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COMPENSATING VACCINE INJURIES: ARE REFORMS NEEDED?

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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COMPENSATING VACCINE INJURIES: ARE REFORMS NEEDED?

TUESDAY, SEPTEMBER 28, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. John L. Mica (chairman of the subcommittee) presiding.

Present: Representatives Mica, Barr, Mink, Cummings, Kucinich, and Tierney.

Also present: Representatives Burton, Weldon, and Waxman.

Staff present: Sharon Pinkerton, staff director, chief counsel; Steve Dillingham, special counsel; Mason Alinger, professional staff member; Lisa Wandler, clerk; Cherri Branson, minority counsel; Ellen Rayner, minority chief clerk; and Jean Gosa, minority staff assistant.

Mr. MICA. Good morning. I would like to call this meeting of the Subcommittee on Criminal Justice, Drug Policy, and Human Resources to order.

This morning's hearing is entitled, Compensating Vaccine Injuries: Are Reforms Needed? I would like to start with an opening statement, and then we will yield to other Members for the same purpose.

Today, our subcommittee will examine a program that is responsible for one of our Government's most sensitive and difficult responsibilities; the duty to compensate fairly, adequately, and efficiently those individuals who are injured or die as a consequence of our universal vaccination policy.

This policy is designed to protect us. Without a national vaccine policy, many illnesses, including measles, polio, diptheria, tetanus, and typhus, would endanger all of us especially our children. Research into hundreds of new vaccines, which range from lowering cholesterol to curing AIDS, is proceeding at a rapid pace. Our need for new vaccines is an absolute certainty.

This subcommittee recently held a hearing on the international AIDS epidemic and related drug treatments and prevention responses. We learned that vaccine development represents the best long-term solution for preventing millions of AIDS-related deaths. I can assure you that people across the globe are anxiously awaiting an effective vaccine for that deadly illness.

I commend the many researchers and pharmaceutical companies for vaccine successes to date, and I wish them God speed in developing new, safer, and more effective vaccines for the future. I also commend those who help to administer vaccines. They have strong support in Congress for accomplishing these critical missions.

Earlier this year, our subcommittee examined adverse reactions that have been linked to the hepatitis B vaccine. Last month, our full committee examined anthrax vaccines and vaccination practices. Today, we will focus on the workings of the HHS Vaccine Injury Compensation Program that was designed to compensate those individuals who are injured from certain vaccines that we routinely administer to our children.

Despite the life-saving benefits of our national vaccine practices, we must not forget the cost of these benefits, particularly to those individuals and families who regrettably experience tragic adverse reactions. In simple terms, our vaccines now protect millions. However, in some rare instances they cause serious harm, even death, to others.

Today, we will examine how we compensate those who are harmed and consider how we might make the system we have established for this purpose, again, of compensating individuals, work even better.

The issue of compensating vaccine injuries is not a partisan issue. In 1984, my brother, Dan Mica, who was a Democrat Member of Congress, helped work with other Members of Congress in creating an awareness for the need to compensate persons injured from vaccines. Also a leading figure in helping to create compensation for those who received injury was the ranking member of our full committee, Mr. Waxman. He was a key author of the vaccine compensation legislation developed in the eighties.

Our hearing today is devoted to examining the workings of the National Vaccine Injury Compensation Program administered by HHS. Is this program, which was established to be a no-fault compensation program, operating in a quick, easy and fair manner, as was originally envisioned by Congress? Is the fund being administered as required under the law, "with generosity," in keeping with the program's authorization language?

In answering these questions, we will hear first-hand from witnesses who have had experience in the program dealing with injuries particularly to their children. We will also hear from attorneys who represent the injured and from experts who provide medical advice at compensation hearings. Finally, we will discuss program issues with Government witnesses who administer the program.

Recently, we have received many letters, calls, and visits from families of children injured after they were administered vaccines. We also have heard from practicing attorneys, medical professionals, and associations with strong interests in this program.

According to many, the current Compensation Program is not operating fairly or in the way Congress originally intended. I want to learn more about these concerns and some of the problems brought to our attention from both sides and what should be done to correct these problems.

Today, we will hear that our national vaccine practices can have rare but sometimes brutal consequences for those who unfortu-

nately and through no fault of their own, experience severe and sometimes even deadly adverse reactions. We will also examine the serious problems experienced by some who have sought compensation, again, under this system that Congress created.

Today, we will hear more about these concerns and recommendations for our Compensation Program. Some issues that I hope will be addressed today and which may require legislative changes include some of the following: first, is the Compensation Program too adversarial; are eligibility and standard of proof requirements too strict; should we use the compensation fund for other purposes?

To address the first question, why must injured families assume the role of petitioners and often go through a cumbersome adversarial and legal process to get final compensation determination? Legislative history indicates that Congress intended just the opposite. The process was intended to be informal and take no longer than 240 days. Many cases now take years; in some cases, as long as 5, 6, even 9 years to reach a final determination.

Why is this? Why must families hire specialist attorneys to process their claims? Why are attorneys declining in some cases to deal with these cases? Why are attorney fees not being paid until sometimes years afterwards?

Families of the injured must now search for the few medical experts who are willing to testify on their behalf. Should medical witnesses have their professional credibility challenged by skilled Department of Justice attorneys seeking to protect the Government coffers? Must some families devote their life savings, incur huge debt, and experience personal hardship while litigation drags on for years? These problems may or may not be typical, but they do raise the issue of whether reforms and safeguards are needed today.

Other questions I hope we address in this hearing: Should the Department of Justice be reimbursed by injured families for costs of unsuccessful litigation in the Federal Circuit Court? Should the Government favor and facilitate mediation in place of litigation? Do we, in fact, victimize again families that have already suffered terrible harm through what has turned into an adversarial process?

I wish to learn more about this today from the Government, from the families, from their attorneys, and from the medical experts who we have assembled as witnesses.

The second concern I would like to address is whether eligibility and standard of proof requirements are too strict. Program participants have told our subcommittee that the vaccine injury table, the key to deciding claims, is unnecessarily restrictive. In fact, since 1986, HHS has restricted coverage dramatically through changes to the injury table. Were the changes always consistent with medical research, and were they necessary?

I realize that some will argue that the changes reflect sound science, which we all support. However, that the table was not designed to reflect only studies with conclusive proof of likely injury cases, conditions, or time requirements. The table also reflects compensation policy. I understand that judges in the Federal Circuit Court have raised the issue in a pending case as to the constitutionality of giving the HHS Secretary authority to revise the injury table.

What will DOJ and HHS do if the court rules against HHS and the revised table? Will the court stop the program? What would happen to claims that were denied? I think there are many unanswered questions here, and I hope that we can learn about some of these problems and solutions from our witnesses.

In summary, I think some very serious programmatic and legal issues have been raised that need to be resolved. A key issue is the injury table. Congress designed the original injury table with sort of a cushion that included injuries where the science was unclear. Although some research has occurred since then, much uncertainty remains as to the causes of many childhood illnesses.

Families and others have expressed skepticism about relying on a rigid chart that has been significantly tightened by HHS. Perhaps the criteria and the spirit of the original table should be preserved. Considering the incompleteness of vaccine injury research, I can understand their concerns.

Also, the standard of proof requirements may need to be reexamined. For example, a claimant's burden might be one of simply demonstrating that the vaccine was related to the injury. The Department of Justice could be required to show by clear and convincing evidence that the injury resulted from something else in order to defeat the claim.

These are types of simple changes that should be explored to ensure fairness under circumstances where everyone agrees the science is incomplete and regretfully will remain incomplete for many years to come. We must all recognize that the standards of proof that are applied in compensation determinations are legal in nature and not scientific.

Finally, I realize that the Federal Government has other benefit programs, such as those for veterans and law enforcement officials, which provide that the benefit of the doubt goes to the injured in resolving benefit claims. Why does this program provide no benefit of the doubt for injured children?

The third aspect I would like to address is whether we should be using the compensation fund for other purposes. Recent proposals call for using the injury compensation fund for other purposes, including research and administrative expenses. While hundreds of potential vaccines are being developed and concerns have been raised about restrictions in the injury table, it does not seem to me that it is now the time to reduce the vaccine tax or to raid the trust fund. The current tax of 75 cents per dose is not exorbitant, and the cushion in the fund may only be temporary.

Who can accurately predict what new vaccines and groups of injured persons will need to be covered in the future? I urge caution before using the trust moneys to fund immediate or less compelling needs. If the fund continues to grow over time, we might consider changes.

In terms of vaccine tax reduction, I think we should first consider redirecting or eliminating that portion of the vaccine tax, 25 percent, that goes into the general fund. Then we might consider use of moneys in the trust fund.

Finally, there is the issue of a possible conflict that exists in having the Compensation Program as part of HHS. HHS conducts and encourages vaccine research and promotes vaccination policies and

programs. Concerns of possible conflicts increase when considering the Advisory Commission that oversees the Compensation Program. Should the commission use HHS staff? Should HHS override commission recommendations?

I look forward to hearing from our witnesses today on these and other issues. I extend my sincere thanks to those who have traveled long distances at great personal sacrifice to be with us and provide testimony. We sincerely appreciate your willingness to share your thoughts, your concerns and your recommendations on these important issues.

[The prepared statement of Hon. John L. Mica follows:]

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BERNARD SANDERS, VERMONT,
INDEPENDENT

"Compensating Vaccine Injuries: Are Reforms Needed?"

Opening Statement of Chairman John L. Mica
Subcommittee on Criminal Justice, Drug Policy and Human Resources
September 28, 1999

Today, this Subcommittee will examine a government program that is responsible for one of government's most sensitive and difficult duties. This is the duty to compensate fairly, adequately and efficiently those individuals who are injured or die as a consequence of our universal vaccination policy. This policy is designed to protect us. Without a national vaccine policy, many illnesses -- including Measles, Polio, Diptheria, Tetanus and Typhus -- would endanger us all, especially our children.

Research into hundreds of new vaccines -- which range from lowering cholesterol to curing AIDS -- is proceeding at a rapid pace. Our need for new vaccines is certain. This Subcommittee recently held a hearing on the international AIDS epidemic, and related drug treatments and prevention responses. We learned that vaccine development represents the best long-term solution for preventing millions of AIDS-related deaths. I can assure you that countries across the globe are anxiously awaiting an effective vaccine for that deadly illness.

I commend the many researchers and pharmaceutical companies for vaccine successes to date -- and I wish them God Speed in developing new, safer and more effective vaccines for the future. I also commend those who help to administer vaccines. They have strong support in Congress for accomplishing these critical missions.

Earlier this year, this Subcommittee examined adverse reactions that have been linked to Hepatitis B vaccines. Last month, the Full Committee examined Anthrax vaccines and vaccination practices. Today, we will focus on the workings of the HHS Vaccine Injury Compensation Program that was designed to compensate those who are injured from certain vaccines that we routinely administer to our children. Despite the life-saving benefits of our national vaccine practices, we must not forget the cost of these benefits to those individuals and families who, regretfully, experience tragic adverse reactions.

In simple terms, our vaccines now protect millions, however in some rare instances, they cause serious harm, even death, to others. Today we will examine how we compensate those who are harmed, and consider how we might do a better job of it.

The issue of compensating vaccine injuries is not a partisan one. In 1984, my brother, Dan Mica, while serving as a Democratic member of the House, helped to create awareness for the need to compensate persons injured from vaccines. Also leading the effort was the Ranking Member of our Full Committee, Mr. Waxman, who was a key author of vaccine compensation legislation.

Our hearing today is devoted to examining the workings of the National Vaccine Injury Compensation Program administered by HHS. Is this program -- which was established to be a "no-fault" compensation program -- operating in a quick, easy and fair manner, as was originally envisioned by Congress? Is the Fund being administered "with generosity", in keeping with the Program's authorization language?

In answering this question, we will hear first-hand from witnesses who have experience in the program because of injuries to their children. We also will hear from attorneys who represent the injured, and from

experts who provide medical advice at compensation hearings. Finally, we will discuss program issues with government witnesses who administer the program.

Recently, we have received many letters, calls and visits from the families of children injured after they were administered vaccines. We also have heard from practicing attorneys, medical professionals, and associations with strong interests in this program. According to many, the current compensation program is not operating fairly, or in the way that Congress originally intended. I want to learn more about these concerns, from both sides, and what should be done about them.

In order to understand this program and provide some context, we will watch a short video on the topic of vaccine injuries and compensation. Let us now watch a CNBC news segment -- "A Shot In The Dark?" which aired on August 27, 1999.

This video illustrates how our national vaccine practices can have rare but brutal consequences for those who, unfortunately and through no fault of their own, experience severe and even deadly adverse reactions. It also highlights the serious concerns of some who have sought compensation.

Today, we will hear more about these concerns and recommendations for reforming the compensation program. Some concerns that I hope will be addressed today, and which may require legislative changes, include the following:

Is the Compensation Program too adversarial?
Are eligibility and standard of proof requirements too strict?
Should we raid the Compensation Fund for other purposes?

To address the first question, why must injured families assume the role of "petitioners" and often go through a cumbersome and adversarial legal process to get a final compensation determination? Legislative history indicates that Congress intended just the opposite. The process was intended to be informal and to take no longer than 240 days. Many cases now take years, in some cases as long as five, six, or even nine years to reach a final determination. Why is this? Why must families hire specialist attorneys to process their claims? Why are attorneys declining these cases? Why are attorney fees not being paid until years later in some instances?

Families of the injured must now search for the few medical experts who are willing to testify on their behalf. Should medical witnesses have their professional credibility challenged by skilled DOJ attorneys, seeking to protect the government's coffers? Must some families devote their life savings, incur huge debt and experience personal hardships while litigation drags on for years? These problems may or may not be typical, but they do raise the issue of whether reforms and safeguards are needed.

Other questions I hope that we address include: Should DOJ be reimbursed by injured families for costs of unsuccessful litigation in the Federal Circuit Court? Should the government favor and facilitate mediation in place of litigation? Do we in fact victimize again, through an adversarial process, families that have already suffered terrible harms? I wish to learn more about this today, from the government, families and their attorneys, and medical experts.

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Program participants have told our Subcommittee that the Vaccine Injury Table -- the key to deciding claims -- is unnecessarily restrictive. In fact, since 1986, HHS has restricted coverage dramatically through changes to the Injury Table.

Were the changes always consistent with medical research and were they necessary? I realize that some will argue that the changes reflect "sound science" which we all support. However, I understand that the Table was not designed to reflect only studies with conclusive proof of likely injury causes, conditions or time requirements. The Table also reflects compensation policy.

I also understand that judges in the Federal Circuit Court have raised the issue in a pending case as to the constitutionality of giving the HHS Secretary authority to revise the Injury Table. What will DOJ and HHS do if the court rules against HHS and the revised Table? Will the Court stop the program? What would happen

to claims that were denied? I think there are many unanswered questions here, and I hope to learn more about them from our witnesses.

In sum, I think some very serious programmatic and legal issues have been raised that need to be resolved. A key issue is the Injury Table. Congress designed the original Injury Table with a sort of "cushion" that included injuries where the science was unclear. Although some research has occurred since then, much uncertainty remains as to the causes of many childhood illnesses.

Families and others have expressed skepticism about relying upon a rigid chart that has been significantly tightened by HHS. Perhaps the criteria and spirit of the original Injury Table should be preserved. Considering the incompleteness of vaccine injury research, I can understand their concerns.

Also, the standard of proof requirements may need to be reexamined. For example, a claimant's burden might be one of simply demonstrating that the vaccine was related to the injury. DOJ could be required to show by "clear and convincing evidence" that the injury resulted from something else in order to defeat the claim. These are the types of simple changes that should be explored to ensure fairness under circumstances where everyone agrees the science is incomplete and, regretfully, will remain incomplete for years to come. We must all recognize that the "standards of proof" that are applied in compensation determinations are legal in nature, not scientific.

Finally, I realize that the Federal government has other benefit programs, such as those for veterans and law enforcement officials, which provide that the "benefit of the doubt" goes to the injured in resolving benefit claims. Why does this program provide no "benefit of the doubt" for injured children?

The third aspect I would like to address is whether we should be raiding the Compensation Fund for other purposes.

Recent proposals call for using the injury compensation fund for other purposes, including research and administrative expenses. While hundreds of potential vaccines are being developed and concerns have been raised about restrictions in the Injury Table, it does not seem to me that now is the time to reduce the vaccine tax, or to raid the trust fund. The current tax of 75 cents per dose is not exorbitant, and the cushion in the fund may be temporary. Who can accurately predict what new vaccines and groups of injured persons will need to be covered in the future?

I urge caution before using trust monies to fund immediate and less compelling needs. If the fund continues to grow over time, we might consider changes. In terms of vaccine tax reductions, I think we should first consider redirecting or eliminating that portion of the vaccine tax -- 25% --that goes to the General Fund. Then we might consider monies in the Trust Fund.

Finally, there is the issue of a possible conflict that exists in having the Compensation Program as a part of HHS. HHS conducts and encourages vaccine research, and promotes vaccination policies and programs. Concerns of possible conflicts increase when considering the Advisory Commission that oversees the Compensation Program. Should the Commission use HHS staff? Should HHS override Commission recommendations?

I look forward to hearing from our witnesses today on these and other issues. I extend my sincere thanks to those who have traveled long distances at great personal sacrifice. We sincerely appreciate your willingness to share your thoughts and concerns with us on this critical issue.

Mr. MICA. Now I am pleased to yield—Mrs. Mink, did you want me to yield to Mr. Waxman?

Mrs. MINK. Yes.

Mr. MICA. Mr. Waxman, and I know he has another engagement.

Mr. WAXMAN. Thank you very much, Mr. Chairman, and I want to thank Mrs. Mink for allowing me to go forward first with my opening statement. Unfortunately, I have a conflict. There is another committee meeting at this very same time, so I am going to be bouncing back and forth.

But I did want to be here for the beginning of this hearing to express some of my thoughts. And I, first of all, want to thank you, Mr. Chairman, because it is important for Congress to exercise its oversight responsibilities by evaluating programs to see what changes are needed to improve these programs.

I have a special concern about this issue, because I was the author of the Vaccine Compensation Program in 1986. We enacted this legislation because people were faced with only one alternative and that was to go into court, a very tough alternative. It was clearly adversarial to try to establish sufficient evidence in order to get compensation and then to establish the damages for compensation. It struck us as an inefficient way to compensate people who deserve to be compensated.

The idea was to have a fair and timely, no-fault alternative to litigation for individuals who suffer vaccine-related injuries. The program is charged with using the best available science in developing the table of compensable vaccine injuries, and it was intended to rely on the advice of an Advisory Commission on Childhood Vaccines that was to bring together all the people who have a stake in the system working effectively.

There were three key reasons for creating the Compensation Program. These reasons are a good measure of whether it is working as intended. First, we wanted to compensate children who were injured by vaccines, which society felt were essential to public health. Second, we wanted to give parents confidence that if their child were to be injured by a vaccine, there would be predictable and generous compensation. In the absence of such assurance, immunization rates, we felt, were sure to fall. And, finally, we wanted to prevent manufacturers from abandoning research into safer vaccines, which is what they did in the 1980's when the number of such companies dropped from 20 to just 3.

Now, we as a society want immunizations to be available. We want companies to manufacture these products and to continue to research how to make these products safer. We thought that with this vaccine compensation system, we would be providing that incentive.

I know there had been a long-standing debate over the timeliness of the program and about the scientific proof underlying vaccine injuries listed on the vaccine injury table. We tried to strike an important balance that we thought should have been respected. Victims of vaccine-related injuries are to be compensated. Any lawyer or plaintiff will tell you that the process is less adversarial than litigation, and the CDC reports that immunization rates are at a record high.

But it is clear this program isn't working perfectly. Congress has acted twice to change the program, to make it more no-fault and less adversarial. The administration recently forwarded recommendations for procedural reforms, which I look forward to moving ahead with legislatively. And today's hearing will be helpful in giving us further guidance as to changes that we need to make the system work as we intended.

There have been disputes about the science and epidemiology of vaccine injury. We have always erred on the side of compensating children, if there was a scientific argument that injuries were vaccine related. At least that was always our intent—to err on the side of making sure that we compensated people who were injured.

We have tried to rely on the best available scientific evidence when revising the vaccine injury table. Injuries have been added, and injuries have been removed from that table. But in 13 years, it has never been Congress' rule to second-guess the scientists. It would be a disservice to the public health if we were to start to do that today.

At every hearing held this year concerning vaccines, I have made the point of emphasizing the tremendous public health value of immunizations. More Americans have been saved by vaccines than by any other medical intervention. Across the globe, 2½ million children die every year from childhood diseases. Another 750,000 are crippled by these diseases. But American children are shielded from this death and misery by vaccinations.

I mention these terrible statistics because I know no one on this committee would want to discourage American parents from immunizing their children. But we want to be sure that when there are rare injuries, we want those children to be compensated. That is why we enacted the Childhood Vaccination Compensation Program. It was supposed to be a no-fault, less adversarial, more efficient way of compensating people so that we wouldn't push these cases into the courts.

But we left the door open for people to go to court, because we didn't want them to be precluded from the opportunity to present their case in a court, if the compensation system was not working. I want us to see whether we have accomplished these goals, do what we need to change the system so that we make it fair to everybody involved. It is important that the system work. A child who is hurt should be compensated. The parents of that child who go into that system shouldn't be faced with all the barriers that they have in a court system. I have a strong feeling about this compensation system, and I am hopeful that we can be sure through our oversight that the program is living up to its objectives.

I am going to be able to review the record. Some of you will notice that very few Members are here, but the record is important, and will be available for all of our colleagues and everyone else to evaluate. I will look forward to reviewing the record, if I am not here to receive the testimony so that the totality of the record will give us guidance as to how to accomplish our important goals for this program.

Thank you, Mr. Chairman, for holding the hearing, and I yield back the balance of my time.

Mr. MICA. Thank the ranking member of the full committee for his testimony—actually, for his opening statement, for his leadership on the issue, and authorship of this Compensation Program.

I am now pleased to recognize the chairman of our full Committee on Government Reform, the gentleman from Indiana, Mr. Burton.

Mr. BURTON. Thank you, Mr. Chairman. You can call this my opening statement and my testimony.

I am pleased that you are holding this hearing today on the Vaccine Injury Compensation Program. As part of our ongoing investigation coming out of both this subcommittee and Mr. Shay's subcommittee, and the issues the full committee uncovered, there is much to be concerned about within the Vaccine Program.

No one is suggesting that we do away with vaccines to protect the public at large. However, we also have a responsibility to protect individuals and their families as well. One way of doing that will be to conduct good research in looking at ways to minimize adverse events with vaccines and to develop safer vaccines and to inform parents of small children of possible risks due to side effects.

Now, the chairman said there are rare side effects, and I may be the exception to the rule, but my granddaughter got a hepatitis B shot and within 6 hours she was in the hospital, about to quit breathing, she turned blue, and she was dying—within 6 hours.

My grandson, the only other grandchild I have, had five shots in 1 day. He had been perfectly normal up to the time he was receiving these shots, and now he is autistic. Two out of two—rare?

We had a man testify before the full committee from Oklahoma University who said that 50 percent—he is a scientist, doctor—said that 50 percent of the kids that got the DPT shot had some side effects—50 percent. Rare? Were the parents informed about that? Was my daughter informed about it? For either of her children? Do children really need the hepatitis B shot between the time they are born and 5 years old when hepatitis B can only be communicated through blood, sex, or the mother being infected with it?

Congress as a way of providing compensation—and I want to tell you, we are going to dig into this—the subcommittee or the full committee—until heck won't have it.

I mean, I am telling you, parents and grandparents, and everybody else ought to know the risks of these vaccines. Granted, they help everybody. They help the society. They have kept our incidence of major epidemics down to almost zero. But parents still have the right to know the possible side effects of these vaccines, and it is criminal not to let them know. They should have all the information. Lincoln said, "Let the people know the facts, and the country will be safe." Well, the same thing applies to medicine.

Congress, as a way of providing compensation, enacted the National Vaccine Injury Compensation Program, subtitle 2 of title 21 of the Public Health Service Act, on October 1, 1988. The Compensation Program is administered jointly by the Department of Health and Human Services, U.S. Court of Federal Claims, and the Department of Justice. It was designed as a Federal no-fault system designed to compensate those individuals or families of individuals who have been injured by childhood vaccines.

Now, let me just tell you a little bit about our family, these two grandchildren of mine. Do you know we can't find an attorney to take on this responsibility? This is supposed to be a no-fault system. The chairman of this committee's grandkids are going to have to fight in court to get compensation in a no-fault system. Baloney! And I want to find out if the pharmaceutical companies are behind any of this.

And unfortunately we are hearing heartwrenching stories, too many to discount, that indicate that this no-fault system has become emotionally and financially devastating for families. My staff received a letter just yesterday from a woman whose child died from the vaccine, and the attorney from the Government grilled her on everything from how many compressions she gave her daughter when trying to resuscitate her to what her educational level was. No fault? Her daughter's death certificate stated the death was due to recent DPT and HB vaccines, and she was grilled and grilled and grilled. Why? No fault?

Why must a parent be subjected to grilling by government lawyers who are oftentimes cruel in their questioning, especially when the evidence from the experts clearly states the death is related to a vaccine? This type of behavior from Government lawyers must stop, and we intend to make sure it does stop, if I have to bring everybody from HHS, FDA, and everybody else up here every day. That has to stop, and the people that are in charge of these programs, that has to stop.

If there is a legitimate reason for those people to be compensated, they shouldn't have to go through this. Losing the child—this woman losing this child is enough pain for her. Or seeing your child in an incapacitated state, that is enough pain for them. They don't need to fight this thing out three or four times in court.

The Department tells us that it typically takes 2 years for a family to go through the Compensation Program. However, we are hearing from lawyers and families that the process is often much longer—4 years, 4 years or more for many, and the Department sometimes even suggests to families that they just give up their case. No fault? No fault? This type of attitude is deplorable! How much money is in that program—$1.4 billion, one thousand four hundred million dollars.

As I stated at our August 3 hearing, the committee will continue investigating the various facets of the Vaccine Program, including the Compensation Program until we can be confident that, one, vaccines are safe and effective; two, that there is adequate research in the long-term safety and the interaction between vaccines; three, that all ingredients and fillers in vaccines are safe; four, that families and their attorneys are adequately compensated in a timely fashion; and, five, that the Government is not keeping families from being compensated for injuries and death related to vaccines through administrative changes, through bureaucratic red tape, or through bullying, and, finally, that families are informed of the possible side effects and the risks.

And I also want to find out if people at HHS, FDA, or any of the other Federal health institutes are getting honorariums, free travel, or any other kind of compensation, directly or indirectly, from pharmaceutical companies that have a vested interest in these

things being on the market. And to that end, we have already asked for all the records from the various people in these agencies to check those out.

Parents should have confidence in their Government and their health agencies, and they shouldn't have to fight when their kids are injured by vaccines.

Thank you, Mr. Chairman.

Mr. MICA. Thank the chairman of our full committee for his opening statement and also personal testimony.

I would like to recognize now the ranking member of our subcommittee, the gentlelady from Hawaii, Mrs. Mink.

Mrs. MINK. Thank you, Mr. Chairman, and I thank you for holding today's hearing on the National Vaccine Injury Compensation Program.

And I concur with the statement just made by the chairman of the full committee, Mr. Burton. I think that there are some serious problems in the program and in the way that it is being administered, and I concur that this committee should undertake an extensive examination of the problems.

As the ranking member of this subcommittee, I receive a number of letters from all across the country suggesting the difficulties that people are encountering. Notwithstanding the fact that the assumption was that it was to be a no-fault system of compensation, many of the families affected by the immunization problems have had enormous difficulty in receiving their due process.

The Congress has attempted to make various amendments to the law designed to make it less adversarial, but obviously we have not gone far enough.

Mr. Chairman, in 1991, one of my constituents filed a claim with the program on behalf of her deceased spouse who had died of polio shortly after receiving the Salk oral polio vaccine. The courts ruled against her; she filed an appeal; the court rejected the appeal, because the attorney failed to list objections justifying the appeal. The court did not allow the attorney to amend the appeal or grant an extension to conform with this technical objection. The case was dismissed, and the final irony, Mr. Chairman, is that the petitioner received no compensation for the death of her husband yet the Government paid her attorneys fees.

Mr. Chairman, when we established this program, we envisioned a system in which citizens would be able to file claims without assistance from attorneys. It does not appear that this is the system that we currently have. Virtually all petitioners feel the need to get legal counsel, because the system is so complicated, and the demand for proof and connection between the injury and the vaccination is so immense that the program has been moved into, again, a very adversarial one, far greater than what the Congress intended.

There are several reform proposals that I believe we should examine. The statute of limitations, for one. Adding specific injuries to the table as medical evidence shows that there is a causal link to the vaccine, and that ought to be extended. Allowing compensation for the cost of setting up a guardianship for an injured child, and counseling of the families ought to be included as part of the compensation.

I would caution against proposals to slash the tax rate on the vaccines. This is a program that is, I think, well grounded, and the fact that there is a surplus in the trust fund I do not believe indicates the lack of necessity for the tax that is currently invoked; rather, it is because of the very stringent, conservative manner in which these cases are processed that the trust balance has now grown to over $1 billion.

So, I would hope that the hearings that we shall be conducting in the subcommittee as well as the full committee will underscore the importance of this program, the necessity of rendering it into a true no-fault process, and granting these individuals not only the notice that the chairman of the full committee insists is appropriate but also the compassion and considerate handling of these cases once they have come to the Government's attention.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Patsy T. Mink follows:]

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OPENING STATEMENT
CONGRESSWOMAN PATSY T. MINK (D-HI)
HEARING ON COMPENSATING VACCINE INJURIES
SUBCOMMITTEE ON CRIMINAL JUSTICE, HUMAN RESOURCES & DRUG POLICY
SEPTEMBER 28, 1999
2154 RAYBURN HOUSE OFFICE BUILDING

Mr. Chairman, thank you for holding today's hearing on the National Vaccine Injury Compensation Program. The program was originally established to provide a no-fault system of compensation for people injured by vaccine immunizations.

In 1990, in response to complaints that the program had become too legalistic, Congress passed amendments designed to make the program less adversarial. We are here again today amidst concerns that the program has once again become more concerned with process than it is with people.

Mr. Chairman, in 1991, one of my constituents filed a claim with the program on behalf of her deceased spouse, who had died of polio symptoms shortly after receiving the Salk oral polio vaccine. After the court ruled against her, she instructed her attorney to appeal. The attorney filed the appeal on the last day available. However, the court rejected the appeal because the attorney failed to include a list of objections. The court did not allow the attorney to amend the appeal or grant an extension to conform with this technical requirement. Instead, the case was dismissed. In the final irony, while the petitioner received no compensation for the death of her husband, the government paid her attorney's fees.

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Mr. Chairman, when we established this program, we envisioned a system in which citizens would be able to file claims without assistance from attorneys. It does not appear that this is the system that we currently have. Virtually all petitioners feel the need to get legal counsel, which indicates that the program is more adversarial than Congress intended. I feel that in those rare cases where a vaccine causes harm, the victim should be compensated without a protracted legal battle.

There are several reform proposals we should examine: expanding the statute of limitations for filing petitions; adding specific injuries to the table as medical evidence shows that they are causally linked to a vaccine; and allowing compensation for the costs of setting up a financial guardianship for an injured child or for counseling the family of an injured party.

I would caution against proposals to slash the tax rate on vaccines from 75 cents to 25 cents. First, we must make the program less adversarial and simpler for petitioners to use and then later revisit the issue to see if adjusting the tax rate may be necessary. Likewise, I feel we should avoid spending any of the program surplus funds for non-compensation purposes, such as vaccine research. I do not support a research earmark within the trust fund, as it should remain reserved for the injured parties only.

I hope that this hearing provides some concrete suggestions for how we can make this compensation system "user-friendly". Again, I thank you for holding this hearing and I look forward to hearing today's witnesses.

Mr. MICA. Thank the gentlelady.

Now I'd like to recognize Mr. Barr. Did you have an opening statement? All right.

And we have also been joined by another of our colleagues, Dr. Weldon, the gentleman from Florida. Did you have a comment or opening statement?

Dr. WELDON. Mr. Chairman, I want to thank you for recognizing me. I believe the people who have preceded me have very eloquently explored all the issues that we are needing to deal with here.

I just want to thank you for extending an invitation to allow me to be here as part of this hearing and, as well, the ranking member for concurring. And I am very pleased to see that a bipartisan consensus is drawing to the same conclusion that I have that we need to make changes in the Vaccine Injury Compensation Program; that it is not working the way its authors intended it to work, and, therefore, your timing on this hearing is very critical.

And I yield back. Thank you.

Mr. MICA. I thank the gentleman, and we will have additional statements added to the record, without objection.

We will now proceed with our first panel, and I would like to call forward those witnesses.

The first panel consists of Michele Clements who is a petitioner and mother of an injured child from Milwaukee, WI. The second panelist is Linda Mulhauser, and she is also a petitioner and mother of an injured child, and she is from New York City, NY. And our third panelist is Mr. John Salamone, president of Informed Parents Against VAPP. We have those three witnesses.

This is an investigations panel and oversight subcommittee of Congress. We do swear in our witnesses, so if you would remain standing, raise your right hands.

[Witnesses sworn.]

Mr. MICA. Thank you. Witnesses answered in the affirmative, and I think these three panelists can give us some insight as to their personal experience with the compensation fund. I might say that we try to limit each of our oral witness testimonies to 5 minutes. If you have additional lengthy statements or other documentation you would like to have included as part of the record, I would be glad to do that by unanimous consent.I21We do have a request from Michele Clements, our first panelist, for presentation of I think approximately a 1-minute video. Is that correct?

Ms. CLEMENTS. Correct.

Mr. MICA. Without objection, we will also allow introduction of that video.

I would, with those comments, then, like to recognize Michele Clements, our first panelist.

STATEMENTS OF MICHELE CLEMENTS, PETITIONER AND MOTHER OF INJURED CHILD, MILWAUKEE, WI; LINDA MULHAUSER, PETITIONER AND MOTHER OF INJURED CHILD, NEW YORK, NY; AND JOHN SALAMONE, PRESIDENT, INFORMED PARENTS AGAINST VAPP

Ms. CLEMENTS. Thank you, Chairman Mica and——

Mr. MICA. Did you want to show that first?

Ms. CLEMENTS. Pardon? Yes.

Mr. MICA. OK. Then we will just go ahead and show that video.

[Video.]

Ms. CLEMENTS. I don't hear the sound to it. Basically, this is the beginning of Andrew's day and starting out with his medicines, his feeds, and things like that. And I think all we are going to see is the starting of his feeds.

[Video.]

Ms. CLEMENTS. I do this on average maybe—not maybe, but four times a day, but I also give him medications the same way—through his stomach. So, on average it is about eight times a day I have to feed him or medicate him through his stomach.

Mr. MICA. If you could proceed with your testimony.

Ms. CLEMENTS. OK, thank you.

Mr. MICA. And you might pull that mic as close as you can so we can hear you. Thank you.

Ms. CLEMENTS. OK. Once again, I want to thank you, Chairman Mica and the members of the committee, for allowing me to share my son's life and my life as to what happened after he was vaccinated.

The day I found out that I was pregnant was a great joy. We couldn't wait for his entry into this world. It took us 3 months to pick his name, because it was something we wanted him to be proud of throughout his life. Strong, kingly and manly is the meaning of his name. On January 31, 1992, he entered this world a healthy, beautiful baby boy. We wanted the best for him as we did for our other son, Michael.

We don't allow smoking, drinking or drugs in our home, because we want a safe and healthy environment for our children. We took our sons to the doctor for their well care checkups as scheduled and vaccinated them, because it was the best way to protect them from life threatening illnesses. We didn't know about all the adverse reactions that can come with vaccinating our children.

On August 6, 1992, we were thrown into a world that many experience but few know little about: the horror of what the DPT vaccine can do to some children.

My husband, Scott took 7 month old Drew in for his checkup and the third DPT shot. I asked my husband to make sure the doctor gave Drew a check-up to see that all was well with him before he got his shots. I called Scott from work after the doctor's appointment to find out how Drew was doing. My husband explained that Drew had been sleeping since his shots and I thought, good, because after Drew's second DPT shot he had cried for a very long time.

When I got home from work, Scott told me that Drew had been sleeping most of the day and was still sleeping. Scott went to work and I woke up Drew so he could eat, but he went back to sleep again. When Scott got home from work later that night, he was passing our boys' room when he heard a strange, rasping sound coming from the room. He checked on Mike, who was fine, and then realized that the sound must have come from Andrew's crib.

When he got to Andrew's crib, he had the shock of his life. Our little boy wasn't breathing and he was as pale as a China doll. Scott yelled for me to come and asked me, "What is this?" All I saw

was my baby laying in his father's arms as limp as a rag doll and as white as a China doll. I ran downstairs and grabbed the phone and dialed 911, but I was in such shock that I forgot my address and street name.

Scott followed me and handed me Andrew, and I realized for the first time that my baby wasn't breathing. I did CPR on him, and after the second breath I gave him, he took in a deep breath himself. The color came back into him and he appeared to be sleeping.

The fire department came. Half of the men worked on Drew while the other half followed me to the boys' room. I showed them Andrew's crib and the puddle of fluids we found him lying in. One fire fighter told us that he believed that Drew had had a convulsion. He said Drew was very warm and asked for some ice bags to cool him down. They told us Andrew would have to go to the hospital.

Andrew was transported to the hospital in an ambulance, and by the time he got to the hospital, he was in the middle of another violent convulsion that was so bad they wouldn't let me in the room with him. Finally he stopped convulsing and the doctors explained that this may be the only time he convulses, and it may never happen again.

One month later, he was crawling on the floor when all of a sudden he collapsed and began to jerk his arms and legs while his head went backward and his neck stiffened. I grabbed him and told Scott to call 911, and at the hospital they explained to us again that sometimes children have seizures and they grow out of them.

Between the ages of 6 months and 3½ years old, Andrew had 84 seizures, the shortest being 15 minutes and the longest being 1½ hours. Almost always, Andrew would run an unexplained fever with the seizures even though he wasn't sick. One doctor told me the fevers he ran with his seizures was because his body's thermostat had been damaged, and his body could not regulate his temperature like it should.

Still, with all those seizures, the miracle was that Andrew learned to walk and talk. At 3, he could count up to 20; he knew his colors and shapes. We learned to live with his seizures even though we always lived in fear that 1 day he would have a really long seizure that would damage our bright, loving, intelligent little boy.

On the night of September 8, 1995, our worst nightmare came to life when Andrew went into a seizure that lasted 4½ hours. Standing by helplessly as our son seized for 4½ hours while his temperature climbed to 108.8 degrees is an experience no parent should ever have to go through. When Andrew finally stopped seizing, we were allowed to see him in the ICU. To our horror, we saw a child double the size he was when he came into the hospital. When we asked what happened, they took us out of his room. At 7 a.m., a doctor told us that Andrew's kidneys and liver were failing.

