THE NATIONAL VACCINE INJURY PROGRAM: IS IT WORKING AS CONGRESS INTENDED?

HEARINGS

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CONTENTS

Page

Hearing held on:
- November 1, 2001 1
- December 12, 2001 135

Statement of:
- Balbier, Thomas E., Jr., Director, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, U.S. Department of Health and Human Services; Paul Clinton Harris, Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice, concerning the National Vaccine Injury Compensation Program; and John Euler, Director, National Vaccine Injury Compensation Program, U.S. Department of Justice 230
- Balbier, Thomas E., Jr., Director, National Vaccine Injury Compensation Program, accompanied by Geoffrey Evans, Medical Director, and David Benor, Office of the General Counsel; and Paul Clinton Harris, Sr., Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice 58
- Barton, Lori, Albuquerque, NM; Tara Dyer, Knoxville, TN; Joe Holder, Bayonne, NJ; Clifford Shoemaker, LLP, Arlington, VA; and Robert Block, M.D., chairman, Advisory Commission on Childhood Vaccinations, Tulsa, OK 164
- Rogers, Thad, Auburn, AL; Harold Sword, Columbus, OH; and Janet Zuhlke, Satellite Beach, FL 29

Letters, statements, etc., submitted for the record by:
- Balbier, Thomas E., Jr., Director, National Vaccine Injury Compensation Program, prepared statements of 62, 232
- Barton, Lori, Albuquerque, NM, prepared statement of 168
- Block, Robert, M.D., chairman, Advisory Commission on Childhood Vaccinations, Tulsa, OK, prepared statement of 213
- Burton, Hon. Dan, a Representative in Congress from the State of Indiana, prepared statements of 6, 140
- Clay, Hon. Wm. Lacy, a Representative in Congress from the State of Missouri, prepared statement of 27
- Cummings, Hon. Elijah E., a Representative in Congress from the State of Maryland, prepared statement of 154
- Duncan, Hon. John, a Representative in Congress from the State of Tennessee, prepared statement of 158
- Dyer, Tara, Knoxville, TN, prepared statement of 178
- Harris, Paul Clinton, Sr., Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice, prepared statements of 71, 240
- Holder, Joe, Bayonne, NJ, prepared statement of 184
- Morella, Hon. Constance A., a Representative in Congress from the State of Maryland, prepared statements of 105, 151
- Rogers, Thad, Auburn, AL, prepared statement of 31
- Shoemaker, Clifford, LLP, Arlington, VA, prepared statement of 191
- Sword, Harold, Columbus, OH, prepared statement of 36
- Waxman, Hon. Henry A., a Representative in Congress from the State of California, prepared statements of 20, 148
- Weldon, Hon. Dave, a Representative in Congress from the State of Florida, prepared statement of 106
- Zuhlke, Janet, Satellite Beach, FL, prepared statement of 43

THE NATIONAL VACCINE INJURY PROGRAM: IS IT WORKING AS CONGRESS INTENDED?

THURSDAY, NOVEMBER 1, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Horn, Davis of Virginia, Platts, Weldon, Schrock, Duncan, Waxman, Norton, Cummings, Kucinich, Tierney, Clay, and Watson.

Staff present: Kevin Binger, staff director; James C. Wilson, chief counsel; David A. Kass, deputy chief counsel; Mark Corallo, director of communications; S. Elizabeth Clay and John Rowe, professional staff members; Robert A. Briggs, chief clerk; Robin Butler, office manager; Elizabeth Crane, legislative assistant; Josie Duckett, deputy communications director; Joshua Gillespie, deputy chief clerk; Nicholas Mutton, assistant to chief counsel; Leneal Scott, computer systems manager; Corrine Zaccagnini, systems administrator; Sarah Despres, minority counsel; Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerks.

Mr. BURTON. The Committee on Government Reform will come to order.

A quorum being present, we'll start our business. I ask unanimous consent that all Members' and witnesses' written and opening statements be included in the record. Without objection, so ordered. I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record. Without objection, so ordered.

Today we're going to focus on the Government's program for compensating families that experience vaccine injuries. We spent about 2 years conducting oversight on Federal vaccine policies. We've looked at these issues from almost every angle. We've looked at the issues related to vaccine safety. Much more research needs to be done in this area. We've looked at conflicts of interest in vaccine policymaking. The Department of Health and Human Services has a real problem in this area that we don't believe they're addressing.

Today we're going to look at the National Vaccine Injury Compensation Program. It was created by Congress to compensate families when their children are injured by vaccines. Is it working the way Congress intended? I think the answer is no.

I want to make a few preliminary points about the vaccines in general. First, vaccines are an important part of our public health system. They've saved millions of lives. They've helped wipe out crippling diseases. We want children to be protected against infectious diseases. Nothing this committee does should be interpreted as anti-vaccine.

Second, we want vaccines to be as safe as possible. No matter how good our vaccines are, there's always room for improvement. The oral polio vaccine saved thousands of children from a crippling disease. It was a good public health tool in its time, but it was not perfect. It had a high rate of adverse events. By doing the research, a new and better vaccine was developed. Today, we're getting the same public health benefit with far fewer side effects with the polio vaccine.

Not enough research is being done in this area. Mercury is a good example. For decades, vaccine manufacturers have used mercury preservatives in vaccines. In the past, maybe the benefits outweighed the risks. But today, there's a consensus that mercury, no matter how small the quantity, does not belong in vaccines. The truth is, we just don't know what the health effects of mercury are, because the research hasn't been done. We know that some forms of mercury cause neurological disorders.

There are some groups of scientists that believe that Alzheimer's and autism are in part caused by the mercury in the vaccines. I want all the Members of Congress to know that the vaccine that they're getting for the flu has mercury in it. It's called thimerosal. That's a preservative, and some scientists believe it does cause, is a major contributing factor to neurological disorders. When you go over and get your shot, all you have to do is look at the package insert, because it does have mercury in it.

I'm not saying you shouldn't get a flu shot. But I think you should be aware that there's a growing body of evidence that the mercury does contribute to Alzheimer's and other diseases of that type. And it's in the vaccine.

Not enough research has been done to tell us if the mercury preservatives used in vaccines are related to neurological problems. But as I said, there's a growing number of scientists that believe it is. The Institute of Medicine said that a connection is biologically plausible, but there's not enough research to know. And we need to do more research to make sure.

When those of us who have really looked at these issues call for more research, and when we say that we should err on the side of caution, I hope we won't be accused of trying to scare the public. We shouldn't bury our heads in the sand when it comes to vaccine safety. The best way to give the American people confidence is to do the research so we can tell the people that their vaccines are as safe as possible and most effective products are as safe as possible.

The third point I want to make is this. We know that no matter how safe a vaccine is, a very small number of people are going to be injured. That's a fact. That's why Congress created the Vaccine Injury Compensation Program, to provide compensation to families when their children are injured. My colleague, Mr. Waxman, who I'm very happy is on the committee, because he is very familiar

with this issue, he wrote the bill that created this program 15 years ago. And he deserves a lot of credit for that.

At the time, vaccine manufacturers were faced with a lot of lawsuits. They were threatening to leave the market. So that would have adversely affected people who needed those vaccines. The stability of our vaccine supply was in question. Mr. Waxman and others stepped in and created this program, and it took a lot of foresight. The program had three basic goals. The first goal was to protect vaccine manufacturers from lawsuits. That was successful.

The second goal was to stabilize the supply of vaccines in this country. Again, that was a success. The third goal was to provide compensation to families in a generous way without tying them up in court for years. And on this point, the program has not lived up to expectations.

This system was designed to be generous to families whose children were suffering crippling injuries. It was meant to provide compensation quickly, without a lot of legal fighting. On close calls, the families are supposed to get the benefit of the doubt.

That's not the way the program has been working today. It had some successes, but it's also had some failures. If you talk to families who have been tied up in this system, it sounds like this program has become every bit as adversarial as the tort system it replaced. Cases drag on for 6 or 8 or 10 years. The GAO said that the average case takes 2 years to complete.

A third of the cases take more than 5 years. The Government hires teams of medical witnesses to try to disprove families' cases. All of the Government's expenses are paid out of the trust fund. Families are not reimbursed for their expenses for years. We're talking about middle class families who are already paying tens of thousands of dollars every year to take care of severely injured children.

We're supposed to be helping these people. But if you talk to some of these families, they feel like they've been put through the wringer by their own Government. We have some clear evidence of overzealous conduct on behalf of the Government. In the case of the Sword family, which we're going to hear about today, the Special Master called the Justice Department lawyer's tactics egregious: "Respondent's argument of independent corroboration from the records is especially egregious in a situation such as the instant case in which death occurs within 4 hours of vaccination."

In the Zuhlke family, one of the special masters recused himself from the case because he became so frustrated with the Government representative. In a case cited in our committee report last year, the Special Master apologized to the family for the Government's conduct: "In the special master's view, respondent's counsel's abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial."

We have three families here today who are going to talk about their struggles under this program. I'd like to talk about each one of these cases in detail because they're all so compelling. But I don't want to make our witnesses wait any longer than is necessary.

Let me just use the Zuhlke case as an example. Janet Zuhlke's daughter received her pre-kindergarten vaccinations in 1990. Ra-

chel had a severe reaction almost immediately. Within 6 hours, she was vomiting and she had fever, severe headaches and pain in her eyes that made her scream. Within 3 weeks, she was in critical condition and she had to be medevaced to the hospital at the University of Florida.

Today Rachel is mentally retarded. She had periodic bouts of blindness. She has neurological breakdowns that confine her to a wheelchair and she'll need care for the rest of her life. A team of medical specialists diagnosed her case as a vaccine-related encephalopathy. That's a condition that's on the vaccine injury table. If you suffer a "table injury" you're supposed to get compensation almost automatically.

Well, that's not what happened to the Zuhlkes. This case has dragged on for 9 years. The Zuhlkes still haven't received one penny from the program.

The Department of Justice and HHS spent years trying to prove that Rachel's illness was caused by a strep infection. This case dragged on so long, they went through three special masters. As I said earlier, one special master recused himself from the case because the Government would not settle. The Zuhlke family finally won their case in July of this year, more than 9 years after they filed their petition.

But they're still probably a year away from receiving any compensation. For them, the second of the process is just kicking in. There's a long period of negotiations to determine exactly how much money they're entitled to receive. Janet Zuhlke's already spent over $25,000 out of her own pocket to care for her daughter and to try to win this case.

And that was a table injury. This was supposed to be one of the easy cases.

Now, not every family has had an experience this bad. But this is not an isolated incident. You hear about these cases over and over again. It's just wrong. Put yourself in their shoes. You have a child who suffers a terrible injury, maybe you have a child who died like Harold Sword did. That takes a terrible emotional toll on your family. You're faced with hundreds of thousands of dollars in expenses, and on top of that, you have to fight the Government, with all of its resources, for years to try to get any help.

Somewhere along the way, this program lost its way. The government collects an excise tax on vaccines so it can take care of families like the Zuhlkes and the Swords and the Rogers. The Government has $1.7 billion in this trust fund, and it's growing every year. These families are supposed to get the benefit of the doubt. They're supposed to be treated with compassion. But instead, they have to fight the Government for years to get any help at all.

Now, the Justice Department and HHS deserve some credit. They've recognized that there are some problems. They've even backed some reforms that the Congress has not yet approved. They've supported a longer statute of limitations, and that's good. They've supported legislation to authorize interim payments to families when they win the first phase. And that's good. These are reforms Congress should enact immediately. Congressman Weldon, on our committee, Dr. Weldon, has introduced legislation that addresses these problems and many others. It's a good bill and I'm

a co-sponsor of it, and I want to thank Dr. Weldon for his hard work on this issue.

But the most important reform does not require legislation. It requires the Justice Department to take a long, hard look at the way it does business in this area. And that goes for HHS, too. They have to use some common sense. Close calls are supposed to go to the families. The Government is not supposed to fight them tooth and nail. Some of these cases don't even look like close calls, and yet the Government fights them for years. That has to stop.

Let me conclude by saying this. Vaccinations are important. We wanted children to be protected against childhood diseases. We should keep trying to make vaccines safer. Most kids who get vaccinated do just fine; but there are cases where children are injured, adults as well. And those are terrible, terrible situations for the families. Instead of treating them like opponents, we have to start treating them with a little more compassion. That's what Congress intended when we created this program, and that's what Mr. Waxman intended when he supported and sponsored the legislation. And that's what we want to see happen.

I want to thank Mr. Sword, Ms. Zuhlke and Mr. Rogers for being here today. We'll be very interested in what you have to say. And I also want to thank the representatives from the Justice Department and HHS for being here. I hope they can offer us some encouragement that they want to address these problems I just mentioned.

And with that I yield to Mr. Waxman.

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

Opening Statement
Chairman Dan Burton
Committee on Government Reform
"The National Vaccine Injury Compensation Program:
Is It Working As Congress Intended?"
November 1, 2001

Good Morning.

Today, we're going to focus on the Government's program for compensating families that experience vaccine injuries. We've spent about two years conducting oversight on Federal vaccine policies. We've looked at these issues from almost every angle.

We've looked at issues related to vaccine safety. Much more research needs to be done in this area.

We've looked at conflicts of interest in vaccine policy making. The Department of Health and Human Services has a real problem that they're not addressing.

Today, we're going to look at the National Vaccine Injury Compensation Program. It was created by Congress to compensate families when their children are injured by vaccines. Is it working the way Congress intended. I think the answer is no.

I want to make a few preliminary points about vaccines in general.

First, vaccines are an important part of our public health system. They've saved millions of lives. They've helped wipe out crippling diseases. We want children to be protected against infectious diseases. Nothing this Committee does should be interpreted as anti-vaccine.

Second, we want vaccines to be as safe as possible. No matter how good our vaccines are, there's always room for improvement. The oral polio vaccine saved thousands of children from a crippling disease. It was a good public health tool in its time. But it wasn't perfect. It had a high rate of adverse events. By doing the research, a new and better vaccine was developed. Today we're getting the same public health benefit with far fewer serious side effects.

Not enough research is being done in this area. Mercury is a good example. For decades vaccine manufacturers have used mercury preservatives in vaccines. In the past, maybe the benefits outweighed the risks. But today there is a consensus that mercury, no matter how small the quantity, doesn't belong in vaccines.

The truth is that we just don't know what the health effects of mercury are because the research hasn't been done. We know that some forms of mercury cause neurological disorders. But not enough research has been done to tell us if the mercury preservatives used in vaccines are related to neurological problems. The Institute of Medicine said that a connection is biologically plausible, but that there isn't enough research to know. We need to have more research done on this.

When those of us who have really looked at these issues call for more research, and when we say that we should err on the side of caution, I hope we

won't be accused of trying to scare the public. We shouldn't bury our heads in the sand when it comes to vaccine safety. The best way to give the American people confidence is to do the research so we can tell people that their vaccines are the safest and most effective products possible.

The third point I want to make is this –we know that no matter how safe the vaccine, a very small number of people are going to be injured. That's a fact. That's why Congress created the Vaccine Injury Compensation Program –to provide compensation to families when their children are injured.

My colleague, Mr. Waxman wrote the bill that created this program fifteen years ago. He deserves a lot of credit for that. At the time, vaccine manufacturers were faced with a lot of lawsuits. They were threatening to leave the market. The stability of our vaccine supply was in question. Mr. Waxman and others stepped in and created this program. That took a lot of foresight.

The program had three basic goals. The first goal was to protect vaccine manufacturers from lawsuits. That's been successful.

The second goal was to stabilize the supply of vaccines in this country. Again, it's been a success.

The third goal was to provide compensation to families in a generous way, without tying them up in court for years. On this point, this program hasn't lived up to expectations.

This system was designed to be generous to families whose children suffered crippling injuries. It was meant to provide compensation quickly, without a lot of legal fighting. On close calls, the families are supposed to get the benefit of the doubt.

That's not the way the program is working today. It's had some successes, but it's also had some failures. If you talk to the families who've been tied up in this system, it sounds like this program has become every bit as adversarial as the tort system it replaced.

Cases drag on for six or eight or ten years. The GAO said that the average case takes two years to complete. A third of the cases take more than five years. The government hires teams of medical witnesses to try to disprove families' cases. All of the Government's expenses are paid out of the trust fund. Families aren't reimbursed for their expenses for years. We're talking about middle class families who are already paying tens of thousands of dollars every year to care for severely injured children.

We're supposed to be helping these people. But if you talk to some of these families, they feel like they've been put through the ringer by their own government.

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"Respondent's argument of independent corroboration from the records is especially egregious in a situation such as the instant case in which death occurs within four hours of vaccination."

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In a case cited in our Committee report last year, the Special Master apologized to the family for the government's conduct:

"In the special master's view, respondent's counsel's abrasive, tenacious, obstreperous litigation tactics were inappropriate in a program that is intended to be less adversarial." (Marks v. Sec. HHS)

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It's just wrong. Put yourself in their shoes. You have a child who suffers a terrible injury. Maybe you have a child who died like Harold Sword did. That takes a terrible emotional toll on your family. You're faced with hundreds of thousands of dollars in expenses. And on top of that, you have to fight the government, with all of its resources, for years to try to get any help.

Somewhere along the way, this program lost its way. The government collects an excise tax on vaccines so it can take care of families like the Zuhlkes and the Swords and the Rogers. The government has $1.7 billion in this trust fund, and it's growing every year.

These families are supposed to get the benefit of the doubt. They're supposed to be treated with compassion. But instead they have to fight the government for years to get any help at all.

Now, the Justice Department and HHS deserve some credit. They've recognized that there are some problems. They've even backed some reforms that the Congress hasn't approved. They've supported a longer statute of limitations. They've supported legislation to authorize interim payments to families when they win the first phase. These are reforms Congress should enact immediately. Congressman Weldon has introduced legislation that addresses these problems and many others. It's a good bill, and I'm a cosponsor of it. I want to thank Dr. Weldon for his hard work on this issue.

But the most important reform doesn't require legislation. It requires the Justice Department to take a long hard look at the way it does business. And that goes for HHS too. They have to use some common sense. Close calls are

supposed to go to the families. The government isn't supposed to fight them tooth and nail. Some of these cases don't even look like close calls, and yet the government fights them for years. That has to stop.

Let me conclude by saying this. Vaccinations are important. We want children to be protected against childhood diseases. We should keep trying to make vaccines safer, but most kids who get vaccinated do just fine. But there are cases where children are injured – adults too. And those are terrible, terrible situations for those families. Instead of treating them like opponents, we have to start treating them with a little more compassion. That's what Congress intended when we created this program – and that's what we want to see happen.

I want to thank Mr. Sword and Mrs. Zuhlke and Mr. Rogers for being here today. We'll be very interested in what you have to say. I also want to thank our representatives from the Justice Department and HHS for being here. I hope they can offer us some encouragement that they want to address these problems.

I now yield to Mr. Waxman for his opening statement.

Mr. WAXMAN. Mr. Gilman has to go to the White House, and I'd like to let him go before me.

Mr. BURTON. Go ahead, Mr. Gilman.

Mr. GILMAN. Thank you, Chairman Burton. I want to thank Ranking Member Waxman for yielding me this time.

I welcome the panelists and I want to thank Chairman Burton for arranging this hearing, which is so important to so many of our people throughout the Nation. Chairman Burton and Ranking Member Waxman, you're to be commended for your concern about these important problems. We look forward to hearing from the panelists As our committee continues to examine the effectiveness of the National Vaccine Injury Compensation Program.

In 1986, when Mr. Waxman farsightedly had the Congress adopt the National Childhood Vaccine Injury Act, it intended to provide fair compensation to any individuals harmed by vaccines while making certain that the vaccine manufacturers would continue to supply and create safe vaccines to the American public. Instead, this program, jointly administered by the Department of Justice and HHS, has regrettably become bogged down in litigation, with cases lasting years, as our good chairman has noted, facing numerous levels of appeal before any final decisions are made.

This program initially, as Mr. Waxman introduced it, was designed to provide fair, expedited compensation to those who may have suffered any vaccine injury. During my years in the Congress, I've been contacted by a number of families in my district, all of whom have experienced varying levels of difficulty and delays with their claims before the compensation program, ranging from being forced to engage in long, drawn-out court battles to outright denial of the claims due to administrative changes in definitions and in criteria.

One such example, Mr. Chairman, is Tommy Sansone, Jr. The family of Tommy Sansone, Jr., a former constituent and a police officer, has been trying to receive compensation for the lingering and devastating effects of a DPT vaccine he received when he was only 6 months old. His family attempted to file a claim immediately after the son developed a severe, chronic seizure disorder less than 2 weeks after receiving the vaccine. Regrettably, they were told that before a claim can be filed, the family needs to spend more than $1,000 in non-reimbursable vaccine related expenses before doing so.

Since Tommy was covered by his father's insurance plan, it took several months before Sansone's met that monetary requirement. By that time, however, the criteria for the DPT vaccine had been changed, eliminating seizures from the table of related side effects. For 10 years, a substantial percentage of those with brain damage and other symptoms were recognized to be DPT injuries. But by 1985, the year in which Tommy's claim was made, it was no longer recognized.

These new definitions have had unintended consequences, using criteria that is so strict that the restitution fund pays fewer claims than ever before, despite the fact that there's over $1.7 billion, capital B, $1.7 billion, in that fund today. As a result, families of children like Tommy find it virtually impossible to win a claim in the Vaccine Injury Compensation Program, another unintended con-

sequence. That was over 6 years ago, and thousands of dollars in medical expenses later.

Congress envisioned that the National Vaccine Injury Compensation Program would be simple, would be straightforward and more streamlined to avoid unnecessary typical litigation. But somehow the congressional intent has been lost along the way.

Tommy faces a lifetime of crippling seizures and mounting medical expenses, in addition to the emotional strain on him and his family. Hopefully, this hearing will lead to necessary adjustments to the program and finally help children like Tommy receive the compensation to which they are entitled.

Mr. Chairman, again I thank you for conducting this hearing, and Mr. Waxman, we thank you for adopting this measure initially, but hopefully we can get it back on the right track. Thank you, Mr. Chairman.

Mr. BURTON. Mr. Gilman, you might take a look at Dr. Weldon's legislation, because he has a bill that might help correct some of that.

Mr. GILMAN. Thank you. I look forward to looking at it.

Mr. BURTON. Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman, for holding this oversight hearing on the vaccine compensation program. I feel a certain sense of pride as the author of that bill 15 years ago. There have been some successes with that legislation that are undeniable, and I think we're going to hear some questions raised today about problems in the way the vaccine compensation system has been implemented.

Let me give some background and put this in perspective. In 1987, when Congress passed the Vaccine Injury Compensation Act, pharmaceutical companies were threatening to leave the business of manufacturing childhood vaccines, citing among other reasons, that the increased litigation was driving them out of producing these vaccines. The United States was facing the very real possibility that we would experience a resurgence of devastating illnesses like polio, which is a debilitating and often fatal disease that infected as many as 20,000 people in some years, or measles, a disease that continues to kill 900,000 people worldwide even today.

So in response to this potential public health crisis, Congress created the Vaccine Injury Compensation Program. The purpose of the program was threefold. First, to be a no-fault program to compensate people from the rare but sometimes serious side effects of vaccines. Let me underscore that. When you immunize large numbers of people, there are going to be some rare cases of adverse consequences, very serious adverse consequences. And we have to acknowledge that reality there.

In that case, we decided that we must compensate those people. We mandate the vaccinations, for the most part, for all the children in this country, as a public health preventative. So if somebody's injured, we ought to make sure that person is compensated. We don't take away their right to sue. But we have a compensation system that offers them an alternative to going into court.

Our second objective was to lower the number of lawsuits against vaccine companies in order to encourage these companies to stay in the business. And of course, to ensure that we had a healthy do-

mestic supply of vaccines. And the third purpose of the bill was to allay parents' concerns about vaccine safety so that parents would continue to have their children vaccinated.

Now, in most respects this program is working. Immunization rates are high. We rarely see outbreaks of vaccine preventable disease like polio or measles. While some vaccine manufacturers have left the vaccine business, they cannot cite liability as a reason for leaving. And finally, people seem generally satisfied with the awards they get under the Vaccine Injury Compensation Program.

The act Congress passed allowed people to reject their awards and sue the vaccine manufacturers once they had gone through the program. Very few people have gone to court. Most have received compensation through the compensation system and have been quite satisfied with it.

Today, we're going to hear from some people who went through the compensation system and did not receive an award to compensate them. We are to try to understand why that took place. There seems to be a greater litigiousness on the part of the Department of Justice. I'd like to know why. The purpose of the program was not to replace the tort system with an adversarial litigious framework, but to move to a more reasoned source for resolving the claim and compensating those who are entitled to be compensated.

Now, there is the question, about whether injuries that people have suffered are related to the vaccine? Because if you have people come forward and say, well, I had a vaccination and then I had some terrible result, but you can't show that it was related to the vaccine, that's not the purpose of the vaccine compensation system to award people money if there's no connection between the two.

So one of the issues that we have to look at is, what is the standard of proof. Well, we have a table of known reactions to some of these vaccines, rare, but they do occur. And in that situation, we provide automatic compensation for those who are suffering from what's called table injuries.

But then you have people who have adverse effects that are not listed. And should they be compensated and what burden of proof would they have in order to make their case to the committee that decides the issue. And the present law says that they have to have a preponderance of evidence to show that their injuries were related to the vaccine.

Mr. Weldon has suggested, in his legislation, that we have a justifiable belief standard. As I understand the standard he set in place, would be to change the burden of proof requirement from the traditional preponderance of the evidence standard to submitting evidence sufficient to justify a belief by a fair and impartial individual that petitioner's claims are well grounded.

Now, that's a very different and lower standard. We ought to take a look at it and examine it. I was impressed by the fact that the Bush administration representatives today are going to tell us that they feel very uneasy with that standard. They feel it moves us away from science, a scientific evaluation of the connection between the injury and the vaccine. They feel that it's too low a standard and would compensate people who wouldn't otherwise be compensated.

Now, I have to say, I'm a liberal Democrat. I like to see people compensated if they're hurt. But if you open this thing too wide open, if anybody comes in and has a claim, and they can just say, I can show that a person should be convinced that there's a relationship between my injury and the vaccine, then maybe that will open things too broadly. So I want us to look at that issue.

We've heard complaints about the program. Specifically today we're going to hear from people who feel they weren't fairly treated. But we've also heard complaints, other complaints, specifically about the statute of limitations, the fact that the program doesn't allow for interim payments for attorneys costs, the length of time it takes to resolve cases, and the difficulty of resolving off-table injury cases. So I'm pleased we're going to hear from people who can shed some light on these issues. Their insights as we look at their experiences will help us understand how this program can be improved.

I'm also pleased that we are going to hear from the administration because they've expressed support for certain changes in the program, including increasing the statute of limitations and allowing for interim payments to petitioners' attorneys for their costs. I think those are obvious important steps in easing the burden of parents to get compensation for vaccine injuries, and I look forward to working with this administration and my colleagues in the Congress in making some of these changes.

But as we discuss this vaccine injury program, we have to be mindful that it's impossible to separate the issue of the Vaccine Injury Compensation Program from the issue of vaccine supply. This is why I, along with Senator Kennedy and Senator Frist, among others, have asked the General Accounting Office to study why vaccine companies are leaving the business.

Currently, the United States is experiencing shortages of childhood vaccines. My office has gotten calls from doctors who cannot get tetanus vaccine, even for their high risk patients. And there are spot shortages of the DTAP vaccine, which protects kids against diphtheria, pertussis, or whooping cough, as well as against tetanus. These are serious childhood diseases. We don't want a resurgence of them in the United States. Some providers are also experiencing shortages of pneumococcal conjugate vaccine, which protects children against diseases caused by pneumococcal bacteria, including meningitis, which can be fatal.

So I think we want to find out what's going on in that area, why we are facing these shortages.

There's also an issue of the flu vaccine. On average, 20,000 people nationwide die from the flu yearly. Secretary Thompson is urging people to get flu vaccines this year, because the symptoms from the flu are the same as from anthrax. However, we currently don't have enough flu vaccine to immunize everyone.

Finally, now that we're facing actual bioterrorism, there's an increasing concern specifically about our supplies of smallpox and anthrax vaccines. There is an anthrax vaccine, there is a smallpox vaccine. I've read media accounts of doctors being flooded with phone calls form people saying they want to take these vaccines. At this time it would not be prudent to have universal vaccination against smallpox or anthrax. However, I'm sure it would be very

reassuring to the public to know that if we needed them, we had adequate supplies of these vaccines. So we ought to be simply stockpiling and manufacturing at a very fast rate both vaccines.

And let me point out that there's something that sometimes comes with being around a long period of time. When I first got elected to Congress, in 1974, in 1975 my first year here, the Ford administration believed that we were facing a worldwide epidemic of what was known as the swine flu. And they immediately moved forward to have every American immunized against this swine flu.

Well, people lined up to be immunized. What they didn't recognize, and we always have to keep in mind, is that when you have mass immunization, there are going to be some adverse events. So some people, intending to prevent this swine flu from attacking them, came down with some very serious side effects that we didn't anticipate. Guillain-Barre syndrome, which caused paralysis in individuals, was creeping up in numbers as a result of this mass immunization. So I say that to point out, when people say, well, why don't we have everyone vaccinated for anthrax or everyone vaccinated for smallpox, that we have to be very concerned about the increase in the adverse events, serious adverse events. And we have to balance the risks and the benefit.

It turned out, we never did get that swine flu epidemic. But we did get some of those terrible side effects.

In the case of childhood vaccines, we know that without immunizations on a mass scale, we will get a resurgence of those diseases. That's why we need to have mass immunizations. But if we're going to have some of those rare terrible adverse events there are some adverse events that are not as serious, but those serious adverse events ought to be the basis for compensation. And that was the purpose for this compensation system.

I mention these specific examples of vaccine supply problems to remind us that the Vaccine Injury Compensation Program serves a very important function in helping to ensure the security of the vaccine supply. Making sure we have adequate supplies of vaccine is a public health priority, especially now with the looming fear of bioterrorism. Our goal should be to further shore up our fragile vaccine infrastructure with safe, effective vaccines and to reassure the public that if they do suffer from the rare but very real side effects of vaccines, that they will be fairly and quickly compensated.

I want to thank all the witnesses for being here today. Unfortunately, what happens often in our congressional day is that we have many things scheduled at the same time. When I was chairman of the Health and Environment Subcommittee, I could schedule the hearings to fit my schedule, and I could plan to be there throughout the hearing. Now I'm experiencing what the majority used to experience when they were in the minority, our day is not up to us to schedule, it's up to those other committee chairmen and those on the floor to set where we have to be. Today I find myself having to be at a number of places at the same time.

I want to assure all the witnesses that if I'm not here personally, I will review their testimony. My staff is here to hear them and we will work with our colleagues in trying to figure out how to make those necessary changes in the vaccine compensation program to

accomplish the goals we had 15 years ago, and the goals we still have today.

Thank you, Mr. Chairman, for giving me this time to make this lengthy statement.

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

STATEMENT OF REP. HENRY A. WAXMAN
RANKING MINORITY MEMBER
COMMITTEE ON GOVERNMENT REFORM
NOVEMBER 1, 2001

In 1987, Congress passed the Vaccine Injury Compensation Act. At that time, pharmaceutical companies were threatening to leave the business of manufacturing childhood vaccines, citing, among other things, increased litigation as their reason for leaving. The United States was facing the very real possibility that we would experience a resurgence of devastating illnesses like polio, a debilitating and often fatal disease that infected as many as 20,000 people in some years, or measles, a disease that continues to kill 900,000 people worldwide even today.

In response to this potential public health crisis, Congress created the Vaccine Injury Compensation Program. The purpose of the program was threefold:

- First, to be a no-fault program to compensate people who suffer from the rare, but sometimes serious side effects of vaccines;
- Second, to lower the number of lawsuits against vaccine companies in order to encourage them to stay in the vaccine business and, thus, to ensure a healthy domestic supply of vaccines; and
- Third, to allay parents' concerns about vaccine safety so that parents continue to vaccinate.

In most respects, the program is working. Immunization rates are high and we rarely see outbreaks of vaccine-preventable diseases like polio or measles. While some vaccine manufacturers have left the vaccine business, they cannot cite liability as a reason for leaving. Finally, people seem generally satisfied with the awards they get under the Vaccine Injury Compensation Program. The Act Congress passed allowed people to reject their awards and sue the vaccine manufacturer once they have gone through the program. Very few petitioners do this.

However, the Committee has heard complaints about the program, specifically about the statute of limitations, the fact that the program does not allow for interim payments for attorneys costs, the length of time it takes to resolve cases, and the difficulty resolving off-table injury cases. I am pleased that we will hear today from people who have gone through the program because their insights will be useful in understanding how the program can be improved.

I am also pleased that we will be hearing today from the Administration. The Administration has expressed support for certain changes in the program, including increasing the statute of limitations and allowing for interim payments to petitioners' attorneys for their costs. These will be important steps in easing the burden of parents to get compensation for vaccine injuries. I look forward to working with the administration on those changes.

As we discuss the Vaccine Injury Program, however, we must be mindful that it is impossible to separate the issue of the Vaccine Injury Compensation Program from the issue of the vaccine supply. This is why I, along with Senator Kennedy and Senator Frist, among others, have asked the General Accounting Office to study why vaccine companies are leaving the business.

Currently, the United States is experiencing shortages of childhood vaccines. My office has gotten calls from doctors who cannot get tetanus vaccine even for their high-risk patients, and there are spot shortages of the DTaP vaccine, which protects kids against diphtheria and pertussis, or whooping cough, as well as against tetanus. These are serious childhood diseases and we do not want a resurgence of them in the United States. Some providers are also experiencing shortages of the new pneumococcal conjugate vaccine, which protects children against diseases caused by pneumococcal bacteria, including meningitis, which can be fatal.

Also, there is the issue of the flu vaccine. On average, 20,000 people nationwide die from the flu yearly. Secretary Thompson is urging people to get flu vaccines this year since flu symptoms can be the same as anthrax symptoms. However, we currently do not have enough flu vaccine to immunize everyone.

Finally, now that we are facing actual bio-terrorism, there is increasing concern specifically about our supplies of smallpox and anthrax vaccines. I have read media accounts of doctors being flooded with phone calls asking for those vaccines. At this time, it would not be prudent to have universal vaccination against smallpox or anthrax. However, I am sure that it would be very reassuring to the public to know that we had adequate supplies of these vaccines if they were needed.

I mention these specific examples of vaccine supply problems to remind us that the Vaccine Injury Compensation Program serves a very important function in helping to ensure the security of the vaccine supply. Making sure we have adequate supplies of vaccine is a public health priority, especially now with the looming fear of bio-terrorism. Our goal should be to further shore up our fragile vaccine infrastructure with safe, effective vaccines and to reassure the public that if they do suffer from the rare, but very real, side effects of vaccines, that they will be fairly and quickly compensated.

I thank the witnesses for appearing today and I look forward to their testimony.

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Mr. BURTON. Well, as the author of the legislation, I think you probably know as much or more about this than anybody, and we appreciate what you've done and hopefully what you can help us do in the future.

Mr. Horn.

Mr. HORN. Mr. Chairman, I commend you for getting these cases, and I would suggest that we move on and get to questioning and not opening statements.

Mr. BURTON. Do you yield your time, then?

Mr. HORN. Yes.

Mr. BURTON. Mr. Kucinich.

Mr. KUCINICH. I want to say briefly, first of all, I too have a simultaneous committee hearing going on, and I'm one of the Democrats who is needed over there. I'm going to try to come back to this hearing.

But I want to say that for those who are here to testify, I think that it's important for the country to hear what you have to say. The efforts that have been made by Mr. Waxman, to assure that if injuries do occur there will be compensation, is something that I think this Congress needs to be mindful of with respect to the moral obligation of Government to compensate people if they are injured through participating in a Government mandated program, or a program that Government is advocating wide subscription by the public.

Certainly in this era, vaccinations take on an even greater concern with the mass public. I think that for those of you who have had families and loved ones, particularly who have suffered an injury, it pains me as a Member of Congress to even have the thought that our Government could be engaging in litigation to contest legitimate claims. And it's something that ought to concern everyone here.

So I appreciate your presence here. I know that along with Mr. Waxman, I'm going to be following very carefully the results of the testimony today. I look forward to the proceedings. And I thank the Chair for calling the hearing.

Mr. BURTON. Thank you, Mr. Kucinich.

Dr. Weldon.

Dr. WELDON. Thank you, Mr. Chairman.

I want to just say that normally I wholeheartedly endorse the sentiments of Mr. Horn at hearings. I think it's important that we get to the testimony as quickly as possible.

However, I want to just make two important comments. No. 1, I want to welcome Janet Zuhlke, we're going to hear testimony from her. She's a courageous lady. The chairman has outlined some of the details of her ordeal. I'm sure she'll be going into that in more detail in her testimony. And I hope one of the things that we can get at in this hearing is why does it take so long for some of these cases to work through the system.

The other point I want to make is I was practicing medicine when the original bill was passed. I want to commend the ranking member, Mr. Waxman. It was, I think, a badly needed piece of legislation. And at the time, from my perspective, it was a well crafted piece of legislation.

I think one of the fundamental problems with the system is that, and no offense to my attorney friends on the committee, it's just that we've allowed attorneys the opportunity to manage a lot of this. I think changing the burden of proof provisions in law is needed. I'm certainly open to discussions of modifying my language. I'm quite pleased that the administration has endorsed many of the provisions in the bill.

And I just want to point out that my bill is definitely very bipartisan. It is supported by a very broad spectrum of Members of the House of Representatives. Any piece of legislation that could have Chairman Burton, myself, Jerry Nadler and Barney Frank on the same piece of legislation has to be correctly labeled as a bipartisan piece of legislation.

And frankly, I think if we all sit down and try to work through some of the details on this issue, in good faith, we should be able to get this bill marked up in Commerce and possibly pass it out of the House of Representatives on suspension. There's pretty broad based agreement, I think, that some changes need to be made.

So I'm looking forward to the testimony of all our witnesses, and certainly my constituent from Satellite Beach, Janet Zuhlke. And I yield back. Thank you, Mr. Chairman.

Mr. BURTON. Thank you, Dr. Weldon.

Ms. Watson, did you have a comment?

Ms. WATSON. No, thank you, Mr. Chairman.

Mr. BURTON. Mr. Cummings.

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

This committee has held several hearings on the issue of vaccinations, adverse reactions to vaccinations, the Vaccine Injury Compensation Program, vaccinations for our military personnel and FDA regulations of vaccines. The purpose of today's hearing is to review the Department of Justice's and the Department of Health and Human Resources' implementation of the Vaccine Injury Compensation Program.

I fully believe in vaccinations. Vaccines are responsible for the eradication of some diseases that are common in this country. Further, in light of recent events, there has been increased talk of vaccinating lab technicians, public health workers, law enforcement officers, clean-up crews and even postal workers as the threat of anthrax exposure widens.

Congress adopted the National Childhood Vaccine Injury Act, which established the Vaccine Injury Compensation Program. The program was established for three main reasons. One, to fairly and quickly compensate children who were injured by vaccines; two, to decrease litigation filed against vaccine manufacturers in order to encourage them to stay in the vaccine market, thus ensuring a sufficient vaccine supply; and three, to reassure parents so that they would continue to immunize their children.

Mr. Chairman, I believe the program is working as Mr. Waxman, the author of the original legislation in Congress intended when it passed it in 1986. Of course, there are some people not fully satisfied with the program. Perhaps the statute of limitations is too short and perhaps it does take too long to compensate claimants.

However, the program has been successful in its policy goals of ensuring vaccine supply and establishing a program for individuals

and families injured by childhood vaccines. Congress was responsive to growing concerns of fears about vaccine safety and the vaccine preventable diseases by creating a no-fault compensation program for people who were injured by vaccines that are part of the routine childhood immunization schedule.

Finally, Congress needs to continue its role to guarantee the safety of vaccines and to ensure that the goals of the program are met in the future. Besides holding hearings on this very important issue, the committee and Congress can update their Web sites and other forms of communication for easy access to information. No vaccine is perfectly safe, but vaccines are responsible for preventing the spreading of infectious diseases and in some cases, eliminating them altogether.

Disease prevention is the key to public health. Parents need to be fully informed of the possible adverse effects and alternate immunization schedules. This can be accomplished by their health care personnel or through useful Web sites and timely communication.

I look forward to hearing from all of our witnesses today. I know that they are all moving in the right direction and I thank them for being here.

With that, I yield back.

Mr. BURTON. Thank you, Mr. Cummings.

Mrs. Davis.

Mrs. DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

Just to show that we work in a bipartisan manner, I have three committee meetings going on at 11 o'clock. So I will have to excuse myself, and I have to apologize that I won't get to hear the panel. But I will come back to the hearing as soon as I can.

Mr. BURTON. We'll give you information on the hearing as well.

Mrs. DAVIS OF VIRGINIA. Thank you.

Mr. BURTON. Mr. Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman.

Very briefly, I want to first of all thank you for calling this very important hearing. I have some great concern about these vaccinations. I remember Shay Beaker, a woman coming to see me at a constituent day in Lenore City, TN, and telling me about her son who was perfectly healthy until he was close to 1 year in age, and she took him for a DPT vaccination. At the time she came to see me, he was 2 years old, weighed 22 pounds, had continuous convulsions and seizures, projectile vomiting and all sorts of horrible things on a daily basis.

The Dyer family from Knoxville, TN, came to me and told me about their son, Andy Dyer, who's now 10 years old. When he was 2, he received a DPT vaccination and his family has been unable to get compensation, although there were 600 incidents from his batch 78 claims from his lot, 44 of them in Tennessee, including 3 deaths. This is a young boy who can't walk, can't talk, requires full time care, on a 24 hour basis. His family was told that his 48 hour symptoms were not severe enough, although he stopped suckling, he started continually flicking his ear and having small seizures right after this vaccination.

So I have great concern, and I'm looking forward to hearing from these witnesses. I think this is a program that is crying out for re-

form, just based on what I've heard from my constituents and from other people from around the country. So I look forward to the testimony of the witnesses, and I thank you for allowing me to be part of this hearing.

Mr. BURTON. Thank you, Mr. Duncan.

Ms. Norton, do you have an opening comment?

Ms. NORTON. Mr. Chairman, only to say that I think this is an important and timely hearing that you're holding. At a time when terrorism must cause us to encourage people to participate, especially as to children, and programs that provide needed vaccines, compensation in case of a mishap is very important.

But I hope that given the fact that we are probably going to see more and more children and more and more adults facing the necessity to take vaccines, I hope that this war we are in will spur us into more research, so that whatever fear there is of those vaccines that have caused problems to a few will not become a more generalized fear at a time when frankly, we can't afford that kind of fear.

But part of the reason for that fear is that these vaccines are not always as perfected as they might be. I think our country has done an extraordinary job, given the small number of injuries and deaths which in fact come out of vaccinations. Medical science is not perfect, and science is not perfect. But we have certainly gone very far in using vaccines to protect our own public.

Now as we hear that it may become necessary once again to vaccinate people against smallpox, and we know that there are, for a very small number of people, some serious side effects, we need to work harder than ever on making sure that those side effects are conquered and disappear, particularly when it comes to something like smallpox. We can't afford to have people saying against the smallpox, sorry, I don't want that vaccine. Because as we learned, one person unvaccinated can do great harm.

But the only way to instill confidence is not only to say to people, don't worry, if something happens, if your child dies, if your child is incapacitated, then there's compensation for you. That's the least we can do. We ought to use what we're going through now to do the kinds of stepped up research that will take away the fear, because we have reduced almost entirely the side effects and certainly the serious side effects or death from vaccine injury.

Thank you again, Mr. Chairman, for this important and timely hearing.

Mr. BURTON. Thank you, Ms. Norton.

Mr. Schrock.

Mr. SCHROCK. Mr. Chairman, I concur with Mr. Horn's opinion about opening statements, because we have to vote. I'm ready to hear the panel members. I'll have no opening statement.

Mr. BURTON. Thank you, Mr. Schrock.

Mr. Clay, do you have any comments?

Mr. CLAY. Yes, thank you, Mr. Chairman. It's a privilege to meet with the committee today.

I especially welcome the parents and spouses who are witnesses today. It is noted that all of the parents and spouses on the panel have family members who have suffered adverse effects as a result

of vaccination. Additionally, I welcome all other witnesses of the panels.

Mr. Chairman, my No. 1 focus, while I am in office, is children. I'm a father, as you are, and I'm especially grateful that you extend that parental concern through this committee. This hearing examines the injury compensation program and has the purpose of fairly and quickly compensating children who are injured by vaccines to decrease litigation against manufacturers, so as to encourage them to stay in the vaccine market.

Overall, the vaccine injury program has worked well. There are still some areas of concern within the program that must be adjusted. We know that the program is not perfect. The intent of this hearing today is to address those areas that need adjustment. And at this point, Mr. Chairman, I ask unanimous consent to enter this statement into the record.

Mr. BURTON. Without objection, so ordered. Thank you, Mr. Clay.

[The prepared statement of Hon. Wm. Lacy Clay follows:]

OPENING STATEMENT-REP WM Lacy Clay
Full Committee Hearing of the Committee on
Government Reform

THANK YOU MR. CHAIRMAN. I WELCOME THE OPPORTUNITY TO MEET WITH THE COMMITTEE TODAY. I ESPECIALLY WELCOME THE PARENTS AND SPOUSES WHO ARE WITNESSES TODAY. IT IS NOTED THAT ALL OF THE PARENTS AND SPOUSES ON THE PANEL HAVE FAMILY MEMBERS WHO HAVE SUFFERED ADVERSE EFFECTS AS A RESULT OF VACCINATIONS. ADDITIONALLY, I WELCOME ALL OTHER WITNESSES OF PANELS TWO.

MR. CHAIRMAN, MY NUMBER ONE FOCUS WHILE I AM IN OFICE IS CHILDREN. I AM A FATHER AS ARE YOU AND I AM ESPECIALLY GRATEFUL THAT YOU EXTEND THAT PARENTAL CONCERN THROUGH THIS COMMITTEE.

THIS HEARING EXAMINES THE INJURY COMPENSATION PROGRAM THAT HAS THE PURPOSE OF FAIRLY AND QUICKLY COMPENSATING CHILDREN WHO ARE INJURED BY VACCINES; TO DECREASE LITIGATION AGAINST MANUFACTURERS SOAS TO ENCOURAGE THEM TO STAY IN THE VACCINE MARKET; AND TO REASSURE PARENTS SO THAT THEY CONTINUE TO IMMUNIZE THEIR CHILDREN. I HAVE A TEN-MONTH OLD SON AND A SEVEN-YEAR

OLD DAUGHTER. EVERY DAY THAT I SEE AND HOLD THEM, I AM REMINDED OF THE NECESSITY OF IMMUNIZATIONS THAT KEEP THEM HEALTHY AND FREE OF DISEASES. TO YOU PARENTS AND SPOUSES WHO ARE WITNESSES TODAY, YOUR FAMILY MEMBERS COULD JUST AS WELL HAVE BEEN MY FAMILY MEMBERS. THIS IS AN AREA THAT MUST BE GIVEN ALL THE RESOURCES AND ATTENTION NECESSARY TO FIND SOLUTIONS.

OVERALL, THE VACCINE INJURY PROGRAM HAS WORKED WELL. THERE ARE STILL SOME AREAS OF CONCERN WITHIN THE PROGRAM THAT MUST BE ADJUSTED. WE KNOW THAT THE PROGRAM IS NOT PERFECT. THE INTENT OF THIS HEARING TODAY IS TO ADDRESS THOSE AREAS THAT NEED ADJUSTMENT.

At this point, I ask unanimous consent to enter my statement into the record.

Mr. BURTON. I apologize to the panels, we will get to you just as quickly as this vote is concluded. We have a vote on the floor, so we will recess the committee and be back here in about 10 or 15 minutes and we'll go to the first panel immediately upon our arrival. Thank you.

We stand in recess.

[Recess.]

Mr. BURTON. The committee will come to order.

I'd like to now have the first witness panel, Mrs. Janet Zuhlke, Mr. Harold Sword and Thad Rogers, please come to the witness table.

It's customary that we swear in our witnesses, so would you raise your right hands, please?

[Witnesses sworn.]

Mr. BURTON. Be seated.

I think Dr. Weldon wants to introduce you, Ms. Zuhlke, so we'll let you speak after he returns. He's on his way back. So we'll start with Mr. Rogers. Do you have an opening statement, Mr. Rogers? If you could, we want to ask questions, so if you could keep your statements as close to 5 minutes as possible, we'd appreciate it. But go ahead, take your time. Mr. Rogers.

STATEMENTS OF THAD ROGERS, AUBURN, AL; HAROLD SWORD, COLUMBUS, OH; AND JANET ZUHLKE, SATELLITE BEACH, FL

Mr. ROGERS. I'm glad we finally got to be here, because you all kept postponing everything on us, and we finally got to make it.

My name is Thad Rogers, and my wife was—her life was destroyed by a tetanus shot—tetanus vaccine. Before the vaccine, my wife bowled, coached basketball and softball, and played tennis with our daughter. She was just a normal, healthy human being.

She did the motherly thing, drove our son and daughter to activities they were involved in, basketball, softball, soccer, tennis, Boy Scouts and Girl Scouts. She did all the household activities like a wife would do. We also fished as a family, we did everything together as a family.

My wife had a vaccine on February 15, 1991. During the summer of 1991, she became unable to drive or do any kind of household work. I had to start taking the kids to the activities and learn how to do housework and cook and do everything else most husbands don't know how to do. At this time, my wife's health was getting worse. Her body was just deteriorating.

We took our last family vacation in the summer of 1996. Ever since then, she has not been able to get out of bed by herself or basically leave the house. She's in diapers. And right now, she's on a catheter, because she's on a special air bed. Someone has to be with her around the clock to feed her, give her medicine, change the diaper, empty the catheter bag.

Since 1997, she's had bed baths, hasn't been able to take a full bath basically since she's been sick. And my kids, they help take care of my wife when I'm at work. Our daughter is in her 4th year of college and our son is in his 2nd year. Soon they'll be starting their own lives, and like I said, they help me take care of her.

In January 2001, my wife got a bed sore. She's been in a special air bed since then, has not been out of it since January. The bed sore requires dressing twice a day to twice a week, whenever it's necessary. Generally, life with her has been extremely hard. I guess you'd say she's real hard to get along with because of the illness. She snaps at everybody, this, that and the other. It's just been hard, it really has.

That's all.

[The prepared statement of Mr. Rogers follows:]

Testimony of:
Thad Rogers

U.S. House of Representatives
Committee on Government Reform
"The National Vaccine Injury Compensation Program,
Is it Working as Congress Intended?"

The Circumstances surrounding the vaccine injury that affected our family:

Before the vaccine my wife bowled, coached basketball, softball, and played tennis with our daughter including two sets February 10, 1991. She drove our son and daughter to activities they were involved in, including basketball, softball, baseball, soccer, tennis, boy and girl scouts. My wife did household activities. We went fishing as a family. My wife had the vaccine on February 15, 1991. During the summer of 1991, she became unable to drive and do housework. I had to start taking the kids to their activities and do the housework. My wife's health was getting worse. We took our last family vacation in the summer of 1996. During 1997, my wife was unable to get out of bed by herself. Someone had to get her out of bed. She became unable to get to the bathroom and has been in diapers since, except when she had a catheter. Someone had to be with her everyday to feed her and give her medicine, changer her diaper or empty her catheter bag. She has had bed baths since 1997. My kids help take care of my wife when I am at work. Our daughter is in her fourth year of college and our son is on his second year of college. Soon they will be starting their own lives. January 2001 my wife got a bed sore, and has not been out of bed since then. The bed sore has required dressing changes twice a day, to twice a week. My wife has been on a rental air bed since January. Life has been hard in our home.

How we became aware of the compensation program:
A lawyer informed us about the Vaccine Injury Compensation Program.

When the claim was filed and how long it took to be resolved:

The petition was filed on February 15, 1994. The court concluded that the petitioner was entitled compensation for her vaccine related injury in June of 2000. The case was appealed in September 2001. The case has not been resolved.

Sincerely,
Thad Rogers

Mr. BURTON. Did you want to make any comment, Mr. Rogers, about the compensation fund at all? Did you receive anything from the compensation fund, for the damage that was done by the vaccine? Did you receive any money from them?

Mr. ROGERS. We have not received anything.

Mr. BURTON. Have you applied for that?

Mr. ROGERS. We filed in 1994.

Mr. BURTON. What happened? Can you just tell us a little bit about that?

Mr. ROGERS. Well, you go through the process, and we had a phone conference with a special master and different lawyers. But in June 2000, we got word that the court concluded that my wife was entitled for help. But of course, they needed to know, I guess you'd say like dollars and cents, what was required to take care of her. Because I've been taking care of her out of my pocket the whole time, except for the insurance part.

And in September 2001, the case was appealed. And we haven't heard anything since then.

Mr. BURTON. OK, we'll ask you some questions about that in just a few minutes.

Mr. Sword.

Mr. SWORD. Thank you, Mr. Chairman.

My name is Harold Sword. I am a lifetime resident of Ohio, a product of Ohio schools and colleges, a veteran of the U.S. Navy, father of six and grandparent of nine. Following the Navy I served a 6-year union apprenticeship, attended school while raising my family and I have worked for 40 years in the newspaper printing industry.

Before I begin, I would like to thank the committee for its work and attention to vaccine injury. I would also like to say that I have no bias against vaccine as a medical treatment as long as it is safe. When vaccine produces something other than safe, I think we are all diminished.

I'm here to discuss vaccine injury because my daughter, Natalie Nicole Sword, died of vaccine injury on her birthday at 3 months of age on May 13, 1975, just 4 hours after a childhood DPT vaccination as part of a normal 3 month exam by her doctor. At the time of Natalie's death, there were no requirements to warn parents of adverse vaccine reactions, despite 30 years of documented medical knowledge and research going back into the 1940's of the dangers. We were told, "she will be sleepy and that is normal."

Consequently, after leaving the doctors' office, on the trip home that included a quick stop for ice cream and to pick up a grape vine, we drove near or past seven hospitals and nearly a dozen other emergency medical sites on the route home. Natalie never awoke from the deepening slumber that started around noon while still in the doctor's office. Unconcerned with the slumber, we allowed her to sleep next to us in a bassinet before discovering Natalie not breathing and blue.

During our frantic efforts to revive Natalie, I spoke twice to her doctor by phone, commenting to him, "there was something in that shot that caused a reaction." Just 4 hours after his examination of Natalie, her doctor's immediate response to me was denial, saying,

"No, it wouldn't be the vaccine, call me as soon as you get to the hospital."

The hospital offered no opinion on cause after talking to the doctor upon our arrival in the unequipped county sheriff's emergency vehicle through miles of major highway construction. That denial continued in a meeting to review the cause of death with Natalie's doctor 2 weeks later, following the autopsy.

Sadly, and outrageously, 30 years after a published article on the vaccine deaths of twin boys in the 1940's, Natalie had died a similar death without warning. Who is at risk, how to know, and is there ever a "morally acceptable" risk of death or injury to any child, even as a well intended protection, but especially without ever knowing of the risk?

Yet, completely ignoring the vaccine, we were told by the doctor that performed the autopsy, the coroner, physician and public health officials that the cause of Natalie's death was something that we had never heard of called SIDS, sudden infant death syndrome. Webster's dictionary describes SIDS as being an unknown cause.

However rare, effected families have both a right and a real need to know the truth about vaccine problems. Morality and law should require accurate reporting of cause in public records when vaccines could be a factor in any injury or death, and information should be provided on the vaccine injury program. More accurate reporting alone could help reduce costs and controversy in the vaccine injury claims.

In Natalie's case, it was 15 years before we even started to learn the truth, and then it was a result of chance, when a co-worker who was deaf noticed a wire story of a deadline for filing vaccine injury claims as we worked on the next newspaper edition. Prior to that article, I knew nothing about a vaccine injury program. I had lived with my suspicions, attending SIDS support groups alone, because Natalie's mother had a whole different approach to her grief.

I found SIDS logic did not work for me. Although I had strong doubts about the "SIDS cause of death" ruling, I had not sought legal counsel. Filing suit seemed to be an impossible option because of the SIDS ruling. I did not want to complicate our grief, did not want to hurt the doctor, feeling that nothing we could do would bring Natalie back.

I now suspect many people have reacted that way, contrary to Government agency adversarial attitudes toward those who managed to discover the Vaccine Injury Compensation Program and file claims. Once we found the program late in July, I collected the information and suit was filed near the end of the deadline.

However, the suits were separated into two classes by time, and there were many suits filed in the pre-1988, creating a huge backlog of cases. From the outset, that volume was a problem for everyone. How that was handled was to wait for the system to get to your case. By the end, for our claim and others, it became an uneven legal field, because attorney fees and expenses for expert witnesses and awards all remained under a cap of mid-1980 dollars, and inflation eroded all three.

The inflation erosion of attorney fees and expert witnesses allowance created limits on resources for claimants that were in the system for the longest time and also altered the equality of the award for those who had to endure to the end. Meanwhile, as far as I knew, there were no similar limits on Government's ability to contest claims. Could that happen again if mass vaccines had to occur for any reason?

While time and adversity were problems for the claimants due to the specific limits, time and adversity became a windfall for what became the other side. For my family, there developed a clear sense of a "betrayal of trust" by our Government's agents as time passed. Advocates and other claimants I came in contact with believed Government was supposed to conduct the Vaccine Compensation Program as adversarial, timely and generous. That was not the way it was handled by my experience, nor was it the experience of some that I heard of.

In Natalie's case, years went by, hearings came and went, and adversity grew as Government experts came with several other possible alternate causes of death that did not agree, not even with one another. It seemed like any answer except vaccine was a possible cause of death and a reason to litigate further, because they could. Neither the circumstances nor the valid evidence nor the experts opinion that were paid for by the program were of any value in resolving that adversity and served at best only to keep the claim alive within that system.

As more time passed, the more hearings, the more experts, the more adversity, the more inflation eroded both the resources to continue the claims and the original value of the awards, Government agents had the budget resources and could just run out the clock. In our case, we struggled to come up with the money rather than to lose the claim. At one point late in the process, we had to unexpectedly change expert witnesses due to problems unrelated to the claim. We had to sacrifice quickly and come up with retainer money for that replacement expert witness. We lost over $1,000 on the first retainer, money we were never able to recover.

By that time we were single parents with split custody, and struggling with post-divorce finances. For both of us, it was a lot of money to fly and lodge separately in order to attend and testify in Boston, and later to attend the appeals court hearing here in Washington. Once the appeals court ruled, and mercifully there was not a further appeal, the judgment was paid within a reasonable time.

By the end, I am sure Natalie's claim went well over the vaccine injury program's limit on both attorney costs and expert witness costs. I paid $10,000 from my portion of the judgment award for experts we used. I'm sure I paid only a portion of those expenses and none of the attorney firm's real costs. Yet when I asked, our attorney, Ron Homer, declined saying, "you've been through enough, that money should belong to you and your family."

I feel all things combined created something other than what was intended in good faith by Congress. I doubt those disadvantages or disparities for claimants were due to any valid intent on the part of Congress; but they may suggest ongoing oversight.

