one of the most severe of the vaccine-preventable diseases.

Dr. Satcher. If you have time, Dr. Regina Rabinovich from NIH can respond to your other question about research.

Mr. Burton. We'll let her answer and then we'll go to Mr. Cummings.

Dr. Rabinovich. Your question, I believe, related to the research that's ongoing looking at vaccine-adverse events. And I think that I'd have to emphasize that looking at all aspects of vaccine safety begin with evaluation of pre-clinical data prior to going to, and deciding that there's enough safety data to go into your first phase I study in humans. The NIH conducts a broad program of clinical research in the number of different candidate vaccines, and for every study, safety is integral to that evaluation. And that is particularly true of the phase I studies, where it it's the first time that it goes into humans, as well as the phase III trials where you can really get more information in larger numbers of the target population.

Mr. Burton. Thank you. The gentleman's time has expired. Mr. Cummings.

Mr. Cummings. Thank you very much, Mr. Chairman. I want to thank all of you for being here. In Baltimore we have probably one of the most effective immunization programs in the country. It is patterned after, as I understand it, the method of getting people vaccinated in Third World countries. I don't know if any of you are familiar with it?

Dr. Satcher. Yes.

Mr. Cummings. You, Dr. Satcher?

Dr. Satcher. Yes.

Mr. Cummings. Is that done other places also?

Dr. Satcher. Well, let me just say in terms of Third World countries, we've made a lot of progress in recent years working with the World Health Organization. And among other things, coming up with schedules, but also implementing national immunization days. I was in India on December 7, 1996, when we immunized 120 million children in 1 day against polio. We've used strategies like that, which we don't have to use in this country because of ongoing programs. But in those countries because of where they were, we had to. And that's why we're very close to eradicating polio. I know CDC has funded Baltimore directly. It's one of those cities we funded directly, and not through the States, to develop exemplary immunization programs. And I agree, that program there has included a variety of strategies to get children immunized that have been very effective.

Mr. Cummings. It's my understanding the hepatitis B is a blood-borne disease. How do children transmit it? Young children?

Dr. Orenstein. You're absolutely correct. It is a blood-borne disease. It is in the blood; it can be in other body fluids. It's in a low amount in saliva. The presumption for childhood transmission is, one, there is transmission from mother to affected baby if the mother is a chronic carrier. Aside from that, we think it may be perhaps from sharing

washcloths with abraded skin; bites that might occur that would break the skin; children with rashes who might be exposed to someone bleeding. It's not really clear how it's happening; we just know it is happening in young children. And about 10 percent of the infections overall are occurring by 9 years of age, about 6 percent of those with no known risk factors.

Mr. Cummings. Say that last sentence again.

Dr. Orenstein. We estimate that about 6 percent of all of the infections that occur with hepatitis B annually would occur without a vaccination program, occur with children with no known risk factors. That includes, that's primarily in Caucasian and African American children.

Mr. Cummings. So a universal vaccination for infants against hepatitis B is very important, is that correct?

Dr. Orenstein. Universal vaccination of infants for hepatitis B is important to protect them both from infection in early childhood as well as from infection later in life. The risk of infections are different when you get them. If you get infected as an infant, one, you're likely to have no symptoms at all. You're likely to never know you were infected. And you have a 90 percent chance of becoming a chronic carrier. And about a quarter of those go on to develop either liver cancer or cirrhosis of the liver 20 to 40 years or so afterwards, and they may never know how they got it. So we vaccinate them because the risk of the consequences of hepatitis B is much more severe, the younger you are. Contrast that with an adult. An adult who gets infected with hepatitis B, they have only a 6 to 10 percent chance of becoming a chronic carrier. About more than one-third of all chronic carriers in the United States are believed to be from childhood infections.

Mr. Cummings. Dr.--I'm sorry, I forgot your name. Next to----

Dr. Satcher. Dr. Rabinovich.

Mr. Cummings. Yes--you were shaking your head. Did you have something?

Dr. Rabinovich. No, I agree that those figures indicate that hepatitis B is an important disease to prevent and that children are at particular risk.

Mr. Cummings. Have there been any published peer review studies that show a link between hepatitis B vaccine and conditions such as multiple sclerosis and SIDS?

Dr. Orenstein. There have been case reports that have suggested that this is a possibility, and that's why we are doing more comprehensive research. The people who are developing these illnesses after vaccination have very, very severe illnesses; there's no question that these are terrible tragedies. The problem is that there are people who develop these same kinds of tragedies, these same kinds of illnesses in the absence of vaccination. And that's why we're engaged, we and others are engaged in substantial research to try and see whether the vaccine increases the risk over what would be expected.

Dr. Satcher. It's important to point out, as Dr. Orenstein said, ``and others,'' because it's not just the Government. The Institute of Medicine has been one of the major players in looking at these relationships between adverse events and

vaccines. And a lot of the information has been reviewed thoroughly by the Institute of Medicine, as well as the Advisory Committee that we relate to. So it's not just those of us within government looking at this. Congress often relies upon the Institute of Medicine and other agencies--the National Academy of Sciences, which the Institute of Medicine is a part of--for independent reviews of issues like this. And we have a lot of reviews from the Institute of Medicine.

Mr. Cummings. My time has run out. Thank you.

Mr. Burton. Thank you, Mr. Cummings. Mrs. Biggert.

Mrs. Biggert. Thank you for having this hearing. Many of those who have been concerned regarding mandatory vaccinations would like to see the States and/or the Federal Government do more in the area of advised consent. I would just like to know from the panel how you would define ``advised consent?''

Dr. Satcher. You mean informed consent.

Mrs. Biggert. Well, it's called ``advised consent,'' but it would be ``informed consent,'' whether parents should make up their mind whether to have such a vaccination.

Dr. Satcher. Oh, yes. I'm sorry. So you're talking about a parent having the choice and obviously having the information to make that choice.

Mrs. Biggert. Right.

Dr. Satcher. Well, I think as we said earlier, the whole issue of immunizations are looked upon both from the standpoint of benefits to the individual, but also benefits to the community. And as you know, the requirement for immunizations are at the State level. But 48 States allow religious exemptions; 15 States allow philosophical exemptions. In all of those States, less than 1 percent of parents decide not to have their children immunized when they have those exemptions. So decisions are being made--but religious and philosophical exemptions are a very small percentage. But States have a responsibility to protect children in schools. And therefore, the requirements for immunization, in the absence of religious or philosophical exemptions, are based on the desire to protect the entire community, not just the individual.

Mrs. Biggert. What I'm asking is, what action has CDC taken to improve the accuracy of information relating to the adverse impacts of a vaccination? Is that given to, to parents, or----

Dr. Satcher. Yes.

Mrs. Biggert [continuing]. Do you have an information campaign really targeted both to doctors and to prospective patients?

Dr. Orenstein. CDC believes very strongly in the need to provide information to parents. We've done a lot. I think we need to do more. I think it's very clear that the information isn't always getting out. We helped develop a vaccine information statement that is required, actually by law, to be given to children for vaccination, if they receive a vaccine covered by the injury compensation program, which contains information on the risks of disease, the complications from disease, known risks, scientifically accepted risks from vaccines. It tells them about the compensation program; it tells them how to report adverse events; who might be at risk for these complications where it is known. And we distribute

them to the States for distribution to all vaccine providers. In addition, we have developed websites where people can get more information. We have hotlines, which are listed in these information statements, where people can get more information. And we also put in each of these information statements, for the parent who wants more, one, to ask their doctor or nurse, and also even refer them to--some parents maybe want to see the package insert, which will contain more detailed information. I think we do a lot and are continuing to do more, and we will need to do more because we know of instances where this is not being done.

Mrs. Biggert. I would imagine that some of these reactions would be something in common, like coughing or rashes or something that might start out that way. But how is it determined that these could be tied to the vaccination? Is there a problem making that connection? Are doctors given enough information?

Dr. Orenstein. I think we provide information as well as others--the American Academy of Pediatrics, the American Academy of Family Physicians--about vaccines, both risks and benefits. I think there are issues, we encourage reporting of serious adverse events, regardless of whether the physician thinks they are vaccine-related or not. I realize there are still physicians who only report adverse events if they think they are related to vaccines. We are trying in multiple venues, and we will continue to try, to get all serious adverse events reported. What's difficult with many of the adverse events that are reported is that, while they are, can be very serious and very problematic, many of them are also occurring in the absence of vaccination. And when that occurs, and the clinical syndrome is not unique, then we need to do special studies. And that's why we have a system we call our Vaccine Safety Datalink, which works with four managed care organizations in the Western United States and independent researchers, to look at what the expected incidence of this illness would be in the absence of vaccination, to compare with the incidence in the presence of vaccination. And if it's higher after vaccination, that will be strong evidence that vaccine is actually causing it.

Mrs. Biggert. I know there was a school in Illinois at one time where there was a measles outbreak. And it was a school for religious purposes, and nobody was vaccinated. Well, the school was shut down for a while until everybody recovered, and I think some of them probably had vaccinations. But is there a plan, if that happens, that addresses that problem in such a school?

Dr. Orenstein. I think that each State would decide how best to deal with that situation. Although we may recommend mandatory immunization because we've seen how effective it is, how it's implemented is a State decision. So in terms of dealing with an outbreak in a college, for example, where there are large numbers of people who are unvaccinated and who can infect the community, that's usually worked out on a case-by-case basis, and there may be actual plans as to whether the States would quarantine the school so that the children didn't go and spread it into many communities, or whether they just

tried to make voluntary efforts to vaccination, or other kinds of efforts to vaccinate.

Mrs. Biggert. Thank you. Thank you, Mr. Chairman.

Mr. Burton. Gentlelady, thank you very much. Let me--I want to apologize to all the other panelists who are here because I know it's been a long day. It's extremely important though that we get through a few more questions and then we'll get to our next panel. I apologize once again for everyone getting saddle sores.

First of all, why are individuals not tested when a series of three or five vaccines is given to determine their antibody levels, since this level would indicate that they may already be protected? Along with that, I understand, as I said before, in Japan they check the antibody levels to make sure a person's immune system is not depressed before they give them some of these shots. And they wait, or they wait until they're a little bit older. I just wonder why we don't look into that as well?

Dr. Satcher. Well, I guess it gets back to risk and benefits, because a lot of the deaths that we have seen from these infectious diseases occur very early in children, 1 and 2 years of age. So----

Mr. Burton. Well Japan, I think, has a very, very good record in this regard. I think they have as good a record or even a better record as far as deaths or diseases caused in infants from these diseases. In fact, I've ordered the studies they have done and they are going to be sending those to us. But the fact of the matter is, they're as good or at least as good or better. And they check the immune system first, before they start administering some of these vaccines. I just wonder why we don't look at that. The cost benefit ratio, is that what you're saying?

Dr. Orenstein. I'm not aware of what's done in Japan. I know Japan had two deaths after pertussis-containing vaccines in the 1970's. They stopped their pertussis vaccination and then had 41 deaths in an epidemic of pertussis afterwards. I do not know what they test for, but I do know that for some of these diseases, there aren't antibody tests. We don't know, for example, what----

Mr. Burton. Where there are, why don't we?

Dr. Orenstein. In many of them it may be maternal antibody. Maybe another antibody passed from the mother to the child. And by the time we would find out that they were susceptible, they may have already become infected. From any of this, it becomes a very difficult thing to do in the setting of a public clinic----

Mr. Burton. Are you indicating to me that there are not antibody tests that can be performed prior to giving these children these shots? Because they get 21 by the time they're 6 years old.

Dr. Orenstein. There are antibody tests that could be performed in some children for some diseases, but as a matter of trying to assure vaccination and assure protection from vaccine-preventable diseases, it would be very difficult to do that for large number of children.

Mr. Burton. But I understand that they do that in Japan. I wonder why?

Dr. Satcher. But these are some areas where we're still doing research in terms of how much can we know about the individual's immunogenicity.

Mr. Burton. Well, if you have any information, please submit it to us for the record. We have heard from individuals who have had remarkable healing after vaccines events through the use of homeopathic remedies. Has our Government or is our Government doing any research into that area?

Dr. Satcher. As you know, Congress has established the National Center for Complementary and Alternative Medicine Center at NIH, so we are doing more research in the different approaches to clinical care.

Mr. Burton. Their budget's very----

Dr. Satcher. It's very early. It's very early.

Mr. Burton. Their budget's very small. Would you recommend that we increase that a little bit?

Dr. Satcher. Well, you know, we have certainly recommended that you increase the budget of NIH overall.

Mr. Burton. Well I know, but when you do that, I'd kind of like for you to shove a little bit into the alternative thing.

Dr. Satcher. And I think that will certainly happen.

Mr. Burton. Would you do that?

Dr. Satcher. Yes.

Mr. Burton. Thank you. How do you explain the huge jump in autism and developmental delays?

Dr. Satcher. Again, I'm taking the prerogative here on some of the questions, but many studies have been done looking at the relationship between autism and vaccines, and there have not been any conclusive studies showing that vaccines cause autism. That's still----

Mr. Burton. There is a large increase.

Dr. Satcher. Yes, and we're still studying it. But to date, we cannot demonstrate the causal relationship, but we continue to look at the issue.

Mr. Burton. Well, if you have any additional information on that, we'd like for you to----

Dr. Satcher. We certainly will. We will update you on what we have.

Mr. Burton. Mr. Waxman, do you have any questions before we break?

Mr. Waxman. Yes, sir. Thank you very much, Mr. Chairman. We know that when we immunize a child, we're trying to protect that child from certain diseases. But we're also protecting children who cannot be immunized, for example, children who have leukemia who can't be vaccinated. Isn't it true that some children who are vaccinated do not respond to the vaccine and develop an immunity to the disease?