When we finally got to see our son again, he looked like another child. We couldn't hold him, because he had a dozen tubes hanging off of him. A special bed rotated his body, keeping his body at one temperature and massaging him all at the same time.

At 9 a.m., we were told by the doctor—and I will never forget those words—we were told: "Your son is dying, and so that you understand what I am saying, he will die before 12 p.m. If you want to see him alive, you better call anyone who wants to see him now. Here is a phone you can use. Are you OK? Mrs. Clements, are you all right?"

Not knowing what to say, I said "No, not my baby" over and over again. "He didn't go through 84 seizures to die. God has a great use for his life. He didn't bring him through all these seizures to die now."

Every organ in Andrew's body was damaged and was functioning at only 10 percent. Andrew didn't die that day as the doctors said he would. By the grace of God, he hung on to life. On September 11, Andrew slipped into a coma.

Andrew was in the hospital for 4 months while we waited for him to come out of his coma. During that time, I called our lawyer, Victor Harding, to tell him what had happened. Mr. Harding was representing Andrew in the U.S. Court of Claims which hears vaccine injury compensation cases, and he told us that the Government had offered us $350,000 to take care of Andrew.

All I could think of was how unfair it was. My son is fighting for his life. He may die, and if he lives, we don't know what kind of condition he will be in. And the Government is telling us that all Andrew is worth, if he lives, is $350,000. That amount isn't going to begin to be enough to care for a severely brain injured child for the rest of his life. I told our lawyer, "You can tell those Government lawyers where they can file that offer."

As you can see, Andrew did live. He fought bravely to live. Andrew is a hero, and now it is my job as his mother to fight for him to have the best kind of life that I can give him.

Andrew can't walk or talk; he can't eat or drink; he has to be fed through a tube in his stomach. Sometimes we give him tiny tastes of food. I will put a drop of apple sauce or pudding on the tip of my finger and put it on his tongue, but it can't be too much or he could choke because he can't swallow properly. His body is 7 years old but his brain is that of a 3-month old.

I was a good parent. I did what the Government and doctors told me to do, and I gave my son the DPT vaccine. And now he is crippled. His life has been sacrificed, and instead of being treated kindly and fairly by the Government's Vaccine Injury Compensation Program, we have been treated unkindly and unfairly.

You may be wondering how we found out about the Vaccine Compensation Program. It wasn't from anyone in the medical field. We found out from a stranger who had heard about what happened to Drew. Her son died from the DPT vaccine. She referred us to a lawyer and sent us information about the DPT vaccine.

Reading the information, I felt like I had just been transported into another world, a world that I didn't believe could exist in our country where the Government keeps such information from us that could help us protect our children from becoming retarded. I didn't know that when Andrew screamed for hours after his second DPT shot at 4 months that it was a warning sign that shot might not be good for him. I didn't know that in 1992 there was a safer

DPT shot called DtaP vaccine that causes fewer reactions. I wish Andrew had a chance to get the DtaP vaccine instead of the DPT.

When we met with our lawyer, Victor Harding, he told us about applying for the Vaccine Injury Compensation Program and what to expect from the Government. He said that a lot of children like Drew are denied compensation or offered so little money that it wouldn't be enough to take care of him for the rest of his life. Like I said earlier, when my son was on what we thought was his death bed, the Government offered us $350,000. We turned it down and proceeded to the next step.

We had to fly to Washington, DC, for our compensation claim hearing in the winter of 1998. My stomach was full of butterflies when I gave my testimony about what happened to Andrew on the night of August 6, 1992. I stayed for 5 hours of the 10 hour hearing and then went back home to care for my son. My lawyer was there for the second half of the hearing on the following day.

In the end, the Government turned Andrew down for compensation. There would be no money to help us care for our son. The Special Master told us that if we had applied for compensation a year earlier, she would have found in our favor but because of the table change, there was nothing she could do but find in favor of the Government.

That angered me, and it still does anger me that this table can be changed by the Government after Congress put the table in the law to help children like Andrew get compensation. That table change sure wasn't for the betterment of the families who go through horrific life changes due to vaccine injuries. The Government forces us to give our children these vaccines and then when something goes wrong, too bad, you are on your own.

The Special Master told us to appeal, but where is the logic in doing that if the rules are still the same? We will take our chances with the vaccine manufacturer in court. Because if we don't, what is going to happen to Andrew?

The doctors told us Andrew could live to be 25 or even 40 years old. We want to care for him as long as we can. We don't want him to be put into an institution where they won't do for him like we can do for him. To care for him the right way, our home needs to be wheelchair accessible, and we need a lift to get him into a van, and we need to be able to afford to buy all the medications and supplies he needs after he turns 18 years old. We just want enough money to care for him the right way, because no amount of money could ever really compensate Andrew or us for what the DPT shot took from him.

Once again, thank you for listening to what has happened to my son and our family, and God bless you.

[The prepared statement of Ms. Clements follows:]

Testimony of Michelle Clements
Subcommittee on Criminal Justice, Drug Policy and Human Resources
U.S. House Government Reform Committee
September 28, 1999

Chairman Mica and Members of the Committee:

I want to thank you for the opportunity to share my life and the life of my child with you.

The day I found out I was pregnant with my second son, Andrew, was a great joy. We couldn't wait for his entry into this world. It took us three months to pick his name because it was something we wanted him to be proud of throughout his life. "Strong, kingly and manly" is the meaning of his name. On January 31st of 1992, he entered this world a healthy, beautiful baby boy. We wanted the best for him as we did for our other son, Michael.

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One month later, he was crawling on the floor when all of a sudden he collapsed and began to jerk his arms and legs while his head went backwards and his neck stiffened. I grabbed him and told Scott to call 911 and at the hospital they explained to us again that sometimes children have seizures and they grow out of them.

Between the ages of 6 months and three and a half years old, Andrew had 84 seizures, the shortest being 15 minutes and the longest being one and a half hours. Almost always, Andrew would run an unexplained fever with the seizures even though he wasn't sick. One doctor told me the fevers he ran with his seizures was because his body thermostat had been damaged and his body could not regulate his temperature like it should. Still, with all those seizures, the miracle was that Andrew learned to walk and talk. At three, he could count up to 20 and he knew his colors and shapes. We had learned to live with his seizures even though we always lived in fear that one day he would have a really long seizure that would damage our bright, loving, intelligent little boy.

On the night of September 8th of 1995 our worst nightmare came to life when Andrew went into a seizure that lasted four and a half hours. Standing by helplessly as our son seized for four and a half hours while his temperature climbed to 108.8 degrees is an experience no parent should have to go through. When Andrew finally stopped seizing and we were allowed to see him in the ICU, to our horror we saw a child double the size he was when he came into the hospital. When we asked what happened, they took us out of his room. At 7 a.m. in the morning, a doctor told us that Andrew's kidneys and liver were failing.

When we finally got to see our son again, he looked like another child. We couldn't hold him because he had a dozen tubes hanging off him. A special bed rotated his body, keeping his body at one temperature and massaging him at the same time.

At 9 a.m., we were told by the doctor - and I will never forget those words - we were told: "YOUR SON IS DYING AND - SO THAT YOU UNDERSTAND WHAT I AM SAYING - HE WILL DIE BEFORE 12 PM TODAY. If you want to see him alive, you better call anyone who wants to see him now. Here is a phone you can use. Are you OK? Mrs. Clements, are you all right?"

Not knowing what to say, I said "NO, not my baby over and over again. He didn't go through 84 seizures to die. God has a great use for his life. He didn't bring him through all these seizures to die now."

Every organ in Andrew's body was damaged and was functioning at only 10 percent. Andrew didn't die that day as the doctors said he would. By the grace of God, he hung on to life. On September 11, Andrew slipped into a coma.

Andrew was in the hospital for four months while we waited for him to come out of his coma. During that time, I called our lawyer, Victor Harding, to tell him what had happened. Mr. Harding was representing Andrew in the U.S. Court of Claims which hears vaccine injury compensation cases and he told us that the government had offered us $350,000 to take care of Andrew.

All I could think of was how unfair it was. My son is fighting for his life. He may die. If he lives, we don't know what kind of condition he will be in. And the government is telling us that all Andrew is worth - if he lives - is $350,000? That amount isn't going to begin to be enough to care for a severely brain injured child for the rest of his life. I told our lawyer: "You can tell those government lawyers where they can file that offer."

As you can see, Andrew did live. He fought bravely to live. Andrew is a hero. And now it is my job as his mother to fight for him to have the best kind of life that I can give him.

Andrew can't walk or talk. He can't can't eat or drink. He has to be fed through a tube in his stomach. Sometimes we give him tiny tastes of food. I will put a drop of apple sauce or pudding on the tip of my finger and put it on his tongue but it can't be too much or he could choke because he can't swallow. His body is seven years old but his brain is like a 3 month old.

I was a good parent. I did what the government and the doctors told me to do and I gave my son the DPT vaccine. And now he is crippled. His life has been sacrificed. And instead of being treated kindly and fairly by the government's vaccine injury compensation program, we have been treated unkindly and unfairly.

You may be wondering how we found out about the vaccine compensation program. It wasn't from anyone in the medical field. We found out from a stranger who had heard about what happened to Drew. Her son died from the DPT vaccination. She referred us to a lawyer and sent us information about the DPT vaccine.

Reading the information, I felt like I had just been transported into another world: a world that I didn't believe could exist in our country where the government keeps such information from us that could help us protect our children from becoming retarded. I didn't know that when Andrew screamed for hours after his second DPT shot at four months that it was a warning sign that the shot might not be good for him. I didn't know that in 1992 there was a safer DPT shot called DtaP vaccine that causes fewer reactions. I wish Andrew had had a chance to get the DtaP vaccine instead of DPT.

When we met with our lawyer, Victor Harding, he told us about applying to the vaccine injury compensation program and what to expect from the government. He said that a lot of children like Andrew are denied compensation or offered so little money that it wouldn't be enough to take care of him for the rest of his life. Like I said earlier, when my son was on what we thought was his death bed, the government offered us $350,000. We turned it down and proceeded to the next step.

We had to fly to Washington, D.C. for our compensation claim hearing in the winter of 1998. My stomach was full of butterflies when I gave my testimony about what happened to Andrew on the night of August 6th 1992. I stayed for five hours of the 10 hour hearing and then went back home to care for my son. My lawyer was there for the second half of the hearing on the following day.

In the end, the government turned Andrew down for compensation. There would be no money to help us care for our son. The Special Master told us that if we had applied for compensation a year earlier, she would have found in our favor but because of the TABLE CHANGE there was nothing she could do but find in favor of the government.

That angered me and still does anger me that this Table can be changed by the government after Congress put the Table in the law to help children like Andrew get compensation. That Table change sure wasn't for the betterment of the families who go through horrific life changes due to vaccine injuries. The government forces us to give our children these vaccines and then when something goes wrong - too bad- you are on your own.

The Special Master told us to appeal but where is the logic in doing that if the rules are still the same? We will take our chances with the vaccine manufacturer in court.

Because if we don't, what is going to happen to Andrew? The doctors told us Andrew could live to be 25 or even 40 years old. We want to care for him as long as we can. We don't want him to be put in an institution where they won't do for him like we can do for him. To care for him the right way, our home needs to be wheelchair accessible and we need a lift to get him into a van and we need to be able to afford to buy all the medications and supplies he needs after he turns 18 years old. We just want enough money to care for him the right way because no amount of money could ever really compensate Andrew or us for what the DPT shot took from him.

Thank you again for listening to what happened to my son and our family. God bless you.

Mr. MICA. Thank you for your testimony, and I would like to now recognize Linda Mulhauser, who is a petitioner and mother of an injured child from New York.

Mrs. Mulhauser, you are recognized.

Ms. MULHAUSER. Thank you.

My son Stephen is sitting in front of me so that he can do as much lip reading as possible, and I am wearing an FM microphone to help elevate my voice for him. The interpreter was not available for today's meeting.

Chairman Mica and members of the Government Reform Committee, thank you for your invitation to appear at today's hearing to tell of our family's experience with the Vaccine Injury Compensation Program.

Our son, Stephen, now 17 years old, was seriously and permanently injured by a DPT vaccination at 3½ months of age. Born healthy and full-term by natural childbirth, Stephen received the highest Apgar score ratings of 9 and 10. At 7 weeks of age, Stephen received his first DPT vaccine. We were reassured by his pediatrician that the swelling at the injectionsite, among other changes we noted, was only a mild reaction and of no concern.

Following the pediatrician's advice that the benefits outweighed the risks, Stephen was given and reacted severely to his second DPT shot with over 9 hours of high-pitched screaming and high fever.

During the next couple of days, Stephen's eyes began wandering independently of each other and then spasm. He could no longer roll over or reach out to play with his crib gym, because his hands were fisted and held at his shoulders.

Over our concern, Stephen was then given his third dose of DPT vaccine in half doses at 5½ and 6½ months of age. His pediatrician said that he must have this vaccine in order to attend school.

We later discovered during our compensation hearing that from the day of the second shot in 1982, Stephen showed failure to thrive as his charted growth plummeted. Stephen's brain had all but stopped growing during the time period he was receiving his DPT vaccines. He remains affected with fine motor and gross motor difficulties, posturing, language-based learning disabilities, visual perception issues, behavioral problems, and profound bilateral hearing loss. He requires special schooling, assistance with simple daily living skills, constant adult supervision, and numerous therapies.

Having your child injured by a vaccine that is supposed to protect him is devastating. Our experience of going through the compensation system only added insult to that injury. After 5 years of preparation for a civil suit through depositions, ready for trial, our attorneys informed us that they had become obligated to advise us to put a stay on our case and apply for Government compensation prior to a 1990 deadline date. It was supposed to be a simple and expedient process, taking about 18 months, with decisions to be made by special masters without a trial. We were advised that we could go back to the lawsuit if the desired outcome was not reached.

Nine months later, we had our hearing in a New York Federal courtroom, requiring preparation and giving of testimony, including

cross examinations. Expert witnesses were called for both sides. Two months later, the special master determined that Stephen was in fact injured by the DPT vaccine, as described within the guidelines of the vaccine injury table.

Although we considered this first step of the process to have been timely and professionally managed, it seemed only to lack a jury to be a traditional court trial.

The next step of the process was to determine an amount of money to be compensated. We already had a life care plan in place, because we were ready to go to trial before entering the Compensation Program. Instead of working with us to determine Stephen's appropriate life care needs, the Department of Justice's attorneys sought for years to trivialize the extent of Stephen's vaccine injuries and to argue for irresponsibly insufficient funds to support a reasonable quality of life.

After 4 years of such negotiations, we needed to request another hearing to come to settlement requiring further testimony from ourselves and Stephen's life care planner. It was determined on the spot by the chief special master that the life care plan the DOJ's attorney and life care planner submitted was indeed unrealistic and ordered specific actions to be completed within 2 months.

This hearing in and of itself, again, was handled professionally. However, 2 months turned into 4 before an agreement was signed. Further delays ensued to correct a significant math error relative to the initial payment. The agreement was then filed at the end of the 90-day filing period. The stipulation then required that we become legal guardians of our own child, causing further delay before any checks would be issued by the annuity company.

From the time we applied to the Vaccine Injury Compensation System to the time we were finally able to access the funds, 6½ years had gone by. Our savings disappeared as we paid for therapies not covered by our insurance, hearing aids, and special schooling, among other extraordinary expenses. Under the guidelines of the program, families are not reimbursed for any past expenses.

We were very fortunate in that the law firm who represented us continued to fight on Stephen's behalf far beyond any financial gain. In fact, the single payment of $30,000 allocated for attorney's fees in pre-1988 cases only covered the expenses incurred in preparation of our two hearings. The law firm itself received nothing for its efforts of representing Stephen over a 10-year period.

Our attorney has described the hearing process as a "full-out liability case." Once our case was won, he then had an item-by-item fight to obtain even the smallest of needs on Stephen's life care plan. Concessions were only made on small items. Much time was spent by the DOJ attorney forcing the discussion of petty matters, such as whether Stephen would benefit from the use of a $10 special needs doorknob—one was allowed throughout his lifetime—rather than getting down to serious matters dealing with the quality of Stephen's future. Deadlines were often extended.

In our view, the recommendations of the DOJ attorney and Government life care planner assigned to our case were unrealistic and irresponsible. For example, to determine the value of residential care, they specified a residential center only in its planning stages or a charitable group home with no day services and a wait list of

over 1,500 persons. We were given a "take it or leave it" final offer, which still did not adequately address Stephen's needs. This prompted our request for the second hearing, which took place 10 months later.

We entered into negotiations for Stephen's life care with the belief that, unable to support himself, his needs would be met, and his future would be sufficiently secure so that he could live as independent and normal a life as possible. We were mistaken. Our experience was a totally exhausting and extremely adversarial process of nickel and dime arguments.

On the Government's behalf, every effort was made by the DOJ attorney to hold on to as much of the fund as possible. This included an attempt to establish a reversionary trust requiring any moneys not spent during the course of each year to be returned to the Government. Such practices place at risk the future care and security of every vaccine-injured child.

The DOJ attorney continued to act as if he was still fighting a case, attempting to minimize the award which he had previously fought to avoid. This conflict of interest deadlocked negotiations and added years to resolving our settlement. After a decision is given that a child should be compensated, DOJ attorneys should step aside and allow others with input from life care planners and families to determine the projected needs of the individual throughout the balance of their lifetime.

As compensation is not retroactive to the date of the decision, each additional year of bargaining is 1 less year to be compensated. This places further undue hardship on already emotionally and financially strained families. Our perception is that the program relies on this tactic to force families and their attorneys to accept less than adequate settlements, which would provide optimal treatments for their vaccine-injured child. Once the determination has been made that an adverse reaction was incurred, both sides should be working together in the best interest of the child.

The all out effort, time, and expense required to successfully negotiate the Vaccine Injury Compensation Program prompted our major law firm to never accept another vaccine injury case.

We are further concerned that life care plans used to determine settlement amounts are forwarded to annuity or trust companies with the stipulation labels remaining. In our experience, copies of the life care plan have also been requested by courts and banks. A child's needs will inevitably vary. Type or frequency of therapies can and do change. New treatments become available. Labels remaining on life care plans used to determine payment schedules leave open a real risk that at any time someone might withhold funds if moneys aren't spent specifically as tagged. We are extremely uncomfortable that an individual as far removed as a bank clerk can potentially have a say over Stephen's care, because a treatment is not listed on his life care plan.

Every family who has gone through this system faces the same threat to their child's welfare. Might I suggest that such labels be removed in the future before sending out the plan and that a letter be issued to clarify the ability of legal guardians to utilize funds in the most appropriate manner for the injured individual in their care.

As parents, we did everything in our power to provide the love, nurturing, and care to ensure a bright future for our first-born child, a life full of dreams and promise. Part of that care was to protect him from harm and life-threatening diseases. We believed we were protecting our son when we took him for his baby shots. Instead, his life and ours have been changed forever.

Each day is a challenge, and we try to meet that challenge to make things a little better. My hope is that by our presence here, today's challenge will make things better for the many families of vaccine-injured children who are in or who are attempting to enter into the Vaccine Injury Compensation System, and for those who have been rejected by the system following changes to the vaccine injury table.

Thank you for the opportunity to share our experience and to express my concerns.

[The prepared statement of Ms. Mulhauser follows:]

Testimony Submitted to the U.S. House of Representatives
Committee on Government Reform and Oversight
Subcommittee on Criminal Justice, Drug Policy and Human Resources

Chairman: Congressman John L. Mica

Submitted by: Linda Mulhauser

Chairman Mica and Members of the Government Reform Committee:

Thank you for your invitation to appear at today's hearing to tell of our family's experience with the Vaccine Injury Compensation Program. Our son Stephen, now 17 years old, was seriously and permanently injured by a DPT vaccination at three and a half months of age.

Born healthy and full term by natural childbirth, Stephen received the highest Apgar score ratings of 9 and 10. At seven weeks of age, Stephen received his first DPT vaccine. We were reassured by his pediatrician that the swelling at the injection site, among other changes we noted, was only a "mild" reaction and of no concern. Following the pediatrician's advice that "the benefits outweighed the risks", Stephen was given and reacted severely to his second DPT shot with over nine hours of high pitched screaming and high fever.

During the next couple of days, Stephen's eyes began wandering independently of each other and then spasm. He could no longer roll over or reach out to play with his crib gym because his hands were fisted and held at his shoulders.

Over our concerns, Stephen was then given his third dose of DPT vaccine in half doses at 5-1/2 and 6-1/2 months of age. His pediatrician said that he must have this vaccine in order to attend school.

We later discovered during our compensation hearing, that from the day of the second shot in 1982, Stephen showed failure to thrive as his charted growth diminished. Stephen's brain had all but stopped growing during the time period he was receiving his DPT vaccines. He remains affected with fine motor and gross motor difficulties, posturing, language based learning disabilities, visual perception issues, behavioral problems, and profound bilateral hearing loss. He requires special schooling, assistance with simple daily living skills, constant adult supervision, and numerous therapies.

Compensation Program Issues:

Having your child injured by a vaccine that's supposed to protect him is devastating. Our experience of going through the compensation system only added insult to that injury.

After 4 years of preparation for a civil suit, through depositions, ready for trial -- our attorneys informed us that they'd become obligated to advise us to put a 'stay' on our case and apply for government compensation prior to a 1989 deadline date. It was supposed to be a simple and expedient process, taking about 18 months, with decisions to be made by special masters without a trial. We were advised that we could go back to the law suit if a desired outcome was not reached.

Nine months later we had our hearing (in a NY federal court room), requiring preparation and giving of testimony, including cross examinations. Expert witnesses were called for both sides. Two months later, the special master determined that Stephen was in fact injured by the DPT vaccine, as described within the guidelines of the Vaccine Injury Table. Although we consider this first step of the process to have been timely and professionally managed, it seemed only to lack a jury to be a traditional court trial.

The next step of the process was to determine an amount of money to be compensated. We already had a life care plan in place because we were ready to go to trial before entering the compensation program. Instead of working with us to determine Stephen's appropriate life care needs, the Department of Justice's attorney sought for years to trivialize the extent of Stephen's vaccine injuries and to argue for irresponsibly insufficient funds to support a reasonable quality of life.

After five years of such negotiations, we needed to request another hearing to come to settlement, requiring further testimony from ourselves and Stephen's life care planner. It was determined on the spot by the chief special master that the life care plan the DOJ's attorney and life care planner submitted was indeed unrealistic and ordered specific actions to be completed within two months. This hearing, in and of itself, was handled professionally. However, two months turned into four before an agreement was signed. Further delays ensued to correct a significant math error relative to the initial payment. The agreement was then filed at the end of a 90 day filing period. The stipulation then required that we become legal guardians of our own child, causing further delay before any checks would be issued by the annuity company.

From the time we applied to the Vaccine Injury Compensation System to the time we were finally able to access the funds, seven and a half years had gone by. Our savings disappeared as we paid for therapies not covered by our insurance, hearing aids and special schooling, among other extraordinary expenses. Under the guidelines of the program, families are not reimbursed for any past expenses.

We were very fortunate in that the law firm who represented us continued to fight on Stephen's behalf far beyond any financial gain. In fact, the single payment of $30,000.00 allocated for attorneys' fees in pre-'88 cases only covered the expenses incurred in preparation of our two hearings. The law firm itself received nothing for its efforts of representing Stephen over a ten year period.

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As compensation is not retroactive to the date of the decision, each additional year of 'bargaining' is one less year to be compensated. This places further undue hardship on already emotionally and financially strained families. Our perception is that the program relies on this tactic to force families and their attorneys to accept less than adequate settlements which would provide optimal treatments for their vaccine injured

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Each day is a challenge, and we try to meet that challenge to make things a little better. My hope is that, by our presence here, today's challenge will make things better for the many families of vaccine injured children who are in, or who are attempting to enter into, the Vaccine Injury Compensation System, and for those who have been rejected by the system following changes to the Vaccine Injury Table.

Thank you for the opportunity to share our experience and express my concerns.

Mr. MICA. Thank you for your testimony. We will withhold questions until we have heard from all the panelists.

Next is Mr. John Salamone, and he is president of Informed Parents Against VAPP.

You are recognized, sir.

Mr. SALAMONE. Thank you, Mr. Chairman, members of the subcommittee. I appreciate the opportunity to talk with you today regarding legislative and policy options for improving the Vaccine Compensation Program.

Before offering specific testimony concerning outlined areas for improving this program, I would like to state for the record that I have served as vice chair of the HHS Advisory Commission on Childhood Vaccines and currently serve as an unpaid consultant to the Subcommittee on Vaccine Safety for the National Vaccine Advisory Committee.

But more importantly, I am the father of David, a 9-year old with polio contracted from the oral polio vaccine. As David's dad and as president of Informed Parents Against VAPP, also known as IPAV, a group of families who suffer from oral polio vaccine injuries, I worked long and hard with immunization advocates to move this country toward an all-IPV schedule or a killed virus schedule.

I am a supporter of immunizations. I have seen first hand in my life the diseases that we can now prevent and believe that we must maintain a strong immunization system—the safest one possible. With my son and others in IPAV having paid a huge personal price for mass immunization, I have also become very familiar with the National Vaccine Injury Compensation Program.

The first topic I was asked to address concerns changing the adversarial nature of the Compensation Program procedures and the hearing process. Given the choice between the program and personal injury lawsuits, the program wins. However, there is room for improvement. In their current form, the procedures are at times adversarial and need to become more user friendly.

Some suggestions to improve the process include: reevaluating the procedures to take into account the literacy level of most applicants. In its current form, either on the website or in the information packet, the language cites legal requirements and can often put off those unfamiliar with such legal terms. In short, put it in plain english.

Provide simple and clearly defined steps an applicant must go through in order to be considered for an award. This will assist applicants in working through the process and lead to a better understanding on their part of what their responsibilities are.

It would be ideal if new applicants could be provided with a counselor who can provide support through the application process. Most of the families who are dealing with vaccine injuries are simply too overwhelmed. They need the kind of assistance that comes from a person, whose job description includes compassion as a requirement.

The counselor can be empowered to provide references where applicants can get legal aid. Perhaps a bar association or other third party group can be asked to provide this special and much needed service.

The second area is reforming the evidentiary and adjudicative standards for determining compensation. From my experience and those of our families, I feel that the evidentiary stage is generally fair and runs smoothly for most applicants.

An overall comment, however, is that the government trust of $1.4 billion is guarded too well. The coffers need to be opened to provide the kind of humane service people in vaccine injury situations not only need but deserve. For example, the damages phase, to use the common term, can become more flexible in allowing for special circumstances. We have had families who have gone bankrupt trying to meet their children's medical and emotional needs while going through the system.

The Government can also provide greater clarity with regard to future lost wages. Some suggestions that come to mind include: administering intermediate funds to those in need based on good faith and a reasonable basis for claim; including family counseling expenses and reasonable fees and costs associated with the establishment of a guardianship or conservatorship; extending the current statute of limitations from 3 years for injury claims and 2 years for death to 6 years, and creating a specific method or formula for calculating lost earnings under VICP that is easily adaptable for individual use.

The final area of review is ensuring the level of funding to meet future needs. Current funding is not in jeopardy and should certainly be maintained. As future vaccines are created, these need to be added automatically to the injury table with assignment of appropriate excise tax. Let me repeat: It is not about funding; it is about access to funds for those who need it. If greater funds would equate to better services for applicants, then I would say, yes, provide more funds earmarked for those services I outlined earlier. If the committee takes action that will enable larger awards, then the criteria for what is covered under an award would need to be reevaluated.

I firmly believe in the VICP. It has done the best job it can under its current design to fulfill its purpose. I have been impressed with the dedication of those I have worked with in the program over the past 6 years. I believe, though, that even they would admit that improvements can and should be made to ensure that this program, which has served us well for a decade, can continue to meet the needs of those who sacrificed themselves for a universal vaccine program.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Salamone follows:]

TESTIMONY OF JOHN SALAMONE AT THE SUBCOMMITTEE ON LEGISLATIVE AND POLICY OPTIONS FOR IMPROVING THE VACCINE INJURY COMPENSATION PROGRAM
September 28, 1999

THANK YOU MR. CHAIRMAN AND MEMBERS OF THE SUB-COMMITTEE. I APPRECIATE THE OPPORTUNITY TO TALK WITH YOU TODAY REGARDING LEGISLATIVE AND POLICY OPTIONS FOR IMPROVING THE VACCINE INJURY COMPENSATION PROGRAM.

BEFORE OFFERING SPECIFIC TESTIMONY CONCERNING THE OUTLINED AREAS FOR IMPROVING THIS PROGRAM, I WOULD LIKE TO STATE FOR THE RECORD THAT I HAVE SERVED AS VICE CHAIR OF THE HHS' ADVISORY COMMISSION ON CHILDHOOD VACCINES AND CURRENTLY SERVE AS A CONSULTANT TO THE SUB-COMMITTEE ON VACCINE SAFETY FOR THE NATIONAL VACCINE ADVISORY COMMITTEE. BUT MORE IMPORTANTLY, I AM THE FATHER OF DAVID, A NINE-YEAR OLD WITH POLIO CONTRACTED FROM THE ORAL POLIO VACCINE. AS DAVID'S DAD AND AS PRESIDENT OF INFORMED PARENTS AGAINST VAPP, ALSO KNOWN AS IPAV, A GROUP OF FAMILIES WHO SUFFER FROM ORAL POLIO VACCINE INJURIES, I WORKED LONG AND HARD WITH IMMUNIZATION ADVOCATES TO MOVE THIS COUNTRY TO AN ALL-IPV SCHEDULE. I AM A SUPPORTER OF IMMUNIZATIONS. I HAVE SEEN FIRST HAND IN MY LIFE THE DISEASES WE CAN NOW PREVENT AND BELIEVE THAT WE MUST MAINTAIN A STRONG IMMUNIZATION SYSTEM - THE SAFEST ONE POSSIBLE. WITH MY SON AND OTHERS IN IPAV HAVING PAID A HUGE PERSONAL PRICE FOR MASS IMMUNIZATION, I HAVE ALSO BECOME VERY FAMILIAR WITH THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM.

THE FIRST TOPIC I WAS ASKED TO ADDRESS CONCERNS "CHANGING THE ADVERSARIAL NATURE OF COMPENSATION PROGRAM PROCEDURES AND THE HEARING PROCESS." GIVEN THE CHOICE BETWEEN THE PROGRAM AND A PERSONAL INJURY LAWSUIT, THE PROGRAM WINS. HOWEVER, THERE IS

ROOM FOR IMPROVEMENT. IN THEIR CURRENT FORM, THE PROCEDURES ARE ADVERSARIAL AND NEED TO BECOME MORE "USER FRIENDLY." FOR THOSE OF US WHO HAVE SEEN OUR FAMILIES DEVASTATED BY THESE INJURIES, A CHANGE IN THE VICP WOULD MEAN AN AWFUL LOT.

SOME SUGGESTIONS TO IMPROVE THE PROCESS INCLUDE:

* RE-WRITING THE PROCEDURES TO TAKE INTO ACCOUNT THE LITERACY LEVEL OF MOST APPLICANTS. IN ITS CURRENT FORM, EITHER ON THE WEBSITE OR IN THE INFORMATION PACKET, THE LANGUAGE OFTEN CITES LEGAL REQUIREMENTS AND CAN PUT OFF THOSE UNFAMILIAR WITH SUCH LEGAL TERMS. IN SHORT, PLEASE PUT IT IN PLAIN ENGLISH AS WELL AS THOSE OTHER LANGUAGES NECESSARY FOR APPLICANTS.

* PROVIDE SIMPLE AND CLEARLY DEFINED STEPS AN APPLICANT MUST GO THROUGH IN ORDER TO BE CONSIDERED FOR AN AWARD. THIS WILL ASSIST APPLICANTS IN WORKING THROUGH THE PROCESS AND LEAD TO A BETTER UNDERSTANDING ON THEIR PART OF WHAT THEIR RESPONSIBILITIES ARE.

* IT WOULD BE IDEAL IF NEW APPLICANTS COULD BE PROVIDED WITH A COUNSELOR WHO CAN PROVIDE SUPPORT THROUGHOUT THE APPLICATION PROCESS. MOST OF THE FAMILIES WHO ARE DEALING WITH VACCINE INJURIES ARE SIMPLY TOO OVERWHELMED, BOTH EMOTIONALLY AND PHYSICALLY, TO EASILY MAKE THEIR WAY THROUGH THE SYSTEM AS IT IS CURRENTLY. A WEBSITE AND INFORMATION PACKET CANNOT PROVIDE THE KIND OF ASSISTANCE THAT COMES FROM A PERSON, WHOSE JOB DESCRIPTION INCLUDES COMPASSION AS A REQUIREMENT.

* YOU MIGHT WANT TO LOOOK AT THE COUNSELLORS AS AN OMBUDSMAN. FOR EXAMPLE, THE COUNSELLOR CAN BE EMPOWERED TO PROVIDE REFERENCES WHERE APPLICANTS CAN GET LEGAL AID. ALL TOO OFTEN,

WOULD-BE APPLICANTS DO NOT HAVE ATTORNEYS FAMILIAR WITH THE PROCESS AND ARE BEREFT OF SOUND LEGAL ASSISTANCE THAT IS IN THEIR BEST INTEREST. PERHAPS A BAR ASSOCIATION OR OTHER THIRD PARTY GROUP CAN BE ASKED TO PROVIDE THIS SPECIAL AND MUCH NEEDED SERVICE.

THE SECOND AREA IS REFORMING THE EVIDENTIARY AND ADJUDICATIVE STANDARDS FOR DETERMINING COMPENSATION. FROM MY EXPERIENCE AND THOSE OF OUR FAMILIES, I FEEL THE EVIDENTIARY STAGE IS GENERALLY FAIR AND RUNS SMOOTHLY FOR MOST APPLICANTS. AN OVERALL COMMENT, HOWEVER, IS THAT THE GOVERNMENT TRUST OF $1.4 BILLION IS GUARDED TOO WELL. THE COFFERS NEED TO BE OPENED TO PROVIDE THE KIND OF HUMANE SERVICE PEOPLE IN VACCINE INJURY SITUATIONS NOT ONLY NEED BUT DESERVE. FOR EXAMPLE, THE "DAMAGES" PHASE, TO USE THE COMMON TERM, CAN BECOME MORE FLEXIBLE IN ALLOWING FOR SPECIAL CIRCUMSTANCES. WE'VE HAD FAMILIES WHO'VE GONE BANKRUPT TRYING TO MEET THEIR CHILDREN'S MEDICAL AND EMOTIONAL NEEDS WHILE GOING THROUGH THE SYSTEM. WE'RE NOT TALKING ABOUT POKEMON CARDS. WE'RE TALKING ABOUT THERAPY AND HELP. THEY ALSO CAN PROVIDE GREATER CLARITY WITH REGARD TO FUTURE LOST WAGES. SOME SUGGESTIONS THAT COME TO MIND INCLUDE:

* ADMINISTERING INTERMEDIATE FUNDS TO THOSE IN NEED BASED ON GOOD FAITH AND A REASONABLE BASIS FOR A CLAIM.

* INCLUDING FAMILY COUNSELING EXPENSES AND REASONABLE FEES AND COSTS ASSOCIATED WITH THE ESTABLISHMENT OF A GUARDIANSHIP OR CONSERVATORSHIP.

* EXTENDING THE CURRENT STATUTE OF LIMITATIONS FROM 3 YEARS FOR INJURY CLAIMS AND 2 YEARS FOR DEATH TO 6 YEARS.

* AND CREATING A SPECIFIC METHOD OR FORMULA FOR CALCULATING LOST EARNINGS UNDER VICP THAT IS EASILY ADAPTABLE FOR INDIVIDUAL USE.

THE FINAL AREA OF REVIEW IS ENSURING THE LEVEL OF FUNDING TO MEET FUTURE NEEDS. CURRENT FUNDING IS NOT IN JEOPARDY AND SHOULD CERTAINLY BE MAINTAINED. AS FUTURE VACCINES ARE CREATED, THESE NEED TO BE ADDED AUTOMATICALLY TO THE INJURY TABLE WITH ASSIGNMENT OF AN APPROPRIATE EXCISE TAX. LET ME REPEAT: IT IS NOT ABOUT FUNDING...IT'S ABOUT ACCESS TO FUNDS FOR THOSE WHO NEED IT. IF GREATER FUNDS WOULD EQUATE INTO BETTER SERVICES FOR APPLICANTS, THEN I WOULD SAY, YES, PROVIDE MORE FUNDS EARMARKED FOR THOSE SERVICES I OUTLINED EARLIER. IF THE COMMITTEE TAKES ACTION THAT WILL ENABLE LARGER AWARDS, THEN THE CRITERIA FOR WHAT IS COVERED UNDER AN AWARD WOULD NEED TO BE RE-EVALUATED.

I FIRMLY BELIEVE IN THE VICP. OUR GROUP, IPAV, IS PRO-IMMUNIZATION DESPITE OUR FAMILY MEMBERS CONTRACTING POLIO FROM THE VERY VACCINE MEANT TO PROTECT AGAINST IT. THE VICP HAS DONE THE BEST JOB IT CAN, UNDER ITS CURRENT DESIGN, TO FULFILL ITS PURPOSE. I HAVE BEEN IMPRESSED WITH THE DEDICATION OF THOSE I HAVE WORKED WITH IN THE PROGRAM OVER THE PAST SIX YEARS. I BELIEVE THOUGH THAT EVEN THEY WOULD ADMIT THAT IMPROVEMENTS CAN AND SHOULD BE MADE TO ENSURE THAT THIS PROGRAM, WHICH HAS SERVED US WELL FOR MORE THAN A DECADE, CAN CONTINUE TO MEET THE NEEDS OF THOSE WHO SACRIFICED THEMSELVES FOR A UNIVERSAL VACCINE PROGRAM.

THANK YOU.

Mr. MICA. Thank you. Thank all of our witnesses for their testimony this morning.

I have a couple of questions, if I may.

First, Mrs. Clements, I think you have been denied participation in the fund because of the original injury table being changed, and I believe you testified you felt this is grossly unfair. What would you recommend as far as a process that you think would be fairer, and, again, what about individuals like you who have been denied the opportunity to participate because of these changes, you think that Congress should take some remedial action to allow your participation?

Ms. CLEMENTS. Basically, when we first applied for—when I first got information on the adverse reactions, I got the papers, and my son fit the—if you want to say qualified—for getting compensated. Then, as I said, the table changed, and all of sudden there is just no one, basically, it sounds like could possibly be compensated because of the way they changed this table.

And if they could put it back to the way it was, more families could be compensated or make it, as Mr. Burton said, stop making it impossible and stop making it where we have to go in and fight to prove that our child reacted. When my son reacted in 15 hours to it, and we have 72 hours at that given time when we first started that if he seized within 72, it is a reaction from the DPT shot. Then all of a sudden it is no longer on the table.