When an unexpected injury does occur, I can tell you from experience the last thing a family needs is a misguided lack of information or a complicated ordeal, compounded by adversity. What families do need is a reliable safety net. For my family, however, the outcome will not be happily ever after. I will always wonder the true effect Natalie's death had statistically or otherwise on our family.

Not long after the vaccine injury claim was filed, Natalie's mother became despondent and expressed feelings of hopelessness. Unexpectedly, we separated. During the counseling that followed, she was diagnosed with depression. But in denial, she declined treatment. A domestic meltdown followed, with problems especially for the children. I'm old enough to know that there have been many factors in those matters. But in families, there can be complicated social side effects surrounding vaccine injury that have little to do with the original event, affecting entire families for a long time.

We are urged by the origins of faith and morality to "love our neighbor." In fact, we are told in Scripture that "love is the law's fulfillment." I urge each of you to consider carefully and tenderly the lives of those who are touched by vaccine injury and this vaccine injury program.

Again, I appreciate the opportunity to share this information with you. In my daughter's memory, I pray it contributes something useful and helps all of us somehow. Thank you.

[The prepared statement of Mr. Sword follows:]

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U.S. House of Representatives
Committee on Government Reform

RE: "The National Vaccine Injury Compensation Program, Is it working as Congress Intended?"

My name is Harold Sword. I am a life long resident of Ohio, a product of Ohio schools and colleges, a veteran of the U.S. Navy, father of six and grandparent of nine. Following the Navy I served a six-year union apprenticeship, attended school while raising my family and I have worked for 40 years in the printing/newspaper industry.

Before I begin, I would like to thank the committee for its' work and attention to vaccine injury. I would also like to say that I have no bias against vaccine as a medical treatment, as long as it is safe. When vaccine produces something other than safe, I think we all are diminished.

I am here to discuss vaccine injury because my daughter Natalie Nicole Sword died of vaccine injury on her birthday at 3 months of age, on May 13,1975, just 4 hours after a childhood D.P.T. vaccination as part of a normal 3 month exam by her doctor. At the time of Natalie's death there were no requirements to warn parents of adverse vaccine reactions despite thirty years of documented medical knowledge and research going back into the 1940's of the dangers. We were told, "she will be sleepy and that is normal". Consequently, after leaving the doctors office on the trip home that included a quick stop for ice cream and to pick up a grape vine, we drove near or past seven hospitals and nearly a dozen other emergency medical sites on the route home.

Natalie never awoke from the deepening slumber that started around noon while still in the doctor's office. Unconcerned with the slumber we allowed her to sleep next to us in a bassinet before discovering Natalie, not breathing and blue. During our frantic efforts to revive Natalie I spoke twice to her doctor by phone. I commented to him "There was something in that shot that caused a reaction". Just four hours after his examination of Natalie, her doctor's immediate response to me was denial saying " No, it wouldn't be the vaccine, call me as soon as you get to the hospital".

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Yet, completely ignoring the vaccine, we were told by; the doctor that performed the autopsy, the coroner, physician and public health officials that the cause of Natalie's death was something we had never heard of, called S.I.D.S. (Sudden Infant Death Syndrome). Webster's Dictionary describes S.I.D.S. as being an unknown cause. However rare, effected families have both a right and a real need to know the truth about vaccine problems. Morality and Law should require accurate reporting of cause in public records when vaccines could be a factor in any injury or death and information should be provided on The Vaccine Injury Program. More accurate reporting alone could help reduce costs and controversy in vaccine injury claims. .

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Once we found the program in late July, I collected the information and suit was filed near the end of the deadline. However the suits were separated into two classes by time and there were many suits filed in the pre-1988 group creating a huge backlog of cases. From the outset that volume was a problem for everyone. How that was handled was to wait for the system to get to your case. By the end, for our claim and for others it became an un-even legal field, because attorney fees, expenses for expert witnesses and awards all remained under a cap of mid-1980 dollars and inflation eroded all three. The inflation erosion of attorney fees and expert witness allowances created limits on resources for claimants that were in that system for the longest times and also unfairly altered the equality of the value of the awards to those who had to endure to the end. Meanwhile, as far as I know, there were no similar limits on our government's ability to contest the claims. Could that happen again if mass vaccines had to occur for any reason?

While time and adversity were problems for the claimants due to the specific limits, time and adversity became a windfall for what became "the other side". For my family there developed a clear sense of "a betrayal of trust" by our government's agents as time passed. Advocates and other claimants I came in contact with believed government was supposed to conduct the vaccine compensation program as non-adversarial, timely and generous. That was not the way it handled by my experience, nor was it the experience of some I heard of. In Natalie's case, years went by, hearings came and went and adversity grew as government experts came with several other possible alternate causes of death that did not agree, even with one another. It seemed like any answer, except vaccine, was a possible cause of death and a reason to litigate further, because they could. Neither the circumstances or the valid evidence, nor the expert opinion's that were paid for by the program were of any value in resolving that adversity and served at best only to keep the claim alive within that system.

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Not long after the vaccine injury claim was filed, Natalie's mother became despondent and expressed feelings of hopelessness, unexpectedly we separated. During counseling that followed she was diagnosed with depression, but in denial she declined treatment. Domestic meltdown followed, with problems, and depression, especially for the children.

I'm old enough to know there have been many factors in those matters and but in families there can be complicated social side effects surrounding vaccine injury having little to do with the original event effecting entire families for a long time. We are urged by the origins of faith and morality to "Love our neighbor" in fact we are told in scripture "that love is the laws fulfillment". I urge each of you to consider carefully and tenderly the lives of those who are touched by vaccine injury and this vaccine injury program.

Again, I appreciate the opportunity to share this information with you. In my daughter's memory, I pray it contributes something useful and helps all of us some how. Thank You

Mr. BURTON. Thank you, Mr. Sword.

Dr. Weldon, do you want to introduce Ms. Zuhlke?

Dr. WELDON. Thank you, Mr. Chairman.

I want to again welcome Janet Zuhlke for coming here. We're all looking forward to your testimony. I think it's very important, and I commend you for your willingness to come and provide the information about your experience with the vaccine injury program.

Mr. BURTON. Ms. Zuhlke.

Ms. ZUHLKE. Thank you, Mr. Chairman. Thank you, Congressman Weldon.

I appreciate the opportunity to be here. My name is Janet Zuhlke. I was invited here today concerning my daughter, Rachel Anne. Rachel was adversely affected by her immunization at the age of 5. Rachel will be 17 this December. She suffers from seizures, mental retardation. I must bathe my daughter, take care of all of her personal needs, dress her, help her with feeding.

Rachel was declared eligible for compensation in June of this year. We are now in the life care planning evaluation process. The circumstances surrounding her injury are basically the same. It was Thursday, March 1, 1990. Rachel again was 5 years old. I had taken her to see her pediatrician, Dr. Richard O'Hern, as a well child, so that she could receive her DPT and OPV immunizations.

Within 6 hours of her immunizations, she was displaying alarming symptoms that were unknown to me, specifically, vomiting and complaining of severe eye pain. Fever and soreness at the injectionsite were also present, but those were not unusual to me as a parent. Rachel is my middle child, I have an older daughter and a younger one as well. This was just different.

On Friday, March 2nd, I phoned the doctor's office, expressing concern about the vomiting and the eye pain. I was told it was unrelated to the vaccines and to give the office a call on Monday if her symptoms had not subsided.

Over the weekend, Rachel's vomiting had stopped, but she was still complaining of severe eye pain, and she had become lethargic, very abnormal for Rachel Anne. I was concerned with Rachel's lack of energy and the issue of the persistent eye pain, so much so that when the doctor's office opened on Monday, I was waiting at their door with my daughter.

Rachel was seen by a nurse practitioner who diagnosed strep throat. There were no signs being exhibited of sore throat, runny nose, enlarged lymph nodes. She still had a low grade temperature. Again, a misdiagnosis.

Over the next 20 days, Rachel became much more lethargic and complained continuously of eye pain. The severity of her condition became so apparent to me that I phoned Dr. O'Hern on that Sunday night, and he agreed to meet us in the emergency room at our local facility. Upon completing his examination of Rachel, he told me that something was affecting her central nervous system, that she would need to be admitted and tests would need to be performed.

During that time, a barrage of questions came to me concerning could the child have ingested any household chemicals, pharmaceuticals, etc. It became more apparent in discussion with her pediatrician that the symptoms were the same as she presented on the

March 5th visit, but with more acuteness. Rachel was air evacuated to Shand's Hospital at the University of Florida in critical condition.

The way I learned about the NVIC program was through Dr. O'Hern. He apparently had checked with the drug manufacturers concerning the lot numbers on the serums that my daughter was given. He was told that there were no other reported cases. It was at that time that he informed me of the NVIC. Rachel's diagnosis then and to date has continued to maintain itself as post vaccine encephalitis.

Filing the claim, I found an individual named Mr. Clifford Shoemaker out of Vienna, VA. I read an article in a newspaper by a family that had been affected as well. The mother was gracious enough to speak with me and give me this gentleman's name. Mr. Shoemaker has been representing Rachel since 1991, when her claim was filed.

Although Rachel is eligible, she has not received any compensation for her injuries. All expenses have been out of pocket, from my family. And as you stated in your opening, sir, I am now going through receipts and trying to obtain this information so that I can be compensated for my out of pocket. In the first 5 years alone, and again, I'm almost going into my 11th year now, I have documented bills showing over $25,000.

Again, I was asked about observations regarding the effectiveness of this program. I also have great respect for immunizing your children. I still to this day think that is a very valuable thing that we must do. I have never fought through a drug manufacturer, nor have I had any sort of confrontation with Dr. O'Hern. I think he was doing his job. I think Rachel was given a drug that she should have been given, I just feel very badly that it turned out as tragically as it did.

In addition to the regular medical exams, Rachel has had at least 30 medical emergencies which include numerous air evacuations and critical care. Every visit and incident that my daughter has undergone, I have had to provide to the Department of Justice information concerning those admissions. And as you can imagine, over time, she would have an episode, if you will, of one neurological dysfunction or another and we would get past that, I would submit that information and my child would neurologically fail again, and I then had to go back through and again provide information concerning that particular episode. It has been a never ending story.

She still has problems. She still requires hospitalizations, and I still to this day am required to submit all medical records and information to the Department of Justice. It's time consuming and it is not cost effective. I have had issues where I have been in conversation with, I'll give an example of delays. Over the years there have been many, many deadlines given. I've been in status conferences with the special masters. Again, my daughter has had four.

During one of these specific conferences, the Department of Justice was not prepared and they requested an extension of time. These extensions are not for days or even weeks. These extensions were for months at a time. I found that unacceptable. We could go

9 months easily without anything being done. And yet we'd come back to the status conference and again, the individual was allowed to have another deadline.

I got so exasperated at one point, and again, I'm speaking to the special master, I didn't show much grace. I was very upset, I voiced my opinion, when is a deadline a deadline. I was not given an answer on that question.

The ongoing impression I had and still have is that the Department of Justice made little effort to prepare for these deadlines. Since they were never challenged or commanded to do so, they knew the delay would be granted. There was never any sense of urgency and even after rescheduling, the DOJ often was still not prepared. Again, I find that unacceptable.

I would like to say, of the four special masters, Rachel had one, the first was for 5 or 6 years. The next was for 2 to 3. She's had two in the last 2 years. May I mention names, sir? It's Chief Special Master Golkowitz, actually, that was extremely helpful to my family. For the first time in many, many years, I felt like possibly seeing a light at the end of the tunnel. He was the gentleman you referred to before that had to recuse himself. He actually came to me after the very first hearing, which was supposed to be a mediation hearing, where the parties had come together on the assumption that we are going to agree.

We went through the whole day, got finished, and the DOJ said, sorry, we offer you no settlement. He was incensed, to say the least. He found me in the lobby, you know what his words were, you repeated them before. He was ashamed. He was absolutely ashamed of how everything had transpired, and told me that he was sorry, but he was no longer impartial to be able to help me. He was no longer impartial.

So we were passed on to a fourth special master who this gentleman is Master Hastings. Master Hastings has finally helped my family to a conclusion. And I'm very grateful.

The adversarial aspects of this I think are just sad. I think Rachel has been treated basically like a criminal, like she's done something wrong, which is not the case. In spite of the early diagnosis that Rachel had experienced, severe central nervous system damage, specifically post vaccine encephalitis, the DOJ attorney repeatedly attempted to suggest alternative theories of the cause of her injuries. At one point, one of the experts for the DOJ actually stated that it must have been a virus that was in the community.

In June 1999, Rachel's pediatrician, a doctor who has been with her since birth, gave a deposition. That same day, her pediatric neurologist also gave his deposition. Both physicians gave unequivocal testimony that it was their medical opinion that Rachel's injuries were directly caused by her vaccine. Yet in spite of that testimony, the DOJ attorney recommended to the third special master that the Government offer nothing.

The adversarial process continues to this day. We are now in the life planning process. A life planner has come in for Rachel Anne. She has commenced the evaluation and the estimation of Rachel's lifetime care costs. The DOJ has appointed another life planner, who I have still not heard one word from. The young lady has come forward on Rachel's behalf to help. She's prepared, she's ready. I

still haven't heard a word from the DOJ. I don't have an appointment time set up. I have nothing. And this is November 1st, and this process has been ongoing since July. Not even a phone call. Again, I find that unacceptable.

The best evidence of the adversarial process, I think, is in the last line of the decision of the special master. He stated that Rachel's eligibility is "a table injury encephalopathy." That is essentially the same diagnosis that was made 11 years ago by her pediatrician and ongoing immunologists and neurologists at Shand's Hospital.

In my opinion, the DOJ's mission is to investigate crime, prosecute criminals and enforce the law. Litigation is their primary tool. The NVICP is based on a medical determination. I don't think the DOJ is the correct agency to make medical determinations.

Based on my experience, I do not believe the program is working as Congress intended. I've read the proposed changes to the current law, and I very much support those proposed changes. In addition, I have three recommendations. I think a total time line for the entire eligibility determination process to be resolved, a fixed deadline, is needed. I think we need to redefine the goals for the process, ensure those goals include a sense of urgency and a total focus on making a compassionate medical decision.

And again, as Harold was explaining, you've got to understand, it does not just affect the child. It affects the entire mechanics of your whole family. My 15 year marriage also fell apart from a unit that I thought was very strong. My other two children have suffered as well, not being able to do the things, possibly because of what their sister's needs were. And I, sir, have not taken a family vacation with my children in 11 years, because there's not the money to do that. Because I have spent every dime on Rachel's medical needs. And again, to this day, have not received one penny in reimbursement.

My third recommendation, and I'll be finished, I think you should create a regular independent oversight to ensure that the process is achieving the intent of providing a fair, expeditious and generous outcome to the families.

Again, I appreciate the opportunity to be here and for the efforts that you are making for families like mine and for the other people that have graciously appeared today. Thank you.

[The prepared statement of Ms. Zuhlke follows:]

Janet Zuhlke

Testimony for the Committee on Government Reform

Good Morning,

My name is Janet Zuhlke and I was invited here today concerning my daughter Rachel Anne. Rachel was adversely affected by her immunization at the age of 5. She will be 17 this December. Rachel was declared eligible for compensation in June and we are now in the Life Care Planning evaluation process.

CIRCUMSTANCES SURROUNDING THE INJURY

On Thursday March 1, 1990 Rachel was seen by her pediatrician Dr. Richard O'Hern, as a well child to receive her DPT and OPV immunizations so that she could start kindergarten. Within 6 hours of her vaccinations she was displaying alarming symptoms unknown to me to be associated with the immunizations. Specifically, she was vomiting and complaining of eye pain. Fever and soreness at the injection site were also present but were not unusual to me as a parent.

On Friday, March 2, I phoned the Dr.'s office expressing concern about the vomiting and eye pain. The receptionist told me that they were unrelated to the vaccines and to give the office a call on Monday if she did not improve over the weekend.

Over the weekend, Rachel's vomiting stopped but she was still complaining of eye pain and had become lethargic. I was concerned with Rachel's lack of energy and the issue of persistent eye pain so much so that when the Dr.'s office opened on Monday, we were waiting at their door.

Rachel was seen by a Nurse Practitioner, who diagnosed strep throat. A throat swab, which was not cultured (a less accurate method than a culture), was seen as positive. Rachel did have a low -grade temperature, but exhibited no signs of sore throat, runny nose or enlarged lymph nodes.

Over the next 20 days Rachel became much more lethargic and complained continuously of eye pain. The severity of her condition became so apparent to me that I phoned Dr. O'Hern and he agreed to meet us in the Emergency Room at our local hospital.

Upon completing his examination of Rachel he told me that something was affecting her Central Nervous System and that tests would need to be performed to assess the clinical situation. She was admitted and a barrage of questions began concerning the probable cause of her illness. When it was determined

that it was not due to her ingesting any household chemicals or pharmaceuticals it became more apparent in discussion, that the symptoms were the same as she presented on the March 5th visit, but with more acuteness.
Rachel was air evacuated for the first time to the University of Florida Shand's Hospital I Gainesville, Florida for evaluation and possible treatment by Neurosurgeons there.

LEARNING ABOUT NVICP

Rachel's pediatrician, Dr. O'Hern checked with the drug manufacturers concerning the lot numbers of the serums that she received. He was told that there were no other reported cases. It was at this time that he informed me of the NVICP. Rachel's diagnosis was listed as Post Vaccine Encephalitis.

I found information about the program, and through a newspaper article I read about a family with similar problems who had been compensated through the NVICP. I tracked down that family and by telephone conversation with the mother, I received information about the law office of Cliff Shoemaker in Vienna, VA.

FILING THE CLAIM AND TIME TO RESOLUTION

Mr. Shoemaker has been representing Rachel since 1991, when the claim was filed. Although Rachel is "eligible", she has not received any compensation for her injuries. The matter is still not completely resolved after almost 11 years of litigation.

OBSERVATIONS REGARDING THE EFFECTIVENESS OF THE PROCESS

I will discuss documentation requirements, delays and extensions, costs of producing documentation, delays in reimbursement, the presence of 4 special masters, and the adversarial process.

Documents and Costs

- In addition to regular medical examinations, Rachel had at least 30 medical emergencies, including numerous air evacuations in critical condition. Every visit and incident required the production of every document, report, X-ray, MRI, etc., for the DOJ atty. Producing these documents was time consuming and expensive. I took this very seriously, in the belief it would help Rachel and hasten the process to determine her eligibility.
- This was not the case. The document production process seemed endless. With each new exacerbation of her disease process I was expected to provide all new medical records. As soon as one medical emergency wa-

covered she would fail neurologically again and the process would start all over. I could never receive feedback from the Govt. atty. as to whether sufficient data had been produced.

- I was told that I would be reimbursed for these documents by the DOJ. I had to borrow money from my parents and the costs amounted to thousands. As an example, for one examination I used my credit card for MRI films at a cost of about $492. I submitted the films and copies of the hospital invoices and the Visa card invoice. After, 6-8 weeks I began to call to find out the status of reimbursement and was repeatedly told.."it is being processed". Finally, a clerk told me the claim was not valid unless the "original" invoice was in their files. I was told this was a requirement of the DOJ. Eventually, after a specific follow up by my atty. the check was received, another 3-4 months later.

Delays

- Over the years many deadlines have been set by the Special Masters for updates on the case via status conferences. Repeatedly, over the past 10 years, I was advised either in writing or verbally by Rachel's attorney that the DOJ was not prepared for the conference and had requested an extension of time. These extensions were not for days and weeks of time, but for months. Extensions of time were granted with such frequency that at times a full 9 months would go by with no progress of any kind.
- For example, I participated in one particular conference call with the special Master, Rachel's attorney and the attorney for the DOJ. During this call the DOU claimed not to have the necessary materials and asked the Special Master for a delay. The delay was granted, without question. I was extremely upset and voiced my opinion.."when is a deadline a deadline?". No answer was given.
- The ongoing impression I had, was that the DOJ made little effort to prepare for these deadlines and since they were never challenged or commanded to be ready, they knew the delay would be granted. There was never any sense of urgency and even after rescheduling the DOJ often, was still not prepared.

Costs

- To date Rachel has received no compensation or reimbursement for any ongoing medical care.

Special Masters

- Four Special Masters have been assigned to supervise the determination process for Rachel. The first was on for 5-6 years, another for 2-3 years, then 2 in the latest 2 years. Every change, except the last, created further delay to bring the new Special Master "up to speed" on the case.
- The handoff from the 3rd to the 4th was beneficial, as it was the 3rd Special Master who fully comprehended and grasped the situation. He forced progress. That (3rd) Special Master selected the next and it is my opinion that he encouraged the new one to bring the matter to a rapid conclusion
- I am very, very grateful for his assistance.

Adversarial Process

- Although Rachel is not a criminal, the process often made it seem so. I will offer three examples.
- In spite of the early diagnosis that Rachel had experienced severe central nervous system damage, specifically Post Vaccinal Encephalitis, the DOJ atty. repeatedly attempted to suggest alternative theories of the cause of her injuries. The initial misdiagnosis of possible strep, was the DOJ's focus. We were continually placed in the position of trying to prove there was not some other cause. I do not know how to prove that something did not happen.
- In June of 1999, Rachel's pediatrician, a doctor who has been with her since birth, gave a deposition. That same day, her pediatric neurologist also gave a deposition. Both physicians gave unequivocal testimony that it was their medical opinion that Rachel's injuries were directly caused by her vaccine. Yet, in spite of that testimony, the DOJ attorney recommended to the 3rd special master that the government offer nothing.
- At the direction of the Special Master, we are now in the Life Planning process. The adversarial process continues to this very day. A life planner for Rachel has commenced the evaluation and estimation of Rachel's lifetime care costs. The DOJ has appointed another Life Planner who is know in the "trade" to be confrontational and to undervalue the costs. I have no problem with a legitimate "second opinion", however, I have been forewarned that this life planner's mission is to undercut and minimize the overall estimated costs and to expect several months delay.
- The best evidence of the adversarial process is in the last line of the decision of the Special Master. He stated that Rachel's eligibility is a "Table Injury encephalopathy". That is essentially the same diagnosis made 11 years ago by Dr. O"Hern.
- In my opinion the DOJ's mission is to investigate crime, prosecute criminals and enforce the law. Litigation is their primary tool. The NVICP is based

on a medical determination. The DOJ is not the correct agency to make medical determinations.

RECOMMENDATIONS

Based on my experience, I do not believe the program is working as Congress intended. I have read the proposed changes to the current law and I very much support those proposed changes. In addition, here are three recommendations.

1. Set a total timeline for the entire eligibility determination process to be resolved. A fixed deadline is needed.

2. Redefine the goals for the process. Ensure those goals include a sense of urgency and a total focus on making a compassionate medical decision.

3. Create regular, independent oversight to ensure that the process is achieving the intent of providing a fair, expeditious and generous outcome.

I hope these recommendations will be taken seriously.

I very much appreciate the opportunity to speak today.

I will answer any questions you may have.

Thank You

Mr. BURTON. Thank you. I want to thank all three of you. I know it's very difficult for you to be here and for you to testify about your family's problems. I can assure you that we will be overseeing the Justice Department on a regular basis as long as I'm the chairman. I don't know about my colleagues, but I will be talking to people at the Justice Department, including, when Mr. Ashcroft gets some time, with the tragedy that's going on here, facing the country, to discuss this as well.

Let me start with you, Ms. Zuhlke. In his written testimony, which we have before us, and we'll hear from Mr. Harris in a little bit, Mr. Harris says that most of the people who complain about the program are people who lost their cases. He says, "I believe it is the denial of scientifically unsupported petitions that may give rise to complaints about the program."

Did you win your case?

Ms. ZUHLKE. Yes, sir.

Mr. BURTON. How long did it take?

Ms. ZUHLKE. 10 years.

Mr. BURTON. You mentioned the complaints about the program, so I'll skip that. Have you talked to other families with similar complaints?

Ms. ZUHLKE. No, sir. I personally do not know other families with children who have been affected.

Mr. BURTON. Mr. Sword, did you win or lose your case?

Mr. SWORD. We finally won our case on appeal.

Mr. BURTON. So they fought you all the way through to the appeals process?

Mr. SWORD. Yes.

Mr. BURTON. How long did that take?

Mr. SWORD. We filed the claim when I discovered the information in the fall of 1990. And the final hearing for the appeals was in the spring of 1999, and we were paid in August 1999.

Mr. BURTON. So it took over 9 years?

Mr. SWORD. Yes.

Mr. BURTON. What kind of complaints do you have about the program?

Mr. SWORD. I don't think it's compassionate enough. I think truthfully that the States need to be comfortable with mandating these vaccines. And I think that the public needs to be assured that the vaccines are both safe and if there is a rare reaction, that there is a mechanism there as a safety net for them to turn to.

One other thing I would say is, I don't think there's enough information provided to families about either the dangers of vaccines, or I don't think there's enough provided about the options available to them when some kind of a question about a vaccine incident does occur. And I also think there's a problem with public records and the reporting that goes on in those areas.

Mr. BURTON. Have you talked to any other families that have similar complaints?

Mr. SWORD. I went to a vaccine conference here in Washington sponsored by the National Vaccine Information Center in, I think it was September 1997. I met many families at that conference. Since then, I've talked also with people in the State of Ohio, there is an advocacy organization in the State of Ohio, and I was asked

to testify to the Ohio Legislature when they were considering mandating Hepatitis B. I told our story basically.

And I met people that ranged from people with children to people that were adults. I heard a story about a volunteer fireman who was similarly affected and couldn't get a medical diagnosis. Many of these people are left in limbo. As I said in my testimony, I think many people either don't know or simply don't approach the program for a variety of different reasons.

Mr. BURTON. Mr. Rogers, I know the Government is now appealing your case. But when the special master made his decision last year, did you win or lose?

Mr. ROGERS. Won.

Mr. BURTON. You won?

Mr. ROGERS. Yes, sir.

Mr. BURTON. But the Government, the Justice Department, is appealing your case?

Mr. ROGERS. Yes, sir.

Mr. BURTON. How long did it take before you won initially?

Mr. ROGERS. Like I said, we started February 15, 1994.

Mr. BURTON. So it took almost 6 years?

Mr. ROGERS. Yes, sir.

Mr. BURTON. What kind of complaints would you have about the program?

Mr. ROGERS. Well, when we had heard about the program, I live next door to Auburn University. I went to their library, I call it the little green book, the one that Mr. Waxman had sort of designed. We read it from cover to cover. It sounded pretty interesting, especially the part like when you file it, and then a year after that, everything is taken care of.

Well, this is not true, sir. It is not true at all. Even though my wife went through the table of the injury process with the tetanus shot, she fell in that table of what would happen if the vaccine was bad. But there's a lot of misinformation in that book that we just didn't understand. And like I say, it's just taking entirely too long. Like I say, they tell you when you file, it should be over within a year of the process.

Mr. BURTON. And it's taken 6 years?

Mr. ROGERS. Yes, sir. It's not.

Mr. BURTON. But the special master, and the initial decision was that she be compensated and you be compensated for her injury?

Mr. ROGERS. Yes, sir.

Mr. BURTON. And the Justice Department has appealed it?

Mr. ROGERS. Yes, sir.

Mr. BURTON. OK. I see that my time has expired. Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman. Thank you for having these hearings. I want to thank all of you for testifying. Any of us that have lost family know how difficult it is.

I have to tell you, I am appalled at just thinking what you've been through in terms of time, whether your claim was ultimately rejected or allowed. The amount of time that you're talking about is just incomprehensible. I've done product liability cases in half the time of what you're talking about, the conclusion. So you have my sympathies on that. I look forward to later testimony and later hearings and then some legislation, perhaps, something that re-

solves even that aspect without getting into who's right or who's wrong. It's just beyond comprehension.

Let me start from left to right if I could. Ms. Zuhlke, you had an attorney named Mr. Shoemaker?

Ms. ZUHLKE. That's correct.

Mr. TIERNEY. Was he an experienced attorney in matters of this kind?

Ms. ZUHLKE. Apparently, he was. Again, I found an article in our local newspaper, a family that had been affected. I tracked them down and spoke with the mother who again provided me with information concerning Mr. Shoemaker.

Mr. TIERNEY. He was aggressive on your behalf, he was a good advocate?

Ms. ZUHLKE. I believe so, yes, sir.

Mr. TIERNEY. And you have no complaints about his performance?

Ms. ZUHLKE. No, sir, I don't.

Mr. TIERNEY. And he didn't cause the delays of which you complained?

Ms. ZUHLKE. Not that I am aware of.

Mr. TIERNEY. Mr. Rogers, did you have an attorney?

Mr. ROGERS. Yes, sir, I sure do.

Mr. TIERNEY. And was he experienced in matters of this kind?

Mr. ROGERS. Very.

Mr. TIERNEY. And did he cause any of the delays or problems that you had in getting attention to your claim?

Mr. ROGERS. No, sir. He wanted to get as much information as possible before he could really go before anybody. But the only problem with finding attorneys for this situation, to my understanding, this is like a specialized field, you just don't go to your local bar association. He did, and they said, they got the program, but they said, we can't handle anything like this, it's way above our head.

So Mr. Ron Homer is my attorney from Boston. And we finally got in touch with him and said he has been dealing with this the last few years.

Mr. TIERNEY. Well, if he's from Boston, I can tell you, he's probably a good guy. [Laughter.]

Mr. Sword, you also had an attorney with some experience?

Mr. SWORD. Actually, I had a series of attorneys. I began with an attorney that I had a relationship with for a number of years in the community. They were part of a firm that is recognized as being one of the better law firms in the central part of Ohio. They did a referral to a firm in Chicago that had the case for, I don't know, maybe a year or two. There were some problems within that firm and the case ended up also in Ron Homer's firm in Boston when it was sent back to the firm in Columbus.

And they located Ron Homer, and I can tell you without hesitation that is excellent representation. I would recommend him to anyone.

Mr. TIERNEY. Have you been able to get any assistance in compensating your counsel during this period of time?

Mr. SWORD. Actually, the limits were the limits. As far as I know, I provided staff with a copy of a letter that was sent to me

when we did settle that stated that the actual costs of the law firm was probably twice, over twice the allowable limit. They said it was over $60,000 and the cap was $30,000.

So they lost a considerable amount of money on that case. In addition to that, we went well over the expense allowances, and I paid additional expense allowances out of awards as I agreed to before the case was actually resolved. I agreed to go ahead and do that.

Mr. TIERNEY. In terms of your expert witnesses, am I right in assuming that all of you relied on your counsel to identify and engage expert witnesses on your behalf?

Mr. SWORD. I did.

Mr. TIERNEY. Mr. Rogers, you did the same?

Mr. ROGERS. Yes, sir.

Mr. TIERNEY. Ms. Zuhlke, of course you did the same?

Ms. ZUHLKE. Absolutely. I didn't know where to go.

Mr. TIERNEY. Ms. Zuhlke, let me ask you something. I'm curious from your comments. You indicated that the last two masters that you had were good and you were happy to have their assistance.

Ms. ZUHLKE. Yes, sir, that's correct.

Mr. TIERNEY. What did they do that made them better than the first two? What were the differences and why were you unhappy with the first two masters?

Ms. ZUHLKE. I think they moved things along, that was basically, I had a sense of, let's get going.

Mr. TIERNEY. Progress?

Ms. ZUHLKE. Right. And I didn't have that, again, the first was John Edwards, who no longer is with the DOJ, I believe he's with HHS. Useless, basically, sir.

Mr. TIERNEY. I think from your testimony it was pretty clear that you thought that they were getting continuances without making any particular showing for extraordinary need for more time?

Ms. ZUHLKE. That's correct.

Mr. TIERNEY. Was that your experience, Mr. Rogers?

Mr. ROGERS. Well, in my wife's case, we had to have the phone conference deal with the special master, Government and our lawyer, everybody there. See, my wife is a registered pharmacist. She knows more, I'm not trying to be insulting, more than any physician in this whole country. She knows every drug, the whole nine yards, everything. And she just was sitting there laughing the whole time at the explanations they were giving of what was wrong with her, which didn't make any sense. The things that they were saying is not possible of what happened to her.

Now, she's not a dummy, she understands every medical term, everything. Because a pharmacist is about as close to being a doctor as you can get. It was just comical the way they were trying to bullskate us with her problem. It just wasn't very professional.

Another thing, the doctor that the Government had diagnosed her kind of like as having MS, which they treated her as, being she doesn't have it. I always thought a physician had to at least look at her or touch her to give a diagnosis. You don't give a diagnosis on the telephone. I mean, that's—even though he was giving his expert testimony, a physician should at least look at you, or at least meet you or something. You just don't do it over the telephone.

Mr. TIERNEY. I want to thank all three of you. My time is up, but I do appreciate how difficult it was for you. We're very grateful that you came here today.

Mr. BURTON. Thank you, Mr. Tierney. We look forward to working with you on this.

Dr. Weldon.

Dr. WELDON. Thank you, Mr. Chairman.

Janet, in your negotiations that are underway, will you be able to get any compensation for lost wages?

Ms. ZUHLKE. No, sir.

Dr. WELDON. Can you give us some kind of an impression of how this tragedy has affected your ability to work, how much lost wages have you incurred? I know you've had a lot of out of pocket expenses. Can you give us a feeling for how much you've lost because you haven't been able to work?

Ms. ZUHLKE. Well, obviously, that would be in the thousands, sir. When Rachel Anne winds up in the hospital, it can be for 2 to 3 weeks at a time. And I am her primary caregiver. I do stay with the child. And again, I'm away from home. I've got to make arrangements for my other two children to either stay with family or friends.

I did lose my job over this. I was a dental assistant with expanded duties. And I had worked for 15 years for a pedodontist, which is a children's dentist. And Dr. Vann had to let me go, understandably. I was unemployed for probably throughout 1990. It was just a hellatious year, just back to back issues for Rachel Anne. Then I went to work for my family, who showed me grace. And even on a Friday when I might not be there, because I was up at the hospital with Rachel, a check would be put into my account to cover my family's needs.

My mother has cancer and my parents sold the business in November of this past year, a business that we had had for 23 years. I went back into the dental field, I'm working as a surgical assistant now to a maxillofacial oral surgeon. And again, I'm working on a part-time basis.

Rachel Anne is picked up at the end of my driveway by a special bus that takes her off to school and I have to make sure that she's taken care of. And again, I have no help. I don't have respite care or anybody else that comes in to help with meeting her needs. I've got to be there to get her off of the bus.

Dr. WELDON. So when the settlement is finally reached, and you're in the negotiations phase for that, it will be for her care, you get nothing?

Ms. ZUHLKE. That's correct.

Dr. WELDON. You said in the written testimony, I'm not sure if you mentioned this, that you had a life planner come in and the DOJ life planner has not contacted you yet?

Ms. ZUHLKE. That's correct.

Dr. WELDON. But you made a very interesting statement in your written testimony. You said the DOJ life planner that's been assigned your case is "known in the trade to be confrontational and to under-value costs." Can you explain to the committee how you were provided that information?

Ms. ZUHLKE. Yes.

Dr. WELDON. And the nature of that information you received?

Ms. ZUHLKE. Yes, sir. The information came through Rachel's attorney. They have had to deal with this individual through the DOJ before. So they have past experiences with her. Also, the individual that has been employed now by myself, and again through Cliff Shoemaker, to come in as the life care planner on Rachel's behalf, gave me a heads up, so that I would have a clear understanding of what I was coming up against.

And now it's the nickel and dime you to death. For every dime that Rachel's physicians will say to the life care planner will be necessary to meet my daughter's needs, apparently the DOJ side will come in and say, no, 2 cents is going to cover that. So now this is going to be another ongoing battle, is the way I perceive it. I have great faith in the people that have taken care of Rachel's needs at this point. I have no reason not to take them at their word on this level.

Dr. WELDON. Were you advised by your counsel how long this process normally takes to come to an agreement? And does this have to go before the special master as well?

Ms. ZUHLKE. I was not given a timeframe, and yes, it does now again have to go back in front of a special master and another hearing.

Dr. WELDON. And another hearing?

Ms. ZUHLKE. Correct.

Dr. WELDON. You have no idea how long this will take?

Ms. ZUHLKE. No, sir. I anticipated at least a phone call by now, with at least scheduling some sort of a timeframe. Because again, I've got to organize Rachel's teachers, the guidance counselors have all of her IEPs, individual education plans, so they can track her course, make arrangements with her PCP so that his time is free, which I've already done that for Ms. Arnold.

Dr. WELDON. PCP?

Ms. ZUHLKE. Primary care physician.

Dr. WELDON. Would you explain to the members what that is?

Ms. ZUHLKE. I'm sorry. A PCP is a primary care physician.

Dr. WELDON. So the doctor has to get involved with the life care planner?

Ms. ZUHLKE. Absolutely. Because he is her care giver. And he understands where she's been, where she's at and where she's going.

Dr. WELDON. So you've already gone through this whole process with your life care planner, and now you have to go through this again with all the parties involved?

Ms. ZUHLKE. Yes, sir.

Dr. WELDON. The pediatrician and everybody?

Ms. ZUHLKE. Yes, sir.

Dr. WELDON. OK. I see that my time is expired, Mr. Chairman.

Mr. BURTON. We'll stay with this panel for a while, if you have additional questions.

Mr. Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman.

Let me first of all say that my wife and I have four children, and I think anyone who's ever had children at least greatly sympathizes with each of you and what you've been through. I can also

tell you, I think it's almost criminal, or should be, that you've been put through all these years of having to deal with the bureaucratic delays and so forth.

I know there are exceptions to almost everything, but you know, State courts, despite having much heavier workloads, usually conclude cases in about half the time on average that the Federal Government does. And you know, we see all the time that the least efficient way to handle anything is to have the Federal Government handle it. But I think it's very sad that people are put through years and years and years of dealing with this program.

I think you all should know, too, that most Federal judges and most Federal hearing officers and special masters almost always rule in favor of the Government, because that's usually the easiest way to deal with things. So you have won big victories, I think, in having rulings in your favor.

But you know, thinking back to when my children were small, we got all these vaccines, and I had never heard anything about these problems. I think that almost all parents, I would say 99.9 percent of parents, don't know about these things and are convinced that they're doing something good for their children. And I know that it must be especially hard for you all to take, what happened to you, because I'm sure that you thought you were doing what you should have been doing for your children to make them healthier.

Do you all think that enough is being done now to ensure these vaccines are safe? Do you have an opinion about that? Have you read research, anything about that? Mr. Sword.

Mr. SWORD. Well, as I commented in my testimony, there was about 30 years between the time of the first reports of the twin deaths in the mid-1940's and the time that my daughter died of vaccine injury. My understanding is, there have been many, many deaths since then. It was my understanding that, I believe it was an acellular vaccine was developed for pertussis in the early 1980's, perhaps in Japan. I may stand corrected if I have that information wrong. But it was not available in this country for a considerable amount of time, and then it was only available as an option.

So I don't think there is enough research, and I don't think there is enough really known about the problems with vaccine injury and the experience. Because it just simply isn't well reported.

Mr. DUNCAN. I think the overwhelming majority of the American people don't even know that this program exists today. And I wonder, I've seen where there have been 6,000 claims filed. I wonder how many thousands of others there are that have been told that it was not the vaccine or they didn't figure it out. Do you all think that's happened or that there are a lot of people who don't know about this? What do you say about that, Ms. Zuhlke?

Ms. ZUHLKE. I think that's factual. I think people aren't aware of it. I didn't know anything about it until Rachel's pediatrician put me onto this path. And again, I have three children. I must say that I heard Mr. Sword's comments before, my children now are past the immunization aspect. So I'm probably not as informed as I should be in helping other people.

I am aware of the fact that at Dr. O'Hern's office, Rachel's physician, everybody that comes in with a child is required to read this

full booklet that gives all symptoms, side effects, adverse reactions, and they must initial each page, that they have understood clearly what could happen to their child. That information is then documented and put into each child's chart. I think that is extremely helpful.

Mr. DUNCAN. Mr. Sword.

Mr. SWORD. My suspicion is that this may very well begin in the medical training process, both for doctors and nurses, and that it may very well be that there is not enough sensitivity on the part of the medical community and the training process to adequately ensure that either the medical providers or the patients are adequately informed in an appropriate way. Not so as to scare people, but to treat them with the care that they really need and to provide to them the information and caution that's necessary in order to prevent a lot of these things from going well beyond where they might otherwise go.

Mr. DUNCAN. Finally, let me just mention, we're going to hear on the next panel a witness who will say that the Justice Department handles these cases in a cooperative and non-adversarial fashion, and that they're much more cooperative than other similar types of cases. I take it none of you have found that to be true, is that correct?

Ms. ZUHLKE. That's correct. And I'd like to be on that panel instead of this one.

Mr. DUNCAN. Do you think that some of these companies, that there's some big money behind some of these companies that produce these vaccines? I mean, so often what we find in these things is the money that's behind it, in other words, they convince the medical establishment that something is good because they're making huge profits out of it.

Do you think that enters in at all? Or why do you think they say the companies are getting out of the vaccine business now, the childhood vaccine business? Have you looked into that at all? Mr. Sword.

Mr. SWORD. I have not looked into that. But I always had the feeling from the people that I came in contact with, and from the attorneys that I came in contact with that there was a giant standing in the shadows of this whole thing, and that that giant had a lot of influence. On the other side of that, you have children, you have a variety of different kinds of people that are mandated as a condition of employment to take these vaccines. You have policemen, firemen, doctors, nurses and so forth who are all, so you have this balance here. And the Government has to in some way sort that out.

But quite frankly, I just don't think that the absence of some kind of oversight because of the presence of these vaccine manufacturers, the possibility of revolving door, and as the chairman stated in his opening statement, the conflicts at the Government agencies, that there could ever be a resolution to this without some kind of ongoing congressional oversight to this.

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

Mr. BURTON. Thank you, Judge.

Let me ask you a question, Mr. Sword. You said that initially somebody said your daughter died of SIDS?

Mr. SWORD. That's correct. And that was a common diagnosis of cause of death, as my understanding was. There were a lot of these cases that were misdiagnosed from the very beginning as being SIDS.

Mr. BURTON. We have known throughout the country that there were a lot of children that died from SIDS and there's been some concern that those may not have been just normal ways for children to die, but that they were as a result of vaccines that were given to the children. I think we ought to take a look at that and see if we can find any statistical data to find out when children who die with SIDS got vaccinations and the proximity of that time to their death, just to have some statistical data. So can we check into that?

Let me ask you a couple of questions, Ms. Zuhlke. In his written statement, Mr. Harris, who will be on the next panel, says the Justice Department lawyers are cooperative and non-adversarial. I know you've answered this a little bit. He says the Justice Department undertakes its responsibilities in a more cooperative manner than would be expected from defendants in civil litigation. He also says, I do not believe that the manner in which the VICP cases are processed has become more adversarial. In fact, I believe it's quite to the contrary.

And would you once more tell me, each one of you, what you think about that statement?

Ms. ZUHLKE. Well, sir, I don't think I can really tell you what I think about that statement, but I don't think it's factual.

Mr. BURTON. I think you just did.

Ms. ZUHLKE. OK, sir.

Mr. BURTON. Mr. Rogers.

Mr. ROGERS. Well, this whole situation is really hard to understand. But I really wish my wife could have come and you could really hear it from the horse's mouth. Because it's really hard to interpret everything she's going through.

And one thing, I don't really think the public really knows about this. They just take stuff for granted. I just think a lot of people are getting the runaround on this. We're just not getting anything professional out of it.

Mr. BURTON. We'll try to make sure the public knows more about it.

Mr. Sword.

Mr. SWORD. I guess it's depending on how you define cooperative and how you define non-adversarial and so forth and so on. In my case, I thought it was rather adversarial, to a fault. Other cases that I've heard of, similar kinds of things, I've heard statistics that somewhere around the area of two-thirds of the claims were rejected for pertussis deaths.

So I think on the whole, there may be some effort on the Government's part to do that. But I don't think they're doing nearly enough, if they are, and they should make a better effort in good faith.

Mr. BURTON. Ms. Zuhlke, did you ever observe a special master lose his temper or lose his patience with a Justice Department lawyer?

Ms. ZUHLKE. Yes, sir.

Mr. BURTON. What happened? Tell me what happened.

Ms. ZUHLKE. That was in the second hearing.

Mr. BURTON. What did he say?

Ms. ZUHLKE. I'm sorry, sir, I cannot give it to you verbatim at this point. But some comments were made, and special master did get a little incensed over it. One thing that does stick in my mind is, at the end of that particular hearing, and again this is the second hearing, the attorney for the DOJ said, "oh, by the way, there is a piece of evidence that we don't have." And it turns out this piece of evidence he had desired, he'd known about for 9 years. And now at the end, literally the end, the closure of that hearing, I also lost my temper.

Mr. BURTON. He asked for evidence that had been known for 9 years?

Ms. ZUHLKE. Yes, sir, and he said parts of it were not available, it had to do with slides of my daughter's brain tissue, because she's had two open brain biopsies. And he was stating that part of that material had never been received. And the special master wanted to know, well, what took you so long to come up and say something. Now is a very inappropriate time and you may not continue with trying to obtain that. And the hearing was closed.

Mr. BURTON. I'd like to maybe, if you can give us the name of that attorney, I'd like to check on that.

Ms. ZUHLKE. Yes, sir.

Mr. BURTON. Mr. Sword, did you find the Justice Department to be cooperative and non-adversarial in your case?

Mr. SWORD. I didn't feel that they were cooperative. I felt that it was, they came with three different causes of death that didn't agree with one another. We got into the hearing in Boston and they had an expert there who kept nodding out in the first part of the proceedings.

As she proceeded into her testimony, this woman kind of led to a fantasy testimony, that if there had been the technology at the time of Natalie's death that existed now, she could have made a different diagnosis. And I don't know how you deal with that kind of a fantasy when you're talking about facts and when you're talking about what was available in the records and so forth.

I kind of sat back in my chair and I started to listen to this, and quite frankly, it upset me so bad that I had to leave the room. I left the room.

Mr. BURTON. So you don't think she had the expertise necessary to actually make comments?

Mr. SWORD. I think some of these people come in there, and they make their living doing adverse testimony, quite frankly.

Mr. BURTON. How about you, Mr. Rogers?

Mr. ROGERS. Well, I know they've got their job to do, but it's——

Mr. BURTON. Well, you were in meetings with these people. What kind of response did you have in the meetings?

Mr. ROGERS. Well, we just did not understand what they were going after. I mean, I know my wife being an adult, which is totally different than a child having this problem, they kept going back to things that had happened to her years prior to anything. Like she had vertigo at one time, they said, well, if you have a tetanus shot

and you have vertigo, you're going to have MS and blah, blah, blah, which is not really true.

With her expertise as far as medicine, she just didn't believe half the stuff they were telling us. But the special master, evidently she's got a lot of medical knowledge, because she knew exactly what was going on. But she was supposed to have been the deciding factor in all this.

Mr. BURTON. My time's just about up. Did you think that the Government was trying to disprove your case? They weren't trying to work with you? Were they working with you or were they trying to disprove your case?

Mr. ROGERS. I really believe they were just trying to disprove it. They just didn't believe it was true.

Mr. BURTON. How about you, Mr. Sword?

Mr. SWORD. I don't think there was any question that was what was at the core of what motivated them. They were attempting as desperately as they could to disprove that case.

Mr. BURTON. Ms. Zuhlke.

Ms. ZUHLKE. Same exact thing. That's exactly my words. That works for me.

Mr. BURTON. Mr. Tierney, do you have any questions?

Mr. TIERNEY. No, thank you. They've been through enough. Thank you.

Mr. BURTON. I think that suffices. If you have any additional comments you'd like to make to the committee, we'd like to have those. We're going to have, when we come back from votes, we've got a series of votes, we're going to have the other panel from the Justice Department and HHS. If you'd like to stay around, we might solicit some comments from you at the conclusion of their remarks.

And with that, we stand in recess until the fall of the gavel, which should be in just a few minutes after the final vote. I think have two or three votes. So it will probably be half an hour before we get back.

[Recess.]

Mr. BURTON. I again call the committee to order.

We'll now hear testimony from the second witness panel. Thomas Balbier and John Euler, would you please approach the committee table? Oh, Mr. Harris, excuse me. Mr. Harris.

[Witnesses sworn.]

Mr. BURTON. Which one of you replaces Mr. Euler? I guess Mr. Harris does.

Do you have opening statements? We'll start with you, Mr. Balbier.

STATEMENTS OF THOMAS E. BALBIER, JR., DIRECTOR, NATIONAL VACCINE INJURY COMPENSATION PROGRAM, ACCOMPANIED BY GEOFFREY EVANS, MEDICAL DIRECTOR, AND DAVID BENOR, OFFICE OF THE GENERAL COUNSEL; AND PAUL CLINTON HARRIS, SR., DEPUTY ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION, U.S. DEPARTMENT OF JUSTICE

Mr. BALBIER. Good afternoon, Mr. Burton.

Mr. Chairman and members of the committee, I'm very pleased to be here this morning to talk to you about the National Vaccine Injury Compensation 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 quickly, while still preserving their rights to file suit in the tort system.

The program significantly reduces, but cannot eliminate, the tension and adversity inherent with any litigation process for resolving claims. I heard members discuss earlier this morning that I would be coming here and talking about a system that was non-adversarial. You will not hear me say that. I've been saying for years that the system is designed to be less adversarial than the tort system that people otherwise would have to go through. And it is.

I was asked specifically to address three major issues in my testimony this morning. They are complaints that the statute of limitations is too narrow and excludes families from the program, complaints that the inability to make interim payments to petitioners places them at a disadvantage, and complaints that the program has, in general, become too litigious and adversarial.

We have attempted to address these issues through a wide variety of methods. In June 1999, a draft bill entitled the "Vaccine Injury Compensation Program Amendments of 1999" was sent to Congress. This proposed bill contains specific legislative proposals that addressed each one of these issues noted above.

I also heard earlier a recommendation that there should be an independent group to provide oversight for the compensation program. That group exists. Those recommendations came from that group. We developed the proposals based on recommendations from the Advisory Commission on Childhood Vaccines, comprised of medical professionals with expertise in pediatrics, attorneys, including those representing families filing claims under the program, and equally important, parents of children injured by very rare, but serious adverse reactions to childhood vaccines.

One of these proposals would extend the current statute of limitations from 3 years for injury claims and 2 years for death claims to 6 years for those claiming injury or death resulting from a covered vaccine. Another proposal would permit the interim payment of litigation costs after a determination that the petitioner is entitled to compensation. Another would allow compensation for family counseling and costs to families related to establishing a guardianship or a conservatorship.

Other proposed legislative changes would address the rulemaking process for changes to the vaccine injury table. Currently, the process for changing the table requires a period of 180 days for public comment, including the opportunity for a public hearing. During the last public hearing for proposed changes to the table, no member of the public attended the hearing. Decreasing the length of time for public comment and eliminating the mandate for a public hearing will enable the program to make needed changes including the addition of injuries to the vaccine injury table in a more efficient manner.

The administration supports these proposals. The statute of limitations is extended, potentially enabling more families to seek compensation. Also, the proposal recognizes and attempts to ease some of the financial burdens of petitioners. 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 significantly aggravated by childhood vaccine to file a petition for compensation. Petitioners' rights, as you heard, are vigorously advocated by their attorneys, who are paid reasonable attorney fees and costs, regardless of whether petitioners are compensated, so long as there is a reasonable basis for the claim and it is brought in good faith.

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.

I also was asked to discuss changes to the vaccine injury table. We have amended the table twice so far, in 1995 and 1997. I spoke extensively to those changes when I testified before in front of this committee. We've now begun the process of making further changes to the vaccine injury table. The most important of these changes is to add intussusception, the telescoping of the intestine, as an injury associated with the rotavirus vaccine. Rotavirus is a childhood vaccine licensed by the Food and Drug Administration in August 1998. A series of reports to the Vaccine Adverse Event Reporting System found that some infants developed intussusception after receiving the vaccine. The VAERS system, as we call it, is a signaling system that has been set up to monitor adverse events. The Centers for Disease Control and Prevention, based on this signal that we received from the VAERS system, then recommended that health care providers and parents postpone the use of rotavirus vaccine while we looked into this further. Shortly thereafter, the manufacturer voluntarily withdrew the vaccine from the market. After consulting with our Advisory Commission on Childhood Vaccines, we published a notice in the Federal Register on July 13th of this year. The notice would add intussusception as a table injury using criteria based on scientific data currently used by HHS and the Department of Justice for recommendations to the court on compensation. Already, four claims of intussusception associated with the rotavirus have been compensated.

In addition, we have taken steps to ensure that potential claimants are notified about their ability to file a claim with the program. We have developed a press release which was distributed on July 25th. We participated in a conference call with State and territorial health officials, asking them to notify all who had reported intussusception following rotavirus immunization, and we sent a followup letter also. We've been publicizing this change on our Web site and through our outreach efforts.

All indications are that the program is working very much as intended by Congress. The process of determining whether, and at what level, compensation should be awarded will always involve conflicting opinions and a natural tension. There will always be

program areas that can be improved, and we continue to try 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 ensure that varied interests of families, health care professionals, attorneys and the vaccine industry are represented in a regular public forum. The Advisory Commission on Childhood Vaccines, with its widely diverse membership, brings good balance and perspective and has been instrumental in identifying program improvements that have consensus support.

The ACCV was established by the act, and I quote from the act, to "advise the Secretary (of HHS) on the implementation of the program." That's very broad oversight responsibility. The 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, also as required by statute, and has made numerous legislative and administrative recommendations over the years aimed at improving the operation of the program.

The ACCV developed and approved legislative proposals that I mentioned previously. The Department remains committed to making this program and to making ongoing improvements to the program, so that children and families 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'll be pleased to answer any additional questions you may have. Thank you.

[The prepared statement of Mr. Balbier follows:]

STATEMENT

OF

MR. THOMAS E. BALBIER, JR.

DIRECTOR

NATIONAL VACCINE INJURY COMPENSATION PROGRAM

BEFORE

THE COMMITTEE ON GOVERNMENT REFORM

November 1, 2001

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 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 the natural occurrence of smallpox and reducing the incidence of many childhood diseases to almost zero. This is a tremendous accomplishment and, one very significant component, critical to the success of our Nation's immunization program over the past decade, 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 higher 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). Since the Program's inception, more than 1,700 families have received compensation through awards totaling $1.3 billion.

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 quickly, while still preserving their rights to file suit in the tort system.

The Program significantly reduces, but cannot eliminate, the tension and adversity inherent with any litigation process for resolving claims. 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. In fact, it is this very flexibility and extension of deadlines that may prolong the resolution of the cases.

I was asked to address three major issues in my testimony this morning. They are:

1.Complaints that the statute of limitations is too narrow and excludes families from the Program;

2. Complaints that the inability to make interim payments to petitioners places them at a disadvantage; and

2.Complaints that the Program has, in general, become too litigious and adversarial.

We have attempted to address these issues through a wide variety of methods. In June 1999, a draft bill entitled, the "Vaccine Injury Compensation Program Amendments of 1999" was sent to Congress. This proposed bill contained specific legislative proposals that addressed each of the issues noted above. These proposals were developed based on recommendations of the Advisory Commission on Childhood Vaccines, comprised of medical professionals with expertise in pediatrics, attorneys representing the vaccine companies and families filing claims under the

Program, and, equally important, parents of children injured by the rare, but serious adverse reactions to childhood vaccines. Specifically, one of the proposals would extend the current statute of limitations from 3 years for injury claims and 2 years for death claims to 6 years for those claiming injury or death resulting from a covered vaccine. Another proposal would permit the interim payment of litigation costs after a determination that the petitioner is entitled to compensation. Another proposal would allow compensation for family counseling and costs to families related to establishing a guardianship or conservatorship. Other proposed legislative changes would address the rulemaking process for the changes to the Vaccine Injury Table. Currently, the process for changing the Table requires a period of 180 days for public comment, including a public hearing. During the last public hearing for proposed changes to the Table, no member of the public attended the hearing. Decreasing the length of time for public comment and eliminating the mandate for a public hearing will enable the Program to make needed changes, including the addition of injuries, to the Table in a more efficient manner. The Administration supports these proposals. We believe that these changes are good for the program and its beneficiaries. The statute of limitations is extended –potentially enabling more families to seek compensation. Also, the proposal recognizes and attempts to ease some of the financial burdens of petitioners.

Although these proposals require Congressional action, we have implemented a number of reforms through administrative action. The Office of Special Masters at the U.S. Court of Federal Claims has issued a new order for Alternative Dispute Resolution. This order was developed by a workgroup comprised of a Special Master from the Court, a Department of Justice attorney, and an attorney who represents many families with VICP claims. The expanded use of ADR has been hailed by petitioners' attorneys and DOJ attorneys alike as a very positive step in adjudicating claims.

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 significantly aggravated by a childhood vaccine to file a petition for compensation.

Petitioners' rights are vigorously advocated by their attorneys, who are paid reasonable fees and costs regardless of whether petitioners are compensated, so long as there is a reasonable basis for the claim and it is brought in good faith. 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.

I was asked to discuss changes to the Vaccine Injury Table, and would like to begin with action already taken to implement legislative requirements. 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 causes of illnesses that coincidentally occur within a short time of vaccination. Congress also realized that the approach in the Act of deeming certain conditions to be vaccine-related 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. Based on the results of these scientific studies, the Secretary of Health and Human Services revised the Vaccine Injury Table in compliance with our statutory requirements to bring it in line with the best scientific knowledge available at the time.

We now have begun the process of making further changes to the Vaccine Injury Table. The most important change is to add intussusception (a telescoping of the intestine) as an injury associated with the rotavirus vaccine. Rotavirus vaccine was licensed by the Food and Drug Administration in August 1998. A series of reports to the Vaccine Adverse Event Reporting System found that some infants developed intussusception after receiving the vaccine. The Centers for Disease Control and Prevention

then recommended that health care providers and parents postpone use of the rotavirus vaccine; shortly thereafter, the manufacturer voluntarily withdrew the vaccine from the market. After consulting with the ACCV, we published a notice in the Federal Register on July 13, 2001 that would add intussusception as a Table injury using criteria based on scientific data currently used by HHS and DOJ to recommend compensation. Already, four claims of intussusception associated with the rotavirus vaccine have been compensated. In addition, we have taken steps to ensure that potential claimants are notified about their ability to file a claim with the Program. We have developed a press release which was distributed on July 25. We participated in a conference call with State and Territorial health officials, asking them to notify those who had reported intussusception following rotavirus immunization; and, a follow-up letter was also sent to them. We have also been publicizing this change on our website and through our outreach efforts.

Finally, we have responded to recommendations from this Committee following my testimony in September 1999 before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources. Along with our partners at the Department of Justice and our Office of the General Counsel, we have aggressively attempted to inform the public, and the medical and legal community, of the availability of the Program. We have provided information about the Program by staffing our exhibit booth at national and local conferences of a wide variety of medical and legal associations. We have implemented improvements to our website and our toll-free information line. As always, each Vaccine Information Statement given to the parents of the child or the adult patient at the time a covered vaccine is administered has contact information about the Program, including our website address and our toll-free telephone number.