Dr. Satcher. Definitely. But the other point you made is so important--in response to Congresswoman Biggert's point about the school, the real question is, in addition to the children in that school who got measles, we don't know how many other people were exposed to measles because of that, who themselves might not have even been subject to vaccination because of an immune problem, or leukemia, or what have you. So when a group of people become infected by an infectious disease like measles, a lot of other people are exposed.

Mr. Waxman. Isn't it the case that there will always be a small percentage of children who will not be immune to these vaccine-preventable diseases, so a parent who chooses not to have his or her child vaccinated is therefore putting these other children who cannot be vaccinated or do not respond to vaccines at a greater risk of----

Dr. Satcher. Yes, I think that's the basis on which States have made the kind of decisions that they've made in terms of requiring immunizations.

Mr. Waxman. I wasn't here for a lot of the questions on anthrax, and I know one of our subcommittees has held hearings and I haven't been a part of those hearings. But, what is your role on the anthrax vaccine compared to the Department of Defense?

Dr. Satcher. Yes, I pointed out that the decision to immunize the troops was a decision made by the Department of Defense, and in some cases using information that's really security information that we don't have access to. I think what we can talk about is the vaccine and the studies that have been done to show both its safety and efficacy. And the FDA has been involved in those studies. It is on that basis that we can say, the vaccine is safe, and it's also effective.

Mr. Waxman. And you haven't made a recommendation that everyone be immunized for anthrax, have you?

Dr. Satcher. No, we haven't.

Mr. Waxman. So that's not even an issue at the moment.

Dr. Satcher. No, we don't anticipate making it. But obviously, as you know, in the area of bioterrorism, it just depends on what happens in the future in terms of what the real risks are.

Mr. Waxman. Thank you very much, Mr. Chairman.

Mr. Burton. Thank you. You've been very patient, this panel, and so have been all of the rest of the people who are going to be testifying. We have to go vote. We will be back as quickly as possible. I think we only have one vote on the floor. As soon as we return, we'll have the next panel. Mr. Surgeon General, thank you very much for being here. We really appreciate it. We stand in recess.

[Recess.]

Mr. Shays [presiding]. Ms. Nelson, Ms. Spaith, and Ms. Cole.

I'm not succeeding in my coup. We have two we are still waiting for. Can we swear them in privately?

Here is what we are going to do. We are going to ask you to stand, and then we will--we are calling our witnesses to come forward on panel two.

Would you raise your right hands, please.

[Witnesses sworn.]

Mr. Shays. We will note for the record all our witnesses were sworn in except Ms. Spaith, and we will start with Tonya and Gerald Nelson. We will invite you to give your testimony.

What we are going to do is we are going to turn the clock on for 5 minutes, and then we will roll over if we have to and welcome your testimony. And please feel relaxed. It is wonderful to have you here, you should feel very comfortable being here.

Ms. Nelson. Thank you.

Mr. Shays. Thank you for being here.

Are you both going to give testimony, or one of you?

Ms. Nelson. I will give mine, and then he will continue.

Mr. Shays. OK. Ms. Nelson, why don't you start.

## STATEMENTS OF TONYA AND GERALD NELSON, INDIANAPOLIS, IN; RICK ROLLENS, GRANITE BAY, CA; CAROLA ZITZMANN, VOICE OF THE RETARDED; ANTONIA C. SPAITH, FALLS CHURCH, VA; REBECCA COLE, PKIDS, CHAPEL HILL, NC; AND KEITH BERGEN VAN ZANDT, M.D., PKIDS, WINSTON-SALEM, NC

Ms. Nelson. Thank you.

Thank you Mr. Chairman and members of the committee. I am grateful to be here today to share with you our story regarding vaccines.

I am the mother of four children. Abigail was my third. Abigail was born at 11:27 p.m., on March 22, 1994. She was a very healthy baby. We stayed 2 days in the hospital. Prior to our release from the hospital, she was given the hepatitis B vaccine.

Mr. Shays. Ms. Nelson, I am going to ask you to put that microphone a little closer to you. That is the problem. It needs to be down. That is all right. We have to remind ourselves that, too. And you don't have to rush. You can speak more slowly.

Ms. Nelson. I asked questions about the injection and was given a booklet to read that stated to expect no side effects except soreness in the area of the injection.

We came home after receiving the vaccine. She was very cranky and her cry was very disturbing. It was more of a scream than crying. She began to spit up a lot.

I called the doctor and was told to give her some water between feedings and to call back in a week. I did as the doctor suggested, but I began to get scared because her stool became loose and greenish-yellow. So I called back in a week and was told that was normal and to keep an eye on her and call if I needed to.

The second week was worse. Her cry was just as bad and stool seemed loose. She became cold to the touch and shivered a lot. I called the doctor again. She told me to put her in her infant hat and to check her temperature four times a day and to call back the following week.

I did this. Her temperature stayed at 96 degrees. Then her third week she began to turn purple in her hands and feet and around her lips. I called the doctor and was told to watch her breathing and they would see the baby the next week for her 1-month checkup and to keep her wrapped tightly in blankets.

I was becoming scared. I asked him to get her in before her checkup and was told they had no appointments. I hung up from that call and called my son's old doctor. She told me that she could not help without seeing the child, and since Abby was on Medicaid and she was not a Medicaid provider, she was restricted from seeing Abby. I offered to pay cash, but she said she could not take the money from a Medicaid patient. At this point Abby is still crying and vomiting and having loose

stools and very cold.

The night before she died she screamed for 6 hours straight, plus she had a lot of bowel movements. She finally fell asleep at 11:30 p.m. We woke up to find her dead at 6 a.m.

I placed my 9-1-1 call and started CPR. The firemen and paramedics showed up. They pronounced her dead shortly after they arrived. The coroner said it would be 2 weeks before the cause of death could be determined.

About 2 months later we received a telephone call from Dr. Thomas Gill of the Marion County Coroner's Office. He told us the cause of death was the hepatitis B virus, which she could only have gotten from the vaccine. He told me that he would get the death certificate out to me soon.

Sixteen weeks later we received the death certificate in the mail, and the cause of death was natural causes, otherwise known as SIDS, Sudden Infant Death Syndrome.

I was shocked to say the least. I called the coroner's office and spoke to a Dr. Manders, the coroner of Marion County, and was told that Dr. Gill had been asked to resign.

Dr. Manders stated he had signed the death certificate. I asked how he could sign the death certificate if he did not perform the autopsy. He told me that he had done so since Dr. Gill was no longer there. We had not been able to determine how he came to the cause of death, since he did not perform the autopsy, and that Dr. Gill told us something very, very different. He told me that if I had questions to call a Dr. Pless, a pathologist at Indiana University.

I did call and made an appointment to speak to Dr. Pless. He was a man without compassion, and the most cold-hearted I have ever met. He told me to stop trying to place the blame on my child's death and to go on with my life. He also stated that if the vaccine did kill my daughter, it was saving more lives than it was taking.

I contacted a lawyer and he said to get all the information together and to call him back. I contacted the Infectious Disease Center at Riley Children's Hospital and spoke to a registered nurse. She was very helpful. She told me the vaccine has been known to take infants' lives and also to make them very sick. She could not help me other than that. She was scared she would lose her job. She also told me that the infant does not develop its own immune system till 3 to 4 months of age. I confirmed this with other doctors, who said they are very uncomfortable giving the injection at such an early age.

I tried to contact the Center for Disease Control and Prevention and the vaccine company. I left messages that were never returned.

To retain my own emotional well-being and to care for my two older children I had to take a break from this, thinking I had plenty of time to pursue this with the Government. I had to return to work because we were already behind the 8-ball financially. Having to pay for a funeral and headstone for Abby only made that worse.

I was not the only member of the family who needed to heal from this trauma. My husband Gerald will share his experiences shortly. My older child needed counseling we could not afford, and the school told us she was young enough, she would soon

forget.

Finally I was able to call the attorney back and was told that it was too late. He said I only had 2 years to get compensated for our loss unless she had lived. Then I would have had 7 years.

We had a lot of bills and misfortunes due to this one vaccine. We had lost the most important things in our lives, and nobody cared. They were too busy or too afraid of losing their jobs or paying too much malpractice insurance.

I also know that my child was not a priority of getting an appointment with the doctor because she was on Medicaid. The doctors do not get enough compensation to encourage them to make Medicaid patients a priority.

Since we were in such financial distress already, I tried to get State funding for her funeral, and was told it would take a few weeks to get approved for this, and that I would have to fill out paperwork. I didn't feel that I could hold off for weeks to bury my child while paperwork was being filled out and reviewed.

I gave up hope and contacted Beth Clay on the committee staff. This has been like an open wound that has been trying to heal for 5 years but has not. I feel like coming and telling our story will be worth it if I can help save just one child's life. I hope through my own experience I will be able to help other parents also.

Of course none of this will make up for the loss we encountered 5 years ago. By testifying today my husband and I may finally be able to bring closure to our grieving. So far we have been so busy trying to survive that we have not done so. Our Abby would have been in school now learning to read and writing songs. Instead we have a baby book that has never been filled out.

Mr. Nelson. Tonya and I are like many other Americans, ordinary Americans, hard-working, struggling to survive. Tonya came into our marriage with two beautiful children, Sabrina and Kegan, whom I love dearly. Abby was a beautiful and healthy child. She was my first child. I was the proudest of fathers.

This tragedy compounded with other family losses really tore me apart emotionally. I ended up losing my job. We have struggled to recover from this tragedy and to further understand how it is appropriate for babies whose immune systems are not even fully developed are being vaccinated. We also want to see more information be provided to parents prior to vaccination and that they be informed that there are medical and religious exemptions.

Physicians also have to be educated about these exemptions and be comfortable giving them. We were told that the worst that would happen to our little Abby was that she would have a sore leg. That was certainly not accurate information.

By coming today we hope that the Government will move forward with more research in the safety of vaccines in infants and the combination of vaccines. We also want medical freedom to be a consideration in finding the balance between public health and each individual's health and safety.

Thank you, Mr. Chairman and members of the committee for this opportunity for us to testify.

Mr. Burton [presiding]. Mr. Shays, you had something you wanted to say?

Mr. Shays. Mr. Chairman, I first wanted to say to both Mr. and Mrs. Nelson that it is, one, very important that you are here. Second, that there is not a person in this room who doesn't find it outrageous that you would have encountered such resistance, one, to look at your child, and, two, that you weren't given the kind of sympathy that any grieving mother and father deserve. I am just glad to know about your case and see how I can be helpful to you. I do appreciate you being here, and since I did swear you in, I want to say that.

Mr. Chairman, we do need to swear in Ms. Spaith. You might want to do that right now.

Mr. Burton. I will be happy to do that.

Before I do that, Mrs. Nelson and Mr. Nelson are friends of my daughter, and of course I told you earlier about my granddaughter having a problem with the hepatitis B vaccine. I want to also express my concern about what you folks went through. I have instructed my assistant here, Beth, to help you make a claim, which I think is justified, against the Government for this problem. And I hope--you have to do that by August 6, so we have got only 3 days, and we will assist you in doing that so that you can be at least partially compensated for that horrible thing.

Ms. Nelson. Thank you.

[The prepared statement of Mr. and Mrs. Nelson follows:]

[GRAPHIC] [TIFF OMITTED] T2560.113

[GRAPHIC] [TIFF OMITTED] T2560.114

[GRAPHIC] [TIFF OMITTED] T2560.115

[GRAPHIC] [TIFF OMITTED] T2560.116

[GRAPHIC] [TIFF OMITTED] T2560.117

[GRAPHIC] [TIFF OMITTED] T2560.118

Mr. Burton. Ms. Spaith, would you stand, please?

[Witness sworn.]

Mr. Burton. Mr. Rollens, you are next.

Mr. Rollens. Mr. Chairman and members, my name is Rick Rollens. I currently reside in Granite Bay, CA, which is located 30 miles east of Sacramento, with my wife of 23 years, Janna, and my two sons, Matthew, 13, and Russell, 8.

Thank you for inviting me today to testify. For me this is somewhat of a homecoming, for in 1973 I had the privilege of serving on the Washington staff of former Representative Jerome Waldie of California.

Following my service in the House, I embarked upon a 23-year career of public service with the California State Senate. Working through the ranks, I was elected by the Members of the Senate to serve as their Secretary of the Senate, until I chose to resign my position in 1996 in order to dedicate myself to the pursuit of effective treatments and a cure for my beloved

son, Russell.

I am here today to share with you the story of my son's case of vaccine-induced autism and to report on the growing autism epidemic in California and the pandemic of autism throughout this country. Russell began his life as a normal, healthy, and robust child, meeting all his age-appropriate milestones. At 7 months old, within 72 hours after receiving his third DPT and first hep B vaccination, Russell developed a high fever and shrieked with a high, wailing scream for days. After these vaccinations, he started losing eye contact, smiling less, losing interest in people, developed constant croup, and was chronically sick. At 7 months old, Russell's life had begun to change along with the lives of all who know and love him.

Within days after his first MMR vaccination, at 18 months, Russell began his final journey into the abyss of what my wife and I now know is autism, losing most of his remaining skills, developing severe sleep irregularities, chronic gastrointestinal problems, and expressing constant pain exhibited by harrowing days of endless crying. Russell was officially diagnosed at 2\1/2\ years old with autism.