I had a great problem with them taking the seizures off the table, because I know a high percent of reactions are seizures from the DPT shot, and that, to me, just showed a sign of saying, "We don't want to pay anyone anymore, and we can get rid of this section of people or children that react," and if they could just look into it deeper and, like Mr. Burton said, investigate it in the long-term and not do a couple weeks, a couple months study, because our children are getting these shots up until possibly 6 years old, and we don't know what can happen at 6 months. The friend of ours whose child died, died at the fourth shot.

So, the other thing of giving warning signs, my son had two prior warning signs to it, but because my doctor and a lot of doctors don't tell us these adverse reactions, I didn't know. My son may not be in this condition if I would have known that the, if you want to say, the junkiness that developed after the—when he was 2 months old.

He had a rattle in his chest, and I kept going to my doctor saying, "Something is wrong. Something is wrong" right after he had his DPT shot, and I was given the normal of "Well, newborns make that sound." I go in for the 4-month old, and he does the excessive crying. And I am not told that is an adverse reaction, so I go in with the 6-months, and now I have a son who has a seizure disorder and ultimately puts him in this condition. Now, I could have been—that could have been eliminated if I would have known the warning signs ahead of time.

So, it is something to make sure that the doctors are forced to give out that information, that it is not a—well, as I view it—a cover up or a hiding, to go into a long study of what is going on with children that react, because some children don't react on the first one.

Mr. MICA. Have you had access to any other legal remedy? Have you pursued a suit against the manufacturers or——

Ms. CLEMENTS. At this present time, our lawyers are looking into the steps of—or looking into going after the pharmaceutical company themselves. They figure there are ways of going after the manufacturers.

Mr. MICA. To date, to deal with the problems you have incurred, how have you had to deal with that financially—just all your family resources or some other——

Ms. CLEMENTS. Originally, when Andrew started out with his seizures, it was financially coming through us, and then we were told that we could go and apply for SSI, and that would help take care of the medical bills and things like that. So, probably within a few months, about 6 months we had to wait, and then SSI kicked in, and it started paying the bills. But, originally, we paid the beginning of those bills for probably the first 6 months of his reacting to it.

Mr. MICA. Ms. Mulhauser, it took you, what is 6½ or 7½ years to receive compensation?

Ms. MULHAUSER. It took 5 years to finalize all of the stipulation. It took another year and a half to go through the court system to establish legal guardianship. So, the annuity company would not release the checks until we had proof of legal guardianship, and it was a process we couldn't start ahead of time, because the guardian courts required the stipulation to be filed.

Mr. MICA. Based on your experience, how can we speed up this process?

Ms. MULHAUSER. Like I testified earlier, I believe that if both the Government and the parents come to the table with the child's best interests instead of fighting over the cost of one item or another or whether it is going to cost $5 or $10, the process would speed up quite a bit.

I think we could have taken 3 years off of our compensation time just by letting the life care planners who are qualified to determine life care needs, with the doctors' reports, the educational reports, the parent input—there are plenty of resources that are available that a mediator, say, who specializes in the life care planning of individuals with disabilities, could bring that process to a conclusion much sooner than having high-priced lawyers arguing over items.

Mr. MICA. Thank you.

Mrs. Mink.

Mrs. MINK. Thank you, Mr. Chairman.

The testimony of all the witnesses on this panel is very, very provocative, and I hope will be utilized to encourage this committee to make some very important changes to the existing law.

Mrs. Clements, what bothers me in the situation that you found yourself in, with respect to the symptoms that occurred immediately after the shots were given to your son, that no one explained to you at that point that those were suggestive of adverse reactions to the vaccination and that you relied on your physician to be able to make an appropriate reading as to what was going on inside your child's system.

I take it from your testimony that your physician did not provide you with such a forecast or analysis of what was going on. Is that correct?

Ms. CLEMENTS. Correct.

Mrs. MINK. Then it seems to me for the compensation system to insist that you as a parent, non-medical professional, be able to make a decision to halt the Vaccination Program, which the Government was insisting that every child have, is perfectly illogical. There is no reason for a parent to know when to insist that the Government stop the vaccination procedure. The physicians, on the other hand, have the knowledge and the training, or should have, and be able to make those decisions. Don't you agree?

Ms. CLEMENTS. Yes.

Mrs. MINK. So, given that circumstance, it would seem to me that one of the things that the committee should look at is the responsibility of the medical profession in each of these cases. Warnings should have been given. The medical profession should exercise sound judgment, and in the absence of exercising that sound judgment, compensation should be automatic. I mean, that is my general feeling.

And to hear your testimony that such technical things as a statute of limitations, that your filing was 1 year late, or that the technicalities of the table had changed so as to disqualify your claim is absolutely unacceptable in tort law.

I happen to be a lawyer. It is always the incident of the injury that establishes the date of the claim. It was through no fault of your own that you were not apprised of your ability to stop this injury from occurring and becoming more serious. The compensation concept of the Federal Government should be an automatic processing of the claim, because certainly there could be no other justifiable reason for your child being in this serious condition that he is in. The medical profession acted inappropriately and this injury could have been prevented.

And given those circumstances, the compensation approach should be categorically in your favor, since there could be no possibility of negligence on your part. It is not the case of trying to find blame on the medical profession, but certainly to deny compensation in your case goes against all semblance of justice and equity in this country.

So, I would hope that the committee would be able to take your testimony and your statement and correct that. And certainly with respect to the timeframe, the Government should have a statute of limitations where if they fail to act within a reasonable time, that the compensation claimed by the victim's family ought to be automatically adjudicated by some third party.

I think that since the Vaccination Program is one that is imposed by the Government for the public safety, that we ought to impose upon the Government strict regulations with reference to the protection of the parties involved, and, Mr. Chairman, those are my views.

Thank you.

Mr. MICA. Thank you.

I would like to yield now to the chairman of our full committee, Mr. Burton.

Mr. BURTON. Thank you, Mr. Chairman.

I am not going to ask but one question. I have to leave to go to a luncheon, but I will be back for further—for another part of this hearing.

I want to express to the parents my sorrow and all the parents across the country that have experienced what you have. I have similar feelings for my grandchildren, and may the good Lord bless you and your families for what you have gone through and what you are going to go through the rest of your lives.

I would like to just make a couple of comments. The reason that this fund was set up, as I understand it, is because the pharmaceutical companies were concerned about massive lawsuits and how it might adversely impact their industry and how many of those pharmaceutical companies smaller in nature, and even the large ones, might go out of business if excessive lawsuits, because of adverse reactions, occurred.

And, so the Government and Mr. Waxman justifiably sat down with them, and said, "OK, we are going to work this out so that there is a non-adversarial process that will take place where people will be compensated fairly, and you will still be able to protect the pharmaceutical companies." And this fund of 75 cents a shot was established to take care of that.

Now, we find it is an adversarial relationship; that people have to fight to get that money; they can't get lawyers to take their cases—and I know; I am speaking from personal experience now. We can't find many lawyers that even want to look at this. So, this adversarial relationship that has been created should not be happening, because that was not the purpose of the fund.

Now, some people have said to me privately that they are concerned that even though we have $1.1 billion in that fund, that the fund may be depleted if they aren't very careful. Well, my view is if it is a non-adversarial situation we are looking for, then if we have to increase the cost per shot to $1 or $1.50, double it, to make sure that these people are adequately compensated for the tragedy that they have to endure, then we should do it. But there should not be this kind of a problem.

And I intend to be back for the gentleman who works for the fund and the people at the Justice Department, because I am sure Congress didn't intend that, and if they are trying to protect that fund, then that is baloney. We can always raise the amount. And I am not for tax increases, but I am for making sure that people who suffer like these people have suffered are fairly and adequately compensated, because it wasn't their fault that this happened.

The second thing that concerns me is that my son-in-law is a doctor, and I have talked to him about this, obviously, because it is our family that is involved. And I ask him about shots, and he says, "Well, we get guidelines from the Food and Drug Administration and from the Health and Human Services, and unless it is approved by the FDA, then, you know, I am very careful, and I don't—" So, they rely—the doctors rely, in many cases, probably in most cases, on the judgment that is coming out of their associations, which is coming from the FDA. And, so if we are not getting enough information, then it seems to me that the Government

health agencies must be more forthcoming to the physicians so that they could be more forthcoming to the patients so that everybody will know the risks involved.

That hepatitis B shot that my granddaughter took, that almost killed her, would not have been administered had I known the risks or my daughter knew the risks. My grandson got five shots in 1 day. You know, sometimes I think it is an overload of the system, like if you put too many plugs into an electrical socket, you are going to blow the breaker switch or you are going to—if you have an old-style home, you are going to have the fuse blown. And we are loading these kids up with 25, 30 shots between the time they are born and they are 5 and 6 years old before they go to school. And we need to know from HHS and FDA and our health agencies, through our doctors, what the risks are, and the parents need to know that so we minimize the kinds of problems we are talking about here today.

So, those are my views. I think I would just like to ask you, Mr. Salamone one question, and your son suffers from the polio vaccine, the live polio vaccine. You were talking about making sure that dead viruses are used. Now, is there any indication from your research or from talking to scientists and physicians that if we use dead viruses that the risk is minimized even though they may get several vaccines?

Mr. SALAMONE. The only cases of polio in the United States for the past 20 years have come solely from the oral polio vaccine.

Mr. BURTON. The live vaccine.

Mr. SALAMONE. That is right. And, so in answer to your question, I don't have any information to indicate anything specific regarding the killed virus, but I guess the facts are that polio in the United States, while we think that it has been eliminated, in reality, we have been creating it by the very vaccine designed to prevent it, and that was the oral polio vaccine. And I am pleased to note that as of January 2000, they are recommending now—the CDC is recommending that the oral polio vaccine no longer be part of the regular vaccination schedule finally after 5 years, I might point out, of a lot of testimony.

Mr. BURTON. And I wonder how many people suffered. Do you have any idea how many people——

Mr. SALAMONE. Well, on the books, they say between 8 and 10 a year, but, quite candidly, virtually every family that we deal with has been misdiagnosed. And in the case of my son, it took them almost 2 years to finally put the pieces together and figure out that he didn't have half of his immune system, and that is why he got polio as a result of the vaccine.

Mr. BURTON. If I might ask just another question of this witness, Mr. Chairman.

So, the people from HHS and the people from the health agencies have known for how many years now that the live virus caused this problem?

Mr. SALAMONE. Oh, I venture to say that the health industry has known for decades that you can get polio——

Mr. BURTON. Well, let me—my time is running out. So, they have known it for decades, and there was an alternative to that—the dead virus—that could have prevented polio, is that correct?

Mr. SALAMONE. That is right. A safer, killed virus was available.

Mr. BURTON. And yet they went ahead and let the American people take the more dangerous virus for, you say, for at least a decade or so.

Mr. SALAMONE. It was just a bad, old habit that went back to those days decades ago.

Mr. BURTON. Well, I am not so sure. And one of the things that we want to investigate is whether or not the pharmaceutical companies, who have a huge investment in this, have influence or undue influence on the departments of health in this country. If you know that a virus that is live causes this kind of damage to a young child, whether it is polio or anything else, and if they continue to use it when there is an alterative—for instance, the DPT shot is still being used today, and they have a DPaT shot that is safer, and when I asked people at the hearing we had not long ago, they could not explain to me why the DPT shot is still being used. The only thing that pops into my mind is there is money involved, and if there is money involved, why are HHS and the FDA allowing that to continue to be used? And, so we are going to check all that out.

It sounds like a similar situation with the polio virus vaccine. We are going to look into all that, and we are going to get the records of all the people who are in the decisionmaking process at the health agencies; we are going to get those records. We are going to go back and find out where the money came from when they go to speak. We are going to go back beyond the organization that puts the meeting together where they speak and find out if the pharmaceutical companies are underwriting all that and if they are paying honorariums for these people. And if that is going on, there are going to be some changes made in the way HHS and the FDA do their business. And we are going to check everybody out, everybody.

Mr. MICA. Thank the chairman.

If I may, Mr. Kucinich, can I recognize Dr. Weldon, and then I go to you? Would that be acceptable? Thank you.

Dr. Weldon.

Dr. WELDON. Thank you, Mr. Chairman.

Ms. Mulhauser, I was looking at your resume. You had a career in fashion design prior to your son's illness coming along, is that right?

Have you been able to work in that field at all or have any income since your son's illness arrived?

Ms. MULHAUSER. No, I have not worked professionally since my son's vaccine injury.

Dr. WELDON. How much of your time is consumed with caring for your son, would you say, on a typical daily basis?

Ms. MULHAUSER. It is 24 hours. I mean, he sleeps at night, but even when he is in school, I am still responsible for overseeing his therapies, scheduling his doctor's appointments——

Dr. WELDON. Can you give me an idea——

Ms. MULHAUSER [continuing]. Paperwork involved with the annuities and the checks coming in, annual accountings, financial accountings, petitions for maintenance to use the fund that has been

allocated for him. And I do a lot of volunteer work related to his school and the rights of the disabled, the rights of the deaf.

Dr. WELDON. And you have another child, is that right?

Ms. MULHAUSER. Yes, I do.

Dr. WELDON. Is it safe to say that the vast majority of your time since your son's illness has been devoted to petitioning the Government for compensation, caring for him, and that has essentially precluded you from working in your field?

Ms. MULHAUSER. Yes, that is true.

Dr. WELDON. I notice there is a gentleman with you. Is he your husband, attorney?

Ms. MULHAUSER. My husband.

Dr. WELDON. Your husband. Your husband has a job, I take it?

Ms. MULHAUSER. Yes.

Dr. WELDON. And I would imagine that the vast majority of his free time when not working has been devoted to supporting your son as well.

Ms. MULHAUSER. Yes.

Dr. WELDON. And when you apply for compensation, you don't request any compensation, and you are not eligible to get any compensation based on your lost income and the time that you have devoted to caring for your child. Is that correct?

Ms. MULHAUSER. That is correct.

Dr. WELDON. OK.

Ms. Clements, I want to ask you the same line of questioning. I see you brought your son with you today, and there is a lady with you. I assume she is a relative of yours?

Ms. CLEMENTS. My sister.

Dr. WELDON. Your sister. I assume for you to go out anywhere and do anything, you have to get either a family member to sit in and help you or to have somebody paid come in and help you? Is that correct?

Ms. CLEMENTS. I have someone in my family come in or take him with me.

Dr. WELDON. OK. And as you have been trying to work through the Vaccine Compensation Program, you are trying to get funds just to take care of him. You are not petitioning for any loss of your time, any pain and suffering on your part for this case. Is that correct?

Ms. CLEMENTS. Correct. There is nothing that can—there is no amount.

Dr. WELDON. Just one additional question I have for you. You mentioned in your testimony that you were considering or you are in the process of filing a claim against the pharmaceutical company directly. Is that correct?

Ms. CLEMENTS. Correct.

Dr. WELDON. The purpose of the Vaccine Injury Program was because the vaccine manufacturers said they were going to get out of the business because of the huge number of claims that were being filed against them. One of the concerns that I have is that the program is so adversarial that individuals such as yourself will start the process anew of filing claims against the pharmaceutical companies, and then we can be right back to square one that the sys-

tem has truly failed us so badly that the pharmaceutical companies are getting out of it again.

Would you say that it is a correct assessment that people with situations such as yours have no choice and that they are going to start filing claims against the pharmaceutical companies?

Ms. CLEMENTS. Yes, I would say that is correct.

Dr. WELDON. Thank you, Mr. Chairman, or Madam Chairwoman. I yield back.

Mrs. MINK [presiding]. Thank you.

I recognize the gentleman from Ohio, Mr. Kucinich.

Mr. KUCINICH. Thank you very much, Mrs. Mink.

There are a few things that emerge when one views this very important public policy issue. First of all, the role of Congress. The question has been asked, and it should be put before this committee, whether or not Congress has essentially delegated away to HHS what is a legislative function.

With respect to the National Institutes of Health, it appears to me that there absolutely is a need for more research of the adverse vaccine reactions, because what we are dealing with here is a system that provides for compensation for those who have had an adverse vaccine reaction, but I think it is incumbent upon us not to simply take it for granted that those reactions will occur; that more emphasis needs to be put on research to make sure that everything is being done to try to limit the amount of reactions which are occurring.

The people who have come here today—and I have had a chance to review the testimony—certainly have pointed stories, and I think all Americans can sympathize with what happens when a perfectly normal child is given a vaccine and ends up with a catastrophic injury. And we have to care about that. We have to be attuned to the kind of suffering that occurs. And, in a sense, there is no amount of compensation that can genuinely help a family and an individual who has gone through that kind of trauma and will continue to go through it through their entire life.

The thing that concerns me, Madam Chair, is that I understand the existing law still permits the Department of Justice to seek cost reimbursements from unsuccessful petitioners who appeal their case to the U.S. Federal Court of Appeals. Is that correct, Madam Chair and Mr. Mica?

See, that is one of the areas where this Congress, I think, can intervene on behalf of those families who have suffered. It just doesn't seem fair that one should have to go through a route of trying to seek compensation or increased benefits and cost reimbursements, and then if you happen to lose, to have the Department of Justice come after you for the cost of an appeal to the U.S. Federal Circuit Court of Appeals.

Again, I want to thank the chairman, Mr. Mica, for his diligence on these issues, and the information that you have already brought forward as a result of this committee's work indicates that reforms are needed, and I am sure that with the Chair working with Mrs. Mink and this committee, that we are going to try to find some relief that will—it will never make you whole again in terms of the damage that has been done to your family and to your children, but

it will let other Americans know that Congress is listening and cares and wants to do something.

So, thanks to all of you right here.

Thank you, Chairman.

Mr. MICA [presiding]. Thank you, Mr. Kucinich.

I recognize Mr. Cummings from Maryland.

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

I can only echo what Mr. Kucinich just said. I think that so often when you think of something like a vaccine, looking at something that is supposed to make life better and prevent problems, and unfortunately in some instances we have a double-edged sword.

I just have a few questions, Mr. Salamone. Is that how you pronounce your name?

In your testimony, you advocate the creation of a specific method or formula to calculate lost earnings. Yet some people oppose such a formula, because it may diminish the awards to successful petitioners. How would you respond to that concern?

Mr. SALAMONE. Well, you know, I have, I think, a very personal reason for addressing that issue. In the case of my son, he received zero, no compensation for future lost wages, and I believe in this case the assumption was if he can walk—which David does like a drunken sailor, but he gets around with his brace—that he can, with educated parents, do as well in this life as everyone else.

Well, within a year of his award, David started intermittent tremors of his arms and hands. And as a result, he now had to do much of his schoolwork on special equipment. Well, our neurologist tells us this is directly related to his polio, yet, again, this is something that was after the fact, and therefore—by the way, if I can use this opportunity, the original legislation provided that if indeed after a claim was made something like this came up that was directly related to the injury, that one had the option of going back to the Government and saying, "This is directly related. We have this evidence," and the Government would work out an arrangement where they could compensate, if you will, for the needs relating to that additional injury.

Unfortunately, that was pulled back, and the Congress actually removed that provision, and, as a result, in a case like my son and others, you have this situation where, again, they are not really being fully compensated for their injury.

Now, as far as the lost future wages, I believe that this is obviously a complex issue, and the—my concern, candidly, is the fact that people are totally eliminated from even consideration for future lost wages. So, I think we, first, have to establish the fact that there should not be a policy with the Government that would allow a special master to have a policy that says, "You will not get future lost wages for your child, because that child can walk or that child has educated parents." Those are the things that concern me.

Mr. CUMMINGS. There is a great deal of concern that if the present program is changed, children whose conditions have not been caused by the vaccines would receive compensation. And how would you address that concern?

Mr. SALAMONE. I am sorry, sir. Repeat the question.

Mr. CUMMINGS. In other words, there is a concern that if the present program was changed, children whose conditions have

not—have not—been caused by the vaccines would receive compensation.

Mr. SALAMONE. Well, I would first say to you I believe that when it comes right down to it, the Government should err on the part of the petitioner, if indeed it is an error. These are very difficult cases. This is supposed to be a procedure that is less adversarial, not non-adversarial, and certainly we don't want to open the doors completely to cases that are not directly related to vaccine injury. But I would say if we have cases that even come close to consideration as vaccine-related, that I would rather the Government with its $1.4 billion trust err on the side of the petitioner.

Mr. CUMMINGS. Well, I certainly would agree with that. Unfortunately, we have many people here in the Congress who probably wouldn't. When I look at all of this, having been a trial lawyer for almost 20 years, to see the results of what happens, for example, in a malpractice case and see how States have limited the liability of doctors who may do the wrong thing or may be negligent, it is interesting.

But when you go through this experience, when you have a problem like this, a vaccine that actually had the opposite effect that it was supposed to have, I think you get a chance to see that—people get a chance to see that side of it. And I would agree with you, and I hope that, as Mr. Kucinich said, that we will be able to come up with some solutions that are fair and that we will do justice to all of those who may have been harmed.

And I want to thank all of our witnesses for being with us today. Thank you very much.

Mr. MICA. Thank the gentleman from Maryland.

I would like to also thank all three of our panelists for being with us and for the testimony you have provided the subcommittee today. Hopefully, it can help us in doing a better job in revising the law that was passed to compensate victims, make the structure and system work that we put in place to compensate for vaccine injuries.

So, we thank each of you, and we will excuse the witnesses at this time.

I would like to call our second panelists. Panel two is Dr. Marcel Kinsbourne, a medical expert with Tufts University; Dr. Arnold Gale, a medical expert with Stanford University, and Mr. Cliff Shoemaker, an attorney with Shoemaker & Horn.

As I indicated to our first panelists, this is an investigation and oversight subcommittee of Congress. We will swear in our witnesses. Also, if you have lengthy statements, they will be made a part of the record.

Let me see, and is Dr. Gale going to testify too?

Can you raise your right hands?

[Witnesses sworn.]

Mr. MICA. Thank you. All of our witnesses answered in the affirmative.

I would like to welcome each of you and thank you for your participation today. And I think each of you have dealt with this compensation fund and process, and we look forward to your testimony at this time.

First, we will hear from Marcel Kinsbourne with Tufts University.

You are recognized, sir.

STATEMENTS OF MARCEL KINSBOURNE, MEDICAL EXPERT, TUFTS UNIVERSITY; ARNOLD GALE, MEDICAL EXPERT, STANFORD UNIVERSITY; AND CLIFF SHOEMAKER, ATTORNEY, SHOEMAKER & HORN

Dr. KINSBOURNE. Thank you, Mr. Chairman, members of the committee.

My name is Marcel Kinsbourne. I am a pediatric neurologist. I have held research grants from the NIH. I have served on study groups of the NIH. I have been involved in the Compensation Program since its inception in 1988; in fact, before its inception, I was part of a workshop offered for special masters in training for that purpose. So, I have an overview of the program from its start.

I have also been involved in civil litigation, both for plaintiff and defense, and so I am in a position to compare the proceedings of the claims court Vaccine Compensation Act with civil litigation in this country at this time.

Now, I might just say what everybody else agrees that I am strongly in favor of public health policies with regard to vaccination. I am addressing specifically the issues nominated by the committee for discussion.

And the first of these, of course, is the question of the adversarial nature of the proceedings as they now occur. Actually, when the proceedings first began in the late eighties, I didn't think they were that adversarial. I really thought that they were somewhat consistent with the wording of the act which was that they should proceed "quickly, easily, and with certainty and generosity."

This changed, however, and the proceedings have become more adversarial and continue to become more adversarial, and that both involves the manner in which the cases are defended, the petitioners are resisted, and the change in the rules that offer a presumption of causation that have already been mentioned by several speakers today.

These changes all go in one direction. I don't believe, as I will explain, that the changes were made based on new science. There isn't any relevant new science. The changes are a matter of policy, in my opinion.

Now, in terms of the manner in which the proceedings are conducted, it is increasingly the case in my experience that the Department of Justice attorneys fight harder and more stubbornly to resist findings of entitlement. They may use two experts. They may change experts if the first expert's opinions didn't serve the purpose. They may bring in three. A petitioner can't usually manage to do that.

In one matter in which I have been involved, the Department of Justice actually paid a group of independent investigators to perform an original study, an expensive study, to overthrow two claims for which entitlement had already been found. These are the cases of Plavin and Hanlon v. HHS.

This kind of funding, this kind of effort isn't possibly available to those plaintiff attorneys that still consent to take these cases.

And I might add that as has been said before, absolutely there is no way of proceeding in these matters without the help of an attorney; not just an attorney, an attorney who is well versed in the procedures in the claims court. It has become a highly specialized aspect of law.

So, not only is it the case that a special master is pressured in many cases to deny entitlement, it is also the case that when the special master nonetheless finds entitlement, that the fight goes on, as you have heard, increasingly at the damages hearings. Issues that had already been settled in the previous hearing are revived yet again, and then there is the nitpicking that has been described so well by previous witnesses.

Now, not only does this make the process arduous and exhausting, particularly for petitioners, it takes up time. I heard it said at the last hearing, at which I also testified, that the average time to settle a claim is 2 years. Well, I don't know where that figure comes from. In my opinion, claims that are contested and go through to entitlement findings take longer. They have taken 4 years, 5 years. The last one that I was involved in had been filed in 1991. As you have heard, the more time passes, the less compensation is subsequently offered.

Now, if the decision is one that is unwelcome to the Department of Justice, the Department has the further resource of resorting to a multi-stage appeals process, and appeals against the decision of special masters have been increasingly frequent in my experience.

Now, it is also my impression that as part of the more stubborn contesting of these claims, there has been an increasing effort to discredit medical experts who assist petitioners by accusing them of bias against vaccination or in favor of petitioners. In fact in the same last hearing I mentioned, the Department of Justice attorney put into the record as an impeachment exhibit the fact of my testimony to this committee last time, and then she argued that the fact that I testified to this committee showed that I was an advocate, and should impeach my credibility as a medical expert. I have the transcript with me.

The special masters——

Dr. WELDON. Mr. Chairman, I ask that that transcript be included in the record.

Mr. MICA. Without objection, so ordered.

[The information referred to follows:]

Final argument by Karen Heidt, Dep't of Justice attorney, in Flanagan v Sec. HHS.

1 patients, and he hasn't for a number of years. So in terms
2 of weighing expert opinions, I think you have to consider
3 that.
4 I also think you have to consider a certain degree
5 of bias that each expert brings to their opinion. Clearly,
6 Dr. Holmes brings a bias of a research scientist, a treating
7 physician who sees patients. That's his view. It's a
8 medical view.
9 But I think that Kinsbourne also has, I mean, it's
10 undisputed he has testified numerous times under the
11 program, and you've heard his testimony before. He's been
12 in frequent situations and found -- his opinion has not been
13 given weight.
14 And in this case, in my mind, he hasn't offered
15 any reason why it should be given weight here. His opinion
16 is not based on the literature. It's a minority view. And
17 in conjunction with what Dr. Holmes has said, it just
18 doesn't hold weight. It's not based on anything other than
19 his theory, and it's a temporal relationship theory more
20 than anything. So for that reason, we submit that you
21 should not give weight to Dr. Kinsbourne's opinion here
22 today.
23 The fact that he recently testified before
24 Congress about a number of issues, but in particular, about
25 his views on the problems with this program I think also

1 shows that, to some degree, he is an advocate on behalf of
2 the Petitioners, and Dr. Holmes is not. Dr. Holmes is a
3 scientist, and he is a physician who treats injured kids
4 with TS and with epilepsy.
5 And so, the task before you in determining which
6 medical judgment you agree with, that you think is the most
7 sound, in making that determination, we submit that you
8 should give the greatest weight to what Dr. Holmes has said.
9 Your Honor, with respect to the relationship of
10 this case to the Omnibus TS cases, Dr. Kinsbourne conceded
11 there really is only one issue, and that's fever, in terms
12 of the list of symptoms, which you have indicated in your
13 order in the Flanagan case was not included to be an
14 exhaustive list in any event from the TS decision.
15 But even if you accept it, there is an Omnibus
16 rule. The only thing that Ashley Flanagan arguably had that
17 would apply would be the fever.
18 And we submit, when you lay all this evidence out
19 and consider what Dr. Holmes said, that in the end, you
20 should conclude, based upon the overwhelming evidence in
21 this case, that Ashley Flanagan's condition is due to her
22 tuberous sclerosis. Thank you.
23 SPECIAL MASTER MILLMAN: Thank you. Mr. Moxley?
24 MR. MOXLEY: Thank you, Your Honor.
25 CLOSING STATEMENT

Dr. KINSBOURNE. In my opinion, the special masters make every reasonable effort to adhere to the principle of a non-adversarial and friendly and expeditious process. They used relaxed rules of procedure. They are invariably courteous and compassionate to the plaintiffs. They try to move the case along, but this gets increasingly hard because of the opposition that is encountered at every step of the way.

I think that in summary, the quality of the proceedings has approximated to the kind of adversarial argumentation and maneuvering that is typical of civil litigation, and the question is, is that what Congress wants?

The second topic nominated by the committee was the matter of criteria for entitlement for compensation. In other words, what are the criteria by which a claim can be automatically accepted as indicating that the damage complained of was caused by vaccine? Now, I would like to explain why this is so important.

If it were the case that we had special tests for vaccine injury, if it were the case that the outcomes of vaccine injury were typical and that you could look at the chart years later and say, "Ah, this must have been a vaccine case," then there wouldn't be such a problem. But in child neurology this is the exception rather than the rule. The reason is that there are a legion of causes of damage to children's brains, but the way the children's brains react to these damages is quite limited, and the most common outcomes are cerebral palsy, mental retardation, and seizure disorders. And it is usually the case that you cannot tell from the cerebral palsy, from the seizures, or from the mental retardation what the cause was.

So, in the case of vaccine injury it is like that. If one had to actually prove that the vaccine definitely caused the outcome, that would be hard and sometimes not a possible job to do, as is the case also with other causes in child neurology.

One reason why this proof is so difficult is that research is lacking. Now, the research that is lacking is research that could, in fact, often well have been done by now. In fact, the initial act instructed the Secretary to commission the Institute of Medicine to prepare reports on the status of the science of vaccine injury causation, and they did so in two reports I think in 1991 and 1994.

In the report in 1994, they made a point of a fact that they had encountered in their efforts, from chapter 11, "The lack of adequate data regarding many of the adverse events of the study was of major concern to this committee. Obvious needs for research and surveillance were identified." This opinion of the committee of the Institute of Medicine was published in 1994. I am not aware that anything was done about it.

Now, in fact, the rule changes that have been referred to, implemented in 1995 and 1996, were changes that, as everybody knows, made it harder for petitioners to prevail in their actions. These changes were not based on new science. There is no new science. They were not based on the Institute of Medicine recommendation. Actually, they ran counter to those recommendations.

Here is a specific about that. In the case of DPT vaccination, which is by far the commonest vaccination complained of, there really is only one epidemiological study that has been recognized as being definitive and reliable, and I quote from a publication of

the Institute of Medicine. The study is called the NCES, National Childhood Encephalopathy study, which was done in Britain. The committee says, "The NCES is the only systematic study of long-term dysfunction after DPT," and the committee endorsed that study, and the following statement is to be found in the same document: "The committee concludes that the balance of evidence is consistent with a causal relation between DPT and the forms of chronic nervous dysfunction described in the NCES in those children who experienced serious, acute, neurological illness within 7 days after receiving DPT vaccine."

So, what are these acute, neurological events? They subdivide into encephalopathy and seizures. The NCES studied serious seizures lasting more than half an hour or complicated seizures. Well, what happened after that? Seizures were removed from the table of entitlement after the IOM accepted the study which incriminated them in relation to DPT.

Encephalopathy. How was encephalopathy defined by the NCES, which was endorsed by the IOM? I would give a list, if I may, of the characteristics that were mentioned in the NCES document: altered state of consciousness, confusion, irritability, changes in behavior, screaming attacks, neck stiffness, convulsions, visual, auditory, and speech disturbances, motor and sensory defects. This is the list the NCES gave, and it is a list that is not inconsistent with neurological practice.

What is left after the change? One thing: lowered level of consciousness after 24 hours. If you don't have that, never mind you have all these other symptoms, you are not on the table, and God forbid you die before the 24 hours are up, because then, certainly, you haven't met the criteria.

So, I wish to present to the committee that the presumption of causation has been restricted to the point that it is tantamount to causation-in-fact. It is tantamount to going and proving the case in court every time over again. So, we have instead this lengthy process, this arduous process which might as well be conducted against the manufacturers as in the court of claims.

And, now, the Secretary has introduced proposals for legislative changes. In section three of the proposals, there is a suggestion which would make it easier for the Government to overthrow even table injuries. Now, when petitioners have to prove causation-in-fact because their injuries aren't on the table, they have to prove that the pertussis vaccine or other vaccine really caused the problem.

But the Secretary would like to change the burden on the respondent to overthrow a table injury by not having them actually prove the specific disease but merely argue, "Oh, there was a genetic cause. There was a metabolic cause." That is in section three. That section would make it even harder to recover under the terms of the act.

Now, with respect to the third point, I have only a brief comment to make. As has been mentioned several times, there is a large amount of money in the trust fund. It was contributed not by manufacturers, not by the Government, but by citizens when they purchased vaccines. The purpose was to compensate people who are injured by vaccines. I believe the money should continue to be used for that purpose.

Thank you, sir.

[The prepared statement of Mr. Kinsbourne follows:]

Testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government Reform

My name is Marcel Kinsbourne. I am a pediatric neurologist; my curriculum vitae has been provided. I have served as an expert witness for Petitioner in many actions under the terms of the 1986 National Vaccine Injury Compensation Act, from when these proceedings began in 1988. Before that, I lectured on neurological aspects of vaccine injury at the two-day training workshop for prospective Special Masters, that was held at the U.S. Court of Claims. I have also testified both for plaintiff and defendant in civil litigation. I am therefore in a position to compare the prevailing practice in vaccine injury litigation at the U.S. Court of Claims with practice in civil litigation. On August 3, 1999, I testified before the Committee on Government Reform on the issue of vaccine safety. My current testimony addresses the three issues that the Subcommittee has chosen for its deliberations.

The adversarial nature of Vaccine Act litigation

The Vaccine Act was introduced in 1986, in the context of a mounting volume of litigation against vaccine manufacturers, especially with respect to the DPT vaccine. It had come to the point that vaccine manufacturers threatened to abandon making this product. The Vaccine Act sought to provide claimants with an alternative to lawsuits, which was intended to proceed "quickly, easily, and with certainty and generosity". Initially, petitions were indeed dealt with in a non-adversarial manner, with the benefit of the doubt given to the Petitioner. This soon changed, and Respondent's defense against petitions on behalf of allegedly vaccine-injured people, mostly children, has become increasingly stubborn and aggressive, to the point that in its spirit, it is now indistinguishable from the adversarial manner in which some civil lawsuits are conducted.

The Department of Justice (DOJ) attorneys make full use of the apparently limitless resources available to them, in order to defeat petitions. They increasingly often substitute one expert for another if the opinion rendered by the first is unfavorable or seems not to impress the Court (or one theory for another), or recruit multiple experts for a single case, as against Petitioner's usually single expert. Multiple Entitlement Hearings result. The DOJ has retained and paid a group of professional investigators to perform a scientific study for litigation purposes, to reopen and defeat claims (Hanlon v. Sec HHS, Plavin v. Sec HHS) for which entitlement had previously been found. This was a considerable expense that Petitioner's attorneys could not remotely emulate under present rules. If the Court's decision in a particular case is unwelcome to the Justice Department attorney, he or she increasingly often reopens issues at the Damages Hearing that automatically follows, that are similar in nature to the arguments that failed at the stage of Entitlement. As a result, Damages Hearings threaten to become as burdensome to Petitioners as Entitlement Hearings. If after all this the outcome remains unfavorable to Respondent, the DOJ attorneys increasingly often resort to the multistage appeals process. The process is adversarial at every step.

Another tactic that is increasing in frequency is an attempt to discredit Petitioner's expert in the eyes of the Court by means of accusations of bias. A striking instance occurred in the most recent Hearing in which I testified (Flanagan v. Sec HHS). The DOJ attorney filed the statement that I had submitted to the Committee on Government Reform ahead of my testimony on August 3, 1999, as an Impeachment Exhibit. Her point was not that my testimony was flawed; when she cross-examined me she challenged none of it. She was content to have me acknowledge that this did represent a submission that I had made at the invitation of a Congressional Committee. Her point was that the fact that I had testified at all before the Committee impeaches my credibility as an objective medical expert (Closing argument, Transcript page 164, lines 21-25):

"The fact that he recently testified before Congress about a number of issues, but in particular, about his views on the problems with this program I think also shows that, to some degree, he is an advocate on behalf of the Petitioners, and Dr. Holmes is not."

I am confining my testimony to matters of which I have direct knowledge. But I do not believe that my experience is unique. I believe that the other medical experts, as well as Life Care Planners, retained by Petitioners, have had similar experiences.

The Special Masters continue to do their best to maintain objectivity, although they appear to be very conscious of the threat of appeals by Respondent. They also maintain a courteous and compassionate attitude toward the families that petition for compensation. They implement relaxed rules of procedure at the Hearings. Finally, they do their best to move the cases along in a timely fashion. This, however, becomes increasingly difficult as the defense stiffens, and families who are ultimately compensated often have waited for many years for this to happen. The Flanagan matter in which I testified last month was filed in 1991.

At the Committee's previous Hearing, I heard mention of two years as typical for the resolution of a claim under the Act. Even two years without interim funding for fees and expenses is burdensome. But in my experience, cases that are contested and finally resolved in favor of Petitioner often take much longer, four or five years, and even nine or ten. This contrasts with the initial expectation of Congress, in 1986, that the proceedings would last nine months at the outside.

I recognize from my experience of testifying in civil cases that the aggressive approach that I have outlined is not unusual in adversarial proceedings. I question whether it is consistent with the intent of Congress, at the time when the National Vaccine Injury Compensation Act was first formulated. By no stretch of the imagination can it be presented as nonadversarial or generous to Petitioner.

Changes in the criteria for a presumption of causation

The scientific basis for establishing causation in vaccine injury is complicated by the lack of disorders that are known <u>only</u> to be caused by a particular vaccine, and the unavailability of specific laboratory tests that identify vaccine injury. Neurological

diseases of children, such as cerebral palsy, epilepsy, mental retardation and autism, are caused by many different factors, and one usually cannot determine simply from what currently ails the child what in his case was the cause. Even after all pertinent tests have been done, the cause often still remains uncertain. So it is with neurological vaccine injuries. The inference that a vaccine injury has occurred can often be neither confirmed nor disconfirmed based on peer-reviewed scientific studies alone, since in many cases the relevant studies have simply not been performed. The argument that the onset of a disorder for which compensation has been claimed was coincidental with, and not caused by, the vaccination, can be adjudicated by epidemiological studies, but these are usually found not to have been performed. Several reports of the Institute of Medicine have pointed to the absence of studies based on which the Committee could determine whether certain complaints can be caused by particular vaccines or not. As new vaccines are now being introduced at an increasing rate, this absence of studies is becoming an even more serious problem.