All indications are that this Program is working very much as intended by Congress. The process of determining whether, and at what level, compensation should be awarded will always involve conflicting opinions, and a natural tension. There will always be program areas that can be improved, and we continue to try 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 ensure that the varied interests of families, health care professionals, attorneys, and the vaccine industry are represented in a regular public forum. The Advisory Commission on Childhood Vaccines, with its widely diverse membership, brings a good balance of perspective and has been instrumental in identifying program improvements that have consensus support. The ACCV was established by the Act to "advise the Secretary (of HHS) on the implementation of the Program." 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. The ACCV developed and approved legislative proposals that I mentioned previously. The Department remains committed to this program and to making ongoing improvements so that children and families 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. BURTON. Mr. Harris.

Mr. HARRIS. Good afternoon, Chairman Burton and members of the committee. I'd like to thank you for this opportunity to appear before you this afternoon on behalf of the administration.

So that I may limit my remarks, I request that my full written statement and our views letter to you, Mr. Chairman, dated October 17th, be entered into the record.

In the early 1980's, Congress faced a looming public health crisis concerning injury from immunizations which involved complex, fiercely debated medical issues overlaid with the emotion of personal loss and tragedy in individual cases. I've sat through the prior panel, and we've heard testimony to this effect this morning.

In order to stabilize our Nation's supply of vaccines and promote our universal vaccination policy to combat childhood disease, Congress established the Vaccine Injury Compensation Program. Petitioners are afforded under this program a more streamlined system of recovery with free counsel provided in each case, in which their meaningful participation in the process is assured.

This supply of life saving vaccines is protected and a safer, better system of vaccines is currently being developed. Vaccines have improved the lives of millions of Americans. This program has been a cornerstone of the Nation's ability to achieve these important objectives. The Justice Department's role is to implement the statute and to uphold the provisions of the act.

By design, this is a program rooted in science. Congress set forth specific eligibility criteria based on the most current and accurate scientific evidence available. We at the Justice Department ensure that fair compensation is provided to those who meet the eligibility criteria determined by Congress and that the vaccine injury trust fund is protected against claims that do not meet this standard.

Over the past 5 years, approximately half of all cases have been compensated. The use of alternative dispute resolution has increased threefold in the last 2 years. We have initiated efforts to further expedite case processing by organizing a group of special masters, members of petitioners' bar, parents and HHS staff to review and revise the court's guidelines for practice.

We have supported many legislative proposals that will benefit petitioners, such as an extension of the statute of limitations, and payment of interim litigation costs, as described in greater detail in our letter to the chairman. We rarely, rarely appeal cases to the Court of Federal Claims, and even less frequently to the Court of Appeals for the Federal Circuit.

Of the 5,400 cases resolved since 1988, 109 cases have been appealed to the Federal Circuit. The Government has appealed only 13 of those cases. Most significantly, since 1993, we've appealed only one case to the Federal Circuit, and that was 3 years ago, in 1998.

In consideration of all this, I simply cannot agree with any suggestion or accusation that the program has become more litigious. It simply has not. Rather, I think it has become less so. The language of the act calls for a less adversarial, expeditious and informal proceeding. The Justice Department has gone to great lengths to fulfill this congressional objective.

We collaborate with the court and opposing counsel in developing creative and novel approaches to resolving each claim. As such, the Justice Department has developed a cooperative atmosphere to move cases along. Our initiatives have contributed to promoting an atmosphere of cooperation among all parties involved.

Admittedly, some cases are prolonged or drawn out for various reasons. And you've heard stories again from families today that illustrate such cases. Resolution of cases simply cannot always be accomplished as quickly as we would prefer. There exists an obvious tension between efficiency and the important principle of due process.

The issues can be difficult and complex. For example, in the entitlement phase, the concept of causality can be difficult to prove, as the Institute of Medicine recognizes, not the Justice Department. The arousal of one's suspicion that a vaccine might be the cause of an adverse event that occurs within hours, days or weeks following the receipt of the vaccine is natural and understandable. But the mere fact that B follows A does not mean that A caused B.

It is for this reason that the act requires scientific evidence that the injury is related to the vaccine, and forbids payment of compensation based on the claims of a petitioner alone. We cannot ignore the statutory criteria or the consensus of the scientific community on medical causation issues.

With regard to determining compensation to be awarded, Congress has set forth a detailed list of categories of compensable items. The amount sought is frequently in excess of several million dollars. While often time consuming, the key is that the program process is far more thoughtful and tailored as compared with other alternatives. The goal is no less than establishing a custom tailored plan of lifetime medical care, and in as many as 90 percent of the cases, this is an issue settled by the parties.

In short, I firmly believe that 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. The debate and the emotion in these cases will never be eliminated, understandably. But an efficient mechanism is in place to address these difficult issues. To date, almost 1,700 families have been compensated nearly $1.3 billion. This is an outstanding measure of this program's success. The truth is that these families would have stood little if any chance of obtaining any relief in the traditional tort system.

Mr. Chairman, members of the committee, I thank you again for this opportunity and I'll be pleased to answer your questions.

[The prepared statement of Mr. Harris follows:]

Department of Justice

STATEMENT

OF

PAUL CLINTON HARRIS, SR.
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING

THE

NATIONAL VACCINE INJURY COMPENSATION PROGRAM

PRESENTED ON

NOVEMBER 1, 2001

STATEMENT OF
PAUL CLINTON HARRIS, SR.
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE THE COMMITTEE ON GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

NOVEMBER 1, 2001

Chairman Burton, Ranking Minority Member Waxman, and Members of the Committee:

Thank you for the opportunity to appear before you today. I am pleased to appear on behalf of the Administration to talk about the National Vaccine Injury Compensation Program (VICP).

With the enactment of the Vaccine Injury Compensation Act of 1986 (Act), Congress created a no-fault system of recovery to provide recourse for families and children alleging injury from vaccines, without requiring them to proceed in the traditional civil court system. A primary goal of the VICP is to encourage childhood vaccination by providing streamlined compensation in rare instances of vaccine-injury. Fortunately, many more of our children are vaccinated today than were immunized a decade ago.[1] Other positive results include the protection of the Nation's supply of

[1] The CDC reports that last year 78% of children under the age of three were immunized. CDC, National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19-35 Months – United States, 2000 50 MMWR 637 (2001). This compares to only 55% of children in the same age group in 1992. CDC, Vaccination Coverage of 2-Year-Old Children – United States, 1993 42 MMWR 705 (1994).

life-saving vaccines, and the research and development of new, better and safer vaccines. Further, costly litigation against drug manufacturers and health care professionals, marked by finger-pointing and lengthy discovery, has been virtually eliminated. The success of the VICP is an integral part of the achievement of these interrelated goals and the overall success of our Nation's immunization program. Indeed, the VICP must be considered one of the Nation's most successful models of tort reform.

Unfortunately, most of the claims brought under the VICP involve children with serious health problems. As many of us are parents ourselves, we feel tremendous sympathy for all claimants and for their families. We know and appreciate the suffering they endure. Regardless of cause, childhood disease and injury is tragic.

At the Justice Department, our role in the VICP is to implement the statute and uphold the provisions of the Act. We do this by representing the Secretary of Health and Human Services (HHS) before special masters designated by the U.S. Court of Federal Claims. Along with our counterparts at HHS, our goal is to ensure that fair compensation is provided to those who meet the Act's eligibility criteria for vaccine injuries. Moreover, it is our responsibility to ensure that the Vaccine Injury Trust fund is protected against claims that do not meet the criteria. By design, the Program's standards are rooted in science, with specific eligibility criteria based upon the most current and accurate scientific evidence available. We strive to do our part to serve the many purposes of the Program, and I believe we do it well.

Department Initiatives

In the spirit of the Act, the Justice Department undertakes its responsibilities in a

more cooperative manner than would be expected from defendants in civil litigation. Numerous improvements have been implemented to help expedite the processing of claims. I would like to take this opportunity to highlight some recent initiatives.

At the suggestion of this Committee two years ago, we sought to increase the use of Alternative Dispute Resolution ("ADR") in vaccine cases. While the VICP incorporates many ADR-like features by its very design, the Department welcomes the use of traditional ADR techniques in appropriate cases. For example, we have utilized processes such as "mini-trials," early neutral evaluation, and mediation. Prior to 1999, these types of ADR proceedings had been instituted in just 17 cases. I am pleased to report that in the past two years alone, that number has increased three fold, to approximately 60 cases. To encourage the use of ADR in Program cases, the Office of Special Masters at the U.S. Court of Federal Claims convened a working group to craft an ADR General Order applicable to all VICP cases. We participated in this working group along with one of the special masters and an attorney who represents numerous families in the Program; the General Order was issued in all pending cases on February 8, 2001 and applies to all cases filed after that date. The Order describes the types of ADR techniques available to the parties, and offers the court's assistance in preparing for and conducting ADR proceedings.

Pleased with the success of the ADR group, we have recently organized another working group in coordination with the Office of Special Masters. It includes special masters, claimants' attorneys, a parent, Justice Department attorneys, and HHS staff. This group will re-evaluate and revise the Guidelines for Practice Under the VICP, with the goal of devising procedures to further expedite case processing. In particular, the group intends to focus on the process of settling the damages portion of these cases, which has

often shown to be a time-consuming aspect of Program cases.

Of course, there are numerous additional steps we take to assist in case processing. For example, if claimants are unable to obtain copies of necessary medical records, we can obtain those for them. When resolving damages, we work with HHS and counsel for the families to resolve potential Medicaid liens that might be levied against a future vaccine award. We alert counsel to this issue by sending letters to this effect. Once a case has been concluded, we help to expedite payment of the award by sending letters to counsel informing them of specific steps to be followed, and providing them with the necessary forms. Through these cooperative efforts with counsel, it is possible to reduce the time necessary to pay a claim by as many as three to four months.

The Department views outreach efforts as critically important to ensure that information about the Program is widely disseminated. Along with HHS staff, we attend professional conferences in the medical and legal communities to publicize the Program and increase its visibility. Eleven such conferences are planned this year, at which more than 1,500 information packets will be distributed, including the toll-free VICP phone number and web site address. It is our goal to expand these efforts in 2002 by participating in even more conferences.

In your letter of invitation, Mr. Chairman, you specifically requested that I address four particular issues: the statute of limitations, interim payments, changes to the Vaccine Injury Table, and the perceived adversarial nature of the Program.

Statute of Limitations

Let me begin with the proposal to extend the statute of limitations. The Department supports the recommendation of the Advisory Commission on Childhood Vaccines ("ACCV") that the statute be amended to extend the filing period after the onset of the injury from three years to six years. For claims alleging vaccine-related deaths, the ACCV proposal called for expanding the filing period from two years to six years after the onset of injury from which the death resulted, although the petition would still have to be filed within two years of the date of the death. We support this.

We estimate that perhaps three to five cases per year may have been untimely filed. Thus, while we do not believe the existing three year limitations period has barred a significant number of claims, an expansion of the limitations period is reasonable, is likely to include the small number of claims that might not otherwise meet the three-year deadline, and will not adversely affect the administration of the Program.

The Department does not support the proposals urging lengthier extensions of the statute of limitations. We oppose any proposal that would run the limitations period from the date of "discovery" of the injury. Due to the serious nature of vaccine-related injuries, the onset of an injury normally coincides with the discovery of the injury, thus the proposed change will not benefit a significant number of claimants. Moreover, an inception date based upon "discovery" of an alleged vaccine-relationship is highly subjective and will likely result in time-consuming proceedings to determine when that date occurred. We continue to believe that the inception date for the statute of limitations should be a definitive date. The current use of the date of onset of the injury encourages efficiency and finality in seeking redress for vaccine-related injuries.

In addition, the Department opposes tolling the limitations period until a claimant

reaches the age of 18, or if he is not competent, until 24 months after a guardian is appointed. The Program primarily is designed for children: to encourage eligible children to promptly obtain vaccine compensation, rather than postpone receipt of funds until the claimant turns 18 years old, or is even older. Parents and guardians are entitled to pursue claims under the VICP. In our experience, they zealously represent their children's interests, making tolling until majority, when a minor might otherwise pursue his own rights, unnecessary. Moreover, delaying the case in this fashion could jeopardize a claimant's ability to establish the facts necessary to support his or her claim. Critical medical records may become lost or destroyed, and the passage of time will likely impair the memory of witnesses, hampering their ability to testify fully and accurately. Simply put, delaying the filing of these cases would negatively impact children.

Further, the Department opposes extending the statute of limitations for an additional 36 months after a claimant first knew or reasonably should have known about his or her eligibility for compensation under the VICP. Aside from the practical difficulties of ascertaining a claimant's subjective knowledge of eligibility for compensation, we think the proposal is unnecessary. Greatly increased outreach efforts by HHS and this Department to publicize the Program and to increase visibility amongst parents, physicians, and other health care providers, not to mention the legal community, make lack of knowledge of the Program less of a concern.

The Department strongly opposes any proposal that would authorize the re-filing of previously adjudicated or resolved claims. The re-litigation of these claims would divert scarce resources from new and pending claims, and delay their processing. Important objectives of tort reform measures such as the VICP are to bring efficiency, predictability, and finality to civil litigation, and such a proposal would thwart these

goals.

Interim Litigation Costs

The Department also concurs with the ACCV recommendation to allow payment of interim litigation costs not attorneys fees after a determination has been made that a claimant is entitled to vaccine injury compensation. We concur that an interim award of litigation costs may provide a needed benefit in some cases. Interim litigation costs might include expert witness expenses, and other costs such as those associated with gathering medical records.

The Vaccine Act is unique in allowing a family to file a petition and be assured that reasonable legal fees and costs will be paid regardless of the outcome, provided that the case was brought in good faith and with a reasonable basis. Because in virtually every case attorneys are paid and litigation expenses met, there is no disincentive to taking a Vaccine Act case. For this reason, attorneys typically cover the costs of bringing a petition, knowing that once the case is resolved, reasonable expenses will be paid. In our experience, it is uncommon for claimants to "front" these costs themselves. Moreover, in this Program, cases do not turn on the amount of resources committed to them, but on the underlying merits of the claim.

In the past, questions have been raised about whether there are enough attorneys available to represent families who believe their children may have been injured by a vaccine. Currently, there are nearly 250 attorneys from around the country representing families in pending VICP cases, of which there are approximately 700. Furthermore, in an effort to encourage *pro se* petitioners to obtain counsel, the Clerk of the U.S. Court of

Federal Claims now maintains a list of more than 100 experienced VICP attorneys, organized by the 39 states in which they are located, who are interested in representing claimants in these cases. These numbers should relieve any concerns about the availability of counsel for potential claimants.

Vaccine Injury Table

With regard to the Vaccine Injury Table, the Secretary's authority to revise it is derived from section 300aa-14(c) of the Vaccine Act. Pursuant to the statute, the Secretary may promulgate regulations to modify the Vaccine Injury Table. 42 U.S.C. § 300aa-14(c)(1). In particular, the statute provides,

> A modification of the Vaccine Injury Table . . . may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of onset or the significant aggravation of any such injury, disability, illness, condition or death.

42 U.S.C. § 300aa-14(c)(3).

The validity of the revised Vaccine Injury Table was upheld by the U.S. Court of Appeals for the First Circuit, in a case that broadly challenged the Secretary's revisions pursuant to section 300aa-32 of the Vaccine Act. O'Connell v. Shalala, 79 F.3d 170 (1st Cir. 1996). The Court held that the Secretary appropriately exercised her authority to create a revised Table and sustained her capacity to delete certain conditions from the Table and amend the Qualifications and Aids to Interpretation.

Further, the constitutionality of the Secretary's revisions was challenged and

upheld in two separate Federal Circuit decisions. In these two appeals, the claimants sought to invalidate the revised Table because they believed it to be a product of an unconstitutional delegation of legislative power to the executive branch. O'Connell v. Secretary, HHS, 217 F.3d 857 (Fed. Cir. 1999); Terran v. Secretary, HHS, 195 F.3d 1302 (Fed. Cir. 1999). In both instances, the Federal Circuit held that the section of the Vaccine Act in question was constitutional. On October 2, 2000, the United States Supreme Court denied petitions for certiorari in both cases.

Nature of Proceedings

Finally, I would like to address the charge that the Program has become more litigious. I do not believe that the manner in which VICP cases are processed has become more adversarial, in fact, I believe quite the contrary is true. The language of the Act calls for "less-adversarial, expeditious, and informal" proceedings. 42 U.S.C. § 300aa-12(d)(2)(A). The Justice Department has gone to great lengths to fulfill this Congressional objective. In addition to the Program-related initiatives I mentioned earlier, our trial attorneys regularly collaborate with the Court and counsel in developing creative and novel approaches to resolving specific claims. DOJ was commended by the ACCV and honored with an HHS award for drafting a guide to assist claimants in proving damages, entitled "Steps to Streamlining Damages Under the Vaccine Program," which includes a section on how to petition for attorneys' fees and costs. Other examples include traveling around the country for the convenience of claimants to attend settlement discussions, hearings, or on-site visits, and expediting the settlement approval process.

Moreover, in each of the past five years, almost half of all cases adjudicated have

resulted in compensation for claimants. If the number of families compensated is the measure of whether the Program is "adversarial," then it has become significantly less so in recent years. From 1991-1996, fewer than 1/3 of cases adjudicated each year were compensated, and the other 70-80% were dismissed. In contrast, from 1997 to the present, compensation has been awarded in 41% to 54% of cases. Approximately $1.3 billion dollars has been paid to nearly 1,700 families. Few, if any of these families would have received recompense in the civil tort system.

In spite of the efforts of HHS and this Department to make the Program more "user-friendly," there are those who remain critical of it. Some challenge that the process takes too long, and sometimes it does. However, 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. Our goal is to move cases along as quickly as possible, while generally acceding to the Court's practice of giving claimants the time they need to attempt to perfect their cases. The procedures employed in any given case, and the length of time required to resolve the case, vary widely. Yet, in our experience, the most significant reason for delay in case processing continues to be waiting for claimants to file medical records, expert reports or life care plans. For example, in July of this year, we undertook a special review of the docket sheets in each of the 163 cases filed in FY2000 to examine the posture of these cases. As an initial matter, judgment on entitlement had been entered in 48 cases. We discovered that in 80 cases, or 49%, there had been no delay, and the case was proceeding appropriately. In 63 cases, or 39%, delay was seen because claimants required additional time to obtain medical records, expert reports, or accomplish other tasks. The government required an extension in 13 cases, or 8% of cases, and in three cases, both petitioners and respondent had sought additional time to file necessary documents. In four cases, delay was attributable to the Court.

Could the process be shortened? Of course, rigid deadlines could be enforced, requests for extensions could be denied, and cases could be decided on the written record alone. Without question, however, and as the above statistics demonstrate, this would only be accomplished to the severe detriment of the compensatory principles of the Program with the inevitable result being far more petitions dismissed and far fewer families compensated.

Other critics point out that appeals cause unnecessary delay in reaching final case disposition. Of course, appeals do add additional time. However, appellate rights have predominantly been exercised by claimants, not the government. The government infrequently appeals VICP decisions of the special master, and even more rarely to the U.S. Court of Appeals for the Federal Circuit. Our review of the Court's decisions identified 335 appeals to the Court of Federal Claims (the first level of appeal), on the issue of entitlement or damages, out of nearly 5,400 cases resolved in this Program. Of the 335 appeals to the Court of Federal Claims, 283 (or 84%) were appealed by claimants. The government appealed 57 cases (or 17%).[2] The number of appeals filed by either party has decreased in recent years. For example, the government has appealed only 6 cases in the past four years. In the same time period, claimants have appealed 49 cases.

At the U.S. Court of Appeals for the Federal Circuit (the second level of appeal), we identified 109 vaccine appeals since the inception of the Program in 1988. Only 13 of

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[2] In five of the 335 cases, affirmative motions for review were filed by both petitioner and respondent.

those were taken up by the government. The other 96 cases (or 58%) were appealed by claimants. Most significantly, since 1993, we have appealed only one case, and that occurred three years ago in 1998. The relative frequency of government appeals occurred early in the Program's history, when legitimate questions of statutory interpretation were being explored. As might be expected, as the law became settled, our appeals to the Federal Circuit have been all but eliminated.

As the appeal statistics demonstrate, the government's decision to appeal a particular case is exercised infrequently and with much caution. We are sensitive to the reality that an appeal prolongs a family's involvement in this process, and if the government's appeal is unsuccessful, will have the effect of delaying delivery of compensation. We are not unmindful of the stress and difficulty associated with any sort of litigation. While we attempt to minimize these unfortunate consequences, there are occasions when, in our view, appeals must nevertheless be taken to defend the Congressional criteria, preserve the integrity of the Program, and promote its overall goals.

We generally appeal only those cases in which we believe an issue of law has been wrongly decided, and is likely to negatively impact future cases. It is the Congressional scheme that we attempt to protect and enforce. In contrast, we generally do not appeal cases in which we simply disagree with the special master's factual determinations or judgments based upon their assessment of the credibility of witnesses.

Finally, I would like to offer some insight as to the origin of complaints that the Program is too "adversarial" or "litigious," and it pertains to the elements of proof that are

required to establish a vaccine injury. As you know, through the Vaccine Act, Congress authorized two specific circumstances under which a vaccine-injury may be demonstrated and compensation awarded: first, by demonstrating a "Table" injury (an injury listed on the Vaccine Injury Table, presumed to be related to the immunization), or second, by proving that the vaccine *actually* caused the claimed injury. The statute forbids the Court from awarding compensation based on the statements of a claimant alone, unsubstantiated by medical records or the opinion of a qualified medical expert.

In general, if the occurrence of a Table injury is conceded, the case proceeds quickly, moving to a determination of damages without need for medical expert testimony or a hearing.

Causation claims, on the other hand, require claimants to produce reputable mainstream medical and scientific evidence showing that the vaccine is the cause of the injury. As opposed to a typical civil tort action, the Program remains "no-fault" in concept and application. In other words, claimants need not prove that the vaccine was defective or there was any degree of negligence on the part of the doctor or clinic that administered the vaccine. In resolving these claims, the Court, consistent with the statutory guidelines and Congressional intent, does not require scientific certainty, simply a preponderance of the evidence.

It is true that causation in fact cases typically require greater time and more resources than do "Table" cases. Causality itself is a concept that can be difficult to understand. As the Institute of Medicine has acknowledged:

> The arousal of one's suspicions that a vaccine might be the cause of an adverse event that occurs within hours, days, or weeks following receipt of the vaccine is

> natural and understandable. But the mere fact that B follows A does not mean that A caused B; inferring causation solely on the basis of a proper temporal sequence is the logical fallacy of *post hoc ergo propter hoc* (literally, "after this, therefore because of this").

Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 23 (Nat'l Academy Press 1994). Proof of causation is more than a coincidental relationship or temporal association.

The government's position in each case is premised on the legal and medical requirements of the statute itself. Where the science demonstrates a causal link, compensation is paid. Yet, where a condition simply appears following vaccination, and there is no other reputable scientific evidence to link the vaccine to the condition, causation is not shown. Again, this is pursuant to the statutory mandate, and Congressional intent. We simply cannot ignore the statutory criteria or the consensus of the medical community on the medical causation issues. 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.

I believe it is the denial of scientifically unsupported petitions that may give rise to complaints about the Program. As with any governmental benefit program with specific eligibility criteria, there will unavoidably 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 are obliged to uphold the provisions of the Act and it's accompanying regulations, thus requiring us to seek dismissal of those claims that lack reputable reliable evidence of the occurrence of a vaccine injury. This Program is not an entitlement scheme that requires every claim be paid, but one with eligibility criteria based on good science.

It bears mention of why we must be mindful of the impact "actual causation" decisions can have. Erroneous decisions based wholly or even partially on unaccepted causation theories will result in the public perception that vaccines are inherently dangerous, or that a vaccine necessarily causes a particular injury, notwithstanding the lack of reputable mainstream medical and scientific support for such a proposition. If this misconception were fostered, it would undercut the very purpose and integrity of the Program, and along with it, the Nation's vaccination policies. We must be diligent in our efforts to maintain high public confidence both in vaccines and our public health system.

Of course, the Department shares the Committee's goal of enhancing Program operations, and we are committed to working further with the Congress, HHS, the Court, and interested groups to effectuate positive change. With regard to other legislative initiatives, I would like to ask that the views of the Department of Justice, outlined in a letter sent to Chairman Burton on October 17, 2001, be made part of the Committee's record on the VICP. 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 questions at this time.

Mr. BURTON. How many cases have been filed?

Mr. HARRIS. In the life of the program, there have been roughly 6,000 cases filed.

Mr. BURTON. And how many did you settle?

Mr. HARRIS. 5,400 have been adjudicated, and how many have been settled, I couldn't give you that number.

Mr. BURTON. I think you just gave a figure there of 1,000 something, wasn't it?

Mr. HARRIS. We have paid compensation to 1,700 families.

Mr. BURTON. So less than a third have received compensation.

Mr. HARRIS. In the early part of the program, clearly, less, there was a tendency not to pay petitioners. But that percentage has gone up, Mr. Chairman.

Mr. BURTON. Ah. But there was a tendency not to pay.

Mr. HARRIS. Yes. And we worked closely with your——

Mr. BURTON. How long have you been doing this, Mr. Harris?

Mr. HARRIS. How long have I been on the job, sir?

Mr. BURTON. Yes.

Mr. HARRIS. Since July of this year, sir.

Mr. BURTON. Well, where did you get all this expertise? It's kind of amazing that you have all the answers so quickly, and you've just done it since July?

Mr. HARRIS. Yes, sir. I do my homework.

Mr. BURTON. Oh, OK. That's very good. I appreciate the opening statements, but what I didn't hear was any meaningful discussion of what we heard this morning. What do you think about the three families that were here this morning?

Mr. HARRIS. Well——

Mr. BURTON. I mean, obviously you've only been on the job 3 or 4 months.

Mr. HARRIS. Clearly.

Mr. BURTON. So maybe you didn't study these three cases, but they've been going on from 6 to 10 years.

Mr. HARRIS. Actually, I have studied those.

Mr. BURTON. Well, then, why were they paid, if there was no merit to their case?

Mr. HARRIS. Two of the cases, as you recognized, Mr. Chairman and members of the committee, are cases that are still pending and——

Mr. BURTON. Why are they pending?

Mr. HARRIS. I cannot comment on specific circumstances of open cases.

Mr. BURTON. But they're being appealed, right?

Mr. HARRIS. Two of the cases this morning are being appealed, that's correct.

Mr. BURTON. For a layman like myself, tell me, a special master says they should be paid, right?

Mr. HARRIS. Correct. In certain cases.

Mr. BURTON. Yes. And then if the Justice Department doesn't agree, then they appeal it?

Mr. HARRIS. Correct.

Mr. BURTON. I see.

Mr. HARRIS. Rarely. Very rarely do we appeal.

Mr. BURTON. Well, we had two of those cases this morning, did we not?

Mr. HARRIS. That's correct. Which is why what we heard this morning, as emotionally tragic as those cases are, they're not a representative sample of what we deal with. Let me throw out some numbers. 300——

Mr. BURTON. Let me just interrupt you real quickly. You say they're not representative of what you deal with, and yet you said there's been over 6,000 cases filed and you gave compensation to less than a third of that. Now, the thing that's interesting is, and I'll be happy to bring you and Mr. Balbier back here every week or every month if you like and bring three or four more people in and have them testify again and again and again about the shortcomings of the system. I'll be very happy to do that if you guys want to spend the rest of your life before my committee. I don't have any problem with that.

But I see no reason to do that, because we had three examples this morning. What I can't understand is, why these people have been judged to be in compliance with the statute and should be paid, one of them is being compensated, and the other two, the special master agreed, one of them I think had three or four special masters, but it has been agreed, and yet the Justice Department decides to appeal the case.

Mr. HARRIS. Mr. Burton, I'd like to answer the question about appeals. Because one might get the impression that our tendency is to appeal. And that is not the case.

Of the 335 cases that have been appealed to the Court of Federal Claims in the history of the program, for entitlement or damages issues, the Department has only appealed 57 times. All the other appeals have been by petitioner. It's important to know that.

Mr. BURTON. What happened on those 57 cases?

Mr. HARRIS. What happened in each case?

Mr. BURTON. I mean, how many were settled in favor of the Justice Department and how many were not?

Mr. HARRIS. I'd be happy to get that information for you.

Mr. BURTON. Well, wait a minute. You said you've been studying this issue. Fifty-seven cases have been appealed and you don't know how many you guys won or lost?

Mr. HARRIS. We have that information but I'm not a statistician and I can't spit out every——

Mr. BURTON. But that's very important.

Mr. HARRIS. It is important, and I'd be happy to get that information.

Mr. BURTON. Because if the Justice Department is appealing these cases and you're not winning, it may be an indication that some of these, the special master may know what they're doing. And they may be cases that shouldn't be dragged out for months and years while these people suffer.

Let me ask a few questions here. Ms. Zuhlke, she didn't lose her case. Mr. Sword didn't lose his case. Mr. Rogers hasn't lost his case. Do you think that those complaints that you heard this morning were just sour grapes?

Mr. HARRIS. Well, I would respectfully have to say that a characterization that they haven't lost the case would be unfair, because

the cases are still pending. And I do not think it's sour grapes. I think it's horrible what has happened to these families, and the problem in each of these cases, given the complexities of the medical and scientific issues involved, overlaid with the emotion, is that no matter how efficient our process is, and respectful of due process rights, given the fact that there is collateral repercussions to the injuries that are involved, you heard breakup of families, that no matter how much we compensate these cases, people are going to be dissatisfied.

Mr. BURTON. Let's go through the process. We have a special master that's appointed by the court, right?

Mr. HARRIS. Correct.

Mr. BURTON. And the special master goes into all the details, looks at the medical evidence, listens to the testimony and everything else, and the special master makes a decision, is that correct, after studying the issue, and hearing all the testimony?

Mr. HARRIS. That would be correct, sir.

Mr. BURTON. OK. So the special master makes a decision. In several of those cases, they had more than one special master. And you heard the outcomes. The special masters in all three cases agreed that compensation should be paid. You in two cases have decided to appeal those cases. And those cases have been going on from 6 to 10 years.

Mr. HARRIS. Right. And the answer to your question is, there are occasions where we do not agree with the special master. But there are rarely occasions we don't agree with the special master that we feel so strongly to take these cases on appeal. In the last 4 years, we've only taken six cases on appeal. There are currently about 700 cases pending. So any impression that we are just willy-nilly taking cases to appeal in an overzealous litigious fashion would be unfair.

Mr. BURTON. Excuse me, now, Ms. Zuhlke's case is not being appealed. And the Sword case was appealed but you lost. So two of the three——

Mr. HARRIS. Correct.

Mr. BURTON [continuing]. Have been appealed, but they've been settled. So the third one is the only one that's on appeal now, right?

Mr. HARRIS. I said two were appealed, correct.

Mr. BURTON. Two were appealed but you lost one of them, right?

Mr. HARRIS. One of the cases is still pending. One we lost, the Sword case is a closed case.

Mr. BURTON. You lost.

Mr. HARRIS. Correct. We appealed that case from the special master to the Court of Federal Claims.

Mr. BURTON. Does it bother you when you appeal a case like that and you lose? Does it bother you that you dragged a case on for 6 or 8 years? And when Congress passed this, you know, you stated the intent of Congress, I was here. I was one of the people that was involved in the decisionmaking process to pass that legislation. And it was our intent to make this much less adversarial for people who had to go through the trauma of having a child or a sibling or a wife or husband injured. And that's why we got the drug companies off the hook, so they wouldn't be sued and have endless litigation, so they could produce these pharmaceutical supplies.

So the intention of Congress, as I recall, because I was here, and you've only been there 3 or 4 months, was that we make this very, a lot less adversarial. As I said, I'll be happy to bring before this committee as many people as you want. I could bring maybe 50, 100 people at different times to tell you about situations like we heard this morning.

So for you to give the impression to this committee and to the Congress that there's not a lot of problems out there, there are a lot of problems. And we haven't brought the attorneys before the committee who have handled these cases. The thing about the attorneys is, they're limited, I think it is, to $30,000?

Mr. HARRIS. That is incorrect.

Mr. BURTON. How much are they limited to? Is there any limit?

Mr. HARRIS. They're limited in retrospective cases. But if the cases are not retrospective, meaning the injuries are post-act cases, there is no limit.

Mr. BURTON. Well, we had the one case, we heard about a while ago, where the attorney worked for almost 10 years and was given $30,000.

Mr. HARRIS. Mr. Sword's case.

Mr. BURTON. Yes.

Mr. HARRIS. That was a retrospective case.

Mr. BURTON. Well, I understand. But the point is, if you're trying to get a counsel, a legal counsel, to take on a case like this, and they have to spend 5, 6, 7, 8 years trying to get the case resolved, a retrospective case like you're talking about, there aren't many attorneys that are going to do that, because they're not going to do it on a pro bono basis, that means no cost basis. They're going to want a fee. And $30,000 for 10 years on a retrospective case is nothing.

Mr. HARRIS. Mr. Chairman, I couldn't agree more. But unfortunately, we have to abide by what the act tells us we have to abide by.

Mr. BURTON. Ah.

Mr. BALBIER. Mr. Burton, I might add that the deadline for filing retrospective claims expired more than 10 years ago. So the cap on attorney fees in cases has not been a problem at all for the program for well over 10 years. That only applies to the vast majority of claims that were filed for injuries that occurred prior to 1988, when the program went into effect.

Mr. BURTON. Let me get back to that. My time has expired and Dr. Weldon's been very patient as well as Mrs. Davis, so I'll let them have some time.

Dr. Weldon.

Dr. WELDON. Thank you, Mr. Chairman.

Can either of you gentlemen tell me if you'll be sending somebody down to do the life care plan on Janet Zuhlke's daughter, Rachel? She's been waiting since July. Is that handled by your office, Mr. Balbier, or you, Mr. Harris?

Mr. HARRIS. I think the policy typically is we don't assign a life care plan provider until we've received the life care plan from the petitioner.

Dr. WELDON. She has sent it to you. In light of the fact that her case has been going on for 12 years, can you get somebody down there before Thanksgiving?

Mr. HARRIS. Thom, do you want to——

Mr. BALBIER. Representative Weldon, one of the initiatives that came out of our advisory commission was the idea that we could develop life care plans using one life care planner for both parties. That is for both the petitioner who has filed a claim, and the Government who has to implement the statute.

In the cases where we've been able to use what we call a joint life care planner, that has tremendously helped the resolution of the case. And we've been using them for many years.

However, that's at the beginning of the damages process. If the family and their attorney agrees with the concept of using one life care planner, it goes very, very quickly.

Dr. WELDON. Well, we heard testimony from her, she's lost a job, she can't work, she's had tremendous out of pocket expenses, it's been going on for 12 years, she hasn't heard a word since July. I'm just asking you a simple question, can you ask somebody in your office to call her and set up an appointment to get the life care planner down there? You can't answer that question? Why not?

Mr. BURTON. Are you asking that question of Mr. Balbier?

Dr. WELDON. Yes.

Mr. BALBIER. I'd like to answer that, actually. It does seem like a very simple question. The honest answer is, there may be a life care planner on the way right now. I honestly don't know. No, I can't answer that question. But we can find out.

Dr. WELDON. Who makes the decision? Who decides when somebody goes down to Florida and—cat got your tongue? You're looking at me like—whose office? Is it Justice or is the vaccine program?

Mr. BALBIER. While the damages negotiations are underway. The Department of Justice trial attorneys handle most of that. We offer assistance wherever possible. And again, there would be no need for a life care planner to go down there had we been able to go with just one. That really helps resolve cases quickly. And we've had many cases resolved that way.

Dr. WELDON. So you're saying you may accept the plan that she submits rather than send another person down and negotiate the plan?

Mr. BALBIER. Mr. Weldon, what I'm saying is that——

Dr. WELDON. The reason you're not responding to me, is it because this is all in negotiations? Is that——

Mr. BALBIER. Well, as you know, with any case that's under litigation, you can never comment on negotiations. This is litigation. We try to make it a less adversarial process.

Dr. WELDON. Let me just ask you a very bland question. Can you try to expedite this case in the months ahead? Is there a place in your heart to find a willingness to expedite this case?

Mr. BALBIER. We try to expedite every case. When I first saw, and it was just yesterday, which witnesses would be here testifying, which families, I recognized the names. I recognized them, although I didn't know immediately why. When I looked into it, I remembered that the Zuhlke's case was one of the lengthiest proceedings in the history of the compensation program.

The facts in the Sword case stand out, when you first see them, you think, why would the Government ever appeal this case. And then when I heard of the other witness, that name was also familiar, Rogers. That was familiar most recently, because Congressman Burton asked me about that case.

Dr. WELDON. Let me ask you another question. She has——

Mr. HARRIS. I may be able to help you out here, if you'd like.

Dr. WELDON. OK, go ahead. If you can make it quick.

Mr. HARRIS. Yes. I did not come prepared to discuss specific details of the Zuhlke case, but I can assure you that I will have one of our attorneys contact her attorney by tomorrow. And I'll be happy to get back with you on that.

Dr. WELDON. I would like another assurance from you, that you will not seek any retribution against this lady and her family based on the testimony she has provided here.

Mr. HARRIS. Let me make clear, the Justice Department never seeks retribution. In fact, we find it offensive for folks to characterize honest Federal Government employees as seeking retribution against U.S. citizens who have suffered such a loss, and we wouldn't do that.

Dr. WELDON. Mr. Harris——

Mr. HARRIS. We have never done that and there is no evidence to support that.

Dr. WELDON. You draw your employees from the ranks of the human race. And you may be a very, very nice person, as may be Mr. Balbier. But as we all know, dealing with every Federal agency, there are occasionally some people who will do things like that. So I would just ask that you would take some personal interest in this matter to make sure personally that nothing of that nature happens.

Mr. HARRIS. I will take a personal interest in this matter, and I can assure you that in any instance where there is an allegation that our attorneys are acting in any untoward fashion——

Dr. WELDON. I'm not saying there's any allegation. I'm just, I'm a little concerned, because she has said some things here that a lot of people would be afraid to say.

Mr. HARRIS. I understand that, and I'm sensitive to that, and I'll look into it and make sure that her attorneys are contacted. But I have to reiterate, there is no tendency on the Justice Department officials to seek retribution against citizens. If you have evidence into that, I'd love to have it.

Dr. WELDON. No, I don't have any evidence of that. I'm just being cautious. Thank you.

Mr. BURTON. I'll be glad to talk to you about a few cases after we adjourn, because there has been some cases of what I would consider retribution I think you probably ought to be aware of.

The other thing I'd like to say before I yield to Ms. Davis is this. You're going to respond to Ms. Zuhlke's problem by calling tomorrow. What about the other people that we can bring in, and I'm sure that there's probably over 100 or maybe more, that would require the same kind of attention that haven't received it? Should we give you a list of those so that you can respond to those quickly?

Mr. HARRIS. Mr. Chairman, if you have a list of folks that we haven't contacted in months, I'd love to have a list of those folks.

Mr. BURTON. Well, you're going to get it.

Mr. HARRIS. I appreciate that.

Mr. BURTON. I will have that for you. And since you've been on the job a short time, I think that maybe you are going to be able to make a difference, and I'll get you that list.

Mrs. Davis.

Mrs. DAVIS OF VIRGINIA. Thank you, Mr. Chairman.

Mr. Harris, I know you've only been on the job since July. Mr. Balbier, how long have you been involved in this?

Mr. BALBIER. For a little over 11 years, I've been the Director of the program.

Mrs. DAVIS OF VIRGINIA. So you're pretty familiar with all three of these cases, then.

Mr. BALBIER. No, I'm not. I was familiar with the histories. The names were familiar when I first heard of them. And again, that was only just yesterday when I saw the witness list.

Mrs. DAVIS OF VIRGINIA. But you made a comment a minute ago that based on the facts, you had to wonder why the Justice Department appealed, I think it was Mr. Sword's, is who you said.

Mr. BALBIER. Well——

Mrs. DAVIS OF VIRGINIA. That was the one, if I'm not mistaken——

Mr. BALBIER. That wasn't——

Mrs. DAVIS OF VIRGINIA. Let me finish. That was the one, if I'm not mistaken, that they just said that it was appealed and it was lost. So who makes the decision to appeal? Does HHS recommend it or does DOJ look at it and make the determination? Who makes that determination?

Mr. BALBIER. That's an excellent question. We make the determination together. However, it's really up to the Department of Health and Human Services. We are the ones who are responsible for administering this program. Our pediatricians are the initial reviewers of cases after they're filed. They make recommendations to the court. They first prepare a medical report.

And then in cases where we concede they've met the criteria of the statute, we move immediately to damages negotiations. And we've had cases resolved in as little as 97 days. But in cases where they don't meet the criteria of the statute, that's where problems arise. People, honest, reasonable people, good families, have very different opinions on injuries that are surrounding the administration of vaccines, and whether they seemingly are caused by vaccines.

And as I said, with the Zuhlke case, I remember that case years ago when we first got a congressional inquiry on that case. And that was my reaction, why did we appeal that case? It wasn't fresh in my memory.

Mrs. DAVIS OF VIRGINIA. The Zuhlke case or the Sword case?

Mr. BALBIER. No, the Zuhlke case.

Mrs. DAVIS OF VIRGINIA. But did you not say a minute ago when you were talking that on the face of it, you didn't understand why the Sword case was appealed. I believe that's what you said.

Mr. BALBIER. OK, I'm trying to remember what the——

Mrs. DAVIS OF VIRGINIA. Mr. Sword. The one that was appealed and was won.

Mr. BALBIER. It's the Sword case, you're right. It's the Sword case I'm thinking of, that's correct.

Mrs. DAVIS OF VIRGINIA. It was appealed, and you lost when you appealed it.

So I guess my question is, I'm assuming then that HHS recommended to DOJ——

Mr. BALBIER. That's exactly how it works.

Mrs. DAVIS OF VIRGINIA [continuing]. To appeal. But you're with HHS.

Mr. BALBIER. That's right.

Mrs. DAVIS OF VIRGINIA. You just said that when you looked at the facts of the case, you had to wonder why it was appealed.

Mr. BALBIER. I raised the question, why did we appeal. I looked into it and I had a very good answer to that question. My staff filled me in.

Mrs. DAVIS OF VIRGINIA. I'd like to hear it.

Mr. BALBIER. I'd like to be able to tell you that.

Mrs. DAVIS OF VIRGINIA. OK.

Mr. BALBIER. That case is in litigation and I can't.

Mrs. DAVIS OF VIRGINIA. I thought you just said it was lost.

Mr. BALBIER. That case is still in litigation.

Mrs. DAVIS OF VIRGINIA. Did you not just say that the Sword's appeal was lost?

Mr. BALBIER. As far as we're concerned, all these cases are in litigation. And we cannot discuss them.

Mrs. DAVIS OF VIRGINIA. Mr. Chairman, I'm sort of confused here.

Mr. BALBIER. If the gentlelady would yield, as I understand it, they're in litigation not on the outcome but on the amount of compensation, is that correct?

Mr. BALBIER. As I said, I cannot discuss these cases, they're on appeal. I can't discuss what the issues are in these cases.

Mrs. DAVIS OF VIRGINIA. But I believe——

Mr. BURTON. Excuse me. The Sword case you can't discuss, even though that's been completed?

Mr. BALBIER. The case actually has not been completed. I don't believe that case has been paid, has it?

Mr. BURTON. The money's been paid, has it not?

Dr. WELDON. The Sword case is a closed case, Mr. Chairman.

Mr. BURTON. And you can't comment on that, Mr. Balbier? You can't comment on the Sword case?

Mr. BALBIER. I did not come here prepared to comment on the Sword case, specifics of that case. As I said, I didn't know that——

Mr. BURTON. Well, I want you to know that you guys are going to be up here more than you ever dreamed you were going to be up here if you don't cooperate with this committee. And hiding behind a case that you say is ongoing and you can run it on for 8 or 10 years is not going to be acceptable. Now, I hope you get used to looking at me, because you're going to be up here a lot. And if you don't want to come, I'll subpoena you. And if I have to go to Tommy Thompson and have him bring you up here, I'll do it. This is ridiculous.

The gentlelady's time—I'm sorry.

Mrs. DAVIS OF VIRGINIA. That's OK, Mr. Chairman. I guess what concerns me, Mr. Balbier, is you're sitting here stating that you cannot comment on a case, yet you yourself without being asked the question commented on the case a minute ago when Representative Weldon was speaking. You said that when you looked at that case, you couldn't understand why it was appealed.

Mr. BALBIER. That is correct.

Mrs. DAVIS OF VIRGINIA. Then you answered the chairman that the appeal had been lost. So I guess I've got a real problem as to why you make a comment that you don't understand why you appealed it——

Mr. BALBIER. I got——

Mrs. DAVIS OF VIRGINIA [continuing]. You just answered me that HHS makes the——

Mr. BALBIER. I was simply confused between the two cases.

Mrs. DAVIS OF VIRGINIA. Well, if you've got your memory back now, can you tell me why you appealed it?

Mr. BALBIER. I didn't come here prepared to discuss the merits of that case.

Mr. HARRIS. I might be able to help.

Mr. BALBIER. I don't have the specifics in front of me. We can, if you would like, we can provide for the record the case history of that case and why it was appealed. And the issues involved. They are complex.

Mr. HARRIS. I'd like to be able to help answer some of your questions, if you would permit me to do so.

Mrs. DAVIS OF VIRGINIA. That would be fine.

Mr. HARRIS. Just to clear up where we are with the three cases that we heard from this morning, the Sword case, to my understanding, if I recall correctly, is a closed case and payment was made on that case, I believe, in August 1999. There's one case pending on damages, which is the Zuhlke case, and there's another, the Rogers case is pending on appeal. So if you have questions about the Sword case, I think I'd feel comfortable in answering those questions.

If your question is, why was that case appealed, it was appealed because we disagreed with the theory used by the special master in determining that case, because it was a theory that was not discussed in the litigation process. Because it was not discussed in the litigation process, we did not have our opportunity to present our side of her theory.

Once the special master made a decision, we tried to introduce evidence that would in effect present our side of what her theory turned out to be. She decided not to hear that, we appealed to the Court of Federal Claims. The Court of Federal Claims agreed with the special master, and we decided not to take it any further. So that's where that case ended.

I think it would be safe to say that because of the appeals taken in the Sword case it was protracted out over months. However, once the decision was made by the Court of Federal Claims in June 1999, payment was made to the family by August of that year.

Mrs. DAVIS OF VIRGINIA. Thank you, Mr. Harris.

I don't know if it's appropriate to make this comment, Mr. Chairman, but I'm going to, and you can call me down if I'm incorrect.

I can understand, Mr. Balbier, why the petitioners feel an adversarial role from the Government, because I felt an adversarial role from you when you responded to me.

Thank you, Mr. Chairman.

Mr. BALBIER. I apologize if you felt that way. That was not my intent.

Mr. BURTON. Mr. Platts, I'm sorry, I didn't see you. Do you have any questions?

Mr. PLATTS. Actually just one to followup, Mr. Chairman.

Mrs. Davis, it sounded like, Mr. Balbier, that you have an answer. I understand you didn't come prepared to get into specifics. But it sounded like you have an answer to the question about the appeal when you asked and you looked at it and you were given an answer, but you didn't think you could share it, because that was a pending case. Now that we have resolved that is a closed case, the answer that you apparently wanted to give but thought you couldn't, it seems like you can now give.

So I'd be interested in hearing that answer.

Mr. BALBIER. I think in the Sword case the medical issues were very complex. I had them explained to me very late last night by my medical staff. And I understood them at the time, and I understood why we appealed the case and I understand that there was confusion, or misinterpretation of the findings of the medical experts in those cases. And we decided to appeal that case based on the interpretation of the statute by the special master.

Mr. PLATTS. Thank you, Mr. Chairman.

Dr. WELDON [assuming Chair]. The Chair now yields to himself 5 minutes for a second round of questions.

Mr. Balbier, you said in your testimony that you have done a lot to let people know about the program. Have you done a study or a poll to see what is the level of awareness on the part of the public of the vaccine compensation program? Specifically, parents of newborns.

Mr. BALBIER. We have not done any studies to date to do that.

Dr. WELDON. I would recommend you do so. Because one of the themes I've heard over and over again is that people hadn't heard about the program. I think we would be well served to get some sort of measure, objective measure of what the level of awareness is. It may help us in the Congress to work with your agency to raise the level of public awareness.

I also want to say to you that I appreciate the endorsement of many of the provisions of the legislation introduced by Congressman Nadler of New York and myself, H.R. 1287. Would you be willing to commit to sit down with my staff or members of your staff with my staff to see if we can work out acceptable language to the administration on some of these reforms that both Congressman Nadler and you and I would like to see moved forward on?

Mr. BALBIER. We'd be happy to do that.

Dr. WELDON. Thank you. I will have my staff set up a time for that. I personally believe we should be able to pass these reforms in a bipartisan fashion.

Mr. Harris, as I understand it, if a family retains an attorney and puts in a claim, it goes before the program and the program has pediatricians, basically, that analyze the merits of the case,

and if the decision is made by the vaccine program managers to deny compensation, it's turned over to you and then you oppose settlement. And if these cases go before the special master, you actually have the ability to bring in experts, is that correct?

Mr. HARRIS. That's correct.

Dr. WELDON. OK.

Mr. HARRIS. And petitioners, I might add, have that as well. One of the problems that petitioners face, once they pass the eligibility phase, or the fact that they are eligible for the program, is the expense involved in hiring experts. And we're sensitive to that. If your bill proposes to provide some fees to help in that, that would be something that we would certainly support.

Dr. WELDON. OK. That was the kind of answer I was hoping to get. That's a complaint I've heard over and over again, that some of these attorneys are big-hearted enough to just wait and wait and wait years and years to get their payments. But it's impossible for them to be paying out for these experts.

I was very, very disturbed in reviewing the case of Ms. Zuhlke, these repeated delays from DOJ. No explanation at some of these hearings why they were asking for continuance. Some of these continuances going on as long as 9 months is what my constituent complained to me. The impression I get, just from listening to her, I'm reading between the lines here, it was often just the case, the attorneys were not prepared.

I don't believe that is acceptable at all. You said you took this job in July. What did you do prior to July?

Mr. HARRIS. I practiced law, and I was also a State legislator in the great Commonwealth of Virginia.

Dr. WELDON. Wonderful. I think we've met before, haven't we?

Mr. HARRIS. I don't think so.

Dr. WELDON. Quite all right. You didn't practice specifically medical malpractice or medical defense, did you?

Mr. HARRIS. No, Congressman. My practice was primarily labor and employment law, although I'm familiar with medical malpractice issues.

Dr. WELDON. OK.

Mr. HARRIS. I would add that, I would hope that I'd have, and I think I do, a Congressman who is as interested in representing their constituents as obviously you are for Ms. Zuhlke. I would find it unacceptable for a lengthy, unnecessary, unsubstantiated delays in cases, and I want to assure you that I will look into that.

I also think the point that you made about making sure that parents are aware of this program is a very good point. For our part, our attorneys and HHS officials, we regularly attend conferences, both in the legal community, and medical community, to try to make sure that information about the program gets out to the general public. We distribute packets with information in it.

This year, we attended 11 such conferences, and certainly hope to improve on that number next year. But your point about making sure that families who are not aware of this program become aware of it is a well taken point. To the extent we can help with that kind of outreach, we welcome that opportunity.

Dr. WELDON. Well, the reason I was asking you about your background is, maybe as you were made aware earlier, I'm a physician.

I practiced medicine for 15 years before I was elected to the House of Representatives. I happen to know the pediatrician pretty well who takes care of her daughter. He's a Duke graduate, he's a really smart guy. And when she first brought her case to me, I actually read the chart.

And you screwed up, basically, in my opinion, on this case. Unless you've got information that you're not revealing, dragging this one on for 12 years is really bad. It makes the program look bad, it makes the Congress look bad. And I would highly encourage you to come to an expeditious resolution of this case. I'm certainly looking forward to working with you in the weeks and months ahead, in crafting ways that we can try to improve the program so that it better meets the needs and intent of Congress.

There's universal agreement that it's too adversarial. I understand your comments, Mr. Balbier, that the way we wrote the law, it's still adversarial. And I accept the responsibility for us to make it less adversarial.

I also recognize the importance that it be based on good, quality medical science. Excuse me 1 second.

Today we have heard that some of the special masters' handling of the compensation cases were frustrated, and/or angry about Justice Department conduct. They made comments like embarrassed, they called prosecutors abrasive, tenacious and obstreperous. They called arguments egregious. Obviously you can see why we are concerned.

Mr. Harris, do you agree with these observations?

Mr. HARRIS. No. I think that our attorneys do the best job they can. They act professionally, they act with compassion in these programs. But they also have a professional responsibility to abide by the standard and the criteria set by Congress, which is a preponderance of the evidence standard, which means that basically, the case that the petitioners present only has to tilt just the slightest bit in their favor, in which compensation awards are paid.

I know that the remarks that you made there from the special master pertaining to one of our attorneys was, I believe, made in the Marks case. And I would have to put those remarks into some kind of a context, look into the case and I'd be happy, again, to get back with you with what we discover. But as a rule or something that happens very infrequently, of course not. Every——

Dr. WELDON. Well, when comments are made like that by a special master, it reflects very, very poorly on the Justice Department. I would hope that you would take appropriate action in your new position to make sure that you do not have attorneys working for you that would engage in practices that would precipitate those kinds of comments by a special master.

Mr. HARRIS. I certainly will do all I can to make sure that kind of conduct obviously does not take place within the Department. I feel very comfortable at this point in saying that it doesn't. I believe that, I mean, you have to put comments into perspective. That same special master who derided our attorney was described as worthless in the prior panel.

Dr. WELDON. Well, I appreciate your sharing that. And I know the special masters are drawn from the human race as well. But

the comments made in the Mann case are not unique. There have been other similar types of complaints.

I'd like to now yield to the chairman of the committee, the gentleman from Indiana, Mr. Burton.

Mr. BURTON [resuming Chair]. Thank you very much, Dr. Weldon.

I just had a couple of followups on this question. It says, when you have those kinds of comments made in a hearing where the special master says that they're embarrassed, they call the prosecutors abrasive, tenacious, obstreperous, do you guys agree with those comments that they made?

Mr. HARRIS. I don't agree with those comments, no.

Mr. BURTON. Well, you're pretty new. Do you agree with these comments?

Mr. BALBIER. I don't know the context in which those comments were made, Mr. Burton. But I've known most of the trial attorneys at DOJ for quite a long time. There are some newer attorneys, but most of them have been with the program for quite some time. And certainly my experience has been just the opposite.

The attorneys come before our advisory commission, too, and have worked with the commission. The advisory commission has had the opportunity to meet several of the trial attorneys at the Department of Justice over the years. They've been more than cooperative, and I think represent us quite well before the courts. If we had any concerns about the quality of representation, we would have made those concerns known with the Department of Justice. But we've never had any problems at all.

Mr. BURTON. When a special master makes comments like those, do they have any place to go? Is there any review process? I mean, if they're talking to somebody over there at your Department or Justice Department and they feel like they've been meeting with people who are arrogant or obstreperous or abusive, where do they go?

Mr. HARRIS. Certainly when a special master makes those kinds of comments with respect to a Justice Department lawyer, we review it, as we did in this case.

Mr. BURTON. Who reviews it?

Mr. HARRIS. The director of the department that oversees the vaccine program, and if necessary, I'll review it myself. But I can tell you that the special master has recently appointed this particular attorney who is the subject of these derisive comments to be chairman of the process group to work very closely with the special masters.

Mr. BURTON. Well, that sounds like a step in the right direction.

Mr. HARRIS. A quality individual.

Mr. BURTON. How does the VICP select expert witnesses? Do you require them to disclose financial ties, either personal or institutional, with vaccine manufacturers or other Government agencies, such as NIH? And that's very important, because we have been, I have subpoenaed the financial records of a lot of people that are on advisory committees over at HHS and so forth, and we have found some people who are on these advisory committees who are making recommendations on vaccines and so forth that have conflicts of interest.

In other words, one of the fellow on the rotavirus, one of the people on the advisory panel that Mr. Balbier referred to regarding the rotavirus vaccine, he was the chairman of that committee and he had a lot of stock in one of the companies that made the rotavirus vaccines. And what you didn't mention was that although the company withdrew the Rotashield from the market, it was because there had been so many adverse reactions and it was less than 1 year after it had been put on the market, No. 1.

And No. 2, there were several people on the advisory panel that had real reservations about that vaccine ever being put into the marketplace in the first place. Nevertheless, the chairman of that committee had financial ties to a pharmaceutical company and it was put on the market. One child died and several others had severe problems.

So we'd like to ask the same kind of question. Do you require these people who are expert witnesses, do you require them to disclose financial ties, either personal or institutional, with some of these vaccine manufacturers?

Mr. BALBIER. Let me try to answer that question, because you asked about the expert witnesses who testify and also about the advisory commission members.

Mr. BURTON. Well, I didn't ask about the advisory commission members, because I already know. I've checked. I've subpoenaed and got their financial records. They didn't want to tell me that, like you didn't want to tell us some things, so I sent a subpoena out and I got the records. We have found, and there are financial records, a lot of them were incomplete, which we're still checking on, we have found that they had financial ties to pharmaceutical companies, and we think that might have tainted their judgment just a bit.

Nevertheless, we're talking about these expert witnesses right now.

Mr. BALBIER. No, we don't require that they fill out any conflict of interest forms at all.

Mr. BURTON. Why wouldn't you think that might taint their judgment just a little bit? Let's say, for instance, I'll give you an example, let's say that a person had strong interest in a pharmaceutical company that manufactured a product. And that product was the one that we suspected caused an adverse event in a child who was vaccinated. Would you think that person would be an unbiased witness?

Mr. BALBIER. I would think that something like that probably would come up in court, or it could come up in court proceedings.

Mr. BURTON. Not unless somebody asked. I mean, your advisory panels over at HHS, nobody ever asked many of those people, they got a financial disclosure statement and many of those were completely vacant. There wasn't anything on it until we checked.

So an expert witness that's testifying, it seems to me logical the first question asked is, do you have any financial ties to the company that manufactured the product that created this adverse event. Seems like you'd want to ask that, wouldn't you? Wouldn't you?

Mr. BALBIER. Quite honestly, it hasn't come up.

Mr. BURTON. I know it, that's why I'm bringing it up now.

Mr. BALBIER. Right. I'll have to look into that and let you know. I honestly don't know. I'm not aware that we require that. I don't think that we do.

Mr. BURTON. Well, I will make a suggestion that you do require it. Because anybody that has a bias, pro or con, on a subject like that, it should be made public. And if they do have a bias, let's say, in favor of a pharmaceutical company that may have been sued, now they're not going to be sued because of the compensation fund, but if you have a company that may have a financial interest in that product, it seems to me logical you'd want to know that before you made that person an expert witness.

Mr. HARRIS. I would be happy to work with your staff, Mr. Chairman, if that's something that you feel strongly about, which apparently you do, to see what we can do to do that. From my own view, if I were an expert influenced by a drug company, I think my tendency would be to tell the folks to pay out in every case so that I wouldn't be sued in State court.