After many months of medical investigation of Russell's condition, including state-of-the-art brain scans, immunological and neurological and genetic workups, we consulted a noted pediatric neurologist who thoroughly examined Russell and reviewed all of Russell's medical history. He advised us that in part Russell's brain dysfunction had very likely occurred as a result of some form of encephalitis resulting in bilateral damage to the temporal lobes of his brain.

Based on the facts that we have absolutely no family history of autism or any other type of brain disorder in our family, that he was born a normal, healthy child, that there exists a strong temporal relationship between the timing of the DPT vaccination he received at 7 months old and the onset of his autistic condition, his classic DPT vaccine reactions, coupled with the 18-month-old hit from the MMR and subsequent deterioration of his condition, as well as the scientific evidence that one of the many serious adverse effects of DPT vaccine is encephalitis and brain damage, I believe that Russell is a victim of vaccine-induced autism.

My story is far from unique. Mr. Chairman and members, next week when you return home to your district, talk to your constituents, many of whom are among the growing number of parents who have children with autism. I can assure you that you will hear firsthand accounts from those parents about their normally developing children and the introduction and reaction to a vaccine or multiple vaccines, the timing of their children's regression and vaccination, and the onset of a multitude of other medical conditions and complications that accompany this acquired autistic condition.

The first rule of medicine is to listen to the patient. A child born today in California will have received his first vaccination between 6 to 8 hours old. By the time that child is 6 months old, he will have received 15 doses of vaccines, and by the age of 5 years old, 33 doses of vaccines.

Vaccines contain numerous active agents such as live viruses, killed bacteria, and toxic chemicals, including aluminum, mercury, and formaldehyde. Where are the safety studies on the short- or long-term effects of the interaction of these numerous multiple vaccines and their agents on the developing brain and immune systems of our children? Where is the science?

Many safety studies of individual vaccines only include a few days of followup periods for reactions, but the CDC tells parents and the news media that the onset of autism after vaccination could only be ``an unrelated chance occurrence.'' Dr. Satcher, show me the studies. Show me the science. Is it appropriate to continue to entrust the CDC and the indemnified vaccine manufacturers with the responsibility of guaranteeing parents of this country that these vaccines do not cause autism or other serious brain disorders when these same groups are the most aggressive promoters of vaccine use?

The situation can easily be likened to charging the tobacco industry to undertake independent scientific studies to find out if there is any relationship between lung cancer and smoking. The science on the safety of vaccines and their relationship to the development of autism is not there. Not there because the pleas of parents have been ignored. I suffered the ultimate betrayal of trust by blindly allowing my child to be injected with a multitude of vaccines, trusting my Government had made sure that my child would not become autistic after his vaccinations.

Responding to the outcry of parents such as myself, professionals, and educators over the concern of the rapidly increasing number of children with autism and autism spectrum disorders, the California legislature and two Governors of different political parties have responded within the past 12 months by requiring a study on whether autism was increasing in the State, and after finding that there was a huge unexpected increase, appropriated several million dollars for independent research as well as an independent followup study into the real factors causing the increase.

Under the leadership of State Senator, now U.S. Representative Mike Thompson, last year the legislature required the Department of Developmental Services to report on the increase of autism from 1987 through 1998. The report was released earlier this year, and documents a very conservative 273-percent increase in the number of children with autism entering the developmental services system, 1,685 new children last year alone, when incidence projections for that population would have predicted between 105 and 263 new children. The report led the Los Angeles Times to declare that the State has an epidemic of autistic children. An epidemic of autistic children? Isn't that an oxymoron? We all know there is no such thing as a genetic disease epidemic. So clearly other factors are involved.

According to the department, this year from January 6 to July 7, 1,027 new children with autism were added to the system, which means that California alone on average is adding 6 new autistic children a day, 7 days a week, 1 new child every 4 hours. Besides the unmeasurable human costs on the child and

the family, the thousands of autistic children already in our system, along with these 1,027 new children, are according to the Department of Developmental Services going to cost the taxpayers of California and the country a minimum of $2 million each for the lifetime of their care.

Surely any intelligent, thoughtful person with a straight face could not suggest that this huge increase in one of the most easily recognizable of all childhood disorders is all due to genetics, better recognition, or to minor changes in the diagnostic criteria that occurred 10 years after the massive increase in autism had already begun over two decades ago.

Earlier this year the local and national news media extensively covered the story of the observations by parents in Brick Township, NJ, that there were a lot of kids with autism in their community. In fact, the CDC publicly announced that they had discovered a cluster of autism in Brick. What the CDC found was that the prevalence of autism in Brick was 1 in 150 children; 1 in 150 children represents a prevalence rate 12 times higher than the published prevalence rate. My family and I live in a community approximately 3,000 miles away from Brick Township, a community that is almost in every way as different from Brick as two communities in America can be. Where we live, our children are served by a single public elementary school district. The prevalence of autism in our elementary school district is 1 in 132 children.

Mr. Chairman and members, Brick Township, NJ, and Granite Bay, CA, are not clusters of autism, but snapshots of what is occurring everywhere. Numerous parent organizations around the world, including the Autism Research Institute, the National Vaccine Information Center, Families for Early Autism Treatment, Autoimmunity Research Project, Cure Autism Now, and Allergy-Induced Autism are all constantly hearing from scores of parents reporting vaccine-related autism. You will find these children throughout the neighborhoods of your own districts.

Vaccine policy has always been a cost-benefit proposition. I am here to tell you today that the once numerically rare sacrificial lambs that society has been willing to tolerate for the good of the whole could now very likely before our eyes be turning into herds of casualties of the most precious resource we have, our children and our grandchildren. We must act quickly by investing in good,
independent research and science to pursue the truth about the link between vaccines and autism. If we don't discover all the causes, we will never find a cure.

Thank you for your time.

[The prepared statement of Mr. Rollens follows:]

[GRAPHIC] [TIFF OMITTED] T2560.119

[GRAPHIC] [TIFF OMITTED] T2560.120

[GRAPHIC] [TIFF OMITTED] T2560.121

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Mr. Burton. Mr. Rollens, that was a very eloquent statement, and I will just pledge to you personally that we will do everything we possibly can as a committee to find out everything we can. We will ask people from the Surgeon General's office and the Departments of Health to stay. They heard your statement as well, and I will just say to them that this isn't the only hearing we are going to have on this. We are going to be beating on this issue as long as I am chairman of this committee, which hopefully will be for a while.

So I hope that you folks will do everything you possibly can to help us find a solution to this problem, because not only does Mr. Rollens have an autistic child, I have an autistic grandchild. I also have a granddaughter that almost died from the hepatitis B shot, I believe. So, you know, we have people that have had that problem with hepatitis B and autism, and the chairman of this committee has had both with two grandchildren. So I don't think it is just a coincidence.

Ms. Zitzmann.

Ms. Zitzmann. Mr. Chairman and members of the committee, I would like to thank you for allowing me as a mother to come here today and testify before you. My story will probably be a little different from what you have heard just now.

When two people marry, they have dreams of life together and having a family. One day this becomes true, but something suddenly goes wrong. You are told that your child has problems but they don't know what because they need to do testing. Much later you discover that while traveling to work on the transit system, a bus and two trains into Manhattan, someone infected you with the rubella virus. You find out later it went directly into the developing fetus in the early stages of your pregnancy, causing the disabilities your son now experiences. But you only find this out after your baby is born, because the virus does not show signs of infection on you. The rubella virus does damage while the infant is developing, and now there are vaccines to prevent this.

The guilt you experience when you learn your child is not normal and will never be is very difficult and hard on the family, and you begin to ask yourself, what did I do wrong to have this happen? Thankfully, I have had a very supportive husband in these last number of years.

My story is that Robert, who is now 34 years old, was born with mental retardation and disabilities because of the lack of the vaccination. I was born and raised in Brooklyn and lived in Queens after I got married, but traveled to Manhattan every work day. Perhaps you recall it was mentioned earlier the 1964 New York rubella outbreak that had happened.

Soon after our son was born in 1964, we knew something was wrong. He couldn't nurse, his sucking reflexes were poor. To this day, he cannot suck on a straw, blow out a candle or blow his nose. He was delayed in holding objects in his hands,

sitting, walking, and he didn't know how to hold onto you when you picked him up. He had many bouts of respiratory infections and pneumonia. His eyes were also affected and he has been wearing glasses since he was 3, and they continue to deteriorate, and I am being told he will develop cataracts.

He has no speech, therefore, no language skills. He needs to be dressed, undressed, bathed, shaved, toileted, many times because he soils himself still. His foods need to be prepared and carefully selected. He has certain food intolerances. He can feed himself when his food is cut up, most of the time with a spoon, a lot of the times with his hands.

His motor skills and coordination are also poor. Bob will wander off if not watched, and we have had to put bolt locks on our front doors to prevent him from leaving, and we have had to call the police to try to find him. We now have an ID bracelet on him.

All through Bob's growing years, I have met many families who share my experiences due to the rubella exposure and have always been a strong proponent for parents to immunize their children against such viruses, recognizing, however, that the decision remains one of family choice, but also knowing that since the vaccine has been developed, many individuals have been prevented from becoming disabled.

Bob lived at home with us for 21 years, when we made a critical decision in his life and placed him in a private, intermediate care facility for the mentally retarded [ICFMR], which is a Medicaid funded and federally certified residential program. He thoroughly enjoys his home in Wide Horizons. When he comes to visit us, within a few days he signs he wants to go back because he is bored.

Before he moved to Wide Horizons, though, and was living with us, we were not able to go out to dinner together, attend church together, picnics, movies, or vacations. I was changing diapers and pants daily on this young man. Sometimes I had to change and strip him twice during the night, which meant little sleep for both of us.

Bob and others like him need more supervision, more structure, and do well with routine and not so well with changes in their daily life. Because his home is an ICFMR, it means that his medical, dental, therapeutic, and recreational needs are also arranged by the facility through community providers.

As a parent, I needed a guarantee of safety and oversight, because he is so vulnerable. He is happy and doing well, even with all his disabilities. We as a family appreciate having the ICFMR available to us to choose from.

As a citizen, we select Members of Congress to serve as our proxy when it comes to matters of public policy, and I thank you for your time today, and trust that you will keep preservation of family choice foremost in your mind as policies impacting people with regard to vaccines is decided, and I truly hope that this committee will consider looking into why there are reactions to these vaccines when it is supposed to be helping people, not hurting them. I always wonder, if we had had this vaccine back then, what would my son be like today?

Thank you.

[The prepared statement of Ms. Zitzmann follows:]

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[GRAPHIC] [TIFF OMITTED] T2560.182

Mr. Burton. Thank you, Ms. Zitzmann. Thank you very much.
Ms. Spaith.

Ms. Spaith. Thank you for inviting me here today. I will preface what I am about to say with the fact that the opinions that I will express in my testimony are my own personal beliefs and not those of the organization for which I work. I would like to request that my formal official testimony be entered in as part of the official transcript for today's hearing, and I will just talk to my abbreviated testimony in the interest of time.

Mr. Burton. That's fine.

Ms. Spaith. I have served at the Department of Defense and in the U.S. Naval Reserve now for 26 years, 5 months. The last 4 years have been in the Office of the Secretary of Defense, Acquisition and Technology, Nuclear, Chemical and Biological Matters, which is now called Defense Threat Reduction Agency, and I work in chemical and biological elimination. My official title is International Project Manager, Biological Weapons Proliferation Prevention.

I manage a team of scientists, veterinarians, and technicians in collaborative research with the Russians at the Russian Biological Weapons Institutes. I travel to Russia, to the various institutes where dangerous pathogens are stockpiled, both bacterium and viral.

In August 1988 I was told by my supervisor to get my shots prior to my first deployment to Russia. I received typhoid, hepatitis A, and tetanus diphtheria vaccines at my agency, Defense Threat Reduction Agency, in late August, early September. I received one anthrax and one botulism vaccine at the U.S. Army Medical Research Institute for Infectious Diseases at Fort Detrick, MD in September and one additional anthrax vaccine in January 1999.

I was never told that any of the vaccines that I was receiving were experimental or investigational, and, in fact, the botulinal toxin, bot-tox, was investigational.

The blood work-up that was done at Fort Detrick indicated that I fell into the normal range--this was prior to receiving the vaccines--I fell into the normal range in terms of the assessments that were conducted on my blood at that time, which was chemistry and hematology.

After receiving the vaccines, my blood chemistry changed significantly. A blood work-up was done at Walter Reed during a routine occupational health physical, and showed that I was anemic in the tests that they did run at that time, and a physical exam by the doctor revealed that I had a severely enlarged thyroid. There had been at that point no followup by any of the medical personnel at Fort Detrick.

My first real symptoms began in October 1998 with significant loss of energy. I had trouble sleeping, which exacerbated the problem. In November 1998, I started having severe headaches in the very back of my head, where I have never had headaches before, way back here. I developed acute

diarrhea. I had hair loss, blood sugar problems, mood swings, sleep deprivation, and acute anxiety.

By December 1998, I had menstrual cycle interruptions, increased PMS symptoms, abnormal feelings of tension, tremendous--tremendous hair loss, extreme fatigue and loss of energy, severely reduced reflexes, and psychological problems.

I had been completely healthy with no medical problems prior to receiving the vaccines. I ran 2 miles every day prior to receiving the vaccines. Every day of my adult life I have done this. I have not been able to resume that activity.

I might also mention as an aside, each time I went to Fort Detrick, MD for my vaccines, I was bled. In other words, they drew blood each time, and I had to prove two different ways that I was not pregnant prior to them administering the vaccines to me. One was that I had to be on the first day of my menstrual cycle to receive the shot. The other was they drew blood and made me wait for 2 hours to prove through the blood test that I was not, in fact, pregnant before they would administer the shot.