The Act in its initial form introduced criteria for a presumption of causation that eased the burden on Petitioner to present scientific studies that simply have not been performed. Where there was uncertainty, Petitioner was given the benefit of the doubt. This was particularly important with respect to claims dealing with the pertussis vaccine, which have constituted the great majority of claims filed up to now. Starting in 1995, the Secretary of HHS has made the criteria for presumption of causation so much more stringent and demanding that the presumption is now unavailable to almost all claimants. The Secretary has effectively changed the guidelines for entitlement from a "mighty very well be due to" to a "no question that" criterion. These additional restrictions on entitlement were implemented in the absence of any new or recent scientific findings that might justify such changes. To the contrary, successive findings of the Institute of Medicine (1990, 1994) have increasingly confirmed the reality of pertussis vaccine brain injury.

An instance of a severe rollback of the presumption of causation is the redefined criterion for encephalopathy, a major subject of pertussis vaccine injury claims. Encephalopathy was redefined so that the diagnosis requires as a *sine qua non* in excess of 24 hours of a diminished level of consciousness, a criterion which is far more restrictive than that of the leading epidemiological study of pertussis vaccine injury, the British National Childhood Encephalopathy Study (NCES). Moreover, seizures have been removed from the Table, although that the pertussis vaccine can cause seizures is uncontested (and warned in the manufacturer's package insert), and although the NCES found a significant association between a severe seizure and DPT administration in the preceding three days (a finding that was endorsed by the Institute of Medicine). Essentially, the presumption of causation has been restricted to the point that it has become tantamount to causation-in-fact. It therefore no longer renders "the benefit of the doubt" to Petitioner, let along any "generosity". Almost all claims for injury by the pertussis vaccine must now meet causation-in-fact criteria, initiating a lengthy and arduous process, that is often unproductive because the relevant science is unavailable. Given the great expense and difficulty of prevailing with a Vaccine Act claim as to pertussis vaccine injury, there has been a resurgence of lawsuits against vaccine manufacturers, a development that the Act

was intended to render unnecessary. Indeed, a plaintiff may well now find it easier and quicker to prevail in civil litigation than in the U.S. Court of Claims.

The dearth of relevant science on which to base a causation-in-fact Petition becomes an even more serious problem when the claim is for an injury inflicted by a newly marketed vaccine, not listed in the Table of qualifications for a presumption of causation. If Petitioner has to produce nonexistent studies to prevail, he or she essentially remains without a remedy. To avoid this undesirable outcome, it is necessary to establish a Table of presumptive causation for the newer vaccines, that lists Table injuries on a "might very well be due to" basis. An example might be the causation of autoimmune diseases by Hepatitis B vaccine.

In sum, the initial intention of Congress, that a relatively informal, generous and friendly process, concluded in a timely fashion, would offer claimants an attractive alternative to launching lawsuits against drug manufacturers, has been undermined. Among the Legislative changes recently proposed by HHS are ones that would undermine it still more. I believe that the current criteria for a presumption of vaccine injury need review and revision. Some revised criteria should be revised back to their original formulations.

Funding for future needs

Up to recently, the great majority of claims were filed with respect to injuries caused by the whole cell pertussis vaccine. Now that an acellular vaccine is available, I expect a greatly diminished rate of injury from vaccination against whooping cough. But this will only occur if the continuing use by some pediatricians of the less safe whole cell vaccine is halted.

The prospect of fewer claims with respect to pertussis vaccine is offset by the continuing introduction of new vaccines, with ill-researched and ill-understood adverse side effects. It is also offset by the increasing practice of combining the administration of multiple vaccines, a practice the safety of which has barely been investigated. Finally, if less adversarial procedures are introduced, more petitions will be recognized to have merit.

Obviously, significant funding will be required for the foreseeable future. However, I learned at the previous hearing that there is a "surplus" of 1.4 billion dollars in the Trust Fund (though how this sum is a surplus, given pending and anticipated petitions, escapes me). The monies in the Trust Fund contributed by citizens as a compulsory surcharge on vaccines should continue to be used only for the purpose for which they were intended, namely, to compensate victims of vaccine injury.

Mr. MICA. Thank you for your testimony.

We will now hear from Dr. Arnold Gale with Stanford University.

You are recognized, sir.

Dr. GALE. Thank you, Mr. Chairman, the ranking minority member, Mrs. Mink, and ladies and gentleman of the committee.

Thank you for the privilege of testifying today about the Vaccine Injury Compensation Program. I am a child neurologist and a member of the faculty of the Stanford University School of Medicine. And for the past decade, I have participated in the program by lending my expertise to the review of the medical records of petitioners filing claims for compensation. At the same time, I have acquired a perspective of the process itself and of the deeper issue of vaccine-related injury, which I should like to share with you this morning. Although a wide variety of vaccines are covered by the program, and while my remarks are pertinent to all of them, I will focus primarily upon the pertussis vaccine, which has given rise to the vast majority of claims.

My role as a medical reviewer for the program is little different than that which I perform in my usual capacity as a clinician. Keeping in mind the criteria that are set forth in the vaccine injury table, I review the medical records and the supporting documents of each claim, seeking to answer these questions: Does a condition described on the table exist? If so, has it occurred within the prescribed timeframe? And if so, can a factor unrelated to the vaccine be identified as the probable cause of the condition?

If a condition described in the table occurs within the prescribed timeframe, and if no factor unrelated to the vaccine can be identified as the probable cause of the injury, then the claim is compensable under the National Childhood Vaccine Injury Act. I file a report with the program to that effect, and the claim typically proceeds to the damages phase of the process.

Alternatively, if no condition described in the table can be identified, or if a condition has its onset beyond the prescribed timeframe, or if a factor unrelated to the vaccine can be identified as the probable cause of the condition, then the claim is not compensable under the act. I file a report to that effect, and the entitlement phase continues, typically proceeding to an adjudicative hearing before a special master. The process is similar in cases in which a child may have suffered a significant aggravation of a pre-existing condition following immunization.

Under the act, a table injury without an identifiable factor unrelated to the vaccine is presumed to have been caused by the vaccine, and proof of causation is not required. Only when injuries occur beyond the timeframe of the table does the petitioner have the burden of the proof of causation. The fairness of the program rests heavily, I believe, upon this principle.

The act provides for periodic revision of the table based upon experience and the evolving understanding of the science and the medicine governing the table. With respect to the pertussis vaccine, perhaps the most significant of these revisions occurred in March 1995, when "residual seizure disorder," was eliminated as a distinct condition, and the definition of "encephalopathy" was changed. The former was undertaken only after careful consider-

ation of the cumulative experience with seizures following immunization.

Most seizures closely following immunization are febrile seizures, which are typically brief, self-limited events affecting genetically predisposed infants and children. They are benign and are not associated with untoward outcomes.

Most of the remaining seizures may be triggered by fever in children who have occult epilepsy—that is, an already existing epilepsy—but there is no evidence that the epilepsy itself is caused by the vaccine, except when accompanied by signs or symptoms of an acute encephalopathy. Relatively few cases have been affected by this change in the table.

In contrast to more than 3,600 DTP-related claims adjudicated under the initial table, fewer than 300 total claims have been filed since the change in 1995. The definition of "encephalopathy" incorporated into the initial table was vague and confusing to my way of thinking and to that of my colleagues, and it disregarded the differences in the signs and symptoms that are observed in infants and older children. Because I had a role in framing the language of the new definition in 1995, I can attest that the change was motivated solely by a desire to clarify. Only a small fraction of cases filed since that change has been affected.

If my description of the mechanics of the program, and of its underlying table, is itself a little mechanical and a bit dry, the same cannot be said of the program's hearing process. Its adversarial nature is ensured by the participation of lawyers and the special master. What should be a quiet, civil, deliberative discussion of facts and medicine too frequently degenerates into a contentious, vituperative, decibel-escalating exchange. Ad hominem attacks on physicians by all attorneys are common.

Most disturbing, from my perspective, has been the injection of pseudo-science provided by self-proclaimed vaccine-ologists. With accumulated experience, however, the special masters appear better able to readily identify such witnesses, crediting their testimony with the weight that it deserves.

Each participant in the program—parents, special masters, attorneys, physicians, and others with stakes in the process—possesses a unique perspective, and it is that perspective which creates perception. Perception is a powerful thing. In 1977, the British Broadcasting Co. televised a documentary warning parents of the potential dangers of the pertussis vaccine. During the ensuing year, the rate of immunization among infants in Great Britain, a nation with accessible, free health care, plummeted approximately 45 percent. During that same period, in a population roughly a quarter that of the United States, the number of deaths from pertussis, or whooping cough, was quadruple our own. All too quickly, the perception of risk, which motivated so many parents to withhold immunizations, was replaced by grief.

The parents who petition the program have their own perspectives and perceptions, and they have my empathy and my sympathy for the loss of the children who would have been adults. Often their children have serious chronic neurologic disabilities, and they grieve for lost hopes and dreams. Among their needs is the need to know why. Compensation from the program, then, pro-

vides more than the financial resources for future care and the accompanying peace of mind. It vindicates the strongly held belief that the vaccine is at fault, despite the fact that there is no method available to determine whether the vaccine did, in fact, injure their child.

The special masters are dedicated to the principles that guide the program, the first of which is compassion. Uncompensated claims are not attributable to their indifference, but rather to the relatively small number of cases that satisfy the minimal requirements of the table. Never is the problem of perception as poignant as in the instance of the sudden, unexplained death of an infant following immunization.

In approximately half of such cases, the medical and pathological records are consistent with Sudden Infant Death Syndrome [SIDS], a condition not associated with pertussis immunization, according to the medical literature and the report of the Institute of Medicine. Still, it is unlikely that anything will dissuade a grieving parent that the close temporal relationship between immunization and an infant's death is coincidental.

In nearly 25 years as a clinician, I have witnessed a few rare cases of infants and children whose acute neurologic disorders began immediately following immunization, and for which no reasonable alternative could be identified. Like most of my colleagues, I think that such events occur, may be vaccine-related, but that they are rare.

With respect to the pertussis vaccine, there is no method available today that permits causation in any individual case to be established. This opinion is widely held and well-supported by the current medical literature. My own decade-long experience with the program has taught me that literally hundreds, if not thousands, of youngsters whose parents believe that they have been injured by vaccines, have, in fact, alternative diagnoses that account for their neurological disabilities. The rarity of vaccine-related injuries makes epidemiological studies difficult to design and execute, and such studies could not establish causation in an individual case nor prove that such injuries never occur.

A half-century after widespread immunization began, our knowledge of such injuries is sparse. What we do know is that countless lives have been saved and serious illness and disability prevented by immunizing against infectious diseases that were once the scourges of humanity. And, those vaccines have never been safer than they are today.

Thank you again for the privilege of testifying before you today on this critical matter.

[The prepared statement of Dr. Gale follows:]

Testimony of Arnold D.Gale, M.D., before the Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources, United States House of Representatives, on September 28, 1999.

Mr. Chairman, Ranking Minority Member Ms. Mink, Ladies and Gentlemen of the Subcommittee:

Thank you for the privilege of testifying today about the Vaccine Injury Compensation Program. I am a child neurologist and a member of the faculty of the Stanford University School of Medicine. For the past decade, I have participated in the Program by lending my expertise to the review of the medical records of petitioners filing claims for compensation; at the same time, I have acquired a perspective of the process itself and of the deeper issue of vaccine-related injury, which I should like to share with you. Although a wide variety of vaccines are covered by the Program, and while my remarks are pertinent to all of them, I will focus primarily upon the pertussis vaccine, which has given rise to the vast majority of claims.

My role as a medical reviewer for the Program is little different than that I perform in my usual capacity as a clinician. Keeping in mind the criteria set forth in the Vaccine Injury Table, I review the medical records and supporting documents of each claim, seeking to answer these questions: Does a condition described on the Table exist? If so, has it occurred within the prescribed timeframe? If so, can a factor unrelated to the vaccine be identified as the probable cause of the condition? If a condition described in the Table occurs within the prescribed timeframe, and if no factor unrelated to the vaccine can be identified as the probable cause of the injury, the claim is compensable

under the National Childhood Vaccine Injury Act; I file a report with the Program to that effect, and the claim typically proceeds to the damages phase of the process. Alternatively, if no condition described in the Table can be identified, or if a condition has its onset beyond the prescribed timeframe, or if a factor unrelated to the vaccine can be identified as the probable cause of the condition, then the claim is not compensable under the Act; I file a report to that effect, and the entitlement phase continues, typically proceeding to an adjudicative hearing before a special master. The process is similar in cases in which a child may have suffered significant aggravation of a pre-existing condition following immunization.

Under the Act, a Table injury without an identifiable factor unrelated to the vaccine is *presumed* to have been caused by the vaccine; proof of causation is not required. Only when injuries occur beyond the timeframe of the Table does the petitioner have the burden of proof of causation. The fairness of the Program rests heavily, I believe, upon this principle.

The Act provides for periodic revision of the Table based upon experience and the evolving understanding of the science and medicine governing the Table. With respect to the pertussis vaccine, perhaps the most significant of these revisions occurred in March, 1995, when "residual seizure disorder" was eliminated as a distinct condition, and the definition of "encephalopathy" was changed. The former was undertaken only after careful consideration of the cumulative experience with seizures following immunization. Most seizures closely following immunization are "febrile seizures", which are typically

brief, self-limited events affecting genetically predisposed infants and children; they are benign and are not associated with untoward outcomes. Most of the remaining seizures may be "triggered" by fever in children with occult epilepsy, but there is no evidence that the epilepsy itself is caused by the vaccine, except when accompanied by signs or symptoms of acute encephalopathy. Relatively few cases have been affected by this change in the Table. In contrast to more than 3,600 DTP-related claims adjudicated under the Initial Table, fewer than 300 total claims have been filed since the change in 1995. The definition of "encephalopathy" incorporated into the initial Table was vague and confusing, and it disregarded the differences in the signs and symptoms observed in infants and older children. Because I had a role in framing the language of the new definition in 1995, I can attest that the change was motivated solely by a desire to clarify. Only a small fraction of cases filed since the change has been affected.

If my description of the mechanics of the Program, and of its underlying Table, is itself mechanical and a bit dry, the same cannot be said of the Program's hearing process. Its adversarial nature is ensured by the participation of lawyers and the special master. What should be a quiet, civil, deliberative discussion of facts and medicine too frequently degenerates into a contentious, vituperative, decibel-escalating exchange. Ad hominem attacks on physicians by petitioners' attorneys are common. Most disturbing, from my perspective, has been the injection of pseudo-science provided by self-proclaimed "vaccine-ologists." With accumulated experience, however, the special masters appear better able to readily identify such witnesses, crediting their testimony with the weight it deserves.

Each participant in the Program—parents, special masters, attorneys, physicians, and others with stakes in the process—possesses a unique perspective; and, it is that perspective which creates perception. Perception is a powerful thing. In 1977, the British Broadcasting Company televised a documentary that warned parents of the potential dangers of the pertussis vaccine. During the ensuing year, the rate of immunization among infants in Great Britain, a nation with accessible, free health care, plummeted approximately 45%. During that same period, in a population roughly a quarter of the United States, the number of deaths from pertussis, or whooping cough, was quadruple our own. All too quickly, the perception of risk, which motivated so many parents to withhold immunizations, was replaced by grief.

The parents who petition the Program have their own perspectives and perceptions. Often their children have serious chronic neurologic disabilities, and they grieve for lost hopes and dreams. Among their needs is the need to know <u>why</u>. Compensation from the Program provides more than the financial resources for future care and the accompanying peace of mind; it vindicates the strongly held belief that the vaccine is at fault, despite the fact that there is no method available to determine whether the vaccine did, in fact, injure their child. The special masters are dedicated to the principles that guide the Program, the first of which is compassion. Uncompensated claims are not attributable to their indifference, but rather to the relatively small number of cases that satisfy the minimal requirements of the Table. Never is the problem of perception as poignant as in the instance of the sudden, unexplained death of an infant following immunization. In

approximately half of such cases, the medical and pathological records are consistent with Sudden Infant Death Syndrome (SIDS), a condition not associated with pertussis immunization, according to the medical literature and the report of the Institute of Medicine. Still, it is unlikely that anything will dissuade a grieving parent that the close temporal relationship between immunization and an infant's death is coincidental.

In nearly twenty-five years as a clinician, I have witnessed a few rare cases of infants and children whose acute neurological disorders began immediately following immunization, and for which no reasonable alternative cause could be identified. Like most of my colleagues, I think that such events occur, and may be vaccine-related, but that they are rare. With respect to the pertussis vaccine, there is no method available today that permits causation in any individual case to be established. This opinion is widely held and well-supported by the current medical literature. My own decade-long experience with the Program has taught me that literally hundreds, if not thousands, of youngsters whose parents believe that they have been injured by vaccines, have, in fact, alternative diagnoses that account for their neurological disabilities. The rarity of vaccine-related injuries makes epidemiological studies difficult to design and execute; and, such studies could not establish causation in an individual case nor prove that such injuries never occur.

A half-century after widespread immunization began, our knowledge of such injuries is sparse. What we do know is that countless lives have been saved and serious

illness and disability prevented by immunizing against infectious diseases that were once the scourges of humanity. And, those vaccines have never been safer than they are today.

Thank you again for the privilege of testifying before you today on this critical matter.

Mr. MICA. Thank you, and we will hear from our third witness, Mr. Cliff Shoemaker. He is an attorney with Shoemaker & Horn. Welcome, and you are recognized, sir.

Mr. SHOEMAKER. Thank you, Mr. Chairman. I am flattered to be included on a panel with two esteemed doctors. I probably would be more appropriately placed on the panel with John Euler who is probably my counterpart in this program.

Mr. Chairman and members of the subcommittee, I am very pleased to be with you here today to talk to you about a subject that is very near and dear to me. Before I begin, let me begin by saying that I would like to place my father's name, Ralph Shoemaker, in the Congressional Record. My father died on September 11 as I was preparing my testimony for this hearing, and my remembrances of him were constantly with me as I prepared this testimony.

I often tell people that I represent saints—the parents of children who have been profoundly injured as the result of vaccinations. But I want you to understand that I am not—and I repeat the word "not"—against vaccinations. It is important that you understand where I am coming from in this regard. You see, my parents are also saints; not because they put up with me, but because they raised a handicapped child and helped her to become a fulfilled, beautiful person.

The year that I was born, one of my sisters, who was then 9, contracted polio. She has lived her life in a wheelchair, because vaccines to protect her against that dread disease had not yet been developed. So now, as Paul Harvey would say, you know the rest of my story and one of the reasons why I am so committed to the development of safe and effective vaccines designed to protect us against serious diseases.

And I might add as a sidelight here, Congressman Burton had an exchange with Mr. Salamone, and it brings up a perfect example of what I am talking about, because I am one of the people who has said we cannot stop giving polio vaccines until we have vaccinated our population for at least 10 years with kill virus vaccine. The reason for that is that we do have cases of people who have contracted polio from live polio vaccine. We know that they can shed that virus for at least 8 years, so there is a pool of polio virus there, and you cannot stop giving polio vaccine, at least not the kill vaccine, until we are absolutely sure that this disease has been eradicated. So, if there is any doubt about my view on vaccines, that is it.

In a very real sense, I am here today testifying on behalf of the United States—excuse me, sir.

Mr. MICA. If I may submit my unanimous consent your request for also the inclusion of your father's mention, Ralph Shoemaker, into the record and also your entire statement. Without objection, so ordered.

If you would care to go ahead and summarize. Thank you.

Mr. SHOEMAKER. Thank you, sir.

In a very real sense, sir, I am here today testifying on behalf of the U.S. Government; that is, that part of the Government which is "of the people, by the people and for the people." Abraham Lincoln once said, "It is as much the duty of Government to render

prompt justice against itself, in favor of its citizens, as it is to administer the same, between private individuals."

I have been involved in vaccine litigation for over 20 years. Prior to the enactment of the Compensation Act in 1986, the families of children, as Congressman Waxman explained, were forced to hire lawyers and file lawsuits against the vaccine manufacturers and vaccine administrators. These suits were expensive and time-consuming, and the results were quite variable.

At a "Symposium on Public Concerns of Immunization" held at Georgetown University in 1978, Dr. Leroy Walters made the following statement, which I think is very appropriate for our discussion today. He said,

> Consider the following metaphor drawn from military service: Mass immunization programs are a significant element in the war on infectious disease. In mandatory immunization programs, a system of conscription is employed to recruit soldiers for this anti-disease campaign. As it happens, most of the recruits in the war on infectious diseases are children. In most cases, participation in the war on infectious diseases is beneficial to the young soldiers themselves. However, at least part of the rationale for conscription is that the pediatric warriors will protect other children and the population as a whole against the onslaughts of infectious disease. As in all wars, some soldiers are injured. The number of child-soldiers and their contacts who are actually wounded in this war is small, almost infinitesimal. Yet service-connected disabilities do occur. At present, the draftees who are injured in the war on infectious disease are in effect told by the conscripting authorities, "Thank you for your contribution to the war effort, and best of success in coping with your disabilities."

If you don't mind, I feel very funny just reading into the record something that I have already written and everyone can read for themselves. I would like to respond to some of the things that I have heard here today. I feel like I am ready to explode with so much information and so much that needs to be talked about.

Congressman Waxman indicated this program was created because plaintiffs only had this alternative to going into court, and that is true. But as Congressman Burton pointed out, this program was created because there was a national emergency, and that national emergency was that the vaccine manufacturers were threatening to stop the production of vaccines. This was an emergency, and Congress dealt with that emergency in a brilliant fashion.

Congress brought together people from all different walks of life. They brought in the manufacturers; they brought in people from the Department of Justice, from HSS; they brought in victims; they brought in groups that represented victims. They took all these people together, and they forged a political compromise. And I think it is important to understand that that was a political compromise, not a scientific decision, not a medical decision, it was a political compromise. The table of injuries that everybody has talked about today was a political compromise.

Dr. Kinsbourne is right—there was no new evidence that justified changing that table when the Secretary changed the table, and I hope you will read what I have said about that. The table is changed now so we have a situation where the only encephalopathy is one where you have reduced level of consciousness for at least 24 hours. Now, maybe Dr. Gale can explain to me how a vaccine that is capable of producing that kind of an injury cannot produce an injury that is less severe? If it can produce a severe injury, it can produce a less severe one.

Congressman Burton asked questions about the hepatitis B vaccine. How do you make a study—when you give a baby a hepatitis B vaccine in the hospital before they leave, how are you going to conduct the study that Dr. Gale asked about, a study of epidemiology? How are you going to design and implement a study, because you have nothing to compare that baby with? At 2 and 4 and 6 months, it is hard enough to know what the baby was like and to show before and after—that is tough enough. But you give it to a baby and the baby has an injury from the vaccine, how can you prove it? How do I prove it as a lawyer? That is the perfect way to disguise an injury from a vaccine. Give it to a baby, and then you can blame it on genetics or structural abnormalities, and that is what the Secretary is asking you to do, to not only make changes to this program but make it more difficult to collect on these cases. If you agree with their language on genetic abnormalities and structural lesions, I can guarantee you that there won't be anybody on this case.

I just returned from Florida where I visited and met with lawyers who are prepared to work on hepatitis B vaccine claims. We filed over 130 such claims, and I can tell Congressman Burton that the problem we have in this program is that our meeting was not to discuss—well, it was to discuss how we are going to prove causation in these cases—but our meeting was to discuss what we are going to do when we are forced out of this program if it is not changed and how we are going to mount civil litigation in these cases. That is the discussion we were holding.

You are absolutely correct in saying if this program is not fixed, I can guarantee you that the hawks that are sitting on the sidelines and calling me crazy for staying involved in this program are going to carry the day, and we are going to be back in court suing manufacturers, suing doctors, doctors who didn't recognize that the first shot caused problems, the second shot caused problems, and they went ahead and gave the third shot.

One of the things we see of hepatitis B vaccine cases is we see people who received a series of vaccines and had repeated injuries after each vaccine to that. We have got to develop methods of showing doctors and telling doctors that if a child has a reaction to one vaccine, you don't give him anymore. Stop this dogma of giving it to a child.

We are working with doctors now who are trying to determine if there are genetic abnormalities or genetic genomes or genotypes that can help us to identify children who are high risk of developing reactions to vaccine. That is research that we are doing—plaintiffs' lawyers, the scourge of the Earth. It is not being done in the places where it should be done. We need research today, but we also need a program, and I encourage you when you think of that military analogy, give us the burden of proof that you use for veterans' claims. Give us a burden of proof where the benefit of the doubt truly goes to the petitioner. Take away this idea that this is a waiver of sovereign immunity and that everything should be narrowly construed against the claimants. That is not the case. This is a compensation program; it is remedial. The benefit of the doubt should be in the favor of the claimants in these cases, and if this program doesn't start working, something is going to happen.

I can't prove causation in a case the way I used to prove in contingency litigation. It was not uncommon for me to spend $50,000 on a case to prove causation—hiring experts, performing epidemiological studies, performing biological testing programs. I can't afford to do that in this program. Today, when I am finally compensated with the meager compensation that I get from this program and the expense reimbursement, I am paying yesterday's bills.

That is why none of my compatriots, none of the litigation lawyers in this country are willing to stay involved in this program. You heard from one of the claimants that her firm is no longer taking any vaccine cases. It is a respectable, well-respected plaintiffs' firm. Those firms will not get involved in these cases, because they can't get paid on time; they can't get their expenses reimbursed until the end of the case; they cannot afford to handle these cases.

The war chest that I once carried when I was in contingency litigation is gone. I can no longer afford to do the things that I need to do. I am embarrassed by the limited amount of things that I can do to prosecute these cases. And I would say to Congressman Burton, sure I will be happy to represent your grandchildren, but can you come up with $40,000 or $50,000 to help me do the studies necessary to prove causation in these cases? Because the Government won't do it, and there is a reason why they won't. They feel like if they show or demonstrate that there is a problem with a vaccine, then people are going to be afraid, and people are going to not get the vaccines.

Let me just say—and this is in the conclusion of my presentation—anybody who points to this program and points to the children who are compensated and uses that as evidence that vaccines are dangerous ought to be ashamed of themselves. And anybody who points to this program on the other side of the case and says that the fact that such a small percentage are compensated shows these vaccines are safe and people are just full of hot air, they ought to also be ashamed themselves.

That is not the purpose of this program. It is not to try vaccines and determine whether they are safe. The purpose of this program is to compensate people in a fair and generous and simple way. If it is going to be highly adversarial, if we are going to have three and four experts hired in every case to testify against us, then give me the resources, give me the money to fight this battle like I would fight it in civil court.

But I can't fight these battles the way this program is structured now. And that is why attorneys like myself are planning for the future, and the planning for the future is if this program isn't fixed, then it will not be the model for tort reform that we all want. It will be a perfect example of how not to reform the tort system.

Thank you.

[The prepared statement of Mr. Shoemaker follows:]

CONGRESSIONAL TESTIMONY
of
CLIFFORD J. SHOEMAKER[1]

Mr. Chairman and other members of this Subcommittee, I am very pleased to be with you today to talk about a subject that is very near and dear to me. Before I begin, let me enter my father's name, Ralph Shoemaker, into the Congressional Record. My father passed away on September 11th as I was preparing my testimony for this occasion, and my remembrances of him were constantly on my mind as I wrote this testimony.

[1]Mr. Shoemaker is the senior partner in the firm of Shoemaker & Horn, located in Vienna, Virginia. The firm has represented hundreds of claimants under the National Vaccine Injury Compensation Program.

I often tell people that I represent "saints" - the parents of children who have been profoundly injured as the result of vaccinations. But I want you to understand that I am NOT (and I repeat, NOT) against vaccinations. It is important that you understand where I am coming from in this regard. You see, my parents are also saints - not because they put up with me, but because they also raised a handicapped child and helped her to become a fulfilled, beautiful person. The year I was born, one of my sisters, who was then nine, contracted polio. She has lived her life in a wheelchair because vaccines to protect her against that dread disease had not yet been developed.[2] So now, as Paul Harvey would say, you know the rest of my story and one of the reasons why I am so committed to the development of safe and effective vaccines designed to protect us against serious diseases.

In a very real sense, I feel that I am here today testifying on behalf of the United States government - or at least that part of the government which is "of the people, by the people and for the people." Abraham Lincoln once said,

> It is as much the duty of government to render prompt justice against itself, in favor of its citizens, as it is to administer the same, between private individuals.

As a lawyer, it is my job to represent the best interests of my clients in one of the greatest legal systems in the world.[3] For over twenty years, I have been involved in representing children and adults who have been seriously injured as the result of the receipt of vaccinations.[4]

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[2] My parents raised her to become a strong, independent person who once won the Miss Handicapped America pageant; who won gold medals at the handiccapped olympics; and who has now taught music to thousands of children in High Schools, Junior Highs and grade schools, positively touching the lives of countless people.

[3]People can complain about our system and make jokes about lawyers and the legal system, but in my humble opinion, we have the best legal system in the world right here in this country.

[4]Beginning in 1978, I represented many people who developed neurological injuries from Swine Flu vaccination. For several years, I traveled all over the country trying those cases in federal courts. Swine flu cases were Federal Tort Claims Act cases where the federal government allowed itself to be sued by stepping into the shoes of the manufacturers and administrators of the vaccine. When then Secretary Califano acknowledged that Guillain Barre syndrome, or GBS, had been shown to be caused by the vaccine, he also announced that anyone who could show that their GBS was caused by the vaccine would not have to prove any theory of liability, such as negligence or failure. A strange system developed where someone who suffered peripheral nerve damage (or GBS) from the vaccine did not have to prove a theory of liability, but someone whose brain - or central nervous system - was damaged by the vaccine was held to a higher standard and did have to prove fault or negligence or some other theory of liability. The Swine Flu cases were probably a perfect example of how NOT to handle claims for vaccine injuries. I tried cases in front of federal judges all over the country. I lost some cases that would clearly have been won in front of a different judge, and, on the other hand, I won some cases which would have been lost in front of other judges. The disparity in results, the differing treatment of people depending on which part of their nervous system was damaged, the policy of the Department of Justice to routinely litigate rather than routinely settle cases - all of these factors and more convinced me that there had to be a better way to handle such claims. The Swine Flu experience was also a totally wasted opportunity to perform the definitive study of Guillain Barre Syndrome (GBS) and to completely understand the pathogenesis (or precise mechanism) of how Swine Flu vaccine caused an autoimmune disease like GBS. Over the years, I have gone on to represent victims of other vaccines, such as the children who develop seizure disorders and encephalopathy (or brain damage) from DPT vaccinations. (And we are proud of the accomplishment of finally replacing whole-cell DPT vaccine with the safer DTaP split-cell product.)

Prior to the enactment of the National Vaccine Compensation Program, injured parties were left to proceed in civil suits against vaccine manufacturers and administrators of vaccines. This litigation was time consuming and expensive, the results were mixed, and, while there were large judgments for some, with large attorney's fees, there were many who were unsuccessful in their quest for needed compensation. (Those whose claims failed most likely today rely on another government program, Medicaid.) Manufacturers were concerned enough about potential liability so that some felt the supplies of vaccines were threatened. It was obvious to many people that, although the risks of serious reactions to vaccinations are small, such injuries are nevertheless devastating to the victims and their families, and they needed a fair and compassionate method of compensation. At a "Symposium on Public Concerns of Immunization" held at Georgetown University on October 25-26, 1978, Dr. Leroy B. Walters set the context for the program that was to follow:

> *Consider the following metaphor drawn from military service: Mass immunization programs are a significant element in the war on infectious disease. In mandatory immunization programs a system of conscription is employed to recruit soldiers for this anti-disease campaign. As it happens, most of the recruits in the war on infectious diseases are children. In most cases, participation in the war on infectious diseases is beneficial to the young soldiers themselves. However, at least part of the rationale for conscription is that the pediatric warriors will protect other children and the population as a whole against the onslaughts of infectious disease . . . As in all wars, some soldiers are injured. The number of child-soldiers and their contacts who are actually wounded in this war is small, almost infinitesimal. Yet service-connected disabilities do occur. . .*
> *At present, the draftees who are injured in the war on infectious disease are in effect told by the conscripting authorities, 'Thank you for your contribution to the war effort, and best of success in coping with your disability.'*

This analogy to the military veteran is particularly appropriate for our discussions today, and I will be referring back to that analogy, so please keep it in mind. The National Vaccine Injury Compensation Act was passed by Congress in 1986 to provide a no-fault compensation program for those individuals who are unfortunately injured by the very vaccines that are designed to protect them and to protect society. The program was supposed to be a non-litigious, compassionate program which would err on the side of over-compensating rather than under-compensating these unfortunate victims. In practice, the program has become a litigious, expensive process where it is becoming more and more difficult to prevail.[5]

[5]Representative Waxman, one of the authors of the original Vaccine Act, was recently quoted as saying, "The whole idea of a system was to show through a no-fault process that an injured child would be compensated generously and easily. We wanted to err on the side of compensating kids." John Hanchette & Sunny Kaplan, National Vaccine Compensation Program for Children Draws Fire, Gannett News Service, August 11, 1998. Congress was also striving to preserve the security of the vaccine supply by preventing law suits against doctors and manufacturers. Denis J. Hauptly & Mary Mason, The National Childhood Vaccine Injury Act, 37 Fed. B.N.J. 452 (1990). However, the Program fails when people find the Program inaccessible or less compensatory than suits filed against manufacturers.

Claimants under the program have two ways of prevailing. First of all, they can try to demonstrate that their claim falls within a "Table of Injuries" that was created by Congress and which, if one were to fit under the table, creates a presumption that the vaccine caused the injury. The burden then shifts to the Respondent[6] to prove, if they want to or can, that the injury was in fact caused by something else instead of the vaccine. The second way that a claimant can prevail is to prove that the vaccine did, in fact, cause the injuries that are being complained of. I will discuss the standard of proof for these types of cases in a moment.

[6]Health and Human Services is the agency that is the designated Respondent in these claims, and it is represented by attorneys from the Department of Justice.

In addition to providing petitioners a presumptive Table of Injuries, Congress also gave the Secretary of Health and Human Services the power to change the Table. This included the power to add newly-developed vaccines to the Table and to provide new presumptions for the injuries. In late 1994, the Secretary of Health and Human Services ("HHS") proposed certain changes to the Table of Injuries. These regulations became effective on March 10, 1995, and they have effectively devastated the Program. Please review my footnote here about this subject.[7] Practically speaking, the Table of Injuries, which, in my opinion and the opinion of others, should have been expanded[8],

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[7]HHS removed the Table Injury of "Residual Seizure Disorder" completely. In addition, HHS eradicated the congressionally-provided definition of "encephalopathy" and put in its place a new definition that is so restrictive that almost no cases fall within the definition's narrow confines. The prior table provided that causation would be presumed in cases where the victim suffered from a residual seizure disorder or an encephalopathy. To prove a residual seizure disorder, the Petitioners merely had to show that the child had no prior seizures (unaccompanied by fever of less than 102^0); that the child had a seizure within 3 days of vaccination; and that there were two more seizures (unaccompanied by fever of less than 102^0) within the next year. The original Table of Injuries adopted by Congress also had a different definition for "encephalopathy":

> The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. . . . Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. (Section 100.3(b)(3)(A), prior to March 10, 1995)

Under that earlier definition, it would certainly have been easier to establish causation in a case. When HHS changed the table, they eliminated the seizure disorder category and severely restricted the definition of encephalopathy. Under the new definitions, "an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours."

[8]For instance, while the original Table of Injuries created a presumption of causation for residual seizure disorders and encephalopathies which had onset within three days of DPT vaccinations, subsequent analyses of NCES studies published by the IOM not only accepted the concept of seizures being causally related, but suggested that cases occurring up to seven days after vaccination may be causally related. I will never forget losing a claim because the first seizure occurred 75 hours after vaccination. The IOM report makes reference to a number of conditions

was instead reduced to a meaningless concept. If anything, the Table of Injuries has almost made it more difficult to prove causation in cases that do not fit it precisely.

The other method of proving causation is supposed to be similar to the method of proving causation in a traditional civil trial. In legal language, that means that the claimant is supposed to demonstrate by a preponderance of the evidence that, more likely than not, the injury was in fact caused by the vaccine. In my experience, the standards of proof that claimants in this program have been held to have been higher than what is typically adequate in front of a jury. The statistics speak for themselves, and it is obvious to me that proving causation in these cases has become an onerous proposition, where we are erring on the side of under-compensation. I would ask that you read carefully my footnote at this point about what I call "the uneven playing field." It is a description of the many difficulties faced by Petitioners in this program.[9]

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following various vaccinations where they conclude that a relationship is "biologically plausible" and they point to case reports in the medical literature as suggesting a relationship, but they conclude that, because there are not adequate controlled epidemiological studies available, they cannot reach a conclusion one way or the other. Obviously, the Secretary has chosen not to include any of these conditions in the Table of Injuries, so the claimants are never given the benefit of the doubt in this program as it stands.

[9]"The Uneven Playing Field"

The parties in these cases are not on equal footing, as they should be. Petitioners currently are forced to pay the costs of litigation and be reimbursed for those expenses years in the future. When possible, petitioners hire experts who can afford to be paid in the future when compensation for their efforts finally is granted by the court. Many experts refuse to work without being paid in advance, and their services are often unavailable to petitioners for that reason. The government can pay their experts as soon as their time is billed. In addition, the government is in an entirely different position when it comes to hiring experts in the first place. In one of my recent cases, one of the government experts admitted that he had received $11 million in government grants. Not surprisingly, the government experts often work for very low hourly rates. In these cases, the most that the government pays an expert is $200 per hour. Because this is the highest government rate, the Department of Justice has been successful in the past in limiting the amount that petitioners were allowed to pay their experts to the same rate. In a recent case, one government expert testified that he was paid $200 per hour for his report and testimony, but he received up to $330 for treating patients in his office. When asked why he chose to work in Vaccine Act cases, the expert stated, "I

ask myself that question every day."

The rates charged by experts is but one area in which the Program limits the abilities of the injured party's attorney to litigate the case. Another good example lies in the changes the Secretary made to the definition of the statutory term "encephalopathy". A review of the Advisory Commission's transcripts reveals that the Secretary never forwarded the complete definition to the ACCV in accordance with the statutory mandate of a notice and comment period. In addition, whereas the original statutory definition provided a broad definition capable of being interpreted by the courts, the new definition that is now in place provides so many limitations and exceptions that it almost certainly could be contested by the government in every single case. Finally, someone should ask where the definition came from. If one were to search the medical literature on this subject, one would never find such a definition of "encephalopathy" anywhere. Its only purpose is to limit applicability of the Table of Injuries.

Congress intended this statute to be a non-adversial, "no fault" system which would provide simple justice to children. Instead it has become an extremely adversarial system which is denying compensation to the majority of claimants. As already discussed, the Department of Health and Human Services, the Respondent in these cases, has undertaken to change the Table of Injuries which Congress wrote into the statute, making it extremely difficult, if not impossible to prove causation in most cases. While HHS is doing this, they refuse to provide any information about the numbers of doses of each lot of vaccine that are distributed so that any kind of analysis can be done of the numbers of different types of reactions reported to the VAERS system per doses. In other words, the data which could assist Petitioners in proving an association between certain conditions and the vaccines they receive are restricted by HHS and not released.