Mr. BURTON. Well, I really ought to show you these advisory committee panel financial statements we have. Because what we found out was that people, and particularly on the Rotashield vaccine, the chairman of that committee had stock in the committee that was manufacturing one of those vaccinations. And he strongly supported it going into the marketplace.

You would think that he would have thought twice about that, wouldn't you? But he didn't.

In 1993, the Institute of Medicine published a report, Adverse Events Associated With Childhood Vaccines. Evidence bearing in causality recommended that research be conducted to answer the following question: Is the age at which the vaccine is given a factor in adverse events experienced? Are some groups of individuals more predisposed to experiencing such adverse events than others? Are there common denominators among individuals who have reported vaccine injuries to VAERS or filed claims through the VICP?

What is the extent to which vaccines can trigger disorders through immune reaction? Are there long latency adverse events following vaccinations? Long term studies and biologically plausible late onset adverse events? Use of newly devised laboratory tools for virus detection to determine vaccines that have been historically accepted as safe to detect additional viruses?

After this report was published in 1993, what actions did your office take in communicating with other HHS agencies such as CDC and NIH to request these research activities take place? I think we'll address that to you, Mr. Balbier.

Mr. BALBIER. Yes, Mr. Burton. We don't conduct any research, scientific research, in our program or for that matter, really in our agency. Research is conducted primarily by NIH, CDC, and of course, the licensing of vaccines is the responsibility of FDA.

Mr. BURTON. Let me interrupt you here. What I'm asking is, this report was published, which would have a direct bearing on a decision that might be made regarding an adverse reaction. So it seems to me these questions would have to be answered in order for you to make an intelligent decision on an adverse reaction. And so what I'm asking is, after this report was published in 1993, did your office take any action to say to these other agencies, HHS,

CDC and NIH, did you say, hey, have you guys done any research in these areas? Because all of these would have a bearing on whether or not the adverse reaction was as a result of the vaccination. And if you didn't do that, I want to know why not.

Mr. BALBIER. All right. There has been quite a bit of research done on adverse events related to vaccines. CDC can discuss that in much better detail than I can. But what I can tell you is what we have done. One of those——

Mr. BURTON. Did you request answers to those questions I just gave you?

Mr. BALBIER. Well, in the one instance that affects our program, and that——

Mr. BURTON. These all affect your program.

Mr. BALBIER. No, I mean——

Mr. BURTON. All of these questions I just read, every single one of them would have an impact on the decisionmaking process on whether or not an adverse event was one that should be compensated. And if you have not asked these agencies if they have done these things and what the results of those studies were, then you don't have the answers.

Mr. BALBIER. No, we work very closely with those agencies and we are——

Mr. BURTON. Let me read those to you again. This is important.

Is the age at which the vaccine is given a factor in adverse events experienced? I'm going to give you this so you can take it with you, because I don't think you have these answers. Are some groups of individuals more predisposed to experiencing such adverse events than others? And have they done any checking on that? Are there common denominators among individuals who have reported vaccine injuries to VAERS or filed claims through the VICP?

What is the extent to which vaccines can trigger disorders through immune reaction? Are there long latency adverse events following vaccinations? Can it be over a longer period of time? Do they lay dormant in somebody? We're talking right now about anthrax. There's some question about whether or not there's a latency period before these anthrax onsets take place. So that's something we ought to know.

Long term studies and biologically plausible late onset adverse events? Use of newly devised laboratory tools for virus detection to determine vaccines that have been historically accepted as safe to detect whether or not they're not safe?

So I'm going to give you this. Those are things that need to be looked into before a decision is made.

I want to say one more thing, and I see all my colleagues are gone, so I'm the only one left, so I'm not going to keep you here any longer than necessary. I have one more question I was asked by one of the families that testified.

The lawyers for the Justice Department that are taking on a case that's appealed, they're paid every week, aren't they? Or do you get paid every month?

Mr. HARRIS. Yes, Mr. Chairman.

Mr. BURTON. Well compensated, or not as well as you could be, but you're compensated fairly well. How are the lawyers paid that are on the other side of the issue? Are they paid monthly?

Mr. HARRIS. No, Mr. Chairman. They are paid at the end of the resolution of the cases. But the Department, frankly, supports interim payments for experts to help ease the costs.

Mr. BURTON. That would include the attorneys?

Mr. HARRIS. I think we would be willing to discuss——

Mr. BURTON. It doesn't include the attorneys?

Mr. HARRIS. No. Expert witnesses is what I'm talking about.

Mr. BURTON. But the attorney, he's the one that's putting all of his time into the case. If the case goes on year after year after year, what does he do? It ends up being pro bono. He just reaches a point where he says, hey, listen, I can't help you any more.

Mr. HARRIS. I understand. We have to abide by what the statute requires. And the statute requires that we pay them at the end.

Mr. BURTON. Maybe we should pay the Justice Department lawyers at the end, too, what do you think?

Mr. HARRIS. Not a good idea. [Laughter.]

Mr. BURTON. Not a good idea?

Mr. HARRIS. No.

Mr. BURTON. You wouldn't do it, would you?

Mr. HARRIS. I'm not sure it would make much difference, but——

Mr. BURTON. Oh, I'm sure, if you can't put food on the table, you wouldn't do it.

Mr. HARRIS. My wife would probably strongly disagree with that.

Mr. BURTON. OK. I will state that the hearing record will remain open until November 15th, so that we can ask additional questions. We'd like you to submit answers to them.

Let me just say this to you. We're going to have you guys back again very soon. I promise you. We're going to bring some more people up here and we're going to ask you to sit there and listen to them. And I'm going to get you a list of the cases that we talked about earlier, as many as I can find, so that maybe you can follow-up and maybe make their lives a little bit easier and make them feel like this Government is responding as it should to very difficult situations that they're involved in.

And I have to tell you one more thing. When you're in the bureaucracy and you're there for a long time, and you've been there for a long time, Mr. Balbier, you hear, I'm not so sure that maybe you don't become a little callous, not intentionally, but I think you do become a little callous, because you hear so many of these horror stories. I mean, we don't hear that many, so many of us up here, our heart bleeds for these people. But you hear them every day.

So after a while, whether you realize it or not, maybe you become a little callous. Not intentionally. I'm not saying you're a callous individual. But there is an appearance of defensiveness and arrogance that sometimes comes across to people, and they feel not only that you don't care, they feel hopeless. And that's really sad. So I would just say to you, because you're going to be there for a while, I'm sure, I can't do anything about that, I can drag you up here and beat you over the head. But I can't get you out of that job, in all probability.

But I wish you would think of one thing. When you talk to those people, they're suffering. They're hurting inside. They've got a child or a sibling or somebody that's really suffering. So when you tell them no or you give them, do it with a heart. Do that for me, even though you and I may not like each other, you may not like me much because I'm such a hard nose. But if you'll do that, it would be a real favor to me. Because a lot of these people are suffering.

We'll have you back here again and you can hear some more of their stories and we'll get some more questions answered. And I will submit this to you so you can take a look at that.

With that, do we have any other questions? If not, thank you for being here. We stand adjourned.

[Whereupon, at 2:04 p.m., the committee was adjourned, to reconvene at the call of the Chair.]

[The prepared statements of Hon. Constance A. Morella, Hon. Dave Weldon, and aditional information submitted for the hearing record follows:]

Full Committee Hearing:
"The National Vaccine Injury Compensation program:
Is It Working as Congress Intended?"
Statement of Congresswoman Constance A. Morella
Government Reform Committee Hearing
Thursday, November 1, 2001
10:00 - 2154 RHOB

Mr. Chairman, I want to thank you for holding this hearing today to examine the many issues surrounding the National Vaccine Injury Compensation program.

I look forward to hearing the testimony of the witnesses. I look forward to learning more about this program and its response and service to our citizens.

I do believe that our Nation's vaccine program is first and foremost about the protection of our citizens, particularly our children. Vaccines are about the promotion of health. Vaccines are often cited as one of, if not the greatest, achievement of biomedical science and public health in the 20th century. There has been remarkable success in controlling many other infectious diseases. We have been very successful in controlling vaccine preventable diseases in the United States, and without these diseases as reminders in our daily lives, we can easily forget how serious and even deadly these diseases are.

However I am aware, and I am concerned about some of the negative reactions to vaccines. Indeed this Committee has held numerous hearings on the Anthrax Vaccines Immunization Program as well as hearings on autism and its relationship to vaccines.

Today, the task at hand is to ensure that the National Vaccine Injury Compensation program is working, that it is fair, that it is doing what Congress intended for it to do.

So I welcome the witnesses today, thank you for coming, and I look forward to hearing your testimony.

Thank you.

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FOR IMMEDIATE RELEASE
November 1, 2001

CONTACT: Brendan Curry (202) 225-3671
http://www.house.gov/weldon

Washington, D.C.--The House Government Reform Committee convened a hearing on the shortcomings in the current Vaccine Injury Compensation Program (VICP)—the program designed to compensate individuals who suffer serious adverse reactions to vaccines. The Committee will hear from parents and program administrators about problems with the program and proposed solutions. Reps. Dave Weldon (R-FL) and Jerrold Nadler (D-NY), along with Committee Chairman Dan Burton have introduced legislation to improve VICP. The bill has 17 cosponsors. There is a growing concern that VICP - passed in 1986 - is failing to provide compensation to all children who have suffered serious adverse reactions to childhood vaccines. The Weldon-Nadler bill, The Vaccine Injured Children's Compensation Act of 2001 (VICCA), ensures that the promises of the 1986 law are fulfilled.

"I am pleased that the Administration has endorsed many of the provisions of our bill, and I look forward to working with them to reach agreement on those areas where agreement still needs to be reached," stated Rep. Weldon. "The program promised to compensate all of those who suffer severe adverse reactions to vaccines and in a less adversarial process. Clearly, the program is failing to fulfill that promise," said Rep. Dave Weldon M.D. "Childhood vaccines are essentially mandated by the government, and we have a moral obligation to compensate those who suffer harm. We are failing in our moral obligation. We have an obligation to bend over backwards in these cases and ensure that the benefit of the doubt goes to the injured child."

Rep. Jerrold Nadler, the principle Democrat cosponsor of the bill added, "Our bill would make a number of substantive and administrative changes to the VICP, to restore this program to the user friendly, non-adversarial, remedial, compensation program that it should be and was intended to be."

The American people benefit from our nation's widespread immunization program. Widespread vaccination, commonly referred to as "herd immunity," prevents dangerous diseases from breaking out in our communities. We receive a great benefit from our comprehensive childhood vaccine program and as beneficiaries we have an obligation to injured children.

Unfortunately, a small number of children suffer severe adverse reactions to vaccines. Congress recognized this when it established this compensation program in 1986. The VICP needs reform to improve its operation and ensure that all children who have a serious adverse reaction to a vaccine are compensated. The bill sponsors and many parents who have tried to access the program believe that it has become too litigious and too adversarial, causing families and children added suffering.

VICCA changes the burden of proof by adopting a standard that closely reflects the standard employed for veterans seeking VA compensation. This standard recognizes that strict scientific proof is not always available. VICCA ensures that when the weight of the evidence is balanced, the program errs on the side of the injured child.

VICCA adjusts statutes of limitation to ensure that a child is not denied compensation simply because a parent did not know the program existed and missed a filing deadline. Changes would allow attorneys to be paid fees and costs on an interim basis, rather than having to wait until the conclusion of the case. This ensures that claimants are able to secure good representation and put their best case forward. The compensation has $1.6 billion in reserves and is funded by a surcharge on each vaccine dose that is administered.

###

H.R. 1287—Vaccine Injured Children's Compensation Act of 2001 (VICCA)

Section-by-Section Summary and Explanation

The "Vaccine Injury Compensation Program Corrective Amendments of 2000" (VICCA) would make a number of substantive and administrative changes to the Vaccine Injury Compensation Program (VICP), in an attempt to restore this program to the user friendly, non-adversarial, remedial, compensation program that Congress intended. The bill would amend the VICP provisions in the Public Health Service Act (PHS Act).

Except as otherwise indicated, references in this summary to provisions of law are to provisions of the Public Health Service (PHS) Act, and references to the Secretary mean the Secretary of HHS.

SECTION 1. SHORT TITLE.

Section 1 gives the bill the short title, the "Vaccine Injured Children's Compensation Act of 2001" (VICCA).

SECTION 2. PURPOSE OF PROGRAM

Section 2 makes it clear that this is a remedial, compensation program, which is consistent with the original intent expressed by Congress in the House Report accompanying the National Childhood Vaccine Injury Act of 1986. The report describes a program of no-fault compensation that distributes funds with generosity.

SECTION 3. THE BURDEN OF PROOF

Section 3 eases the burden of proof for claimants under this compensation program. The program should recognize that the science is rarely 100% conclusive as to the cause of many such possible childhood vaccine injuries, and that the benefit of the doubt should be given to the child when the weight of the evidence is evenly balanced.

In this program we are trying to provide compensation for all claimants whose injuries may very well have been caused by the vaccine. Strict scientific proof may not be available and should not be required. It is important to look at the weight of the evidence and give the benefit of the doubt to the claimant when the science is not conclusive. Compensating individuals under this program should not be used as proof that vaccines are dangerous, any more than denying compensation under this program should be used as proof that vaccines are without side effects. Side effects are rare, and, as such, it is often difficult to prove causal relationships with the certainty that science and medicine often expect. This program should recognize this.

This section does not create a totally new burden of proof, but rather adopts the burden of proof that has been used in the Veterans claims process. The federal government encourages vaccination because of the good it provides to society as a whole in battling disease. Because universal vaccination is promoted by the federal government and is mandatory in the states, it is important to provide just compensation to those children who suffer adversely from vaccination.

SECTION 4, COMPENSATION ISSUES

This Section adopts some of the recommendations of the Secretary and additional changes. First, it allows funding for the establishment and maintenance of trusts for claimants. Second, with regard to awards for pain and suffering (where there is a $250,000 cap), it stops the practice of reducing future pain and suffering to present value. In practice, very few claimants ever receive the full $250,000, regardless of the severity of the injury, because of discounting. This change makes it clear that Congress did intend that some claims, where the pain and suffering is substantial, should receive up to the full amount of the cap.

This Section also allows for the funding of family counseling and training where appropriate. In many of these claims, families are left to deal with and care for profoundly injured children and siblings. The impact of these injuries go well beyond the child who is injured. Other children and parents are often in need of counseling to deal with these situations, and they likewise need training to learn how to care for such profoundly injured individuals. HHS proposed this section.

This Section also provides for the payment of interim fees and costs. Many of these cases last years, and the number of very skilled attorneys who are willing to take these cases is dwindling. This hinders the ability of claimants to put their best case forward. Unfortunately, in many instances it is only claimants who can afford to advance costs without reimbursement for years who see their cases move forward and who are able to put their best case forward. Claimants who cannot afford to advance the costs (and who are often the ones who most desperately need compensation) are not able to pay for the experts they need and put their best case forward.

Since attorneys for the claimants are going to be paid for their fees and costs at the end of a claim, regardless of whether or not they prevail, there is no logical reason why they should not be allowed to petition for interim fees and costs. Claimants deserve representation by counsel who are not only qualified, but who can also afford to pay their bills and concentrate on pursuing the claims of claimants.

SECTION 5, LIMITATIONS OF ACTIONS

Section 5 adopts the Department's recommendation for a six-year statute of limitations. The federal government has done a very poor job of publicizing this program. This is understandable given that advertising VICP could harm efforts to encourage higher vaccination rates. With this understanding it is only reasonable to ensure a longer statute of limitation to give parents a better opportunity to pursue these claims.

The bill also adds a tolling provision for minors. Most states allow for a tolling provision, and, since this is a compensation program where the purpose is to help victims, it does not seem logical to make the limitations of actions provisions more restrictive than traditional civil statutes that toll during minority.

ONE HUNDRED SEVENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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November 16, 2001

Mr. Thomas E. Balbier, Jr.
Director
National Vaccine Injury Compensation Program
5600 Fishers Lane, Room 8A-46
Rockville, Maryland 20857

Dear Mr. Balbier:

On behalf of the Committee on Government Reform, I would like to thank you for testifing at our recent hearing entitled "The National Vaccine Injury Compensation Program: Is it Working as Congress Intended?"

I stated at the hearing that I would be submitting further questions that were not addressed completely during the hearing (See Attachment A). I want to remind you that these questions are still considered to be under oath. I hope that you will answer them to their fullest extent possible.

Please provide these responses by November 30, 2001. If you any other questions please call Elizabeth Crane at (202) 225-5074.

Sincerely,

Dan Burton
Chairman

cc: Henry Waxman, Ranking Minority Member

Follow-up Questions for the Department of Health and Human Services from the November 1 Government Reform Committee Hearing on the Vaccine Injury Compensation Program

1. IOM found that existing scientific evidence favored acceptance of a causal relationship between tetanus vaccines and brachial neuritis and HHS added the condition to the table. However, IOM also found evidence of a causal relationship between tetanus and oral polio and Guillain-Barre syndrome, but HHS did not add this condition to the injury table. Why the disparity in applying the advice of the IOM? Is HHS trying to exclude items on the table that would create more claims?

2. When an individual files a VAERS form with the FDA, are they automatically informed that they may be entitled to compensation through the Vaccine Injury Compensation Program? (If so, how is this done?) If not, why not?

3. In 1993, the Institute of Medicine published their report: Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality recommended that research be conducted to answer the following questions:
   - Is the age at which a vaccine is given a factor in adverse events experienced?
   - Are some groups of individuals more predisposed to experiencing such adverse events than others?
   - Are there common denominators among individuals who have reported vaccine injuries to VAERS or who have filed claims through the VICP?
   - What is the extent to which vaccines can trigger disorders through immune reaction?
   - Are there long-latency adverse events following vaccinations?
   - Are there long-term studies in Biologically plausible late-onset adverse effects?
   - Is there Use of newly devised laboratory tools for virus detection to determine if vaccines that have historically been accepted as safe to detect adventitious viruses.

After this report was published in 1993, what actions did your office take in communicating with other HHS agencies such as CDC and NIH to request these research activities take place? (Please provide a copy of these memoranda to the Committee by November 30, 2001)

What HHS-funded studies have been conducted to answer these questions? (Please provide copies of all published studies that address research needs as well

as abstracts of research, grants or contracts issued to address these issues by November 30, 2001)

4. Additionally, in April 1996, the Institute of Medicine's Vaccine Safety Forum convened a workshop entitled, "Research to Identify Risks for Adverse Events Following Vaccination: Biological Mechanisms and Possible Means of Prevention." At this meeting, the workshop discussed the various immunologic and genetic factors that might influence individuals' responses to vaccines, current research aimed at assessing what populations are at increased risk for experiencing adverse events from vaccines, and research avenues that could be pursued in this regard.

The Workshop members concluded that a number of questions remain unanswered regarding risks for adverse events following vaccination and ways to lower such risks. They included recommendations for research on the following topics:

- The risk of adverse events after vaccination in specific genetic populations;
- On a molecular biology level, the impact over time of multiple vaccinations;
- The potential for a link between learning disabilities and vaccination;
- Whether autistic children have different immune responses than non-autistic children;
- Whether health care workers vaccinated with the Hepatitis B virus vaccine (HBV) experience more autoimmune disorders; and
- Whether the antigens in vaccines are likely to cause demyelinating disorders.

After this report was published in 1996, what actions did your office take in communicating with other HHS agencies such as CDC and NIH to request these research activities take place? (Please provide the Committee a copy of these memoranda by November 30, 2001)

What HHS-funded studies have been conducted to answer these questions? (Please provide copies of all published studies that address research needs as well as abstracts of research grants or contracts issued to address these issues by November 30, 2001)

5. The GAO concluded in 1999, "Where science is insufficient to determine causal relationships between vaccine and injuries, it is not clear that HHS' criteria and approach to making injury table changes are consistent." Has HHS established a criterion? (If so, please provide a copy of these criteria by November 30, 2001)

6. Do you think Congress intended for HHS to remove from the Table of Injuries any conditions included In the original act? Do you think Congress intended for HHS to alter the definitions in the Aids to Interpretation that would result in conditions originally considered as "table injuries" to become "non-table injuries"?

7. The IOM reviewed 76 different types of adverse events, looking for evidence of a causal relationship to vaccines. Of these 59 (66 percent) had no or inadequate research. Has the HHS funded studies to look at these 59 conditions? (Please provide by November 30, copies of published articles on these studies and or abstracts from the grants or contracts that have been funded to gather this research data.)

8. Are epidemiologic studies sufficient to prove biological plausibility of an adverse event or will basic and clinical research be necessary?

9. How does the average American find out about the VICP program? What specific actions has your office taken to assure that this program is well publicized? How do you measure the performance of these actions? (How do you know that what you are doing is working?)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Office of Special Programs
Rockville, Maryland 20857

DEC 6 2001

The Honorable Dan Burton
Chairman, Committee on Government Reform
United States House of Representatives
Washington, DC 20515

Dear Mr. Burton:

Enclosed is the response to your November 16, letter which requested me to respond to "questions that were not addressed completely during the hearing." This response was developed by staff from my office, the Centers for Disease Control and Prevention, the Food and Drug Administration and the National Institutes of Health.

If you have any questions, please contact Patricia Stroup, Director, Office of Legislation, Health Resources and Services Administration at telephone: 301-443-1127 or e-mail: pstroup@hrsa.gov

Sincerely,

Thomas E. Balbier, Jr.
Director, National Vaccine Injury
Compensation Program

Enclosure

HHS Response to Questions Submitted by Chairman Dan Burton
Committee on Government Reform Dated November 16, 2001

QUESTION 1

The guiding principle in changing the Table was to carry out the statutory mandate that conditions listed in the Table be based on scientific evidence that there is a causal relationship between the vaccine and the condition. This is because the inclusion of an injury on the Table allows petitioners to benefit from a legal presumption of causation. Both the 1995 and 1997 changes to the Table required nearly 4 years, utilizing rigorous scientific and policy analysis and input from several advisory committees and an overall public process including a public hearing, as required by the statute. The decision-making in each proposed Table change was detailed extensively in the preambles to the proposed and final rules. Ultimately, the Secretary's decision not to add Guillain-Barre syndrome (GBS) to the Table for both oral poliovirus vaccine (OPV) and tetanus-containing vaccines was based on an extensive scientific and public policy analysis, and in the case of GBS and OPV, evaluation of research published subsequent to the release of the 1993 IOM report.

The 1993 IOM report entitled, "Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality," concluded that the evidence favored the acceptance of a causal relation between OPV and GBS. The conclusion was based on an increased incidence of GBS in a six-year surveillance study for GBS in a southern province of Finland (Uusimaa) reported by Kinnunen et al in 1989 (Neurology 1989;39:1034-6). Ten cases of poliomyelitis occurred between August 1984 and January 1985 at a time when IPV was generally used, and a mass immunization program with OPV immunized 94% of the Finnish population between 2/10/85 and 3/15/85. Ten cases of GBS occurred in OPV recipients within 10 weeks after immunization, and the relative risk calculated by the IOM committee among adult OPV recipients in a population previously immunized with inactivated (injected) polio vaccine (IPV) was statistically significant when calculated on calendar quarters. However, the discussion of the report by Kinnunen et al states that "if we add the 4 cases in the 4th quarter of 1985, there are 7 cases before OPV and 7 cases after OPV in this 6-month period." Thus, OPV in this population could not be the only explanation for the GBS cases since the analysis by calendar quarters contradicts the analysis of GBS cases that occurred before and after the administration of OPV or if the calendar quarters were constructed in another way. In addition, a U.S. study published in early 1994 (Rantala et al. J Pediatr 1994;124:220-3) failed to show a temporal association between GBS and OPV after studying 93 cases of GBS from 22 hospitals over 6 years.

Following release of the IOM report, the Advisory Commission on Childhood Vaccines (ACCV), whose membership by statutory directive, reflects a variety of views relating to childhood immunizations (section

2119 of the Act), recommended that the Secretary convene a task force of experts to review the conclusions of the IOM committee and to consider appropriate changes to the Vaccine Injury Table. An ad-hoc subcommittee of the National Vaccine Advisory Committee (NVAC) (section 2105 of the Act) met to review the IOM report in March, 1994. The subcommittee was composed of members of the NVAC, representatives from the Advisory Committee on Immunization Practices (ACIP), the Advisory Commission on Childhood Vaccines (ACCV), the FDA Vaccine Related Biological Products Advisory Committee, the American Academy of Pediatrics Committee on Infectious Diseases (the "Redbook" committee), and appropriate PHS staff. Where appropriate, the subcommittee also solicited the views of other experts from the field of childhood vaccines.

The NVAC subcommittee concurred with the IOM's conclusions in almost all cases. However, it did not agree with the IOM's conclusion regarding OPV and GBS, voting not to add it to the Table. At its regularly scheduled meeting that December, the ACCV considered the IOM report and NVAC subcommittee review and voted in concurrence not to add GBS to the Table under OPV.

The IOM's conclusion that GBS is causally related to tetanus-containing vaccines was based on an assessment of biologic plausibility and case reports, and not epidemiologic studies as was the case with OPV and GBS. (In fact, population studies have failed to show any measurable increase in the risk of GBS after receipt of a tetanus toxid-containing vaccine.) One case in particular (Pollard and Selby, 1978), that of a 42 year old man who experienced three separate bouts of a GBS-like illness after tetanus immunizations and later had further relapses without antecedent immunizations of any sort, was relied on very heavily as evidence that there was more than a theoretical possibility of GBS brought on by tetanus immunizations.

CDC presented data to the NVAC subcommittee from epidemiologic studies on this issue available since the IOM review. These large population studies showed that there was no increased risk of GBS after tetanus toxoid-containing vaccines in either adults or children. These findings suggest that while certain individuals may have a predilection for GBS after various triggers (including vaccination), such individuals are extremely rare.

The significance of this case and other evidence was debated by the NVAC subcommittee before it made its recommendations. By a vote of 6 to 5, the subcommittee split in favor of the IOM's conclusion regarding GBS and tetanus-containing vaccines, but voted not to add GBS to the Table. After reviewing the IOM report and NVAC subcommittee recommendations, the ACCV voted to add GBS to the Table by a 5-4 margin, *provided that* VICP staff develop specific language for the Qualifications and Aids to

Interpretation to distinguish between a vaccine-related versus a non-vaccine related GBS claim. However since there is no known scientific means of making such a distinction, GBS was not added to the Table.

The issue of consistency in HHS decision making both past and future is one of great importance. Beyond the scientific and public policy aspects discussed above, is the statutory requirement of "preponderance of the evidence." Requiring petitioners to prove causation is appropriate in these instances, and it is for this reason that GBS was not added to the Table for OPV and tetanus-containing vaccines.

QUESTION 2

As of November 26, 2001, the Vaccine Adverse Event Reporting System (VAERS) is including information on the VICP in their response letters routinely sent to individuals filing VAERS reports. The VICP narrative is as follows:

> The National Vaccine Injury Compensation Program (VICP) is a separate government "no-fault" system directed to compensate individuals whose injuries may have been caused by vaccines recommended by the CDC for routine use in children. Please be aware that reporting an event to VAERS does not constitute filing a claim with the VICP. Information on the VICP can be obtained by calling 800-338-2382 or visiting their website at **www.hrsa.gov/osp/vicp**.

QUESTION 3

HHS agencies (NIH, FDA, CDC and HRSA) working on vaccine safety issues have worked diligently on these types of questions since the IOM report, and indeed well before its issuance. One example is the CDC's Vaccine Safety Datalink (VSD) project. Since its inception in 1991, the VSD has been actively involved in research to provide evidence bearing on the causal relationship between vaccines and adverse events. The VSD has produced a number of studies that have investigated whether age is a risk factor for adverse events following immunization, and whether other particular groups of individuals are more predisposed to adverse events following immunization.

For example, with regards to age effects of vaccination, in 1997 the VSD published a study that showed that the second MMR vaccination was associated with fewer side effects when administered at 4-6 years of age compared to 10-12 years of age (Davis Rl, Marcuse E, Black S, Lewis E, Chen R, et al. MMR2 at 4-5 years and 10-11 years of age. A comparison of adverse event rates in the Vaccine Safety Datalink (VSD) Project. Pediatrics. 1997 Nov;100(5):767-71). Regarding groups of individuals that might be more predisposed to experiencing adverse events, the VSD

published a study that looked at whether children with asthma were particularly prone to have an exacerbation of asthma following influenza vaccination (Kramarz P, DeStefano F, Gargiullo P, chen RT, Lieu Ta, Davis RL, et al. Does influenza vaccination prevent asthma exacerbations in children? J Pediatr. 2001 Mar;138(3):306-10). This study found that children with asthma were in fact less likely to have an asthma attack if they received influenza vaccine than those children who were not vaccinated, likely due to preventing asthma attacks triggered by acute infection with the flu. Another study under development for the VSD will examine whether genetic factors (HLA type) might influence the occurrence of rheumatoid arthritis following hepatitis B vaccine.

The Vaccine Adverse Event Reporting System (VAERS) has also looked at possible age effects of vaccination. A recently published study of VAERS data suggests that advanced age might be a risk factor for severe adverse events following yellow fever vaccine (Martin M, Weld LH, Tsai TF, Mootrey GT, et al. Advanced age a risk factor for illness temporally associated with yellow fever vaccination. EID Nov-Dec; 7(6)).

The VSD is also involved in a number of studies of immune reactions and autoimmune disorders following vaccination, and is looking at whether health care workers or other adults are at increased risk for autoimmune disorders or demyelinating disease following hepatitis B vaccine.

Currently in manuscript preparation are results of a VSD study examining the possible association of multiple sclerosis (MS) in women receiving hepatitis B vaccine who are not at risk for developing MS, compared to women who did not receive the vaccine. The VSD is also currently planning (and about to begin) a large-scale study of vaccination of women with Grave's disease – a thyroid disease that is believed to be largely autoimmune in nature, and has proposed a study to investigate the occurrence of systemic lupus erythematosus (SLE) following hepatitis B vaccine.

The VSD has also been active in studying autoimmune diseases among children. For over 10 years, the VSD followed a large cohort of children who received Haemophilus Influenzae type b (Hib) vaccine. This long term follow up study looked at whether diabetes mellitus, an autoimmune disease, was more common among children vaccinated against Haemophilus b infection compared to unvaccinated children. The results showed that there was no relationship between receipt of Hib vaccine in infancy and likelihood of developing diabetes. (Lewis E, Shinefeld HR, Black S. et al. Long term follow-up of the HbOc efficacy trial cohort: no evidence of an increased risk of diabetes associated with early Hib immunization. Presented at the 2001 Pediatric Academic Societies Meeting. May 2001) The VSD is planning to study the risk of Type I diabetes mellitus in adolescents following hepatitis B vaccine

The VSD also studied inflammatory bowel disease among adolescents and young adults – a disease that some researchers have suggested is autoimmune in nature. This study found that there was no link between the receipt of measles containing vaccines and subsequent risk for developing inflammatory bowel disease (Davis RL, Kramarz P, Bohlke K, Thompson RS, Mulloly J, et al. Measles-Mumps-rubella and other Measles-containing vaccines do not increase the risk for inflammatory bowel disease. A case-control study from the Vaccine Safety Datalink Project. Arch Pediatr Adolesc Med. 2001 Mar;155(3):354-9).

These latter two studies – of diabetes and inflammatory bowel disease - also serve as examples where the VSD was able to look at diseases with long latency and their relationship to receipt of vaccines in infancy or early childhood.

There is a wide range of other studies currently underway or in the planning stages within the VSD that are specifically looking at vaccination and immune reactions or autoimmune diseases. These include studies of atopic skin disease (eczema) and vaccination and a number of studies that are looking at asthma and wheezing among infants and children following vaccination.

In terms of research into a link between learning disabilities and vaccination, the VSD has been actively involved in studying the risks of thimerosal exposure in early infancy and risk for learning disabilities. The VSD is currently conducting a retrospective study of over 100,000 children, assessing whether the risk for neurologic disorders and neurobehavioral disabilities was related to thimerosal in vaccines. Other appropriate follow-up studies are under discussion.

Research using new laboratory tools to detect adventitious viruses in vaccines is ongoing. At the CDC, most of the work has been done looking at the possibility of avian leucosis viruses that are known to be present in chick embryo firbroblast cultures in which measles and mumps are grown for vaccine use. There has been no evidence of transmission of these avian viruses to man. Several articles have been published on this research: (Tsang SX. Switzer WM. Shanmugam V. Johnson JA. Goldsmith C. Wright A. Fadly A. Thea D. Jaffe H. Folks TM. Heneine W. Evidence of avian leukosis virus subgroup E and endogenous avian virus in measles and mumps vaccines derived from chicken cells: investigation of transmission to vaccine recipients *Journal of Virology. 73(7):5843-51, 1999 Jul.)* (Johnson JA. Heneine W. Characterization of endogenous avian leukosis viruses in chicken embryonic fibroblast substrates used in production of measles and mumps vaccines. *Journal of Virology. 75(8):3605-12, 2001 Apr.*) (Hussain AI. Shanmugam V. Switzer WM. Tsang SX. Fadly A. Thea D. Helfand R.

Bellini WJ. Folks TM. Heneine W. Lack of evidence of endogenous avian leukosis virus and endogenous avian retrovirus transmission to measles, mumps, and rubella vaccine recipients *Emerging Infectious Diseases. 7(1):66-72, 2001 Jan-Feb.*)

QUESTION 4

Although HHS agencies working on vaccine safety issues have worked diligently on these type of questions since the IOM report, and indeed well before its issuance, the answers are not easily obtained. Scientifically, studying whether risk factors (age, genetics, or otherwise) for a vaccine reaction exist or not is extremely challenging. This is because establishing such a risk factor usually requires both of the following conditions to be met: 1) the adverse event has scientifically been shown to be causally related to the vaccine; and 2) this vaccine reaction occurs frequently enough that subpopulations can be defined actually to study the risk group(s). Seizures after vaccination is one example where both conditions are met and study of risk groups is therefore possible. But unfortunately, this is the exception rather than the rule.

At the present time, it is unclear how genetic factors might affect the response to vaccines. The VSD has one study under development that is intended to examine whether genetic factors (HLA type) might influence the occurrence of rheumatoid arthritis following hepatitis B vaccine. This study could be a prototype for the conduct of subsequent studies evaluating genetic factors, immune disease, and vaccine.

HHS research to examine the impact of multiple vaccinations on the immune system is ongoing. The CDC and NIH have asked the Institute of Medicine to establish an independent expert committee to review hypotheses about existing immunization safety concerns. In November 2001, the committee met to consider the evidence that multiple immunizations in newborns and infants might affect the immune system. The committee approached the evaluation of this topic by considering three hypotheses.

- First, whether the increase in the number of infant immunizations can overload the capacity of the infant immune system.
- Second, whether altered priming of the immune system can lead to changes in the way the immune system develops. This is otherwise known as the "hygiene hypothesis", in that we live in a much cleaner world than in the past, with reduced exposure to germs and infectious diseases that were once common in childhood, and that caused much suffering.
- Third, whether immunizations can lead to autoimmune disorders such as diabetes and some diseases of the nervous system.

As part of the overall question of multiple vaccines and immune system dysfunction, the committee also reviewed materials concerning the relationship between autism and autoantibodies. However, research in into the immune system functioning of autistic individuals is still limited. The committee will release its report within the next three months. The report will contain recommendations for future research.

The VSD is also involved in a number of studies of immune reactions and autoimmune disorders following vaccination, and is looking at whether health care workers or other adults are increased risk for autoimmune disorders or demyelinating disease following hepatitis B vaccine. A VSD study currently in manuscript preparation compares women vaccinated with hepatitis B vaccine were not at increased risk for developing multiple sclerosis to women who did not receive the vaccination. In addition to the VSD study, two other studies have been published by non-VSD researchers that have demonstrated no increased risk of developing or exacerbating multiple sclerosis following hepatitis B vaccine. (Ascherio A, Zhang SM, Hernan MA, et al. Hepatitis B vaccination and the risk of multiple sclerosis. N Engl J Med. 2001;344:327-332.) (Confavreux C, Suissa S, Saddier P et al. Vaccinations and the risk of relapse in multiple sclerosis. N Engl J Med. 2001; 344:319-326.)

The VSD is also currently planning (and about to begin) a large-scale study of vaccination of women with Grave's disease – a thyroid disease that is believed to be largely autoimmune in nature, and has proposed a study to investigate the occurrence of systemic lupus erythematosus (SLE) following hepatitis B vaccine.

Currently in press are three FDA studies (Ellenberg SS. Evaluating the safety of combination vaccines. *Clinical Infectious Diseases)* (Ellenberg SS. Safety considerations for new vaccine development. *Pharmacoepidemiology and Drug Safety)(*Ellenberg SS, Braun MM. Monitoring the safety of vaccines: Interpreting the risks. *Drug Safety*), which should further inform this discussion.

QUESTION 5

The guiding principle in changing the Table was to carry out the statutory mandate that conditions listed in the Table be based on scientific evidence that there is a causal relationship between the vaccine and the condition. This is because the inclusion of an injury on the Table allows petitioners to benefit from a legal presumption of causation. Both sets of Table changes required nearly four years, utilizing rigorous scientific and policy analysis and input from several advisory committees and an overall public process including a public hearing, as required by the statute. The decision-making for each proposed Table change was detailed extensively in the preambles to the proposed and final rules, including the results of

relevant scientific studies and their analysis. The GAO report's recommendations for a more clear methodology implies that the Department should publish a formula using the IOM findings. Indeed, the IOM in its 1991 presentation to the ACCV cautioned against this very approach.

The GAO report highlights a few examples of apparent inconsistencies in the decision making, suggesting that the IOM findings are the only consideration. If anything, these examples demonstrate the complexity of the scientific review and how difficult it is to try and fit causation science into very narrow boxes. It is simply not practical. As was the case with GBS and OPV, ongoing scientific research called into question conclusions from the 1993 IOM report that was barely six months old. The Secretary's decision making needs to be based on current science, something not possible using a mechanistic approach. What is important is the scientific underpinning behind the final decisions regarding what should be listed as a Table condition, which is ascertaining information provided by not only the IOM, but others. Clearly the dynamic nature of scientific research and the difficult public policy issues surrounding vaccine causation make a successful framework for decision making based on only one criterion very unlikely.

QUESTION 6

Yes. Section 2114(c) of the Public Health Service Act, 42 U.S.C. 300aa-14, explicitly authorizes the Secretary to modify the original statutory Vaccine Injury Table by regulation. Subsection 2114(c)(3) provides that the modification "may add to, or delete from, the list of injuries... for which compensation may be provided." (Emphasis added.) Furthermore, section 312(c) of Public Law 99-660 mandated that the Secretary propose regulations to amend the original Table based on the Institute of Medicine's first study of conditions associated with the pertussis vaccine. Finally, the Act's grant of authority to delete conditions from the Table encompasses the authority to revise the definitions which are included in the Qualifications and Aids to Interpretation. O'Connell v. Shalala, 79 F. 3d 170 (1st Cir. 1996); Terran ex rel. Terran v. Secretary, 195 F. 3d 1302 (Fed. Cir. 1999), cert. denied.

QUESTION 7

HHS, through research sponsored by NIH, FDA, CDC and HRSA (see attached list or copies of grants/publications) has been investigating many of the vaccines and conditions reviewed by the IOM. (Also attached are copies of other relevant research publications.) Moreover, VAERS (jointly managed by CDC and FDA) and the VSD project (CDC) provide the infrastructure necessary to do many of these types of studies.

The VSD is involved in a number of studies of immune reactions and autoimmune disorders following vaccination, and is looking at whether health care workers or other adults are at increased risk for autoimmune

disorders or demyelinating disease following hepatitis B vaccine. Currently in manuscript preparation are results of a VSD study examining the possible association of multiple sclerosis (MS) in women receiving hepatitis B vaccine who are not at risk for developing MS, compared to women who did not receive the vaccine. The VSD is also currently planning (and about to begin) a large-scale study of vaccination of women with Grave's disease – a thyroid disease that is believed to be largely autoimmune in nature, and has proposed a study to investigate the occurrence of systemic lupus erythematosus (SLE) following hepatitis B vaccine.

In addition to learning disabilities and immune reactions and autoimmune disorders, the possible link between vaccines and numerous other conditions have been studied. For example, VSD studies of the MMR vaccine have found no increased risk of aseptic meningitis after MMR vaccine containing the Jeryl-Lynn strain of mumps (Black S, Shinefield H, Ray P, Lewis E, et al. Risk of hospitalization because of aseptic meningitis after measles-mumps-rubella vaccination in one-to two-year-old children: an analysis fo the Vaccine Safety Datalink (VSD) Project. Pediatric Infect Dis J 1997;16:500-3). And, in another VSD study, no association was found between rubella vaccination and risk of chronic arthropathy (Ray P, Black S, Shinfield H, et al. Risk of chronic arthropathy among women after rubella vaccination. JAMA 1997;278:551-6).

A recent study by the VSD investigators looked at the risk of a first seizure, subsequent seizures, and neurodevelopmental disability in children following receipt of DTP or MMR vaccines. The investigators found that there were significantly elevated risks of febrile seizures after receipt of DTP vaccine or MMR vaccine, but that these risks did not appear to be associated with any long-term adverse consequences. (Barlow W, Davis RL, Glasser JW, Rhodes PH, et al. The risk of seizures after receipt of whole-cell pertussis or measles, mumps, rubella vaccine. N Engl J Med. 2001;345(9):656-661.)

The CDC also conducted a study of Guillain-Barré syndrome (GBS) and tetanus toxoid containing vaccines using 2 large active surveillance databases. No association was detected. (Tuttle J, Chen RT, Rantala H, Cherry JD, et al. Am J Public Health. 1997;87:2045-2048).

In addition to studies funded or conducted by HHS, researchers in the U.K., Sweden, Finland, and other countries have completed studies that address some of the research questions identified by the IOM.

For instance, a detailed follow up of the National Childhood Encephalopathy Study (NCES) indicated that children who had a serious acute neurological illness after DTP administration were significantly more likely than children in the control group to have chronic nervous system

dysfunction 10 years later. However, it was unclear whether the vaccine was simply a trigger as opposed to a cause; it could not be determined whether DTP increases the overall risk for chronic nervous system dysfunction in children (Miller D, Madge N, Diamond J, et al. BMJ 1993;307:1171-6.).

Several studies have looked at the possible association between Guillain-Barré syndrome and polio vaccine. A reanalysis of Finnish data and a U.S. study have not demonstrated a causal relationship between GBS and polio vaccine (Kinnunen E, Junttila O, Haukka J, et al. Nationwide oral poliovirus vaccination campaign and the incidence of Guillain-Barré syndrome. Am J Epidemiol 1998;147:69-73) (Rantala H, Cherry JD, Shields WD, et al. Epidemiology of Guillain-Barré syndrome in children: relationship of oral polio vaccine administration to occurrence. J Pediatr 1994;124(2):220-3.

It is now well-recognized that MMR can rarely cause thrombocytopenia. The risk of thrombocytopenia ranges from 1 in 30,000 to 1 in 40,000 in several different studies. (Farrington CP, Pugh S, Colville A, et al. A new method for active surveillance of adverse events from diphtheria/tetanus/pertussis and measles/mumps/rubella vaccines. Lancet 1995;345:567-9) (Nieminen U, Peltola H, Syrjala MT, et al. Acute thrombocytopenic purpura following measles, mumps, and rubella vaccination: a report on 23 patients. Acta Paediatr 1993;82:267-70) (Bottiger M, Christenson B, Romanus V, et al. Swedish experience of two dose vaccination programme aiming at eliminating measles, mumps, and rubella. Br Med J (Clin Res Ed) 1987:295:1264-7.

A final example of research conducted by scientists outside of HHS is a study using the Swedish Childhood Diabetes registry. This study examined the relationship between diabetes mellitus and pertussis immunization. The investigators found no difference in the cumulative incidence rate of diabetes mellitus up to the age of 12 years when birth cohorts for 1978 and 1979 with high DTP vaccination coverage were compared with the cohorts of 1980 and 1981 with low pertussis vaccination coverage. (Heijbel H, Chen RT, Dahlquist G. Diabetes Care. 1997;20:173-5)

While all 50 conditions identified by the IOM have not been studied, great progress has been made and research is ongoing. Recently, the CDC established a mechanism that will further enhance scientific knowledge of vaccine safety issues, the Clinical Immunization Safety Assessment (CISA) centers. The CISA centers are a new initiative designed to improve our scientific understanding of vaccine safety issues at the individual "patient" level. The CISA network is comprised of clinical academic centers in partnership with the Centers for Disease Control and Prevention (CDC) and will serve as a source of clinical expertise in adverse events following immunization. With the creation of the CISA network, coordinated facilities

exist in the U.S. to investigate and manage adverse events on an individual level for the purpose, in addition to patient care, of systematically collecting and evaluating the experiences.

Clinically significant adverse events occur rarely, but CISA centers are working to improve the understanding of these events. Through participation in the CISA network and with CDC, medical and professional staff with expertise in vaccine safety will systematically evaluate cases of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). Selected cases will undergo enhanced follow up and targeted clinical evaluation, to better understand the mechanism and risk factors for the event. Health care providers will also be able to refer patients to a CISA center for a consultation, either by filing a VAERS report and including a specific request, or through usual consultation mechanisms already in place to specialists at the institutions with whom a center is affiliated. The results of these evaluations will be used to develop clinical evaluation protocols or patient management guidelines that can be used by all health care providers.

In all, the network's goals are to:

- Develop clinical protocols for the evaluation and management of adverse events possibly related to immunization, and disseminate them through professional publications or other appropriate mechanisms.
- Evaluate groups of patients with similar adverse events, using a standard protocol, in order to elucidate the mechanism by which these unusual or severe adverse reactions occur. Thus genetic or other risk factors that predispose to these reactions may be determined.
- Provide immunization guidelines and clinical management protocol for patients who have had an adverse reaction that may not contraindicate further vaccination but where there is concern regarding continuation of the particular vaccine series.
- Serve as a public and provider regional referral center for clinical vaccine safety inquiries.

In the U.S. immunization safety system, CISA centers will serve as an intermediate step between passive reporting of individual cases of adverse events with no or minimal follow-up, and the more rigorous epidemiological investigations into vaccine safety, such as the use of large linked databases, clinical trials and case-control or cohort studies. These goals will help to better define the level of risk of an adverse event for the individual patient, identify areas for additional scientific investigation to keep vaccines safe and help maintain the public's confidence in our immunization programs.

The first group of CISA centers was funded in October 2001, and has begun the process of coordinating their activities and the mechanisms by which

adverse event cases reported to VAERS will be reviewed, and clinical evaluations defined and performed. The centers include Johns Hopkins University partnering with specialists at the University of Maryland, in Baltimore; Northern California Kaiser with collaborators at Stanford University in San Francisco, California and Vanderbilt University in Nashville, Tennessee; Boston University Medical Center in Boston, Massachusetts and Columbia Presbyterian Hospital in New York City, New York.

Currently in press are 3 FDA studies (Silvers L, Ellenberg S, Varricchio F, Krueger CL, Wise R, Salive ME. Pediatric deaths reported after vaccination: The utility of information obtained from parents. *American Journal of Preventive Medicine)(*Silvers LE, Ellenberg SS, Wise RP, et al. The epidemiology of fatalities reported to the Vaccine Adverse Event Reporting System, 1990-1997. *Pharmacoepidemiology and Drug Safety)(*Walker AM, Wise RP. Precautions for Proactive Surveillance. *Pharmacoepidemiology and Drug Safety)*, which should further inform this discussion.

QUESTION 8

No. Epidemiologic studies focus on disease in groups of individuals and do not include more basic, clinical research methods needed to assess biologic plausibility. Animal experiments and in vitro studies are usually needed to prove biologic plausibility, which refers to the biology of the vaccine and adverse event in question. Other aspects of biologic plausibility may include background knowledge of the pathophysiology of an adverse event, attributes of a particular vaccine, or other biologic information derived from research in such areas as immunology and physiology.

QUESTION 9

The primary vehicle for dissemination of information about the VICP is the Vaccine Information Statement (VIS) required by the Act to be provided by health care professionals to the parent or guardian of each child, or to an adult patient receiving a vaccine covered under the Program. The statement for each vaccine includes a bolded subtitle for the Program and provides an 800-line phone number as well as a webpage address where interested individuals can obtain detailed information about the Program.

Program staff answer questions through telephone calls and letters to advise any interested party about how the Program operates and the process involved in filing a petition for compensation.

An ongoing and aggressive outreach effort is carried out to inform the broadest possible audience about the Program, especially the medical and legal communities which are integral components of the Program.

Primarily, the outreach efforts are focused on health care professionals who are directly responsible for administering vaccines, but also include groups whose knowledge about the Program may help identify and guide affected families in the right direction. An extensive number of health care providers and other professionals have been educated about the Program through presentations and the staffing of the VICP exhibit booth at professional conferences, such as those of the American Academy of Pediatrics, the National Immunization Conference, the Child Neurology Society, the American Academy of Neurology, the American Academy of Family Physicians, the National Association of Pediatric Nurse Associates and Practitioners, the American Public Health Association, the National Association of Social Workers, the American Bar Association, and the American Trial Lawyers Association. Feedback has been consistently positive and productive at these meetings, and has helped identify other groups which need to be included in future outreach efforts.

VICP staff are developing a proposal to evaluate the Program's current communication strategies and potential solutions, all in consultation with the ACCV. One approach under study would be to utilize focus groups consisting of families with children, health care providers and attorneys in order to evaluate current VICP outreach efforts. Any communication gaps that exist should then be more easily addressed.

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

October 17, 2001

The Honorable Dan Burton
Chairman
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter of October 10, 2001, to the Attorney General regarding legislative proposals to improve the National Vaccine Injury Compensation Program ("VICP"). Your letter was forwarded to this office for response.

We have reviewed the proposals outlined in Attachment A of your letter, and this response provides the views of the Department of Justice with respect to each. The Department of Justice supports many of the proposals; however, we do have serious concerns about others as described in detail below. As an initial matter, we generally support those proposals of the Advisory Commission on Childhood Vaccines ("ACCV"). As you know, the nine-member advisory body created by Congress is comprised of parent representatives, medical experts and attorneys, and advises the Secretary of Health and Human Services on matters of vaccine policy and legislation pertaining to the VICP. The diversity and expertise of the Commission members lend great credibility to their recommendations, particularly given the Commission's non-partisan nature. Thus, that many of the ACCV recommendations were advanced during a prior Administration does not detract from their appropriateness.

Statute of Limitations

The first group of proposals suggests an enlargement of the time periods for filing claims under the Vaccine Act. The ACCV recommended that the Vaccine Act be amended to extend the filing period after the onset of the injury from three years to six years. For claims alleging vaccine-related deaths, the ACCV proposal called for expanding the filing period from two years to six years after the onset of injury from which the death resulted, although the petition would still have to be filed within two years of the date of the death. The Department supports this recommendation. While we do not believe the existing three-year limitations period has barred a significant number of claims, an expansion of the limitations period is reasonable and will not adversely affect the Program. Yet, we continue to believe that the inception date for the statute of limitations should be a definitive date. The current use of the date of onset of the injury encourages efficiency and finality in seeking redress for vaccine-related injuries. We therefore

support Section 5(1)(A) and (B)(ii) of H.R. 1287.[1]

The Department does not support the proposals urging lengthier extensions of the statute of limitations. We oppose H.R. 1003 from the 106th Congress, which would run the limitations period from date of "discovery" of the injury.[2] Due to the serious nature of vaccine-related injuries, the onset of an injury normally coincides with the discovery of the injury, thus the proposed change will not benefit a significant number of claimants. Moreover, an inception based upon "discovery" of an alleged vaccine-relationship is highly subjective and will embroil the Program in time-consuming proceedings to determine when that date occurred. The Department opposes Section 5(3) of H.R. 1287 which would toll the limitations period until a petitioner reaches the age of 18, or if he is not competent, until 24 months after a guardian is appointed. The Program is designed to encourage eligible petitioners to promptly obtain vaccine compensation, rather than postpone receipt of funds until the claimant turns 18 years old, or is even older. Moreover, delaying the case in this fashion could jeopardize petitioner's ability to establish the facts necessary to support his or her claim. Critical medical records may become lost or destroyed, and the passage of time will likely impair the memory of witnesses, hampering their ability to testify fully and accurately. Most significantly, parents and guardians are entitled to pursue claims under the VICP. In our experience, they zealously represent their children's interests, making tolling until majority, when a minor might otherwise pursue his own rights unnecessary.

The Department opposes Section 5(1)(C) of H.R. 1287, which would extend the statute of limitations for an additional 36 months after a petitioner first knew or reasonably should have known about his or her eligibility for compensation under the VICP. Aside from the practical difficulties of ascertaining a petitioner's subjective knowledge of eligibility for compensation, we think the proposal is unnecessary. Greatly increased outreach efforts by the Department of Health and Human Services and this Department to publicize the Program and to increase visibility amongst parents, physicians, and other health care providers, not to mention the legal community, make lack of knowledge of the Program less of a concern.

Finally, the Department strongly opposes the portion of Section 5(3) of H.R. 1287 that would authorize the re-filing of previously adjudicated or resolved claims. The re-litigation of these claims would delay the swift processing of pending and future claims. Important objectives of tort reform measures such as the VICP are to bring efficiency, predictability, and finality to civil litigation. H.R. 1287 would thwart these goals. Indeed, the final provision within Section 5(3) of H.R. 1287 appears to permit the re-filing of claims that were dismissed for failure to satisfy the Vaccine Injury Table criteria, a proposal that would encourage the re-filing of thousands of the 5,300 dismissed claims.

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[1] We note that the limitations of actions provisions of H.R. 1287 (section 5), and H.R. 5327 (section 5) from the 106th Congress are identical. Our comments, while citing to H.R. 1287, are thus equally applicable to H.R. 5327.

[2] We note that H.R. 2056 of the 107th Congress appears to be identical to H.R. 1003 of the 106th Congress.

Payment of Interim Costs

The Department supports all three proposals regarding authorized costs, as described in your letter. In particular, we concur with the ACCV recommendation to allow payment of expenses associated with the establishment of a guardianship or conservatorship for the injured individual. Similarly, we concur with the ACCV recommendation to amend the Vaccine Act to permit a special master to award interim litigation costs, but not attorneys fees, after a determination has been made that a petitioner is entitled to vaccine injury compensation. As your letter suggests, interim litigation costs might include expert witness expenses, and other litigation costs such as expenses associated with gathering medical records.

Burden of Proof and Table Changes

The proposed designation of the VICP as "remedial" is an unnecessary change. By design, the Program is a model of a limited no-fault system of recovery, and has successfully served a remedial purpose for more than a decade. It provides a viable avenue for compensation in the rare cases of vaccine injury without resort to civil suits, and has stabilized the supply of vaccines. Nearly 1,700 families and individuals have received compensation for vaccine injuries, and as of September 2001, the Program has paid close to $1.3 billion to claimants. All of this evidences the Program's tremendous success in providing relief to vaccine-injured claimants who would have stood little, if any, chance of obtaining awards in the traditional tort system.

The Department opposes Section 2 of H.R. 1287, which would make inapplicable "concepts of sovereign immunity" to VICP cases. By way of background, under the doctrine of sovereign immunity, the government may only be sued to the extent it consents to suit. "Waivers" of immunity from suit, or statutes permitting actions against the government, must be expressly made and strictly construed. Thus, Congress must unequivocally express its intent regarding the nature and scope of the authorized relief against the government. Where there are ambiguities, the provisions of the statute are strictly construed so as not to expand the statute giving it a broader reach than its plain terms authorize. This proposition has been firmly established by the U.S. Supreme Court.

The prerogative of establishing criteria for claims against public funds lies with the Congress. The rules Congress sets by statute must then be strictly followed. Abrogation of that principle is an invitation to confusion, uncertainty and irresponsibility. The reality is that the doctrine of sovereign immunity itself cannot be abolished, or deemed inapplicable. As these principles apply here, the Vaccine Act is a waiver of the government's traditional immunity from suit. Congress may alter the *scope* of the waiver of sovereign immunity in this particular statute, by expanding or narrowing the specific conditions upon which the government consents to suit in Vaccine Act claims. However, the specific terms and conditions must be explicitly delineated.

The Department opposes Section 3 of H.R. 1287, which would change the existing burden of proof from the commonly accepted "preponderance standard" to an even less exacting standard based upon "evidence sufficient to justify a belief that the petitioner's claims are well-grounded." A "preponderance of evidence" is evidence that is more convincing than the evidence

offered against it, the fact sought to be proven is more likely than not. It is a "simple preponderance" standard, and does not require scientific certainty or "strict scientific proof." Authorizing compensation in cases failing to meet this minimal standard will result in compensating cases in which the evidence shows that the injury is not likely to be a vaccine-related injury, an anomalous result in a program designed to compensate for vaccine injuries.

Indeed, we suspect that most if not all claims would meet a "justifiable claim" standard jeopardizing the integrity of the Program and its credibility in the medical and scientific community. The preponderance standard preserves the goal that vaccine-injuries, not all injuries, are compensated by the Program. "Vaccine-relatedness" is the linchpin of this Program, and the preponderance standard promotes the original Program design as one rooted in science.

The Department has concerns about Section 3(2) and (3) of H.R. 1287 regarding evidence of a "factor unrelated." Under the existing law, the Secretary of HHS may rebut a prima facie case by proving that the injury or death was in fact caused by a "factor unrelated" to the administration of the vaccine. 42 U.S.C. § 300aa-13(a). We oppose limiting the types of conditions that may constitute a "factor unrelated." If an injury isn't caused by the vaccine, but is the result of another non-vaccine cause – such as a genetic disorder or structural lesion – evidence of this alternative cause should be considered by the court. Similarly, we oppose increasing the government's burden of proof when evidence shows that the injury is due to some cause other than the vaccine. If an injury is not likely due to the vaccine, then compensation under this Program is not appropriate. Increasing the government's burden of proof to the level of "clear and convincing evidence" would create an irrefutable presumption that the vaccine is the cause under any circumstances, regardless of medical reality. Likewise, we oppose Section 3(4) of H.R. 1287, which would impose limits on what the special masters may consider when evaluating evidence and determining whether an injury is related to the vaccine. Special masters are "inquisitorial" in nature and should be free to consider all aspects of the injured party's condition and relevant available scientific evidence, including evidence about the nature and course of the illness. The proposed change is literally unscientific and will only hinder the court's ability to determine the medical "truth" regarding the cause of an injury.

Administrative Issues

The Department generally supports the use of grantor reversionary trusts in administering Vaccine Act awards. We have concerns about authorizing payment of fees for establishment and maintenance of private trusts, due to the uncertainty of required administration fees and the high expense of maintaining private trusts. A separate payment of trust administration fees is not necessary under a grantor reversionary trust, the type of trust routinely recommended by the government. Further, as noted above, the Department supports the proposal to allow payment of costs necessary to establish a guardianship or conservatorship.

The ACCV has recommended that expenses associated with counseling for the family of the injured person be permitted under the VICP. The Department concurs with this recommendation.

.....