This is basically why I believe that the vaccines I received at Fort Detrick, combined with the ones that I received at my own agency, and their cross-reactivity, contributed to or directly caused my illnesses and conditions.

By December 1998, I was terribly distraught and suffering, and having psychological problems. I went to an endocrinologist specialist. She conducted blood work and it revealed that I had no thyroid function at all, whatsoever. It was completely dead and not functioning. She told me that I had Hashimoto's Disease. She started me on Levathoid, which is a synthetic thyroid medicine.

The thyroid regulates the pituitary gland and regulates messages from the brain. However, my thyroid produces no thyroxin, which results in mixed signals that my body was receiving from my brain. As messages were sent from my pituitary, and my brain to my thyroid, there were no receptors to stimulate secretion of the thyroid gland hormone and no thyroxin was produced, so the messages go right back up in a closed loop. I was not performing in quite the organized way as people whose thyroids function properly. I am currently on three types of medications. The Levathoid is for the thyroid condition and I am also on Paxol and Adavan.

What caused my thyroid to stop functioning? That is the question that I have. There is no history of this in my family. I believe it was the vaccines that caused the change in my brain chemistry and my thyroid to stop functioning, which have further resulted in this very debilitating auto-immune deficiency which I am classified as having.

While I have had some favorable progress from the medications, I believe that my health will never be restored as it was before I received the vaccines. My psychological problems continued and worsened. I was over-reacting to situations and having terrible mood swings, still not sleeping. I could get upset very easily over the least little things. I developed a great deal of difficulty in my inter-personal relationships at work, particularly when I thought people were not cooperative. I got overly upset and said things that were

not characteristic of me. I felt out of control, filled with anxiety, and nothing but despair. I was also disoriented and I had a great deal of difficulty focusing. I basically thought I was losing my mind.

At work the situation became so bad that my supervisor found my behavior to be so out of character, and my personality so radically changed, that I was called in and counseled on my behavior problems and given a letter of reprimand. This had never before happened to me. It was an emotional nightmare, and it was the lowest point in my career.

Then I realized that if management thought that I had changed that much, that something was seriously wrong with me, enough to write me a letter of reprimand, that I had better get back to a doctor. So I went back to the endocrinologist, and I discussed it with her, and I told her exactly what was going on. She immediately referred me to the mental health facility. I went that same day. I was diagnosed with depression and anxiety disorder, those are the other two medications that I am taking.

I learned that anxiety disorder is a biological malfunction in the body and not just something which is in your mind. It stems from a malfunction in brain chemistry. Depression, on the other hand, is a whole body illness and it affects the nervous system, mood swings, thoughts, and behavior. It, too, begins with a disturbance in the part of the brain that governs moods.

Medical experts believe that thyroid disorder, as well as chemical imbalances in the brain, can actually cause depression. I attended classes at my HMO's mental health facility where I learned these facts, as well as new skills to cope with my disorders.

I believe that my agency placed me in harm's way and then abandoned me in my personal crisis. Instead, they told me I had behavior problems and wrote me a letter of reprimand.

Now, I am worried about blood pressure, it has always been very low and now it is very high, and the doctors are monitoring that. I also recently discovered that I have arthritis in several parts of my body. I am now taking anti-inflammatory drugs and waiting to get scheduled to see a bone specialist. That is on top of the other three medications.

Again, no one in my family has any history of these disorders or illnesses. I continue to perform my job, however, I will not take any more vaccines. I will be on the synthetic thyroid stimulating hormone every day for the rest of my life. As for the other two psychotropic drugs that I am taking, I will continue for as long as the doctors feel it is necessary.

I would like to ask a question. I have a daughter who is a First Lieutenant in the Air Force, and since we share the same DNA and biological make-up, wouldn't it make sense that she not be forced to have to take these shots, considering what she has inherited from me and my predispositions? I am very concerned for her. The Air Force has told her that she and the other people at her command, which is Space and Missile Command in Los Angeles, will have to take the anthrax vaccines. It is either that or they will leave the service. I have great concerns for her. She has got an application in to become a pilot.

[The prepared statement of Ms. Spaith follows:]

[GRAPHIC] [TIFF OMITTED] T2560.183

[GRAPHIC] [TIFF OMITTED] T2560.184

[GRAPHIC] [TIFF OMITTED] T2560.185

[GRAPHIC] [TIFF OMITTED] T2560.186

Mr. Burton. Does that conclude your remarks, Ms. Spaith?

Ms. Spaith. Yes, sir.

Mr. Burton. Well, in answer to your last question, there are a number of Congressmen, myself included, that have legislation that is going to be introduced and will be pending--we had a press conference today--that would allow members of the Armed Services to decline to have the anthrax shot. But we are working on that right now.

Ms. Cole.

Ms. Cole. I have a poster with some children on it. Could somebody put that up, please?

Mr. Burton. Would somebody post that, please?

Ms. Cole. I want to show you mine. This is Christopher.

Mr. Burton. How old is Christopher?

Ms. Cole. Christopher was 12 when he passed away.

Mr. Chairman, members of the committee, thank you for letting me speak to you today.

My name is Rebecca Cole and I am from Chapel Hill, NC. I am the mother of five children. I am here today because I faced the worst nightmare any parent can possibly face. There is no experience on Earth that compares to the horror and devastation of losing a child. It is shattered dreams, crushed wishes, and a future that suddenly vanishes before our eyes. It cannot be wished away, slept away, prayed away, or screamed away. It is darkness, agony and shock. It leaves our hearts broken, bleeding and bursting with pain and it changes us forever.

My life changed forever on June 30, 1988 when I had to stand by helplessly as an infectious disease claimed the life of my oldest child, Christopher Aaron Chinnes, at the age of 12.

Christopher was a beautiful little boy who had light blond hair and deep brown eyes. He was full of compassion, joy and energy. He loved baseball and every living creature on the Earth. He wanted to be a scientist or doctor. I can honestly say that my son was one of the most beautiful human beings I have ever known, and I am proud to have been his mother.

Christopher was born a very healthy child but at the age of 8 he developed asthma. It was never a problem for him and it never kept him from doing the things he loved. But, on June 16, 1988, 4 years after he was diagnosed, he suffered his first and only severe asthma attack. He had to be hospitalized and was treated with all of the normally prescribed drugs including a corticosteroid. For those who don't know, corticosteroids are anti-inflammatory drugs. They are used routinely in asthma, arthritis, and allergies. Oral surgeons also prescribe them for swelling in the gums.

Well, Christopher was released from the hospital 4 days later with several medications to finish at home, and he was well on his way to recovery. On June 23rd, exactly 1 week after the asthma attack, he broke out with the chicken pox. ``Don't worry, you will get over it,'' I told him. What I didn't know was that the corticosteroid had lowered his body's immune response and he could not fight the disease.

The chicken pox began to rampage wildly through his young body. As I drove him to the emergency room on June 27th my four younger children watched silently in shock and horror as their brother went into seizures, went blind, turned gray, and collapsed due to hemorrhaging in his brain. That afternoon Christopher was flown from Camp Lejeune's Naval Hospital to East Carolina University School of Medicine's Medical Center, but the chicken pox was uncontrollably sweeping through him like a wildfire, and there was nothing anyone could do.

The next day he suffered cardiac arrest and slipped into a coma. As my beautiful little boy lay swollen beyond recognition and hemorrhaging from every area imaginable including out into the blisters on his skin, I learned that a vaccine existed but was not yet licenced by the FDA. A vaccine that could have prevented the unimaginable suffering of my child and all who knew him.

On June 30, 1988, exactly 1 week after breaking out with chicken pox, Christopher passed away. He died. He was not injured. He did not act differently. He was not crippled. He died. My priceless little boy lay on a cold, steel table swollen beyond recognition, cold and dead, gone from me, gone from life itself.

I cannot hold him, kiss him, see him smile or listen to his laughter as he chases a ball or bullfrog. The chicken pox virus destroyed every organ in his body and it cut pieces from the hearts of everyone who witnessed its devastation.

Vaccines prevent countless deaths each year. Without them the number of valuable human beings we would lose would be staggering. Yes, sadly, some injuries and deaths occur as a result of vaccines, but unfortunately there are risks with every single drug we use. We have and will not ever reach perfection. We must remember that the benefits of our vaccines far outweigh the risks. Especially for those who are ill or immunosuppressed like Christopher was. There are innocent children and adults who come in contact with the public every day who would die if they were exposed to the diseases we can prevent.

If everyone around them is vaccinated, they are also protected. We owe it to them and to ourselves as a Nation to achieve the highest level of safety and protection possible. We must win the war against infectious disease, and vaccines are our most powerful weapons. We cannot win, however, if we do not use them. Leaving any of our population unprotected is like surrendering to a defeatable foe, and we must never surrender. Thank you.

Mr. Burton. Thank you, Ms. Cole.

[The prepared statement of Ms. Cole follows:]

[GRAPHIC] [TIFF OMITTED] T2560.187

Mr. Van Zandt. Thank you, Mr. Chairman and committee members. My name is Dr. Keith Van Zandt, and as a practicing family physician I appreciate the opportunity to address this committee regarding vaccines.

I have degrees from Princeton and Wake Forest Universities and completed residency training in family medicine here in Washington at Andrews Air Force Base. Today, however, I am here as a dad. I have five children, two of whom my wife, Dede, and I adopted from Romania. Our youngest, Adriana, was nearly 4-years-old when we adopted her from the orphanage and was found to have chronic active hepatitis B when we performed bloodwork prior to bringing her home. She had contracted this from her mother, who died when Annie was 9 months old from the effects of her liver disease as well as tuberculosis.

We have been very fortunate to have had some excellent medical care for Annie, but her first year with us was an endless procession of liver biopsies, blood draws, and over 150 painful Interferon injections that I gave my new daughter at home. Interferon is a form of chemotherapy for hepatitis B that has many side effects and only a 25 to 40 percent response rate. We know first-hand the pain and family disruption this completely preventable disease can bring.

As a family doctor, I see patients every day whose lives have been significantly improved by the immunizations we now have available. My forbearers in family medicine struggled in the pre-vaccination era with the ravages of horrible diseases that are now of only historical interest. Preventive immunizations have so changed our world that I am afraid that we no longer remember how horrible some of these diseases were.

My family and I have made multiple trips to Romania to work in the orphanages and unfortunately I have seen the effects of many of these diseases there. I am certainly aware of the potential for adverse reactions to our current vaccines but we must maintain the perspective that these reactions are extremely rare.

My partners and I in Winston-Salem care for over 40,000 patients, and I can honestly say that in over 20 years of practice, we have never seen a serious adverse reaction to any vaccine. I believe that the vast majority of family physicians around the country can say the same. Certainly I do not wish to minimize the suffering and losses of families who have experienced these problems, but we must remember that immunizations remain the most powerful and cost-effective means of preventing disease in the modern era.

Personally, it still sickens me to know that the disease that my daughter has was completely preventable if hepatitis B vaccines had been available to Annie and her mother. Whereas 90 percent of adults who contract hepatitis B get better, 90 percent of children under the age of 1 go on to have chronic disease and 15 to 20 percent of them die prematurely of cirrhosis or liver cancer.

I know first-hand the gut-wrenching feeling of being told your child has a chronic disease that could shorten their life. I know first-hand the worry parents feel when their hepatitis B child falls on the playground and you don't know if her

bleeding knee or bloody nose will infect her playmates or teachers. Our kids are all over this country. They play with your kids in preschool. They date your kids in high school. I know first-hand the concern for my other children's health with a 1 in 20 chance of household spread of hepatitis and the thankfulness I feel that they have had the availability of successful vaccines. I know first-hand the pain a parent feels for their child as they undergo painful shots and procedures for their chronic disease with no guarantee of cure.

I am not the world's leading expert on hepatitis B or the hep B vaccine, but I am an expert on delivering the best medical care I can to my patients in Winston-Salem, NC. I am also not the world's leading expert on parenting children with chronic diseases, but I am the world's best expert on parenting my five children.

I know professionally that immunizations in general have hugely improved the lives of those patients who have entrusted their medical care to me. I know personally that had the hepatitis B vaccine been available to my daughter, her life and mine would have been drastically different. I am also thankful that my other children have been spared Annie's suffering by being successfully vaccinated.

Anecdotes of vaccine reactions are very moving, but they are no substitute for good science. Please allow me to continue to provide the best medical care I can with the best system of vaccinations in the world and allow me to keep my own family safe. Thank you very much.

[The prepared statement of Dr. Van Zandt follows:]

[GRAPHIC] [TIFF OMITTED] T2560.188

[GRAPHIC] [TIFF OMITTED] T2560.189

Mr. Burton. Thank you, Dr. Van Zandt. I hope that the impression has not been given that anybody on this committee thinks vaccinations aren't important. I think we all agree that they are. The question is, are all of them absolutely necessary and are there things that can be done to make sure that they are necessary?

In your particular case, you adopted a child where they probably didn't have available to them on a regular basis those kinds of vaccines. I mean Romania has had some difficult times and had some very unfortunate situations, but I just talked to a family where, and I won't identify them because the lady did not want anyone to know she has hepatitis B, but she had hepatitis B and she came to the United States and married and her child was born with hepatitis B.

Had she been tested for hepatitis B during her pregnancy, it would have been very clear that the child should get a hepatitis B shot to prevent hepatitis. As I understand it, hepatitis B is spread through blood or from birth through the mother, or from needles, or from sexual contact. That being the case, it seems to me that if there are side effects to hepatitis B shots, as I believe there are because my granddaughter almost died--I think you heard that in my comments--then it seems to me that one of the first lines of

defense would be to test every pregnant woman while she is pregnant to see if she has the hepatitis B virus.