So we have a statute which is remedial in nature and which Congress intended to be simple justice for children. However, HHS is not only the defendant, but they also have the power to rewrite the rules (which they did), and they control the adverse event reporting system so that no one can use it to derive meaningful data. Additionally, the Department of Justice has attacked these cases with a vengeance, so that what was supposed to be a non-adversial process is anything but that. And, of course, the program has been set up in such a way as to completely discourage the plaintiffs' bar from pursuing these cases with the same zeal that would be given to a civil case (because of limitations on fees and expenses and the extreme time delays involved in getting paid).

The Department of Justice has taken the position repeatedly in these claims that this program is not a compensation program, but rather a "waiver of the doctrine of sovereign immunity" where the government is allowing itself to be sued and therefore the statute must be narrowly construed against the claimants.[10] This is the attitude that is behind the HHS proposal to include genetic anomalies and structural lesions as being evidence of alternate causes of injury. It is important that you understand this concept. If you punch someone who is a hemophiliac and they bleed to death, or if you punch someone with a cardiac condition and they have a heart attack, you cannot say that you are not liable for the death or the heart attack because of the person's preexisting condition. This is what we refer to as the "eggshell" principle, where you take your victims as you find them, and you are responsible for the outcomes of your actions. Obviously, when some children are injured by vaccines, it is because of their genetics and/or prior sensitizations that have predisposed them to

[10]In the case of *Childers v. Secretary of HHS*, my office specifically argued before one of the special masters that the statute at issue is remedial in nature and must be construed broadly. The government filed a brief arguing that the statute is a waiver of sovereign immunity that must be narrowly construed in the government's favor at every stage. A copy of that brief is attached to this document. The special master in the case agreed with the government and provided the most restrictive interpretation of the statute available, even though the legislative history specifically states that the statute should be "generous" and overly compensatory. The special master recognized the legislative history but felt compelled to follow the government's lead and hold that the doctrine of sovereign immunity "trumps" the generous nature of the program. The special master's decision on the subject is attached as well.

react in the way they do. If this were not the case, then either all children would have a reaction or none of them would. The government is trying to convince you to take the position that because some kids are susceptible to injury from vaccination, they should therefor be barred from recovery under this no-fault compensation program. That position is absurd, and I urge you not to adopt it.

AMENDING THE BURDEN OF PROOF

This is one of those moments when I would ask you to reflect back on the military analogy which I raised earlier. My first proposal to Congress is that you change the burden of proof in these vaccine claims by putting into the statute the exact same language that is used in **38 U.S.C. sec. 5107** for military veterans claiming injuries and seeking benefits.

> (a) Except when otherwise provided by the Secretary in accordance with the provisions of this title, a person who submits a claim for benefits under a law administered by the Secretary shall have the burden of submitting evidence sufficient to justify a belief by a fair and impartial individual that the claim is well grounded. The Secretary shall assist such a claimant in developing the facts pertinent to the claim. Such assistance shall include requesting information as described in section 5106 of this title.
> (b) When, after consideration of all evidence and material of record in a case before the Department with respect to benefits under laws administered by the Secretary, there is an approximate balance of positive and negative evidence regarding the merits of an issue material to the determination of the matter, **the benefit of the doubt in resolving each such issue shall be given to the claimant.** Nothing in this subsection shall be construed as shifting from the claimant to the Secretary the burden specified in subsection (a) of this section.

Id. (Emphasis added).

In my humble opinion, this is the one most important change that you can make to improve this program and start us on the road to realizing its potential as an alternate dispute resolution system.

AMENDING THE STATUTES OF LIMITATIONS

The second most important issue that I feel needs to be dealt with involves the Statute of Limitations for filing claims. In that regard, the Department of Health and Human Services has forwarded a proposal that would increase the Statute of Limitations from 3 years to 6 years, and I applaud them for at least putting forth this modest proposal. IT DOES NOT GO FAR ENOUGH!

Most states have provisions which toll (or stop) the running of the statute of limitations while the injured party is a minor. Most states have provisions which toll the statute of limitations while an injured party is incompetent (and many of the victims of vaccine injuries are incompetent under those definitions). Many states have what are called discovery rules, which allow for someone to file within several years of when they first knew or should have known that their injuries were caused by the vaccine.[11] I would encourage you to read my footnote at this point which describes

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[11]**42 USC Sec. 300aa-10**

TITLE 42 - THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A - PUBLIC HEALTH SERVICE
SUBCHAPTER XIX - VACCINES
Part 2 - National Vaccine Injury Compensation Program
subpart a - program requirements

Sec. 300aa-10. Establishment of program

(a) *Program established*

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) *Attorney's obligation*

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

(c) *Publicity*

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(Emphasis added)

numerous situations that I have experienced and which are simply wrong. This footnote also discusses my specific proposals for change.[12]

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[12]What do I tell the mother or father who calls me 3 years and 6 days after their child was vaccinated and says they just heard about the program? I had one such case, and, of course, I filed a claim the very day they called, but since the child's symptoms had begun within 3 days of the vaccination, we were 3 days late in filing the claim, and it was dismissed for that reason alone. What do I tell the many parents who are calling me and saying they just heard about some kind of a "class action" for hepatitis B vaccine injury claims? "When was your child vaccinated," I ask. "August 1, 1997," was the answer. "Sorry, it's too late to file a claim, unless Congress does something to extend the deadline." And then I have to go on to explain that if their child had been vaccinated on August 7, 1997 , instead of the 1st, they would have until August of 2000 to file. Go figure! What do I tell all the people who are calling and claiming that their child's autism was caused by MMR vaccines received years ago, and now they have been reading about a possible relationship? For all of these people, the answer is the same: "You will have to file a civil suit. The compensation program designed to protect your children does not apply to you."

SPECIFIC PROPOSAL:

I would encourage Congress, therefore, to change the Statute of Limitations under the Vaccine Compensation Act to the six years that the Secretary porposes, but I would also encourage you to allow claims for minors to be brought within two years of their achieving majority (or by age 20). I would encourage you to toll the statute of limitations during periods of disability for at least ten years. I would encourage you to include a discovery rule for claims under the Program, and I would suggest using the same discovery rule that applies to Federal Tort Claims Act cases, as enunciated in the case of *Kubrick v. U.S.* Finally, I would implore you to extend the deadline for filing claims for injuries due to Hepatitis B, HIB and varicella vaccines administered on or before August 6, 1997. That deadline expired on August 6, 1999, and we are receiving calls almost daily from people who were unaware of that deadline.

INTERIM FEES AND COSTS

One of the most critical needs that petitioners have in these claims is the benefit of highly qualified trial attorneys. This is particularly true because of the highly litigious nature of the program and the fact that the government has the capability of recruiting highly qualified experts and paying them promptly for their services. Unfortunately, because of the extremely low hourly rates that are being awarded to attorneys and the fact that we often wait for years to be paid and to be reimbursed for expenses incurred in connection with the claim, many top-notch litigators have been driven out of the program or refuse to participate. A well-qualified, experienced litigator has to be either very dedicated or very stupid (or both) to stay involved in this system as it currently exists.[13]

My proposal to Congress is simple. I would suggest that each Petitioner be given the opportunity to petition for fees and expenses on three separate occasions in addition to their final petition at the end of the claim process. The petitioners should not be limited, as the HHS proposal suggests, to one petition for only interim costs after an entitlement hearing. The petitioners and their

[13]As someone who has litigated cases in a contingent fee context and has won judgments of $5 million, $3.9 million, and $2.4 million, among many others, and as someone who has over 20 years of litigation experience, I am probably one of the highest paid lawyers in the program, and I have just recently been raised from $175 an hour to $190 an hour. We receive no interest on our fees or on the costs we have expended (and which can be quite substantial), even though it often takes years to be compensated. The "war chest" that I was once able to maintain and use to advance expenses in cases is long since gone. Today, I am faced with the situation where the claims that move forward the fastest are the ones where the claimants have enough money to pay their own expenses as incurred. So we have a situation where the people who most need the money cannot hire the experts they need, and I can no longer afford to help them in that regard. I recently filed over 130 hepatitis B vaccine injury claims, and the filing fees alone were over $16,000. Payments for obtaining medical records in that many cases will probably exceed $40,000, and if I could find an expert willing to review records, give a report and testify for only $1,000 per case (something which is highly unlikely), that would cost over $130,000. At $190 an hour, I simply cannot afford to advance these costs, so, if the claimants can't pay their own costs, their claims will not move forward.

counsel should be allowed to select the times when they apply for these reimbursements. Anything short of this will result in a situation where the victims who are most in need will not be able to move their claims forward successfully because they cannot afford to advance the costs, and attorneys in the program no longer have the resources to advance such costs.

I do not have the time to talk about all of my proposals, but please review them carefully, and I would be happy to answer specific questions about them.

SPECIFIC PROPOSALS:

1. Reinstate the table of injuries as originally created by Congress (as to the vaccines originally included) and remove the Secretary's power to change the table in such a way as to make it more difficult to receive compensation[14];

2. Reject the proposal for adding further defenses regarding alternate causes, such as genetic abnormalities and structural lesions;

3. Make it clear that this is a generous compensation program; this is NOT a waiver of sovereign immunity, but rather a welfare program which should be broadly construed so as to achieve its remedial purposes;

4. Change the burden of proof to reflect the standard used for Veterans' cases;

5. Change the statute of limitations to six years, but add a discovery rule such as is employed in other FTCA cases;

6. Toll the statute of limitations during minority and during periods of disability due to mental incompetence;

[14]Counsel would have no objection to the Secretary's proposal to shorten the process for administrative revisions of the vaccine injury table, so long as it is clear that the Secretary can only make changes that add vaccines to the table or that add additional injuries to the table. It is suggested that any changes which would reduce, rather than expand the numbers of victims to be compensated must come before Congress. The Secretary should not be given the power to restrict or narrow the people who are compensated without the specific approval of Congress.

7. Allow Petitioners to apply for interim fees and expenses at least three times prior to the final petition for fees and costs;

8. Allow interest to be paid on past damages from the date incurred, and allow post-judgment interest.

9. Reject the proposed language of the Secretary concerning the basis for calculating projected lost earnings. It is simply a way of reducing the amount of damages that will be paid to victims;

10. Do allow compensation for family counseling expenses and expenses of establishing a guardianship, but also allow compensation for the costs of creating and administering special needs trusts; and

11. In all the changes that are made, remember that there are some victims whose claims would have been successful had these changes been in place when their claims were dismissed. Please give consideration to allowing those individuals a time period - two years perhaps - within which to reinstate their claims.

Let me just say, in conclusion, that this program should not be used to demonstrate whether vaccines are safe or dangerous. Those people who point to the failures of victims who are seeking compensation as evidence that vaccines are safe SHOULD BE ASHAMED OF THEMSELVES. Those people who point to the victims who are awarded compensation and use this as evidence that vaccines are dangerous SHOULD LIKEWISE BE ASHAMED OF THEMSELVES.

This program has been successful in many ways:

Manufacturers are happy and vaccine supplies are plentiful;

Doctors who administer vaccines are happy and no longer threatened with lawsuits;

The federal bureaucracy is happy that they have a system in place that can be firmly controlled.

The people who are largely dissatisfied with this program are the very people it was designed to help - the rare, but unfortunate victims. Again, read the articles attached to my statement, and you will see what I mean.

The sponsors of this program should want to see it fixed. Those who want to help our pediatric warriors cope with their disabilities should want to see it fixed. Those who champion tort reform should want to see it fixed. If it is not fixed, I can assure you that the "hawks" among my profession are sitting on the sidelines ready to pick up the pieces and move us back into the tort arena. If this program is not fixed, I will be one of them.

Thank you!

Dr. WELDON [presiding]. Thank you, Mr. Shoemaker.

We will now proceed with the questioning phase. And the ranking member and the chairman had to step out, so I am going to continue until they return.

Dr. Kinsbourne, I would like to begin with you. I have to apologize, I was paged out of the room by a phone call, but I was told that in your testimony you mentioned that after you appeared before the committee the last time, you were testifying in another case, the objectivity of your testimony was impugned by the Government attorney because of your willingness to testify before the committee. Is that correct?

Dr. KINSBOURNE. That is exactly what happened.

Dr. WELDON. And what was the name of the attorney who made that claim?

Dr. KINSBOURNE. Her name is Hewitt.

Dr. WELDON. And what is her position? Is she Department of Justice?

Dr. KINSBOURNE. Department of Justice, yes.

Dr. WELDON. Could we get a copy of that exchange between you and her for the record, and I ask unanimous consent that it be included in the record.

What was the nature of her argument? Could you just go over that?

Let me just explain, the reason I am bringing this up is I am very disturbed by this. Because if this means that every time we petition an attorney to provide us with testimony that the Government attorneys who are trying to protect this huge trust fund for some reason, I don't understand—it is growing, and yet they keep trying to protect it—then we are going to have a hard time getting people to objectively tell us what the problems are in this system. And I find that testimony you provided extremely disturbing. You are free to proceed. I am curious to know what was the nature of the exchange?

Dr. KINSBOURNE. As I said, I do have the transcript, and I will make it available.

Dr. WELDON. Just summarize it.

Dr. KINSBOURNE. What happened was that in her cross examination of me, she produced my written testimony to the previous committee meeting as an exhibit; had me identify it; had me read passages out of it into the record; did not, in fact, challenge anything I said; asked me no questions about what I said, but established that this was my document, this was my testimony.

Dr. WELDON. As I understand it, though, reviewing your personal background, you have a pretty impressive record of working on both sides of this issue, correct?

Dr. KINSBOURNE. I have an impressive record—thank you, sir—of working of both sides of issues; of plaintiff and defense. However, in the claims court, it is not customary for the Department of Justice to include experts who testified on the other side. So, I have not, in fact, had the opportunity of testifying for respondent, although I have expressed my willingness to do so in appropriate cases.

Now, when it came to closing argument, Ms. Hewitt said to the judge "The fact that Dr. Kinsbourne did testify to a congressional

committee and had criticisms of the process shows that he is to some extent an advocate," and she compared me unfavorably, in terms of my credibility as a medical expert, with her medical expert who she felt was not an advocate.

Dr. WELDON. One other question I have for you. You provided in your testimony some information on a report from the Institute of Medicine, actually, a fairly old report from the Institute of Medicine—I think it was 1991 or 1992—where they recommended a series of studies that needed to be done to get at some of these issues of low incidence of very serious side effects regarding vaccines. I would like to ask that we get a copy of that from you and get that included in the record. I ask unanimous consent for that.

Mr. MICA [presiding]. Without objection, so ordered.

Dr. WELDON. As I understand it, none of those studies have been done. Is that correct?

Dr. KINSBOURNE. To my knowledge. The point is not only that when they asked whether particular vaccines do or do not in principle cause certain outcomes, they have no studies to refer to, and they were stuck with this and went out of their way to make that point, and I will provide the information.

Since that time, this problem has become more serious as new vaccines are being introduced, which almost without exception would have been classified by them in this way had they been available at the time. In other words, vaccines about which one really simply couldn't say one way or the other whether the relationship existed, not because studies conflict, because studies don't exist; have not in fact been done.

The hepatitis B issue that Mr. Shoemaker mentioned is a major problem in this case. Hepatitis B has been put on the table for a very rare, almost unknown complication—anaphylaxis. But the impression that many people have that hepatitis B can cause liver damage, it can cause autoimmune disorders, has not been addressed by systematic scientific study. So, if one is asked, as one currently is, to proceed on a causation-in-fact basis and one has to show biological plausibility, one has to show that actually, in fact, there is evidence that the vaccine did that based on available scientific evidence, there is no such evidence, and the petitioner is out of luck.

Mr. SHOEMAKER. May I add to what Dr. Kinsbourne just said?

Dr. WELDON. Sure.

Mr. SHOEMAKER. There are studies and then there are studies. To use the hepatitis B example, we are seeing a lot of cases of post-vaccinal encephalomyelitis—that is injury to the nervous system, the brain, the spinal cord. So, what does the study do? What is the study that is mounted to look at that? It is a study to see if there is an increased incidence of multiple sclerosis in hepatitis B vaccine—people who receive the vaccine.

Now, multiple sclerosis is this great big category of injuries. All it means is multiple lesions in time and space. Post-vaccinal encephalomyelitis is a very little piece, and actually if it is post-vaccinal encephalomyelitis, it shouldn't even be included in multiple sclerosis, because it has another cause.

So, you look at this great, big universe and study it to try to disprove a relationship between vaccine and post-vaccinal

encephalomyelitis? If that is the study that is being done, then I say forget the study, save your money. Don't spend your money on a multiple sclerosis study, because there are so many causes of multiple sclerosis that if you try and look and see if the total universe of multiple sclerosis because of hepatitis B vaccine, you won't find it. I can tell you that before you spend the first dollar, and that is not the type of study that needs to be done.

So, there are studies, and then there are studies, and you have to do the right kind of study. What we are seeing in those cases, for instance, is people that have a reaction to the first vaccine in the series, they start getting better, having some recovery. They get the second vaccine in the series, and they have a much more immediate and more pronounced response to the vaccine.

It is what the Government and other doctors refer to as positive rechallenge. In other words, once could be a coincidence, but twice, now you see what is happening. You have heard this from one of the victims who testified today where it wasn't until after the third vaccination that they finally said, "OK, we have got to stop these vaccines."

Dr. WELDON. I would like to ask all three of you to comment on this one question or concern I have. I am a physician, and this is my first political job, and the devil is always in the details when we try to address these problems. And now we have an act, the Vaccine Compensation Program; it had very good intentions; it has gone astray, and, frankly, I think the attorneys have led us astray. Not to impugn you, Mr. Shoemaker or your profession, but it is just by nature, as Mr. Gale said, you put two attorneys in the room and it becomes who is going to win. And one side has more funds in their pocket to fight their battle. I don't think you can get the attorneys out of the room, frankly. I don't see how you can do that, and that is one question I have—could you do this without attorneys? I don't know if it is possible.

But one of the questions I have is should we have language in the law that requires that the plaintiffs' attorneys get compensated better, because this system is terrible the way it is described where there are virtually no attorneys willing to practice this type of law anymore? I believe that is going to need to be addressed.

And, No. 2, do we need to mandate that a certain amount of the money gets dispersed each year? Because if you are going to have all these Department of Justice attorneys going to work each day, and their definition of winning is that no money is given out, and they have got the deeper pockets to defend their position, then the ultimate solution may be to mandate that a certain amount of the money each year be given out and that it not become a case of who wins and who loses.

I am just looking toward, ultimately, the day when we begin to draft language that will attempt to try to address the problems with this program, because I think we are going to have to do that. It is critically important that we protect the Vaccination Program.

Mr. SHOEMAKER. If I may respond to that. I hope you will read what I have written about interim fees and costs, because the Government experts, when they testify in these cases, they submit bills; they are paid within 30 days. I could have brought a stack of bills here today from doctors that I can't afford to pay right now.

It is kind of hard for me as a plaintiffs' lawyer to go out and beg some doctor to testify for me in a case when I can't pay them up front, and I tell them, "You may have to wait years to be compensated at the end of this program." I mean, that is me asking them to testify versus somebody calling them from Health and Human Services and asking them to testify. That is not quite an even playing field, and I hope you will read that section about interim fees and costs.

It is important that we be allowed to petition for costs. I just filed 130 hepatitis B claims. The filing fees alone were $16,000. If it costs me $500 a case to obtain medical records, multiply that by 130, you are looking at $30,000 or $40,000 to collect records. Now, if I can get an expert at $1,000 apiece to review those claims, that is $130,000. I am paying yesterday's bills with the fees that I am getting today on cases that have been going on for years.

I have remortgaged my house twice. I have taken my kids out of private school and put them in public school. I have gotten rid of the boat. I am no longer living the life of a contingent fee lawyer, and my friends think I am an idiot to stay involved in this program, and maybe I am, but I am dedicated to the program. But if we are going to have to fight causation battles in these cases, give us the resources to do it.

And I reject the Government's proposal to give us interim costs after an entitlement hearing. That is a token offer, and I reject it. If you are going to give us interim costs and fees, give it to us at least several times during the course of a proceeding so we can finance the cases and pay for them.

Dr. WELDON. Dr. Gale, did you have anything you wanted to add to that?

Dr. GALE. Yes, if I might. There are ways to streamline the process and to make the process less cumbersome, to have the process take much less time to compensate people. It could be an administrative process. That isn't what it is now. Now, it clearly is a litigative process. I don't have experience in civil court, so I don't have a basis for comparison, but I am told that it is a milder experience, but it is still a litigative process.

There would be no need to review records if there weren't a table to compare medical records against. And there would be no reason to have medical opinions if we didn't have a table. So, clearly, the table, which is the linchpin of the program means that there will be a need for physicians on both sides to review records and come up with professional opinions about what likely happened to this youngster, when did it happen, and whether or not it was caused by something other than the vaccine.

That could be eliminated. People could fill out a simple, plain English form, explain what happened to their youngster, submit a form, and be compensated. That could happen. I can't do that, but the Congress could do that, if that is what it envisions for the program. If it maintains the table, however, then there will be physicians involved. It does not, however, have to be an adversarial process if there is a bank of physicians reviewing records with the broadest possible definition of the injuries.

There are three things that can be done to the table, because the table essentially mandates three things. It describes the injuries

that are compensable. It describes the timeframe during which the onset of the injury must occur, and then it describes, I suppose you could call it, "an out," and that is, if there is a factor readily identifiable separate from the vaccine that could have caused that injury in that timeframe, then that becomes a non-compensable case.

For example, you could do away with the provision for factors unrelated; that is, you wouldn't bother to look for a factor unrelated; you wouldn't care. Then a prescribed injury occurring within a certain timeframe, no matter what the child's medical record or history suggested, would be compensable.

Second, you could expand the timeframe. For example, in pertussis vaccines for encephalopathy it is currently 3 days. You could make it 7; you could make it 14; you could make it a month or more. That clearly would expand, not only scientifically, the probability that you would not have permitted any potentially vaccine-caused injuries to fall through the cracks, but necessarily, using the principle, I suppose, of unanticipated consequence, you would include an awful lot of youngsters with neurologic diseases that almost certainly couldn't have been caused by the vaccine. But that is a decision you could make; you could expand the time window.

And last but not least, you could change, again, the definitions in the table, if you keep a table, and make them as broad as possible.

Mr. SHOEMAKER. In that regard, making them broad, if you look at the IOM report that you referred to, there are many conditions that describe, with reference to various vaccines, where the report will say specifically this condition—like, let us take brachial neuritis—this condition is biologically plausible. In other words, it is plausible that the vaccine caused it and that there have been case reports in the literature reporting this, but there have been no controlled epidemiological studies performed, and therefore their conclusion is that there is not enough evidence to either accept or reject the fact that this was caused by the vaccine.

If those were put in the table, if you included all those things where it is biological plausible and where there are case reports and there haven't been epidemiological studies, you would include a lot more cases within the table. I like the idea of eliminating the alternate causes to be able to streamline the table. Sure, you would overcompensate more than you are now, but so what? Otherwise, you end up with people on Medicaid; you end up with people with other programs. I mean, let us open this program up and make it compensate, make it do some good.

Dr. WELDON. Did you have anything you wanted to add to that, Dr. Kinsbourne?

Dr. KINSBOURNE. Yes, sir. I think that Dr. Gale's suggestions are very humane, and I could certainly not take issue with them. I do think that the medicine, as I have explained, is particularly technical here, and it is not always obvious to a layperson what is or what is not a vaccine injury, or even what could be or what could not be a vaccine injury. I have reviewed many files sent to me, and many times I am unable to support the claims, because I can tell that this really wasn't the vaccine.

So, I think regardless of how one sets one's criteria, we still need some legal assistance and some medical consultation, but it could

be an awful lot less than currently happens. It could absolutely streamline in the ways that my colleagues have suggested.

Mr. SHOEMAKER. You still need to leave open the possibility of people that don't fit a table, even an expanded table. You need to leave open the possibility of being able to prove causation-in-fact in those cases, and I would encourage you in those cases to adopt the standard of proof that is used in veterans' claims.

If you look at what I have written here on veterans' claims—and if I can point to that page very quickly since I didn't follow my script here today—it is at the bottom of page 8 and on page 9. I have put in the specific language that is used in 38 U.S.C. section 5107 for veterans' claims. And it has the language in it where it says specifically "The benefit of the doubt in resolving each such issue shall be given to the claimant." It is taking it out of the civil context. If we are not going to be in civil courts and if we are not going to be litigious, if we are going to make this a program that is non-litigious, then let us use a standard like this.

I think the military analogy that I referred to at the beginning about our pediatric warriors, it makes sense to use the same standard of proof that we use in veterans' claims. So, I would encourage you to look at that on page 9, and it is specific language; it is being used somewhere else; it is nothing we have to reinvent; it is language that is there; it has got material behind it; it can easily be plugged into this statute.

Dr. WELDON. Thank you, Mr. Chairman.

Mr. MICA. Thank you, and thank you for leading a discussion on the questioning that I think will be helpful as we try to find some way to fix a well-intended program that has some very distinct problems.

The only question I might have is if we could take this totally out of the legal realm. Dr. Kinsbourne, you thought it might have to be a little of both, but if this could be made strictly an administrative process and then give recourse, if there isn't satisfaction, into the legal realm, do you think that might be something that could be done?

Dr. KINSBOURNE. I think yes, if the potential petitioners had some guidance counseling from informed people. Some people simply don't have very clear ideas either way of what is a vaccine injury. As you have heard, often doctors don't have a clear idea of what is a vaccine injury; in fact, the information to doctors has mostly been, "Oh, vaccine injuries are overstated." That is more what they are being told than how to recognize them when they occur. So, somebody with, I think, both medical and legal knowledge should be able to advise them. It doesn't have to be in legal proceedings.

Mr. SHOEMAKER. I think given the history—thank you, sir—I think given the history of the way the Department of Health and Human Services has administered this program, making it more restrictive and more difficult and more litigious and more—very difficult to prove cases—I think if the administrative process takes lawyers out of it and if claimants don't have lawyers representing them, then all I can say is I will be waiting at the other end to file their civil lawsuits.

Mr. MICA. Dr. Gale, do you want to respond?

Dr. GALE. I am not sure that I have more to add to that.

Mr. MICA. Well, I think you have pointed out that we could establish some broader parameters for acceptance as possible victims of vaccine injury, and I think you both have—both Dr. Gale and Dr. Kinsbourne have pointed out the difficulty in pinpointing the connection, although you make some assumptions within certain parameters. I think you said that you could identify those cases and medically it may be a guesstimate but a pretty accurate assumption. And some that fall outside of those parameters could be handled through litigation, but for the most part we could probably expedite many of these cases by going to an administrative procedure.

If we had a panel of medical experts to—if we set the general parameters and made them broad, as you said, Dr. Gale, and then had a review by a panel of medical personnel, then we went basically to a mandatory arbitration or mediation, do you think that would work, Dr. Kinsbourne?

Dr. KINSBOURNE. If the panel were given very clear guidelines as to the criteria that they should adhere to, doctors will—then naturally think the way they do. They will be skeptical; they will be critical; they will have a high standard for accepting any diagnosis, and it will be the easiest thing in the world for them to say, "I am not convinced," and so on. They would have to be told very specifically at what level of confidence a positive decision needs to be made. If that were done, I think it would work.

Mr. MICA. Dr. Gale, did you want to respond?

Dr. GALE. I would agree with that. Like Dr. Kinsbourne, I have reviewed records for the Department of Health and Human Services that seemed immediately, upon review, to fulfill the qualifications in the table and in my opinion were compensable. That is a very short process. You read the record, make a call later that day, file a report. That is compensable.

If you keep the concept of a table, that is, if there is a reference to which injuries or conditions are going to be compensable, which means that you will not compensate others, and if there is going to be a time window, which means that somebody will be an outlier, that is the consequence of that. If the window is at 3 days, if you are on the 4th day, you will be an outlier. That will change the nature of how your petition is handled. If you expand the window to 7 days, 8 days will make you an outlier.

So, if you keep those two elements of the table for physicians to refer to, and then you will have to decide do you or don't you want to keep the concept of factors unrelated to the vaccine as part of the process for physicians to review. That is, if we can clearly identify that a youngster has a tumor that accounts for his or her neurological disorder, do we take that into consideration in deciding whether a case is compensable or is it sufficient for the disorder occurring within a time window to simply occur, in which case the case would be compensable in spite of the tumor or in spite of the automobile accident?

If you eliminate, as preposterous as this sounds, but it is preposterous examples that usually help us to focus on what we are doing, a preposterous example would be a youngster who gets an immunization for school at age 5 or 6 on a Monday and is struck

by an automobile on Tuesday and goes into a coma and comes to the hospital and is never well again. If there is no factor unrelated to the vaccine as part of the reference table; that is, if you have a condition, encephalopathy, that occurs within 3 days of the administration of the vaccine, and in this case, in my hypothetical, it would—that would become a compensable case, and that is fine, if that is what you intend to do. You would need to codify those guidelines so that if physicians are going to participate in the process, they know what you want of us.

Mr. SHOEMAKER. To expand a little bit on that, I think I would like to represent the outliers in this case. I will never forget a case I had where it was determined that the residual seizure disorder started 75 hours after the vaccination instead of 72 hours after. So, I would certainly encourage expanding the table, including these cases that I talked with Dr. Weldon about where there are—where there is this information that it is biologically plausible, there are case reports, people suspect there could be relationship, but it hasn't been proven or disproven because there have been no epidemiological studies. Get all these things into the table, grossly reduce the alternate cause aspects of the table, and if those two things are done, I would say, yes, I am all in favor of improving the table to include more cases, to make it a more inclusive program.

But then the next step is, I think you have to go beyond that for these other cases, and there are going to still be causation-in-fact cases out there that don't fit whatever table you come up with. I am still encouraging you to look at what I have written about making it clear that this is not a waiver of sovereign immunity, this is a remedial program; making it clear and changing that burden of proof to what is used in veterans' cases, and doing the things that I have asked in here.

And that brings me really to an issue of the statute of limitations. There are all kinds of statutes of limitation in these cases, and one of the things I keep thinking about as I puzzle over what to do with them is why do we have a statute of limitations? This is a compensation program. Leave the States to take care of the statutes of limitation as to whether people can file civil lawsuits. That is their job; let them do it. This program won't affect it.

I suppose as long as you are in the program, it will toll the State statute of limitation. That is fine; I agree with that. But why do we even have a statute of limitations in this? I get calls all the time. I get calls from people who were vaccinated August 5, 1997, with hepatitis B vaccine. They had to file their claim by August 6, 1999, whereas somebody vaccinated 2 days later had until August 7, 2000. Now, that doesn't make any sense. The only purpose of that is to get lawyers in trouble and have them call their malpractice carrier because they screwed up. It doesn't make any sense at all.

I applaud the Department of Justice for asking for a 6-year statute, but why have any statutes of limitation at all? I am getting calls from people—now, in the literature, it is coming out about whether or not MMR vaccine causes autism. Well, eventually that may be proven, and if it is proven, what about all those old cases

that had autistic children from MMR vaccine? Are they out of luck or can they file the claim?

You are going to have all kinds of problems—if you change the statute of limitation to 6 years, what do I tell the person who was dismissed 2 years ago because he came to me 3 years and 6 days after the statute of limitation, and his child's seizures had started 3 days after the vaccination? So, when he walked into my office the first time it was too late. I filed the claim; I got dismissed, because it was too late. I was bound to 3 years.

Now, if you add 6 years soon enough, I should be able to refile his claim I hope. But what if you don't get it added until it is more than 6 years since the vaccine? Now, I can't file his claim, but I can still go into civil court and sue, because it is a child, and in most States, the statute of limitations is tolled during minority. It makes no sense.

Anybody that thinks this an easy program to work in as a lawyer—I can guarantee you there are plenty of pitfalls in this program, and we all are looking over our shoulder every day because of the myriad of problems that we have like this. And I could go on and on and talk about them, but why even have a statue of limitations?

Mr. MICA. Mr. Burton.

Mr. BURTON. Let me just say, Mr. Shoemaker, and I apologize, I just walked in, but if you could send the chairman of the subcommittee and myself a list of things that you think could or should be done to eliminate these inequities, we will see if we can't work on it together——

Mr. SHOEMAKER. Thank you, sir.

Mr. BURTON [continuing]. Mr. Mica and myself, to get them corrected.

Mr. SHOEMAKER. Thank you, sir.

Mr. MICA. I would like to thank each of the panelists on our second panel for their insight and for their recommendations. We are going to try our best to see how we can reform this Vaccine Injury Compensation Program that was set up with good intent but has gone astray here.

We particularly appreciate Dr. Kinsbourne and your besmirched reputation having dealt with our committee. We hope that you recover, but professionally we admire you and thank you again for offering your testimony. Once again, sometimes people come back for a second dose of abuse.

Mr. Chairman.

Mr. BURTON. Yes, I am sorry I missed your testimony, Dr. Kinsbourne. My assistant just told me how you were discriminated against, I guess you would say, because you testified before our committee. We will be back in touch with you and talk to you about that as well. Thank you, sir.

Dr. KINSBOURNE. Thank you, sir.

Mr. MICA. Thank you. We will dismiss this panel and call our third panel.

Our third panel consists of two witnesses, Mr. Thomas E. Balbier, Jr. He is the Director of the National Vaccine Injury Compensation Program with the Department of Health and Human Services. The second witness is Mr. John L. Euler, and he is the

Deputy Director of the Torts Branch, Civil Division of the Department of Justice.

Gentleman, if you will stand and be sworn.

[Witnesses sworn.]

Mr. MICA. The witnesses answered in the affirmative.

As I said, if you have any lengthy statements or documentation you would like to be made part of the record, on unanimous consent request, that will be done.

First, we will recognize the Director of the National Vaccine Injury Compensation Program, Mr. Thomas E. Balbier, Jr.

You are welcome, sir, and recognized.

STATEMENTS OF THOMAS E. BALBIER, JR., DIRECTOR, NATIONAL VACCINE INJURY COMPENSATION PROGRAM, DEPARTMENT OF HEALTH AND HUMAN SERVICES; JOHN L. EULER, DEPUTY DIRECTOR, TORTS BRANCH, CIVIL DIVISION, DEPARTMENT OF JUSTICE

Mr. BALBIER. Good afternoon, Mr. Chairman and members of the committee. I am pleased to be here this morning to talk to you about the National Vaccine Injury Compensation Program. With me to provide additional information if needed, are Dr. Geoffrey Evans, the Medical Director for the program, and Mr. David Benor from our Office of the General Counsel.

The National Vaccine Injury Compensation Program has been hailed by Secretary Shalala as the cornerstone of our Nation's successful childhood immunization program. It provides a unique service to families suffering through one of the most difficult experiences imaginable. It makes a system available through which families can receive financial help in the most efficient and fair manner possible, while still preserving their rights to file suit in the tort system.

The program significantly reduces, but it cannot eliminate, the tension and adversity inherent within any litigation process. As with every Federal benefit program, there are going to be eligibility requirements which seem unfair to some applicants. I can assure you that everyone involved in the administration of the program makes a concerted effort to ensure that fairness is the operating principle in dealing with every family filing a claim under the program.

We have been listening to concerns raised by those who may feel the system has been unfair and more adversarial than they had expected. It is critical to remember that although the program is far less adversarial than the tort system, it does encourage anyone who believes they have a condition caused or aggravated by a childhood vaccine to file a petition for compensation. Petitioners' rights are vigorously defended and advocated by their attorneys, who are paid regardless of whether petitioners are compensated. However, it was never intended to serve as a compensation source for a wide range of naturally occurring illnesses or conditions, which unfortunately affect many of our children.

The process of determining whether, and at what level, compensation should be awarded will always involve conflicting opinions and a natural tension. This has been recognized by everyone involved in the day-to-day administration of the program as well as

by the Advisory Commission on Childhood Vaccines [ACCV], which was established by the act to "advise the Secretary—of HHS—on the implementation of the program."

The members of the ACCV include parents of children injured by vaccines, their attorneys, representatives of vaccine companies, and recognized medical experts in childhood diseases. This diverse body has provided constant oversight of the operation of the program, advised the Secretary on each and every modification of the vaccine injury table, and has made numerous legislative and administrative recommendations over the years aimed at improving the operation of the program.

Most recently, it developed and approved a series of recommendations that form the basis for legislation recently proposed by the Secretary of HHS. These proposals include many enhancements aimed at making the program more streamlined and less adversarial for its intended beneficiaries. The proposals would double the statutory time limit for filing a claim, expand compensation to families, and simplify the process for adjudicating claims.

I would like to talk for a minute about concerns related to the Vaccine Injury Compensation Trust Fund. The trust fund was established to ensure that a constant source of funding would be available for the payment of compensation under the program. The trust fund is financed by an excise tax of 75 cents per dose imposed on each vaccine covered under the program. At this time, the trust fund balance is in excess of $1.4 billion. During fiscal year 1998, the trust fund received total income of $183 million, with $116 million coming from excise tax revenue. The remaining $67 million came from interest on the balances in the trust fund and more than covered the 1999 outlays for awards, and for attorney fees and costs, of just less than $50 million.

The trust fund should be viewed as a specialized public health insurance fund, maintained with adequate reserves to handle liability exposure as new childhood vaccines come to the market and as important ongoing surveillance activities of the Public Health Service spawn new scientific studies of theoretical vaccine-related adverse events.

Recently, coverage under the program was expanded to include four additional vaccines for which 279 petitions have been filed. In addition, there are more than 300 vaccines in various phases of research and development, some of which may eventually be added for coverage under the program and result in increased liability.

There is good reason for the public to have confidence in the overall operation of the program. There have been two comprehensive, independent program evaluations conducted since the program was first enacted. The first, conducted by the HHS Office of Inspector General in 1992, concluded, "The case process is efficient; the program is well organized with good procedures; no unnecessary duplication of effort exists; roles and responsibilities are clearly defined; coordination and communication among the Federal agencies is strong, and petitioners and their attorneys are generally satisfied with their experience in the program."

The second study was done just last year when the Federal Judicial Center completed a report on the program, which concluded, in part, that "the case-management innovations and handling of ex-

pert testimony function well in the VICP." Currently, the General Accounting Office is conducting a review of the program at the request of Senator Jeffords, and the GAO has indicated that the results of the review should be released by the end of this year.

All indications are that this program is working very much as intended by Congress. There will always be program areas that can be improved, and we continue to implement initiatives to address these areas. The program has always been open to advice from all interested parties, and mechanisms are in place to assure that the varied interests of families, health care professionals, attorneys, and the vaccine industry are represented at a regular public forum.

The ACCV, with its widely diverse membership, brings a good balance of perspective and has been instrumental in identifying program improvements that have consensus support. With strong ACCV support for the administration's proposed legislative agenda to make this innovative program even better, it is now up to Congress to move these important changes forward as quickly as possible so that our children can reap the benefits of the program "in the most efficient and fair manner possible."