In summary, the Department opposes H.R. 1287. This bill proposes a dramatic departure from the current structure, operation, and objectives of the VICP as originally designed, and would convert a science-based Program to one that ignores science. In so doing, H.R. 1287 would expand the Program far beyond its original intent, and impose a significantly greater liability on the Trust Fund and taxpayers. Moreover, with only a few exceptions, these proposals have not been presented to or considered by the ACCV, the advisory body specifically appointed to make recommendations on appropriate legislative changes to the Program.

We appreciate your interest in this very important Program, and we look forward to working with the Congress to further improve this unique statute. We appreciate the opportunity to provide our views on these legislative proposals, and hope that the information contained herein is helpful. Please do not hesitate to contact me regarding this or any other matter. The Office of Management and Budget has advised that there is no objection from the standpoint of the Administration's program to the presentation of this report.

Sincerely,

Daniel J. Bryant
Assistant Attorney General

cc: The Honorable Henry A. Waxman
Ranking Minority Member

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

NOV 6 2001

The Honorable Dan Burton
Chairman, Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

This letter is provided to correct and clarify two statements made by Deputy Assistant Attorney General Paul Clinton Harris, Sr., during the hearing convened on Thursday, November 1, 2001 regarding the Vaccine Injury Compensation Program (VICP).

In his testimony on behalf of the Department of Justice, Mr. Harris informed the Committee of a newly formed working group organized by the Justice Department in conjunction with the Office of Special Masters at the U.S. Court of Federal Claims. This Process Committee, which met for the first time last month, includes special masters, claimants' attorneys, a parent, Justice Department attorneys, and Health and Human Services staff. The Process Committee will re-evaluate and revise the Guidelines for Practice Under the VICP, with the goal of devising procedures to further expedite case processing. In particular, the Process Committee intends to focus on the process of settling the damages portion of these cases.

Subsequently, Mr. Harris was asked about a special master's written remarks in a 1998 vaccine case, Marks v. HHS, in which the government's counsel was criticized. Mr. Harris mistakenly believed that the attorney in the Marks case was the same attorney who has been asked by the Chief Special Master to chair the Process Committee, described above. In fact, the attorney who handled the Marks case no longer works in the Vaccine Section, and is not involved with the Process Committee. The attorney selected by the Chief Special Master to chair the Process Committee is an experienced senior counsel in the Vaccine Section, and is the attorney who is assigned to handle Zuhlke v. HHS, another case discussed at the hearing. We therefore ask that the record be corrected in this regard.

In addition, we wish to clarify and correct any potential misinterpretation of a statement made by Mr. Harris in response to a series of questions posed by Congressman Weldon. In summarizing the testimony of the witnesses on the first panel, and citing the Marks case, Dr. Weldon stated his impression that some of the special masters were frustrated or angry about Justice Department conduct. Mr. Harris testified that Justice Department attorneys handle their responsibilities with professionalism, and urged the Committee to consider critical comments in the full context in which they were made. In conveying the importance of context with respect to the negative comments made in the Marks case, Mr. Harris pointed out that these comments were

made by the same special master who was severely criticized by Ms. Zuhlke, one of the witnesses on the first panel. Mr. Harris's comment should not be construed as an endorsement of this witness's view of the special master. We ask that the record be clarified to reflect that we do not consider the remark about the special master to be fair or accurate, just as we objected to the remarks about the Justice Department attorney having been considered out of context

I hope this letter clarifies these two matters. Please do not hesitate to contact me regarding this or any other matter.

Sincerely,

Daniel J. Bryant
Assistant Attorney General

cc: The Honorable Henry A. Waxman
Ranking Minority Member

THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM: IS IT WORKING AS CONGRESS INTENDED?

WEDNESDAY, DECEMBER 12, 2001

HOUSE OF REPRESENTATIVES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 1:37 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the committee) presiding.

Present: Representatives Burton, Gilman, Morella, Horn, Davis of Virginia, Weldon, Duncan, Waxman, Norton, Cummings, Kucinich and Tierney.

Staff present: Kevin Binger, staff director; Daniel R. Moll, deputy staff director; James C. Wilson, chief counsel; David A. Kass, deputy chief counsel; Mark Corallo, director of communications; Thomas Bowman, senior counsel; S. Elizabeth Clay and John Rowe, professional staff members; Robert A. Briggs, chief clerk; Robin Butler, office manager; Elizabeth Crane, legislative assistant; Elizabeth Frigola, deputy communications director; Joshua Gillespie, deputy chief clerk; Leneal Scott, computer systems manager; Corinne Zaccagnini, systems administrator; Josh Sharfstein, minority professional staff member; Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerks.

Mr. BURTON. First of all, let me apologize for our late start. We had a vote on the floor, and I'm sure you understand getting all the Members to the floor and back, it's kind of difficult sometimes. Mr. Waxman, I understand, will be on his way here pretty quickly, but in order to expedite the hearing, we will go ahead and start.

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

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

Today we are holding our second hearing on the Vaccine Injury Compensation Program. I have made it clear that I believe this program has become entirely too adversarial. After our hearing last month, I think that most of the members of the committee came to the same conclusion. This is a program that's meant to help families that have a serious problem. These families have children who received serious injuries. They need medical care for the rest of

their lives, and these are families that are traumatized. This program is supposed to help them get the compensation they deserve and they need. It's supposed to be fast. It's supposed to be generous. It's supposed to be nonconfrontational.

What we found instead is a program that's slow and difficult and highly adversarial. Cases get dragged on for years and years and years. Government lawyers are sometimes very aggressive. Last month we had three witnesses testify. Two of them were parents of vaccine-injured children. One was the husband of a woman who was injured by a tetanus vaccine. They were each tied up in the system for over 8 years. The government had spent 8 years trying to prove that the vaccine did not cause the injury. The Government lost each of those cases. Those three people told us about the hardships their families had to endure as they went through this process. They told us about the tens of thousands of dollars they had to spend out of their own pockets while they waited for the cases to be resolved. They told us about how disillusioned they were with our government.

Then we heard from the Justice Department and HHS. There was some suggestion from our government witnesses that these were isolated cases. I have a problem with that for two reasons. First, I don't think it's true, and second, I don't think these are isolated cases. But, that's beside the point. We're not talking about statistics. These are people. They have serious problems.

The responses we got at our last hearing were not reassuring in the least. When Dr. Weldon asked Mr. Balbier if someone could just pick up the phone and call Ms. Zuhlke, who struggled through this program for 10 years after her daughter was injured by a vaccine, Mr. Balbier apparently had a problem with that. That's not reassuring. So I said, fine, we'll meet again in a couple of weeks. We'll bring in three more families. We will see if we can't convince you that these aren't isolated cases. They are real people who deserve to be treated with dignity, and that's what brings us here today.

I intend fully to have a whole series of hearings for next year on a regular basis, and I ask the same people from HHS and Justice to come in to listen to these horror stories until we get some answers that are positive.

Today we are going to be hearing from Lori Barton of Albuquerque, NM; we are going to hear from Tara Dyer of Knoxville, TN; and we are going to hear from Joseph Holder of Denville, NJ. And I want to thank each of one of them for being here today to tell us about their stories and their problems.

At my last hearing in my opening statement, I highlighted the case of Janet Zuhlke because I thought it really explained our frustrations with the program. Janet's daughter was injured by a vaccine in 1990. She is now permanently disabled. She is mentally retarded. She suffers from periodic bouts of blindness. At times she is confined to a wheelchair. It took Janet 10 years to win compensation for her daughter because the government tried to prove it was caused by a strep infection. The government still lost. She still has not received the money she is entitled to because there are more hoops to jump through, and it's now going on 11 years, and that's just wrong.

Today I want to again highlight one of the cases that are before us. All three deserve to be highlighted, but in the interest of time, I'm going to focus for now on the Barton case because I find it so troubling, and I hope my colleagues from government, the Justice Department and HHS, will listen to this.

Lori Barton's son Dustin received his third DTP shot in 1989. He began to have seizures. His body became rigid. He stopped looking at things. He became legally blind. In the words of Lori Barton, he was a different child. He was eventually diagnosed with residual seizure disease, disorder. In 1991, the Bartons filed a petition for compensation, 11 years ago.

Now, I should acknowledge from the outset that this was not an open and shut case. It was complicated by the fact that Dustin was born with a condition known as PVL that causes lesions on the brain. However, that does not excuse the way the Justice Department handled this case. They had their first hearing in 1993. Lori Barton and her mother testified. They were subjected to severe cross examination by the Justice Department lawyer. The lawyer tried to pick apart their statements like a hard-nosed litigator. Lori Barton felt like she was being treated like a criminal. The special master overseeing the case called it overkill. Despite that, the Bartons won round one. After it took 4 years for them to get to the second round, the next hearing, 4 more years.

That was in August 1997. Three months later Dustin had a massive seizure, and he died. What started out as an injury case turned into a death case because it dragged out so long. In 1999, 8 years after the Bartons filed their petition, and 2 years after Dustin died, the special master awarded them compensation.

But there was one final indignity, and I want you to get this. The Justice Department told the Bartons that they didn't agree with the decision, and they didn't want it to be published. They were paying them, but they didn't want anybody to know about it. They didn't want it published. They didn't want it to become a precedent that might help other families, and if they didn't get this agreement that it wouldn't be published, they might appeal the decision and delay the compensation for another year or two. That in the private sector would be called blackmail, but the Justice Department was saying, we're not going to give you your money even though you have gone through this and your son died, even though it has taken 8 or 9 years, but we will give you the money if you don't publish this; but if you don't, we're going to appeal the case.

Those are the kind of blackjack tactics that the American people just get sick about, but it happens in our government. And right now we've got our troops fighting overseas for our freedoms and this Republic that we enjoy, and we have government officials beating people over the head like that. That's not right.

Well, the Bartons had been worn down over 8 years. They had lost their son. Lori's health was not good, so they agreed, and who can blame them. What did Lori have wrong with her? She had lupus. All the time she was going through this, she was suffering from lupus, and so she was dead tired, and she finally said OK.

That's not how Congress intended for this program to work, and these are not isolated cases. At our last hearing I said that we had some clear evidence of overzealous conduct by the government. In

the case of the Sword family, the special master called the Justice Department lawyer's tactics egregious. In the Marks case the special master called the government's tactics abrasive, tenacious, and obstreperous.

In the Barton case we are seeing the same thing again. I have the transcript of the 1993 hearing. That's the hearing where the Justice Department lawyer was so brutal in her cross examination. I want to read to everyone what the special master said about the Justice Department lawyer representing the government. This is what the special master said, "In my opinion, counsel for the respondent has unfortunately mischaracterized much of the testimony and much of the evidence in this case, which leaves the court to tend to discount some of her closing arguments because, frankly, they are of the characterization that tends to misconstrue facts in a way that gives lawyers a bad name."

They're talking about the Justice Department. They were giving the lawyers a bad name because of the way they were handling the case.

He went on, "Frankly, I believe counsel has been inaccurate and has jumped to conclusions that are not supported by the record and, in such a way, does somewhat of a disservice to the court."

These are our government lawyers.

Now, that's not how Congress meant this program to work. Each time we see those comments from a special master, it gets harder and harder to believe that they're isolated incidents.

I want to wrap up without taking too much more time, but there are a couple final points I want to make. The Zuhlke case involved encephalopathy. The Barton case involved a residual seizure disorder. These are conditions that everyone agrees are related to vaccines. They were listed in the table of injuries that Congress created. These are supposed to be easy cases; yet they took 8 years or more to decide, and they caused a lot of heartaches for those families.

We have very few table cases being filed today, and this is due in part to the new DTaP vaccine, but it also is due in large part to the changes to the table of injuries. Almost half of the injuries that the program compensated were for injuries that were removed from the table of injuries by HHS. The cases being filed today are much more difficult. Today's cases involve complications related to the tetanus shot and the hepatitis B vaccine. They involve Thimerosal, which contains mercury, and autism and speech and planning delays. These are very difficult questions, and scientific research is woefully inadequate. If the system we put in place couldn't handle the easy cases, how on Earth is the system going to handle these hard new cases?

One thing that's for sure is that we need more research on vaccine safety, and we can't wait. In the case of autism we used to have 1 in 10,000 children that were inflicted with autism. Now throughout the country it's 1 in 500. In some parts of the country it's 1 in 200 or less. We have an absolute epidemic, and we need to get on with finding out the reasons why. We can't wait, and the Federal Government needs to take the lead to make sure it's done.

I also want to point out that I am very concerned about this business of the government pressuring families not to have the deci-

sions published. I don't know if Mr. Waxman was here when we were talking about this, but we had a case decided because the government said they would go ahead and pay the person after the child had died, after 10 years of litigation, if they wouldn't publish it because they didn't want to set a precedent, and they literally were beating them over the head, and the woman who was the mother had lupus, and she agreed because she was simply worn down, and she is going to testify today.

We're waiting for that information from the Justice Department that we have talked about, but the reason for it is very clear. The government doesn't want other families to benefit from those precedents when the government loses while the government is supposed to be helping these families, not putting obstacles in their path, and when we get to our second panel I'm going to have some very pointed questions about that.

My final point is this. At our last hearing we heard some graphic testimony about injuries that were caused by vaccines. We're going to hear the same kind of testimony today, and it's important that we hear these stories, but we don't want to scare people into not having their kids vaccinated. Vaccines save lives, and vaccines injuries are rare. We would like them to be even more rare, and that's why I'm so serious about pushing for more research.

We also want this: When a family has a child who has been injured by a vaccine, we want them to get the compensation they deserve and not have to wait 10 or 12 years until the child dies and to be beaten over the head by the Justice Department and the people who are supposed to be protecting our liberties. We want them to be treated with dignity and respect. We owe that to the Zuhlkes, and the Bartons, and the Dyers and the Holders. We owe it to all the other families who suffer from this kind of a crisis. I'm not saying that the Justice Department has handled every case badly, but I want what I'm sure the Attorney General wants, and that is for every case to be handled with a little compassion.

I want to thank our witnesses for being here today, and I look forward to all their testimony, and I'm planning to introduce legislation to try to fix these problems and, hopefully Congressman Waxman and I can work together to get that problem solved. And I look forward to working with Dr. Weldon, who will be here shortly, who's working on this, and with Mr. Waxman and others.

The hearing record will remain until December 27, and I now yield to Mr. Waxman.

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

Opening Statement
Chairman Dan Burton
Committee on Government Reform
"The National Vaccine Injury Compensation Program: Is It Working As Congress Intended? – Part II"
December 12, 2001

Good Morning.

Today, we're holding our second hearing on the vaccine injury compensation program. I've made it clear that I believe this program has become entirely too adversarial. After our hearing last month, I think most of the Members of the Committee came to the same conclusion.

This is a program that's meant to help families that have a serious problem. These families have children who've received serious injuries. They need medical care for the rest of their lives. These are families that are traumatized. This program is supposed to help them get the compensation they deserve and they need. It's supposed to be fast. It's supposed to be generous. It's supposed to be non-confrontational.

What we've found instead is a program that's slow and difficult and highly adversarial. Cases get dragged out for years. Government lawyers are sometimes very aggressive.

Last month we had three witnesses testify. Two of them were parents of vaccine-injured children. One was the husband of a woman who was injured by a Tetanus vaccine. They were each tied up in the system for over eight years. The government had spent eight years trying to prove that the vaccine didn't cause the injury. The government lost each of those cases.

Those three people told us about the hardships their families had to endure as they went through this process. They told us about the tens of thousands of dollars they had to spend out of their own pockets while they waited for the cases to be resolved. They told us about how disillusioned they were with their government.

Then we heard from the Justice Department and HHS. There was some suggestion from our government witnesses that these were isolated cases. I have a problem with that for two reasons. First, I don't think it's true. I don't think these are isolated cases. But second, that's beside the point.

We're not talking about statistics here. These are people. They have serious problems. The responses we got at our last hearing were not reassuring in the least. When Dr. Weldon asked Mr. Balbier if someone could just pick up the phone and call Mrs. Zuhlke, who struggled through this program for ten years after her daughter was injured by a vaccine, Mr. Balbier apparently had a problem with that. That's not reassuring.

So I said fine. We'll meet again in a couple of weeks. We'll bring in three more families. We'll see if we can't convince you that these aren't isolated cases. They're real people who deserve to be treated with dignity. That's what brings us here today.

Today we're going to hear from Lori Barton of Albuquerque, New Mexico. We're going to hear from Tara Dyer of Knoxville, Tennessee. And we're going to hear from Joseph Holder of Denville, New Jersey. I want to thank each one of you for coming here today to share your stories with us.

At our last hearing, in my opening statement, I highlighted the case of Janet Zuhlke because I thought it really explained our frustrations with the program. Janet's daughter was injured by a vaccine in 1990. She's now permanently disabled. She's mentally retarded. She suffers periodic bouts of blindness. At times she's confined to a wheelchair. It took Janet ten years to win compensation for her daughter because the government tried to prove it was caused by a strep infection. The government lost. She still hasn't received the money she's entitled to because there are more hoops to jump through. It's now going on eleven years.

Today, I want to again highlight one of the cases that's before us. All three deserve to be highlighted, but in the interest of time, I'm going to focus for now on the Barton case because I find it so troubling.

Lori Barton's son Dustin received his third DTP shot in 1989. He began to have seizures. His body became rigid. He stopped looking at things – he became legally blind. In the words of Lori Barton, "he was a different child." He was eventually diagnosed with residual seizure disorder.

In 1991, the Barton's filed a petition for compensation. Now, I should acknowledge from the outset that this was not an open and shut case. It was complicated by the fact that Dustin was born with a condition known as PVL that causes lesions on the brain. However, that doesn't excuse the way the Justice Department handled it.

They had their first hearing in 1993. Lori Barton and her mother testified. They were subjected to severe cross-examination by the Justice Department lawyer. The lawyer tried to pick apart their statements like a hard-nosed litigator. Lori Barton felt she was being treated like a criminal. The Special Master overseeing the case called it "overkill." Despite that, the Bartons won round one.

After that it took four years for them to get to the next hearing – four years. That was in August 1997. Three months later, Dustin had a massive seizure and he died. What started out as an injury case turned into a death case because it dragged out so long.

In 1999, eight years after the Bartons filed their petition, two years after Dustin died, the Special Master awarded them compensation. But there was one final indignity. The Justice Department told the Bartons that they didn't agree with the decision, and they didn't want it to be published. They didn't want it to become a precedent that might help other families. And if they didn't get this agreement, they might appeal the decision and delay compensation another year or two.

Well, the Bartons had been worn down over eight years. They lost their son. Lori's health wasn't good. So they agreed. Who can blame them?

That's not how Congress intended for this program to work. And these are not isolated cases.

At our last hearing, I said that we had some clear evidence of overzealous conduct by the government. In the case of the Sword family, the Special Master called the Justice Department lawyer's tactics "egregious."

In the Marks case, the Special Master called the government's tactics "abrasive, tenacious and obstreperous."

In the Barton case, we're seeing the same thing again. I have the transcript of the 1993 hearing. That's the hearing where the Justice Department lawyer was so brutal in her cross-examination. I want to read to everyone what the Special Master said about that lawyer representing the government:

> *"In my opinion, counsel for the Respondent has unfortunately mischaracterized much of the testimony and much of the evidence in this case, which leaves the Court to tend to discount some of her closing arguments because, frankly, they are of the characterization that tends to misconstrue facts in a way that gives lawyers a bad name. Frankly, I believe counsel has been inaccurate and has jumped to conclusions that are not supported by the record and, in such a way, does somewhat of a disservice to the court."*

That's not how Congress meant this program to work. Each time we see these comments from a special master, it gets harder and harder to believe they're isolated incidents.

I want to wrap up without taking too much more time, but there are a couple of final points I want to make.

The Zuhlke case involved an encephalopathy.

The Barton case involved a residual seizure disorder.

These are conditions that everyone agrees are related to vaccines. They were listed in the table of injuries that Congress created. These are supposed to be the easy cases. Yet they took eight years or more. They caused a lot of heartache for those families.

We have very few "table cases" being filed today. This is due in part to the new DTaP vaccine, but it also is due in large part to the changes to the Table of Injuries. Almost half of the injuries that the Program compensated were for injuries that were removed from the Table of Injuries by HHS.

The cases being filed today are much more difficult. Today's cases involve complications related to the Tetanus shot and the Hepatitis B vaccine. They involve Thimerosal and Autism (and speech and language delays). These are very difficult questions, and the scientific research is woefully inadequate.

If the system we put in place couldn't handle the easy cases, how on Earth is the system going to handle these new cases?

One thing that's for sure is that we need more research on vaccine safety. We can't wait, and the Federal government needs to take the lead to make sure it's done.

I also want to point out that I'm very concerned about this business of the government pressuring families not to have their decisions published. We don't know yet how often this happens. We're waiting for that information from the Justice Department. But the reason for it is very clear – the government doesn't want other families to benefit from those precedents when the government loses. Well, the government is supposed to be helping these families, not putting obstacles in their path. When we get to our second panel, I'm going to have some very pointed questions about this.

My final point is this. At our last hearing, we heard some graphic testimony about injuries that were caused by vaccines. We're going to hear the same kind of testimony today. It's important that we hear these stories, but we don't want to scare people into not having their kids vaccinated. Vaccines save lives, and vaccine injuries are rare. We'd like them to be even more rare. That's why I'm so serious about pushing for more research.

We also want this: when a family has a child who is injured by a vaccine – we want them to get the compensation they deserve. We want them to be treated with dignity and respect. We owe that to the Zuhlkes, and the Bartons, and the Dyers, and the Holders. We owe it to all the other families who suffer through this kind of a crisis. I'm not saying that the Justice Department has handled every case badly. But I want what I'm sure the Attorney General wants, that every case should be handled with a little compassion.

I want to thank all of our witnesses for being here today. I look forward to your testimony. I am planning to introduce legislation to try to fix some of these problems. I look forward to working with Dr. Weldon and Mr. Waxman and others on this. The hearing record will remain open until December 27, 2001.

I now yield to Mr. Waxman for his opening statement.

Mr. WAXMAN. Thank you very much, Mr. Chairman, for raising these points. There are few strategic resources more important to our Nation's health than a reliable and safe supply of vaccines. By preventing illness, vaccines reduce the spread of disease and eliminate the need of costly and potentially dangerous treatments. It is indisputable that immunizations have saved tens of thousands of lives in our country and millions more around the world.

Fifteen years ago the supply of vaccines in the United States was vulnerable. At that time pharmaceutical companies were threatening to leave the business of manufacturing childhood vaccines, citing among other things litigation costs as their reason for leaving. The United States was facing the very real possibility that we would experience a resurgence of such devastating illnesses as polio and measles, a disease that killed 450 Americans in each year of my childhood. In response to this potential public health crisis, Congress created the Vaccine Injury Compensation Program in 1987.

The purpose of the program was threefold: first, to be a no-fault program to compensate people who suffer from the rare, but sometimes serious side effects of vaccines; second, to lower the number of lawsuits against vaccine companies in order to encourage them to stay in the vaccine business and thus to ensure a healthy domestic supply of vaccines; and, third, to allay parents' concerns about vaccine safety so that parents continue to have their children vaccinated.

Now nearly 15 years later it is again time to pay attention to the vaccine supply. The good news is that immunization rates are high, and we rarely see outbreaks of vaccine-preventable diseases like polio or measles. While some vaccine manufacturers have left the vaccine business, they cannot cite liability as a reason for leaving. People seem generally satisfied with the awards they get under the Vaccine Injury Compensation Program. The act Congress passed allowed people to reject their awards and sue the vaccine manufacturers. Once they have gone through the program, very few petitioners have followed this route.

However, there are also causes for concern. Several weeks ago the Federal Government reported shortages of vaccine to protect against the devastating disease of diptheria, tetanus, whooping cough and certain common forms of severe pneumonia and meningitis. In addition, serious delays have been noted in delivery of vaccines against influenza, chickenpox, measles, mumps, rubella, and hepatitis B. These vaccine problems are not due to concerns about litigation. Nonetheless, the lives of thousands of American children and adults are in jeopardy.

Congress must be prepared to act in order to shore up the vaccine supply. I expect that the House of Representatives will soon pass a bill to combat bioterrorism. This legislation authorizes millions of dollars for the stockpiling of a vaccine against smallpox. Such an effort is essential, but it is important to keep in mind one key fact. Smallpox will only threaten American lives if an evil terrorist uses the virus to attack us. For many other infectious diseases, no terrorist needs to lift a finger for the health of our children to be threatened. Simple neglect of our vaccine supply will cause epidemics and claim lives around the country.

Today we focus on the Vaccine Injury Compensation Program. It needs to be as fair and efficient as possible. Today we will hear about the problems with the program and discuss possible solutions, and I'm pleased that we will hear today from families with direct experience with this system.

I'm also pleased we will be hearing today from the administration. The administration has expressed support for certain changes in the program, including increasing the statute of limitations and allowing for interim payments to petitioners' attorneys for their costs. These will be important steps in easing the burden of parents that get compensation for vaccine injuries, and I look forward to working with the administration on these changes.

I want to comment on the point that Mr. Burton made a minute or two ago about the fact that after some settlements, people were told not to discuss their complaint. I don't know the facts of the case he cited, but I do know that there are many, many lawsuits for tort that are settled with the demand by the defendant that in exchange for the settlement, that all the facts be kept quiet. I think that's wrong. I don't think facts ought to be kept quiet. I don't think they ought to be under seal. After all, to keep facts from getting out means that other people won't have the benefit of the information that could prevent the same thing happening over and over again to others. Litigation may be a lawsuit between private parties, but there is a broader public interest, and we shouldn't allow the records to be sealed and information withheld when that information can benefit other people.

I thank Chairman Burton for focusing attention on the need for a fair and efficient vaccine compensation system. I thank the witnesses for appearing today, and I look forward to their testimony.

Mr. GILMAN [presiding]. Thank you, Mr. Waxman.

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

Statement of Rep. Henry A. Waxman
Ranking Minority Member
Committee on Government Reform

Hearing on
"The National Vaccine Injury Compensation Program:
Is It Working As Congress Intended?"

December 12, 2001

There are few strategic resources more important to our nation's health than a reliable and safe supply of vaccines. By preventing illness, vaccines reduce the spread of disease and eliminate the need for costly and potentially dangerous treatments. It is indisputable that immunizations have saved tens of thousands of lives in our country and millions more around the world.

Fifteen years ago, the vaccine supply in the United States was vulnerable. At that time, pharmaceutical companies were threatening to leave the business of manufacturing childhood vaccines, citing, among other things, litigation costs as their reason for leaving. The United States was facing the very real possibility that we would experience a resurgence of such devastating illnesses as polio and measles, a disease that killed 450 Americans in each year of my childhood.

In response to this potential public health crisis, Congress created the Vaccine Injury Compensation Program in 1987. The purpose of the program was threefold:

First, to be a no-fault program to compensate people who suffer from the rare, but sometimes serious side effects of vaccines;

Second, to lower the number of lawsuits against vaccine companies in order to encourage them to stay in the vaccine business and, thus, to ensure a healthy domestic supply of vaccines; and

Third, to allay parents' concerns about vaccine safety so that parents continue to vaccinate.

-over-

Now, nearly 15 years later, it is again time to pay attention to the vaccine supply. The good news is that immunization rates are high and we rarely see outbreaks of vaccine-preventable diseases like polio or measles. While some vaccine manufacturers have left the vaccine business, they cannot cite liability as a reason for leaving. People seem generally satisfied with the awards they get under the Vaccine Injury Compensation Program. The Act Congress passed allowed people to reject their awards and sue the vaccine manufacturer once they have gone through the program. Very few petitioners follow this route.

However, there also are causes for concern. Several weeks ago, the federal government reported shortages of vaccines that protect against the devastating diseases of diphtheria, tetanus, whooping cough and certain common forms of severe pneumonia and meningitis. In addition, serious delays have been noted in the delivery of vaccines against influenza, chicken pox, measles, mumps, rubella and hepatitis B. These vaccine problems are not due to concerns about litigation. Nonetheless, the lives of thousands of American children and adults are in jeopardy. Congress must be prepared to act in order to shore up the vaccine supply.

I expect that the House of Representatives will soon pass a bill to combat bioterrorism.. This legislation authorizes millions of dollars for the stockpiling of a vaccine against smallpox. Such an effort is essential, but it is important to keep in mind one key fact. Smallpox will only threaten American lives if an evil terrorist uses the virus to attack us. For many other infectious diseases, no terrorist needs to lift a finger for the health of our children to be threatened. Simple neglect of our vaccine supply will cause epidemics and claim lives around the country.

Today we focus on the Vaccine Injury Compensation Program. It needs to be as fair and efficient as possible. Today, we will hear about problems with the program and discuss possible solutions. I am pleased that we will hear today from families with direct experience with this system.

I am also pleased that we will be hearing today from the Administration. The Administration has expressed support for certain changes in the program, including increasing the statute of limitations and allowing for interim payments to petitioners' attorneys for their costs. These will be important steps in easing the burden of parents to get compensation for vaccine injuries. I look forward to working with the Administration on those changes.

I thank Chairman Burton for focusing attention on the need for a fair and efficient vaccine compensation system, and I thank the witnesses for appearing today. I look forward to their testimony.

Mr. GILMAN. Mrs. Morella.

Mrs. MORELLA. Thank you, Mr. Chairman, and I am pleased that Chairman Burton is holding this hearing to continue to examine in more detail the effectiveness of the National Vaccine Injury Compensation Program. I welcome the witnesses today. I appreciate their coming and look forward to hearing their testimony. I also look forward to learning more about this program and its response and its service to our citizens.

I believe that our Nation's vaccine program is first and foremost about the protection of our citizens and their health. Today many more Americans are looking at vaccines as a major accessory against the threat of bioterrorism. We as a Nation need to have in place a vaccine program that all Americans can trust. We need to have confidence in all aspects of all vaccine programs. We need to be confident in the production of vaccines and need to ensure that those who deserve to be compensated for injuries suffered from the vaccines are compensated in a fair and just manner.

As a member of this committee, I want to ensure that all vaccine programs operate in a manner that Congress intended, so it is with this objective in mind that I look forward to the testimony of the witnesses, and, Mr. Chairman, I thank you. I yield back whatever time was allotted me.

Mr. GILMAN. Thank you, Mrs. Morella.

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

Full Committee Hearing:
"The National Vaccine Injury Compensation program:
Is It Working as Congress Intended? Part II"
Statement of Congresswoman Constance A. Morella
Government Reform Committee Hearing
Wednesday, December 12, 2001
1:00 - 2154 RHOB

Mr. Chairman, Thank you for holding this hearing today to continue to examine in more detail the effectiveness of the National Vaccine Injury Compensation Program.

I welcome the witnesses today, thank you for coming, and I look forward to hearing your testimony. I look forward to learning more about this program and its response and service to our citizens.

I do believe that our Nation's vaccine program is first and foremost about the protection of our citizens and their health. Today many more Americans are looking at vaccines as a major

accessory against the threat of bioterrorism.

We as a Nation need to have in place a vaccine program, that all Americans can trust in. We need to have confidence in all aspects of all vaccine programs. We need to be confident in the production of vaccines, and we need to ensure that those who deserve to be compensated for injuries suffered from the vaccines are compensated in a fair and just manner.

As a member of this Committee, I want to ensure at that all vaccine programs operate in a manner which Congress intended, ~~for them to.~~

It is with this objective in mind that I look forward to the testimony of the witnesses.

Thank you, Mr. Chairman.

Mr. GILMAN. Mr. Cummings.

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

Vaccinating children against infectious diseases has been one of the most effective public health initiatives ever undertaken in the United States. Vast nations have reduced vaccine-preventable diseases by more than 95 percent.

Unfortunately vaccination programs carry a human cost. The U.S. Government acknowledges that a vaccine can have severe side effects, including death or disabling conditions requiring lifetime medical care. Other conditions that may be associated with vaccines include autism, neurological injuries, seizures, and a number of autoimmune disorders. These reactions can be devastating to an effective family.

As a result, in 1986, the National Childhood Vaccine Injury Act established a Vaccine Injury Compensation Program to compensate individuals or families of individuals who had been injured by childhood vaccines whether administered in the private or public sector. Over the years I believe the Vaccine Injury Compensation Program has achieved its policy goals of providing compensation to those injured by rare adverse events, liability protection for vaccine manufacturers and administrators, and vaccine market stabilization. It has succeeded in providing a less adversarial, expensive and time-consuming system of recovery than the traditional tort system that governs medical malpractice, personal injury and product liability cases. More than 1,500 people had been paid in excess of $1.18 billion since the inception of the program in 1988.

However, there are certain aspects of the program that should be reviewed regularly. For example, to reserve the integrity of the program, it is essential to continue relying on scientific evidence when making additions or changes to the table listing the conditions that can be compensated through the program. Science-based changes or additions including new vaccines should be made promptly.

Much of the ongoing research as well as the development and appropriate supply of vaccines are benefits of the program. Before the program was in place, many vaccine manufacturers stopped producing certain vaccines due to potential liability issues. As a result, vaccine supplies dwindled, endangering the health and safety of the Nation's children. The program, the only Federal no-fault system, has made it possible to continue vaccine production and research in order to improve existing vaccines and develop new ones. Vaccine safety research must continue to be a top priority, including working to eliminate adverse reactions.

I want to thank the witnesses for being with us today, and I look forward to hearing their testimony. I yield back.

Mr. GILMAN. Thank you, Mr. Cummings.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Statement of Congressman Elijah E. Cummings
Full Government Reform Hearing
"The National Vaccine Injury Compensation Program: Is it Working as Congress Intended? - Part II"

Wednesday, December 12, 2001

Thank you, Mr. Chairman.

Vaccinating children against infectious diseases has been one of the most effective public health initiatives ever undertaken in the United States. Vaccinations have reduced vaccine-preventable diseases by more than 95%.

Unfortunately, vaccination programs carry a human cost. The U.S. Government acknowledges that a vaccine can have severe side effects, including death or disabling conditions requiring lifetime medical care. Other conditions that may be associated with vaccines include autism, neurological injuries, seizures, and a number of auto-immune disorders. These reactions can be "devastating" to affected families.

As a result, in 1986, the National Childhood Vaccine Injury Act established the Vaccine Injury Compensation Program (VICP) – to compensate individuals, or

families of individuals, who have been injured by childhood vaccines, whether administered in the private or public sector.

Over the years, I believe, the vaccine injury compensation program has achieved its policy goals of providing compensation to those injured by rare adverse events, liability protection for vaccine manufacturers and administrators, and vaccine market stabilization. It has succeeded in providing a less adversarial, expensive and time-consuming system of recovery than the traditional tort system that governs medical malpractice, personal injury and product liability cases. More than 1,500 people have been paid in excess of $1.18 billion since the inception of the program in 1988.

However, there are certain aspects of VICP that should be reviewed regularly. For example, to preserve the integrity of the program, it is essential to continue relying on scientific evidence when making additions or changes to the table listing the conditions that can be compensated through the VICP. Science-based changes or additions, including new vaccines, should be made promptly.

Much of the ongoing research, as well as the development and appropriate supply

of vaccines, are benefits of the VICP. Before the program was in place, many vaccine manufacturers stopped producing certain vaccines due to potential liability issues. As a result, vaccine supplies dwindled, endangering the health and safety of the nation's children. The VICP, the only federal no-fault system, has made it possible to continue vaccine production and research in order to improve existing vaccines and develop new ones.

Vaccine safety research must continue to be a top priority, including working to eliminate adverse reactions.

I look forward to hearing from all of our witnesses today.

Thank you.

Mr. GILMAN. Mr. Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman, and first I want to thank Chairman Burton for his calling this hearing today and for his heartfelt concern about this issue. At our last hearing a few weeks ago on this same subject, I told about a woman who had come to see me, a constituent today, in Lenoir City, TN, who told me that she had taken her perfectly healthy small son to get a DPT shot and the severe horrible reactions that he had following that shot and the fact that he was now 2 years old and weighed 22 pounds and had continual seizures all day and all night long, projectile vomiting, and all sorts of horrible things.

And then later I met one of my constituents, Mrs. Tara Dyer, who I also mentioned at the last hearing, and I'm pleased that Mrs. Dyer and her family are here today. She is here with her husband and her three children, Kaylee, Kelsee and Andy. Mrs. Dyer is here today to share with the committee the story of her son Andy, who led a perfectly normal life up until the time he received his first DPT shot. Shortly after receiving this routine vaccination, Mrs. Dyer began to notice changes in Andy's physical and emotional behavior, which she will discuss in depth today.

Like so many of the witnesses we have before us on this, the Dyers are frustrated with the current National Vaccine Injury Compensation Program. After filing for compensation in 1995, the Dyers had to wait until 1999 to find out they had been denied compensation under this program. To me as well as many people, Andy's case was and is one that should have been a clear case for compensation. Andy's vaccine came from a batch that was associated with 78 adverse events and 3 deaths; 44 of those events came solely from the State of Tennessee.

I share the frustration felt by the Dyer family. The National Vaccine Injury Compensation Program has become nothing more than another giant government bureaucracy that is not operating in the spirit in which Congress envisioned.

Mr. Chairman, I would like to thank you for conducting this hearing, and I think it's a very important topic, and I hope that we can lead to improvements because it is such a sad thing, as I said at the previous hearing, when parents take their children for something that they think is an absolutely wonderful thing for them to do for their health and then have the kinds of things happen that we heard about at our last hearing and we will hear about from our witnesses today.

And I also want to welcome my constituent Mrs. Dyer to our hearing today. Thank you very much.

Mr. GILMAN. Thank you, Mr. Duncan. We look forward to hearing Ms. Dyer's testimony.

[The prepared statement of Hon. John Duncan follows:]

Hon. John J. Duncan, Jr.

Committee on Government Reform

Mr. Chairman,

Thank you for the opportunity to introduce my constituent, Tara Dyer. Mrs. Dyer lives in Knoxville, Tennessee, with her husband David, who is also here today, and her three children, Kaylee, Kelsee and Andy.

Mrs. Dyer is here today to share with the Committee the story of her son, Andy, who led a perfectly normal life up until the time he received his first DPT vaccine.

To me, as well as many other trained professionals, Andy's case was and is a no-brainer. Andy's vaccine came from a batch that was associated with 78 adverse events and three deaths. 44 of those events came from the State of Tennessee.

I share the frustration felt by the Dyer family. The National Vaccine Injury Compensation Program has become nothing more than another giant government bureaucracy that is not operating in the spirit in which Congress envisioned.

Shortly after receiving this routine vaccination, Mrs. Dyer began to notice changes in Andy's physical and emotional behavior, which she will discuss in depth today.

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After filing for compensation in 1995, the Dyers had to wait until 1999 to find out that they had been denied compensation under the program.

CHAIRMAN

Mr. ~~Speaker~~, I would like to thank you for your continued interest in this flawed program, and I look forward to hearing the testimony of my constituent, Mrs. Tara Dyer.

Mr. GILMAN. Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman. I want to thank you and I want to thank Chairman Burton for having this hearing today. I understand the Federal Government sets up systems, our judicial system, obviously, to the Constitution and this system with the best intentions. The intentions are to solve and resolve issues and problems that our population has. We don't always get it right, and I share the frustration of many people here that this particular system that was set up had all of the best intentions and has resolved for a lot of people some of the issues, but as for some, obviously, appears to be missing the mark.

The testimony we heard in our previous hearing on this subject was moving and was also troubling. In each of the cases the witnesses described how they waited for years for compensation while the Justice Department seemed to be obstructing their efforts, and for this reason I'm glad that we're going to have the opportunity to hear again some more of the possible changes that are needed.

The program, the compensation program, was created to provide assistance to individuals. Last month we learned that this is not quite the less than adversarial system that we hoped it would be, and it is looking more like the traditional tort system that is cumbersome, it is long in process, it is very adversarial.

When the committee first reported out this particular piece of legislation, it indicated that it chose to provide compensation to all persons whose injuries meet the requirements of the petition in the table and whose injuries cannot be demonstrated to be caused by other factors. But the testimony that we've heard recently and the testimony we are going to receive again today seem to indicate quite clearly that the Department of Justice does not always seem to have followed the committee's intent. We heard from families of several individuals who described years of what they believed was stonewalling. It was followed by subsequent appeals by the Department of Justice. For those families it took an unacceptably long amount of time to be compensated.

I think the testimony of our witnesses today may surely be further evidence that the individuals we heard from last month were not merely telling us about anecdotal evidence, but something that is real. The Department continues to claim that these cases are not representative about the manner in which they treat most vaccine injury compensation cases, but the data that was provided by the Department shows that the majority of cases that have been appealed for which the initial decision favored the petitioner also had the appeal resulting in favor of the petitioner. That strongly supports that the claims we heard last month indicating that the Department of Justice is being overly and perhaps wrongly adversarial.

There are a number of other improvements that are needed in this compensation program, and I think I look forward to examining all of them. I'm pleased that there seems to be some areas of consensus among members of the committee on both sides, including support for the payment of interim fees to attorneys working on behalf of claimants. I think we should be able to find a way to make that change quickly to begin to properly defray the families' obligation to their counsel while they are pursuing these matters.

While I may not, Mr. Chairman, be able to stay for all of the testimony, it will be taken down and will be available for us to read.

I think, as I said earlier, it is important for this committee to hear the circumstances. I regret that these families have had to live under these circumstances and just pledge that this committee will work together to try to resolve this so that others will at least benefit from your experience. Thank you.

Mr. GILMAN. Thank you, Mr. Tierney.

Mr. Horn. Thank you, Mr. Horn.

I would like to welcome the panelists and thank Chairman Burton for holding this hearing today. We look forward to hearing from the witnesses as our committee continues to examine the effectiveness of the National Vaccine Injury Compensation Program. In 1986, when Congress passed legislation introduced by the ranking minority member, Mr. Waxman, it intended to provide fair compensation to individuals harmed by vaccines while ensuring that the vaccine manufacturers would continue to supply and create safe vaccines for the American public. Instead the program has become bogged down in litigation in cases lasting years, facing numerous levels of appeals before any final decisions are made.

During my years in the Congress, I have been contacted by many families, all of whom experience varying levels of difficulty with their claims before the compensation program ranging from being forced into long, drawn-out court battles to outright denial of claims due to changes in definitions and criteria.

One such example is Tommy Sansone, Jr. Tommy's family has been trying to receive compensation for the lingering devastating effects of a DPT vaccine he received when he was just 6 months old. His family tried to file a claim immediately after their son developed a severe chronic seizure disorder less than 2 weeks after receiving the vaccine. Regrettably they were told that before a claim could be filed, the family needed to spend more than $1,000 in nonreimbursable vaccine-related expenses before they can file such a claim, and since Tommy was covered by his father's insurance plan, it took several months before the Sansones met that monetary requirement. By that time, however, the criteria for the DPT vaccine had been changed, eliminating seizures from the table of related side effects. For 10 years a large percentage of those with brain damage and other symptoms were recognized to be DPT injuries, but by 1995, the year in which Tommy's claim was made, it was no longer recognized. Those new definitions have had unintended consequences, using criteria that is so strict that the restitution fund pays fewer claims than before despite the fact that there's over $1.7 billion in that fund today. As a result, the families of children like Tommy find it virtually impossible to win a claim against a vaccine injury compensation program. That was over 6 years ago and thousands of dollars in medical expenses later.

Congress envisioned that the program would be a simple one, would be straightforward and more streamlined than typical litigation. Somehow congressional intent was lost along the way. Tommy faces a lifetime of crippling seizures and mounting medical bills in addition to the emotional strain on him and his family. Hopefully these hearings will lead to a necessary adjustment to the program

and will finally help children like Tommy receive the kind of compensation to which they are entitled.

Mr. GILMAN. If there's no further opening statements, we will now hear testimony from the first witness panel, which includes—and I'd like to ask the witnesses to take their seats—Lori Barton, Tara Dyer, Joseph Holder, Clifford Shoemaker, and Robert Block, Dr. Block. Please approach the witness table, and I'm going to ask you to please, before you are seated, raise your right hands.

[Witnesses sworn.]

Mr. GILMAN. The witnesses have indicated yes. Let the record reflect that the witnesses have responded in the affirmative.

Please be seated. On behalf of the committee we welcome you today. We will start with Ms. Barton. You may summarize your testimony, and we will put the full testimony in the record, or you may read, whichever you deem appropriate. Please proceed, Ms. Barton.

STATEMENTS OF LORI BARTON, ALBUQUERQUE, NM; TARA DYER, KNOXVILLE, TN; JOE HOLDER, BAYONNE, NJ; CLIFFORD SHOEMAKER, LLP, ARLINGTON, VA; AND ROBERT BLOCK, M.D., CHAIRMAN, ADVISORY COMMISSION ON CHILDHOOD VACCINATIONS, TULSA, OK

Ms. BARTON. My name is Lori Barton, and I'm here speaking on behalf of my son Dustin. Dusty was born on July 14, 1988, slightly premature, apparently normal, with Apgar scores of 8 and 8. He and I went home after 3 days. He developed normally, lifting his head, recognizing favorite items, learning to rock, roll from stomach to back and finally at 5 months starting to rock on his hands and knees as babies do before they begin to crawl.

He had his DPT shots as scheduled at 2, 4 and 6 months, September 15, 1988; November 16, 1988; and January 18, 1989. After his first DPT vaccination, he cried for 24 hours straight until he would exhaust himself to sleep for a few minutes at a time. Before the second DPT I asked the doctor, Dr. Marek, who was our family doctor, about this reaction to his first vaccine. He said it was a normal reaction and, "He's fine now." Besides, is it was, "the law that required the vaccines," which I found out later was not exactly true.

So we gave him the second DPT. This time was much worse. His continuous screaming lasted for at least 2 days, with weeks of intermittent bouts of screaming. He had begun to roll over from stomach to back and could no longer do this. The doctor said the screaming was colic, and that it was probably a fluke that he had rolled over and would do it again real soon.

My mother baby-sat Dustin while I worked and was going to take Dusty for his third DPT shot. She and I talked about both our reservations regarding this shot, and she was going to ask if it was absolutely necessary he receive it. I told her she could ask, but I trusted this doctor and said if he said he needed the shot, then we would have to go ahead and give it to him. This was January 18, 1989.

That night Dustin began to exhibit what I then called shivers. I called my mom, and she told me to phone the doctor. Dustin was just stiff. The doctor told me that Dusty probably had a low-grade

fever and had developed a habit out of these shivers. This time, though, there was no crying, and Dustin was unusually quiet. From 24 hours after the third DPT shot until 11 months of age when he began physical therapy, he was virtually without movement except during his shivers, which I later found out were seizures.

We finally started taking Dustin to other doctors. We took him to a pediatric ophthalmologist because he was no longer looking directly at us, who told us Dusty was legally blind. He went from seeing and laughing at fans on the ceiling to barely seeing brightly colored objects right in front of him.

Our initial doctor, Dr. Marek, testified against us at the first evidentiary hearing. The special master found him to have, "selective memory." She also asked him if he wrote everything in his medical records. He said only if he deemed them medically necessary. The special master then asked him if he would write down the words of a hysterical mother or grandmother, which is what he had called us. His answer was no.

I accidentally found out about the compensation system and the VAERS. I was in a support group for parents of disabled children, and one of them showed me some information on a group called DPT, Dissatisfied Parents Together, which I joined. They sent me a law firm directory, and from there I picked a lawyer and wrote him a letter.

This case was filed on November 15, 1991. Elizabeth Kroop, the Department of Justice attorney, was assigned this case for the respondent. The first evidentiary hearing was held 2 years later on September 28 and 29, 1993. At that time the Justice Department attorney treated me and my witnesses, my mother and two friends, as if she were prosecuting a criminal trial and we were the criminals. She was rude and actually cruel to my mother, insinuating that she was not a good caretaker of Dustin. At one point she almost had my mother in tears, and in walked our old doctor, Dr. Marek, who had to testify right then. So my mother had an overnight reprieve. All I could tell her was to not let the Justice Department attorney get to her. We didn't do anything wrong. The next day my mom did much better. At the end of the hearing, the special master berated Ms. Kroop for her treatment of us, as you heard in Chairman Burton's opening statement.

It was found at that hearing that Dustin did have a table time injury from his third DPT shot, and he had a resulting seizure disorder from this injury.

After agonizing delays, I even commented to family and friends that the government was waiting for Dustin to die so they would only have to pay a death benefit.

The second hearing finally occurred on August 7, 1997. This was the hearing of the expert witnesses. Again during this hearing the Justice Department attorney was very abusive toward me and even called me a liar because she asked when Dustin became a patient of his current neurologist. I gave her the date that we actually became—began a doctor/patient relationship with him. She brought out this paper and showed the date was earlier than I had said. I had taken Dustin to this neurologist about a year before for a second opinion and had forgotten about that. Through the rest of the

hearing she would comment on my credibility because of that one incident.

Closing arguments were to be scheduled for a later date, but on Friday, October 24, at about 9 p.m., my husband and I put Dustin to bed. Before going to bed myself, I checked on all three of our boys. Dusty was sound asleep on top of his blankets, which is where I had put him earlier. I covered him with his blankets and left the room. He was sleeping soundly, snoring a little, as usual, and breathing fine. It was about 12:15 a.m., October 25, 1997.

Early on October 25, Dillon, my 5-year-old, woke me to fix breakfast. I got up, dressed, and fixed cereal for Dillon and Shane, my 10-year-old. I began to fix Dusty's breakfast because he normally was awake by this time, and even if he wasn't, he would awaken while we were fixing his breakfast. When I didn't hear him, I went to his room. The time was approximately 6:25 a.m. The first thing I noticed was that his blankets were all wrapped around his legs. This was very unusual as he didn't normally move much in his sleep, especially his legs. He did not have much muscle control or strength in his legs. He was facing away from the door, so I went around to the other side of the room and squatted down beside him to wake him. When I touched Dustin's face, it was cold.

I ran into my bedroom to grab the cordless phone, screaming for Kevin to get up. I dialed the speed dial number for my mother and said, come over, I have to call 911. I hung up and dialed 911 as Kevin began to give Dustin CPR. I gave directions to the emergency service and then took over the CPR. Within 5 minutes the paramedics arrived. My mother and father were there 2 minutes later. We were at the hospital by 6:50 a.m., and Dustin was pronounced dead 10 minutes later. The staff at the hospital believed he had died about 3 hours earlier. The ER doctor said that she believed Dustin to have died of a seizure and that an autopsy wasn't necessary, although Dustin's pediatrician felt that we should have one done as she had not seen Dustin since January or February of that year because he had been so healthy.

Before he died, Dustin was making great progress. He could walk short distances with his walker, crawl wherever he wanted to go, and speak well enough for family and friends to understand.

After receiving the death certificate showing the cause of death as seizures, I filed a motion to recaption and convert the case to a death claim.

About this time I also heard from Dustin's neurologist and the pathologist who did the autopsy saying that the Justice Department attorney did her best to intimidate them as well. This was January 1998. At this time a new Justice Department attorney, Mike Milmoe, was assigned Dustin's case. Dustin's attorney, Bob Moxley, informed Mr. Milmoe that I had been diagnosed with cerebritis as a result of my lupus, and the doctors told me I had little time left to live. After Mr. Milmoe was granted many more delays, the final arguments were heard. Special Master French filed her published decision on May 2, 2000. The respondent filed a motion to reconsider, which was granted. The final decision was filed June 1, 2000. This final decision was again in our, the petitioners', favor, only it came with a condition. The respondent prom-

ised not to file another appeal in this case if we agreed the decision be unpublished.

I agonized over this decision as that meant no other family would be able to cite this case in any of their proceedings, but in the end my fatigue won out. I was mentally and physically exhausted and was also quite ill. I didn't think I could make it through another 10 years of appeals and motions. Luckily my lupus has gone into remission and is no longer a major threat to my life.

I also didn't want Dustin's lawyer, Bob Moxley, to go through another 10 years of working on our case without getting paid, and I had already borrowed thousands of dollars in expert witness and attorney expenses from Dustin's grandparents. I felt after 10 years of work, his attorney deserved to be paid as well as all four of Dustin's grandparents.

I believe the attorneys should be paid in increments after it is proven that the case is not fraudulent. I also believe that families whose cases drag on for years should receive moneys for those years their cases were in the system. Even if the child should die during the process, the family has been fighting with the government to get help for their child while doing it all along.

I also believe there should be a limited number of extensions and delays granted to each party. I believe that doctors should be well educated on what to look for in vaccine adverse reactions. I'm sure Mr. Milmoe's tactic of published versus unpublished must be legal, but to me it was extortion.

I initially filed this claim so if any money were ever to come of it, it would help Dusty when he needed it, but that never happened. It took almost 10 years to settle this, and Dustin died in the process. It seems to me the government got what it was waiting for, a death benefit.

I often wonder if the case had not dragged on for so many years, if Dustin's outcome would have been different. He would have had the money to seek treatment and therapies outside of Albuquerque that his insurance would not cover. Maybe one of those could have saved his life.

Mr. BURTON [presiding]. Thank you, Ms. Barton.

[The prepared statement of Ms. Barton follows:]

Statement of Lori Barton
Before the Committee on Government Reform
December 12, 2001

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Again during this hearing, the Justice Department Attorney was very abusive toward me and even called me a liar because she asked when Dustin became a patient of his current neurologist. I gave her the date that we actually began a doctor/patient relationship with him. She brought out this paper and showed the date was early than I had said. I had taken Dustin to this neurologist about a year before for a second opinion. Through the rest of the hearing she would comment on my credibility because of that one incident.

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I covered him with his blankets, and left the room. He was sleeping soundly, snoring a little--as usual--and breathing fine. It was about 12:15 a.m., October 25, 1997.

Early on October 25, Dillon, my five-year-old, woke me to fix breakfast. I got up, dressed, and fixed cereal for Dillon and Shane (my ten-year-old). I began to fix Dusty's breakfast, because he normally was awake by this time, and if he wasn't, he would awaken while we were fixing breakfast. When I didn't hear him, I went to his room.

The time was approximately 6:25 a.m. The first thing I noticed was that his blankets were all wrapped around his legs. This was very unusual, as he didn't normally move very much in his sleep, especially his legs. He did not have much muscle control or strength in his legs.

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Within five minutes, the paramedics arrived. My mother and father were there two minutes later. We were at the hospital by 6:50 a.m., and Dusty was pronounced dead 10 minutes later. The staff at the hospital believed he had died about 3 hours earlier.

The ER doctor said that she believed Dusty to have died of a seizure, and that an autopsy was not necessary, although Dusty's pediatrician felt we should have one done as she had not seen Dusty since January or February, 1997 (because he was so healthy). Before he died, Dustin was making great progress – he could walk short

distances with his walker, crawl wherever he wanted to go and speak well enough for family and friends to understand.

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At this time a new Justice Department Attorney, Mike Milmoe, was assigned Dustin's case. Dustin's attorney, Bob Moxley, informed Mr. Milmoe that I had been diagnosed with cerebritis (as a result of my Lupus) and the doctors told me I had little time left to live. After Mr. Milmoe was granted many more delays, the final arguments were heard. Special Master French filed her "Published" decision on May 2, 2000. The Respondent filed a motion to reconsider; which was granted. The final decision was filed June 1, 2000. This final decision was again in our (Petitioner's) favor and came with a "condition", the Respondent promised not to file another appeal in this case if we agreed the decision be "Unpublished".

I agonized over this decision as that meant no other family would be able to cite this case in any of their proceedings. But in the end, my fatigue won out. I was mentally and physically exhausted and was also quite ill. I didn't think I could make it through another ten years of appeals and motions. Luckily my Lupus has gone into remission and is no longer a major threat to my life.

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proven the case is not fraudulent. I also believe that families whose cases drag on for years should receive monies for those years their case were in the system. Even if the child should die during the process – the family has been fighting with the government to get help for their child, while doing it all along. I also believe there should be a limited number of extensions/delays granted to each party. I also believe doctors should be well educated on what to look for in vaccine adverse reactions. I'm sure Mr. Milmoe's tactic (of Published vs. Unpublished) must be legal, but to me it was extortion.

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I often wonder if this case had not dragged on for so many years if Dustin's outcome would have been different. He would have had the money to seek treatment and therapies outside of Albuquerque that his insurance would not cover. Maybe one of those could have saved his life.

Mr. BURTON. I had read your story before, so I apologize for not being here at the beginning of your testimony, but I want you to know we are very sympathetic to the problem you had, and yours is another story that we shouldn't have to hear. We just shouldn't have to hear.

Ms. Dyer.

Ms. DYER. Good afternoon. My name is Tara Dyer. I'm the mother of three, Kaylee, who is 14; Kelsee, who is 12; and Andy, who is 9. I'm here on behalf of my son Andy, who at 2 months of age suffered brain damage as the result of a required vaccination.

Andy was a perfectly healthy baby at birth with Apgars at 9 and 10 respectfully. The first 2 months of his life were uneventful. He would respond happily to his surroundings, laughing and giggling when spoken to, tracking with his eyes, kicking with his arms and legs when recognizing familiar faces, and he had a very hearty appetite.

On August 28, 1992, I took Andy in for his first DPT vaccine. As I did with his sisters previously, I gave him Tylenol beforehand to help with any fever that might incur. After his first shot, he began to show symptoms that were unknown to me to be associated with vaccines. The first thing that I remember that was different with Andy's shot was that he cried much louder and longer than did his sisters. By the time the nurse came to tell us we could leave, he had virtually cried himself to sleep. He slept all the way home and approximately 3 hours thereafter. He completely missed a feeding, and I was sure that when he awoke, he would be starved. However, upon awakening, he seemed to have difficulty sucking, and my assumption was that he was still sleepy. We were told that being sleepy after the vaccination is normal.

Andy continued to run a mild temperature, sleep more than usual, and not eat as he normally did.

After about 48 hours, his fever broke. Yet he seemed more quiet and much more lethargic than before.

On September 2nd, I took Andy to his pediatrician for a scheduled well baby visit. The doctor felt Andy was all right.

During September 3rd through the 14th, Andy developed symptoms which to me appeared to be cold related. He appeared to be having difficulty breathing, as if he had a stuffy nose. He was not eating well, and this I associated with having the difficulty breathing.

Then we noticed Andy flicking his ear occasionally. At first we thought that he was just playing with his ear. Then we noticed that he was doing this cuffing and flicking several times a day.

At this time I believed that Andy had possibly developed an ear infection. I took Andy to the doctor again and told him the things Andy was doing. The doctor diagnosed him with an upper respiratory infection. He was put on antibiotics and Dimetapp.

Within days the flicking of the ear episodes turned into a complete stiffening of the body along with the flicking of the ear. We videotaped this and took it to the doctor. He was then diagnosed with a seizure disorder. It is now known that the difficulty breathing, not wanting to suck and the cupping and flicking of his ear were all effects of neurological damage taking place, not an upper respiratory infection.

During the next 2 years, we were seen by several specialists to try and find out why Andy was having these uncontrollable seizures. There was no history of seizures in our family. During this time, his seizures continued, as did his delayed development. Never during these 2 years was there a mention that there could be a relationship between his shot and the brain injury.

Shortly after Andy's second birthday, a friend mentioned that she had seen a show on vaccines and children with seizures and other disorders. This is when I began to research Andy's vaccine.

The first vaccine Andy received was Lederle 322914. I found that there was a suspicious clustering of events with this vaccine. This lot contained 78 events with 3 deaths; 44 of the 78 were from Tennessee, as were the deaths. All of these occurred between February 1992 and June 1993. It is known that vaccine lots manufactured by Lederle, which have the same first three digits, are all from the same bulk of vaccine. Therefore, his lot contained a reported—again, I just say reported—total of 246 events and a total of 12 deaths. This is substantial evidence that my son received a bad batch of vaccine.