Mr. Van Zandt. We do that.

Mr. Burton. Well, this woman was not tested when she was pregnant. The hospital evidently neglected to do that.

If the mother doesn't have hepatitis B, then it may or may not be necessary for that child to have the hepatitis B vaccine and that I think should be something that parents should be aware of, especially if there are side effects. Now this is just my own opinion. I am not a scientist or a doctor, but I have talked to a lot of people who feel the same way I do who do have this expertise.

If you would like to comment, I would be happy to have you----

Mr. Van Zandt. If I could respond to that, we have heard earlier today that 40 percent of the cases of hepatitis B there is no identifiable cause, no identifiable risk factor.

Mr. Burton. About 25 percent I think.

Mr. Van Zandt. It varies. I have read different, but nonetheless like I said I will defer to my CDC colleagues on that. The problem is that children with infectious diseases are out there. They often are totally asymptomatic. We don't know that they have these infectious diseases and that puts the population at risk.

We cannot simply target those populations that we think are prone to the disease and only gear our immunizations toward them. We tried that with hepatitis B in the past with adolescents. We tried to simply immunize adolescents. It didn't work.

Mr. Burton. Let me ask you this question----

Mr. Van Zandt. We got dismal immunization rates by doing that and it didn't work and we moved back to the infancy time.

Mr. Burton. May I ask you a question?

Mr. Van Zandt. Sure.

Mr. Burton. This lady's child died and it is believed by the coroner that it was caused by the hepatitis B shot, because we called the coroner this week, did we not? We called the coroner and asked him.

My granddaughter, within 12 hours of the hepatitis B shot, wasn't breathing. She was in a hospital, turned blue, and they thought she was going to die. She had to go on oxygen and she did survive, thank goodness.

What do you say to the two of us?

Mr. Van Zandt. Certainly I can't speak specifically to the cases. That would be unfair to you and to me. I don't have the details.

What I can say is that the system of vaccinations we have in this country works well. My personal experience is all I can speak to on that. The experience of my partners in Winston-Salem is all I can speak to on that. The reaction rates are rare. We rarely see them. There may be associations between the timing of the shot and diseases that develop. I think we need more data and more information to truly determine whether there is a cause-effect relationship or simply an association between those two and that is a big difference.

Mr. Burton. Well, I agree with that and I think those are

things that the Surgeon General and CDC and the FDA and everybody else ought to get on with as quickly as possible because vaccinations are absolutely necessary. But if vaccinations are causing autism, like in my grandson, or almost killing someone, like my granddaughter, or killing these people's child, then I think that it ought to be found out so that we can make corrections.

Mr. Van Zandt. Absolutely.

Mr. Burton. We agree.

Mr. Van Zandt. We are all on the same page. I think that we don't want to throw out the whole system based on that, however.

Mr. Burton. Ms. Spaith, did your supervisor get those shots?

Ms. Spaith. No, sir, he didn't.

Mr. Burton. He did not?

Ms. Spaith. No, sir, he did not.

Mr. Burton. Why did he ask you to get those shots?

Ms. Spaith. Because I travel to Russia to dangerous sites, as he does, and my second level supervisor and other people in the office do.

Mr. Burton. And they didn't get the shots?

Ms. Spaith. No, sir, they did not. They said they didn't have time.

Mr. Burton. So you were the only one and you ended up being the guinea pig?

Ms. Spaith. Yes, sir.

Mr. Burton. Let's see. Mrs. Cole, if a child is immuno-suppressed, could they be vaccinated?

Ms. Cole. They hold off on that with the live virus vaccines. There are children who can't be vaccinated because of a drug they are on or a disease they have and that is why it is important that the rest of the population be protected so they are not exposed to it.

There could be four or five children in one classroom in a school that haven't been able to be vaccinated because their immune system is down a little, not enough to make them obviously ill, but down, and anything they are exposed to in that room could really, really harm them and as in my son's case, kill them.

Mr. Burton. Mr. Waxman.

Mr. Waxman. Thank you, Mr. Chairman, I regret that I wasn't able to be here to listen to all the oral presentations, but we do have written testimony and I thank all the witnesses for being here, and I know it is not easy to come before Congress and share your personal loss and pain.

Dr. Van Zandt, how has contracting hepatitis B affected your daughter's current health and future health, and will she be more susceptible to diseases of the liver?

Dr. Van Zandt. This is unknown at this time. She did respond fairly well to the Interferon shots we gave her. Her viral titers, which is how we measure that, are undetectable at the present time. The problem is we never know. She fell several months ago and split her forehead, like anybody, parents have had children that do that, and with blood all over the floor, my first thought was hepatitis B. Not will she scar,

or will we need to clean the rug? It was hepatitis B and who is at risk, and who will be at risk for that. If it had happened at school, without universal precautions being performed, I don't know.

Mr. Waxman. Some physicians have stated that hepatitis B is more a disease of sexual behavior and drug needle use and that it is unethical to mandate the vaccine for school children. Do you agree with that sentiment?

Dr. Van Zandt. I think those are two mutually exclusive sentences. I believe that it is more likely to be related to sexual patterns and IV drug abuse, but to say that it is morally unethical to vaccinate against it, I don't get the connection on those. Certainly, the higher risk population groups of sexual activity and IV drug abuse do have a higher incidence of hepatitis B.

What I am here to tell us is that our kids are out there with hepatitis B and they may be completely asymptomatic. You don't know it, and they are at risk, or there is a risk of them transmitting the disease. Because of that, I feel that the vaccinations--it is morally unethical not to vaccinate in that sense, to protect the public health.

Mr. Waxman. As a family physician, what do you tell your patients about the risk of possible adverse effects of immunizations?

Dr. Van Zandt. We use the CDC's vaccine information sheet to get out to every parent. The tough part about that, as many people on this panel will say, is that it has information that may or may not be really relevant and comprehensible to what can happen.

We know there are serious adverse reactions, and to counsel accordingly is appropriate. But it is also very important to counsel the risk of not getting the vaccine and the risk of having an infectious disease, and what that can do to your life.

Mr. Waxman. As a scientist, have you heard of any work that would show that there may be a connection between immunizations and autism?

Dr. Van Zandt. I am not aware of that, but, again, I am a practicing physician, not a research physician.

Mr. Waxman. I just don't know if there is something in the scientific literature. You know, I must say that I hear there is an increase in autism. I hear there is an increase in dyslexia and learning deficiencies. Maybe in the latter it may be more of an ability to discern these problems.

It is frustrating to think that we may be causing all these terrible things happening to our children, and we don't know if it is environmental. Just yesterday, the EPA started to deal with the problems of pesticide residues in foods that we know from the Institute of Medicine adversely affect children more than adults. We don't know what other things we are being subjected to.

Whenever many of us try to fight for environmental protections, we get all the industry groups coming in and saying, oh, it can't be us, we are fine. But you wonder with all the information that comes out, in dribs and drabs sometimes, what we are going to learn later on, whether it is

immunization. If it is immunizations, if it is chemicals in our food, if it is toxic substances in the air, in the water, we, as a society, have got to understand what is happening and try to protect people, particularly children.

Mrs. Cole, many parents are not aware that chicken pox can be fatal. How have you been able to educate others about chicken pox and the need for vaccines? Have you taken that on to talk to folks about?

Ms. Cole. I worked more or less as a mom through FDA to get warning labels put on all cortico-steroids about their dangers, potential danger with chicken pox and measles. Chris has been gone for 11 years. I worked for 7\1/2\ years through letters and phone campaigns to see the vaccine for chicken pox licensed by the FDA.

I went to FDA twice and spoke before two FDA Advisory Committees about my experience with chicken pox. I listened to what they had to say about the vaccine, and there were many, many articles written about Christopher, because chicken pox being fatal is something not many people ever hear about. Most people think, OK, I can expose my children on purpose and it is better for them, but they don't realize that it can be dangerous.

Yes, I have worked for a long time to try to educate the public as to the facts. It is not just immuno-suppressed children or individuals that can have a problem with chicken pox. From what I understand, and this may have changed, about half of the people that die each year of the varicella virus are not immuno-suppressed, they are healthy, normal people.

Mr. Burton. Thank you very much.

Mr. Weldon. I have seen that. I had a 21 year old come in. He acquired--actually, he was about 25, acquired it from his child who ended up passing away. So it is a mistaken notion that chicken pox is a harmless disease. Occasionally, it can be fatal.

I want to thank each and every one of you for coming. I guess the question that I would have, and maybe I can start with you, Mr. Rollens, what do you think we should be doing? I have a constituent in my congressional district who believes that his son became autistic in response to the MMR. You provided testimony that you thought in your particular situation it could have been the DPT and the MMR might have made it worse.

We have testimony from the people sitting next to you about the devastating effects of the lack of immunization for some of these diseases. There are epidemiologists who have come into my office and explained to me the tremendous impact that it could have on our population if there was a large scale rejection of these immunizations on the part of parents, if we were to have outbreaks of these clearly preventable diseases.

I would be very interested to hear comments from the other panelists. What do you recommend we do as policymakers? You know, we are here to pose the tough questions and get the answers. But then after all the talking is done, where do we go from here? Your thoughts?

Mr. Rollens. Yes, sir. The first thing that needs to be done is to stop politicizing this issue. There isn't anyone

sitting in this room who is in favor of infectious diseases, and everyone is in favor of eradicating infectious diseases. So I think it is an issue that, unfortunately, those sometimes on both sides tend to politicize to make either pro-vaccine or anti-vaccine. I don't think that is the case at all.

I know the parents that I deal with in the world of autism around the country and around the world, all are conscientious parents who want the very best for their children. They don't want their children to pass away from any infectious disease. They want to provide the very best they can for their kids.

What we are asking, and what I am asking particularly from you is that before we deal with bringing new vaccines onto the market, and before we decide to mix such potent chemicals and potent viral and bacterial agents together, that independent safety studies be done about their effects.

And when I say independent, I mean devoid of the public health community's involvement. It is a conflict of interest to have the CDC, the NIH or anyone else who is involved with the promotion of vaccines to be telling us if they are safe or not. Like I said before, it is like asking the oil industry to come in and tell you that there is no relationship between smoking and lung cancer. It is ludicrous to have these people who are in charge of promoting this policy to be telling you if they are safe or not.

We have able immunologists, virologists, and neurologists around this country and around this world who are very able to look at the science of the interactions and the effects that these vaccines have on a certain percentage of the population.

I would also say that when I keep hearing that it is a rare chance occurrence, or this is a rare effect, I am telling you, as honestly as I can, that I have witnessed in the last 6 years alone, since my son was diagnosed, an explosion of autism, and parents are reporting objective reports, nothing besides the parent's observation of what happened to their children, of this strong temporal relationship between the vaccinations that they received, primarily the DPT, hepatitis B, and MMR, to the onset of their child's autism. The numbers are there. The California Department of Developmental Services has reported two reports within the last year on this epidemic of autism in California.

I challenge you again, when you go home next week to your districts, walk the neighborhoods, talk to the parents, they will tell you what is going on.

Mr. Burton. Thank you. Mr. Rollens, I don't want to belabor this point, but you quoted some statistics from California. I have just instructed Beth here to contact the Departments of Health in California to get that statistical data.

Mr. Rollens. Yes, sir.

Mr. Burton. But we got an e-mail last night from a doctor in Louisiana who said that she has had reported to her over 600 vaccine-related autism cases. So that is Louisiana, it is not California. Have you talked to anybody in other States? I know that you are very involved in this, and I am very interested in it, too, because of the personal problem we have in our family. Have you talked to people in other States to see how pervasive it is?

Mr. Rollens. Yes, I have, and I can speak in volumes to what is happening in California, because I have been very involved in that.

Mr. Burton. Well, tell me about other States that you are conversant with.

Mr. Rollens. Well, this is anecdotal. Once again, there has not been the kind of comprehensive study that was compiled in California in any of the other States. But the U.S. Department of Education has reported increases in every State in reported cases of autism.

What makes the California situation interesting and very significant is that in California we have something called the Lanterman Act, and I am sure Mr. Waxman remembers, in the California legislature, passed in 1969, which is essentially a program that entitles people who are diagnosed with autism, cerebral palsy, mental retardation, and epilepsy to services from the State. In order to qualify for those services, you have to have a diagnosis by the regional centers of our State in order to receive those services.

The report that California came out with last year shows that in the cases of what is known as DSM4-autism, this is full blown autism, not pervasive developmental disorder, or any other autism spectrum disorder, that there was an unexpected huge increase in the numbers of cases coming to the regional centers.

Now, one would say, well, this is an entitlement program, so people are coming for services. That is true. But they don't get those services unless they are diagnosed by a licensed psychologist or a professional person who uses the DSM4 for the criteria to diagnose for autism.

The other issue is that in California we have almost 16,000 children in the Early Start program, this is a program for children ages zero to 3 with developmental delay and language delay, but have yet to receive a diagnosis. When you see development delay and language delay, many people, including myself, feel, and I am sure time will show this, that a number of those children will also be added to the ranks.

The other concern that we have, of course, in California is that in the last 6 months, from January until July of this year, we have added 1,027 new children to our system. On average, six new kids a day, one new child every 4 hours. As you can see from my chart over there, that baseline of 200 new children stayed very steady all the way until the late 1970's, and there was a massive increase that occurred, it broke the 200 new cases a year, and has continued to go up, till today we are adding people at a rate of one child every 4 hours.