Thank you once again for allowing me to come here today to tell you about the National Vaccine Injury Compensation Program. I will be pleased to answer any additional questions which you may have.

[The prepared statement of Mr. Balbier, Jr., follows:]

STATEMENT

OF

MR. THOMAS E. BALBIER, JR.

DIRECTOR

NATIONAL VACCINE INJURY COMPENSATION PROGRAM

BEFORE

THE COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY, AND HUMAN RESOURCES

September 28, 1999

Good morning Mr. Chairman and members of the Committee. I am pleased to be here this morning to talk with you about the National Vaccine Injury Compensation Program (the Program), one of the most unique and innovative programs ever created by Congress. With me to provide additional information if needed, are Dr. Geoffrey Evans, Medical Director for the Program, and Mr. David Benor from our Office of the General Counsel.

In the United States, the health of our Nation's children takes a high priority. In the recent past, our children faced serious, debilitating, and deadly diseases with little protection and parents lived in constant fear that their children would contract infectious diseases such as polio. The modern miracle of vaccines has changed this by eliminating smallpox and reducing the incidence of many childhood diseases to almost zero. This is a tremendous accomplishment, but we often overlook one very significant component which has been critical to the success of our Nation's immunization program over the past decade. This is the National Vaccine Injury Compensation Program.

As recently as 1986, this country was on the verge of losing the battle against preventable childhood diseases. The companies that produced vaccines were under serious threats of legal action because of media reports of serious injuries or death thought to be related to adverse reactions to vaccines. The potential costs of such lawsuits were more than many vaccine companies were willing to risk, so some companies simply stopped making vaccines, resulting in serious vaccine shortages throughout the United States. Demanding a national solution, a coalition made up of physician and public health organizations, industry,

government, and private citizens developed the idea for a no-fault alternative to the tort system. This new system would reduce the tension associated with traditional civil court proceedings by having the Federal Government assume liability for injuries and deaths thought to be vaccine-related, and by allowing payment of attorneys' fees and costs to petitioners regardless of whether compensation was awarded. This became the National Vaccine Injury Compensation Program (the Program), which has been hailed by Secretary Shalala as the cornerstone of our Nation's successful childhood immunization program.

The National Vaccine Injury Compensation Program provides a unique service to families suffering through one of the most difficult experiences imaginable. It makes a system available through which families can receive financial help in the most efficient and fair manner possible, while still preserving their rights to file suit in the tort system. The Program significantly reduces, but cannot eliminate, the tension and adversity inherent within any litigation process for resolving claims arising from conditions or injuries thought to be related to childhood immunizations. The key words here are, "the most efficient and fair manner possible." As with every Federal benefit program, even those subject to an administrative review, there are going to be eligibility requirements which seem unfair to some applicants. I can assure you that everyone involved in the administration of the Program makes a concerted effort to ensure that fairness is the operative principle in dealing with every family filing a claim under the Program. Petitioners are provided with every opportunity to document and present their claims to Special Masters in the U.S. Court of Federal Claims (the Court), who provide a great deal of flexibility to petitioners in meeting deadlines.

More than 1,400 families have received compensation under the Program through awards totaling in excess of $1 billion. Currently, 42 percent of petitions adjudicated under the Program have been awarded compensation. On average, it takes only two years to resolve claims and issue any appropriate payments. This compares to a compensation rate of only 23 percent for those who file medical malpractice lawsuits through the usual tort system.

We have been listening to concerns raised by those who may feel the system has been unfair and more adversarial than they had expected. It is critical to remember that although the Program is far less adversarial than the tort system, which it was designed to replace, it was established for a very specific group of intended beneficiaries. The Program encourages anyone who believes they have a condition caused or aggravated by a childhood vaccine to file a petition for compensation. Petitioners' rights are vigorously defended and advocated by their attorneys, who are paid regardless of whether petitioners are compensated. However, the Program was never intended to serve as a compensation source for a wide range of naturally occurring illnesses and conditions, which unfortunately, affect many of our children.

This Program was established by the National Childhood Vaccine Injury Act of 1986 (the Act). At the time of enactment, the Congress recognized that there was public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination and that the deeming of vaccine-relatedness adopted in the Act might result in the provision of compensation to some children whose conditions or illnesses were not, in fact, vaccine-related. In creating the Program,

the Congress drew the original list of injuries on the Vaccine Injury Table broadly to ensure that all injuries believed to be vaccine-related at the time would be compensated. At the same time, scientific studies were mandated to ensure that injuries related to vaccines were identified and that only those with a scientific basis eventually would be compensated. The completion of these studies and application of their findings were essential, because without scientifically based evidence upon which to establish award decisions, countless unjustified awards might be made. Potentially, this could lead to the exhaustion of the Vaccine Injury Compensation Trust Fund (the Trust Fund), putting at risk the ability to compensate those with demonstrated vaccine-related injuries. Coupled with the mandate in the original Act for the Secretary of HHS to modify the Vaccine Injury Table to bring it in line with science, the Internal Revenue Code, which governs payments out of the Trust Fund, is very specific in requiring that no payments may be made from the Trust Fund except for the compensation of vaccine-related injuries or deaths and for the administration of the Program.

The process of determining whether, and at what level, compensation should be awarded will always involve conflicting opinions, and a natural tension. This has been recognized by everyone involved in day-to-day administration of the Program as well as by the Advisory Commission on Childhood Vaccines (ACCV), which was established by the Act to "advise the Secretary (of HHS) on the implementation of the Program." The members of the ACCV include parents of children injured by vaccines, their attorneys, representatives of vaccine companies, and recognized medical experts in childhood diseases. This diverse body has provided constant oversight of the operation of the Program, advised the

Secretary on each and every modification of the Vaccine Injury Table, and has made numerous legislative and administrative recommendations over the years aimed at improving the operation of the Program. Most recently, it developed and approved a series of recommendations that form the basis for legislation recently proposed by the Secretary of HHS. These legislative proposals include many enhancements aimed at making the Program more streamlined and less adversarial for its intended beneficiaries. The proposals would double the statutory time limit for filing a claim, expand compensation to families, and simplify the process for adjudicating claims. A draft bill titled, the "Vaccine Injury Compensation Program Amendments of 1999" was sent to the Congress on June 14, and will hopefully receive expeditious and favorable consideration.

I would like to talk for a minute about concerns related to the Vaccine Injury Compensation Trust Fund. The Trust Fund was established to ensure that a constant source of funding would be available for the payment of compensation for vaccine-related injuries and deaths, as well as for attorney fees and costs incurred by families in presenting their case to the Special Masters who adjudicate petitions. The Trust Fund is financed by excise taxes of 75 cents per dose imposed on each vaccine covered under the Program. At this time, the Trust Fund balance is in excess of $1.4 billion. During FY 1998, the Trust Fund received total income of $183 million, with $116 million coming from excise tax revenue. The remaining $67 million came from interest on the balances in the Trust Fund and more than covered the FY 1998 outlays for awards, and for attorneys' fees and costs, of just less than $50 million. The Trust Fund should be viewed as a specialized public health insurance fund, maintained with adequate reserves to

handle liability exposure as new childhood vaccines come to the market and as important ongoing surveillance activities of the Public Health Service spawn new scientific studies of theoretical vaccine-related adverse events. Recently, coverage under the Program was expanded to include four additional vaccines (hepatitis B, *Haemophilus influenzae* type b, varicella, and rotavirus) for which 279 petitions have been filed. In addition, there are more than 300 vaccines in various phases of research and development, some of which may eventually be added for coverage under the Program and result in increased liability.

There is good reason for the public to have confidence in the overall operation of the Program. Just last year, the Federal Judicial Center completed a report on the Program entitled "Use of Expert Testimony, Specialized Decision Makers, and Case-Management Innovations in the National Vaccine Injury Compensation Program." This report concluded in part, that ". . . the case-management innovations and handling of expert testimony . . . function well in the VICP." Currently, the General Accounting Office (GAO) is conducting a review of the Program at the request of Senator Jeffords, Chairman of the Senate Health, Education, Labor and Pensions Committee. The GAO has indicated that the results of the review should be released by the end of this year.

All indications are that this Program is working very much as intended by Congress. There will always be program areas that can be improved, and we continue to implement initiatives to address these areas. The Program has always been open to advice from all interested parties, and mechanisms are in place to assure that the varied interests of families, health care professionals, attorneys, and

the vaccine industry are represented in a regular public forum. The ACCV, with its widely diverse membership, brings a good balance of perspective and has been instrumental in identifying program improvements that have consensus support. With strong ACCV support for the Administration's proposed legislative agenda to make this innovative program even better, it is now up to Congress to move these important changes forward as quickly as possible so that our children can reap the benefits of the Program in "...the most efficient and fair manner possible."

Thank you once again for allowing me to come here today to tell you about the National Vaccine Injury Compensation Program. I will be pleased to answer any additional questions which you may have.

Mr. MICA. Thank you, and we will suspend questions until we have heard from our other panelist.

Mr. John L. Euler, Deputy Director of the Torts Branch, Civil Division, Department of Justice, you are recognized.

Mr. EULER. Thank you, Mr. Chairman and members of the subcommittee. I appreciate the opportunity to appear before you today. So that I may limit my remarks, I request that my full written statement be entered into the record.

Mr. MICA. Without objection, so ordered.

Mr. EULER. Thank you, sir.

Congress in the 1980's was faced with a looming public health crisis concerning immunizations which involved complex, hotly debated medical issues overlaid with the emotion of personal loss and tragedy in individual cases. In order both to provide a more feasible avenue of compensation and stabilize the national immunization policy, Congress established this program.

Petitioners are afforded a less adversarial system with free counsel in which their meaningful participation is assured. The debate, the emotion, the complexity of the cases were not eliminated and never will be, but an effective mechanism is in place. As a result, almost 5,000 cases have been resolved and numerous families compensated while the supply of life-saving vaccines has been assured.

The act of 1986 created a much needed alternative to products liability and medical malpractice litigation for vaccine injuries. It removes many of the more difficult elements of proof that plaintiffs faced in traditional civil court. The program is no-fault. In other words, claimants need not establish that the vaccine was defective or that the doctor was negligent. The process itself is characterized by streamlining features. Neither the rules of evidence or procedure apply rendering virtually all evidence that petitioners seek to present admissible. The special masters make every effort to allow the parties to present their best case.

By design, this is not a straight claims process nor traditional litigation but rather a hybrid system that blends the best of both, even if it cannot escape entirely the frustrations inherent in any adjudication. Critical to the prompt resolution of cases is the completeness of the petition. This is a front-loaded system. In other words, petitioners are responsible for identifying the specific nature of their claim and providing all medical records and related documents. When the initial filing is incomplete, petitioners are granted liberal extensions. If there is delay, it is most often because of an incomplete record or an underdeveloped medical position. The pace of the process is largely controlled by petitioners.

The role of the Justice Department is to implement the statute and uphold the provisions of the act. In other words, we help ensure that compensation is provided to those who meet the criteria determined by Congress. We are obliged to protect the trust fund against claims by those who have not suffered a vaccine-related injury.

In the spirit of the act, we do this in a far less adversarial manner than defendants in civil litigation. We participate in an early telephonic conference with petitioners and the court to discuss the deficiencies in the petition. The format of the hearings is informal and accommodating. The hearings are undertaken with a sensitiv-

ity to the fact that these cases involve highly emotional and personal issues often concerning severely injured children.

With regard to determining compensation, Congress has set forth a detailed list of compensable items. While it is often time-consuming, the key is that the program process is far more thoughtful and tailored than other systems. In most vaccine cases, the goal is no less than establishing a custom tailored plan of life time medical care, frequently a cooperative effort. I estimate that 90 percent of the damages cases are settled without a hearing.

The Department published a packet entitled, "Steps to Streamlining Damages Under the Program," which sets forth ways to expedite the damages phase. We distribute this document to counsel, and I have copies of it with me today. We also issued a guide to assist petitioners' attorneys with attorneys' fees and costs, and I have copies of that as well.

In spite of these numerous accommodations, resolution of these cases simply cannot always be accomplished quickly. There exists an obvious tension between efficiency and due process. The issues can be difficult and complex. The amount sought is frequently in excess of several million dollars.

In short, I believe the program is working as designed. As with any Government program, with specific criteria, there will be applicants who are dissatisfied, even among those who are awarded compensation. Yet we cannot ignore the statutory criteria or the consensus of the scientific community on medical causation issues. It is a program that relies heavily upon the most current and accurate scientific evidence available—it does in fact rely on the most current and accurate scientific evidence available.

In resolving claims, the court, consistent with statutory guidelines, does not require scientific certainty, simply a preponderance of the evidence.

Mr. Chairman, thank you again for this opportunity. I will be pleased to answer any of your questions.

[The prepared statement of Mr. Euler follows:]

Department of Justice

STATEMENT

OF

JOHN LODGE EULER

DEPUTY DIRECTOR - TORTS BRANCH

CIVIL DIVISION

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

COMMITTEE ON GOVERNMENT REFORM

UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING

THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

PRESENTED ON

SEPTEMBER 28, 1999

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear before the Subcommittee today to talk about the National Vaccine Injury Compensation Program. The National Childhood Vaccine Injury Act of 1986, which established the Vaccine Compensation Program, created a much needed alternative to traditional products liability and medical malpractice litigation for persons alleging injury from vaccinations. This unique Program may fairly be considered as the cutting edge of tort reform and serves as a model of a successful limited no-fault system of recovery. Over the past eleven years, the Program has compensated the claims of over 1,400 families through a system that was created specifically to handle the complexity and uniqueness of vaccination-related injuries. Without this Program, at most only a handful of these families would have received any recompense at all.

The Vaccine Program is a less adversarial means of obtaining compensation for vaccine-related injuries. It significantly relaxes traditional evidentiary standards, affords compensatory presumptions, and virtually eliminates discovery in return for petitioners' early and complete production of documents. Making the process more streamlined for all participants, especially those who are filing claims, has been and continues to be a priority of the Program.

To appreciate the unique statutory design and operation of this Program, I would like to begin by providing a brief overview of the adjudication process. Claims are filed in the U.S. Court of Federal Claims and adjudicated in the first instance by a Special Master, whose expertise lies in resolving such claims. The "respondent" in all claims filed under the Program is the Secretary of Health and Human Services, who, in turn, is represented by attorneys from the Department of Justice.

The Vaccine Act removes many of the more difficult elements of proof that

plaintiffs faced in traditional civil court. The Program is "no fault." In other words, claimants need not establish that the vaccine was defective or that there was negligence on the part of the doctor or clinic that administered the vaccine. Instead, establishing causation is made easier by creation of the "Vaccine Injury Table," a burden-shifting device, which extends a rebuttable presumption that listed injuries were caused by covered vaccines if the first symptom of the injury occurred within a particular time period after its administration. Even when the Table is not applicable, petitioners do not have to prove fault, only medical causation. In "Table" cases, sometimes the "temporal" relationship between vaccination and onset of injury is apparent from the medical records alone, in which case liability, or "entitlement," is conceded outright, obviating the need for an in-court hearing. Under these circumstances, we move immediately into the process of determining damages.

The streamlining is also apparent in the procedural mechanics of litigation. Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure apply, rendering virtually all evidence petitioners seek to present to the Court admissible. Burdensome traditional civil discovery as a matter of right is not allowed; the cooperative informal exchange of information is the ordinary and preferred practice. In short, the manner in which vaccine causation is resolved in any particular case is within the discretion of the Special Master, guided only by the notion of fundamental fairness.

Recognizing that each case involves a unique set of facts, and a unique medical condition, each case is handled individually. In practice, this means that the Special Masters make every effort to allow the parties to present their best case, and liberally grant extensions to comply with filing deadlines. The six Special Masters

who adjudicate these cases bring valuable accumulated medical expertise to each claim. They take an active role in case processing, and have published the "Guidelines for Practice Under the National Vaccine Injury Compensation Program" to facilitate prompt and efficient resolution of claims.

By design, this is not a straight "claims" process, nor is it like traditional litigation. Rather it is a "hybrid" system of adjudication that blends the best of both processes, even if it cannot escape entirely the frustrations inherent in any adjudication process. In short, ours is a system that balances the rights of due process and an opportunity "to be heard" with the stated Congressional goal of resolving cases in a "less-adversarial," expeditious and informal proceeding, with flexible standards for admissibility of evidence and limitations on discovery.

Critical to the prompt resolution of cases is the completeness of the petition. By statute, this is a "front-loaded system," whereby petitioners are responsible for identifying the specific nature of their claim and providing all medical records and related documents, as well as factual affidavits, in their initial submission to the Court. When the initial filing is incomplete, as is often the case, petitioners are granted liberal extensions to supplement the record. If there is delay in processing the case, it is most often attributable to an incomplete record or an underdeveloped medical position. The pace of the adjudication process is thus largely controlled by petitioners themselves. Of course, only when all available relevant materials are supplied can HHS fully review the petition for medical compliance with the statutory criteria, and can the Court issue a decision on entitlement.

As for the Justice Department, our role is to implement the statute and uphold the provisions of the Act. In other words, my office ensures that compensation is provided to those who meet the eligibility criteria determined by Congress. We are

thus obliged to protect the Trust Fund against claims by those who have not suffered a vaccine-related injury, and to preserve the Fund for future deserving claimants.

In the spirit of the Act, we do this in a far less adversarial manner than would be expected from defendants in civil litigation. We approach each case with the recognition that it is unique. Accordingly, we cooperate with the Court and opposing counsel in developing creative and novel approaches to resolving each claim.

As a general matter, we attempt to expedite the processing of all cases in a number of ways. For example, we participate in an early telephonic status conference convened by the Court within 30 to 45 days of the filing of a petition, to discuss any deficiencies in the petition, such as jurisdictional impediments, or the absence of pertinent medical records necessary for proper review of the claim. Petitioners are thus notified early on in the process of any defects in their case and are advised how to remedy them. Where appropriate, we even assist in obtaining missing medical records by issuing subpoenas.

In our initial court filing, submitted within 90 days if the petition is complete when filed, we formally communicate our medical and legal position, in essence putting our "cards on the table" from the start.

For those cases where factual disputes exist, the Special Master will schedule a hearing, and most often, the Special Master and the Department attorney travel to the city where petitioners reside. The format of the hearings is another example of how the compensation process is informal and "custom-tailored" to accommodate petitioners. Although testimony is taken under oath, it is often elicited in unconventional ways, with witnesses testifying by telephone, or via video-conferencing. Evidence is never excluded on the basis of standard evidentiary

objections such as irrelevance, hearsay, or lack of authentication.

Finally, the hearings are undertaken with a sensitivity to the fact that these cases involve highly emotional and personal issues. Understandably, the parents of catastrophically injured children find it difficult to discuss their child's injury, even years after the event. Thus, scheduling of testimony is always at petitioners' convenience, and hearings are routinely completed within one day.

Petitioners are often given multiple opportunities to present favorable evidence, even if that requires several attempts to find expert witnesses, or the scheduling of more than one hearing. For example, petitioners may be granted the opportunity to pursue alternative theories if they are unsuccessful in their first effort to obtain compensation. Obviously, this prolongs the process significantly. So too, do appeals contribute substantially to the length of time it takes to conclude a case. The Government rarely appeals — for example in the U.S. Court of Appeals for the Federal Circuit, of 85 Vaccine Act appeals, only 13 were filed by the Government, and only one in the last four years.

With regard to determining the appropriate amount of compensation to be awarded under the Program, Congress has set forth a detailed list of categories of compensable items. While often time-consuming, the Program process is far more thoughtful and tailored as compared with the other alternatives of traditional civil litigation or a claims process with a pre-determined monetary schedule of benefits. The parties employ "life care" experts, usually nurses and vocational or rehabilitative specialists, who assist in developing a "care plan" that predicts the child's life-long medical, rehabilitative and residential needs. The length of time devoted to this aspect of the cases is appropriate considering the complexity of the task and the seriousness of the inquiry. The goal is no less than establishing a

custom tailored plan of life time medical care. The determination of damages is usually undertaken as a cooperative effort by the parties, occasionally with the use of a joint life care expert to simplify the process. Indeed, I estimate that approximately 90% of all damages cases are settled between the parties without a hearing.

Towards that end, the Department drafted a comprehensive packet entitled "Steps to Streamlining Damages Under the Vaccine Program," which sets forth ways to expedite the damages phase and maximize petitioners' compensation. We distribute this document to counsel when we reach this phase in the proceedings. Although the authority to determine the types and amounts of compensation to be awarded in Vaccine Act cases lies with the Special Masters at the U.S. Court of Federal Claims, the Department frequently negotiates settlements, eliminating the need to go to hearing. Our ability to do this and do it quickly is most profoundly affected by the availability of documentation from the petitioners to support the requests for specific items of compensation. In order to get the case in best posture for settlement, we identify for petitioners' counsel the steps they can take to move through the process as quickly as possible. For instance, we stress the importance of providing relevant updated medical and school records, and receipts to verify costs of existing care and services. We understand that this can be an onerous process, and in fact, we even assist in gathering documents if petitioners' counsel run into logistical or financial difficulty.

Similarly, we've drafted a guide to assist petitioners' attorneys with their applications for reimbursement of attorneys' fees and litigation costs. As you know, petitioners are reimbursed for reasonable attorneys' fees and costs — whether petitioners win or lose — so long as the petition was filed in good faith and there

was a reasonable basis for doing so. In "Practical Points About Attorneys' Fees under the Vaccine Program," we summarized the applicable case law governing the scope of available fees, and identify for petitioners exactly what supporting documentation is needed and what criteria the Department considers in evaluating the requests. Finally, it bears mentioning that the Department of Health and Human Services has developed a system for payment of compensation awards that may well be unrivaled in terms of speed and efficiency.

In spite of these numerous accommodations, resolution of these cases simply cannot always be accomplished quickly. Some of the medical issues are extremely complex, even at the cutting edge of medical science. Similarly, determining adequate and appropriate life time medical compensation simply takes time. There exists an obvious tension between efficiency and due process in a Program that can fairly be described as "petitioner-friendly." The Court has developed into a forum of liberal process; the Special Masters give petitioners every realistic opportunity to prove their case, and that, too, may take time.

Given the relaxed substantive standards of proof, and the flexible and informal procedures currently in place, it is hard to conceive of additional ways to further streamline the process, other than proposals that HHS has already put forth. So long as the parties diligently work to provide the medical evidence and other documentation needed to substantiate a claim, the process is in fact, efficient. Certainly the process could be shortened — rigid deadlines could be enforced, requests for extensions denied, and cases decided on the written record alone. Without question, this could only be accomplished to the detriment of the prosecution of these cases with the inevitable result being far more petitions dismissed and far fewer families compensated.

It bears mention that the vast majority of the unsuccessful claimants simply lack medical evidence to support their claims. Thus, the statistics on the number of cases dismissed should not be used to create the dangerous and false impression that large numbers of vaccine injuries are left uncompensated. As for the medical criteria that form the basis for the current awards of compensation, we defer to HHS's assessment regarding any changes to the Program. We note, however, that those criteria, set forth in administrative regulations, are based upon the consensus view of all the major medical organizations in this country — the American Academy of Neurologists, Child Neurology Society, and American Academy of Pediatrics — as well as the Institute of Medicine, tasked by Congress to investigate the matter of vaccine-associated adverse events. The pronouncements by the foremost authorities on the subject are the reason that many claims have been denied — not an overly zealous defense mounted by this Department or the Department of Health and Human Services. Simply put, most of the unsuccessful claims are hinged on science that is not accepted by the mainstream medical community, or no science at all.

Moreover, even for those who are ultimately unsuccessful in this Program, we believe there is value in the process itself. Petitioners are granted the right to fully participate in each phase of the adjudication, and their rights are vigorously asserted by their attorneys. Moreover, the work of those attorneys is funded by the Program. The relevant evidence is heard in a unique Congressionally designed forum. Admittedly, these cases involve complicated issues that are medically complex and emotionally charged. Congress recognized this fact, and created this forum as the best way to address them. Creation of the Program certainly did not solve the underlying questions regarding vaccine-caused injuries, but it does compromise the

debate and provide an efficient and fair way to deal with them. Indisputably, this Program has improved the quality of life of the hundreds of individuals and provided them with assistance they would not have received otherwise. Moreover, the "transaction costs" (legal costs and expenses incurred by all parties, including the Court) are a fraction of those in the tort system.

As with any Governmental benefit program with specific eligibility criteria, unavoidably, there will be applicants who are dissatisfied. This will be true even of those who are awarded compensation since success under the Program cannot reverse the fact that the family has suffered mightily. Yet, we cannot ignore the statutory criteria or the consensus of the medical community on the medical causation issues. This is not an entitlement scheme that requires that every claim be paid regardless of merit. It is a program that relies heavily upon the most current and accurate scientific evidence available. The Department of Justice is required to uphold the statutory scheme established by Congress. In resolving disputed claims, the Court, consistent with the statutory guidelines, does not require scientific certainty, simply a preponderance of the evidence. We caution that further relaxation of the minimal standards currently in place could threaten the medical integrity of the Program.

Nevertheless, the Program can be improved, and the Department has been willing to support justified modifications. Over the eleven years the Program has been in operation, the various participants, including the nine-member Advisory Commission on Childhood Vaccines, have discovered through experience those aspects that haven't worked as effectively as envisioned. Appropriate steps have been initiated to improve the Program. Indeed, the Department took an active role in instigating and drafting many of the legislative proposals now under consideration

by the Congress. The amendments contained within the HHS draft bill include changes that will further streamline the process and better serve the interests of children and families. For instance, we supported an amendment that will extend the statute of limitations for filing petitions by an additional three years, and promoted another amendment that will revise the method of calculating lost future earnings resulting in a substantially increased awards to petitioners. We agreed that amendments should be proposed that will allow compensation for counseling of the family of the injured individual and permit compensation to establish a guardianship for the injured child. We hope the bill, titled the "Vaccine Injury Compensation Program Amendments of 1999," will receive expeditious and favorable consideration.

I would also like to mention that we supported an amendment to eliminate the requirement that petitioners prove that they incurred in excess of $1,000 in unreimbursable vaccine-related expenses, a provision in the original Act that spawned a lot of litigation. The provision was originally intended as a measure of severity of injury, based on the assumption that claimants expending less than $1,000 were not seriously injured and should not be granted access to the Compensation Program. Yet, the statutory requirement had the unintended result of excluding recipients of public benefits, such as Medicaid, who did not incur medical expenses and who were therefore unable to meet this requirement. We were pleased when a provision eliminating this requirement was included in the 1998 Omnibus Appropriations Act; however, the provision did not specify whether the new law applied to pending cases. In a case before the U.S. Court of Appeals for the Federal Circuit in which the issue was raised, we successfully argued that the law should be given retroactive effect. Just last week, the Court issued its decision,

and the statutory provision will no longer prevent claimants from receiving compensation.

In conclusion, Congress in the 1980s was faced with a looming public health crisis concerning immunizations which involved complex, hotly debated medical issues overlaid with the emotion of personal loss and tragedy in individual cases. In order both to provide a more feasible avenue of compensation and to stabilize national immunization policy, Congress established a compensation system setting forth detailed criteria both for entitlement and the appropriate elements of compensation. Petitioners are afforded a less adversarial adjudicatory system with free counsel in which their meaningful participation in the process is assured. The debate, emotion, and complexity of the cases were not eliminated and never will be but an effective mechanism is in place to resolve the issues and determine the claims. As a result, almost 5,000 cases have been resolved and numerous families compensated while the supply of life saving vaccines has been assured.

I appreciate the opportunity to present the Department's views on the National Childhood Vaccine Injury Compensation Program, and would be pleased to answer any additional questions at this time.

Mr. MICA. Thank you, and I would like to yield now to the chairman of the full committee for questions.

Mr. BURTON. Mr. Euler, I understand your employee, Ms. Hewitt, was the one who challenged the credibility of Dr. Kinsbourne when he testified recently at a case. Can you tell me why that happened?

Mr. EULER. According to Dr. Kinsbourne, Mr. Chairman, Ms. Hewitt entered into the record the fact that Dr. Kinsbourne had testified.

Mr. BURTON. What does that have to do with anything?

Mr. EULER. Well, it has to do with cross examination. Normally, in cross examination, previous testimony of a witness, things that have been published, things that they have said have been used. Certainly, petitioner's counsel will use things that experts have said in an effort to cross examine.

Mr. BURTON. So, it was assumed that he had a bias, because he testified before our committee and what he said?

Mr. EULER. I have not seen the record. I understand from Dr. Kinsbourne that she argued bias. Now, this is a pending case——

Mr. BURTON. Yes.

Mr. EULER [continuing]. And I hesitate to talk about a pending case.

Mr. BURTON. Ms. Hewitt works for you, doesn't she?

Mr. EULER. Yes, she does.

Mr. BURTON. Here is what she said: "The fact that he recently testified before Congress about a number of issues, but in particular about his views on the problems with this program, I think also shows that to some degree he is an advocate on behalf of the petitioners, and Dr. Holmes is not."

I didn't know that testifying before Congress impeded people's ability to testify in courts of law.

Mr. EULER. Well, I——

Mr. BURTON. I think you ought to talk to Ms. Hewlitt—Hewitt, or whatever her name is. I mean, it seems to me, you don't know everything that she said, and she is your employee, isn't she?

Mr. EULER. That is correct.

Mr. BURTON. And you haven't talked to her about this?

Mr. EULER. I have not. But I appreciate—and I think that point that Dr. Weldon made is a good one. I think he raised the point that this might chill expert testimony. And in that respect, I think we are duly rebuked. I don't think we should be——

Mr. BURTON. Well, we have had problems like this with the Justice Department before.

There have been 6,000 cases filed, 3,500 dismissed, 1,400 settled, and 1,100 pending according to the records we have. This is supposed to be a non-adversarial process, and yet when you were testifying, Mr. Balbier, you said it is less adversarial. It is supposed to be non-adversarial, isn't it?

Mr. BALBIER. That is not my understanding of the statute at all.

Mr. BURTON. Well, Mr. Waxman who wrote the law said it was.

Mr. BALBIER. I heard Mr. Waxman say that the program is supposed to be less adversarial than the tort system. If it truly were a non-adversarial system——

Mr. BURTON. I guess we could go back and read the record earlier today, but I was sitting here, and I am pretty sure he said non-adversarial. But, anyhow, let us not dwell on that.

Mr. BALBIER. I would think that if it truly were a non-adversarial system, you would not have advocates representing the families that are affected by childhood vaccines.

Mr. BURTON. The reason you have advocates appearing on behalf of these people is because their kids have been harmed, and they are not getting proper treatment by the Federal Government, and because of that, they have to hire attorneys.

You know, my two grandkids, we have tried to find attorneys. Do you know how hard it is to find an attorney to take one of these cases because of the way you guys run them around? They don't want to do it. They don't want to take 2, 3, or 4 years, because they know you can't afford to pay it.

You know, you said that among those that participate in setting the standards in the decisionmaking process were the vaccine-producing companies. Is that correct?

Mr. BALBIER. That is correct.

Mr. BURTON. Why?

Mr. BALBIER. The statute requires, or sets out who serves on the Advisory Commission of Childhood Vaccines.

Mr. BURTON. And the vaccine companies are required to sit on that board to make——

Mr. BALBIER. Yes, they are, sir.

Mr. BURTON. Well, I think that is something that should be looked into.

Why should those who have a vested interest be involved in the decisionmaking process. The reason this system was set up in the first place was because the pharmaceutical companies said that they were in jeopardy of having severe lawsuits that could jeopardize the viability of the companies.

And so what Congress said was, "OK, we are going to try to help you out by coming up with a non-adversarial situation, procedure, where you won't be jeopardized, but money will be put into a fund for each shot that is given to protect the people who might be harmed."

And, so it has become adversarial, and they are involved in the decisionmaking process. That makes no sense. It just doesn't make any sense to me. They should not be involved. You should have medical professionals and scientists who understand, like Dr. Kennedy who appeared before this committee, who said that 50 percent of the DPT shots—50 percent of those who got the DPT shot had adverse effects. He said 50 percent, and he is a scientist that has been working on this at the University of Oklahoma.

And yet the people who make the DPT shots can be involved in the decisionmaking process when we are talking about settlements. I don't understand that. And the DPT shots are still being given even though we have known for years that they have 50 percent side effects; some severe, some not so severe.

I mean, these pharmaceutical companies make major investments in vaccines; I understand that. And they have a very strong financial interest. And if something goes wrong with these vaccines and they are taken off of the market, they suffer severe losses.

And, so I can understand why they want to keep those on the market and why some people maybe—maybe—at HHS and FDA protecting and allowing them to give things that are dangerous to people these vaccines, these kids.

And, so for them to be involved in any way in the decisionmaking process doesn't make any sense to me, because they do have a vested interest.

Mr. BALBIER. I would agree with that. They are not involved in the decisionmaking process, sir. They are represented on the Advisory Commission, which is strictly advisory. They do not make any decisions through the adjudicative process, but they do make recommendations to the Secretary.

Mr. BURTON. I am sure they do.

Mr. BALBIER. And there is one person representing vaccine companies.

Mr. BURTON. Yes, I know.

Mr. BALBIER. We also have petitioners, attorneys; we have two parents who sit on that——

Mr. BURTON. You know, Shakespeare said, "A rose by any other name would smell as sweet." If they are involved in the process at all because they have a vested interest, it is a mistake, especially those who have a lot of money invested in vaccines that are questionable.

We heard just a little while ago—and I am sorry if I am going too long, Mr. Chairman—we heard just a little while ago about a fellow whose child suffered from polio, because they gave him live vaccine, and they have known for decades that there was that risk, while at the same time, for decades, they have dead virus vaccines that could be given to people that were not nearly as risky.

Why was that live vaccine kept on the market all those decades? Why is the DPT shot being used today when we had people testify here before the full committee that it was a problem, a danger? And then on the Advisory Committee you have the pharmaceutical companies. I think it is something we need to take a hard look at.

One-quarter of the claims have been adjudicated and finalized—one-quarter. So, we have 3,500 people who thought they had a legitimate case in a non-adversarial system. Their case was dismissed—I don't know what happened to them—1,100 are pending, and out of 6,000 only 1,400 have been settled.

I just don't understand that. Are the decisions made by this board objective or subjective?

Mr. BALBIER. I would say that the recommendations made by our Advisory Commission are as objective as they can be, and in fact whenever anybody who serves on that commission does have a vested interest on any matter that is being voted upon, they recuse themselves from a vote on that matter, which has happened frequently, especially with the vaccine companies' representatives. For any issue that involves the vaccine made by the company that they represent, they do not vote on that issue; they never have.

Mr. BURTON. OK, we have—my staff just told me they have 24 people on one of the decisionmaking bodies, and 11 of those have received money from the pharmaceutical companies that were being investigated. That is almost half. You say they all recuse themselves?

Mr. BALBIER. No, that is a different advisory committee, I believe. I believe the staff perhaps is referring to the Advisory Committee on Immunization Practices, which makes recommendations on immunization policy; that is, which vaccines are given and when, to children.

Mr. BURTON. It says it is an FDA advisory committee, Vaccines and Related Biological Products Advisory Committee, Center for Biologic Evaluation and Research.

Mr. BALBIER. That is yet again another advisory committee involved in immunization, which makes recommendations to the Food and Drug Administration for licensing.

Mr. BURTON. Can you give me the makeup of the committee we are talking about?

Mr. BALBIER. Yes, I can. The Advisory Commission——

Mr. BURTON. How many of those people are physicians or scientists?

Mr. BALBIER. I'll be happy to answer. The Advisory Commission on Childhood Vaccines, by design of Congress, is a very diverse group. Its purpose is to make recommendations to the Secretary on the operation of the Compensation Program. It is comprised of nine voting members—three doctors, three lawyers, and three members of the general public.

Mr. BURTON. OK, now the three doctors, where do they come from?

Mr. BALBIER. Two of them have to be pediatricians; one does not.

Mr. BURTON. Do they have anything to do with HHS or FDA or any of the Government agencies?

Mr. BALBIER. That is a tough question to answer. By their very service on the commission——

Mr. BURTON. I don't know if it is very tough or not. Do they have anything to do with FDA, HHS, or any governmental agency?

Mr. BALBIER. Many of the members on our commission have served on other advisory committees, for example. The current members in the medical community—Dr. Sam Katz has served on——

Mr. BURTON. How are they compensated?

Mr. BALBIER. They are compensated for their actual service that day on the Advisory Committee at a rate of compensation that is set in the statute.

Mr. BURTON. Do any of them serve on any advisory boards or any pharmaceutical advisory boards connected with the pharmaceutical industry?

Mr. BALBIER. If they do, they have to indicate that to us.

Mr. BURTON. Well, I would like to have, for the record, the backgrounds, the biographical sketches, and their connections for all three of those people, if it is possible.

Mr. BALBIER. OK.

[The information referred to follows:]

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Yale University, J.D., 1972.
United States Naval Academy, B.A., 1966.

Professional Experience

Member, Venable Board, 1994-present.
Chair, Litigation Group, 1994-present.
Chairman, Labor/Litigation Division, 1991-94.
Head of Litigation Department, 1988-1990.
Partner, Labor/Litigation Division, concentrating in pharmaceutical and product liability law, commercial litigation, administrative law and health services litigation.

Deputy Attorney General, State of Maryland, 1982-84.

Chief of Litigation, Maryland Office of Attorney General, 1980-82.

Professional Memberships and Activities

Member, Maryland, District of Columbia and American Bar Associations.

Member, Section of Litigation, Tort and Insurance Practice, American Bar Association.

Member, International Association of Defense Counsel.

Member, Defense Research Institute.

Member, The Fellows of the American Bar Foundation.

Member, Maryland Association of Defense Trial Counsel.

Fellow, Maryland Bar Foundation.

Member, Standing Committee on Rules of Procedure, Maryland Court of Appeals, 1983-84.

Member, Board of Directors, Maryland Legal Services Corporation, 1987-89.

Panel Member, MICPEL, "Ethics and Negotiation in Trial Practice".

Instructor, Trial Practice, University of Maryland School of Law.

Board of Directors, Trinity School, Member, 1985-1991; Chairman, 1987-89.

Representative Publications

Author, "Key Statutes and Regulations Impacting the Defense of Medical Device Cases," Defense Research Institute, 1992.

Author, "Media Relations: Practical Considerations & Legal Issues," Defense Research Institute, 1990.

Co-Author, "Recent Developments in Causation Law," Presented to Chemical Manufacturers Association Toxic Litigation Group, October 1989.

RESUMÉ OF
MICHAEL G. McLAREN

Education:

BA Yale University, 1972
JD Loyola University of Chicago, 1976

Employment:

1976 - 1979	Rickey, Shankman, Blanchard, Agee and Harpster Memphis, Tennessee
1979 - Present	Thomason, Hendrix, Harvey, Johnson & Mitchell Memphis, Tennessee

Personal:

Born:	January 29, 1950, Joliet, Illinois
Married:	Karen Y. McLaren
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Vaccine Injury Litigation Experience:

I have been active in vaccine injury litigation since the early eighties, always acting for petitioners/plaintiffs. Prior to the advent of the Compensation Program, I handled several cases before various District and State Courts. Once the Program was initiated, I became an active petitioner's attorney and have handled dozens of cases through settlement and/or trial and/or appeal to the Federal Circuit. I have lectured and presented seminars on the Program and litigation within the Program.