Why after so many deaths and events was this still being given to our children? Because the FDA says there is no trigger number for a recall. The lot distribution number, including the number of doses per lot, is confidential. Can you believe this? The lot distribution number is confidential? To this day, we still do not know how many doses and how many adverse events occurred.

At the age of 3½, Andy was diagnosed as having a seizure disorder and being severely developmentally delayed. He could walk, but communication was very limited. At this time, he developed liver failure due to the anticonvulsant he was taking. He was in a coma for 8 weeks, and when he came out, he had lost all neurological function, except for the ability to breathe on his own.

We were told that he would never walk, talk, or eat orally again. We were told that he was blind and that he was deaf as well, all of this stemming from a required DPT vaccination.

My experience with the Vaccine Compensation Injury Program was not a pleasant one. First of all, I believe this program was intended to be generous, user-friendly, fair and expedient. It fails in all of these areas.

We filed for compensation in July 1995. We were denied compensation in August 1999. Going into the hearing after being assigned Special Magistrate Millman, we felt prejudiced against before ever even starting. She is quoted as saying in the Washington Post, "when I have to refuse an award, it is hard, but I know these children's basic needs are going to be taken care of either way. It is not like the ancient days when they just threw you off a cliff."

How dare this government official imply that it won't bother her not to grant an award for a vaccine injury, we should be happy our child is just not being disposed of? And, as far as basic needs, these children need much more than food, clothing and shelter. There is the therapies, medications, special equipment. There is wheelchair lifts, ramps, adapted bathrooms and beds. The list goes on.

As my husband and I get older, we worry as to what will happen when physically or mentally we can no longer care for Andy. As with our healthy children, we want these injured children to live

under the best circumstances possible and be the best and most that they can be.

We hear daily of awards being given to cancer victims or their families because of cigarette smoking. These are people who made the decision to smoke, even though they were misled as to the dangers of tobacco, but these same people are justifiably compensated for their injuries. Why can't our children be compensated for injurious, mandatory vaccinations? Why are they receiving nothing?

One reason is because the timetable is next to impossible to meet unless yours is a child who dies. Many symptoms are delayed and appear not to be life threatening.

Is your child extremely sleepy, or are they actually suffering, "a significant change in mental status?"

Is your child playing with his ear, or is this, "repetitive movement of the part of his body a seizure?"

Is my new child just not hungry, or is there difficulty sucking, quote, an injury to the neurological function?

These were signs my son showed, yet I did not know how to recognize a severe vaccine reaction so that I could report it to the doctor, and I believe many parents have received to the same. Had the facts been given to parents whose children received the contaminated vaccine, parents could have been spared much wasted effort, and the child could have been committed to earlier and more meaningful treatment.

We were told that, in order to receive compensation, injuries should have been indicated within 72 hours. How could this have possibly been done if we didn't even know it was the vaccine until nearly 2 years later?

Second, it has been stated numerous times the burden of proof is on the petitioner. We are continually put in the position to prove that there was not some other cause.

One, my child was normal at birth and until his first vaccine was developing normally. Two, he immediately showed signs of a reaction after the vaccine. Three, the vaccine itself showed to be a hot lot. Four, after many tests and no other explanation, Andy's neurologist believed the vaccine to be the cause.

We know of no other children unaffected who partook of this bad batch of vaccine. As far as we are concerned, 100 percent of those who were immunized by this bad batch were affected. This is more than substantial proof. If you have a glass of water and 100 kids take a drink and 100 get sick, there is something wrong with that glass of water.

The standards need to be changed and made retroactive. Much of the testimony given in these cases is more than required in a normal court of law. I have read that the NVCP was, "not intended to serve as a compensation source for a wide range of naturally occurring illnesses and conditions." If this is the case and a petitioner has given substantial evidence that this was not a naturally occurring illness, the burden of proof should now be on the government to prove that it was not the vaccine.

If this drug were an automobile, a car seat, a toaster, a toy, how much more aggressive action and remedy would be taken against the manufacturer in favor of the damaged individual?

Finally, finding a qualified attorney who is willing not to receive compensation until the claim is settled is very hard. These attorneys are required to cover all costs incurred for medical experts, copying charges, mailing charges, telephone communications, etc., severely taxing theirs and the petitioner's resources, while the government attorneys receive regular pay, pay increases and other benefits and are able financially to access an unlimited amount of resources. This makes for a very uneven legal playing field.

Additionally, that can drag out the process, discouraging and stretching the petitioner's resources to impossible limits.

Do any of you know what it is to watch day in and day out a child who lives and moves essentially in only two dimensions on the floor, have a 9-year-old who has never experienced running through the grass, hitting a ball, stubbing his toe, telling his parents and family members that he loves them or requesting a gift from Santa? Realize that your child will always have to wear diapers, realize that your child will never participate in a team event, date, attend a prom or bring home a report card, or see a lonely child in a corporate-produced solitary confinement, while that corporation thrives on the pain and deaths of children?

Is it too much to ask that once a drug such as this is found to be deadly, its use is immediately stopped, participants notified, causes determined and corrected and injured children compensated?

In closing, thousands and thousands of children are injured or die each year due to vaccines. However, I wonder how many more like me are out there who do not know and maybe still do not know that their child's death or injury was vaccine-related? And how many doctors are not reporting these events? I believe the true number of injured children is much higher, and these injuries do not just affect the child but the whole family. There is depression, resentment from other children for time taken away from them and tension between the husband and wife.

But there is also good that comes from such a tragic event—an appreciation for the small things, a hug or a touch, the voice of someone saying I love you. It is often in the very midst of adversities that we experience God's love, the kindness of a neighbor, the prayers of a church family and a peace that could only come through faith in our Lord Jesus Christ. My prayer is that Andy's story can make a difference, and I thank you for the opportunity to share it. God bless you all.

[The prepared statement of Mrs. Dyer follows:]

Good Afternoon.

My name is Tara Dyer. I am the mother of three. Kaylee who is 14, Kelsee who is 12 and Andy who is 9. I am here on behalf of my son Andy, who at 2 months of age was injured by a vaccine.

Andy was a perfectly healthy baby at birth. With apgars at 9 and 10 respectfully. The first 2 months of his life were uneventful. He would respond happily to his surroundings: laughing and giggling when spoken to, tracking with his eyes, kicking his arms and legs when recognizing familiar faces and he had a very hearty appetite.

On August 28, 1992, I took Andy in for his 1st DPT vaccine. As I did with his sisters previously, I gave him Tylenol before hand to help with any fever that might incur. After his first shot he began to show symptoms that were unkown to me to be associated with vaccines. The first thing that I remember that was different with Andy's shot was that he cried much louder and longer than did his sisters. By the time the nurse came to tell us we could leave, he had virtually cried himself to sleep. He slept all the way home and approximately 3 hours after. He completely missed a feeding and I was sure that he would be starved when he awoke; however,upon awakening he seemed to be having difficulty sucking and my assumption was that he was still sleepy. We were told that being sleepy after the vaccination is normal. Andy continued to run a mild temperature, sleep more than usual, and not eat like he had been doing. After about 48 hours, his fever broke, yet he seemed more quiet and much more lethargic than before. On September 2, I took Andy to his peditrician for a scheduled well-baby visit. The doctor felt Andy was alright.

During September 3 through the 14, Andy developed symptoms which to me appeared to be "cold" related. He appeared to be having difficulty breathing (as if he had a stuffy nose.) He was not eating well, this I associated with having the difficulty breathing. Then we noticed Andy "flicking" his ear occasionally. At first we thought that he was just playing with his ear, then we noticed that he was doing this "cupping and flicking" several times a day. At this time, I believed that Andy had possibly developed an ear infection. I took Andy to the doctor again and told him the things Andy was doing. The doctor diagnosed him with an upper-respitory infection. He was put on antibiotics and Dimetapp. Within days, the flicking of the ear episodes

turned into a complete stiffening of the body along with flicking of the ear. We videotaped this and took it to the doctor. He was then diagnosed with a seizure disorder. It is now known that the difficulty breathing, not wanting to suck, and the "cupping and flicking" of his ear were all effects of neurological damage taking place, not an upper-respitory infection.

During the next 2 years we were seen by several specialists to try and find out why Andy was having these uncontrollable seizures. There was no history of seizures in our family. During this time his seizures continued as did his delayed development. Never, during these 2 years was their a mention that there could be a relationship between his shot and the brain injury.

Shortly after Andy's 2nd birthday, a friend mentioned that she had seen a show on vaccines and children with seizures and other disorders. This is when I began to research Andy's vaccine.

The first vaccine Andy received was: Lederle 322914. I found that there was a suspicious "clustering" of events with this vaccine. This lot contained 78 events with 3 deaths. Forty-four of the seventy-eight were from Tennessee as were the deaths. All of these occurred between 2/92 and 6/93. It is known that vaccine lots manufactured by Lederle, which have the same first three digits, are all from the same bulk of vaccine. Therefore; his lot contained a total of 246 events and a total of 12 deaths. This is substantial evidence that my son recieved a bad batch of vaccine. Why, after so many deaths and events reported was this still being given to our children? Because, the FDA says that there is no "trigger" number for a recall. The lot distribution information (including # of doses per lot) is confidential!

At the age of three and a half Andy was diagnosed as having a seizure disorder and being severely developmentally delayed. He could walk, but communication was very limited. At this time, he developed liver failure due to the anti-convulsant he was taking. He was in a coma for 8 weeks and when he came out he had lost all neurological function except for the ability to breath on his own. We were told that he would never walk, talk or eat again. WE were told that he was blind and deaf as well. All of this stemming from a DPT vaccine.

My experience with the Vaccine Compensation Injury Program was not a pleasant one. First of all, I believe this program was intended to generous, "user friendly", and expedient. It fails in all these areas.

We filed for compensation in July of '95. We were denied compensation in August of '99. Going into the hearing, after being assigned Special Magistrate Millman, we felt prejiduced against before even starting. She is quoted as saying in the Washington Post, " When I have to refuse an award, it's hard. But I know theses children's basic needs are going to be taken care of either way. It's not like the ancient days when they just threw you off a cliff." How dare this government official imply that it won't bother her not to award for a vaccine injury, we should be happy our child is not being "disposed of." And as far as basic needs, these children need much more that food, clothing and shelter. There's the therapies, medications and special equippment. There's wheelchair lifts, ramps, adaptive bathrooms and beds. The list goes on. As my husband and I get older, we worry as to what will happen when physically or mentally we can no longer care for Andy. As with our healthy children, we want these injured children to live under the best circumstances possible and to be the best and most they can be! We hear daily of awards being given to cancer victims or their families because of cigarette smoking. These are people who made the decision to smoke and are being rewarded for it. Yet our children are told they must be vaccinated and are dying as well as being permantely brain injured and many are receiving nothing.

Why are they receiving nothing? One reason is because the time-table is next to impossible to meet unless yours is a child who dies. Many symptoms appear not to be life-threatening. Is your child extremely sleepy or are they actually suffering a "significant change in mental status?" Is my child playing with his ear or is this "repetive movement of a part of his body" a seizure? Is my child just not hungry or is their difficulty sucking an "injury to their neurological function?" These were signs my son showed, yet I did not know how to recognize a severe vaccine reaction so that I could report it to the doctor. And I believe many parents have testified to the same. We were told that in order to receive compensation, injury should have been indicated within 72 hours. How could this have possibly been done if we dididn't even know it was the vaccine until nearly 2 years later!

Secondly, it has been stated numerous times "the burden of proof is on the

petitioner." We are continually put in the position to prove that there was not some other cause! 1) My child was normal at birth and up until his first vaccine was developing normally. 2) He immediately showed signs of a reaction after the vaccine. 3) The vaccine itself showed to be a "hot-lot." 4)After many tests and no other explanation, Andy's neurologist believe the vaccine to be the cause. This is more than substantial proof. If you have a glass of water and 100 kids take a drink and 78 get sick...there is something wrong with the glass of water! The standards need to be changed and I believe made retroactive! Much of the testimony given in these cases is more than required in a normal court of law. I have read that the NVCP was "not intended to serve as a compensation source for a wide range of naturally occurring illnesses and conditions." If this is the case, and a petitioner has given substantial evidence that this was not a "naturally" occurring illness, the burden of proof should now be on the government to prove it was not the vaccine.

Finally, finding a qualified attorney, who is willing not to receive compensation until the claim is settled is very hard. These attornies are required to cover all cost incurred for medical experts, copying charges, mailing charges, telephone communications etc., limiting theirs and the petitioners resources! While the government attornies receive regular pay and are able financially to access an unlimited amount of resources. This makes for a very uneven legal field.

In closing, thousands and thousands of children are injured or die each year due to vaccines. However, I wonder how many more like me are out there who did not know and maybe still don't know that their childs death or injury was vaccine related. And how many doctors are not reporting these events. I believe the true number of injured children is much higher. And these injuries do not just affect the child but the whole family. There is depression, resentment by other children for time taken away from them, and tension between husband and wife. There is also the good that comes from such a tragic event. An appreciation for the small things, a hug or a touch, the voice of someone saying "I love you". It is often in the very midst of adversities that we experience Gods love. The kindness of a neighbor, the prayers of a church family and a peace that can only come from faith in our Lord Jesus Christ.

My prayer is that Andy's story can make a difference and I thank you for the opportunity to share it.

Mr. BURTON. I would like to have the information on that lot number that you can't get. I will subpoena that today. We will subpoena that, and if the company does not give us that information, I will have—was it Lederle?

Mrs. DYER. Lederle.

Mr. BURTON. We will subpoena the president of the company before the committee to ask us why they would not give us that information. And you said, to your knowledge, every child that got a shot from that lot was adversely affected?

Mrs. DYER. It has not been proven to me otherwise.

Mr. BURTON. I see. OK. I want you to know that, in defense of some of the doctors and maybe because of their own carelessness, many of them don't know what is in these shots. Every Congressman that is concerned about the flu vaccine, about getting the flu because of anthrax, we're all going over to the doctor's office here at the Capitol, and we're all getting flu shots, and what no Congressman knows or very few knows is that the shots we're getting contains mercury, mercury, a toxic substance that they won't even allow in topical dressings, and scientists all around the world including Canada have told us that mercury, even as a topical dressing, has adverse effects. But as a shot—given in a shot as a preservative, that it can cause—it is a contributing factor to autism and Alzheimer's.

A lot of us are older guys here in the Congress, and we're getting shots we don't even know contains mercury because it is called thimerosal, and I don't know why the FDA doesn't do something about that. We've talked to them until we're blue in the face, and we'll ask them about that again at later hearings. You'll hear about that, guys, again. You'll be back up here again.

But it really is kind of troubling that we're not getting answers to these questions.

Be sure to give me that lot number, and we will subpoena that today.

Mr. Holder.

Mr. HOLDER. Thanks very much for having me here. It was kind of short notice. I'm real glad I could make it.

I'm here on behalf of my son, Brandon Holder; and please let the record show I'm from Bayonne, NJ.

Anyway, Brandon was born on January 7, 1992. His Apgar was a 9 and 10. He was injured when he was 5½ months old on July 10, 1992, from his second DPT vaccination; and his first seizure occurred 6 hours later, which was a generalized seizure.

We found out about NVIC by chance in April 1993 when Brandon was hospitalized for multiple seizures. A woman whose child was in the same room informed us of the NVIC at this time.

There was a lot of difficulty finding an attorney who would handle the case, but we finally located Tom Gallagher in August 1994. The claim was filed in October 1994 and resolved in July 2000, a total of 6 years from beginning to end.

Throughout this period, Brandon's development regressed daily. Medical bills piled up. His mother quit her job to care for him. Bankruptcy was filed, and I worked three jobs to make ends meet.

We helplessly watched as the seizures gradually changed Brandon from a brilliant child who could say his ABCs, count to 20,

pledge allegiance to the flag and meet most of his milestones to a child who has a limited vocabulary and the mentality of a 2-year-old.

Upon the settling of the case, a lump sum was put into an irrevocable trust for Brandon by the laws that govern the State of New Jersey. Several things were outlined in Brandon's life care plan as to how this money should be spent. One example of this was financial assistance toward a home in light of our past monetary problems due to Brandon's condition, the logic being that with all of our lost time and wages that it was fair to assume that, being productive individuals, we would have achieved home ownership by this time. A specific amount was outlined, and to date the bank holding the trust has denied our request for assistance based on the laws that govern New Jersey.

Basically, New Jersey law states that you must go to court to prove you need the assistance, while the Federal Government has already acknowledged and made provisions for the assistance that is required within the life care plan. Keep in mind this is just one example of how difficult it is to access the money.

The flaws in this program are to me very plain.

First and most important for the child is the amount of time that case takes to settle results in lack of quality, early intervention for the injured child and financial difficulty for most parents. I believe that had the case been settled in a more timely fashion, Brandon would have been able to get sufficient early intervention from quality professionals, and he may not have regressed as drastically.

The second one is the inability of the Federal Government to fulfill the terms of its settlement because of the laws that dictate State government. You should not have to prove your need for something to the State that has already been approved on a Federal level.

And if one of the primary purposes of this program is to provide fair and expedited compensation, I can agree that the settlement was fair but far from expeditious. Claimants are left to suffer for years before receiving compensation and then years after trying to justify to their State government that which was already promised by the Federal Government.

And that is pretty much all I've got. Thank you.

Mr. DUNCAN [presiding]. All right. Thank you. Thank you very much, Mr. Holder.

[The prepared statement of Mr. Holder follows:]

Testimony of
JOSEPH HOLDER
Father of
Vaccine Injured Child

GOVERNMENT REFORM COMMITTEE
VICP Part II
Wednesday, December 12, 2001

Brandon was injured at 5 1/2 months old on July 10, 1992 from his 2nd DPT vaccine. His first seizure occurred six hours later, which was a generalized seizure.

We found out about the NVIC by chance in April of 1993 when Brandon was hospitalized for multiple seizures. A woman whose child was in the same room informed us about the NVIC at this time.

There was difficulty finding an attorney who would handle the case but we finally located Tom Gallagher in August of 1994.

The claim was filed in October of 1994 and resolved in July of 2000. A total of six years from beginning to end.

Throughout this period Brandon's development regressed daily. Medical bills piled up, his mother quit her job to care for him, bankruptcy was filed and I worked three jobs to try and make ends meet.

We helplessly watched as the seizures gradually changed Brandon from a brilliant child who could say his ABC's, count to twenty, pledge allegiance to the flag and meet most of his milestones to a child who has a limited vocabulary and the mentality of a two year old.

Upon the settling of the case, a lump sum was put into an irrevocable trust for Brandon by the laws that govern the state of NJ. Several things were outlined in Brandon's life care plan as to how this money should be spent. One example of this was financial assistance towards a home in light of our past monetary problems due to Brandon's condition. The logic being that with all of our lost time and wages that it was fair to assume that being productive individuals we would have achieved home ownership during this time. A specific amount was outlined and to date the bank holding the trust has denied our requests for assistance based on the laws that Govern NJ.

The flaws in this program are very plain:

1. The amount of time that a case takes to settle results in lack of quality early intervention for the injured child and financial difficulty for most parents. I believe that had the case been settled in a more timely fashion, Brandon would have been able to get sufficient early intervention from professionals and he may not have regressed as drastically. I guess that's something I'll never know for certain.

2. The inability of the Federal Government to fulfill the terms of a settlement because of the laws that dictate State Government.

Mr. DUNCAN. Mr. Shoemaker.

Mr. SHOEMAKER. Thank you, Mr. Chairman.

First of all, I'd like to say that I'm honored to be on the panel today with Dr. Block, who, as many of you know, is retiring as chairman of the Advisory Commission on Childhood Vaccinations; and I think we all should thank him for his role in that capacity and the work that he has done over the years. And I'm honored to be with you today on that.

I'm even more honored to be on the panel with the parents of Brandon and Andy and Dustin. These are stories that, unfortunately, I hear every day of my life. I brought along some of the members of my office, and I'd like them to stand up, if you don't mind, please. These are some of the people that hear these stories every day of their lives, too, and I think they were entitled to be here today.

Today, we represent over 400 children and adults in the Vaccine Compensation Act, and I think Dr. Block and I will agree on a lot of things here today. One is that adverse reactions to vaccinations are rare. Vaccinations have done more for public health in this country than—I can't say how many things. Clean water, vaccinations—there are a few things that we can point to—antibiotics—that have done a lot for this country. So both of us agree that these vaccine adverse reactions are rare, but when they happen to your child, that is 100 percent. That is very real.

There was something in Dr. Block's testimony that I would like to read—and he's going to be reading it to you. He says, speaking for myself, I think it is sad that a child allegedly injured by a vaccine can turn to the program for compensation, but a child injured by a vaccine-preventable disease may have little or no access to appropriate care and no source for financial resources to support that care.

I know what he's talking about there, because the year I was born, my sister had polio. There was no program to pay for her expenses. There was no vaccine to protect her. So polio vaccination has been a very important thing in this country, and I recognize that. But I think my sister would be the first person to say that Zachary Strain who lives up in Syracuse, NY, deserves the benefits of this program.

At 2 months of age, Zachary was given oral polio vaccination. Today he is paralyzed from the neck down, on a respirator for life because he has polio from that vaccine. Now this was after the recommendations had already been changed saying that they should give the kill virus vaccine first. I don't know why he was given an oral polio vaccine at 2 months, but he was, and today he's paralyzed from the neck down.

And that little boy is a beautiful child. He is so smart. He's been living with nurses all of his life. He has a personality that is years older than him. He flirts with the nurses. But for the rest of his life, he will be paralyzed and on a respirator. And my sister, who had no compensation program when she developed polio, would be the first to say that Zachary Strain needs to be taken care of.

A little bit of an update on Rachel Zuhlke, who is our client. Rachel is back in the hospital, I'm sorry to say. She is still having continuing problems.

We are working now actively on the life care plan, because, as you pointed out, we did win the compensation in that case, the entitlement portion of that case.

There were a lot of reasons why Rachel's case was delayed over the years. Some of them were my fault. Some of them were not my fault. Every time we'd get ready to go to a hearing, Rachel would end up back in the hospital. Then we would have to go get more records and provide more records to the experts.

But the important thing to understand about Rachel's case is the treating doctors all said this was postvaccinal encephalopathy. Dr. Rick O'Hearn in Dr. Weldon's district, a great pediatrician, a wonderful man, said this is a postvaccinal encephalopathy. John Sleasman, the head of immunology at Shands, who I think Tim Westmorland knows, said this is postvaccinal encephalopathy.

This wasn't a case that should have ever been challenged, but it was. Experts were hired. So we had to hire experts and bring them in, and the expenses of these cases are unbelievable.

There came a point in time when the government wanted to have all of the radiological films in that case. It would have cost $5,000 or $6,000 to produce those films. I said I don't have the money.

At first, the government was going to pay for it. Then they said, no. No, we can't do that because if we do it in this case it will set a precedent. We'll have to do it in all the other cases.

So I said to my client, I don't have $5,000. I'm representing hundreds of people. I don't have—you know, you can't squeeze blood out of a turnip. I don't have it. So she went and put $5,000 on her credit card to pay for those films to be sent.

I don't know how much money Mrs. Zuhlke spent over the years helping us to finance that case because I couldn't pay the expenses. For me as an attorney, that is embarrassing.

But do the math. We represent 400 children in the program. At $150 apiece for filing those cases, that is $60,000. If it only costs me $500 apiece to get the medical records, that is $200,000. If I only pay one expert $1,000 to get a report in each of those cases, that is $400,000. I have a half a million dollars outstanding in expenses in these cases. I have no more to give.

I don't care if this program is adversarial. Make it adversarial, but give us the resources to fight the battle. Give us the money to be able to pay for the experts, to do things that I know need to be done to win these case. I can win them, but I can't win them without resources.

I'm getting $190 an hour in this program. My colleagues who are out there in contingent fee litigation think I'm an idiot. They think I'm crazy.

But the reason I'm still in this program is because of people like this. These are saints. They live day in and day out with devastated children. I could bring you videotapes that would make you bawl, because we see them every day. I saw one this morning, a child violent, throwing things around the room, his parents trying to control him. I can't take that very much longer. I don't care if it is adversarial. Give us the resources.

There are three things that I asked for in September 1999. None of them have been done.

The next paper I write is not going to be for Congress. It is going to be for the American Trial Lawyers Association magazine, saying tort reform is dead. It does not work. Any child can go out there on the street and be injured in an automobile accident, and they don't have to file a lawsuit until they're 18 years of age or older. And yet every day I get phone calls from people saying, 4 years ago, 5 years ago my child was injured. And I have to sit there and explain to them, I'm sorry, the Federal Government won't let you make a claim because it is more than 3 years from the onset of your symptoms.

I know that some of you on this panel are lawyers. Read 51 Am. Jur. 2d Limitations of Actions, section 178 and 747. They are on the front page. Every State in this Union has a tolling provision for minority, every State. This program, it's 3 years from the onset of symptoms. It doesn't matter if the parents didn't find out about the fact that the vaccine caused the injury. It doesn't matter that they didn't find out about the program until it's too late. They're out of luck.

And you know what's even better? There is a vicious decision from the Federal Court of Appeals saying there is no equitable tolling in this program. There is no excuse for not filing on time.

Now there's a case out of New Jersey, the McDonald case, saying, well, I'm sorry, if you didn't file in that program soon enough, then you can't file a State civil action either. So these kids cannot only not file in the program, they can't go file a civil action either, if the McDonald case holds up.

This has got to be changed. There is a glaring inequity in the program, that if you do nothing else, change the statute of limitations to what every State in this Union allows. Any complaint, any objection to doing that has been answered by all 50 State legislatures in the country. You can't say, well, the proof is going to go away. It's going to be hard to get evidence years later. If that's true, it works against the claimants, not against the respondent, because we have the burden of proof.

You can't make any arguments against this. It's already been argued in all 50 legislatures, so do it.

The second thing I've asked for is a different burden of proof. I would invite you to look at page 6 of my testimony, because the Chief Special Master has given you the language for legislation. He's a judge. He can't legislate. But in the Stephens case, which is on page 6, I point out what he is proposing as a burden of proof.

Work with the Chief Special Master. He's a judge hearing these cases. He is inviting you. He is giving you this decision, saying, legislate it. I can't. It's right there.

I was encouraged to be at the ACCV meeting chaired by Dr. Block on December 5th, and the American Academy of Pediatrics made a proposal about a new burden of proof which I thought was very promising, and I think Dr. Block will agree with that, that I think this is something where progress can be made.

You have to understand, this compensation program is the model that is being used for distribution of funds, the September 11 funds. This is the program that is being used. I don't think it's going to be run the same way for that. I hope the lawyers up in the Eastern District of New York who are running this program

and the Special Master that's been assigned to this is going to run it a little differently, but I'll be anxious to see what happens with that program.

The third thing that I'm not even going to argue about, because nobody wants to hear a lawyer complain about fees. Nobody wants to hear it. I've written what I think about interim fees and costs. I don't care what you do with fees. You know, you can deal with my wife. She'll come up here and talk to you about fees. But cost, give us the cost to prosecute the cases.

The chairman referred to thimerosal. The Institute of Medicine in Cambridge had a meeting, and they came back and said it's biologically plausible that thimerosal in these vaccines—and the amount was tremendous the kids were getting—has caused neurodevelopmental disorders in some of these children. So it's biologically plausible. And they've recommended studies. Do you know how long it's going take to do those studies—2 to 5 years at a minimum.

So don't put pressure on the Special Masters to rush me through the program. Don't focus on how long it takes to get through the program. Focus on the reasons why it takes time to get through the program. The reasons why these cases don't get through the program faster is because of the burden of proof, because we don't have interim fees and costs so we can prosecute the cases.

If you want to make the system move smoothly, do those two things. If you want it to be fair to all people, pass that statute of limitations. Put it in there. It's got to be done.

I would also like to say—I think it was Mr. Horn mentioned Tommy Sansone. Tommy Sansone's father is a New York City policeman. He has a private bill that's been on this Hill for some time. I would ask you to pass it. We represented the Sansone family. We've brought them up here. We've come to the Hill with him. When Moynihan was here, we were in his office. The Sansone bill needs to be passed. It's a private bill.

I had a call today, this morning before I came here, from a lady down in the western part—I didn't even know we bordered Tennessee, but she's down close to Tennessee. And she said that she and six of her friends, nurses in a hospital, 6 years ago received hepatitis B vaccinations, all the same lot and everything else. There were seven of them. All seven of them developed MS-like disease. One of them recently died.

Now, I intend to investigate that. If I have to find Erin Brockovich and make her work for free, we're going to investigate that and find out what happened out there.

But there is a case where I have to say to her, "ma'am, I can't bring your case in this program. Because in August 1997, hepatitis B vaccine was added to the program, and your case could have been filed, but it had to be filed before August 1999. Sorry. It's too late."

I answer these questions every day.

Thank you.

Mr. BURTON [presiding]. We are working on some legislation to try and correct some of those things right now. And regarding that private bill, I'll have to know more about that. They're very difficult to get passed, but we'll take a look at that.

[The prepared statement of Mr. Shoemaker follows:]

CONGRESSIONAL TESTIMONY
of
CLIFFORD J. SHOEMAKER[1]

Mr. Chairman, Mr. Waxman, Committee members. Thank you for the invitation to speak with you again about the National Vaccine Injury Compensation Program. Since I spoke to you in September of 1999, the problems I described have not gone away – if anything, they have gotten worse.[2] I am saddened by the fact that Congress has done very little to address these problems. I would, however, like to offer special thanks to Dr. Weldon and Congressman Nadler, who have co-sponsored HR 1287, and I would like to thank all who have signed on as co-sponsors for that legislation. While that bill does not address all of the problems that I perceive in this program, it does address three very important issues. I would like to briefly address those three areas at this time, and I will take them in the order of importance as I see it.

The Statute of Limitations

As I am sure all of you know (especially those of you who are lawyers), all 50 states suspend (or "toll") the statutes of limitations in favor of children and in favor of those with mental disabilities. (*See* 51 Am. Jur. 2d Limitations of Actions, section 178, 747). Ironically, the Vaccine Program's statute of limitations (whether the present three years or the six years proposed by HHS and the DOJ) has no such tolling provision. This will remain a glaring inequity, even if the statute is extended to six years. It is inconceivable that the vaccine

[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.
[2] Since the problems are still the same, my prior testimony is attached hereto and incorporated herein by reference. I will keep resubmitting this testimony until something actually does change.

manufacturers, the Secretary of HHS, or Congress would object to such a uniformly accepted principle of law.

Think about it! If your two-year old child is injured in an automobile accident because of some other driver's negligence, you have over 16 years to file a lawsuit. If that same child is injured by a vaccination, a claim must be brought in three years, even if the parents are unaware of the program, and even if the parents have no idea that the vaccine is the cause of the injury until it is too late. That is inexcusable. Minor children are being penalized for the failure of their parents to file a timely claim. There can be no purpose for this inequity, other than to deny compensation to otherwise deserving children.

Apparently, the HHS and DOJ have opposed a minority tolling provision for a number of reasons. They have argued that the program was designed to provide prompt, expeditious recoveries. By that logic, just shorten the statute of limitations to two years or one year and deny even more people the right to recover. That should streamline the process even more. They have also argued that the longer after an injury that a claim is filed, the more likely it is that it will be hard to get records and present the necessary proof. If that is true, the delay hurts the child's case, not the respondent. Another argument is that the people who run the program cannot accurately predict how many more claims will be filed as the result of changing the statute of limitations. So what? Is the point of this program to take care of vaccine-injured children, or is it to generate nice statistics and pretty charts? Don't forget that any argument offered by DOJ and HHS against a minority tolling provision ignores the fact that every state has such a provision, and every state has successfully dealt with these criticisms. We are not asking for any special privileges; just give these children the same rights as are afforded in every state in the union.

Let me tell you a story about Mikey Zezulak. Mikey lives in Western Springs, Illinois. Mikey was born on December 8, 1994. He was delivered by natural childbirth and breast fed for

the first four months of his life. On June 22, 1995, Mikey started to crawl. His baptism was July 11, 1995, and everyone remembers that he was alert and had wonderful eye contact with everyone who approached him. He was "cooing and ahhing." By July 30, 1995, he started imitating mouth gestures like when you make fish lips. By September 10, 1995, Mikey was repeating words, like "bye-bye" after an adult would say it, and he was also saying Mama and Dada. He had also started walking by then. October 3, 1995 was Mikey's grandma's birthday, and there was a party. While everyone was singing "Happy Birthday" Mikey went to sit on his sister's lap, and he clapped while everyone sang. On October 31, 1995, Mikey's first Halloween, Mikey walked along behind his older sister, imitating her actions at each stop. On June 2, 1995, Mikey received a DPT vaccination at the office of his pediatrician at about 9:15 a.m. On June 3 at about 3:00 a.m. Mikey experienced his first seizure. After a short period of time, Mikey seemed to return to normal. By November 25, 1995, Mikey was walking very well. He would play ball with his sister in a game where they took turns rolling the ball. He also enjoyed playing peek-a-boo for long periods of time. December 8,1995 was Mikey's 1st birthday, and he was very excited to see all the relatives together. He would imitate what others were doing with toys and stacking blocks. He was also very happy when 25 people stood around him to sing "Happy Birthday", and he even clapped for himself. He also ate most of his cake with a spoon and drank milk from a cup on his own. He was interested in his toys and was playing with the little tyke people putting them in the school bus and fastening them where they belonged. By December 16, 1995, Mikey was asking for his drink, and he would say things like, "Mama cup wawa." Mikey was given his first MMR vaccination on December 22, 1995. The next day he experienced fever (measured at 102.7) most of the day and night. For two days he had a swollen leg and kept screaming with this high-pitched scream. On December 25, 1995 (Christmas Day), Mikey was still very fussy. He did not want to eat or be held by anyone, and it was hard to get him to sleep. His family noticed that he was no longer repeating words or saying words spontaneously. This behavior continued. Mikey also started walking funny and staring into space a lot with minimal eye contact. Relatives asked if he was feeling well because he did not seem like his normal self. He was still not repeating words or saying them on his own, behavior that began right after the MMR shot. Mikey became more and more distant, doing abnormal things with his head. His language was still not returning. This behavior continued, and at Easter 1996 Mikey was not interested in anybody or any toys. He just fell asleep with a heavy cushion in a corner away from everybody. On April 11, 1996, on a trip to Disney Land, Mikey was in his own world, not interested in the environment around him. Also, he seemed overly sensitive to loud noises. By his second birthday, Mikey still had minimal eye contact, but his attention span was great for musical toys. He still had no speech. During his 2nd birthday party he did not like the amount of people in the house and wanted to be in a room by himself. He did not show any sign of interest in his presents, when people sang Happy Birthday, he threw a fit, would not sit and ran off. The beginning of 1997 was more of Mikey being in his own world - watching stuff spin, wanting to be alone all the time, understanding some commands, and making eye contact only while being tickled. On July 16, 1997, Mikey received his 2nd MMR shot, which was given to him by mistake because the first pediatrician's office forgot to write about his prior reaction on his record. On July 17, 1997, Mikey had a fever and was very fussy again. From that time on, he seemed to regress even more. By the end of July, his baby-sitter was reporting that Mikey was not sitting at the table for lunch any more. He was also not responding to his name at all. The baby sitter had to basically lead him around by the hand all day. Mikey also started having fits for no apparent reason. Today, Mikey is still in his own

world – the world of autism. EEG tests have shown that he is having seizure activity.

Why, you ask, am I telling you about Mikey? Well, Mikey's parents did not find out about this program until the summer of 1999. That was when they first learned that vaccinations might have played some role in Mikey's condition. That is when they contacted our office. We filed a claim right away, and at first we thought we were dealing with hepatitis B vaccinations. When the records showed that we were really dealing with MMR vaccines, we were still optimistic, because we assumed Congress would soon change the statute of limitations to six years. After all, back then, even HHS was proposing a six-year statute of limitations. We also thought we might be able to show that the second MMR vaccination, given in 1997, significantly aggravated Mikey's condition. When pressured, we asked the Special Master to allow the claim to be stayed in order to give Congress time to act, but we were not allowed such a suspension of proceedings. We were forced to dismiss the claim without prejudice to re-file the claim if Congress does change the statute of limitations. On December 22 of this year, it will be six years since Mikey reacted to his first MMR vaccination. I intend to re-file Mikey's claim before that date, but if you do not act quickly, Mikey may again be forced out of the program. Every day that you fail to act, some child is losing the right to file a claim.

Specifically, I would propose that the following language be added to the statute as section 300aa-16(a)(4):

> "In the case of (4) any vaccine on the Vaccine Injury Table, regardless of when administered, and irrespective of sections (1), (2), and (3) above, the statute of limitations will be suspended in favor of persons with mental disability or persons who lack the capacity to file a petition, until six (6) years after such mental disability has been removed or such capacity to file a petition has been legally attained. In the case of a child, it shall be presumed that he or she shall attain the legal capacity to file a petition on his or her 18th birthday."

If Congress will not pass HR 1287, and if you do nothing else, please add this language to the statute.

The Burden of Proof

Since the table of injuries has been decimated by the Secretary, it is important to reduce the burden of proof for these claimants. I have numerous clients who have won workers compensation claims, but who, in my opinion, will not be able to meet the burden of proof under this program. I would encourage you to add language, such as that contained in HR 1287, that will make it clear that this is a remedial compensation program and not a waiver of sovereign immunity. These are not suits against the government. The Department of Health and Human Services is not a defendant, and we are not representing plaintiffs. Our clients are petitioners or claimants, and HHS is the respondent.

On December 5, 2001, I attended a meeting of the ACCV. I was very encouraged to hear the presentation made by the American Academy of Pediatrics. While I have some concerns about a few of the specific proposals, overall it was a positive approach to the problems that we face. I would welcome the opportunity to work with Congress to further develop this proposal.

Another alternative for you to consider would be to legislate the language used by the Chief Special Master in a case called *Stephens v. HHS*. Below is a description of that decision, and I would encourage you to work with the Chief Special Master to develop legislation using this case as the basis for a burden of proof in this program.

Prong One: Proof of medical plausibility

- Met by showing that "it is medically plausible for the vaccine received to cause the injury alleged."
- "This is done by proffering a theory of biologic mechanism by which a *component* of the vaccine can cause the type of injury suffered."
- "This is not a rigorous burden."
- This is typically provided by some expert report
- You are not responsible for showing that literature associates the vaccine itself with the injury. That is left to Prong Two. All that is needed here is a theory.

Prong Two: Proof of confirmation of medical plausibility from the medical community and literature.

- "Here, petitioner must establish that peer-reviewed literature reports that the vaccine is related in some sense to the injury alleged."
- "The court is concerned with the *fact* that a relationship is reported, rather than how that relationship is defined or by what criteria."
- "This is not a demanding burden."
- Proof here can include "epidemiological studies, animal studies, case series, case reports, anecdotal reports, journal articles, manufacturing disclosures, Physician Desk Reference citations, and institutional findings, like those reported by the Institute of Medicine."
- "The court would be hard-pressed to find causation in an individual case if the medical community is not even witnessing or contemplating a causal relationship."
- "Petitioner's successful satisfaction of these two prongs also complies with *Daubert* which seeks to ensure that petitioner presents a medical theory based on medically or scientifically valid concepts, and ones preferably rooted in published or peer-reviewed literature."

Prong Three: Proof of an injury recognized by the medical plausibility evidence and literature.

- The case scenario at hand must conform to the medical evidence presented in Prongs One and Two.
- This evidence typically comes from the medical records.

Prong Four: Proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury.

- The relationship must be *medically acceptable* rather than just *temporally* acceptable. (i.e., it must make good medical sense).
- "The medically acceptable time frame is defined through peer-reviewed literature, most likely submitted to establish Prong Two."
- "In practice, this prong has proven easily satisfied as the experts are cognizant of and routinely testify to medically accepted time frames for the onset of injuries."

Prong Five: Proof of the elimination of other causes.

- Must show that "there is no reasonable evidence that an alternate etiology is the more probable cause of the alleged injury."
- "Petitioners may successfully support this prong with evidence from a treating physician indicating that alternate causes were considered and eliminated as the more likely causative agent; this evidence may include oral testimony, written reports, and/or contemporaneous medical records showing the completion

of a differential diagnosis. Reasonable efforts to rule out known alternate causes is sufficient to meet the preponderance standard."

- Only a showing of *reasonable* efforts to rule out *known* causes is necessary.
- "[P]hysicians may eliminate a sub clinical infection through laboratory testing. However, a spontaneous or asymptomatic infection or illness which cannot be tested through laboratory or other means is necessarily speculative, and the court refuses to require that petitioners eliminate speculative alternate causes."

- **All of the prongs must be met to prove causation.**[3]

INTERIM FEES AND COSTS

I am not going to say much about interim fees, because no one seems interested in listening to lawyers complain about inadequate pay. If you decide to do anything in this regard, my wife, who has borne the brunt of our sacrifices for far too long, would appreciate it. If you think this program is a great deal for lawyers, maybe you should ask why there are so few of us willing to handle these claims. Either we are dedicated to these people or we are just plain stupid, or both. Actually, you could do something very quickly by simply providing that we be paid interest on our fees and expenses. I can assure you I have to pay interest on the money I have to borrow to finance these cases.

Interim costs are actually more important, because we need to be able to pay for medical records and for experts to render opinions in these claims. It's a little difficult to get experts to testify against the government in the first place, and not being able to pay them in a timely manner doesn't help.

At the ACCV meeting I referred to a moment ago, a proposal was discussed that would pay interim fees after entitlement is determined. I would hope that you could provide for interim costs earlier than that in the process. Right now, the only claims that I can move forward are the

[3] J. Bradley Horn of Shoemaker & Horn prepared this outstanding analysis of a very long decision.

ones where the clients can afford to advance the costs. That means that the people who need the help the most are not getting it because I can't afford to hire experts for them.

Delay is not the problem; Deal with the reasons for delay

Let me set the record straight. You can continue to focus on delays and all the horror stories about people whose claims took years to resolve, but unless you deal with the reasons for the delays, you are only hurting other claimants. The delays in this program are not caused by the Special Masters, and if you continue to put pressure on them to rush cases to judgment, the only result will be more people who lose in this program. Most of the delays in this program are the result of petitioners' attorneys not being able to pay for experts, or petitioners' attorneys who need time for the medical literature and scientific understanding to advance far enough so that they can hope to prevail under the program.

Let me give you an example. At the recent IOM meeting in Cambridge, Massachusetts, the committee concluded that the hypothesis that thimerosal–containing vaccines could be associated with neurodevelopmental disorders is biologically plausible. Further studies were recommended, and many are now underway. Most of these studies will take two to five years to complete. Don't keep putting pressure on the Special Masters to litigate these claims faster. When you do that, it is the Petitioners who will suffer. Change the statute of limitations; change the burden of proof; give us interim fees and costs. These changes will make the system work more smoothly. Otherwise, you are simply pushing lemmings over the cliff.

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 vaccines are safe SHOULD BE ASHAMED OF THEMSELVES. Those people who point to the victims who are awarded compensation and use

this as evidence vaccines are dangerous SHOULD LIKEWISE BE ASHAMED OF THEMSELVES.

I would like to conclude with a quote by Dr. Leroy B Walters at a "Symposium on Public Concerns of Immunization" held at Georgetown University on October 25-26, 1978:

> *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.'*

The National Vaccine Injury Compensation Program was supposed to solve this problem, but a lack of Congressional oversight has resulted in the program falling short of its goals. For far too many people, the program is an empty promise. In the two years since I testified about these problems, nothing has changed. I sincerely hope and pray that this situation will not be allowed to continue.

CONGRESSIONAL TESTIMONY
of
CLIFFORD J. SHOEMAKER[4]

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.

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.[5] 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.

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[4]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.

[5] 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.

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.[6] 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.[7]

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*

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[6]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.

[7]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.)

> *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.[8]

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[9] 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.

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[8]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.

[9]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.[10] Practically speaking, the Table of Injuries, which, in my opinion and the opinion of others, should have been expanded[11], 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

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[10]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."

[11]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 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.

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.[12]

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.

[12]"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.[13] 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 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

[13]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.

> 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.[14] I would

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[14] **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*

encourage you to read my footnote at this point which describes numerous situations that I have experienced and which are simply wrong. This footnote also discusses my specific proposals for change.[15]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

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> 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)

[15]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:

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.[16]

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 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[17];

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

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[16]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.

[17]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.

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;

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!

Mr. BURTON. Dr. Block.

Dr. BLOCK. Good afternoon, Mr. Chairman and members of the committee. I am delighted to have been invited here to discuss my observations as Chair of the Advisory Commission on Childhood Vaccines, on the National Vaccine Injury Compensation Program, and to offer observations regarding the effectiveness of the program. I would like to thank Chairman Burton and also Mr. Waxman for their continuing interest in the program and the health and welfare of our children.

As a pediatrician, I provide care for patients and their families; and as the Chair of an academic department, I teach pediatrics to young physicians in training. I have personal vivid memories of watching children severely disabled or dying of diseases that are now preventable by vaccines. It is doubly difficult for me to watch today as a child suffers from one of those diseases, knowing that such suffering could have most likely been avoided.

I appreciated your comments, Chairman Burton, when you said vaccines are important parts of our public health system and we want children to be protected against infectious diseases.

Some will make the argument that vaccines exact a toll on children and, in rare instances, they do. Medicine cannot always be an exact science. There are no guarantees in medicine, just as there are no guarantees in life.

Mr. Chairman, you also said in your opening remarks at the previous hearing that although the oral polio vaccine was a good public health tool in its time, it wasn't perfect. If perfection is to be our goal, no government program, no vaccine, no part of medical science will ever achieve that goal.

I have no doubt that the establishment of the National Vaccine Injury Compensation Program was one of—if not the—major reason that we generally have an adequate supply of vaccines today. There is no doubt in my mind that the program works well, but with some adversity or differences of opinion, especially in the non-table injury cases. However, I have been continually impressed over the last 3 years with the efforts of HHS and DOJ to decrease the adversarial process. I have seen a continuing effort to achieve that goal.

At the last ACCV meeting, we had the opportunity to discuss two very pertinent topics related to this committee's concern that the program was too adversarial. The first was a proposal from the American Academy of Pediatrics on an alternative standard for adjudication of claims for non-table injuries. The second was a presentation by members of your staff on legislation that is currently being drafted. We were pleased to see that most of the recommendations that the ACCV made in 1999 were included in the draft legislation. As former Chair of the ACCV, I hope that in the future the Commission can be a point of focus for discussions on vaccine-related issues, allowing the ACCV to collect the best information from which to advise the secretary.

As a pediatrician, I envision the time when this program is not needed to the extent it is today. Because we might all agree, based on reliable data, that we have vaccines that have extremely rare adverse events and because we have a national health care system

that provides adequate care for all of our disabled children, regardless of the cause of their disability.

Speaking for myself, or having been spoken for, I think it is sad that a child allegedly injured by a vaccine can turn to this program for compensation, but a child injured by a vaccine-preventable disease may have little or no access to appropriate care and no source for financial resources to support that care.

I have listened with concern to the stories told here today by parents who I don't believe represent the majority of parents who have dealt with the program but who have perceptions of their experiences we should not ignore.

I watched video clips presented by your staff of similar parent presentations at the ACCV meeting last week. I find it difficult to respond to perceptions, when the actual facts of a case are not presented by both parties. But based on 3 years of experience with the ACCV, I do feel these cases, while compelling, are isolated, unusual and emotional representations of a definite minority of cases coming through the program. Based on my personal conversations with and reports presented to the ACCV by past and current parent members of the Commission and presentations by petitioners' attorneys and on data reviewed at each meeting by the ACCV, I believe the program works quickly and generously in most cases.

I know that I speak not only for myself but also for the next Chair of the ACCV when I say that we welcome the opportunity to continue working with the public, with professional organizations and with Members of Congress to continuously improve the National Vaccine Injury Compensation Program and to ensure a safe future for our children.

It is difficult, Mr. Chairman, to listen to accounts from parents whose lives and whose children's lives have been affected the way these parents today have had to experience and some of the parents that you listened to before. You share now a common experience with my everyday life, but the children that I hear about and care for are not vaccine injury children but are children with disabilities and other illnesses that have nothing to do with the purpose of today's hearing.

I would go back to my statement that I am concerned that we have a program, maybe perhaps needing improvement, to help these families and would hope that some day we won't have to argue about these things because their needs would be covered by the same program that would cover all the children in this country.

I want to thank you for the opportunity to express my views on the importance of the program and the ACCV and the critical roll they will continue to play in preserving the health of our children. More dialog with the ACCV will only benefit us all.

I'll be happy to answer questions later.

[The prepared statement of Dr. Block follows:]

STATEMENT

OF

DR. ROBERT BLOCK, M.D.

CHAIRMAN

ADVISORY COMMISSION ON CHILDHOOD VACCINES

BEFORE

THE COMMITTEE ON GOVERNMENT REFORM

December 12, 2001

Good afternoon, Mr. Chairman and members of the Committee. I am delighted to have been invited here to discuss my observations, as Chair of the Advisory Commission on Childhood Vaccines (ACCV), on the National Vaccine Injury Compensation Program (the Program); and to offer observations regarding the effectiveness of the program. I would like to thank Chairman Burton and Rep. Waxman for their continuing interest in the Program, and the health and welfare of our children.

As a Pediatrician, I provide care for patients and their families; and as the Chair of an academic Department, I teach Pediatrics to young physicians in training. I have vivid memories of watching children severely disabled or dying of diseases that are now preventable by vaccines. It is doubly difficult for me to watch today as a child suffers from one of these diseases, knowing that such suffering could have most likely been avoided. I appreciated your comments, Chairman Burton, when you said, "Vaccines are an important part of our public health system," and, "We want children to be protected against infectious diseases." Some will make the argument that vaccines exact a toll on children, and, in rare instances, they do. Medicine cannot always be an exact science. There are no guarantees in medicine just as there are no guarantees in life. Mr. Chairman, you also said, in your opening remarks at the previous hearing, that although the oral polio vaccine, "...was a good public health tool in its time, ...it wasn't perfect." If perfection is to be our goal, no program, no vaccine, no part of medical science will ever meet that goal.

I have no doubt that the establishment of the National Vaccine Injury

Compensation Program was one of – if not the – major reason that we have a generally adequate supply of vaccines today. There is no doubt in my mind that the Program works well, but with some adversity, or differences of opinion, especially in the non-Table injury cases. However, I have been continually impressed over the last three years with the efforts of HHS and DOJ to decrease the adversarial process. I have seen a continuing effort to achieve that goal. At the last ACCV meeting, we had the opportunity to discuss two very pertinent topics related to this committee's concern that the Program was too adversarial. The first was a proposal from the American Academy of Pediatrics (AAP) on an alternative standard for adjudication of claims for non-Table injuries. The second was a presentation by members of your staff on legislation that is currently being drafted. We were pleased to see that most of the recommendations that the ACCV made in 1999 were included in the draft legislation. As Chair of the ACCV, I hope that in the future, the Commission can be a point of focus for discussions on vaccine-related issues, allowing the ACCV to collect the best information from which to advise the Secretary.

As a pediatrician, I envision the time when this Program is not needed to the extent it is today – because we all agree, based on reliable data, that we have vaccines that have extremely rare adverse effects, and because we have a national health care system that provides adequate care for all of our disabled children, regardless of the cause of the disability. Speaking for myself, I think it is sad that a child allegedly injured by a vaccine can turn to the Program for compensation, but a child injured by a vaccine preventable disease may have little or no access to appropriate care, and no source for financial resources to support that care.

I have listened with concern to the stories told here today by parents, who do not represent the majority of parents who have dealt with the program, but who have perceptions of their experiences we should not ignore. I watched video clips presented by your staff of similar parent presentations at the ACCV meeting last week. I find it difficult to respond to perceptions, when the actual facts of a case are not presented by both parties. Based on three years of experience with the ACCV, I do feel these cases, while compelling, are isolated, unusual, and emotional representations of a definite minority of cases coming through the Program. Based on personal conversations with, and reports presented to the ACCV by past and current parent members of the Commission; and presentations by petitioner's attorneys; and on data reviewed at each meeting by the ACCV, I believe the Program works quickly and generously in most cases.

I know that I speak not only for myself but also for the next Chair of the ACCV when I say that we welcome the opportunity to continue working with the public, with professional organizations, and with members of Congress to continuously improve the National Vaccine Injury Compensation Program and to ensure a safe future for our children.

Thank you for the opportunity to express my views on the importance of the Program and the ACCV and the critical role they will continue to play in preserving the health of our children.

I would be pleased to answer any questions that you have.

Mr. BURTON. Let me start off the question period by making a comment.

I was never really too concerned about breast cancer until my wife became a victim, and she's very ill right now. And then you start looking into it, and you start realizing that things that could be done or should be done or haven't been done.

My granddaughter received a hepatitis B shot, and within 3 hours she quit breathing. She was rushed to the hospital, and my daughter gave her mouth-to-mouth resuscitation and, thank God, she survived. Now there are those who say that had nothing to do with the hepatitis B shot, but the people at the hospital truly believed it. It was a problem.

My grandson—and I only have two grandchildren. My grandson, he received nine shots in 1 day, and we found out that the thimerosal that was in those shots included mercury, and within a very short time he became autistic, running around himself, banging his head against the wall, cupping his hand, screaming and hollering incessantly, and before that he was normal.

Now, you know, there will be people who say those are just coincidences, but it happened to me personally, my granddaughter and my grandson.

We used to have 1 out of every 10,000 children—and they could have been off in the statistics on that, it may have been 1 in 9,000—but they estimated 1 in 10,000 children were autistic. But now it's fact—fact that 1 in 500 nationwide are autistic, and in some parts of the country—it approaches 1 in 200 in the Northwest of this country. We've got data to prove that.

Now when I listen to pediatricians and doctors who say, you know, we're doing everything that can be done and there's no indication that the vaccines are causing this. Then what is causing it? My grandson got about 50 times what the normal amount of mercury that a child would have or an adult would have in 1 day in nine shots, and he became autistic almost immediately. And yet, you know, the people at CDC and FDA and HHS all say, you know, there is nothing that can prove that. We can't prove that. But I can tell you, 1 in 500 kids nationally are autistic. You know, that is pretty bad when it used to be 1 in 10,000. That is a pretty big increase, 20 times increase.

So, you know, we have some real problems with that. And as I said before, I would say most doctors don't know thimerosal contains mercury, because the Capitol Hill physician, who is one of the finest men and nicest doctors I know, Admiral Issold over there, when I said, do you know that these vaccines have mercury in them? He says, no, they don't.

And I said, look at this; and I got the insert out and showed him thimerosal. And thimerosal contains mercury as a preservative because they don't want to have single-shot vials. They put 10 shots in one vial. And the Members of Congress that are getting these shots don't even know it.

And yet Canadians and scientists from around the world say and they showed us—we had a video here showing that the sleeve that surrounds the nerves in the brain are destroyed by the mercury immediately upon a very minute amount of mercury upon contact, and there are scientists all over the place that are saying that Alz-

heimer's and autism and other neurological disorders are being caused by the mercury and other substances that are in vaccines and that are in the environment.

So, you know, we really need to take a close look at this. I'm not denigrating what you said. I'm just telling you that we need more research, No. 1.

No. 2, there needs to be a more humanistic or humane attitude toward these people who are suffering like this. These people are really suffering. She lost her son, she went through all of this stuff, and yet when you get the CDC and the FDA and the Justice Department and they come up here, you know, I don't know how they defend this stuff.

Now, let me ask you a few questions, because we've got some votes coming up here. After 8 years of fighting to get compensation, the Special Master ruled in your favor, Mrs. Barton, in 1999. At that point did the Justice Department ask that your lawyers agree not to—wanted you to agree not to have that published? That's what you said in your testimony.

Mrs. BARTON. Yes.

Mr. BURTON. Why do you think they did that?

Mrs. BARTON. They didn't want the case to be cited in any other cases, in any other people coming up——

Mr. BURTON. So they didn't want somebody with similar problems——

Mrs. BARTON. Right.

Mr. BURTON [continuing]. Being able to use that case as a basis for a claim?

Mrs. BARTON. Exactly.

Mr. BURTON. So they were blackjacking you?

Mrs. BARTON. Well, I called it extortion.

Mr. BURTON. Well, either way, blackjack, blackmail, extortion, it all amounts to the same thing.

Mrs. BARTON. Yes.

Mr. BURTON. Mr. Shoemaker, you're an attorney who represents lots of families in this program. What is the practical effect of a decision that goes against the government not being published?

Mr. SHOEMAKER. Any unpublished decision cannot be used as precedent.

Mr. BURTON. So if you didn't agree to this condition, Mrs. Barton, and you insisted that the decision be published, the Justice Department would have said what?

Mrs. BARTON. Well, it was put to me through my attorney, Mr. Milmoe. The Justice Department attorney said that if I didn't agree to it being unpublished, that he would file another appeal.

Mr. BURTON. And drag it out?

Mrs. BARTON. And drag it out.

Mr. BURTON. And you were very sick at that point?

Mrs. BARTON. And he knew that.

Mr. BURTON. I see my time is expired.

Do you gentlemen have questions at this time? Judge.

Mr. DUNCAN. Yes.

Mr. BURTON. I'll have more questions later, and let me just say, Judge, before you start, we have about 11 minutes on the clock,

and we'll go to 5 minutes, so we'll give you your time, and then we'll move.

Mr. DUNCAN. OK. Thank you. Thank you, Mr. Chairman.

Mr. Shoemaker, you heard Dr. Block say that it's his experience that this program has been very quick and generous. Has it been your experience that the program has operated very quickly? We have a staff memo here that says the program was intended to be less adversarial than civil litigation and was intended by Congress to compensate quickly, easily and with certainty and generosity, and yet all of these cases that I hear about, they seem to take several years. What is the average length of time and what has been your experience in all of these cases you've handled?

Mr. SHOEMAKER. Let me repeat what I said. I don't think that the problem is a problem of delay. I think the problem is the reasons for the delay. In other words, if I am given the resources, if I am given interim fees and costs so I can finance these cases, so I can pay for things expeditiously, so I can hire the experts I need, I can move these cases through the system much more quickly.

I tell all of my clients—for instance, hepatitis B clients, I tell them, look, here's the situation. If you want to go to a hearing right away, I'll take it to a hearing right away. But in my opinion, as the state of science is today, we have a good chance of losing.

There are two things that have to come together for me to win a case. The science, the medical knowledge has to go up and reach a level where I have enough proof, and I'm trying to get Congress to reduce the burden of proof so that those two lines will cross sooner rather than later.

Mr. DUNCAN. Let me ask you this. I was a plaintiff's trial lawyer and a judge before I came to Congress, and you know and I know that there are certain—there are some members of the profession out there who might take advantage of that if we had some sort of unlimited expense program. So have you come up with or could you come up with some type of recommendation on some type of expense-type program that you think would have some reasonable limitations on it? Or have you thought about that?

Mr. SHOEMAKER. Yes, sir. As a matter of fact——

Mr. DUNCAN. What have been your average expenses on one of these cases?