Mr. Burton. Let me ask one more question. There is the chart he is talking about Henry. I don't think you saw that earlier. The other thing I would like to ask, and we have some people from the health agencies here, you implied that there might be a vested interest in them not giving information to the Congress and to the country regarding various vaccines. That is a pretty serious allegation. You said we ought to have independent studies from outside. What makes you say that?

Mr. Rollens. Well, first of all,----

Mr. Burton. I mean do you think they are being influenced

by pharmaceutical companies or what is it?

Mr. Rollens. The lack of responsiveness to the call that we have made for years now about this growing problem between the relationship between our children being damaged by vaccines and becoming autistic, and no response, or being literally blown off, that it is a rare chance occurrence that your child has become autistic right around the same time as the vaccine, with absolutely no safety studies to back it up.

I want to see from Dr. Satcher and others where the CDC's safety studies are that tell me as a parent, and as a taxpayer, and as a good person, a father who loves his child, that these vaccines will not cause autism or that my child, most importantly, did not become autistic because of the vaccines that he received.

Mr. Burton. When they come up with a new drug at CDC and FDA, I have talked to them, they say they have to do a double blind study and sometimes more than one before they will attest to the veracity of the particular product. Since they are vaccinating everybody in the country, how do you propose they do a double blind study?

Mr. Rollens. Well, sir, I am not a scientist.

Mr. Burton. No, I am just curious, from your perspective.

Mr. Rollens. Yes. I feel that when someone asked me to turn over the most precious thing in my life to them and trust them that my child would be out of harm's way, that the people that are doing the medical procedure, it is their responsibility. It is not my responsibility as a parent to ensure that every vaccine that I give my child, when I have been told that they are safe by the pediatrician, I have been told by society that there is no such thing, essentially, as an adverse effect.

You know, we are all sitting here with this issue on our minds, but how many parents out there really understand what can possibly happen from the documented research that has been done, and documented cases of adverse vaccine reactions?

Mr. Burton. Thank you very much.

Mr. and Mrs. Nelson, you have come out here and I know you. Let me just ask you, when your child passed away, as I understand it from my daughter, when she talked to you, you called the doctor a number of times telling them of various symptoms, the temperature dropping, wrap her in blankets they said, and so on and so forth, and then, of course, the child, you took her to the hospital and she didn't make it. Can you really quickly tell us what happened, what the initial decision was that was made or what initial analysis was that was made of the death of the child, and what they told you?

Ms. Nelson. In the beginning they told us it would take 2 weeks to get the cause of death back. It was approximately 2 months later we heard from the coroner's office, Dr. Thomas Gill, who told us our daughter died of hepatitis B due to the vaccine. Sixteen weeks later we received the death certificate in the mail stating that she died of natural causes, SIDS. I called to find out how they determined that.

Mr. Burton. Who told you that she died of SIDS?

Ms. Nelson. Dr. Karl Manders, the coroner of Marion County.

Mr. Burton. The coroner of Marion County, Dr. Manders. OK.

Ms. Nelson. He stated that he had read over the autopsy

documentation and that he signed the death certificate due to the fact that Dr. Gill was asked to resign. They filed the autopsy report the day after the autopsy. They did not wait for the toxicology report to come in, which came in 2 months later.

I asked him why he did not go back and check that over. He told me it was already signed. Then recently I have contacted the coroner's office. They refuse to give me her records. They refuse to give me any notes of Dr. Gill's, and they continue to tell me it was SIDS.

Mr. Burton. I want those subpoenaed. We will subpoena those records. We will get those records. We will look into that.

Ms. Nelson. And they refused to tell me Dr. Gill's location, where he was or anything like that.

Mr. Burton. All right.

We talked to the coroner's office and they said it was hepatitis. So, evidently the records do reflect that. So we will check into it.

Ms. Nelson. OK.

Mr. Burton. Do you have any more questions Mr. Waxman?

Mr. Waxman. Yes, Mr. Chairman.

Mr. Rollens, you said that you entrusted the care of your child. People told you there were no such things as adverse reactions, and I think it is a mistake when people are told that there is no risk. As we know, there is some risk.

I know it is frustrating because so many of these people that you are looking at don't see it the way you see it. They don't see the connection. You may be right, they may be wrong.

Mr. Rollens. I hope I am wrong, sir.

Mr. Waxman. But they are people who are scientists, and they are not making any money out of having vaccines out there, and they are certainly not doing a service to anyone if they are not monitoring whether these vaccines are safe. I just want to point out there is an Advisory Commission on Childhood Vaccines and its membership is made up of public representatives as well, and I hope maybe we can look at that commission with you and it would give a sense of comfort that it is not just people who are professionals at the CDC.

But I have to say that I have always had the highest regard for the people at the CDC, and I think they are trying to do the best job they can, and I don't think they have any ulterior motives.

Mr. Chairman, I know there are people here from the NIH and maybe they could tell us, although it is probably unfair to ask anybody to come up and talk about what research is going on in the area of autism. But if we don't have a response now, I would like to hold the record open, ask you if you could hold the record open. I want to know what our Government is doing in terms of autism research.

Mr. Weldon. Would the gentleman yield?

Mr. Waxman. I find what you have said, Mr. Rollens, and others, very, very sobering and of great concern.

Yes, I yield.

Mr. Weldon. I had CDC and NIH in my office on this issue, and there is really quite a bit of research going on. I have already asked them to provide that for the record.

Mr. Waxman. Good.

Mr. Weldon. I will share with you, though, that I think they need to do more, but, in that regard, they will need funding to cover it. I think that I would like to see that ultimately be one of the recommendations that comes out of these hearings is that the Congress of the United States takes initiative and funds more studies on this issue, particularly because I think it is going to be very important to restore public confidence in the system.

Mr. Waxman. Well, I certainly agree with you that we have got to spend more money on this research and try to find out what is causing autism and to try to see if we can find a way to prevent it or cure or control it because it is a very painful situation for everybody involved.

I don't want to say that because we don't have the answer to what causes autism that there is a lack of confidence in the system because science doesn't always give us the answer we want right away. We have got to make a commitment to invest in scientific research so that we can find some answers that can be replicated, can be validated and believed in because it has been scientifically established, not believed in because people want to believe in something, because that is not going to lead us to where we want to go.

So I want to join you in saying that perhaps one of the good results of this hearing might be a commitment that all of us will share to increase the research in this particular area.

I have no other questions and I thank all the witnesses. Thank you, Mr. Chairman.

Mr. Burton. Thank you. I want to thank this panel very, very much, and I think, regardless of what your position is on vaccinations, we all share the heartache that you have gone through. I really feel empathy and sympathy for all of you. Thank you very much for being here.

The next panel is Dr. Kennedy, Dr. Kinsbourne, and Dr. Katz, and I would like for them to come forward at this time, and I apologize to you folks for this panel being so late.

One thing while they are coming up, I would like to say to our friends before you leave from the health agencies, I hope that somebody, if you haven't done this research, if they could look into whether or not all of these vaccinations coming in such a short period of time might cause overload on the immune systems of these children. Maybe the vaccinations, if given over a longer period of time might be less hurtful to the children, and maybe you can give me some information on that.

We heard from the people who just testified that some of them experienced 30 vaccinations by the time their child was 3 or 4 years old. We understand there are 21 different vaccinations they have to get from the time they are born to the time they get into school in many States. I know when we had the old electric system, if you put too much electricity on one fuse, you would blow the fuse, and I know that is an oversimplification of the problem, but it seems to me that might be one of the causal effects of too many vaccines in too short a period of time.

Would you gentlemen please stand?

[Witnesses sworn.]

STATEMENTS OF RONALD C. KENNEDY, PROFESSOR, DEPARTMENT OF MICROBIOLOGY AND IMMUNOLOGY, UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER; SAMUEL L. KATZ, PROFESSOR EMERITUS, DEPARTMENT OF PEDIATRICS, DUKE UNIVERSITY MEDICAL CENTER; AND MARCEL KINSBOURNE, PEDIATRIC NEUROLOGIST

Mr. Burton. We will start with you, Dr. Kennedy.

I apologize for it being so late in the day.

Dr. Kennedy. It's OK. I apologize for putting on these glasses and not being able to see any of the members of the committee anymore.

Mr. Burton. They will all be informed of your testimony. There are a lot of people paying attention across the country. Thank you.

Dr. Kennedy. I would like to take this opportunity to thank you for the invitation to speak to this committee regarding issues related to vaccines, public safety, and personal choice. My name is Ronald Kennedy, and I am a professor of microbiology and immunology and obstetrics and gynecology at the University of Oklahoma Health Sciences Center. I am a research scientist and teach medical and graduate students.

My education has taken me from Connecticut, where I was born, to New Jersey, to Hawaii, where I received my master's and doctoral degrees, Houston and San Antonio, TX, and finally Oklahoma City.

My training is in microbiology and immunology and I have been working in the area of vaccinology since 1981, when I first started working on the immune response to hepatitis B surface antigen, the component of the hepatitis B vaccine.

Since that time I have performed basic and applied research as it relates to a variety of viral, bacterial and cancer vaccination strategies. Included in these efforts were studies to develop and/or improved vaccines to hepatitis B virus, the human immunodeficiency virus, HIV, hepatitis C virus, and simian virus 40, among others a virus that been recently associated with cancer in humans.

Because of my expertise in animal models for infectious diseases, particularly non-human primate models, I've also performed a number of collaborative studies with investigators on vaccines for haemophilus influenza type B, group A and group B streptococcus and meningococcus, among others.

As a number of these infectious diseases cause diseases in newborns and infants, I have become aware of the difference between how newborns respond to vaccination when compared to an adult.

I consider myself pro-vaccine. However, growing up in the field of vaccinology as I have, I am aware of a number of issues and considerations that should be brought forth when it comes to vaccines, public safety, and personal choice.

I would like to briefly mention three issues as it relates to the subject of this hearing.

The first is a lack of a mechanism to study the basis for adverse reactions to vaccines.

The second is, how can we improve vaccine safety, particularly when immunizing infants?

The final issue is that certain vaccines are just not

appropriate and have not been tested well enough to mandate mass vaccination of infants, and this deals with informed consent and the parents' right to personal choice.

Regarding the lack of a mechanism to study the basis for adverse reactions to vaccines, I along with several colleagues have submitted grant applications to the National Institutes of Health to study the basis and mechanism of adverse reactions seen as a result of the hepatitis B vaccine. We made three attempts.

In each attempt the grant application was not considered for funding. The reasons of the peer review panel were the application was descriptive and a fishing expedition. We had compelling evidence but no direct cause and effect, and limited preliminary data.

As someone who has been funded continuously from the National Institutes of Health since 1984 and who has served on grant review panels for the National Institutes of Health since 1987, I was aware that such comments were a kiss of death. More importantly, I did not disagree with the panel's perception of the grant application. However, it was the nature of the subject matter. Since everyone has a perception that vaccines are completely safe, why would they want to study adverse reactions?

If the National Institutes for Health or Centers for Disease Control and Prevention will not support research by investigators outside their institutions into the basic mechanisms of adverse reactions of vaccines that are presently being used to immunize infants, perhaps the pharmaceutical companies who make the vaccines would fund such work by outside investigators. Honestly, I do not think that the vaccine manufacturers would be interested in supporting efforts that might show that their product is harmful.

I would urge you to provide research funds that are currently unavailable to study serious adverse reactions to vaccination such as those seen with hepatitis B.

My second issue is how can we make vaccines safer, particularly in infants? In my opinion, this requires more substantial testing, a requirement that each lot of vaccine be tested in non-human primate models for safety and comparative potency. Many of the present vaccine products have bypassed non-human primate studies and gone directly from rodent studies into human clinical trials. This was based on cost and comparability issues.

Additionally, other vaccines have shown problems in non-human primate models, and these were ignored and the product went into human clinical trials anyway.

It is important to test vaccines in immunologically similar animals and in an outbred population like us, particularly when addressing issues like long-term safety and comparable potency of a given vaccine lot.

My final issue relates to whether certain vaccines are appropriate for infant immunization and whether parents should be informed about the risk versus benefit of vaccination. More importantly, the physician who administers that vaccine is probably not aware there are any risks.

Two specific vaccines come to mind, hepatitis A and

hepatitis B. I will not go into a long-winded scientific process and simply state that the chance of an infant or child getting either hepatitis A or hepatitis B is close to none or nonexistent. When the potential for exposure does exist, those risk factors are easily identified. Even more disturbing is that hepatitis A causes a self-limiting infection and does not cause chronic disease. It is my opinion that parents should be made aware of the risks and benefits of each vaccine where the chance for infection during infancy is minimal to nonexistent.

Certain vaccines, such as the enhanced and inactivated polio, diphtheria, tetanus, acellular pertussis, and the haemophilus influenza type B conjugate vaccines have significantly reduced infant mortality and morbidity and should be considered for infant immunization. However, other vaccines such as hepatitis B may be more effective when given at a later age rather than at birth. Informed consent for vaccines such as hepatitis A and hepatitis B should be considered and parents allowed to choose based on their perceived risk to benefit from vaccinating their infant.

To further illustrate my points, I would like to discuss adverse reactions and the need to support funding activities. The example I am going to pick is the whole cell pertussis vaccine.

This vaccine started for universal immunization of infants in developing nations in the 1940's. The whole cell pertussis vaccine causes frequent systemic symptoms such as irritability, lethargy, loss of appetite, and fever in 72 hours following immunization in up to 50 percent of subjects. More severe reactions include prolonged inconsolable crying, high pitched fever, screaming, fever above 104.9 degrees Fahrenheit, febrile and afebrile seizures, and shock-like states that can last up to 36 hours. In comparable trials, these adverse effects were more common in DTP recipients than in DT vaccinees. This suggested that the pertussis vaccine caused these reactions.