I feel I have a very good relationship with the Special Masters and government attorneys and have had a very successful record in Program cases.

Honors and Activities:

1. Editor, Law Journal ("Blackacre"), Loyola University of Chicago Law School

2. All East Coast Basketball, Yale University

3. Member: Memphis Bar Association
American Bar Association
International Association of Defense Counsel
Tennessee Defense Lawyers Association

4. Court Admissions:

A. Tennessee Supreme Court (and all courts of Tennessee)
B. United States Supreme Court
C. Sixth Circuit Court of Appeals
D. United States Court of Appeals for the Federal Circuit
E. United States District Court, Western District of Tennessee
F. United States District Court, Middle District of Tennessee
G. United States District Court for the Eastern District of Arkansas
H. United States District Court for the Northern District of Mississippi
I. United States Claims Court

5. Board of Directors: Circuit Playhouse, Inc.
Deer Island Club Corp.
TN Head Injury and Trauma Assn.

6. Committees: ABA Litigation Committee
IADC Products Liability Committee
Construction Law Committee
Toxic Tort Committee
Fidelity and Surety Committee
Memphis Bar Association Membership Committee
Campaign for Equal Justice, Co-Chair
Tennessee Supreme Court Investigatory Committee on Ethics and Moral Fitness
Yale Alumni Fund
United States District Court, Committee on Pro Bono Representation
Memphis Bar Association, Committee on Pro Bono Representation

7. Lecturer: University of Memphis Law School
University of Tennessee Medical School (Medical malpractice issues)
Memphis Association of Paralegals
University of Tennessee Law School (Trial Advocacy)
1997 Faculty Member of the Trial Academy of the International Association of Defense Counsel

8. Actor: Credits include:

The Firm
A Time to Kill
Separated by Murder
Her Hidden Truth
People v. Larry P

Flynt

Litigation Experience:

Litigation has been my specialty since I became an attorney in 1976. I have tried scores of cases, both jury and non-jury, and participated in hundreds of trials and hearings in several states, including Tennessee, Mississippi, Arkansas, Texas, Colorado, Massachusetts, Louisiana, Kentucky, South Carolina and New York.

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EXPERIENCE

1980 – Present — *Mediation Trainer*, Rockville, Maryland — Train professionals in mediation theory, process and skills for the following organizations: National Center for Mediation Education (30 national training sessions 1980-1992); District of Columbia Multi-Door Mediation Training (1987, 1988); Montgomery County Bar Association Mediation Training (1987, 1989); Judicial Institute of Maryland (1988); American Arbitration Association (1983); Maryland Institute for Continuing Legal Education Generic Mediation Training (1992).

1980 - Present — *Attorney Mediator*, Rockville, Maryland — Engaged in legal/mediation practice in Maryland and the District of Columbia. Mediation services constitute over 75 percent of caseload in civil law disputes.

1986 - Present — *Court Coordinator, Mediation Service, Circuit Court for Montgomery County*, Rockville, Maryland — Coordinate court-ordered mediation service for couples with contested custody cases.

1982 - Present — *Fact Finder, Montgomery County Personnel Grievance Process* — Review and make written recommendations on grievance appeals from Montgomery County Personnel Director's decisions regarding personnel actions.

1984 - Present — *Arbitrator, American Arbitration Association Commercial Panel* — Arbitrate civil law disputes.

1984 - 1989 — *Adjunct Faculty, The Catholic University of America, Post Graduate Certificate Program in Family Mediation* — Taught graduate courses in conflict resolution.

1979 - 1980 — *Trial Attorney, Equal Employment Opportunity Commission, Office of Systemic Programs*, Washington, D.C. — Served as a trial attorney responsible for preparation and prosecution of complex class discrimination actions in the Federal District Court. Also investigated large class action suits and negotiated conciliation and settlement agreements.

1976 - 1979 — *Attorney, National Labor Relations Board, Office of Appeals*, Washington, D.C. — Analyzed and formulated legal theories in appealed unfair labor practice cases involving terms and conditions of work, organizing and collective bargaining activities and discrimination.

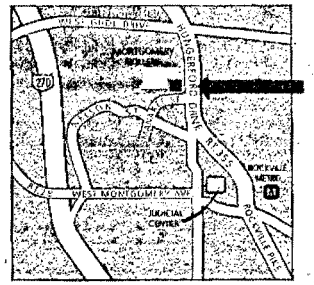
EDUCATION

J.D., Antioch School of Law, Washington, D.C. (1976)
M.A., Psychology, University of the Americas, Puebla, Mexico (1973)
B.A., Hollins College, Roanoke, Virginia (1971)

Admitted to practice in the District of Columbia and Maryland.

CATHERINE G. CROCKETT

Catherine G. Crockett, J.D., M.A., Mediator, is an experienced divorce mediator with both a law degree and a Master's Degree in Psychology. For over 16 years she has engaged in a private family law and mediation practice in Maryland and the District of Columbia. Between 1984 and 1989 she taught family law and conflict resolution courses in Catholic University's post graduate family mediation program. From 1980 to 1996 she trained family mediators for the National Center for Mediation Education. She has also trained civil mediators through the Montgomery County Bar Association and the Maryland Institute of Continuing Professional Education of Lawyers. Catherine coordinated the Montgomery County Circuit Court Family Mediation Service for families with contested custody cases from 1986 to 1993. She is a member of the Maryland State Bar Alternative Dispute Resolution Committee and since 1994 has coordinated Divorce Law Question and Answer Sessions for the general public through the Center for Divorcing Families.



Directions from DC, VA and lower Montgomery County: Take Rt 270N to Exit 6A (Route 28 - Rockville Town Center/East Rockville). At end of ramp take left toward Mongomery College/Nelson Street. Follow Nelson Street for 1.2 miles to the first stop light at Manakee Street. Turn left onto Manakee Street and proceed for .4 miles to Hungerford Drive (Route 355). Turn Left onto Hungerford Drive. Proceed 100 yards to first left turn lane. Turn left into the Jackson Place South and North Town House complexes. Turn right toward Jackson Place North and go around to the rear of the complex. The office faces the Montgomery College athletic fields. There is plenty of free parking.

From Gaithersburg and more northern points: Take Route 270S Exit 6A. Turn left onto Route 28. Take the first left onto Nelson Street. Follow the above directions from Nelson Street.

CATHERINE CROCKETT, ATTORNEY MEDIATOR
966 HUNGERFORD DRIVE, SUITE 318
ROCKVILLE, MARYLAND 20850
TELE: 301-279-6720 FAX: 301-279-6904

FAMILY & DIVORCE MEDIATION

A COLLABORATIVE PROCESS

CATHERINE CROCKETT
ATTORNEY MEDIATOR

RESUME

DUANE L. EDWARDS JR.
22 Camino Dimitrio
SANTA FE, NM. 87505
(505) 466-1870 HOME
827-8478 WORK

OBJECTIVE: TO OBTAIN A POSITION IN THE CHILDREN, YOUTH, AND FAMILIES DIVISION OF STATE GOVERNMENT, AS A MANAGEMENT ANALYST III, IV OR SUPERVISOR.

PERSONAL:

I AM THE PARENT OF A CHILD WITH SPECIAL NEEDS. THROUGHOUT MY SON'S LIFE I HAVE BEEN VERY INVOLVED WITH VARIOUS ORGANIZATIONS, IN HOPES OF ACQUIRING SERVICES FOR ALL INDIVIDUALS WITH DISABILITIES. I WAS VERY INVOLVED IN THE INFANT STIMULATION PROGRAM IN NORTH DAKOTA. UPON MOVING TO NEW MEXICO, MY SON WAS PLACED ON THE DD WAIVER PROGRAM. DUE TO THE SEVERITY OF HIS DISABILITY HE WAS MOVED TO THE MEDICALLY FRAGILE PROGRAM. ALTHOUGH MY SON DIED TWO YEARS AGO, I FEEL THAT WITH THIS BACKGROUND, AS WELL AS MY EXPERIENCE AT PARENTS REACHING OUT, I COULD BE AN ASSET TO THE CHILDREN, YOUTH AND FAMILIES DIVISION. I AM A STRONG SUPPORTER OF CHILDREN, YOUTH AND FAMILIES DIVISION PROGRAMS AND AM COMMITTED TO HELPING FAMILIES AND PROFESSIONALS SECURE THE PROPER SERVICES FOR ALL INDIVIDUALS.

1. EXCELLENT HEALTH
2. MARRIED/ 1 CHILD
3. LOCAL HOMEOWNER

EDUCATION:

BUSINESS ADMINISTRATION/MANAGEMENT (BBA)
- COLLEGE OF SANTA FE 87/88
- GRADUATED WITH HONORS
- WHO'S WHO IN AMERICAN COLLEGES AND UNIVERSITIES 87/88
- SPAIN MEMORIAL ACADEMIC SCHOLARSHIP
- TERRI WELTE BUSINESS SCHOLARSHIP

EXPERIENCE

SUPERVISION: 9 1/2 YEARS

STATE GOVERNMENT -- 6 MONTHS -- (10/93 - PRESENT)

1. INTERSTATE COMPACT ON JUVENILES -- MANAGER II

DUTIES:

A. TO ADMINISTER THE INTERSTATE COMPACT ON JUVENILES
B. TO TRAIN AND EDUCATE JUVENILE PROBATION OFFICERS, SOCIAL WORKERS AND INSTITUTION WORKERS ON COMPACT LAWS, POLICIES AND PROCEDURES.
C. TO MONITOR THE STATE AND FEDERAL LAWS PERTINENT TO INTERSTATE PLACEMENT OF ADJUDICATED DELINQUENTS.
D. ADMINISTER $12,000.00 BUDGET FOR THE RETURN OF RUNAWAYS, ESCAPERS AND ABSCONDERS.

SERVICE INDUSTRY -- 2 3/4 YEARS --(1/91 - 10/93)

1. PARENTS REACHING OUT - DIRECTOR, PROJECT ADOBE

DUTIES:

A. DEVELOP AND PLAN TRAINING SESSIONS THROUGHOUT THE STATE. THE PURPOSE OF THESE TRAINING SESSIONS IS TO DEVELOP A CORPS OF COMMUNITY BASED ADVOCATES. THESE INDIVIDUALS WILL SUPPORT FAMILIES OF CHILDREN WITH DISABILITIES AT INDIVIDUALIZED EDUCATION PROGRAM (IEP) MEETINGS.

B. PROVIDE INFORMATION AND REFERRAL FOR FAMILIES OF INDIVIDUALS WITH DISABILITIES, ABOUT SERVICES AVAILABLE IN THEIR AREA.

C. SET UP DATA BASE FOR COLLECTION OF DATA FOR FEDERAL REPORTING REQUIREMENTS. FILE FEDERAL REPORTS BOTH QUARTERLY AND ANNUALLY.

D. SUPERVISE STAFF TRAINERS AND COMMUNITY BASED ADVOCATES IN PERFORMANCE OF ASSIGNED DUTIES.

E. PROVIDE SUPPORT TO PARENTS OF CHILDREN WITH SPECIAL NEEDS.

RETAIL -- 2 YEARS -- (12/88 -- 12/90)

1. SEARS- ASSISTANT MANAGER, HARDWARE/LAWN AND GARDEN

DUTIES:

A. TRAIN AND SUPERVISE 10 INDIVIDUALS IN CARRYING OUT OF RETAIL FUNCTIONS.

B. PLAN AND DEVELOP WORK SCHEDULES FOR 10 PERSON RETAIL CREW.

C. OVERSEE INVENTORY CONTROL AND REPLENISHMENT OF DEPARTMENT STOCK.

CONSTRUCTION: -- 5 YEARS -- (9/80 -- 10/85)

1. FOREMAN / GENERAL FOREMAN -- LABORER'S LOCAL #580 -- JOHNSON BROTHERS CORP., HENRY J. KAISER CO.

DUTIES:

A. PLAN AND DEVELOP WEEKLY AND DAILY WORK SCHEDULES FOR CREWS VARYING IN SIZE FROM 7 TO 50.

B. SUPERVISE CONSTRUCTION OF VARIOUS PROJECTS WITH TIME AND BUDGET CONSTRAINTS.

COMPUTER EXPERIENCE:

A. ACADEMIC -- COLLEGE OF SANTA FE
1. COMPUTER PRINCIPLES AND APPLICATIONS
2. INTRODUCTION TO MICRO COMPUTERS

B. WORK RELATED -- SEARS AND PARENTS REACHING OUT
1. WORDPERFECT 5.1
2. Q & A DATABASE
3. DBXL DATA BASE
4. SEARS ELECTRONIC MAIL
5. SPECIALNET - PARENTS REACHOUT E-MAIL

SUMMARY OF ACCOMPLISHMENTS/ATTRIBUTES

TEAM BUILDER	DEDICATED	MOTIVATOR
PERSISTENT	PROBLEM SOLVER	CONFIDENT
SELF STARTER	DILIGENT	COMPETENT
EFFECTIVE COMMUNICATOR		

ACTIVITIES

1. ADVISORY BOARD MEMBER
   A. NEW MEXICO MEDICALLY FRAGILE CHILDREN'S PROGRAM

2. TASK FORCE MEMBER

   A. SANTA FE PUBLIC SCHOOL'S IFP REVISION
   B. ALBUQUERQUE PUBLIC SCHOOLS SECTION 504 TASK FORCE
   C. ROCKY MTN. ADOPTION POST LEGAL TASK FORCE
   D. LONG TERM CARE TASK FORCE
   E. NUTRITION IN SCHOOLS TASK FORCE

3. PARENTS REACHING OUT MEMBER

   A. SUPPORT GROUP FOR PARENTS OF CHILDREN WITH SPECIAL NEEDS.

4. SPORTS

   A. SKIING
   B. BOWLING
   C. GOLF
   D. BOATING

Angela Grant, B.S.N.
813 Booker Drive
Seat Pleasant, Maryland 20743
(301)499-4612

OBJECTIIVE: A professional nursing position offering an opportunity for growth using my knowledge expertise

REGISTERED: Washington,D.C.
Maryland

WORK EXPERIENCE:

1/93 to 5/93 Children's Home Health Center
Michigan Avenue, N.W. (Trinity Square)
Washington, D.C.

PEDIATRIC FIELD NURSE

-Performed initial admission evaluations.
-Instructed families on the use of pulmonades and other respiratory equipment.
-Provided CPR and emergency training.
-Reviewed medication administration.
-Taught baby care skills.
-Assessed growth and development to include vital signs and growth measurements.
-Taught medically related parenting skills.
-Some telephone triage experience.

4/86 to 12/92 Children's Hospital

STAFF NURSE
(PRN Critical Care Pool and Regular Pool)

-General nursing care of a wide variety of patients to include but not limited to: cardiology; neurology; orthopedics; infectious diseases; hematology; emergency treatment; and burns .
-Critical care nursing in Pediatric Burn; Neonatal; and Step Down Intensive Care Units. Duties included interacting with other health care professionals, administration of medications, chemotherapy, IGG administration, blood and blood products. Assessment of body systems, admissions, transfers, etc. Utilized ventilators; CPAP; O and suction; medication pumps; pulse oxygen machines; cardiac monitors and oxygen hoods.

ANGELA GRANT, B.S.N.

PAGE TWO

-Managed Over Flow Unit (Rainbow Unit) to include: opening the unit; obtaining supplies for unit; communication with other hospital units and staffing. Also admitted patients with a diversity of needs. Transcribed doctor's order. Transferred patients and closed the unit.

4/84 to 4/86 George Washington Hospital
Pennsylvania Avenue, N.W.
Washington, D.C.

-Assigned to Neonatal Intensive Care Nursery providing care to high risk, low birth weight babies.

4/82 to 4/83 Washington Hospital Center
Irving Street, N.W.
Washington, D.C.

-Attended to high risk mothers in a postpartum unit with "rooming-in" privileges.
-Assisted with circumcisions and physical assessments.
-Instructed mothers on breast feeding.

Intermittent/1986 SRT MED Staff
Quality Care
Kimberly

Private Duty Nurse
(Temporary)

EDUCATION:
1979 Hampton University Bachelor of Science

Ongoing (In-Service) Training in Pediatrics
Children's Home Health Care

-In Home Phototherapy
-Home Management of Children with Seizure Disorder
-Home Care of H.I.V. Patients
-Home Administration of Desferol
-In-Home Pain Management

REFERENCES AND TRANSCRIPTS AVAILABLE UPON REQUEST

STEVEN K. GAER
163 – 59th Street
West Des Moines, Iowa 50266
(515) 225-9732 (home)
(515) 365-6022 (work)

WORK EXPERIENCE

1994 - Present — **Vice-President, Associate Counsel and Assistant Secretary**: Kirke-Van Orsdel, Incorporated, West Des Moines, Iowa. Practicing general corporate law (emphasis in contract drafting and negotiation in the areas of insurance and benefits administration, benefits and human resources outsourcing, software licensing, managed care and consulting).

1986 - 1994 — **Shareholder** (1992-94) and Associate (1986-92); Ahlers, Cooney, Dorweiler, Haynie, Smith & Allbee, P.C., Des Moines, Iowa. Practiced general business law involving both transactional and litigation matters. Appellate practice before Eighth Circuit Court of Appeals, Iowa Supreme Court and Iowa Court of Appeals.

1996 - Present — **City Council Member At Large**; West Des Moines, Iowa (Mayor Pro Tem 1998-1999).

1996 - Present — Vice President (1996) West Des Moines Development Corporation (1997-1998, ex officio board member serving as City Council liaison).

EDUCATION

J.D. - Drake University Law School (1986), Des Moines, Iowa.
- graduation with honors
- Order of the Coif
- American Jurisprudence Award

B.B.A. - University of Kentucky (1983), Lexington, Kentucky.
- graduation with high distinction (cumulative G.P.A. of 3.86 on a 4.0 scale)
- dean's list 8 of 8 semesters
- Omicron Delta Epsilon (economics honorary - 1983)
- Beta Gamma Sigma (business honorary - 1982)
- Scholarship member and varsity letter winner (1979-83) of University of Kentucky golf team
- Outstanding Christian Athlete Award recipient (1982-83)

H.S. - Valley High School (1979), West Des Moines, Iowa.
- State of Iowa Scholar
- National Honor Society (1977-79), President (1978-79)
- American Citizenship Award (Iowa Bar Association)

PROFESSIONAL MEMBERSHIPS/ COMMUNITY ACTIVITIES

Admitted to bar; Iowa Supreme Court (1986), U.S. District Courts Northern and Southern Districts of Iowa (1986), Eighth Circuit Court of Appeals (1986), and U.S. Supreme Court (1991).

Member; American, Iowa and Polk County Bar Associations, National Health Lawyers Association, American and Iowa Corporate Counsel Associations.

Valley Church, Variety Club, West Des Moines Chamber of Commerce.

PUBLICATIONS

Co-author: "General Overview of Federal Rule of Civil Procedure II", 38 Drake Law Review 261 (1989).

Mr. BURTON. Then you have three lawyers. Do the lawyers represent any agencies of the Federal Government in addition to serving on these boards?

Mr. BALBIER. No. The statute requires that one of the lawyers has to be a petitioners' lawyer, somebody who represents petitioners under the compensation program. One has to be a lawyer who represents a vaccine company, and then——

Mr. BURTON. One of them has to be a lawyer that represents a vaccine company.

Mr. BALBIER. That is in the statute.

Mr. BURTON. Why?

Mr. BALBIER. Because it is in the statue.

Mr. BURTON. That seems, again, like a possible conflict of interest, because they represent a vaccine company who has a vested interest in what is paid and what isn't paid and where they are sued. I think we need to look at that.

I would like to know who that lawyer is and what companies he represents.

Mr. BALBIER. OK.

Mr. BURTON. OK?

Mr. BALBIER. His name is Paul Strain.

Mr. BURTON. Well, I don't want it right now.

Mr. BALBIER. We can provide that for you.

Mr. BURTON. I want to have the complete background—what companies he represents, what his background is, and whether or not any of the vaccines that are under investigation as far as compensation being paid to patients.

Mr. BALBIER. Right.

Mr. BURTON. And if he has represented in the past or currently any of those companies—in the past or currently.

[The information referred to follows:]

SAMUEL LAWRENCE KATZ, M.D.

Born	29 May 1927, Manchester, New Hampshire
	Social Security Number: 003-18-7430
1944	Graduated from public schools in Manchester, N.H.
1948	Dartmouth College, A.B., magna cum laude
1952	Harvard University, M.D., cum laude
1952 - 1953	Intern, Medical Service (Herrman L. Blumgart, Chief) Beth Israel Hospital, Boston, Mass.
1953 - 1954	Junior Assistant Resident, Medical Service (Charles A. Janeway, Chief) Children's Hospital Medical Center, Boston, Mass.
1954 - 1955	Assistant Resident, Children's Medical Service (Alan M. Butler, Chief) Massachusetts General Hospital, Boston, Mass.
1955 (6 mo.)	Co-Chief Resident, Medical Service, Children's Hospital Medical Center, Boston, Mass.
1956 (6 mo.)	Exchange Registrar (from Children's Hospital Medical Center) to the Paediatric Unit (Reginald Lightwood, Chief), St. Mary's Hospital Medical School, London, England
1956 - 1958	Research Fellow in Pediatrics, Harvard Medical School at the Research Division of Infectious Diseases (John F. Enders, Chief), Children's Hospital Medical Center, Boston, Mass.
1958 - 1968	Research Associate, Research Division of Infectious Diseases, Children's Hospital Medical Center, Boston, Mass.
1958 - 1961	Pediatrician-in-Chief, Beth Israel Hospital, Boston, Mass.
1961 - 1968	Visiting Pediatrician, Beth Israel Hospital, Boston, Mass.

Samuel L. Katz, M.D.

1958 - 1963	Associate Physician, Children's Hospital Medical Center, Boston, Mass.
1963 - 1968	Senior Associate in Medicine, Children's Hospital Medical Center, Boston, Mass.
1961 - 1967	Chief, Newborn Division, Children's Hospital Medical Center, Boston, Mass.
1958 - 1959	Instructor in Pediatrics, Harvard Medical School, Boston, Mass.
1959 - 1963	Associate in Pediatrics, Harvard Medical School, Boston, Mass.
1961 - 1963	Tutor in Medical Sciences, Harvard Medical School, Boston, Mass.
1963 - 1968	Assistant Professor of Pediatrics, Harvard Medical School, Boston, Mass.
1967 - 1968	Co-Director, Combined Beth Israel Hospital-Children's Hospital Medical Center, Infectious Disease Career Training Program, Boston, Mass.
1968 - 1990	Professor and Chairman, Department of Pediatrics, Duke University School of Medicine, Durham, N.C.
1972 -	Wilburt C. Davison Professor of Pediatrics, Duke University School of Medicine, Durham, N.C.

Board Certification & Licensure

National Board of Medical Examiners (1953) Cert. #27450
Massachusetts Board of Medical Examiners (1954) Cert. #23830
American Board of Pediatrics (1958) Cert. #6369
North Carolina Board of Medical Examiners (1968) Cert. #16180

Samuel L. Katz, M.D.

Professional Societies

American Academy of Pediatrics (Fellow)
New England Pediatric Society (Secretary-Treasurer, 1963-68)
New York Academy of Sciences
Society for Pediatric Research
American Association for Advancement of Science
American Society for Microbiology
Infectious Diseases Society of America (Fellow)
American Association of Immunologists
American Public Health Association
American Society for Clinical Investigation
American Association of University Professors
North Carolina Pediatric Society (Honorary Membership)
Southern Society for Pediatric Research
American Pediatric Society
American Epidemiological Society
American Society for Virology
American Federation for Clinical Research
Pediatric Infectious Diseases Society (Fellow)
Australasian Society for Infectious Diseases (Honorary Life Member)
International Society for Antiviral Research

Honors and Awards

Rufus Choate Scholar (1947-48)
Phi Beta Kappa (1948)
Alpha Omega Alpha (1951)
Sigma Xi (1958)
Boylston Medical Society (President, 1963-64)
Grulee Award (American Academy of Pediatrics, 1975)
Recipient of Golden Apple Award for excellence in teaching clinical sciences, from Duke University Medical Students (1969 and 1978)
Institute of Medicine of National Academy of Sciences (1982)
Thomas D. Kinney Teaching Award, 1984 (from the Senior Class of Duke University School of Medicine)
Abraham Jacobi Memorial Award, American Medical Association & American Academy of Pediatrics, 1986
Distinguished Teacher Award, from Duke Medical School Alumni, 1987
Joseph St. Geme, Jr. Future of Pediatrics Award (from the American Pediatric Society, Society for Pediatric Research, American Academy of Pediatrics, American Board of Pediatrics, Ambulatory Pediatric Association, Association of Medical School Pediatric Department Chairmen, Association of Pediatric Program Directors) 1988
Duke University Award of Merit, 1988

Samuel L. Katz, M.D.

Bristol Award, Infectious Diseases Society of America, 1988
Distinguished Physician Award, Pediatric Infectious Diseases Society, 1991
Presidential Medal of Leadership and Achievement, Dartmouth College, 1991
Society Citation, Infectious Diseases Society of America, 1993
University of North Carolina (Wilmington) Razor Walker Award, 1993

Military Service

Active Duty U.S. Navy, 1945 and 1946 (PhM3/c)

Personal History

Married (Betsy Jane Cohan) 1950 - 4 sons, 3 daughters
Married (Catherine Minock Wilfert) 1971 - 2 step-daughters

Fellowship Awards

1956 - 1958	Research Fellow of the National Foundation for Infantile Paralysis
1965 - 1968	Research Career Development Award of the National Institute of Allergy and Infectious Diseases, National Institutes of Health

Committees, Boards, Study Sections, etc.

1966 - 1976	National Committee on Infectious Diseases, American Academy of Pediatrics, Chairman, 1969-1976; Consultant 1976-1978
1967 - 1969	Vaccine Development Committee, National Institute of Allergy and Infectious Diseases, National Institutes of Health
1967 - 1968	Expert Advisory Committee on Standards for Live Mumps Virus Vaccine, Division of Biologics Standards, National Institutes of Health
1967 - 1970	Advisory Committee on Fundamental Research, National Multiple Sclerosis Society

Samuel L. Katz, M.D.

1968 - 1973	Consultant, Infectious Diseases Branch, Collaborative and Field Research, National Institute of Neurological Diseases and Stroke, National Institutes of Health
1968 - 1970	Scientific Advisory Committee on Standards for Live Rubella Virus Vaccines, Division of Biologics Standards, National Institutes of Health
1968 - 1990	National Scientific Advisory Council, National Jewish Center for Immunology and Respiratory Medicine, Denver, Colorado
1969 - 1971	Infectious Disease Committee, National Institute of Allergy and Infectious Diseases, National Institutes of Health
1969 - 1972	Commission on Immunization, Armed Forces Epidemiological Board, Associate Member
1970 - 1973	Councillor, Harvard Medical Alumni Association
1970 - 1974	Advisory Committee on Faculty Fellowships, Josiah Macy, Jr. Foundation
1971 - 1974	General Research Centers Committee, Division of Research Resources, National Institutes of Health
1971 - 1974 1979 - 1981	Executive Committee, Association of Medical School Pediatric Department Chairmen
1971 - 1974	Advisory Committee on Fellowships, National Multiple Sclerosis Society
1972 - 1981	Consultant, Biologics Review Steering Committee, Bureau of Biologics, Food and Drug Administration
1974 - 1976	National Advisory Child Health and Human Development Council, National Institutes of Health
1977 - 1979	President - Association of Medical School Pediatric Department Chairmen

Samuel L. Katz, M.D.

1977 - 1985	Scientific Advisory Board, St. Jude's Children's Research Hospital
1980 - 1990	Board of Directors, National Foundation for Infectious Diseases
1982 - 1986	Immunology and Microbiology Research Study Committee, American Heart Association
1982 - 1985	Chairman, Committee on Issues and Priorities for New Vaccine Development, Institute of Medicine, National Academy of Sciences
1982 - 1991	Advisory Committee, Robert Wood Johnson Foundation Clinical Nurse Scholars Program
1982 - 1986	Awards Committee for Mead Johnson Pediatric Research of the American Academy of Pediatrics (Chairman, 1985-1986)
1982 - 1993	Advisory Committee on Immunization Practices, USPHS, Centers for Disease Control (Chairman, 1985 - 1993)
1984 - 1990	Consultative Board, James N. Gamble Institute of Medical Research
1985 - 1993	Coordinator, Advisory Expert Panel on Infectious Diseases in Infancy and Childhood, International Pediatric Association
1985 - 1986	Vice-President (President-elect), American Pediatric Society
1985 -	Public Policy Committee, Infectious Diseases Society of America (Chairman 1990 - 1992)
1986 - 1987	President, American Pediatric Society
1986 - 1987	Consultant, National Institutes of Health, AIDS Executive Committee
1987 - 1993	Board of Directors, Georgetown University
1988 - 1989	North Carolina State Vaccine Study Commission

Samuel L. Katz, M.D.

1988 - 1993	Member, Scientific Advisory Committee, Children's Hospital Research Foundation, Cincinnati
1988 -	Board member, Hasbro Children's Foundation
1988 - 1991	Burroughs Wellcome Fund, Wellcome Research Travel Grants Advisory Committee
1989 - 1993	American Academy of Pediatrics, Subcommittee on Human Rights
1990 -	Member, Handicapped Housing Corporation of Durham (AIDS apartments) Board
1990 - 1993	Board of Trustees, Children's Miracle Network Telethon
1990 -	Medical Advisory Board, Group B Strep Association
1990 - 1993	Secretary, Harvard Medical Alumni Council
1990	Chair, World Health Organization Panel on Diagnosis of Pediatric AIDS
1991 - 1992	Chair, World Health Organization panels on measles vaccines
1991 -	Member, Lenox Baker Children's Hospital Foundation Board
1991 -	Member, Children's Hospital (Boston) Scientific Advisory Committee
1991 -	Burroughs Wellcome Fund, Board of Directors, Chairman (1995-)
1992 - 1994	Chairman, Committee on Investment Strategy for Measles Control, Children's Vaccine Initiative
1992 -	Member, Standing Committee, International Pediatric Association
1992 -	National Advisory Committee, Americans for Medical Progress

Samuel L. Katz, M.D.

1993 - 1996	Scientific Advisory Committee, Pediatric AIDS Foundation
1993 - 1995	Pediatric Scientist Development Program, Steering Committee and Evaluation Committee
1994 -	Pediatric Executive Committee, NIAID, AIDS Clinical Trials Group
1994 -	Policy Board, Albert B. Sabin Vaccine Foundation
1994 - 1995	National Research Council - Institute of Medicine Committee on the Impact of War on Child Health in the Countries of the Former Yugoslavia
1994 - 1995	Institute of Medicine Steering Committee on the Children's Vaccine Initiative
1995 - 1996	Institute of Medicine Committee on Priorities for Vaccine Development

Editorial Boards (past and present)

Annual Review in Medicine
Postgraduate Medicine
Reviews of Infectious Diseases
Pediatrics Clinical Digest Series
Current Problems in Pediatrics
Ped Sat (TV Education)
Pediatric Annals (Associate Editor)
Report on Pediatric Infectious Diseases

Reviewer

Pediatrics
New England Journal of Medicine
Journal of Infectious Diseases
Reviews of Infectious Diseases
Journal of the American Medical Association
American Journal of Public Health
Clinical Pediatrics
Annals of Internal Medicine
Journal of Pediatrics
Pediatric Infectious Disease Journal
Epidemiological Reviews
North Carolina Medical Journal
AMA Journal of Diseases of Children

Samuel L. Katz, M.D.

Clinical Infectious Diseases
Pediatric Research
Yearbook of Pediatrics
Infection and Immunity
Vaccine

Selected List of Visiting Professorships and Lectureships

Special Lecturer of Southern Medical Association, University of Texas Medical School, San Antonio, 1970

Physician-in-Chief pro tempore, Rhode Island Hospital, Brown University Medical School, 1971

Harold Jacobziner Lecturer, New York University School of Medicine, 1973

Queen Elizabeth II Lecturer, Canadian Pediatric Society, 1974

A. Ashley Weech Visiting Professor, University of Cincinnati Medical School, 1975

Convocation Lecturer, University of Missouri Medical School, 1975

Samuel Lilienthal Visiting Chief of Pediatrics, Mt. Zion Hospital
Medical Center, San Francisco, 1975

Aaron Brown Lecturer, Baylor College of Medicine, 1976

Visiting Professor pro tempore, Cleveland Clinic Educational Foundation, 1977

R. Cannon Eley Memorial Lecturer, Children's Hospital Medical Center, Harvard Medical School, 1977

Visiting Professor, University of Massachusetts Medical School, 1978

Adam Thorpe Memorial Lecturer, University of North Carolina Medical School, 1978

Salerni Collegium Visiting Professor, University of Southern California School of Medicine, 1979

Stacy White Lecturer, Emory University School of Medicine, 1979

M. Hines Roberts Memorial Lecturer, Emory University School of Medicine, 1981

Carl C. Fischer Lecturer, Philadelphia Pediatric Society, 1981

Herman M. Biggs Lecturer, New York Academy of Medicine, 1981

Samuel L. Katz, M.D.

Centennial Lecturer, University of Illinois Abraham Lincoln School of Medicine, 1981

Lori Haker Memorial Lecturer, Milwaukee Children's Hospital, 1982

C. Henry Kempe Visiting Professor, University of Colorado School of Medicine, 1983

Luis Guerrero Memorial Lecturer, University of Santo Tomas Faculty of Medicine and Surgery, 1983

Warren Wheeler Visiting Professor, Ohio State University School of Medicine, Columbus Children's Hospital, 1984

Anne Yeager Memorial Lecture, California Chapter-American Academy of Pediatrics, 1985

Arthur E. McElfresh Lecture, St. Louis University, 1985

Upjohn Visiting Professor, Oxford University & John Radcliffe Hospital, 1986

Saul Blatman Memorial Lecture, Beth Israel Hospital, Mt. Sinai Medical School, 1986

Culpeper Foundation Visiting Professor, Howard University, 1986

Robert L. Moore Lecture, University of Texas Southwestern Medical School, 1986

Lewis F. Cosby Pediatric Lecture, East Tennessee State University Medical School, 1987

Professor John D. Crawford Lecture, Massachusetts General Hospital, 1987

Visiting Professor and Renata Ma. Guerrero Memorial Lecturer, University of Santo Tomas Faculty of Medicine and Surgery, 1987

Edmund R. McCluskey Memorial Lecture, Children's Hospital of Pittsburgh and University of Pittsburgh School of Medicine, 1987

Alpha Omega Alpha Lecture, University of Pittsburgh School of Medicine, 1988

Herman Rosenblum Lecture, Medical Center of Delaware, 1988

Milton Markowitz Visiting Professor, University of Connecticut Medical School, 1988

John I. Perlstein Lecture, University of Louisville School of Medicine, 1988

Stubenbord Visiting Professor, New York Hospital-Cornell Medical Center, 1988

Warren Wheeler Lecture, University of Kentucky Medical School, 1989

Samuel L. Katz, M.D.

Alpha Omega Alpha Visiting Professor, Ohio State University School of Medicine, 1989

Sir McFarlane Burnet Lecturer, Australasian Society for Infectious Diseases, Auckland, New Zealand, 1989

Marshall Kreidberg Lecture, Tufts University Medical School, 1989

Jeffrey O'Brien Lecture, Toronto Hospital for Sick Children, 1989

Phyllis Lewander Memorial Lecture, National Children's Medical Center, 1990

Bilderback Lecture, Oregon Health Sciences University, 1990

Lowell A. Glasgow Visiting Professor, University of Utah Health Sciences Center, 1991

Ben Kagan Lectureship, Cedars-Sinai Medical Center, Los Angeles, 1991

Erwin Neter Memorial Lecture, Buffalo Children's Hospital, 1991

Brennemann Memorial Lectures, Los Angeles Pediatric Society, 1991

Douglas Reye Memorial Lecture, Royal Alexandra Children's Hospital, Sydney Australia, 1991

Maurice Hilleman Lecture, Children's Hospital, University of Pennsylvania, 1991

Matthew R. Nuckols Distinguished Visiting Professor, East Virginia Medical School and King's Daughter's Hospital, 1992

Kenneth D. Blackfan Lecture, Children's Hospital, Boston, 1992

Carolyn and Maxwell Stillerman Lecture, North Shore University Hospital - Cornell Medical School, 1992

House Staff Visiting Professor, University of Florida Medical School, 1993

House Staff Visiting Professor, Boston Floating Hospital, Tufts University Medical School, 1993

Arnold H. Einhorn Lecturer, Children's National Medical Center, Washington, DC 1993

Lewis Wannamaker Lecturer, University of Minnesota Medical School, Minneapolis, 1993

John H. Erskine Lecture in Infectious Diseases, St. Jude's Children's Research Hospital, Memphis, 1994

Samuel L. Katz, M.D.

Alpha Omega Alpha Lecture, University of New Mexico Medical School, 1995

Phi Beta Kappa Lecture, Troy State University, 1995

Donal Dunphy Lecture, Moses H. Cone Memorial Hospital, 1995

Hattie Alexander Memorial Lecture (with Catherine M. Wilfert, M.D.), Columbia University, College of Physicians & Surgeons, 1995

Jimmy L. Simon, M.D. Distinguished Lecture, Bowman Gray School of Medicine, 1995

Harris D. Riley, Jr., M.D. Pediatric Society Lecture, Oklahoma Children's Hospital, 1995

Robert Ward Memorial Lecture, Los Angeles Children's Hospital, 1996

Published Articles

Katz, S.L., Milovanovic, M.V. and Enders, J.F.: Propagation of measles virus in cultures of chick embryo cells. Proc. Soc. Exp. Biol. & Med. 97:23, 1958

Katz, S.L., Medearis, D.N., Jr., and Enders, J.F.: Experiences with live attenuated measles virus. Amer. J. Dis. Child. 96:430, 1958

Katz, S.L.: Laboratory techniques for diagnostic virology. Mass. J. Med. Technology I:10, 1959

Katz, S.L. and Enders, J.F.: Immunization of children with a live attenuated measles virus. Amer. J. Dis. Child. 98:605, 1959

Enders, J.F., Katz, S.L., Milovanovic, M.B. and Holloway, A.: Studies on an attenuated measles-virus vaccine. I. Development and preparation of the vaccine. Technics for assay of effects of vaccination. New Eng. J. Med. 263:153, 1960

Katz, S.L., Enders, J.F., and Holloway, A.: Studies on an attenuated measles-virus vaccine in institutionalized children. New Eng. J. Med. 263:159, 1960

Haggerty, R.J., Meyer, R.J., Lenihan, E., and Katz, S.L.: Studies on an attenuated measles-virus vaccine. VII. Clinical, antigenic and prophylactic effects of vaccine in home-dwelling children. New Eng. J. Med. 263:178, 1960

Katz, S.L., Kempe, C.H., Black, F.L., Lepow, M.L., Krugman, S., Haggerty, R.J. and Enders, J.F.: Studies on an attenuated measles-virus vaccine. VIII. General summary and evaluation of the results of vaccination. New Eng. J. Med. 263:180, 1960

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Samuel L. Katz, M.D.