Mr. SHOEMAKER. Expenses can vary, but they can certainly approach $5,000 to $10,000, and I'm not even doing the cases right. I mean, you've been a trial lawyer. You know how much a case can cost.

Mr. DUNCAN. I know about that.

Mr. SHOEMAKER. I know how much money I would like to spend on a case.

Mr. DUNCAN. Have you made a recommendation?

Mr. SHOEMAKER. I was just going to say Congressman Weldon had introduced a bill, H.R. 1287, which I think does address that issue, and I would encourage anybody to support H.R. 1287 because it does all three things I talked about.

Mr. DUNCAN. How do we strike the balance between, you know, what everybody says has been a very effective program and we don't want to scare people away from having their children vaccinated yet still educate the public? Because, as I said in my state-

ment a while ago, it's a very sad thing that people take their children in for something that they think is good for them and then these things happen. And I think probably all three of these parents would tell you they had no idea. Did any of you have any idea that there would be adverse reactions when you took your children in?

Mrs. BARTON. Not at all. After the fact, I've done a lot of research on vaccine reactions, and there are some kids that are high risk for adverse reactions, and I think that certain—you know, that doctors definitely need to be aware of that especially.

What scares me is when they do these big, you know, come to the mall and we'll vaccinate, you know, 200 children for free, and the doctors don't know these kids at all and don't know their medical histories.

Mr. DUNCAN. Should we require that pediatricians give out understandable pamphlets after these shots are given, telling parents that if they see any of these symptoms that something should be done? Or what is being done?

Mr. SHOEMAKER. Your Honor, that actually already is required. Dr. Block and I were talking about that earlier, that under the statute there is a provision that says that there's supposed to be forms developed that are supposed to be given to all the parents when their children are vaccinated. The form is supposed to advise as to the risks, the benefits and so forth. It's all supposed to say in there that there is this compensation program so that people would be made aware of the program. That's by statute. That's already in the program.

Mr. DUNCAN. Is that a fairly new thing? Were all three of you given that information?

Mr. HOLDER. Back when Brandon got his shot, all we got was that he might have a febrile seizure and he might be uncomfortable, to give him some Tylenol. I believe that things have changed, from what I understand, to what Mr. Shoemaker is saying.

Mr. SHOEMAKER. Actually, it has been there since the beginning of this program, but the problem is there's no penalty for it. For failure to comply, there's nothing that says if a doctor doesn't do it, so what?

And a lot of—as Dr. Block and I were talking about, a lot of doctors, you're dealing with a short period of time that you're dealing with a parent. You don't have a lot to do as a pediatrician. You know, if you go overboard on this thing, the fear is you're going to frighten parents. I mean, there are a lot of issues involved in this, as you know.

But it is statutory right now. There is no penalty for failing to do it, but there is a statutory provision that says the Secretary is to develop these forms, and they are supposed to be handed out to the parents at the time, and I think they are even supposed to be signed. I'm not sure if the signature is required.

Mrs. BARTON. Can I make one comment——

Mr. DUNCAN. Yes.

Mrs. BARTON [continuing]. To Dr. Block? You stated that there are kids out there with all these other diseases that, you know, that hopefully we'll be able to help pay for children with all diseases. This was something that was mandatory. This was some-

thing that we were forced to give our children. It's not like it was just a random luck or luck of the draw or a terrible tragedy that my child got this disease. Our children were forced to get these vaccines. So it's a little bit different than just a disease that would come about randomly. I believe it is, anyway.

Mr. DUNCAN. Well, my time is up, and we've got to go vote, but I want to thank all of you for being here and this testimony you've given today.

Mr. WELDON [presiding]. The Chair will now recess this hearing for approximately 10 minutes to give the members time to go vote and return.

[Recess.]

Mr. BURTON [presiding]. The committee will reconvene and come to order. I want to apologize for the duration.

Would the previous panel come back up—Mrs. Barton, Mrs. Dyer, Mr. Holder, Mr. Shoemaker, and Dr. Block.

Let's get back to our questioning. Mr. Shoemaker, you've been a counselor for a long time on these kinds of problems. On Mrs. Barton's case, if they had appealed it and had not settled with her, based upon her not publishing the results, how much longer would that compensation have been delayed?

Mr. SHOEMAKER. It could have been years. I mean, an appeal typically goes to the U.S. Court of Federal Claims, to a judge first, and then from there it would go on to the U.S. Court of Appeals for the Federal Circuit; so it could take a considerable period of time.

Mr. BURTON. So you think this was kind of a blackjack tactic that they used?

Mr. SHOEMAKER. Well, I actually agree with Mr. Waxman in his comments, because he was saying the same thing that you're saying, that is, that we shouldn't have any unpublished decisions. It kind of reminds me of the Firestone tire situation, where for years plaintiffs' attorneys were settling those cases under seal so that they couldn't release——

Mr. BURTON. People were getting killed, yes.

Mr. SHOEMAKER. That's exactly right. And I don't think we're dealing with the same thing here, but it's important for lawyers, like me, working in the program to have these precedents when they are favorable.

I think also there's a digest of opinions that's used by the claims court that needs to be published on the Web site so that lawyers can easily research this area. There are a lot of lawyers out there around the country that maybe have one or two cases in the program. They can't possibly know what we know, representing hundreds of cases, and they need access to some research so they know what the law is.

Mr. BURTON. It's obvious why the Health and Justice Departments didn't want that published, because of that very reason.

We received a letter last night from the Justice Department saying that in the Barton case it was in both parties' interest to have the case unpublished in lieu of appeal.

What do you think about that argument?

Mr. SHOEMAKER. You'd have to ask Ms. Barton.

Mr. BURTON. What do you think about that, Ms. Barton?

Ms. BARTON. Could you say that one more time?

Mr. BURTON. We received a letter last night from the Justice Department saying that, in your case, it was in both parties' interest, yours and the Government's, to have the case unpublished in lieu of appeal.

What do you think about that?

Ms. BARTON. No. The only reason I agreed was just for the fact that——

Mr. BURTON. They pressured you?

Ms. BARTON [continuing]. That I needed to get it over with. I felt like I couldn't go through any more appeals.

I mean, had we gone through more appeals, I'm sure that we would have won. It would have kept coming back in our favor. But I just didn't feel like I could keep going through it.

So maybe they're saying it was in both parties' interest because of my illness, because I was sick. They're saying it was that it was in my best interest to not publish it because—but still it goes back to their saying that they would appeal if I didn't.

Mr. BURTON. You don't agree?

Ms. BARTON. I don't agree, no.

Mr. BURTON. Mr. Shoemaker, has the Government ever employed this tactic with any of your other clients?

Mr. SHOEMAKER. I can't think of that specific tactic. I had a situation one time where an attorney tried to tie my fees to a settlement, and I immediately expressed indignation; and when I did that, the attorney realized right away that it was inappropriate and, in fairness, backed off and said, no, that wasn't right.

You have to understand that's not issue today too and this program—if I were only interested in making fees and making a living, I would rush these cases through the program. I wouldn't care if I won or lost because I'm going to get my fee and expenses anyway. But I can't live with myself if I do that, and that's one of the reasons why I want you to lower the burden of proof and give us the resources so that we can win these cases. Because, Congressman Burton, I want to assure you of something: The thrill of victory is never as great as the agony of defeat in these cases. It's not the same thing.

Mr. BURTON. Ms. Barton, how did you feel when your lawyer told you that you had to make this kind of a choice, either agree to not have it published or face appeal? What was your thought?

Ms. BARTON. It was agonizing. It made me feel, like I said, that I was being blackmailed; that I was—it was either, take the money and don't let anybody else ever be able to use this information again, or don't take the money and go through years and years more of appeals.

Mr. SHOEMAKER. Chairman Burton.

Mr. BURTON. Yes, sir?

Mr. SHOEMAKER. Could I just raise one issue. You had talked with Ms. Dyer about subpoenaing information about the numbers of doses per lot.

Mr. BURTON. In her case in Tennessee, right.

Mr. SHOEMAKER. Right. And I think it's important to understand that we need that data in all cases because there's no way we can determine whether or not a case is a hot lot unless we know the

denominator data. You may have one lot that has 10 reactions reported and another lot that has 100 reactions reported; and that may be perfectly normal because the one lot may be 10 times as big, but we don't know that until we have the numbers of doses per lot.

That information we've been trying to get for years. The manufacturers say it's proprietary, which I don't have any clue why. It doesn't make any sense——

Mr. BURTON. Let me ask Ms. Dyer, you did contact Merck about this?

Ms. DYER. I'm sorry. Say that again.

Mr. BURTON. No, it wasn't Merck. Who was it?

Ms. DYER. Lederle.

Mr. BURTON. Lederle. You did contact——

Ms. DYER. I gathered my information through the FDA Freedom of Information branch.

Mr. BURTON. I know. But did you contact Lederle about this?

Ms. DYER. No, I did not.

Mr. BURTON. Whom did you contact who said that this was proprietary and wouldn't give you that information?

Ms. DYER. I don't understand the question. I'm sorry. Who did I contact?

Mr. BURTON. You said that they wouldn't give you the information, and we said we'd subpoena the information on those lots.

Ms. DYER. Right. I was told by the FDA when I asked them how many shots come out of a bulk of vaccine, that that was confidential information.

Mr. BURTON. And they said they couldn't tell you?

Ms. DYER. Yes.

Mr. BURTON. I see.

Ms. BARTON. I was told by Lederle, and I asked the same question——

Mr. BURTON. And they said the same thing?

Mrs. BARTON. Yes, and——

Mr. BURTON. That sounds like both the FDA and the companies are trying to protect the company.

Ms. BARTON. What they said is that certain—you know, it just depends. Some lots will have 700 doses; some will have 1,000; some will have—but it's confidential as to how many——

Mr. BURTON. No, I understand. I understand. But it sounds like the FDA is scratching the back—and that probably bothers them for me to say this—scratching the back of those pharmaceutical companies because they're concerned about the liability exposure.

Mr. SHOEMAKER. Your Honor, there is actually information that—we know that the Government has this information because there was an article published, and I can provide that to you, which compared the two manufacturers of hepatitis B vaccine; and it stated that the one manufacturer had four times the rate of reactions as the other manufacturer.

Interestingly enough, when you go back and look at the data that they submitted, when they were having them tested to approve the vaccines, that same pattern held true. The conclusion of the article was that, well, we don't know why this is, but it probably does not mean anything.

Well, I think it means something if one vaccine manufacturer has a rate of reaction that's four times greater than another manufacturer; and to be able to publish that and state that, they had to know the numbers of doses per lot in order to make that calculation. So that information is available to the Government, not just the manufacturers.

Mr. BURTON. Well, why do you think that the FDA wouldn't allow a claimant to have information——

Mr. SHOEMAKER. I think you can talk to NVIC. They have tried to get this information under the Freedom of Information Act. We've tried to get it. It's been——

Mr. BURTON. Well, what's your opinion?

Why do you think they don't want to let it out?

Mr. SHOEMAKER. I think because if you did it, you're probably going to find hot lots. You're probably going to find lots where——

Mr. BURTON. So why wouldn't you want the hot lots——

Mr. SHOEMAKER. I think you want that information——

Mr. BURTON. I know, but why would the FDA and the manufacturer not want the hot lots revealed?

Mr. SHOEMAKER. I don't know and I've been trying to figure out why that would be considered proprietary. I mean, it——

Mr. BURTON. No. But I mean, assuming that, take the proprietary out of it, why do you think they wouldn't want to know?

Mr. SHOEMAKER. I can't speak for——

Mr. BURTON. You don't want to speculate about that?

Well, I'll speculate on it.

Ms. BARTON. I think they wouldn't want any more claims——

Mr. BURTON. Lawsuits or many claims.

Ms. BARTON. Right.

Mr. BURTON. Right. I think that's exactly right, and I've had a suspicion for a long time that a lot of the people that work at FDA and HHS have direct or indirect ties with pharmaceutical companies, and they protect them; and it's really sad.

And when we look at the financial disclosure forms, we have found people on the advisory committees that make recommendations to the FDA on drugs being put on the market for vaccination purposes. We have found conflicts of interest. What was that vaccine we had?

The RotaShield vaccine, the chairman of that advisory committee had stock in a company that was working on the RotaShield virus, a vaccine. And they brought in three people from the FDA, or four people, to vote on that because they didn't have a quorum present; and they urged them to vote for it, and within a year children had died. There had been all kinds of problems with it, and it had not been properly tested even though there had been concerns—some concerns about it at the advisory committee meeting. But it looked like, because the chairman was recommending it, they went ahead with it. And he had a financial interest. That's sad.

And this brings up a question about these other things like this, these hot lots and the statistical information we'd like to have, because it sounds like, because of this arrangement, that there are people at the FDA that are trying to protect interests that they may have with pharmaceutical companies, either prospective or in the past. They may have worked for a pharmaceutical company or

they anticipate working for one or they get benefits from them in one way or the other.

And some people may say, that really is a pretty serious charge to level, but I will tell you, I have a lot of friends who are doctors, and it's a constant thing for the pharmaceutical companies to be spending a great deal of money taking people out and wining them and dining them, who are in governmental agencies, taking them on trips, as well as the doctors themselves who use those products. And so there's a real interplay there that I think does a disservice to the American people, and that's one of the reasons why we're going to have probably about 14 or 15 of these hearings in the next year, and the FDA is going to be over here listening to this and asking questions about it.

Mr. SHOEMAKER. When you have a couple hours for me to talk about flu vaccine, I'd be glad to——

Mr. BURTON. I'll get back to you on that because those of us who were concerned with the anthrax threat—and all of our mail has been taken away from us; we haven't had mail in the Capitol for 6 weeks now, 7 weeks, and it's because of the anthrax scare. So we have been told that we should all get a vaccine for—the flu vaccine because the threat is there that we may be exposed to anthrax. And it looks like the flu, and so we have to be able to protect ourselves against the flu so we'll know what it is if it hits; and so we're all forced to take the vaccine in the form of a shot, and every one of us is getting thimerosal or mercury in that vaccine. We don't have any choice.

And most of the doctors, as I've said, don't even know what's in there.

Let me get back to the questions here. Let me go to Ms. Dyer.

When Andy and your other children were vaccinated, did your doctor or the nurse tell you there was a chance there would be an adverse reaction and how to recognize it?

Ms. DYER. Before we recessed I wanted to say yes, I was given the pamphlet that lists reactions. I don't remember the exact numbers, but a one-in-so-many-thousand chance of death, one-in-so-many-thousand chance of seizure.

The thing that I disagree with is the fact that a lot of these symptoms appear to be non-life-threatening. Parents, unless you have a child who has a seizure or you know somebody with a seizure disorder, I don't think that a lot of people realize that just a stare off into one direction could be a seizure, this right here, which is what my son started doing——

Mr. BURTON. You didn't recognize that as a problem?

Ms. DYER. You don't recognize that as a seizure—or the doctors——

Ms. BARTON. Or the shivers that I said my son was having at night.

Ms. DYER. They tell you that a child being sleepy is normal.

Mr. BURTON. Let me ask you, were you asked to sign a form stating that you'd been told your child might have an adverse reaction?

Ms. DYER. Yes.

Mr. BURTON. But you thought it would be a minor thing?

Ms. DYER. Seizure, death, swelling at the injectionsite——

Mr. BURTON. So you were aware of that?

Ms. DYER [continuing]. Fever. Yes.

Mr. BURTON. OK. In your testimony you stated that your petition for compensation for your child's vaccine injury was rejected in 1999.

How do you provide for his care now? How do you take care of the financial requirements?

Ms. DYER. It's difficult. We have parents that live nearby that help us out quite a bit. My husband is self-employed, and because of Andy's injury, I can't really work outside the home. We have a church family that helps provide a lot of financial assistance when we need it.

Mr. BURTON. But you have an unusual financial burden because of that?

Ms. DYER. Yes, sir.

Mr. BURTON. How much extra does it cost to care for Andy each year over that of your other kids?

Ms. DYER. With therapies and extra things that he needs that his insurance does not cover, I would guess as much as $9,000 to $10,000 a year.

Mr. BURTON. Really?

Did you find out about the number of adverse events reported in that lot of vaccine that Andy received?

Ms. DYER. I contacted the FDA Freedom of Information branch and——

Mr. BURTON. So you only got it from the FOA, Freedom of—or FOI?

Ms. DYER. Right. And after 2 years and during those 2 years never being told that there was a relationship, a friend of mine mentioned that she had seen a show on the vaccine and the shots; and so I called his physician and got the information as far as the drug company name and lot number and called the FDA.

Now, when I called the FDA, you were mentioning about how maybe they were scratching each other's back. I felt really put off. They asked me why I needed that information, has your son already been vaccinated?

Well, if he's already been vaccinated, you don't need that information. They did not want to give it to me freely. I mean, I had to fight for it.

Mr. BURTON. Are you aware of whether the FDA ever contacted Lederle about this hot lot, or if they were ever found to be in violation of good manufacturing practices regarding this product?

Ms. DYER. Not to my knowledge.

Mr. BURTON. So you don't know if this hot lot—where they had all of these adverse reactions, if the FDA even contacted Lederle?

Ms. DYER. Not to my knowledge.

Mr. BURTON. I want to subpoena any records that the FDA has regarding Lederle and this hot lot. I want to get the hot lot number, and I want to send a subpoena over to the FDA regarding any correspondence between them and Lederle regarding that.

Ms. BARTON. I know that Dateline did a show that was completely about hot lots on DPT vaccines.

Mr. BURTON. I understand that, but the point is——

Ms. BARTON. I'm just saying that they talked with the FDA and Lederle. So they did a show completely about the hot lots and certain ones. I don't know if yours was one of them.

Ms. DYER. Mine was not one of those.

Mr. BURTON. Well, in any event, was all that information exposed in that television show?

Ms. BARTON. Not the number of doses, but the hot lots were there.

Mr. BURTON. Well, what we want to find out is the number of——

Ms. BARTON. Is the number of doses, right.

Mr. BURTON. What we want to find out is the number of doses, the number of adverse reactions, whether or not there was any correspondence between Lederle and the FDA; and if so, we want to see it. OK?

What's the long-term prognosis—I need you to pay attention to me now because we've to get through a lot of work here. I've got these people from the FDA and the Justice Department that are going to have to testify.

What is the long-term prognosis ran for Andy?

Ms. DYER. Andy's condition right now, he's severely developmentally delayed. Mentally, he's at an 18-month-old level.

Mr. BURTON. How old is he?

Ms. DYER. He's 9.

Mr. BURTON. He's 9 and he has an 18-month-old——

Ms. DYER. He's at an 18-month-old level, mentally. Physically, he is very strong. He's able to crawl on all fours and actually able to pull himself to a stand, but he will never be a normal child. He will always require assistance in everything that he does.

Mr. BURTON. And I'm sure you worry about what's going to happen when he gets older and you get older.

Ms. DYER. Yes, sir. He's 9 years old and weighs 100 pounds now, so——

Mr. BURTON. I understand.

Ms. DYER [continuing]. He's a big boy.

Mr. BURTON. Mr. Holder, we haven't asked you a great many questions about your situation. Would you like to expand and expound on that a little bit before we change to the next panel?

Mr. HOLDER. Were there any specific questions you had?

Mr. BURTON. Well, you heard the kind of problems that Ms. Barton and Ms. Dyer had. Do you have any comments regarding the way—I know you mentioned the State in which you live is not living up to the same standards that other States are, or the Federal Government.

Mr. HOLDER. Well, no. See, I understand more now and speak to Mr. Balbier that—and I did understand before that the State laws are really trying to protect the interests of the child, but I think my point of contention with that was that you were awarded money for specific things, but yet you still had to go through the State again; and with Brandon's disability and a job and it's just very hard to try to fight for all of the things that were already promised, once again.

Mr. BURTON. But you did get a settlement?

Mr. HOLDER. Yes.

Mr. BURTON. And you're not dissatisfied with the way you were handled?

Mr. HOLDER. I am dissatisfied with the length of time that it took to settle the case. It was a total of 6 years that it took for——

Mr. BURTON. And during that time you had to have an attorney, you had to pay expenses and all that sort thing, and it was a real burden on the family?

Mr. HOLDER. Yes, very much a burden. And again——

Mr. BURTON. Did you recoup any of those moneys that you spent during that 6 years?

Mr. HOLDER. Yes. Those moneys for unreimbursed medical and any legal were reimbursed through the lump sum.

The most important thing about the length of time, to me, is the impact it has on the child, the additional therapies, professional help, these quality cares that he could have been getting all along were not gotten. And my point with that is, I don't know if it would have made him better, but I never will know if it would have improved——

Mr. BURTON. So if they had moved quicker, you think he might have gotten additional treatment that would have helped?

Mr. HOLDER. Absolutely. I believe that to the bone, yes.

Mr. BURTON. I think that's an important point that we need to look at too.

Anything else I need to—oh, yes, Dr. Block——

Mr. HOLDER. There was also—oh, I'm sorry.

Mr. BURTON. Go ahead. Sure.

Mr. HOLDER. There was also—in 1998 they did an MRI, and there was a shadow. And the doctor clearly stated on the bottom that this shadow was because the child had turned his head. And the Special Master had tried to just throw it out based on that, immediately had it dismissed; and we had to run and get the records and say, you know, look, it says this. But they did try to throw it out because——

Mr. BURTON. There was a shadow where, on his brain?

Mr. HOLDER. The shadow—yeah, in the MRI. And the doctor who read it clearly stated, this is because the child moves; and he was shaking his head, and they—it seemed as if they just chose to ignore that little part and——

Mr. BURTON. So the constant shaking of his head was causing additional damage; is what they were saying?

Mr. HOLDER. I'm sorry?

Mr. BURTON. The shaking of his head was causing damage or——

Mr. HOLDER. No, no. He was saying the shadow that was showing on his MRI was because he had moved his head during the MRI——

Mr. BURTON. Oh, I see.

Mr. HOLDER [continuing]. And the interpretation of the defense was, oh, they looked at the MRI and they said "shadow," but they omitted the part that the doctor said it was because he had moved his head toward it, trying to get the case dismissed.

So that—to me, that is an example of being adversarial and not, you know, having the full information and trying to have it tossed out because of this.

Mr. BURTON. But finally you did get restitution?

Mr. HOLDER. Well, yes, sir. Absolutely.

Mr. BURTON. OK. So your main concern is that it took too long?

Mr. HOLDER. It took too long, correct.

Mr. BURTON. Dr. Block, do you have any opinion on whether the nonpublication of decisions is appropriate?

Dr. BLOCK. No, sir. I don't understand that legal implication at all.

Mr. BURTON. Do you think they should be published?

Dr. BLOCK. I don't know what the legal standards would be for that. I would probably have to defer to my lawyer friends for that.

Mr. BURTON. I know, but you're a doctor and you're a pediatrician. Ms. Barton, she was told they would settle her claim if they didn't publish this.

As a pediatrician knowing the kind of problem that she had, do you believe that should be published?

Dr. BLOCK. Well, Mr. Chairman, it's very, very hard to give a specific answer to a case, when I don't know the details, and to offer a legal opinion. In science, we think all facts should be before everybody. Whether that's true in the legal arena or not, I just don't know, but it certainly would be true in science.

Mr. BURTON. Thank you.

Well, I want to thank you very, very much. I hope you'll stay around for just a little bit because we're going to have the people from the agencies involved to testify now and ask them some questions, and it might be of interest to you and help us in the future.

The next panel, we would like to come forward now. Mr. Balbier, Mr. Harris, Mr. Euler, would you please stand so we can have you sworn, please.

[Witnesses sworn.]

Mr. BURTON. I appreciate your being so patient today. I'm sorry we have had so doggone many votes.

Do any of you have an opening statement you want to make?

Mr. Balbier, do you have an opening statement?

Mr. BALBIER. Yes, I do.

Mr. BURTON. OK.

STATEMENTS OF THOMAS E. BALBIER, JR., DIRECTOR, DIVISION OF VACCINE INJURY COMPENSATION, OFFICE OF SPECIAL PROGRAMS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; PAUL CLINTON HARRIS, DEPUTY ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION, U.S. DEPARTMENT OF JUSTICE, CONCERNING THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM; AND JOHN EULER, DIRECTOR, NATIONAL VACCINE INJURY COMPENSATION PROGRAM, U.S. DEPARTMENT OF JUSTICE

Mr. BALBIER. Good afternoon, Mr. Chairman and members of the committee. I'm pleased to be here this afternoon to talk to you about the National Vaccine Injury Compensation Program. And, first, I would like to thank the members of this committee and Chairman Burton, Representative Waxman, and Dr. Weldon in particular for your interest in the program and your participation in our ongoing efforts to improve the program.

The Department of Health and Human Services is committed to making this program more expeditious and less adversarial. I am very encouraged by the recent developments toward this common goal that have taken place.

At the committee's last hearing on November 1, I was asked if I would be willing to work with this committee and its staff to craft legislation aimed at improving the operation of the program that could receive broad consensus for approval within the legislative and executive branches of government. In response to that request, I can report that substantial progress already has been made due to extensive cooperation with committee staff.

On November 19, the chairman of the Advisory Commission on Childhood Vaccines wrote a letter to invite Chairman Burton and Representative Waxman, or your staffs, to the ACCV's December 5 meeting to present Chairman Burton's newly drafted legislative proposal to make improvements to the program. Both of you accepted this invitation and sent your staffs to the ACCV meeting to discuss your proposed legislation. I would like to thank Chairman Burton and Representative Waxman for allowing your staff to take time out of their busy schedules to present this draft bill at the ACCV meeting.

The ACCV is comprised of nine voting members including three medical professionals, three attorneys and three members of the general public. Two of the medical professional members are required to have expertise in pediatrics; one of the attorneys is required to represent claimants under the program and one attorney is required to represent a vaccine company. Of the general public members, two are required to be parents of children injured by the very rare but serious adverse reactions to childhood vaccines.

Many of the provisions in Chairman Burton's draft bill are the same as those proposed by HHS in its proposed amendments sent to Congress in June 1999, but never introduced as a bill. These proposals were developed based on strong consensus recommendations of the ACCV and enjoy the support of the current administration.

We are looking forward to working very closely with Chairman Burton, Representative Waxman, the Department of Justice, and the ACCV to make needed improvements to the National Vaccine Injury Compensation Program.

I'll be pleased to answer any additional questions you may have. Thank you.

Mr. BURTON. Thank you, Mr. Balbier.

[The prepared statement of Mr. Balbier follows:]

STATEMENT

OF

MR. THOMAS E. BALBIER, JR.

DIRECTOR

DIVISION OF VACCINE INJURY COMPENSATION

OFFICE OF SPECIAL PROGRAMS

HEALTH RESOURCES AND SERVICES ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

CONCERNING THE

NATIONAL VACCINE INJURY COMPENSATION PROGRAM

December 12, 2001

Good afternoon, Mr. Chairman and members of the Committee. I am pleased to be here this afternoon to talk with you about the National Vaccine Injury Compensation Program (the Program). First, I would like to thank the members of the Committee, and Chairman Burton, Rep. Waxman, and Dr. Weldon in particular, for your interest in the Program, and your participation in our ongoing efforts to improve the Program.

The Department of Health and Human Services (HHS) is committed to making the Program more expeditious and less adversarial. I am very encouraged by the recent developments toward this common goal that have taken place. At the Committee's last hearing on November 1, I was asked if I would be willing to work with the Committee staff to craft legislation aimed at improving the operation of the Program that could receive broad consensus for approval within the Legislative and Executive Branches of government.

In response to that request, I can report that substantial progress already has been made, due to extensive cooperation with Committee staff. On November 19, the Chairman of the Advisory Commission on Childhood Vaccines (ACCV) wrote a letter to invite Chairman Burton and Rep. Waxman, or your staffs, to the ACCV's December 5 meeting to present Chairman Burton's newly drafted legislative proposal to make improvements to the Program. Both of you accepted this invitation and sent your staffs to the ACCV meeting to discuss Chairman Burton's proposed legislation. I would like to thank Chairman Burton and Rep. Waxman for

allowing your staff to take time out of their busy schedules to present this draft bill at the ACCV meeting.

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We are looking forward to working very closely with Chairman Burton, Rep. Waxman, the Department of Justice, and the ACCV to make needed improvements to the National Vaccine Injury Compensation Program. I will be pleased to answer any additional questions you may have.

Mr. BURTON. Mr. Harris, do you have an opening statement?
Mr. HARRIS. Yes, sir.
Mr. BURTON. OK.
Mr. HARRIS. Good afternoon, Chairman Burton, Ranking Minority Member Waxman, members of this committee. Thank you for the opportunity again to appear before you to talk about the Vaccine Injury Compensation Program. With me this afternoon is John Euler, Acting Director of the Torts Branch, which oversees the vaccine litigation group. So that I may limit my remarks this afternoon and allow more time for discussion and questions, I request that my full written statement be entered into the record.

In the face of such traumatic personal tragedies as those described by members of the preceding panel, Justice Department lawyers, along with officials from the Department of Health and Human Services, face the daunting responsibility of carrying out congressional intent as we implement the statute and uphold the provisions of the Vaccine Injury Compensation Act. Each claim under the program has its own personal story.

The cases very often involve complex legal and medical issues, but are always overlaid with heavy emotions. Nevertheless, we endeavor to exercise our responsibility with the highest degree of professionalism and with the goal that each case is handled in the most efficient and fair manner possible.

To attain this goal, we have been and remain firmly committed to working with the Congress, HHS, the court and other interested groups, such as the Advisory Commission on Childhood Vaccines and petitioners' bar to make this program the best that it can be. Indeed there are encouraging examples of positive developments in the program.

Today a greater percentage of families is compensated than in the early years of the program's existence. In each of the past 5 years between 41 percent and 54 percent almost half of all cases adjudicated have resulted in compensation for claimants.

In contrast, from 1991 to 1996, fewer than one-third of the cases adjudicated each year were compensated and the other 70 percent were dismissed.

In addition, we have increased our use of alternative dispute resolution threefold in just the 2 years alone in an effort to resolve more cases informally without the need for court hearings. Furthermore, one of our attorneys recently organized a working group in coordination with the Office of Special Masters. The working group includes Special Masters, claimants' attorneys, a parent, Justice Department attorneys and HHS staff. This group will reevaluate and revise the guidelines for practice under the Vaccine Injury Compensation Program with the goal of devising procedures to further expedite case processing. In particular, the group intends to focus on the process of settling the damages portion of these cases, which is often shown to be a very time-consuming aspect of program cases.

We do recognize this committee's oversight responsibilities and indeed appreciate your commitment to ensuring that the program operates fairly and in accordance with congressional objectives. Again, we are pleased to work with the committee and to assist you in carrying out these responsibilities.

I would like to remark on the concerns and issues raised by the witnesses on the panel that preceded me. At the Justice Department we, too, are concerned by comments from individuals such as those who testified today that indicate that the program has become too adversarial. We are also concerned by examples of cases that have taken too long to process.

Having resolved more than 5,400 cases since the inception of the program, we acknowledge that some cases indeed have not been processed as efficiently as possible. Of course, the most difficult aspect of each individual case is that it involves a person, usually a child, with serious health conditions. Indeed, many of us at the Department are parents ourselves and therefore feel tremendous empathy and compassion for each claimant and for their family as well. We know and appreciate the suffering they endure.

Regardless of the cause, childhood disease and injury are always tragic. Regrettably, whether a family receives a prompt compensation or whether the case is dismissed because the injury is found to be unrelated to vaccine, this program simply cannot reverse the family's tragedy or eliminate the inevitable sadness, pain, or anger they understandably experience.

Like all cases filed under the program, the three cases described this afternoon are obviously very difficult to hear about. We understand that these claimants are disappointed with the process and, indeed, we regret that their experiences were not more positive. It is important to hear concerns like the ones that have been expressed today so that we may hope to improve the program where it is possible to do so. Indeed, I have required our attorneys to either review the transcript or view a videotape of these proceedings.

I trust that the committee also has reached out to hear from families and practitioners that are pleased with the program. Certainly it would be unfair to the public to leave the impression that all, or even most, of the families have had bad experiences with the program. I understand that the committee has heard complaints from many individuals that your staff has spoken to. But I also know that there are many satisfied program participants as well.

I would like to comment briefly on some of the remarks made from the preceding panel beginning with Ms. Barton's statement regarding her son Dustin's case. I understand that Ms. Barton is very disappointed with her experience in the program. In fact, we too agree that a case should not take 8 years to process.

This is not something I came here to defend. Fortunately, the vast majority of cases are handled in far less time. To be sure, the average time for processing newly filed petitions is 2 years. Dustin's case was exceedingly complex medically and procedurally, which resulted in significant delay.

As an example, the medical records did not support Ms. Barton's initial claims that the vaccine was the cause of Dustin's injury. This made the case difficult from a factual perspective. From a medical standpoint, Dustin suffered from significant structural brain abnormalities which were present before he received his immunization and were known to cause the type of neurological problems he suffered.

This case was also complicated by the fact of Dustin's unfortunate and unexpected death in 1997, therefore changing the situa-

tion from an injury case to a death case. Finally, as the Special Master's decision acknowledged, "This case met with agonizing delays. The parties had difficulties in obtaining the required expert reports and critical autopsy materials including slides of the brain needed for expert analysis."

All parties would have liked for this case to have been processed more quickly than it was. I can assure you and this committee, Mr. Chairman, however, that there was never any intentional delay or neglect by the Department, nor do I believe that it is appropriate to place blame on any of the parties for the length of time it took.

Ms. Barton stated that she was treated unkindly by the Department attorney who handled her case. We absolutely do not condone disrespectful treatment of claimants, their families, or any other program participants. We regret that her experience with the program caused her further anguish.

I understand that at the hearing very sensitive personal and medical matters needed to be explored to best understand the likely cause of Dustin's condition. While I cannot discuss these matters in further detail, I can understand that it was difficult for all parties to address them.

Ms. Barton stated that she was required to agree to have her decision designated as unpublished in order that the Government agree not to appeal her case. I would like to advise the committee that in every case the final determination of whether a vaccine in that case will be published or unpublished rests with the presiding Special Master.

The Government has occasionally sought petitioner's agreement to jointly request that a Special Master-designated decision is not published with the understanding that the Government would not appeal the decision. Those situations arise when we are concerned that an erroneous decision may adversely impact the program but do not believe that further litigation is appropriate given the circumstances of each individual case.

In some situations, we determine that the interest of all parties may be best served by our agreement to forgo appeal and further litigation and further delay so long as the decision is not published. That was the situation in this case. Although we disagreed with the Special Master's evaluation of the factual and medical evidence and believe that the child's condition and tragic death were caused by a pariventricular leukomalacia [PVL], a condition he was unfortunately born with, we agreed to compensate this case without further litigation if it would be designated unpublished. Ms. Barton's attorney then joined us in making that request of the Special Master.

Turning to the case involving Ms. Dyer's son, Andy, I understand that Ms. Dyer was also happy with her experience under the problem. There were two significant issues that complicated this case. First, the claimants required almost 3 years to submit the necessary medical reports and expert report and second, the medical records did not support a finding that Andy suffered a table injury.

This case illustrates perhaps the most common reason for case delay, the difficulty in acquiring and producing medical records and an expert report. There were 15 court orders in this case setting

and resetting the deadline for the Dyers to provide these documents.

I can assure the committee that the Department did what it could to contribute to swift processing of this case. For example, our initial report was submitted within the 90-day time period established by the courts. We filed our expert report just 3 weeks after the Dyers filed their report, and the hearing was held 1 week later.

Understandably, Ms. Dyer was disappointed with the outcome of the hearing. Although the Special Master heard the Dyers' testimony, she concluded that the medical records were more persuasive evidence of the events that occurred at the time of the vaccination. The Special Master was convinced, as the medical records indicated, that Andy's condition began over 3 weeks after his DPT vaccination and, importantly, was unrelated to it.

The Special Master's decision to credit the medical records over the Dyer testimony is based on well-established case law, which explains the principle that, "oral testimony which is in conflict with the contemporaneous documents is entitled to little evidentiary weight."

Of course, one role of the Special Master is to resolve difficult factual discrepancies, such as existed in this case, and therefore it is not unusual for a Special Master to rely upon medical records which were prepared by a physician at the time the events are occurring.

Finally, I would like to address Jim Holder's comments about his son Brandon's case. Like the other children described today, Brandon too, unfortunately, suffered a seizure disorder. One significant issue affecting the processing of this case was evidencing the medical record of a factor unrelated to the vaccine which might explain Brandon's seizure disorder. However, after the submission of additional documentation, the government conceded Brandon's entitlement to compensation. The claimants required over a year to submit a life care plan and another 6 months to submit supporting documentation. Ultimately, the parties cooperated in negotiating and agreeing upon a life care plan and the Special Master issued a decision based on this plan.

Mr. Holder testified that it took him a long time to find an attorney to represent him. We are sympathetic to the difficulty of finding an attorney. Oftentimes a family's experience with the program is the first time they have had to work with a lawyer. To help eliminate the challenge of finding an attorney, the Court of Federal Claims recently compiled a list of more than 100 attorneys from around the country willing to represent vaccine act claimants. We are also pleased to report that nearly 250 attorneys clearly represent claimants in pending cases. Moreover, the program's outreach efforts have increased substantially in recent years.

As I stated before, many of the claims under the program often involve complex legal and medical issues, which are compounded by a heavy emotional element. Nevertheless, I can assure this committee that our attorneys endeavor to exercise our responsibility to each claimant, to the families involved and to the goals of this program with the highest degree of professionalism, with the ultimate

objective that each case is handled in the most efficient and fair manner possible.

Mr. Chairman, again I thank you and members of this committee for allowing me this opportunity to appear before you again today, and I want to in closing assure the committee that we hear what you're saying about the need to have compassion in this program. It is something that I am certainly driving home with the ones that work in the program. It is something that I will certainly share with my superiors back at the Department of Justice.

Thank you.

[The prepared statement of Mr. Harris follows:]

Department of Justice

STATEMENT

OF

PAUL CLINTON HARRIS
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

CONCERNING

THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

PRESENTED ON

DECEMBER 12, 2001

STATEMENT OF
PAUL CLINTON HARRIS
DEPUTY ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

BEFORE THE COMMITTEE ON GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

DECEMBER 12, 2001

Chairman Burton, Ranking Minority Member Waxman, and Members of the Committee:

Thank you for the opportunity to appear before you today. I am pleased to appear on behalf of the Administration to talk about the National Vaccine Injury Compensation Program ("Program" or "VICP"). With me is John L. Euler, Acting Director, Torts Branch, who oversees the Vaccine Litigation Group at the Justice Department.

On November 1, 2001, I appeared before this Committee to talk about the Program. At that time, I provided the Committee with lengthy written testimony. So as to limit my remarks this afternoon, and to allow more time for discussion and questions, I ask that my written testimony from the November 1, 2001, hearing be incorporated into the record of this hearing.

In your letter of invitation, Mr. Chairman, you stated that there are several issues of particular interest to the Committee, one of which is proposed changes to the Program. The Department was pleased to receive and review your draft bill containing many important legislative improvements to the VICP. In particular, the recommendations of the Advisory Commission on Childhood Vaccines ("ACCV") such as the extension of the statute of limitations to six years, and the provisions to enable payment of guardianship and family counseling expenses, and interim litigation costs, would constitute tremendous improvements to the Program. We hope these provisions receive favorable consideration by the Congress. We compliment you and your staff on these efforts, and look forward to an opportunity to work further with the Committee regarding other provisions in the draft bill.

In addition, Mr. Chairman, in your letter of invitation you mentioned other areas of concern, including the concern that the Program has become increasingly adversarial in nature, and the frequency with which Program cases involve protracted proceedings.

At the Justice Department we, too, are concerned by comments that indicate that the Program has become more litigious, and by examples of cases that have taken too long to process. Of course, the most difficult aspect of handling Program cases is that each individual case involves a person, usually a child, with serious health problems. We

feel tremendous sympathy for all claimants and for their families. We know and appreciate the suffering they endure. Regardless of cause, childhood diseases and injuries are tragic. Regrettably, whether a family receives prompt compensation or whether the case is dismissed because the injury is found to be unrelated to the vaccine, the Program cannot reverse the family's tragedy or eliminate the inevitable sadness, pain or anger they may feel.

In the face of these personal tragedies, we attempt to carry out Congressional intent as we implement the statute and uphold the Act's provisions. As you can imagine, it is not always an easy task. Yet, I do not believe that the manner in which the Department of Justice and the Department of Health and Human Services process Program cases has become more adversarial, but less so. In fact, we have increased our use of Alternative Dispute Resolution three-fold in the past two years in an effort to resolve cases more informally without the need for court hearings. There are other examples of positive developments in the Program. A greater percentage of families is compensated now than in the early years of the Program's existence: in each of the past five years, between 41% and 54% – almost half – of all cases adjudicated have resulted in compensation for claimants. In contrast, from 1991-1996, fewer than 1/3 of cases adjudicated each year were compensated, and the other 70-80% were dismissed. Further, a Justice Department attorney has recently organized a working group in coordination

with the Office of Special Masters. It includes special masters, claimants' attorneys, a parent, Justice Department attorneys, and HHS staff. This group will re-evaluate and revise the Guidelines for Practice Under the VICP, with the goal of devising procedures to further expedite case processing. In particular, the group intends to focus on the process of settling the damages portion of these cases, which has often shown to be a time-consuming aspect of Program cases.

We acknowledge that sometimes the process of adjudicating cases has taken too long, and we, too, would like to see cases processed more quickly. Even when the parties diligently work to provide the medical evidence and other documentation needed to substantiate a claim, some cases are extraordinarily complex and simply require great time and effort on the part of all parties and the Court. In these types of complex cases, despite the best efforts of all parties, lengthy proceedings are unlikely to be eliminated. Moreover, we generally accede to the Court's practice of giving claimants the time they need to attempt to gather the evidence, develop their theory of causation, or compile a life care plan. The procedures employed in any given case, and the length of time required to resolve the case, vary widely. It is important to recognize that these procedures must be authorized by a special master of the Court.

Even when the process has not worked as efficiently as the parties would like, we believe this Program continues to serve one of its primary purposes: providing an alternative to traditional civil litigation. The Program allows any petitioner who is dissatisfied with the nature or pace of proceedings to withdraw from the Program after 420 days and pursue private rights of action in civil court. 42 U.S.C. § 300aa-21(b). I am unaware of any petitioner having pursued this course of action, a testament that petitioners believe that, while not always perfect, these proceedings are preferable to the traditional tort system.

Of course, all Program participants would like to see cases resolved in the shortest time possible. However, we are also mindful that speed and efficiency oftentimes may be inconsistent with the compensatory principles of the Program. That is, enforcement of rigid deadlines, denial of requests for extensions, or refusal to accept additional evidence would inevitably result in the dismissal of far more petitions and the denial of compensation to far more families. On balance, while prompt resolution is a worthy goal, the Program tends to consider efforts to complete the record by allowing time to investigate and submit all relevant evidence to be of greater importance.

I want to assure the Committee that the Department is dedicated in its resolve to improve Program operations. We attempt to take a forward looking view: while we

unfortunately cannot change the length of time it has taken to resolve cases that have already been adjudicated, we will do all we can to ensure that pending and future cases are handled as expeditiously and fairly as possible. To help us meet this goal, we are committed to working further with the Congress, HHS, the Court, and other interested groups, such as the ACCV and petitioners' bar. I would be pleased to answer any questions you may have.

Mr. BURTON. Thank you, Mr. Harris. Mr. Euler, do you have a comment?

Mr. EULER. I have no opening statement, Mr. Chairman.

Mr. BURTON. Thank you. Do you think that the results of these settlements in these cases should be published, Mr. Harris? If not, why?

Mr. HARRIS. The unpublished situations occur when there is an issue of whether we are going to appeal or not appeal, and these decisions are not sealed, as has been previously described. The effect of an unpublished decision basically relates to a lawyer's ability to cite a case as a credible reference in future cases. In the case of the Special Master, unpublished decisions just simply would not appear on Westlaw. That is the effect of having unpublished——

Mr. BURTON. Well, if you settle——

Mr. HARRIS [continuing]. Opinions.

Mr. BURTON. If you settle a case, like you did in the one we're referring to, the Barton case, why would you object to having that published?

Mr. HARRIS. The——

Mr. BURTON. Because according to her, Mrs. Barton, the settlement was based upon it not being published, and if she insisted on it being published, there would be an appeal. So why shouldn't that be published?

Mr. HARRIS. We didn't think the case should be published because we thought that the Special Master's decision in the case was erroneous.

Mr. BURTON. Well, then why did you settle?

Mr. HARRIS. Because we have to weigh competing interests here. We can't further litigate an appeal on the one hand and drag this case out even more.

Mr. BURTON. Had you not lost one appeal on this, in that case? Didn't you lose an appeal on the Barton case initially?

Mr. HARRIS. The case was we handled, if I recall, correctly.

Mr. EULER. There was a motion for reconsideration in the case, which the Special Master did hear, short of the time, and as she mentioned, per opinion that we filed before the appeal period had come. So she did reconsider the case and then issued another decision which was published at the time.

Mr. BURTON. And that decision was?

Mr. EULER. The decision was to compensate.

Mr. BURTON. OK. So the first decision was to compensate, and then there was a second decision to compensate?

Mr. EULER. That's correct.

Mr. BURTON. And then you guys decided, the Justice Department, to appeal it. But you said rather than appeal it and fight this out, if you don't publish this, we'll settle it. Is that right?

Mr. EULER. Well, we didn't—we said we think this case—well, we were told by our medical adviser that this case is wrongly decided and may have programmatic impact. There is a problem——

Mr. BURTON. Let's take that one step at a time. It would have a programmatic impact.

Mr. EULER. Yes, sir.

Mr. BURTON. Which means that in layman's language, if that had been published, it would probably increase the amount of liti-

gation in those kinds of cases, right, and it might adversely affect the program?

Mr. EULER. It might—that's right. We take very seriously the scientific integrity of the program.

Mr. BURTON. Well, what about the Special Master? The Special Master made the decision it should be compensated not once but twice, and evidently the Special Master, who has legal standing and who also had all the facts in the case concerning the medical records and everything, I assume they talk to experts, the Special Master talked to some experts before he made her, or she made her decision. But you talked to a different medical expert that didn't agree and so you decided not to appeal it because you're goodhearted?

Mr. EULER. There are competing interests, as Mr. Harris said. On the one hand, you've got a decision that we think is wrong. On the other hand, we're trying to expeditiously resolve the case so that there isn't further litigation and the petitioner gets paid.

Mr. GILMAN. Would the chairman yield?

Mr. BURTON. I'll be happy to yield.

Mr. GILMAN. I don't understand withholding erroneous—what you consider to be erroneous decisions from publication. Is this a common practice in your department?

Mr. EULER. It is not. From what we can tell, we've had agreements not to publish a case perhaps once or twice a year.

Mr. GILMAN. How many cases have been withheld from publication?

Mr. EULER. We don't know the answer to that. I suspect it would be 8 or 10.

Mr. GILMAN. And does the Department of Justice approve that kind of withholding of information to the public?

Mr. EULER. First off, it's not withheld except in the sense that it is not published in Westlaw, but——

Mr. GILMAN. That is withholding it from the public, is it not?

Mr. EULER. It cannot be cited. Petitioners are free to circulate the decision. It is not sealed. It is not kept secret. Petitioners can in fact do what they will with the decision. We don't seal settlements. What this is is——

Mr. GILMAN. Well, except when you tell them that part of the agreement on settlement is they're not to publicize the settlement and the basis for it.

Mr. EULER. We do that as a way to try to expedite the case, and we suggest that it's in both parties' interest. It's in our interest not to have the case published. It's in their interest to be done with the—it's in everybody's interest to be done with the litigation, and this was a tool to try to resolve the——

Mr. GILMAN. And has the Justice Department approved that kind of procedure?

Mr. EULER. Yes.

Mr. BURTON. Let me ask you a question. Why was this in Mrs. Block's interest that not be published?

Mr. EULER. It was in her interest——

Mr. BURTON. Why was it in her interest to not have it published?

Mr. EULER. So that the litigation would not continue, so we can get her the money?

Mr. BURTON. Oh, so you said to her——

Mr. EULER. I did not.

Mr. BURTON. Well, whoever it was said to her, Mrs. Block, we'll settle with you as long as this isn't published. That's correct, right?

Mr. EULER. I think—yes.

Mr. BURTON. I think if you talk to the average citizen in this country who was dying and who had to go through this for a long period of time, who was suffering from lupus, who was very depressed and they said, I'll tell you what we'll do, we'll settle this thing as long as you don't publish it, I think most people would think that was unseemly by the Federal Government.

Mr. HARRIS. I'd like to comment on that, if I could.

Mr. BURTON. Let me just tell you one thing. I'm going to ask for a GAO audit. I want you to know this, Mr. Harris, and we are going to have all of these cases reviewed. And if the GAO can't do it, we're going to have to spot check these, as well as the cases of these individuals. So all of this is going to be scrutinized by the GAO. I want you to know that. We're going to be looking over your shoulder on every case that's been decided and every one that's coming up. And you can use all the legal technicalities you want to on why you do this and why you do that and why you don't want to have things published, but I want you to know this is not going to end. It's not going to end, and you're going to have Democrats and Republicans, whoever is in charge of the Congress, doing this.

And I just don't understand, you talk about compassion, let me just say a couple words here. The Vaccine Compensation Program would—and I was in Congress, and I voted for it to help the pharmaceutical companies who are afraid of lawsuits, as well as making sure that people who had this kind of a problem could get a just compensation without going through tons and tons of litigation and years of heartache. So I voted for it. I was here. But the Vaccine Compensation Program was intended by us in Congress to be a remedial compensation program, not litigation, as you continue to talk about. We didn't intend there to be miles and miles and miles of legal wrongdoing going on and for lawyers at the Justice Department to be second-guessing and third-guessing a Special Master who made a decision.

In the Barton case, the Special Master who looked at all of the information, the medical information, who studied this case said there should be compensation. Then they looked at it again, because there was some concern with the Justice Department. Again the Special Master said, a lawyer, a judge in this case, should be compensated. But you went to some other expert and said, oh, no, it shouldn't be compensated, and you said but we will settle it as long as you don't publish it. That just isn't right.

Mr. HARRIS. Mr. Chairman, again, I——

Mr. BURTON. Am I misstating what happened?

Mr. HARRIS. Well, I'd like to state it in my own words, if I could.

Mr. BURTON. Sure.

Mr. HARRIS. But I want to say before I do that, I certainly appreciate the frustration and the action that you feel, and clearly that I understand the frustration and the angst of the families and the program participants feel. That is what makes our job at the Jus-

tice Department a difficult one, because on the one hand we are required to implement the mandates of the statute.

As Mr. Cummings said earlier, there is a requirement in the statute that these claims be based on credible medical scientific evidence. The statute also provides the Justice Department in appropriate cases the right to appeal cases that we feel are erroneously decided. That is in the statute. We're within the statute in doing that, but——

Mr. BURTON. I understand. Let me interrupt you for just——

Mr. HARRIS. Oh, no. Why we want to cut down on litigation, when we do cut down on litigation by doing things that both cut down on litigation and don't hurt the program, is so that we can continue to pursue the important national goals of having kids vaccinated.

Mr. BURTON. Well——

Mr. HARRIS. And——

Mr. BURTON [continuing]. I understand. I understand.

Mr. HARRIS. I think that's important.

Mr. BURTON. But we're talking about a specific case here. We'll get to the other cases as time goes by and maybe later today.

In the Barton case, you had a judge, a Special Master, who has legal standing, who was assigned to review the case, all the medical records and everything was looked at. And after a great deal of time and study, it was decided to pay the claim. There was a concern at the Justice Department about differences of opinion, and so they asked it to be rereviewed. It was rereviewed, and so then there was a question about, well, we don't agree with that, because you are evidently talking to some other medical experts, quote-unquote. Obviously the Special Master had talked to special experts, not once but twice, to make these decisions, and you decided that you would appeal the case, even though this had been dragged on ad infinitum.

If that isn't an adversarial type operation, which was never the intent of Congress, I don't know what it is. How many hoops does a parent like that have to jump through? I just don't understand it. That was not the intent. Now, the legislation had to be written in legalese. We had to set up certain things that had to be done, but we did—it's hard to legislate compassion, and if you get lawyers over there who are looking strictly at getting in front of a judge or a jury or whoever it happens to be to pound their views out, it doesn't serve the purpose of what we were trying to accomplish in helping both the pharmaceutical companies and the patients and their families.

Mr. HARRIS. I understand, Mr. Chairman. I think, I really do believe that if our attorneys approach these cases in an incompassionate way, that they would have appealed this case. The fact that they did not appeal this case on one hand and preserved the integrity of the program, as we see it, on the other hand is I think a testament to the way that we try to approach these cases and the difficult balancing situation that we have to apply in each case.

Now, we have had on occasion where appeals have gone forward at the petitioner's request, and the result not be what the petitioners expected on appeal. And we do not take these kinds of appeals frequently. This kind of issue in the published versus unpublished

decision that we were talking about occurs about twice a year max, and right now about 200-plus cases that we actually resolve each year.

So it is not something that happens over and over again, but on occasion we do differ with the Special Master, and the statute provides us the right in those cases to have a different person take a look at the case, and of course there is where the tension comes in. If we decide that we want a different person, the Court of Federal Claims, to take a look at the case in this instance, as you heard from Mr. Shoemaker, that would probably result in dragging the case out another 3 years and on the other hand, saying, OK, while we don't agree with the Special Master on this decision, we'll compensate the victims at this point, as long as we can reach an agreement that this decision that we view as erroneous is not published and later cited as a legal precedent.

Mr. BURTON. Mr. Gilman, do you have some comments?

Mr. GILMAN. Thank you, Mr. Chairman. I still don't understand the rationale for an unpublished decision. I don't know of any other court system in our country that has unpublished decisions. Our case law is based on precedents, and you suddenly are removing that opportunity for the law profession to examine prior decisions, and it seems to me that you're arbitrarily adopting that kind of a procedure. And I have never heard of this in any other agency. Is there any other agency that follows unpublished decisions? And if that be the case, we certainly want to find out about it.

Mr. HARRIS. Mr. Gilman, there are courts throughout the land that do have unpublished decisions, and the effect is the same, which means that attorneys operating in that jurisdiction cannot rely on the unpublished decisions as precedence when they are practicing in other cases.

Mr. GILMAN. Well, refer us to at least another agency, a Federal agency that has unpublished decisions.

Mr. HARRIS. Frankly, I don't study other Federal agencies, but this is according to——

Mr. GILMAN. This is the first agency that I've heard that has unpublished decisions.

Mr. HARRIS. Yes, sir. I think it's important to note again that the fact that there are unpublished opinions and published opinions is an issue that is decided by the courts. I believe that this is a rule of the courts, and I understand that courts are today looking at this issue of published versus unpublished opinions and may soon offer some comment on whether this practice that you're concerned about ought to continue in the future.

Mr. GILMAN. And the court has not approved your unpublished decision at this point. Is that right? The courts have not put their stamp of approval on unpublished decisions? Is that what you're telling us, that the issue is now in contention?

Mr. HARRIS. I'm saying that the courts have put their impression on published versus unpublished opinions, and in fact the ultimate decision in each of these cases is one that is made by the Special Master. So it's not the Justice Department that decides unilaterally that this case decision is not going to be published.

Mr. GILMAN. Now, let me follow this. We heard testimony that in settling a case, you told the claimant that you would settle the

case providing they agreed to the decision being an unpublished decision. Didn't that come from your Department?

Mr. HARRIS. I think that's mostly correct, except to say that this is not a settlement issue. It's an issue of whether we're going to appeal, and the issue really is——

Mr. GILMAN. Well, no, I'm not talking about the appeal now. I'm talking about your conditionality on the settlement.

Mr. HARRIS. It——

Mr. GILMAN. That you would settle a case, providing the claimant agreed that this would be an unpublished decision.

Mr. HARRIS. Yes, sir.

Mr. GILMAN. That seems to me to be putting a great deal of pressure on the claimant, so that the case law in that case would not be disclosed to other claimants.

Mr. HARRIS. And I would respectfully try to explain again that this really is not a settlement issue. It's an issue of whether we're going to appeal a decision that has already been made. In this case the Special Master made a decision that went against us that we did not agree with, we strongly disagreed with. And the issue was——

Mr. GILMAN. And because you disagreed with it, you didn't want it published. Is that correct?

Mr. HARRIS. Correct, because we felt that decision would interfere with and adversely affect the program objectives that Congress set forth, which is——

Mr. GILMAN. Does that excuse the agency for not publishing it because you felt that it was erroneous?

Mr. HARRIS. I say again, the agency doesn't publish any opinions. It's the courts that decide whether an opinion is published or not.

Mr. GILMAN. Right. And if you went to the court for a settlement, eventually that would be disclosed that there's been a settlement, but the court would disclose that. And yet you're refraining from allowing the court to publish your decision.

Mr. HARRIS. If we went to settlement and we settled a case, of course the courts would disclose that, unless the file was sealed. The only difference between——

Mr. GILMAN. Unless you requested it not be disclosed, which you did in this particular case that we heard earlier today.

Mr. HARRIS. What we in effect asked the court was that this decision not be permitted to be used as precedential value in future cases because we strongly disagree with it, and we thought that it would undercut the objectives of the act.

Mr. BURTON. Would the gentleman yield just a minute?

Mr. GILMAN. I'd be pleased to, Mr. Chairman.

Mr. BURTON. As I understand it, you sat down with Mrs. Barton and her family, and you said—your Department—here's what we'll do. We'll settle this, but you've got to sign the document, and the agreement is going to be that you're not going to request that it be published. That was given to the court, and the court decision then was this is a settlement, and it's not going to be published. Right?

Mr. HARRIS. The court's decision was that——

Mr. BURTON. But it was signed—it was agreed to and it was signed by her before it went to the court for the court to ratify it?

Mr. HARRIS. By her counsel, correct.

Mr. BURTON. Right. But the point is, it was a suggestion by the Justice Department to the court in writing that she had signed and agreed to, that it would not be published and that she would get a certain amount of money in the settlement?

Mr. HARRIS. Correct and——

Mr. BURTON. OK. But the point is this, she didn't want to do that, but in order to get the settlement, you hand the pen to her and you say, look, if you want the money and you don't want the appeal, then what we want you to do is we want you to sign this because we're going to give it to the court and it's going to be an order of the court saying we're paying this money and we're requesting that it not be published and you agree to that.

Mr. HARRIS. The option that the petitioner had in this case was, one, to jointly agree to petition the Special Master, that the decision be unpublished, the erroneous decision.

Mr. BURTON. And she signed it and——

Mr. HARRIS. It was jointly—that's correct.

Mr. BURTON. It went to the court and it was in the court order. It was in the court order then.

Mr. HARRIS. They just reissued the first——

Mr. BURTON. But I mean the court agreed to it and that was the court order and——

Mr. HARRIS. But——

Mr. BURTON. But the point Mr. Gilman and I are both making, and I think every Member of Congress would make the same thing, every Democrat or Republican, was that she wanted to get this thing settled. She was sick, had lupus. Her son had died. This had gone on for ad infinitum. The Special Master on two occasions said it should be paid. You didn't agree with that, and so you said, you sign this agreement and we'll give you the money, and the agreement is that you agree that it's not going to be published and the court will make the agreement that is in law, that the court agrees passes on.