The public believes that the whole cell pertussis vaccine causes brain swelling and permanent neurologic damage and is widespread. However, scientific epidemiologic data to support a casual relationship are said to be inadequate, and this is simply not true.

Why is this the perception? First, there is no support for basic research into adverse reactions. The data on the casual relationship and inadequate nature to show a cause and effect, a lot of the data comes from the vaccine manufacturers. New and improved vaccines should decrease the adverse reactions, and the acellular vaccine is certainly associated with the lower incidence of these reactions.

Will we ever understand the mechanism of how the whole cell vaccine produced these side effects, and is there any association with neurologic problems? This is unlikely, because this has been going on for 50 years, and what research really has been done? My question is, why then is the whole cell vaccine still being used?

Regarding the area of informed consent, I would like to quote from Chapter 17 in a textbook entitled Pediatric Infectious Disease, Principle and Practices. The editors are two pediatric infectious disease specialists. The textbook was

published in 1995 and it is one that I use to teach medical students. In the area of informed consent, I am quoting directly from the book.

Vaccines should be administered only after consent has been obtained from the parent, guardian, or in some cases the vaccine recipient. In the United States informed consent should be in writing and include an explanation of the disease to be prevented, the benefits and risks of immunization and the side effects that parents should look for following immunization.

Relative to requirements, again I am quoting from this chapter.

Every time a public or private health care provider in the United States administers a particular vaccine, it is required to provide a legal representative of a child or any other adult or individual receiving a vaccine a copy of the vaccine informed statement prepared by the CDC. In addition, the names of the patient and parent, the date, site of immunization, dose, manufacturing vaccine lot number, name of person who administers the vaccine, and the place where the vaccine is administered should be recorded. This information is absolutely important if an adverse reaction occurs following immunization.

I think this is part of the problem with the adverse vaccine effects reporting system. Health care providers are not required to obtain the signature of the patient, parent or child's legal representative to acknowledge receipt of the vaccine information statement. This is an absolute must.

I want to thank you for the opportunity to appear before this distinguished committee. I would be happy to answer your questions at the end of the testimony.

Mr. Burton. Thank you, Dr. Kennedy. I will have some questions in just a minute.

Dr. Katz.

[The prepared statement of Dr. Kennedy follows:]

[GRAPHIC] [TIFF OMITTED] T2560.190

[GRAPHIC] [TIFF OMITTED] T2560.191

[GRAPHIC] [TIFF OMITTED] T2560.192

Dr. Katz. Good evening, Mr. Chairman. I am Dr. Samuel L. Katz, a pediatrician involved in immunization research, development, patient care, teaching, and policy for over 40 years. I have served and continue to serve on a number of national and international committees that study, review, and formulate vaccine research and immunization recommendations.

Also, I am a father and grandfather whose eight grandchildren have all received their recommended childhood immunizations. The deliberations and recommendations that come from committees such as this will eventually affect every child and grandchild in the United States, including my own.

Today I am here representing the American Academy of

Pediatrics [AAP], or Academy, and the Infectious Disease Society of America [IDSA].

I want to emphasize and restate three points.

First, our vaccines are highly effective and safe, but the diseases they prevent are still spreading through many other parts of the world.

Second, the system of research and development, of clinical testing, of licensing, of recommendation and monitoring of vaccine use, that system is in place and working well.

Third, there is a need to continue the education of parents and clinicians about diseases they no longer see because these serious diseases have been prevented so effectively by our immunization policies, but they are only a jet plane ride away from our shores.

Immunization is the single intervention that has most dramatically reduced childhood morbidity and mortality in the United States. Immunizations have reduced by almost 99 percent the vaccine-preventable infectious diseases in this country, although once again the causative germs continue to circulate widely elsewhere.

Most young parents cannot appreciate, fortunately, as I do, the horror of polio with iron lungs and crutches; measles with encephalitis; meningitis due to haemophilus influenza B, with death or with crippling or with mental retardation; the deafness, blindness and brain injury that you heard about from Ms. Zitzmann, caused by congenital rubella; tetanus of newborn infants with overwhelming mortality; and a number of the other infectious diseases that we fortunately do not see.

It is true that despite all that vaccines have done to improve the health of individuals and communities in the United States and throughout the world, they are not perfect. However, one simple fact cannot reasonably be disputed--the benefits of immunizations far outweigh any possible risks.

Dr. Satcher pointed out a number of features which I won't reemphasize, but how susceptible unimmunized individuals in a community threaten not just their own well-being, but that of their contacts, whether they are in day care, in school, in various settings where people crowd and gather.

I would just like to remind you of a few anecdotal events. Where were the last big measles outbreaks in older youngsters in this country? In a school for Christian Science college students where there were deaths due to measles because they don't follow immunization. I respect their religious point of view. I only use it as an example.

The last epidemics of polio in this country, where were they? In a boys school in Greenwich, CT, for a religious group who do not practice immunization; among an Amish population in Pennsylvania and several other States because they do not practice immunization.

These are only examples, and there could be many quoted to you. You heard about diphtheria. We've only had one case of diphtheria in this country in the last year. There were over 100,000 in the countries of the former Soviet Union within the last several years. The bacillus of diphtheria hasn't disappeared; we've just protected our population well.

You heard about haemophilus influenza B disease. Over

20,000 cases a year in children under the age of 5, causing meningitis, pneumonia with empyema or other invasive disease. Do you know how many cases there were last year in just the 10-years since we've had that vaccine? 125 cases in contrast to 20,000. Our results are striking and remarkable.

You heard about deaths from varicella. There have been an increasing number of deaths from varicella among children who are not immunized because of the interaction of what you have read about in the newspapers of the ``flesh eating'' streptococci, the group-A streptococci which superinfect youngsters with varicella and can cause death.

The fact that States have inaugurated requirements for school entry are based on trying to prevent these episodes occurring within their own venues. A recent article, which again I believe Dr. Satcher quoted, in the Journal of the American Medical Association pointed out the 35-fold greater risk of contracting measles among unimmunized individuals as compared to those who had been immunized, and that paper also demonstrated that the disease that occurs more commonly in these exemptors has the ability to initiate and propagate an epidemic in the community at large.

Should we allow our community immunity to wane, we will negate all the progress we have made and allow our communities to be at risk from threats that are easily prevented.

Immunization has a clear community benefit in addition to its benefit to the individual patient. An individual's freedom to ignore a stop sign while driving, to pollute the environment, to drive with his child without a car seat or a seat belt, or to spread disease do not serve the public good ultimately. We do place certain restraints on individual freedom because of our belief in the greater social well-being and the community well-being of certain responsibilities.

Ongoing vaccine safety efforts and continuous monitoring of adverse events, be they alleged, potential, or real, are crucial to our Nation's childhood immunization program. As science and resources allow, we are obligated to continue to improve the effectiveness of these safety monitoring measures.

The Academy and the IDSA have seen allegations that a variety of illnesses may be caused by various vaccines. It's easy to understand how a family with a tragedy can believe that a vaccine caused the sudden unexpected death of a child or the appearance of autism or another illness of unknown cause.

We give these vaccines in the first 2 years of life when all of these disorders have their common onset, so that guilt by temporal association is very difficult to separate from guilt by causality. The available scientific data have shown, for example, that with increasing use of hepatitis B vaccine there has been a marked diminution in Sudden Infant Death Syndrome [SIDS] in this country. I don't think the two are related. Don't misunderstand me. Why are we seeing less SIDS? Because we are placing babies on their backs instead of their stomach. The same thing has been observed in the United Kingdom, a remarkable reduction in SIDS, but having nothing to do with more or fewer vaccines.

A robust system of checks and balances exists to monitor the safety and effectiveness of our vaccines, a system that we

strive continuously to perfect. These efforts are designed to ensure that our recommendations about immunization and procedures reflect the best available science. There can be no doubt the public and private sectors and academia continue to be alert and responsive to vaccine safety needs.

The identification of potential safety issues, rapid review, and broad dissemination of interim guidelines demonstrate that we have an early warning system in place, that has the ability to detect and rapidly respond to new information. We must pay attention to this system to assure that it performs to the best of its ability. When any concern about vaccine safety arises, we have the capacity to evaluate the issue scientifically, to act both rapidly and prudently in the interest of what is best for our children, which is our overriding concern.

The role of parents as well as physicians in vaccine safety is paramount. Physicians must regularly update their knowledge about specific vaccines and their use. Information about the safety and efficacy of vaccines and recommendations relative to their administration continue to develop even after a vaccine is licensed.

As pediatricians we know that families are more likely to have their child immunized if they understand the risks and the benefits of immunizations and the consequence of the diseases they prevent. To ensure that parents and other caregivers take advantage of the benefit of immunizations, particularly for preschool children, the AAP and the IDSA recommend public education efforts on the importance of immunization, and that these continue. The Academy provides a variety of easily read patient educational materials for parents, for guardians, for physicians, for nurses, for whomever is involved in the setting.

Mr. Chairman, I greatly appreciate this opportunity to present this statement and will be pleased to answer any questions that you and your colleagues may have.

Thank you.

Mr. Burton. Thank you, Dr. Katz.

Dr. Kinsbourne.

[The prepared statement of Dr. Katz follows:]

[GRAPHIC] [TIFF OMITTED] T2560.193

[GRAPHIC] [TIFF OMITTED] T2560.194

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[GRAPHIC] [TIFF OMITTED] T2560.207

[GRAPHIC] [TIFF OMITTED] T2560.208

[GRAPHIC] [TIFF OMITTED] T2560.209

Dr. Kinsbourne. Thank you, Mr. Chairman. I am Marcel Kinsbourne. I am a neurologist with a special interest in children, and particularly in learning disability, attention deficit, and in developmental disability such as autism.

I have not had the good fortune of Dr. Katz to have any grandchildren, but all four of my children have been vaccinated. One is healthily present with us in this room today.

I would like to talk to you briefly about serious adverse effects of vaccination. Many are known. In some cases we don't know quite whether there are any, and some we have not yet identified.

Briefly, there are three types of vaccines that may cause three types of adverse reactions.

There are those that cause toxic or poisonous reactions. The whole cell pertussis vaccine is the best example of that. That poison may attack a child's brain within hours or a few days of the vaccination. That one issue has been subjected to adequate epidemiological study, unlike almost all the other issues that I will be mentioning.

A second way of being damaged by vaccine is when the vaccine is a live virus, attenuated virus particles made harmless, except not always so harmless, and occasionally the infection that is protected against in fact happens. Polio is an example of that.

Both bacterial and virus vaccines are apt in susceptible people to generate autoimmune disorders. These are disorders where the immune system of the person defends not only against the vaccine itself, but also, as it were, mistakenly against some crucial component of the person's own body, say the nervous system, causing damage which can be severe.

Incidentally, if there is a relation between the MMR vaccine and autism, this may be a mechanism for it to happen, and I totally agree with Mr. Rollens. There has been no approachingly adequate study of this possibility in this country to my knowledge, and I am unaware of any going on now.

It is easy to say do studies; studies are not easy, not at all straightforward. I would like to mention some reasons why

that is.

One reason is that every disorder that a vaccine can cause other causes can also cause. So one has to distinguish the vaccine causation from coincidence. To do that, one has to study epidemio-logically. These studies are expensive; they take a long time. Many have not been done. A report of the Institute of Medicine has stressed how often they could not draw conclusions about whether a particular alleged side effect was due to vaccine or not because the epidemiology has not yet been done.

The second point I would like to stress is that indeed some of these are rare complications. To study those, you have to have large populations. Most studies that have been done don't have adequately sized populations to investigate one way or the other whether a rare complication was due to the vaccine or not. That needs to be done.

The third point is that not all vaccine reactions happen immediately, as in pertussis. In the case of viruses and autoimmune disorders they may take weeks; they may take months to emerge. And most safety studies don't last for weeks and months. What we are left with is passive monitoring which has major weaknesses, which had been alluded to and which we could discuss further.

Yet another problem is that you may have an acute reaction to a vaccine which, however, appears to get better, and the child appears to become normal again. Yet months or years or several years later the child shows cerebral palsy, a learning disability, attention deficit, autism, and the studies have not yet been done to determine whether these were late consequences of those early vaccine reactions or not, and they should be done.

Finally, in my list, and that has been mentioned already by, I think, Dr. Kennedy, vaccine safety tends to be established for individual vaccines, but they are nowadays increasingly often given in combination. That's a new administration, needs new safety studies all on their own, because there is no guarantee that the combined vaccine will only show the adverse effects that each individual constituent shows.

It's my opinion that if studies of the kind I've indicated were done and known to be done and perceived to have been done that this difficulty of balancing the public health against personal choice would be much mitigated.

I would like to briefly add to a point Dr. Kennedy made about informed consent. It is very difficult in a busy pediatric practice for the patient to get access to the doctor or the nurse, to ask proper questions, read the materials, understand them. I would suggest that the information be given to the families well ahead, maybe even when the baby is discharged from the hospital at birth, so they have time to study the materials and ask their questions before they bring the children to the vaccination.

A brief point, sir, has to do with the compensation program. As you very well know, the Congress meant this program to be expeditious, to be generous, and to be non-adversarial. I have extensive experience as a witness in these programs, and I

find them not to be any of those things. I have to say that the special masters who are in charge of adjudicating these matters are, in my opinion, highly competent, compassionate, and courteous.

Nonetheless, it is a lucky person who actually gets their case resolved in 2 years, as was mentioned before. I have many cases in my files that have been around for many more years than that, and to my mind the proceedings are nowadays much more like civil litigation in their rigor than they are in any sense not nonadversarial.