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Katz SL. Children unprotected: a U S emergency. Medical and Health Annual 1994, p. 34-36, Encyclopedia Britannica, Chicago, 1993.

Markowitz L, Katz SL. Measles vaccine. Chapter 9 in "Vaccines" edited by Plotkin SA, Mortimer EA Jr., 2nd edition, WB Saunders Co., Philadelphia, 1994.

Katz SL. Immunization for HIV-infected children. pp 859-867 Chapter 46 in "Pediatric AIDS" edit by PA Pizzo, CM Wilfert, 2nd edition, Williams & Wilkins, Baltimore, 1994.

Gellin BG, Katz SL. Editors. Measles Control: Resetting the Agenda. J Infect Dis 1994; 170:Supplement, 66 pages.

Katz SL, Ogra PL, Editors. Strategies for pediatric vaccines: Conventional and molecular approaches. Report of the 104th Ross Conference on Pediatric Research, Columbus, Ohio, 1994.

Palfrey J, Schulman I, Katz SL, New MI, Editors. The Disney Encyclopedia of Baby and Child Care, Hyperion Press, New York, Vols. 1 and 2, 1995.

Katz SL, Measles, in Rudoph's "Pediatrics", edited by Rudoph AM, Hoffman JE, Rudolph CD. 20th edition, Appleton & Lange, Stanford, CT, 1996.

Update: 4/4/96

CURRICULUM VITAE

April, 1997

ROBERT W. BLOCK, M.D., FAAP

Home Address: 256 East 27th St.
Tulsa, OK 74114

Office Address: Professor and Chair
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The University of Oklahoma College of Medicine-Tulsa
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Tulsa, OK 74129-1045

Office Phone: 918-838-4726

Office Fax: 918-838-4729

Date of Birth: April 21, 1943

Place of Birth: Cedar Rapids, Iowa

Marital Status: Married: Sharon A. Block, R.N.
Children: Erika, 6-17-79, Andrea, 5-13-82

Education:

1967-1969	M.D.	University of Pennsylvania, School of Medicine
1965-1967	B.S.	University of South Dakota School of Medicine

Postgraduate Training:

1983-1984	Sabbatical: Adolescent Behavior, Tulsa, OK
1970-1972	Residency: Pediatrics, Children's Hospital of Philadelphia
1971-1972	Assistant Chief Resident, Pediatrics
1969-1970	Internship: Children's Hospital of Philadelphia, Straight Pediatrics

Military Service:

1972-1975	Major, MC, U.S. Army; Chief, Department of Pediatrics, and Chief, Department of Clinics at Munson Army Hospital, Ft. Leavenworth, Kansas

Faculty Appointments:

1996-	Chair, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1985-	Professor, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1975-1996	Vice-Chairman, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1978-1985	Associate Professor, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1975-1978	Assistant Professor, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1980	Tenure awarded

Hospital and Administrative Appointments:

76-79 & 83-86	Medical Director, Pediatric Clinic, The University of Oklahoma College of Medicine-Tulsa
76 to 83	Director, Division of Ambulatory Pediatrics
77-80, & 84	Outpatient Medical Director, At-Risk Parent-Child Program
78 to 92	Pediatric Consultant, Tulsa Child Development and Regional Guidance Center
1978-	Pediatric Consultant, Tulsa County Health Department Child Health Clinics
79 to 84	Director, Division of Adolescent Medicine, The University of Oklahoma College of Medicine-Tulsa
1981-	Director, Pediatric Residency Program, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
83 to 90	Medical Director, Adolescent Chemical Dependency Treatment Center, Hillcrest Medical Center

Faculty Appointments:

1996-	Chair, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1985-	Professor, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1975-1996	Vice-Chairman, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1978-1985	Associate Professor, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1975-1978	Assistant Professor, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
1980	Tenure awarded

Hospital and Administrative Appointments:

76-79 & 83-86	Medical Director, Pediatric Clinic, The University of Oklahoma College of Medicine-Tulsa
76 to 83	Director, Division of Ambulatory Pediatrics
77-80, & 84	Outpatient Medical Director, At-Risk Parent-Child Program
78 to 92	Pediatric Consultant, Tulsa Child Development and Regional Guidance Center
1978-	Pediatric Consultant, Tulsa County Health Department Child Health Clinics
79 to 84	Director, Division of Adolescent Medicine, The University of Oklahoma College of Medicine-Tulsa
1981-	Director, Pediatric Residency Program, Department of Pediatrics, The University of Oklahoma College of Medicine-Tulsa
83 to 90	Medical Director, Adolescent Chemical Dependency Treatment Center, Hillcrest Medical Center

1990-	The state of Oklahoma Chief Child Abuse Examiner
1992-1997	Medical Director, Justice Center

Specialty Certification:

1974-	American Board of Pediatrics
81 & 88	Recertification, ABP

Licensure:

1975-	Oklahoma
1972-	Iowa

Awards, Honors:

1977, 1996	Aesculapian Award for excellence in teaching, Nominee
1978, '81, '82	Aesculapian Award for excellence in teaching, Winner
1990	Nominated for recognition from the United States Department of Justice for work with child victims of crime
1990	Nominated from Oklahoma State Medical Association for AMA Adolescent Health Congress Award
1991	Oklahoma Institute for Child Advocacy - Professional Individual Award
1991	Oklahoma Chapter, NAPNAP - Excellence Award
1993	American Academy of Pediatrics - Citation Award
1998	Stanton L. Young Master Teaching Award

Memberships in Professional and Honorary Societies:

1974-	Fellow, American Academy of Pediatrics -Member, Section of Community Pediatrics -Member, Section on Adolescent Health -Member, Section on Child Abuse

1981-1994	Member, American Public Health Association

1981-1994	Member, American Public Health Association
1983-	Member, Society for Behavioral Pediatrics
1984-1994	Member, Society for Adolescent Medicine
1985-	Member, Association of Pediatric Program Directors
1987-1994	Member, International Academy for Research in Learning Disabilities
1987-1994	Member, William's Syndrome Association Professional Advisory Board
1990-1993	President-Elect, Oklahoma Chapter, American Academy of Pediatrics
1993-1996	President, Oklahoma Chapter, American Academy of Pediatrics
1990-	Member, American Professional Society on the Abuse of Children
1996-	Member, AMSPDC: Association of Medical School Pediatric Department Chairmen

Editorial Boards:

1996-	*Southern Medical Journal*. J. Graham Smith, editor. 1995.

National Advisory Committees and/or Activities:

1977	Chairman, Oklahoma Chapter AAP, Committee on CME and Recertification
1978, 1979	Consultant, Oklahoma Health Systems Agency Task Force on Facilities and Services
1988-	Chairman, Oklahoma Chapter AAP, Committee on Child Abuse
1988-1990	Governor's Appointment: Study Commission on Child Abuse, Task Force, Chair
1990-	Chief Child Abuse Examiner, State of Oklahoma Board of Child Abuse Examination
1996-	Member, American Academy of Pediatrics Committee on Child Abuse & Neglect (COCAN)

Community Advisory Committees and/or Activities:

1972-1975	Medical Director, Handicapped Children's Swimming Program, Ft. Leavenworth
1972-1975	Board Member and Treasurer, Leavenworth County Association for the Handicapped
1972-1975	Advisor, Medical Explorer Post 2466, Munson Army Hospital
1975-1986	Volunteer, Neighbor-for-Neighbor Free Medical Clinic
1976-1995	Member, Advisory Council, Oklahoma Learning Disabilities Association
1977-1984	Member, Board of Directors, Rainbow House Nursery and Family Counseling Program
1977-1986	Member, Board of Director, Town and Country School for Learning Disabled Children, (*Chairman* 1977-1980)
1977-1979	Member, Task Force on Child Development - The Governor's Committee on Children and Youth
1977-1979	Chairman, Greater Tulsa Area Council on Learning Disabilities
1979-1993	President (1979-1983) and Member, Board of Directors, The Margaret Hudson Program for Teenage Parents
1979-1982	Member, Advisory Council, Tulsa Association for Children with Learning Disabilities
1980, 81, 82	Member, Tulsa Area United Way Budget Panel
1980-1984	Member, Governor's Advisory Committee on Children, Youth and Families
1984-1990	Member, Advisory Board, Parents Anonymous
1986-1987	Member, Oklahoma Committee for Prevention of Child Abuse
1986-1990	Member, Board of Directors, At Risk Parent-Child Program, Inc.
1989-	Member, Board of Directors, Child Abuse Network
1990-1992	Member, Board of Directors, Developing Capable People, Inc.
1990-1993	Member, Medical Advisory Committee, Parent Child Center of Tulsa, Inc.

1991-	Member, Advisory Board, Jr. League of Tulsa, Inc.
1996-	Member, Council on Medical Education, Tulsa County Medical Society

Research Grants, Contracts, Awards:

1978-1981	DHEW, PHS, Bureau of Health Manpower, #1- D28-PE-16014-01. Funded. Residency Training in General Internal Medicine and Pediatrics. 3 years. $842,400, Funded.
1978-1979	DHEW, Office of Human Development At-Risk Parent-Child Program (Co-author) 3 years, 1st yr. $119,500. Funded.
1980/1981	DHEW, Office of Adolescent Pregnancy Programs. "Adolescent Pregnancy Prevention and Services." $250,000 1st year. Funded.
1986	DHS, PHS, Health Resources and Services Administration, #1-D28PE-56004-01. Faculty Development in General Pediatrics. Approved but not funded.
1986	Oklahoma DHS, Project ENTRY, $150,000. **Re-funded $150,000, Annually 1987.
1991	Oklahoma Commission on Children and Youth, Child Abuse Examiner, $40,000, Annually 1992. **Re-funded $40,000. 1992-
1991	Department of Human Services, Oklahoma Governor's Advisory Committee on Child Abuse, Training Child Abuse Medical Examiners. Varying amounts. **Re-funded - 1992-1995**
1996	OCCY, State Appropriation, Training (etc.) $15,000 Annually. **Re-funded – 1997-

Invited Lectures, Workshops, Site Visits:

Presentations, Regional, State, National, International:

7/97	To be updated
4/30/79	"Outreach Education: A Possible Preventer of Teenage Pregnancy," at the APA National Meeting
5/1/79	"At-Risk Program" Workshop presentation at the APA National Meeting

5/10/79	"Attention Deficit Disorders" at the Rogers County, Arkansas, Medical Meeting arranged by ACLD and CIBA Medical Horizons. Also: Parent talk at same ACLD meeting
6/4/79	"Teenage Pregnancy," Paper and Workshop Presentation at the ACCH International Meeting
1/81	Visiting Professor, Guadalajara, Mexico
6/8/81	"Learning Disabilities" talk at Family Practice Medical Society, Tahlequah, OK
1982	Program Speaker, Midwestern States Family Practice Program, Hawaii
5/28/82	"Adolescent Seminar" at Department of Pediatrics, Lubbock, Texas
9/24/82	"School Health" at AAP Workshop, Austin, Texas
4/3-4/85	Visiting Professor, The University of Oklahoma Health Sciences Center, Oklahoma City, OK
8/1-2/85	Visiting Professor, University of Nebraska
4/8/88	"Adolescent Medicine Behavioral Issues" at Southern Medical Association regional meeting, Tulsa, OK
9/16/88	Sexual Abuse Workshop and Mock Trial at Training Meeting, Oklahoma City, OK
9/29/88	"Attention Deficit Disorder - Pediatric Grand Rounds, University of Oklahoma Health Sciences Center, Oklahoma City, OK

Invited Faculty Presentations

(7/97 To be updated) Fall 1995	Southern Medical Association Annual Scientific Assembly, Kansas City, Missouri.
Summer 1995	The Pediatric Patient, Southern Medical Association, Sea Island, Georgia.
Fall 1994	Southern Medical Association Annual Scientific Assembly, Orlando, Florida.
Summer 1994	The Pediatric Patient, Southern Medical Association, Sea Island, Georgia.

Summer 1994	3rd Annual Pediatric Emergency Medicine Review Conference, Las Vegas, Nevada.
Summer 1994	Driscoll Children's Hospital Pediatric Reunion Meeting, Corpus Christi, Texas.
Spring 1994	National Children's Advocacy Center Annual Symposium, Huntsville, Alabama.
Fall 1993	American Academy of Pediatrics Annual Meeting, Washington, D.C.
Fall 1993	Southern Medical Association Annual Scientific Assembly, New Orleans, Louisiana.
Summer 1993	2nd Annual Pediatric Emergency Medicine Review Conference, Las Vegas, Nevada.
Summer 1993	The Pediatric Patient, Southern Medical Association, San Destin, Florida.
Summer 1992	The Pediatric Patient, Southern Medical Association, The Homestead, Virginia.
Summer 1991	The Pediatric Patient, Southern Medical Association, Hilton Head, South Carolina.

Invited Grand Rounds Presentations

University of Oklahoma Health Science Center, Tulsa Campus.
University of Oklahoma Health Science Center, Oklahoma City Campus.
Louisiana State University School of Medicine, New Orleans, Louisiana.
Medical City Hospital Department of Pediatrics, Dallas, Texas.

Local Grand Rounds & Rounds:

7/97	To be updated
5/11/76	"Complement and the Clinician" at Pediatric Grand Rounds
8/10/76	"Pertussis - An Outbreak and a Fatality" at Pediatric Grand Rounds
4/26/77	"The Problem of Rabies, 1977" at Pediatric Grand Rounds
9/13/77	"Biochemical Aspects of Learning Disorders" at Pediatric Grand Rounds
7/11/78	"The Handicapped Child in the School System" at Pediatric Grand Rounds

5/22/79	"Preventing Teenage Pregnancy" at Pediatric Grand Rounds
2/12/80	"The Chiropractor, The Child and The Pediatrician" at Pediatric Grand Rounds
3/13/80	"Adolescent Sexuality" at OB/GYN Grand Rounds
2/24/81	"Discipline" at Pediatric Grand Rounds
10/27/81	"Childhood Vice in Tulsa" at Pediatric Grand Rounds
12/8/81	"Attention Deficit Disorders" at Pediatric Grand Rounds
2/17/83	"Teenage Parents and Their Children," OB/GYN Grand Rounds
4/26/83	"L.D./A.D.D. in Adolescence," Pediatric Grand Rounds
6/28/83	"The Hurried Child - Child Development and the School System," Pediatric Grand Rounds
4/24/84	"Adolescent Chemical Dependency I" at Pediatric Grand Rounds
5/22/84	"Adolescent Chemical Dependency II" at Pediatric Grand Rounds
12/11/84	"Managing Drug Withdrawal" at Pediatric Grand Rounds
4/10/90	"Teen Music" at Pediatric Grand Rounds
6/26/90	"Physical Findings in Sexual Abuse" at Pediatric Grand Rounds
11/19/85	"William's Syndrome" at Pediatric Grand Rounds
9/23/86	"PCP Poisoning" at Rounds
9/22/87	"Sexual Abuse" at Pediatric Grand Rounds
5/10/88	"Reports from the Annual Meetings" at Pediatric Grand Rounds
9/13/88	"Attention Deficit Disorder - Controversies" at Pediatric Grand Rounds
10/18/88	"Familying," Etiologies of the "New Morbidity" at Pediatric Grand Rounds
7/25/89	"New Information about Chemical Dependency in Pediatric Patients" at Pediatric Grand Rounds
1/23/90	The Oklahoma Child Abuse Study Commission Report- Comments and Discussion, at Pediatric Grand Rounds

Other Local Presentations:

1/17/75	"Emergency Immunizations" at the AMA Continuing Medical Education Program, Tulsa
10/2/75	"A Pediatric Approach to Learning Disorders" at the Annual Tulsa Pediatric Colloquy
10/76	"A Double-blind, Crossover analysis of the K-P Diet for Hyperactivity" at the Annual Tulsa Pediatric Colloquy
10/13/78	"The Clinical Consequences of Complement" at the Annual Tulsa Pediatric Colloquy
1/27/79	"Recent Advances in Pediatric Antibiotic Use" at the Family Medicine CME Conference IV
1/27/79	"An Update on Learning Disorders" at the Family Medicine CME Conference IV
3/16/79	"Drug Use and Abuse - Diagnosing and Rx the O.D." at Pediatric CPC
3/23/79	"Treatment: Fact or Fancy" at the Regional Seminar, "MBD: Concepts and Controversies"
3/27/80	"School Problems" at the Oklahoma Academy of Family Physicians, Tulsa, OK
5/15/80	"Implications of Teen Pregnancy" at Seminar, "Birth Defects and Problems in Clinical Genetics," Tulsa, OK
11/6/81	"Feingold Diet" at Children's Medical Center Study Group
7/15/82	"Teenage Pregnancy" at Perinatal Conference, St. Francis Hospital, Tulsa, OK
3/16/83	"CPC: Prader-Willi Syndrome," HMC Pathology CPC
9/28/85	Adolescent Chemical Dependency Workshop at Adolescent Medicine and Ambulatory Pediatric Tulsa, OK

Medical College Committees:

1990	Member, College of Medicine Promotion and Tenure Committee, Chair
1978 & 1991	Chairman, Tulsa Medical College Search Committee, Dean Position

Medical College Teaching:

1975- The University of Oklahoma College of Medicine - Tulsa, Oklahoma:

1. MSIII Clerkship
   a. Lectures
   b. Students Rounds/Case presentation discussions
   c. Oral Examinations

2. MSIV Ambulatory Rotation
   a. Ambulatory clinic attending
   b. Family support clinic attending

3. Resident Ambulatory Rotation & Continuity Clinics

4. Resident Adolescent Behavioral Health Care Program

BIBLIOGRAPHY

ORIGINAL PAPERS

1. **Block, R.W.**, A Guide for the Management of Drug Abuse. *Advances in Pediatrics*, Vol. 19, 1972. Irving Schulman, Ed.2.

2. **Block, R.W.**, A Pediatric Approach to Learning Disabilities. *J. Okla. St. Med. Assoc.* 69:121-124, 1976.

3. **Block, R.W.**, and Block, S., Outreach Education: A Possible Preventer of Teenage Pregnancy. Abstract. Ambulatory Pediatric Association, Program and Abstracts, p. 25, 1979.2.

4. **Block, R.W.**, and Block, S., Outreach Education: A Possible Preventer of Teenage Pregnancy. *Adolescence, SV* (59):657, 1980.

5. **Block, R.W.**, Block, S., and Saltzman, S., Teenage Pregnancy, *Advances in Pediatrics*, Vol. 28, p. 75-98, 1981.

6. **Block, R.W.**, Chiropractic and Child Care, *Clinical Pediatrics*, Vol. 20, No. 5, p. 362-363.

7. **Block, R.W.**, Intimacy before responsibility: Teenage Parents, *J. Calif. Perinatal Ass'n.* III (1):39-41, 1983

8. **Block, R.W.**, and Miller, E., The Maladroit Adolescent: Learning Disorders and Attention Deficits, *Advances in Pediatrics*, Vol. 33, 1986.

9. **Block, R.W.**, Inpatient treatment for chemically dependent adolescents, *AAP Adol. Health*, 8(2):12-16, 1987.

10. Gibson, G.L., **Block, R.W.**, Child Abuse: A Time for New Awareness, *J. OK. State Med. Assoc.*, 83(4):169-171, 1990.

11. **Block, R.W.**, Confer, D., "Adolescent Drug and Alcohol Abuse: A Time For Physician Response" *J. OK. State Med. Assoc.*, 83(10): 487-488, Oct., 1990.

12. **Block, R.W.**, Gibson, G. Child abuse: Pediatricians' comments on family law. *OK Fam Law J*, 8:137-139, 1993.

13. Block, R. W., Medication for Attention Deficit Hyperactivity Disorder: Balancing Art & Science, South. Med. J., 89 (1): 95, 1996.

14. **Block, Robert**. Rewards and Challenges of Opening a Children's Advocacy Center, *APSAC Advisor*, 11(2): 13, 1998.

1. **Block, R.W.**, and Plunket, D.C., Pediatrics, Chapter in *Women's Health Care in Obstetrics and Gynecology*, Williams and Wilkins, 1990.

2. **Block, R.W.** 'Substance Abuse', in "Be Nice ... But Firm". *Guildcraft*, 1992.

3. **Block, R.W.**, "Chemical Dependency in the Adolescent," in, *Behavioral Pediatrics*, Springer-Verlag, 1992.

4. **Block, R.W.**, Gibson, G. "Child Abuse" in *Synopsis of Pediatric Emergency Care*, Andover, 1993.

5. **Block, R.W.**, Gibson, G. "Sexual Abuse" in *Synopsis of Pediatric Emergency Care*, Andover, 1993.

BOOKS

Block, R.W., and Rash, F., *Handbook of Behavioral Pediatrics*, Yearbook Medical Publishers, Chicago, 1981.

MEDIA PUBLICATIONS

Block, R.W., Moretti, V., Kirk, S., and Peters, J. "Employing the Learning Disabled Adult," W. Hartman, Ed.D., Exec. Producer, National Symposium of Learning Disabilities, c1979 (Videotape) Syndrome Assoc. Prof. Advisory Board

Block, R.W., Co-editor, *Practical Reviews in Pediatrics*, audiotape produced by Educational Reviews, Inc., 1985-present.

ADELE E. YOUNG
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LICENSE

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Inactive
British Columbia, Canada License # 483504
Ontario, Canada License # 78-3756 0
New York License # 263980
Maryland License # R070347

CERTIFICATION

American Nurses Association Certification as a Pediatric Nurse Practitioner # 065759-06
January 1, 1985 - December 31, 1989
Renewed
January 1, 1990 - December 31, 1994
Renewed
January 1, 1995 - December 31, 1999

EDUCATION

University of Maryland School of Nursing Baltimore, Maryland	9/88 - 1/96	Doctor of Philosphy
University of Maryland School of Nursing Baltimore, Maryland	2/82 - 5/84	Masters of Science in Nursing, Pediatric Nurse Practitioner
Univesity of Pennsylvania School of Nursing Philadelphia, Pennsylvania	9/70 - 6/74	Bachelor of Science in Nursing

Kent School Kent, Connecticut	9/68 - 6/70	High School Diploma

PROFESSIONAL EXPERIENCE

Pratt Medical Ltd.	Part Time 6/97-	Nurse Practitioner
George Mason University	Part Time 9/96-	Instructor: Family Nurse Practitioner Program, Undergraduate course in communitee health
Germanna Community College	Part Time Spring 1996	Clinical Instructor
University of Maryland School of Medicine Division of Geographic Medicine Baltimore, Maryland	Full Time 5/86 - 9/88 Part Time 9/88 - 7/95	Pediatric Nurse Practitioner responsible for all phases of research trials, including protocol development, budget, data collection, data analysis, and physical assessment of children

VACCINE TRIAL PARTICIPAITON

8/93 - 7/95	Merck Sharp & Dohme Research Laboratories - Safety, Immunogenicity and Efficacy of a Live Quadrivalent Human - Bovine Rotavirus Reassortment Vaccine in Healthy Infants
4/93 - 7/95	Lederle - Praxis Laboratories - Trial of Safety and Immunogenicity of Two Models of Pentavalent Pneumococcal Conjugate Vaccine at Three Dose Levels in Infants
7/92 - 7/95	Lederle - Praxis Laboratories - Safety and Immunogenicity of Three Production Lots of Poliovirus Vaccine (Sabin - Inactivated, trivalent - LIPV) Compared to Commercially Available Inactivated Poliovirus Vaccine and Poliovirus Vaccine Live, Oral Treatment

	at 2 and 4 month dose and Booster dose at 12 - 15 months.	
9/91 - 10/92	National Institutes of Health - A Double - Blind Placebo - Controlled Safety and Immunogenicity Study of Acellular Pertussis Vaccines Combined with Diptheria and Tetanus Toxoids Compared to Whole Cell Pertussis Vaccine Combined with Diptheria and Tetanus Toxoids in 15 - 20 Month Old Infants	
4/90 - 10/91	National Institutes of Health - A Double - Blind Placebo - Controlled, Efficacy, Safety, and Immunogenicity, Study Comparing Three Doses of Oral Tetravalent Rhesus Rotavirus Vaccine ($4x10^5$ PFU/Dose) with Serotype 1 Reassortant Rhesus Rotavirus Vaccine ($4x10^5$ PFU/Dose) in Infants	
1988	A Safety & Immunogenicity Study of Oral Rhesus Rotavirus Vaccine (RRV serotype 3) in Healthy Adult and Infant Subjects.	
1986 - 88	Randomized Double - Blind, Placebo - Controlled Efficacy Trial of Oral Altenuated Rhesus Vaccine MMU 18006 in Young Children	
University of Maryland School of Nursing Baltimore, Maryland	Part - Time Spring 1993	Instructor, Junior Students in inpatient and outpatient clinical settings.
University of Maryland School of Nursing Baltimore, Maryland	1/89 - 5/92	Research Assistant, all phases of faculty research. Teaching Assistant, Research Course.
University of Maryland School of Nursing Baltimore, Maryland	8/84 - 5/86	Instructor, Junior and Senior Students in inpatient and outpatient clinical settings.

Sinai Hospital Baltimore, Maryland	Full Time 9/79 - 8/81 Part Time 11/81 - 12/83	Staff Nurse Intensive Care Nursery Responsible total care of critically ill infant
Lions Gate Hospital	9/78 - 6/79	Staff Nurse Special Care Nursery Total care of low birth weight infants less than 24 hours old.
New York Hospital Cornell Medical Center New York, New York	8/77 - 5/78	Charge Nurse - Evenings Pediatric Research Unit. Responsible for implementing research protocols for 8 -10 pediatric patients, and promoting normal growth and development during long-term hospitalization.
Addenbrooks Hospital Cambridge, England	1/76 - 5/77	Staff Nurse General and Intensive Care Pediatrics; responsible for total care of critically ill children, supervision of care of all patients on seventeen bed unit, including four ICU beds, supervision of second and third year nursing students.
New York Hospital Cornell Medical Center	8/74 - 9/75	Staff Nurse Intensive Care Nursery; responsible for total care of critically ill infants.

MEMBERSHIP IN PROFESSIONAL ORGANIZATIONS

Sigma Thata Tau, National Honor Society of Nurses Pi Chapter	1983-
National Association of Pediatric Nurse Associates and Practitioners	1986-
Virgina Council of Nurse Practitioners	1997-
National Organisation of Nurse Practitioner Faculty	1996-

PUBLICATIONS

Rennels, M.B., Losonsky, G. A., Young, A. E., Shindledecker, C.L., Kapikian, A.Z., & Levine, M.M. 1990. An efficacy trial of rhesus rotavirus vaccine in Maryland. American Journal of Diseases of Children, 144, (01), 601-604.

PERSONAL INFORMATION

Date of Birth 10-04-52
Married, three children
Social Security # 047-48-9811

References available upon request

Mr. BURTON. OK, now what about the third lawyer?

Mr. BALBIER. The third lawyer doesn't have to be of any specified affiliation.

Mr. BURTON. Could he be one that worked for a pharmaceutical company?

Mr. BALBIER. No, in my view, that would exclude him from being eligible.

Mr. BURTON. Well, I want to check on that too. I want the same on his as well. And, also the lawyer that represents the families, I want to find out if any of those lawyers had any connection whatsoever with any pharmaceutical companies in the past.

I would like to have that in detail, and if I don't get it, we will subpoena them. I am prepared to subpoena them, so you be sure to tell me that.

Now, what about the three civilians?

Mr. BALBIER. There are three members of the general public. Within that category——

Mr. BURTON. Do any of those have any connections with pharmaceutical companies?

Mr. BALBIER. I can't answer that question.

Mr. BURTON. Well, I want that too. I want to know if anybody that serves on this advisory panel—any of them—have any connection to pharmaceutical companies, have ever received any moneys from pharmaceutical companies, represented them in any way, and we are prepared to send subpoenas to any of them if we don't get complete backgrounds on them. OK?

I think I have talked long enough, Mr. Chairman.

Mr. MICA. Thank you, Mr. Chairman.

I have some questions, first, for Mr. Balbier. You have resolved 1,400 cases in which there has been compensation. Is that correct?

Mr. BALBIER. That sounds about right.

Mr. MICA. And over what period of time?

Mr. BALBIER. That is over the entire history of the program since it was first created.

Mr. MICA. Is that 1988, was it, or 1987? Are we talking about 140 cases a year?

Mr. BALBIER. There are about 100 or so claims filed, on average, each year, but the vast majority of claims filed were for years prior to the creation of the program. There was no statute of limitations.

Mr. MICA. Right now, there are about 100 cases filed per year?

Mr. BALBIER. Roughly. This year is an exception, of course, because——

Mr. MICA. Tell me about your budget.

Mr. BALBIER. Sure.

Mr. MICA. And you said this year you awarded how much in compensation?

Mr. BALBIER. So far this fiscal year, we have paid out $47.7 million for the——

Mr. MICA. That would be just through to August?

Mr. BALBIER. That would be through the end of August, and that is just for the pre-1988 program.

Mr. MICA. Your last complete year of awards, how much was that? That would be 1998?

Mr. BALBIER. A total of $135 million divided between the pre-1988 program and the post-1988 program—$79 million for the pre-1988 program and $56 million for the post-1988 program.

Mr. MICA. How big is your staff?

Mr. BALBIER. My staff is about 21 employees.

Mr. MICA. Twenty-one employees. Full-time. And your expenses in the last fiscal year that you have a complete record for, I guess that would be 1998?

Mr. BALBIER. That would be $3 million, and that includes not only the funding for our staff but also funding for all the expert witness testimony that is provided to the court as well.

Mr. MICA. So, $3 million and hundred and some million in awards—$135 million?

Mr. BALBIER. Yes, sir.

Mr. MICA. Have there been any dramatic changes in the size of staff or expenditures for administrative costs of late, the last couple of years?

Mr. BALBIER. No, sir. It has been $3 million since 1994.

Mr. MICA. Pretty much steady? How many of your staff are dedicated to analyzing the caseloads and outcomes?

Mr. BALBIER. We have physicians that work for the staff, and currently we have three full-time physicians on staff right now who review claims.

Mr. MICA. Are you seeking to add staff in the near future or do you have staffing requirements?

Mr. BALBIER. No, we are not seeking to add new staff.

Mr. MICA. And how do you determine the amount the medical reviewers are paid?

Mr. BALBIER. It is really set by the standards used Government-wide for physicians.

Mr. MICA. There has been—there was testimony earlier about the change in table eligibility as the result of changes in table. What is the difference in caseload before and after—was it 1994 or 1995—1995, March 1995 table changes? Was there a substantial change in the number of cases before and after?

Mr. BALBIER. There really isn't; no, sir. The number of claims filed in fiscal year 1994, which was the year before the table change——

Mr. MICA. And how many was there?

Mr. BALBIER [continuing]. Was 106. The number of claims filed during 1995 did increase to 179, and 75 of those claims were claims that were filed for the period of time between when we published the final rule amending the table and the 30 days later when it went into effect. So, we received a number of claims that were filed clearly to get within the guidelines under the original table. And, so the claims went down the following year to 84 and then picked back up to a level of 103 the year after.

Mr. MICA. Now, you cited a couple of reviews of this whole process that have been done, and I guess there is one ongoing. I guess the Senate has requested a review also. And you say for the most part most folks who have had to deal with the fund are satisfied. You heard dissatisfaction about the length of time, particularly one case that was brought to our attention—the Mulhauser case—which took some 6 plus years.

I think that you are one of the two witnesses that testified that some of the delay was due to the victim as opposed to the Department. How do you respond to the charges from the victim that the delay is due to the Department?

Mr. BALBIER. One of the difficulties I think that we have in the damages process, which as I understood her testimony, the part of the process that she said took a rather lengthy time, is that from the petitioner's standpoint and from their attorneys who represent them, their job is to get as much money for their client as they possibly can.

On the Government side, we have a different task. Our task is not to limit compensation to pay out as little as possible. Under normal litigation, that would be the role of anybody who is sued in any sort of a lawsuit, but that is not our role. Instead, our role is to try to provide a reasonable level of care for the vaccine-related injuries.

I think that is perhaps the reason for the problem. Not only do we have to develop a life care plan that meets the requirement of the statute, and that provides for all the various elements of compensation in the statute, but we also have to try to figure out which items of care are related to the vaccine injury and only pay for those injuries.

Mr. MICA. Well, it sounds like a lot of—there was a great deal of dispute, at least in this case, about small ticket items as opposed to the larger picture and also giving sort of benefit of the doubt to the petitioner.

Is there any way that we can speed this process up or make it less contentious and adversarial?

Mr. BALBIER. There is. We have been looking at this, and our Advisory Commission has been looking at this issue to try to speed up the whole process.

Mr. MICA. Does that mean a statutory change?

Mr. BALBIER. Yes, it does, although we have done a number of things administratively to try to speed up the process as much as we can.

However, I think to view the litigative process—and it is a litigative process—with only an eye toward speeding up the process, could create some problems that we may not want to create. In other words, we could have a speedy process, but then people's rights would not be protected.

Another difficulty, quite frankly, is the time it takes to negotiate damages on a claim—and that is done by the Department of Justice trial attorneys—they have to develop a life care plan that will meet the needs of that child for the rest of their life. Oftentimes it is in the interest of the petitioner to delay that so that they can see how the child develops. That is done as part of their strategy.

So, yes, we could make a quicker process, and there are many ways that you heard earlier individuals testify that could make it quicker, but in so doing I think we have to be very careful so that we don't sacrifice the rights of people to get what they truly deserve under the program.

Mr. MICA. Mr. Burton.

Mr. BURTON. I find that interesting when we have deadlines. My two grandchildren, we had to file—we found out the week before

the deadline that they had to file. And if we had gone past that deadline, I guess we would have had no recourse—the week before. So, I mean, I am glad you have this concern about being fair to these people, but if you only have a certain date that you have to comply by, it kind of leaves people out in the cold.

This is supposed to be a no-fault system, and you keep talking about litigation. I just don't understand that. I mean, it was designed to be a no-fault system. Why litigation? Litigation denotes adversarial problems—an adversarial situation. That doesn't sound like no-fault. You can answer that in just 1 second.

How much, Mr. Euler, will it cost to care for an injured child for the lifetime of that child?

Mr. EULER. It depends on the child, Mr. Chairman.

Mr. BURTON. Give me a rough idea, say, for one that lives to be 25.

Mr. EULER. I can't. It is very hard to have a hypothetical, because each child is different.

Mr. BURTON. No, but we have had some children here today who have had some severe problems. I have a severe problem in my family. We have already laid out several thousand dollars. And I know that a lot of families can't afford that. So, what are they to do?

If the vaccination was responsible for it and we don't find out for 10 years and the statute or the time period runs out, what are they to do? Go to SSI?

Mr. EULER. Congress has the ability to change the statutory criteria, which we are charged with implementing. We have already recommended that the statue be essentially doubled, the statute of limitations, from 3 years to 6 years.

Mr. BURTON. Why not just take the lid off of it?

Mr. EULER. That is something Congress has the power to do.

Mr. BURTON. Would you think that would be a good idea?

Mr. EULER. I think we would have to consider it. I think every program has time limits. Every program anywhere——

Mr. BURTON. But you don't know how a child is going to—I mean, the child may not have a problem that is visible for 5, 6, 7 years, and then all of sudden the statute has run out, and that child is ruined for life, and the parent has no resources to take care of it.

Mr. EULER. The statute begins to run from the onset of the condition, now, whenever that it is. It doesn't necessarily run from the date of vaccination, though there can be debate over when that onset is, but it may be several years out.

Mr. BURTON. Mr. Chairman, I thank you very much. It sounds like to me we are going to have to come up with some amendments to the current statute, and we have to do it relatively soon.

Thank you, sir.

Mr. MICA. Thank you. The President in an Executive order in 1996 recommended agencies adopt alternative dispute resolutions and that we try to proceed in that fashion.

Has the Department of Justice or HHS instituted a formal program of alternate dispute resolution with regard to the Vaccine Compensation Program?

Mr. EULER. Much of the process itself has elements of what we call ADR. For example, I referred in my testimony to that initial telephone conference that the special master convenes with the petitioner and with Justice counsel. What is done there is the petitioner is advised of the deficiencies in the complaint and how they can go about fixing it. I am not aware of any other system that does that. And that type of informal processing exists throughout the program.

The court, in addition, does in fact take additional ADR steps at times in the damages phase. If it doesn't look like it is being worked out, we have some success getting another special master to take a look at the case to try to resolve it. That has worked out well on occasion, and that is sometimes one of the things we do.

But this is clearly a less adversarial, informal process, and there are not rules of evidence, there is not civil discovery. The idea is to get all of the information out on the table and then to come to a resolution for that child's care. That is what we are trying to do. That is not an easy process for petitioners, I grant that. They work hard at it, but sometimes it takes awhile.

Mr. MICA. Mr. Balbier, do you keep a log of the cases that have been resolved and then how—or when they were initiated and when they were resolved? Do you have such a log from the time—on each case? Like, this year, you said you resolved, what, *X* number?

Mr. BALBIER. We have a system, of course, where we input data——

Mr. MICA. But what I would like——

Mr. BALBIER [continuing]. That tracks the date of the claimant's——

Mr. MICA [continuing]. If you could provide us, just get this year's or the last year's cases and get us the date when the claim was instituted and then was—well, we know when it was resolved—so we could see how much time they were taking up. If you could provide us with that.

Mr. BALBIER. We do track that, and the average is about 2 years.

[The information referred to follows:]

NATIONAL VACCINE INJURY COMPENSATION PROGRAM					
POST-ACT FILING/ADJUDICATION TIME-LINES (as of 9/14/99)					
ALL CASES	days	774.3			
	mos	25.8			
	years	2.1			
NOT	days	613.6			
CONCEDED	mos	51.1			
	years	1.8			
CONCEDED	days	996.1			
	mos	83.0			
	years	2.8			

Mr. MICA. I have additional questions. I do want to also learn from HHS what you are doing to inform the public about the program. I can't take any responses at this time, and I am going to adjourn the hearing. I will leave the record open for at least 3 weeks by unanimous consent request. We will be submitting to both the Department of Justice and HHS and the program a lengthy series of questions for response, to be included in the record.

I do want to thank both of you gentlemen for appearing with us today and providing information. Also thank the other witnesses who participated in the hearing.

Hopefully everyone working together—and I have directed staff to meet within the next week to come up with some legislative remedies. I know that some have been recommended to the Speaker, and we will consult with Mr. Waxman, Mrs. Mink, and others who have expressed an interest hopefully to come up with a legislative package that is remedial and hopefully effective.

There being no further business to come before this subcommittee at this time, this meeting is adjourned.

[Whereupon, at 1:57 p.m., the subcommittee was adjourned.]