It has also been mentioned that in 1995 there was a change in the regulations relative to the most important, often complained of, vaccine, the pertussis vaccine, making compensation for alleged injury by that vaccine virtually impossible to secure. I think that deserves reviewing.

A final point, sir, is I heard mention of what is called a surplus in the moneys available to compensate victims. I am perplexed at this, because I know that there are many children whose cases are still being adjudicated and many more whose petitions have not yet been filed. They will be filed. And I don't know how anybody could tell that the available moneys are too great relative to the needs of those children.

Thank you very much.

[The prepared statement of Dr. Kinsbourne follows:]

[GRAPHIC] [TIFF OMITTED] T2560.210

[GRAPHIC] [TIFF OMITTED] T2560.211

[GRAPHIC] [TIFF OMITTED] T2560.212

[GRAPHIC] [TIFF OMITTED] T2560.213

Mr. Burton. Thank you, Dr. Kinsbourne.

Dr. Kennedy, you said you submitted an application to NIH for a research grant on the hepatitis B vaccine; is that correct?

Dr. Kennedy. Yes. Myself and a number of other colleagues.

Mr. Burton. You have had grants before? You have done research before?

Dr. Kennedy. Yes, since 1984. In fact I had the early grants on looking at the immune response to the plasma-derived hepatitis B surface antigen.

Mr. Burton. Did they give any reason why they turned your grant request down?

Dr. Kennedy. Yes. Essentially that it was--the term ``fishing expedition'' means that you have a big juicy worm and you are throwing it out there and hoping that someone will bite on it.

Mr. Burton. Do you still have a copy of that grant application?

Dr. Kennedy. Yes. I can provide that.

Mr. Burton. Can you give me a copy of it?

Dr. Kennedy. Certainly can.

Mr. Burton. I would like to have a copy as soon as possible.

Dr. Kennedy. We did two additional revisions on the grant through the process.

Mr. Burton. I want to take a close look at it, if I could.

Dr. Kennedy. OK.

Mr. Burton. Maybe we will have a hearing on that grant application itself and haul the people in here.

Dr. Kennedy. I would rather you not. The process of NIH does work, but I think the problem is the understanding of----

Mr. Burton. Wait just a minute. You say the process does work. How long ago did you submit this grant application?

Dr. Kennedy. 1997. And how we are supporting our present efforts to address these issues relative to adverse reactions are kind of through private funds.

Mr. Burton. I don't mean to interrupt you, but my granddaughter almost died. While your grant application sits there, how many other adverse reactions have occurred like that and how many other parents may have lost their child like the lady that was sitting over there? I think something as important as that should get timely review. So I would like to see your application. You let me worry about what to do with it, OK?

Dr. Kennedy. OK.

Mr. Burton. Dr. Katz, have you had any kids suffer adverse reactions?

Dr. Katz. Yes.

Mr. Burton. What kind?

Dr. Katz. I've had a youngster whose arm got so swollen it ran from his wrist up to his shoulder. I've had children who have developed what apparently were febrile seizures. That is, they got such high fevers that they had a seizure following a previous immunization.

Mr. Burton. Do you have any that were autistic?

Dr. Katz. No. I happen to work in an institution with a neurologist whose life work has been on autism, and he has presented us as well as published in the neurology literature, some as recently as June 1999, his approach to autism, and it has nothing to do with vaccines.

Mr. Burton. I'm sure. The question that I would like to ask is the pertussis vaccine that they were talking about a while ago. If you thought that it caused autism in some children, would you give it to your grandchildren?

Dr. Katz. I think that if I believed it caused autism, I would have severe reservations. I agree with you.

Mr. Burton. That's all I want to know, because there are a lot of people that believe that it does, and I'm one of them. Do you think that people that feel there is a real risk to their loved ones should give that kind of a vaccination or be required to do it?

Dr. Katz. I don't believe that you should labor under the burden of saying I really believe this and I don't want my child to be immunized. I think you have to accept the fact, however, that if your child goes to school or to day care, for example, and there is a case of whooping cough in the school, your child would be banned from school because they are not immunized.

Mr. Burton. Let me ask Dr. Kennedy a question. What did you

say was the percentage of reactions to the pertussis vaccine within the first 48 hours?

Dr. Kennedy. It was within the first 72 hours. Approaching 50 percent.

Mr. Burton. Fifty percent. Just a second. Fifty percent would have an adverse reaction within the first 72 hours?

Dr. Kennedy. I will provide you with the documentation that quotes that.

Mr. Burton. In many cases that is not of long duration.

Dr. Kennedy. Right. Correct.

Mr. Burton. It is something that comes and goes.

Do you have any percentages that show the adverse reaction that is of long duration?

Dr. Kennedy. No, I don't.

Mr. Burton. So we really don't know. You know that there is an adverse reaction that is pretty substantial within the first 72 hours in half of the cases where they give those shots.

Dr. Katz. We haven't used that vaccine for several years, Mr. Burton. I think one of the things that I would love to point out to you is that we do improve. We use the acellular vaccine in this country. The British continue to use the vaccine that Dr. Kennedy has described. We haven't used it for several years in this country.

Mr. Burton. Is the DTP vaccine rather than the DTaP vaccine still being used?

Dr. Katz. The DTaP vaccine is being used, which has an infinitesimal degree of reactivity compared to the DTP.

Mr. Burton. The Department is behind you. Is the DTP vaccine still being used in this country?

Mr. Egan. Yes.

Mr. Burton. It's still being used in this country. So, Dr. Katz, you are incorrect. It is being used in this country.

Dr. Katz. If it is, it's in a very small percentage.

Mr. Burton. It doesn't matter if it's your kid or your grandchild. If they get a DTP vaccine and there is this adverse reaction that Dr. Kennedy is talking about, it's of great concern to people, and we don't know whether it leads to autism or not, but I have an autistic grandchild, and we've had a number of other people that have seen tremendous problems with autism, and they are still using that vaccine. You said you didn't think they were.

Dr. Katz. I said they are still using it in the United Kingdom. They don't use acellular pertussis vaccine.

Mr. Burton. That's the United Kingdom. It's not the United States of America.

Dr. Katz. The World Health Organization is using it throughout the world. We are the only country with the exception of Japan that made the switch.

Mr. Burton. I know, but if it's causing adverse reactions that are so severe that they affect people in the first 72 hours, 50 percent of them, it should be something that is clearly looked into, and if there is any indication it may cause autism, it should be really scrutinized.

Let me yield to the doctor here, and I will come back for some more questions in a moment.

Mr. Weldon. Maybe our friends in the back can answer. I

thought we withdrew all the DPT, the cellular pertussis in the United States. It is still licensed and it is still sold in the United States; is that correct?

Mr. Egan. Yes.

Mr. Weldon. The FDA has never ordered that to be withdrawn? Why was it not ordered to be withdrawn considering the higher incidence of side effects? They felt that the side effects were not sufficiently life-threatening to warrant it's withdrawal? Is that the rationale?

For the record, Mr. Chairman, this pertussis issue is something that I followed through the years, and I thought it was completely off the market. That may be something that we may need to address.

If I may just go a little bit further. Dr. Kinsbourne, I really enjoyed your testimony. You seem to get at a lot of the problems. Some of the issues that you brought up I've had conversations with other scientists and some of the folks that have already testified. The real bottom line issue is that there would have to be very significant funding to get at these issues, because it would require some very large studies that would have to be extended over many, many years, correct?

Dr. Kinsbourne. Yes, sir.

Mr. Weldon. Unless those studies are done, the questions that you were posing are very difficult for us to answer, correct?

Dr. Kinsbourne. Could not be answered until they are done. So the sooner they are started the sooner they will be answered.

Mr. Weldon. The only other point I would like to make, Mr. Chairman, is that if these studies are done, they may show that the vaccines are much safer than is being alleged by some of the people who have provided testimony. Until they are done, the public discontent that exists among some element in our country is not going to go away, and it would be a mistake for us to just take the face value of some who have testified alluding to the fact that all is well. All may not be well, and the responsibility ultimately is going to fall to political leaders in this country to make sure that the proper research is done.

I again want to thank you, Mr. Chairman, for holding these hearings.

Mr. Burton. Thank you, doctor.

Mr. Weldon. Did you want to respond to my comments at all?

Dr. Kinsbourne. Only to agree wholeheartedly. I think even if the public were to see that the work was being done they would comply more willingly with the mandates.

Mr. Weldon. I will share this with you, Dr. Katz. In politics they say perception is reality. If your opponent buys $500,000 worth of TV ads and says that you cheated on your wife even though you have never cheated on your wife, if the end result is that three out of four voters conclude that you cheated on your wife and therefore they should vote against you and you lose your reelection, that is reality. Even if our vaccines are extremely safe, if the perception is growing out there that the vaccines are not safe and people are starting to refuse their vaccinations, then we've got a problem. The way to

address this, though, is we need to better fund the agencies that need to do the research.

Mr. Burton. I think that is a very good point, doctor.

Who manufactures the DTP vaccine?

Dr. Kinsbourne. Lederle.

Dr. Kennedy. Wyeth Lederle Pediatric Vaccines it is now called.

Mr. Burton. Is that the only one that manufactures that?

Dr. Kennedy. No. There are a couple others that make the whole cell pertussis. I don't know it off the top of my head.

Dr. Kinsbourne. Connaught is another company.

Mr. Burton. Those are both domestic companies here in the United States?

Dr. Kinsbourne. I think Connaught is largely Canadian.

Dr. Kennedy. It's Pasteur Merieux Connaught, but they have a manufacturing facility in the United States, in Pennsylvania.

Mr. Burton. You may not know this. I may have to check into this in a later hearing or something. Do you know if they give any funds or grants or honorariums to anybody over at NIH or CDC?

Dr. Katz. No.

Mr. Burton. They do not?

Dr. Katz. No.

Mr. Burton. You're sure about that?

Dr. Katz. I am sure that people at NIH are not allowed to take funds even from universities. If I invite an NIH investigator to give a lecture at Duke, I can't even pay him an honorarium.

Mr. Burton. According to my assistant here, that isn't the case.

Dr. Katz. Maybe you could ask Dr. Rabinovich. She works at NIH.

Mr. Burton. They can accept honorariums, I believe. Can't you?

Dr. Katz. Regina, do you want to respond?

Mr. Burton. Aren't you the general counsel?

Dr. Rabinovich. No. I'm here from the National Institutes of Health. We do receive ethics training, and I've never accepted an honorarium. There may be other situations in which intramural investigators can. We can provide that information for you.

Mr. Burton. I'd like to have that.

Dr. Rabinovich. But I do not.

Mr. Burton. Thank you. I would like to have that information if I could.

I just can't for the life of me fathom why that one vaccine is still on the market and being manufactured and sold here and used in the United States. I just don't understand that.

Can you explain that, Dr. Kennedy?

Dr. Kennedy. I can maybe address the situation relative to the issue of combination vaccines and why it may still be there. There were studies done where they were combining the DTaP vaccine with the haemophilus influenza type B glyco-conjugate vaccine, and a number of studies, both in non-human primate models and in children, suggested that by combining and then giving it at a single site that you would interfere with

the ability to respond to the haemophilus influenza type B [HIB] component, and the interference appeared to be as a result of the acellular components.

They do not know the mechanism. They knew if they took out the acellular component and did a DT/HIB combination, it went fine. If they did the DTaP at one site and then the HIB at the other site, the response was fine. If they did the DTP/HIB, it appeared to be fine from a standpoint of responding to all four of the components.

That could be one of the potential reasons, because some of the first licensed combination vaccines are DTP/HIB, et cetera. It doesn't make sense, but that's----

Mr. Burton. I'm not sure I comprehend if there is that kind of a reaction in 50 percent of the cases in the first 72 hours why it's on the market. I just do not understand that.

Do you have any reason why that would be the case, why they would keep that on the market and continue to use it?

Dr. Kennedy. Yes. If people are not complaining, you can make quite a bit of money. What it comes down to the vaccine manufacturers, it's money if the vaccine has already been produced; its already licensed.

Mr. Burton. I know, but the people sitting behind you are not influenced by these pharmaceutical companies. I'm sure of that. So why would they not insist that it be taken off the market?

Dr. Katz. This vaccine has been used for 40 years in this country and its record of achievement has been a very successful one. What he is describing as 50 percent is sore arms, sore legs, redness, fever. It's not life-threatening reactions. It is more reactive than the acellular vaccine, which is why most people have switched to the acellular vaccine, but these are not life-threatening reactions that have been shown with the whole cell pertussis to be any more than with any other acellular pertussis.

Mr. Burton. These are FDA serious events in 1999. How many are in here, 1,500 or more?

Dr. Kennedy, of these 50 percent of the reactions were any of them pretty severe?

Dr. Kennedy. Yes. Quite a few were more severe, such as the high pitched screaming, the crying, the fever, the shock-like syndrome.

Mr. Burton. Running around and waving their arms and that sort of thing?

Dr. Kennedy. Yes, but the percentage I could not find.

Mr. Burton. I will tell you that is exactly what happened to my grandson. Exactly. He ran around waving his arms, a high pitched scream, waving his arms up and down, and everything else, and he's autistic now.

I'm getting a little emotional about this. I think we will conclude this hearing. But I want to tell you, this isn't the end of it.

We stand adjourned.

[Whereupon at 7:30 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

[GRAPHIC] [TIFF OMITTED] T2560.214

[GRAPHIC] [TIFF OMITTED] T2560.215

[GRAPHIC] [TIFF OMITTED] T2560.216

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