Mr. HARRIS. I would only alter what the—your statement by saying that it was totally—that we actually approached this in a more considerate and compassionate way.

Mr. BURTON. Really?

Mr. HARRIS. Yes, and I would like to explain.

Mr. BURTON. How many years transpired between the first time the Special Master made a decision and you ended up agreeing to the settlement? How long a period was that?

Mr. HARRIS. I believe it was—the first—if you would repeat that.

Mr. BURTON. The Special Master made a recommendation it would be settled. When was that? What date?

Mr. EULER. That was in February. The final decision was issued in June.

Mr. BURTON. So it was about 4 or 5 months?

Mr. EULER. Right.

Mr. BURTON. And during that time it had been reviewed a second time by a Special Master and you went and reached an agreement?

Mr. HARRIS. Yes, sir.

Mr. BURTON. She was ill during that time, too. She had gone through 6 or 7 years of all this hell, and then she was told, this

is what it is going to be or we're going to continue to run this thing on for another year, 2, 3, 4 years or however long it takes, and that is compassionate?

Mr. HARRIS. Well, I would like to explain, if I could. We're aware of Mrs. Barton's condition, and obviously sympathetic to what had happened to her son. Congress charged us to administer this program and to ensure that compensation under this program is based on credible scientific evidence. That is the charge that we have from Congress.

Mr. BURTON. Credible scientific evidence. The Special Master said twice there was credible scientific evidence.

Mr. HARRIS. The same Special Master——

Mr. BURTON. Said twice.

Mr. HARRIS [continuing]. Looked at this, and we wanted a different level of appeal to—we wanted to take this to the Court of Federal Claims. So it did——

Mr. BURTON. Well, who in the Justice Department had this medical expertise that thought it should be appealed twice after a second opinion by the Special Master? Do you have somebody over there that has both a law and medical degree?

Mr. HARRIS. No.

Mr. BURTON. Because the Special Master made a decision. You wanted to rereview it. The Special Master reviewed it again. After looking at all the medical evidence and talking to experts, they made that decision. And then some lawyer over there said, well, we don't agree with that, so we're going to get somebody else in the medical profession to review it. Is that correct?

Mr. HARRIS. No.

Mr. BURTON. That's not what happened?

Mr. HARRIS. No, Mr. Chairman. Actually what happens is when there are issues involving very medically complex situations, as was the case here, because we don't have—as lawyers don't have the medical knowledge to make those kinds of determinations, we consult with a panel of doctors that have expertise in the area that are nationally renown and have great credentials, and they are concerned about the program's objectives, too, that nothing be done or decisions not be published that would hurt the objectives. That's to say that this kind of vaccine causes this kind of injury, because then folks might have a different view about taking the children to be vaccinated.

Mr. BURTON. Do any of those——

Mr. HARRIS. So we get that kind of information and rely on that medical expertise. In rare cases, as I said before, 2 out of maybe 200 a year, do we take this step.

Mr. GILMAN. Mr. Chairman, if I might reclaim my time, I'm not going to be able to return. Mr. Balbier, did you on behalf of HHS go to this kind of conditional settlement without disclosing the prohibited disclosure of the case determination? Did you agree to that?

Mr. BALBIER. Mr. Gilman, my understanding is that a—whether a decision is published or not——

Mr. GILMAN. No, I'm just asking you not what you consider, did you agree in this particular case that this decision would not be published? Were you consulted, and did you agree to that?

Mr. BALBIER. Yes, sir.

Mr. GILMAN. And was it because you're trying to protect the agency? Is that why you agreed to it?

Mr. BALBIER. We believed that the Special Master made a mistake in the decision, and this case had not gone to a judge.

Mr. GILMAN. Did you have any other cases of that nature where you have made that agreement?

Mr. BALBIER. There have been very few cases——

Mr. GILMAN. And were there other cases where you made such an agreement? Can you answer that yes or no?

Mr. BALBIER. To be real honest, I honestly don't remember whether a decision would be published or not coming up as a major issue in terms of whether we would settle a case or not. This case, as I understand it, was not really settled in the way that we normally think of settlements. This was decided by——

Mr. GILMAN. Will you provide to our committee the number of cases where you withheld the decisions for publication? Can you provide us with that following this hearing?

Mr. HARRIS. I don't think we can provide that information because all of these decisions are reached typically in informal settings, where there is no reporter, it's off the record. And because it's off the record, it's not reflected in any——

Mr. GILMAN. Well, I'm sure your Department has some record of these cases, and I'd like to ask you, with the chairman's indulgence, that you provide our committee with the number of cases where the decisions were not reported. Can you do that?

Mr. HARRIS. I would be happy to.

Mr. GILMAN. And I have one other question.

Mr. BURTON. We have about 7 minutes on the clock.

Mr. GILMAN. Yes. One other question. When you see that there's a bad lot of vaccines based on the cases coming before you, what do you do with regard to that? Do you report that to some agency? Do you try to do something to correct the bad lot? What does your Department do once you find there's a bad lot claimed?

Mr. HARRIS. We handle the legal issues, and maybe HHS is in a better position to answer questions about that.

Mr. GILMAN. Mr. Balbier, what do you do when there's a bad lot?

Mr. BALBIER. That comes under the jurisdiction of the Food and Drug Administration.

Mr. GILMAN. Oh, you mean once you people find there's a bad lot, you throw up your hands and say that's another agency?

Mr. BALBIER. No, sir. No, sir.

Mr. GILMAN. Well, what do you do when you find there's a bad lot of vaccines?

Mr. BALBIER. We have not found that there is a bad lot of vaccines.

Mr. GILMAN. We just heard some testimony today about a bad lot, and the case is based on a bad lot. Isn't that correct, Mr. Harris?

Mr. HARRIS. The first I heard of the issue of there being a bad lot of vaccine, clearly this is, to say the least, a very, very serious issue, and someone with proper jurisdiction should look into whether in fact there are.

Mr. BURTON. Well, we have that jurisdiction, and we're issuing a subpoena this afternoon on that. Let me just—I'm going to—

you're going to have to stay for a little bit because we have some more questions for you. I'll be back in about 10 minutes, but one of the questions I have to ask, Mr. Balbier, do you have any stock or do you have any financial interest at all in any pharmaceutical companies?

Mr. BALBIER. No, sir.

Mr. BURTON. You have none?

Mr. BALBIER. None.

Mr. BURTON. Have you ever had any?

Mr. BALBIER. No, sir.

Mr. BURTON. Never had any financial interest in any pharmaceutical company?

Mr. BALBIER. No.

Mr. BURTON. Do any of the people that you know of who are in the decisionmaking process at FDA or HHS own stock or have any financial interest of any type in any pharmaceutical company?

Mr. BALBIER. I can't answer that question.

Mr. BURTON. Have we subpoenaed all of those records from—OK. I want to issue a subpoena for all of the financial records of the top decisionmakers at HHS, too. OK.

We'll be back in just a minute. We stand in recess. I'll be back in about 10 minutes.

[Recess.]

Mr. BURTON. I know that you gentlemen have been here a long time, so I'm going to try to not belabor this. I would like to preface my questions. I just have a series of them for the record, and then we'll be finished, but I'd like to say that there's a great deal of suspicion, not just from this Congressman but from others about the connection between pharmaceutical companies and people who are making decisions in the various agencies in government, not necessarily the Justice Department, but you in the Justice Department are relying upon people in the health agencies for some of the decisions that you're making. Now, the RotaShield virus was a concern. It wasn't something that was really going to be that fatal, but they came up with a RotaShield vaccine, and as I said before, you probably heard me, the RotaShield vaccine was decided to be put into the marketplace by an advisory commission. Now, the advisory commission doesn't make the final decision. It's made by the FDA. But the FDA has never, ever, that we can find, turned their back on a decision made by the advisory commission. So in effect, the advisory commission makes the decision. The head of the advisory commission that put the RotaShield vaccine on the market, the head of that advisory commission, was a man who owns stock, a lot of stock in the company that made the RotaShield virus—vaccine, was in the process of doing that. There was a concern raised about it and not enough testing but they put it in the marketplace anyway. And the way they did it—I won't go into all of the details—in a year some children had died. Many others had been adversely impacted and they pulled it off of the market.

Now, the reason I bring that subject up is I hope you, Mr. Harris and Mr. Euler, at the Justice Department, will take a hard look at the connection between people at the health agencies who are involved in the decisionmaking process, who may have other reasons for taking positions that they do, especially in view of the Victims

Compensation Program. If you've got people out there who are having their kids dying or become autistic, or whatever the case may be, and you find that there's lots of vaccines, that according to—who was it? Ms. Dyer—that she found out that was a bad lot, and yet that cannot be made public. Why can't it be made public? Why was 200 or 300 people adversely impacted by that, other than maybe they didn't want that public, because the pharmaceutical company would have a black eye and it might hurt sales and it might hurt business? It might keep people from making a lot of money.

Now, I'm a free enterprise advocate, big time, you know, but not where health is concerned. If somebody is covering up or hiding information that may adversely impact the people of this country, then we've got to do something about it. Now, the Victims Compensation Fund that we established was supposed to be a way for people to get compensation from vaccine injuries without a lot of litigation, without any litigation really, but nevertheless we've gotten into that.

But the other end of it was that we were protecting pharmaceutical companies from liability suits. They said that they couldn't produce a lot of vaccines in bulk, because they had so many suits and they wanted to be protected. So we agreed in Congress that we would provide a mechanism for them to put money into a fund so there wouldn't be a lot of litigation, we'd protect them and we'd be able to take care of the public at the same time. It sounded like a winner for everybody. It has helped a lot of people, but it hasn't been perfect, and I still am suspicious and we have found—I have subpoenaed financial documents from people in the FDA, and we have found that there are conflicts of interest, that people have owned stock in pharmaceutical companies who were in decision-making positions. And that is something that I hope you'll look at, because it's your responsibility at the Justice Department to make sure these things are handled adequately and right, and we're going to continue to do that, but I think you really—we may disagree, but I think you're sincere that you want to do the right thing to help make sure people are compensated properly.

But if this gentlelady from Tennessee found that there was a bad lot and 200, 300 people were adversely affected by this vaccine, she did not get compensation. She cannot get information, except through the Freedom of Information Act, and there is a whole bunch of other information that is being withheld. It needs to be looked at, because if there was a bad lot and all those people were injured, they ought to be compensated. You see what I'm saying?

Mr. HARRIS. Yes. Yes, Mr. Chairman.

Mr. BURTON. I hope you'll——

Mr. HARRIS. And I am very sympathetic to your concern here, and I will take your statements back to my boss, who I'm sure will handle it appropriately.

Mr. BURTON. What I'd like to do is have Beth here and I, when we get this information, share it with you so that you can be a colleague, if you will, in trying to get to the bottom of this and make sure that everybody is being treated fairly. That would really help.

Now, Mr. Euler and Mr. Harris, let me ask you real quickly a few questions. Then I'll let you go have dinner and me, too. You've

heard Lori Barton's testimony. My staff discussed this case with you last week. Have you had a chance to review it?

Mr. EULER. Yes.

Mr. BURTON. You have had a chance to review it.

I'd like for each of you to tell me if you think the Justice Department handed that case appropriately. Do you think they did? And you know we've talked about this—or talked about this sometime now.

Mr. EULER. Yes, Mr. Chairman. I appreciate it. The case was very, very difficult medically. As I think has been pointed out, there was an alternative condition. Mr. Harris was able to pronounce the name of that condition, which essentially means a loss of white matter from the brain. So that was the central thing that made the case very difficult.

In the words of the Special Master, there were agonizing delays which weren't particularly anybody's fault. The petitioner had a difficult time getting records. The petitioner filed several motions for summary judgment, for example, and then in the middle of the case where we had this very difficult condition, which our medical evidence indicated was the real cause of the condition and it was not vaccine related, the child died. And as the Special Master pointed out, that created a new kind of case. It had to be reviewed from that sort of standard, and we moved it along as quickly as we could.

Now, I'm concerned about what was said concerning the cross-examination that occurred at the hearing. We do not condone confrontational cross-examination. Mr. Chairman, I hear you on that. This program has to have a human face, and I'd like to kind of, if I could, tell you what I try to do about that, if you have just a moment.

Mr. BURTON. Sure. No, no.

Mr. EULER. I know we're all busy. We start with the interview process. When we interview somebody coming into the program, we say this is different. Not every lawyer can handle this. This is a case that involves injured people who believe more seriously that they have an injury. You may have to ask some hard questions, but you will treat people with compassion, and you will treat them with courtesy and you will treat them with respect and empathy, because they are in fact people that have had a tragedy, and then the question is, can you do that, can you handle that?

So that is where it started. We repeat that all the time in the staff meetings. When we showed the staff a tape of your hearing last time—that was required for all of them to sit down and see the hearing that we had, I think it was in November, so that they could see what the issues were, so that they could see what the concerns were. And then if something is brought to my attention, I look into it.

Now, the Barton cross-examination was never brought to my attention. It was not reflected in the decisions. The Special Master never personally brought it to my attention, nor did petitioner's counsel. If they had, I would have looked into it at the time and I would have taken—and I say that because that's not what we're about.

Mr. BURTON. OK.

Mr. EULER. And that's what I tell my people.

Mr. BURTON. Well, the Special Master, though, to my knowledge never relented on the opinion that he had that this should have been a paid case?

Mr. EULER. That's correct. That's correct.

Mr. BURTON. So—and the one thing that was—I'm sure you relied at least in part on recommendations from the health agency as to whether or not this should be appealed?

Mr. EULER. Yes, sir.

Mr. BURTON. Well, in the future when you look at those cases, I hope you'll be a little—I don't mean to be suspicious, but I hope you'll be a little interested in whether or not there is an interest to an outside entity that may be involved. Now, if you find cases that might set a precedent where a vaccine injury might cause repercussions out there for an investment, a company that has an investment like a pharmaceutical company, you might look at that at least with a jaundiced eye before you make a decision, because after all of the hearings we've had and all of the research that we've done, Beth and others, and I am convinced that in some cases, not in all cases, but in some cases there is outside influence, and it's very unfortunate because it does have an adverse impact on a lot of people.

Now, you heard me read the remarks of the Special Master in that case, the Barton case, and you heard Lori Barton state that she felt she was being—well, we've already answered that. In fact, you've already answered that just now. Mr. Harris, you weren't around back in 1993. You're much too young for that. And Mr. Euler, were you supervising this office at that time?

Mr. EULER. I was.

Mr. BURTON. Oh, you were?

Mr. EULER. Yes, sir.

Mr. BURTON. And this matter was brought to your attention?

Mr. EULER. It was not until now.

Mr. BURTON. OK. Well, that answers that question.

Do either of you think that it's appropriate that the 4 years expired between one hearing and the next? That is an awful long time. Why did——

Mr. HARRIS. That is a long time, Mr. Chairman. I would like to——

Mr. BURTON. The child may be—you know, the next condition, succumb to it, I mean——

Mr. HARRIS. Right. I agree with and concur with everything that Mr. Euler just stated, but as the representative of the administration, I want to assure you that this administration is absolutely committed to making sure that your concerns about a compassionate program are addressed. And I wasn't here when these awful things happened to Mrs. Barton as she alleged during the course of her case proceedings, and the Department and the administration regrets that any program participant is ever treated in that way. And we will be certain to take measures in the future to ensure that this does not happen, because this is not something that we will tolerate in this administration.

Mr. BURTON. When we subpoena this information—and I hope you might do likewise, but if you don't, I will provide this to you

once we get the documentation. But when we subpoena information regarding the Tennessee case that we heard here today, if we can corroborate what has been said, I'd like for you to have that so you can look at that and find out why—if that was a bad lot and there were all those adverse events, why those cases weren't looked at in a little different light, because it wasn't just this case. But if there were several hundred, like she alleged—I think you said there were 200 or 300. How many?

Mrs. DYER. 246.

Mr. BURTON. 246 cases and it was from this same lot, the same lot number. That's something that should really be looked into, and we're going to subpoena that. And if you could do likewise or if you want to wait and we'll give it to you, we'd like for you to take a look at that as well.

Now, this is a tough question. Do you have any regrets about the Barton case, them having to choose between the opinion unpublished or facing that appeal?

Mr. HARRIS. Well, I'm glad you raised that issue. The regret that I have is that it caused additional trauma to a family that was already traumatized very, very personally in an unfortunate event. That I'm very sympathetic with.

I would like to clarify this distinction between an unpublished decision versus a public decision. An unpublished decision, first of all, there are courts throughout the land that frequently issue unpublished decisions, district courts in Virginia are courts not of record. There are no opinions on that. Second, the Special Masters under this program issue unpublished decisions in most of the cases that they decide on.

Mr. BURTON. Well, then why did that question even arise? Why would that even come up? If you thought it might not be published, why would you even say this is conditional upon this being an unpublished case?

Mr. HARRIS. Because the Special Master had decided to publish.

Mr. BURTON. OK. So the Special Master thought it was relevant for future cases, otherwise he wouldn't have requested it be published?

Mr. HARRIS. Correct.

Mr. BURTON. And so you've got to look at this. He had two reviews of it. He thought it should be published, because he wanted it to be a precedent?

Mr. HARRIS. Right.

Mr. BURTON. And you guys didn't agree, and you were concerned about that, and so you made the decision. So once again——

Mr. HARRIS. I think if we look at this fairly from both sides and go back to the Dyer case or any case where a Special Master makes a decision that is adverse to the petitioners, certainly we wouldn't want to foreclose their opportunity to appeal, and I don't think it's fair as a matter of justice to foreclose the opportunity for us to appeal when we're not satisfied with the Special Master decision.

Mr. BURTON. See, we have a difference of opinion, because this was supposed to be a program with a heart, where people who got a just settlement wouldn't have any concern, but people who didn't have a just settlement would have the right to appeal. That didn't necessarily mean in our opinion, and I don't think any Congress-

man, at least the ones I talked to, felt like the Justice Department ought to be fighting what was considered a just decision. So you're saying, well, it ought to be fair on both sides. I think in most cases that go before a court you're right, but in this particular case we're talking about people who need compassion, and we tried to protect the pharmaceutical companies as well as to show compassion. So the way we thought the compassion should be shown—and I remember all of these issues vividly when the legislation came up—was that they would get a just settlement. If there wasn't a just settlement, there would be an appeal process. But I don't think we envisioned that the Justice Department would be fighting people wanting to—you know, when a decision had been reached.

Mr. HARRIS. I understand that, Mr. Chairman, I really do, and I'm sure that our attorneys understand that as well, which is reflected in the extreme infrequency with which we petition the courts to make a decision that they've already decided should be made published to be unpublished. The effect is that an unpublished opinion does not have precedential value. It is available to the public.

Mr. BURTON. No. I understand.

Mr. HARRIS. So if someone wanted to find out what happened in this case——

Mr. BURTON. No. I understand.

Mr. HARRIS [continuing]. They could walk into the court——

Mr. BURTON. No. I understand. But a Special Master who was a judge in this case and had reviewed the case twice wanted it to be a precedent setting case, but you didn't. And where did you get the information that you used in saying that you might appeal it and that you didn't want it published? You got that information from the health agencies?

Mr. HARRIS. Not just the health agencies. In part, that is true. We get that from the health agencies, but in all fairness, there were anywhere from three to six cases, PVL cases prior to this one, where Special Masters had decided that this was not a condition——

Mr. BURTON. Caused by vaccination?

Mr. HARRIS. Correct. And so we have to consider that as well.

Mr. BURTON. No. I understand, but I hope you'll at least in the future, when you get these—if there's a case that's decided, let's say by a Special Master, and it's reviewed by a Special Master and then somebody at the health agency says, well, you know, we don't agree with that and you ought to take another look, and they try to convince you that it should be appealed, look at that real thoroughly because there may be other reasons why.

And Mr. Balbier, I have just two questions for you. Did you have a chance to review the Barton case?

Mr. BALBIER. No, I did not.

Mr. BURTON. Who in your agency made the recommendation that the case be appealed?

Mr. BALBIER. We——

Mr. BURTON. Didn't you make a recommendation or discuss this with the Justice Department people?

Mr. BALBIER. At the time the decision was made by the court, is that——

Mr. BURTON. No, no, before the court made the decision, didn't your agency recommend to the people at the Justice Department that were talking about an appeal, didn't you make some kind of a recommendation or give them some information about this?

Mr. BALBIER. Yes, sir. The way the process works is that's the very beginning of the process, is that one of our medical officers that work with the program reviews the case.

Mr. BURTON. After the Special Master made a decision?

Mr. BALBIER. Actually before. What we do is we provide recommendations to the Special Master——

Mr. BURTON. OK.

Mr. BALBIER [continuing]. For decision.

Mr. BURTON. Let's talk about this case. The Special Master, you gave him information, he reviewed it. He said it should be settled. He reviewed it again, because the Justice Department people said it should be reviewed. Evidently you had not convinced him. And he said, yes, it should still be paid.

Then you talked to the—or somebody from your agency talked to the Justice Department and said this should be appealed. Is that correct?

Mr. BALBIER. I do not remember the discussions on that particular case. I——

Mr. BURTON. Can you find out? Can you run the traps on that and get the information for us?

Mr. BALBIER. We can look at our records and go back and——

Mr. BURTON. Yeah. I'd like to find out what exactly transpired.

Mr. BALBIER. I can tell you—yes.

Mr. BURTON. And I understand what you're saying, at the beginning you give a recommendation based upon the information you have to the Special Master, but in this case he made a decision, maybe you didn't agree with it. The second time he reviewed it he made the decision you may not agree with. I want to find out if after that there was a recommendation made that there be an appeal directly to the Justice Department.

Mr. HARRIS. I think I can state for certain that HHS as our client, that the Justice Department work closely with HHS in the decision that you're concerned about, which is whether to stop the litigation, to forego the trauma and the pain and just to cut this short and have an unpublished decision. That was jointly discussed in consultation between Justice Department officials and HHS. And it's my understanding that officials at HHS rely heavily on medical experts that are familiar, in this case with PVL, when they make—and I know you're concerned—when they make this kind of a decision. So if the question was was there a consultation, the answer is yes.

Mr. BURTON. Medical experts, many of whom serve on advisory committees, who have financial interest in the pharmaceutical company, do they have a tainted view when they make those recommendations? Those are things I hope you'll look at in the future.

We normally don't do this, but Mrs. Barton, did you have something?

Mrs. BARTON. I just wanted to say that the second hearing on August 7, 1997 was the medical expert hearing, and during that hearing PVL, periventricular leukomalacia, was discussed between

both our medical expert and the respondent's medical expert at that hearing during that entire day with the Special Master there. So that was what the entire day was about, was about the PVL.

Mr. BURTON. OK. This was prior to the second decision made by the Special Master?

Mrs. BARTON. Yes. This was——

Mr. BURTON. And he still——

Mrs. BARTON. He was still alive, he was still alive at this point. This was the second hearing.

Mr. BURTON. OK. All right. Let me ask one more question. Even acknowledging the fact, Mr. Balbier, that there was some complicated issues involved, do you think this case was handled appropriately from the standpoint of the health agencies?

Mr. BALBIER. Well, again, Mr. Burton, we too would like to see the process made more expeditious, as much as it can be. That's exactly why we've proposed legislation to try to do that. So our goal has always been to try to get cases processed through the system just as quickly as we can. This case did take a long time. I wish it hadn't.

Mr. BURTON. Well, hopefully we'll——

Mr. BALBIER. We'd like to get them all handled much faster. It's a common goal that we all have.

Mr. HARRIS. Mr. Chairman——

Mr. BURTON. Let me—I'm sorry, go ahead.

Mr. HARRIS. If I could take a minute to clarify a couple of things on the record, I would appreciate it.

Mr. BURTON. Sure.

Mr. HARRIS. There has been much discussion about published and unpublished decisions in the context of a settlement, and I tried earlier to make clear that what we're talking about here is not a settlement. It's a decision on whether to appeal. And I think this is important, because in fact we do settle many cases that are processed through our program, and in none of those settlement cases is there any provision that the stipulations in the settlement provision should not be made public. We never do that, and I just wanted to be absolutely clear about that as a——

Mr. BURTON. But in this case——

Mr. HARRIS [continuing]. A practical matter.

Mr. BURTON [continuing]. The Special Master wanted it published but it was a condition of the settlement, according to Mrs. Barton. She had to sign that document saying that she would not request it be published in order for her to get that settlement.

Mr. EULER. That there would not have been a document.

Mr. BURTON. That there would not be an appeal.

Mr. EULER. There would have just been an informal arrangement between counsel, and we assumed counsel talked to her counsel——

Mr. BURTON. That was not in any document given to the court?

Mr. EULER. That's correct.

Mr. HARRIS. These are informal. Our attorneys sit down with the petitioner's attorney off the record in an informal setting. There's no arm-twisting.

Mr. BURTON. So there was nothing given to the judge saying—that was not requested by the Special——

Mr. HARRIS. A petition to the Special Master is a joint petition that both parties file with the Special Master.

Mr. BURTON. And did that document say that there would not be a request for publishing it?

Mr. EULER. Now, even that would have been by an informal status conference. In other words, the parties would have got on the telephone with the court and said we both agree that the opinion should not be published. I don't think there's——

Mr. HARRIS. There's no documentation where we——

Mr. EULER. So I just want to be——

Mr. BURTON. There's no paper trail to that, but the fact is the Special Master would request that it be published had it not been for this agreement?

Mr. EULER. We do appreciate your concern. As I mentioned to your staff, this is an issue we hadn't been aware of before, and we appreciate the concern.

Mr. BURTON. In looking at the level of research evidence on a possible causal connection between an injury and a vaccine, does HHS consider whether or not research was funded by the vaccine manufacturer, Mr. Balbier? When you're looking at the level of research evidence on a causal connection between an injury and a vaccine, does HHS consider whether or not the research was funded entirely or in part by the vaccine manufacturer?

Mr. BALBIER. Not to my knowledge. We don't look at actually how the research was funded. Most of the research is actually funded by the Federal Government, including——

Mr. BURTON. But——

Mr. BALBIER. Even CDC.

Mr. BURTON. But the vaccine manufacturers have funded a lot of this research?

Mr. BALBIER. Indeed they do.

Mr. BURTON. And they work with some of the people over there at HHS quite frequently in trying to solve problems, and they would have a fairly good relationship many times?

Mr. BALBIER. And research is peer reviewed and it's subject to the requirements of the journal that it's published in, and they're the ones that have responsibility for deciding what gets published, whether they're—and that sort of thing. We don't get involved in those decisions certainly.

Mr. BURTON. Is it true that the Finnish epidemiological study that the HHS uses to discount laboratory research by Dr. Wakefield that there's no connection between the MMR vaccine and autism was funded by the Merck Laboratories, or do you know the answer to that?

Mr. BALBIER. Well, I certainly have no special expertise in that area, but I can say that what I understand is that it would be absolutely impossible to prove from a scientific standpoint any sort of a negative assertion; so that's not something that would even be possible in science to prove that any vaccine cannot and absolutely cannot cause any particular injury.

Mr. BURTON. Well, but I think that's not my question. Maybe I didn't state it. I said is it not true that the Finnish epidemiological study that HHS uses to discount laboratory research by Dr. Wakefield that there is no connection between the MMR vaccine and au-

tism was funded by Merck? Do you guys know if it was funded by Merck?

Mr. BALBIER. I'm not aware, sir. I don't know.

Mr. BURTON. Well, I wish you would look into that if you would and give us an answer because according to the information we have is that it was funded by Merck through this Finnish epidemiological organization and that HHS is using that study as a reason to discount a lot of the assertions made by Dr. Wakefield and if it was funded by a pharmaceutical company that has a financial interest in discounting what he did, it's something that you guys ought to take a look at, and we'd like to know about because that's the information we have.

Let me just end up, I don't know if the gentlemen from HHS and the Justice Department want to apologize to you, Mrs. Barton, for what you had to go through but we certainly will and I'll leave it up to them. And to you, Mrs. Dyer, please forgive me for forgetting your name, but we will continue to pursue the information. We will issue that subpoena and we will get the information on that lot, and maybe 1 day there will be vindication for you. We don't know, but we'll sure look into it. And with that, thank you very much.

I'm sure that you, Mr. Balbier, Mr. Harris, and Mr. Euler will all get to know each other a lot better. Maybe I'll serve cookies and coffee the next time you come up, but we'll see you soon. Thank you very much. We stand adjourned.

[Whereupon, at 6:15 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 15 2002

The Honorable Dan Burton
Chairman
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Chairman Burton:

Thank you for the letter of December 19, 2001, to the Food and Drug Administration (FDA or Agency), requesting further information related to the Committee's ongoing investigation into vaccine safety.

Please note that this correspondence contains trade secret, commercial confidential, or other privileged information that, by law, is not releasable to the public. We request that the Committee not publish or otherwise make public any information in this letter. We would, of course, be glad to discuss with the Committee staff the confidentiality of any specific information.

Your questions have been restated, followed by our response.

1. **Copies of all Vaccine Adverse Event Reports on the following vaccine lots:**

   Lederle lot 322914 (DTP)
   SmithKline lot 839A2 (DTaP)
   Connaught lot 7H81507 (DTaP)

   Enclosed are print outs of the line listings of reports from the Vaccine Adverse Event Reporting System (VAERS) for the requested lots.

2. **The actual number of vaccines in each of the lots listed above.**

   The "actual number of vaccines" or doses in each of the lots is information that the manufacturer would have to provide. However, FDA can provide the following information that was received by the manufacturers about the number of doses distributed:

Manufacturer/Lot	Doses distributed
Lederle lot 322-914 (DTP)	230,070*
SmithKline lot 839A2 (DTaP)	234,467
Connaught lot 7H81507 (DTaP)	708,315

* Calculated from the following information provided by the manufacturer: release quantity of 15,338 vials, with each containing 15 doses.

3. **Copies of all correspondence between the FDA and the manufacturers regarding adverse events for the vaccines listed above.**

   The Agency was unable to identify or locate any correspondence between FDA and the manufacturers regarding adverse events reported to VAERS for the lots you have referenced.

   If any of the lots referred to were used in clinical trials conducted under an Investigational New Drug application (IND), it is possible that "correspondence between FDA and the manufacturers regarding adverse events" may be filed with the IND application. As you know, IND applications are voluminous and it would be extremely resource intensive to conduct such a review. If the Committee would like to pursue such a review, as in the past, we would be happy to make accommodations for your staff to review specific IND application files.

4. **Copies of all correspondence, memorandum, and reports between FDA and other HHS components regarding adverse events related to these lots.**

   The Agency was unable to locate any correspondence, memorandum or reports between FDA and other HHS components regarding adverse events for the lots you referenced.

Thank you again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives

VAERSID

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date

42769

1.3 M 23-Apr-1992 Rx@ 24-Apr-1992 1 17-Jun-1992 TN PUB-TN9256 15-Sep-1999

COSTARTS: FEVER/INFECT/LACRIMATION DIS/NAUSEA/OTITIS MED/VASODILAT/VOMIT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	RL	IM
	HIBV	LEDERLE(PRAXIS)	M210HK	3	LA	IM
	MMR	MSD	1898T	0	LL	SC
	OPV	LEDERLE	653B2	2		PO

SYMPTOM TEXT: Suddenly on 24APR92 early PM, mom took pt to ER w/c/o fever 104, pulling @ ears, n&v x 2; poss acute viral infect; pts face flushed; pos tears;

OTHER MEDS: TB skin test 23APR92

LAB DATA: WBC 6.4x 10 to 3rd power; hgb-11.0;

HISTORY: NONE

PREX ILLNESS: NONE

42779

1.3 F 07-May-1992 Rx@ 12-May-1992 5 17-Jun-1992 TN PUB-TN9266 15-Sep-1999

COSTARTS: HYSN INJECT SITE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	2	LA	
	HIBV	LEDERLE(PRAXIS)	M210HK	2	RA	
	MMR	MSD	1898T	1	LL	
	OPV	LEDERLE	0635B	2		PO

SYMPTOM TEXT: Rash @ site of inject occurred on or about may 12th;

PREVIOUS VAX ILL: NONE

OTHER MEDS: NONE

LAB DATA: NONE

HISTORY: NONE

PREX ILLNESS: NONE

42782

5.4 F 15-May-1992 Rx@ 16-May-1992 1 17-Jun-1992 TN PUB-TN9269 15-Sep-1999

COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/PAIN INJECT SITE/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	4	LA	IM
	MMR	MSD	1898T	1	RA	SC
	OPV	LEDERLE	0646D	4		PO

SYMPTOM TEXT: 5-6cm reddened area noted on lt deltoid surrounded by large amt of edema; area warm to touch; c/o very tender painful to touch;

VAERS ID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

42783
1.2 F 13-May-1992 Rx@ 13-May-1992 0 18-Jun-1992 TN PUB-TN9270 15-Sep-1999
COSTARTS: HYPOKINESIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LA	
HIBV	LEDERLE(PRAXIS)	M210HK	3	RA	
MMR	MSD	1898T	0	RA	SC
OPV	LEDERLE	0653B	2		PO

SYMPTOM TEXT: Pt has been walking for 2 wks a/vax; p/vax mom states pt stopped walking; pt bears wt & walks holding on & crawls, but not walking alone; pt taken to MD who felt wait 2 wks & if not walking will refer to neurologist;
PREX ILLNESS: NONE

42784
2.6 F 14-May-1992 Rx@ 14-May-1992 0 18-Jun-1992 TN PUB-TN9271 15-Sep-1999
COSTARTS: FEVER/HEADACHE/PAIN ABDO/PAIN NECK/PHARYNGITIS/SOMNOLENCE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	LA	
HIBV	LEDERLE(PRAXIS)	210HK	1	RL	
MMR	MSD	1898T	0	RA	
OPV	LEDERLE	0653B	1		PO

SYMPTOM TEXT: 14MAY92 fever 101 18MAY92 fever 101, sore throat, neckk hurting, h/a behind eyes, stomachache, lethargic; mom did not want pt to have further OPV;

42787
1.3 M 12-May-1992 Rx@ 14-May-1992 2 18-Jun-1992 TN PUB-TN9274 15-Sep-1999
COSTARTS: EDEMA/FEVER/INFECT/NO DRUG EFFECT/OTITIS MED/RASH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LL	IM
HIBV	LEDERLE(PRAXIS)	M210HK	3	LA	IM
MMR	MSD	1898T	0	RL	SC
OPV	LEDERLE	0653B	2		PO

SYMPTOM TEXT: 12MAY92 pt recvd vax 17MAY92 (evening) fever @ 101 R & neck swollen temp later inc 103 R; 15MAY92 seen by MD had sl red ears & gave Ceclor; 17MAY92 pt broke out w/rash on stomach, ears, face, neck & on 18MAY92; dx measles;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: 15MAY92 throat culture-neg;
HISTORY: NKDA
PREX ILLNESS: NONE

VAERSID

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date

42789

.3 M 18-May-1992 Rx@ 19-May-1992 1 18-Jun-1992 TN PUB-TN9276 15-Sep-1999

COSTARTS: MASS INJECT SITE/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	LL	IM
HIBV	LEDERLE(PRAXIS)	M210HK	1	RL	IM
OPV	LEDERLE	320933	1		PO

SYMPTOM TEXT: 4 cm non-tender, non fluctuant mass in lt thigh; no heat; (report from MD); 4JUN92 knot lasted 2 wks; MD told mom this was "nl" rxn;

LAB DATA: NONE

HISTORY: allergic to milk & soy formula

PREX ILLNESS: NONE

42791

.2 M 02-Jun-1992 Rx@ 02-Jun-1992 0 18-Jun-1992 TN PUB-TN9278 15-Sep-1999

COSTARTS: EDEMA INJECT SITE/SCREAMING SYND/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	RL	IM
HIBV	LEDERLE(PRAXIS)	M130HJ	0	LL	IM
OPV	LEDERLE	320933	0		PO

SYMPTOM TEXT: Mom called 3PM stating pt had very large amt swelling on leg & had not stopped crying since shot given;

HISTORY: NONE

PREX ILLNESS: NONE

43246

2.0 M 01-May-1992 Rx@ 01-May-1992 0 02-Jul-1992 NY PUB-NYS92026 15-Sep-1999

SERIOUS: Hospitalized(1)

COSTARTS: FEVER/TREMOR/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LL	
OPV	LEDERLE	316946	2		PO

SYMPTOM TEXT: Pt recvd vax approx 1030AM & approx 1230 shaky, t102 as precautionary measure; MD adm to hosp for 1 day observation; exam revealed ear infect; pt improved p/receiving antibiotics;

HISTORY: NONE

PREX ILLNESS: ear infect

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

43499
5.1 M 02-Jul-1992 Rx@ 02-Jul-1992 0 16-Jul-1992 NJ PUB- 15-Sep-1999
COSTARTS: ASTHENIA/PALLOR/SWEAT/SYNCOPE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	4	LA	IM
	OPV	LEDERLE	0647D	4		PO

SYMPTOM TEXT: apparent vaso-vagal reaction 5 to 10 minutes p/recvd DTP inject; pt became very pale, sweaty, appeared weak but did not lose consciousness, vomit, nor have a sz; pt taken to hosp ER;
HISTORY: NONE
PREX ILLNESS: NONE

43720
.2 F 13-Jun-1992 Rx@ 13-Jun-1992 0 29-Jul-1992 ID PUB-ID92036 15-Sep-1999
COSTARTS: AGITATION/CRY ABNORMAL/EDEMA INJECT SITE/FEVER/HYSN INJECT SITE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	0	RL	IM
	HIBV	LEDERLE(PRAXIS)	M575HJ	0	LL	IM
	OPV	LEDERLE	0645C	0		PO

SYMPTOM TEXT: Approx 4 hrs p/pt recvd vax awoke w/an unusual high-pitch cry, sl elevated temp & very agitated; this episoded last approx 1 hr & mom took pt to pvt MD; pt rt thigh extremely red, swollen;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

43723
5.2 F 18-May-1992 Rx@ 20-May-1992 2 29-Jul-1992 ID PUB-ID92039 15-Sep-1999
COSTARTS: FEVER/PHARYNGITIS/RASH VESIC BULL/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	4	LA	IM
	IPV	MERIEUX INST	30100	3	LA	SC
	MMR	MSD	1349T	1	RA	SC

SYMPTOM TEXT: 20MAY92 pt devel an elevated temp & a blister formed on lt shoulder; blister size approx 2" in diameter; no itching; c/o sore throat-no difficulty breathing or swallowing;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

43726
1.3 F 24-Jun-1992 Rx@ 24-Jun-1992 0 29-Jul-1992 ID PVT-ID92042 15-Sep-1999
COSTARTS: AGITATION/CONVULS/FEVER/HYPERKINESIA/STUPOR/TREMOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	LL	IM
	HIBV	LEDERLE(PRAXIS)	M575HJ	3	RL	IM
	MMR	MSD	1157T	1	A	SC
	OPV	LEDERLE	0657H	2		PO

SYMPTOM TEXT: pt recvd vax 24JUN92 @ 1200; arrived ER 0325 25JUN92 febrile-104 R, 3 tonic clonic vs coarse tremor episodes; prior to arrival in ER; pt sent home w/instructins & APAP suppositories-further sz activity noted;
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

43727
.4 F 04-May-1992 Rx@ 04-May-1992 0 29-Jul-1992 ID PVT-ID92043 15-Sep-1999
COSTARTS: AGITATION/CRY ABNORMAL/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	OPV	LEDERLE	0645C	1		PO
	DTP	LEDERLE	322914	1	RL	IM
	HIBV	LEDERLE(PRAXIS)	M660HH	1	LL	IM

SYMPTOM TEXT: 4MAY92 approx 2 hrs p/vax pt devel high pitched crying; lasting approx 2 days; occurred approx q 4 hrs;
PREVIOUS VAX ILL: pt exp rxn p/1st DTP on 31JAN92 high pitched crying;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

43903
.2 M 24-Jul-1992 Rx@ 26-Jul-1992 2 05-Aug-1992 TN PUB-TN9292 15-Sep-1999
SERIOUS: Died
COSTARTS: APNEA/HEART ARREST/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914		LL	
	HIBV	LEDERLE(PRAXIS)	M210HK		RL	
	OPV	LEDERLE	0646E			PO

SYMPTOM TEXT: Mom fed pt @ 230AM; awoke 3-4 hrs later & found pt w/o pulse & or respirations; No CPR done;
OTHER MEDS: NONE
LAB DATA: Autopsy;
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date

44086

1.6 F 17-Jul-1992 Rx@ 17-Jul-1992 0 11-Aug-1992 NY PUB-NY92042 15-Sep-1999

COSTARTS: ECCHYMOSIS/EDEMA INJECT SITE/HYPOKINESIA/HYSN INJECT SITE/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	RL	
HIBV	LEDERLE(PRAXIS)	M145HH	3	LL	
OPV	LEDERLE	316946	2		PO

SYMPTOM TEXT: 17JUL92 mom called c/o redness, edema, ecchymosis of 1PM; rt thigh where DTP inject was given; pt does not want to use leg;

PREVIOUS VAX ILL: NONE

OTHER MEDS: NONE

LAB DATA: NA

HISTORY: NONE

PREX ILLNESS: NONE

44131

.3 F 27-Apr-1992 Rx@ 27-Apr-1992 0 13-Aug-1992 VA PUB-VA92081 15-Sep-1999

COSTARTS: EDEMA INJECT SITE/FEVER/HYSN INJECT SITE/MASS INJECT SITE/VOMIT/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	LL	IM
HIBV	LEDERLE(PRAXIS)	N210HK	1	RL	IM
OPV	LEDERLE	320950	1		PO

SYMPTOM TEXT: Pt recvd DTP 27APR92 had fever to 101-102 next 2 days & vomited, swelling noted w/in 24 hrs w/small area of redness & induration which gradually inc up to 1MAY92 inject site; small nodule & mild dimpling skin noted when last seen 1JUN92;

OTHER MEDS: Dicloxacillin

LAB DATA: WBC-10,100 w/20 segs, 76 lymphs, 1 mono, 2 EOS 1band

HISTORY: NONE

PREX ILLNESS: NONE

44328

.3 F 24-Jul-1992 Rx@ 24-Jul-1992 0 21-Aug-1992 NJ PUB-NJ9218 15-Sep-1999

COSTARTS: CRY ABNORMAL/FEVER/SCREAMING SYND/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	RL	IM
HIBV	LEDERLE(PRAXIS)	M155HJ	0	LL	IM
OPV	LEDERLE	0654H	0		PO

SYMPTOM TEXT: Mom stated pt had shrill cry for approx 2 1/2 day p/vax; t100;

PREVIOUS VAX ILL: pt's sibling exp severe crying w/DTP

OTHER MEDS: Bactrim

HISTORY: genito urinary tract reflux-on Bactrim

PREX ILLNESS: rash chicken pox

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

44351
1.6 F 05-Aug-1992 Rx@ 05-Aug-1992 0 24-Aug-1992 NJ PUB-NJ9219 15-Sep-1999
COSTARTS: AGITATION/CRY ABNORMAL/MYALGIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	LA	IM
	OPV	LEDERLE	0654H	2		PO

SYMPTOM TEXT: Pt given APAP then backed into a corner & screamed unconsolably for approx 1 hr fell asleep on moms lap for 1-hr-then awoke & screamed unconsolably for 2 more hrs; screaming subsided 1/2 hr p/2nd dose of APAP; no local rxn x/sore arm;
LAB DATA: NONE
HISTORY: tx w/Amox x 4 wks for lymes disease 14JUN92;
PREX ILLNESS: NONE

44386
.6 F 13-Aug-1992 Rx@ 14-Aug-1992 1 24-Aug-1992 TX PUB- 15-Sep-1999
COSTARTS: DYSPNEA/EYES GAZE UPWARD/HYPERTONIA/TREMOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	1		
	HIBV	LEDERLE(PRAXIS)	M070HP	1		
	OPV	LEDERLE	0653F	1		PO

SYMPTOM TEXT: 14AUG92 according to pts mom @ approx 850AM pt began shaking; mom picked up the ashking subsided w/in 5 mins pt becam rigid, eyes rolled back & resp were labored; this episode lasted approx 2-3 mins;
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

44480
.2 M 28-May-1992 Rx@ 28-May-1992 0 25-Aug-1992 TN PUB-TN9279 15-Sep-1999
COSTARTS: CRY ABNORMAL/FEVER/HYPOTONIA/PALLOR/SCREAMING SYND/SOMNOLENCE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	0	LL	IM
	HIBV	LEDERLE(PRAXIS)	M210HK	0	RL	IM
	OPV	LEDERLE	320953	0		PO

SYMPTOM TEXT: following vax 28MAY92 pts t1-3 ran fever 103-104.6 ax for 3 days; slept continuously until next AM; cried high pitched cry for 8 hrs; appeared limp;
OTHER MEDS: Ceclor
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: cough, sl rhinitis-ear infect 2wks ago

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

44483
1.6 M 04-Jun-1992 Rx@ 04-Jun-1992 0 25-Aug-1992 TN PUB-TN9282 15-Sep-1999
COSTARTS: FEVER/REACT AGGRAV/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	RA	IM
OPV	LEDERLE	320933	2		PO

SYMPTOM TEXT: seizures oqcuring approx 1 hr p/vax; mom states no MD visit was made; pt called MD for guidance; high fever 104-105 precipitated mom thinks; states MD told probably should suggest DT;
PREVIOUS VAX ILL: NONE
OTHER MEDS: Phenobarbital
LAB DATA: NONE related to event-CAT Scan, EEG had been done prior to vax;
HISTORY: NKA; seizures since NOV91;
PREX ILLNESS: NONE

44484
5.7 M 25-Jun-1992 Rx@ 25-Jun-1992 0 25-Aug-1992 TN PUB-TN9283 15-Sep-1999
COSTARTS: PALLOR/STUPOR/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	4	LA	IM
MMR	MSD	2028T	1	RA	SC
OPV	LEDERLE	0648M	4		PO

SYMPTOM TEXT: pt became pale, hands clutched to sternum head back eyes open; no response to verbal stimuli;
PREVIOUS VAX ILL: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

44486
.2 F 02-Jul-1992 Rx@ 02-Jul-1992 0 25-Aug-1992 TN PUB-TN9285 15-Sep-1999
COSTARTS: CYANOSIS/HYPERTONIA/PALLOR/SALIVA INC/TWITCH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	
HIBV	LEDERLE(PRAXIS)	M210HK	0	RL	
OPV	LEDERLE	653B	0		PO

SYMPTOM TEXT: stiffness & jerking of both arms-slobbering from mouth, lasting only few minutes; arms, legs, feet & hands turned blue; face turned very white-seen by MD;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

44490
1.3 F 19-Jun-1992 Rx@ 19-Jun-1992 0 25-Aug-1992 TN PUB-TN9289 15-Sep-1999
COSTARTS: FEVER/MALAISE/VOMIT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3		IM
HIBV	LEDERLE(PRAXIS)	M210HK	3		IM
MMR	MSD	1662T	0		SC
OPV	LEDERLE	0648M	2		PO

SYMPTOM TEXT: pt recvd vax 19JUN92 in AM by 3PM started running temp, vomiting; pt given Pedialyte which did not work; t104 ax; took to ER 9PM that noc was lifeless acting, vomiting; given APAP supp/Phenegan supp; next day fine;
PREVIOUS VAX ILL: pt screaming @ 2mos w/DTP #1 dose
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: diaper rash

44492
1.3 M 10-Jul-1992 Rx@ 18-Jul-1992 8 25-Aug-1992 TN PUB-TN9291 15-Sep-1999
SERIOUS: Hospitalized(2)
COSTARTS: APNEA/CONVULS/FEVER/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LL	IM
HIBV	LEDERLE(PRAXIS)	M210HK	3	RL	IM
MMR	MSD	0118V	0	RA	SC
OPV	LEDERLE	0658E	2		PO

SYMPTOM TEXT: 18JUL, eight days p/vax pt seizured & quit breathing; was hospitalized & observed until fever subsided; was dc'd 19JUL on Ceclor & to have follow up w/MD;
PREVIOUS VAX ILL: NA
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

44496
.2 M 10-Jun-1992 Rx@ 10-Jun-1992 0 26-Aug-1992 TN PUB-TN9296 15-Sep-1999
COSTARTS: AGITATION/CRY ABNORMAL/EDEMA INJECT SITE/HYSN INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	IM
HIBV	LEDERLE(PRAXIS)	M210HK	0	RL	IM
OPV	LEDERLE	0642A	0		PO

SYMPTOM TEXT: Approx 4 hrs p/vax lt thigh became red, swollen & hot; pt began crying a high pitch cry for over 1 hr until pt was carried to MD & got a shot to reduce swelling; cried about 30 mins longer; no fever; slept all noc & leg was down & OK;
PREVIOUS VAX ILL: NA
HISTORY: NONE
PREX ILLNESS: NONE

44769
5.3 M 25-Aug-1992 Rx@ 25-Aug-1992 0 10-Sep-1992 VA PUB-VA92086 14-Sep-1999
COSTARTS: FEVER/HEADACHE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	4	LA	IM
MMR	MSD	0272V	1	RA	SC
OPV	LEDERLE	326956	3		PO

SYMPTOM TEXT: 25AUG92 4PM h/a, fever 101 as evening progressed fever 105, mom giving APAP & cool water baths; phoned MD 26AUG92-MD prescribed APAP, Pediform; temp dropped 101 then to 98.6;
OTHER MEDS: NONE
HISTORY: Mediterranean anemia
PREX ILLNESS: NONE

44928
1.5 M 07-May-1992 Rx@ 14-May-1992 7 16-Sep-1992 TN PUB-TN9297 14-Sep-1999
COSTARTS: FEVER/PRURITUS/RASH/RHINITIS/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	2	RA	IM
MMR	MSD	1898T	0	LA	SC
OPV	LEDERLE	0653B	2		PO

SYMPTOM TEXT: mom reports fever, runny nose @ 7 days p/MMR: On 3rd day of fever rash appeared in face & spread down to cover entire body; fever d/c p/rash appeared; mom used Caladryl to control itching;
OTHER MEDS: UNK
LAB DATA: neg Koplik's; EENT unremarkable;
HISTORY: down's synd
PREX ILLNESS: NONe

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

44929
1.3 M 22-Apr-1992 Rx@ 29-Apr-1992 7 16-Sep-1992 TN PUB-TN9298 14-Sep-1999

COSTARTS: CONVULS/FEVER/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	RA	IM
HIBV	LEDERLE(PRAXIS)	M21HR	3	LL	IM
MMR	MSD	1898T	0	LA	SC
OPV	LEDERLE	0653B	2		PO

SYMPTOM TEXT: sz on 29APR92; no know fever; temp in ER 100.6 R; had serous otitis; tx w/Augmentin; referred to ENT 7 neuro; seen @ ER;
OTHER MEDS: PPD given 22APR92; Septra since MAR92;
LAB DATA: CBC, Chem 10, serum Ca; mom said EEG & CT Scan were nl;
HISTORY: LOM of 22APR92 was treated w/Amoxicillin; rash consistant w/viral exanthem 22APR92; PMH OM MAR92;
PREX ILLNESS: mom c/o subjective fever x 2 days; LOM;

44930
4.8 M 13-Jul-1992 Rx@ 01-Aug-1992 19 16-Sep-1992 TN PUB-TN9299 14-Sep-1999

SERIOUS: Hospitalized()
COSTARTS: CONVULS/EYES GAZE UPWARD/HYPERTONIA/TREMOR/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	RA	IM
MMR	MSD	2028T	1	LA	SC
OPV	LEDERLE	0656C	3		PO

SYMPTOM TEXT: sz x 2 1AUGu92; initial sz witnessed by mom eyes rolled back & shaking all over; 2nd sz seen by RN eyes rolled back, extremities rigid;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: CT Scan performed through ER
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

44931
1.0 F 06-Aug-1992 Rx@ 06-Aug-1992 0 16-Sep-1992 TN PUB-TN92100 14-Sep-1999
COSTARTS: AGITATION/ALLERG REACT/FEVER/INSOMNIA/RASH MAC PAP/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	RA	
HIBV	LEDERLE(PRAXIS)	M155JA	1	LA	
OPV	LEDERLE	0653B	1		PO

SYMPTOM TEXT: mom phoned 13AUG92 states pt has rash big red patches all over body; rash, fever that will not go away even when APAP is given; also reports pt does not sleep @ noc since vax; on 6AUG92 parent informed to take tp to Er immed;
HISTORY: NONE
PREX ILLNESS: NONE

44932
1.9 F 17-Aug-1992 Rx@ 17-Aug-1992 0 16-Sep-1992 TN PUB-TN92101 14-Sep-1999
COSTARTS: CRY ABNORMAL/SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LL	
HIBV	LEDERLE(PRAXIS)	M210HK	3	RL	
MMR	MSD	0456V	0	RA	
OPV	LEDERLE	0658E	2		PO

SYMPTOM TEXT: according to mom pt cried high pitch cry x 3 hrs ending 8PM when pt cried self to sleep;
PREVIOUS VAX ILL: NONE
LAB DATA: NA
HISTORY: NONE
PREX ILLNESS: NONE

44933
.5 F 19-Aug-1992 Rx@ 19-Aug-1992 0 16-Sep-1992 TN PUB-TN92102 14-Sep-1999
COSTARTS: AGITATION/ANOREXIA/CRY ABNORMAL/NERVOUSNESS/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	2	RL	IM
HIBV	LEDERLE(PRAXIS)	M155JA	2	LL	IM

SYMPTOM TEXT: awakened from nap & was playing then got a little restless then began having period of high pitched crying for about 1 hr; refused nursing; mom took to MD;
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

44934
1.3 F 19-Aug-1992 Rx@ 20-Aug-1992 1 16-Sep-1992 TN PUB-TN92103 14-Sep-1999
COSTARTS: FEVER/HYSN INJECT SITE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LL	
HIBV	LEDERLE(PRAXIS)	M155JA	3	RL	
MMR	MSD	2028T		RA	
OPV	LEDERLE	320933	2		PO

SYMPTOM TEXT: t103 ax, red legs @ site of administration seen by MD who ordered DPH;
HISTORY: NONE
PREX ILLNESS: NONE

44995
.6 M 24-Jul-1992 Rx@ 30-Jul-1992 6 17-Sep-1992 ID PUB-ID92054 14-Sep-1999
COSTARTS: ABSCESS INJECT SITE/HYSN INJECT SITE/MASS INJECT SITE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	LL	IM
HIBV	LEDERLE(PRAXIS)	M575HJ	1	RL	IM
OPV	LEDERLE	0653H	1		PO

SYMPTOM TEXT: On 30JUL92 pt was seen by MD & on lt anterior thigh was noted an indurated area approx 2 cm w/erythema approx 1.5cm & dx as an abscess; Ceclor prescribed;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

44996
.2 M 06-May-1992 Rx@ 06-May-1992 0 17-Sep-1992 ID PUB-ID92055 14-Sep-1999
COSTARTS: SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	IM
HIBV	LEDERLE(PRAXIS)	M660HH	0	RL	IM
OPV	LEDERLE	0645C	0		PO

SYMPTOM TEXT: following the administration of 1st vax, that evening pt cried unconsolably for 3 hrs; pt was taken to ER where was observed for an hr & given some pain reliever & sent home w/mom;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

45448

.3 M 10-Jun-1992 Rx@ 10-Jun-1992 0 25-Sep-1992 ID PUB-ID92059 14-Sep-1999

COSTARTS: AGITATION/CRY ABNORMAL/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	1	LL	IM
	HIBV	LEDERLE(PRAXIS)	M575HJ	1	RL	IM
	OPV	LEDERLE	0645C	1		PO

SYMPTOM TEXT: pt had an unusual high pitch cry & was unconsoleable for 9 hrs;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

45535

1.8 F 18-Jun-1992 Rx@ 18-Jun-1992 0 28-Sep-1992 TN PVT-TN92105 14-Sep-1999

COSTARTS: AGITATION/CRY ABNORMAL/FEVER/SCREAMING SYND/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	LL	
	MMR	MSD	2028T	0	RL	
	OPV	LEDERLE	320933	2		PO

SYMPTOM TEXT: t105 ax, very irritable high pitched scream all noc;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONe
LAB DATA: NA
HISTORY: NONE
PREX ILLNESS: NONE

45536

1.4 F 19-Aug-1992 Rx@ 19-Aug-1992 0 28-Sep-1992 TN PUB-TN92106 14-Sep-1999

COSTARTS: MASS INJECT SITE/SKIN DIS/SKIN DISCOLOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	LA	IM
	HIBV	LEDERLE(PRAXIS)	155JA	3	LL	IM
	MMR	MSD	0456V	0	RA	SC
	OPV	LEDERLE	0658E	2		PO

SYMPTOM TEXT: today, pt has 1" long x 1/2" wide hardened area inside lt deltoid area where DTP was given;
non-tender; skin over area darkened w/dimpling; mom states the area no larger; has been rubbing it w/alcohol;
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

45540
1.3 F 25-Aug-1992 Rx® 25-Aug-1992 0 28-Sep-1992 TN PUB-TN92110 14-Sep-1999
COSTARTS: FEVER/SCREAMING SYND/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	LA	
	HIBV	LEDERLE(PRAXIS)	M155JA	3	RL	
	MMR	MSD	0456V	0		SC
	OPV	LEDERLE	0653B	2		PO

SYMPTOM TEXT: t104.0 R APAP would not reduce x/sl; cried all noc;
PREVIOUS VAX ILL: NA
OTHER MEDS: APAP
HISTORY: NONE
PREX ILLNESS: NONe

45542
.2 F 15-Sep-1992 Rx® 17-Sep-1992 2 28-Sep-1992 TN PUB-TN92112 14-Sep-1999
COSTARTS: AGITATION/HYPERTONIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	0	LL	IM
	HIBV	LEDERLE(PRAXIS)	M155JA	0	RL	
	OPV	LEDERLE	0653K	0		

SYMPTOM TEXT: 415PM pt awoke crying; mom attempted to feed, but pt's head drawn to left pt's whole body bowing to left;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: CBC & EEG to be done today;
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

45843
.4 F 08-Jun-1992 Rx@ 08-Jun-1992 0 01-Oct-1992 NJ PUB-NJ9223 14-Sep-1999
COSTARTS: CRY ABNORMAL/FEVER/SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	
HIBV	LEDERLE(PRAXIS)	M175HH	0	RL	
OPV	LEDERLE	318941	0		PO

SYMPTOM TEXT: pt had fever of 101 x 24 hrs & high pitched cry x 48 hrs; pvt MD notified & recommended that pt receive only DT; pt back to nl p/48 hrs according to mom;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: functional heart murmur @ birth;
PREX ILLNESS: NONE

45845
5.6 M 26-Aug-1992 Rx@ 26-Aug-1992 0 01-Oct-1992 NY PUB-NY92047 14-Sep-1999
SERIOUS: Hospitalized(4)
COSTARTS: EDEMA/FEVER/INFECT/PAIN/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	4	LA	IM
MMR	MSD	0228V	1	RA	SC
OPV	LEDERLE	0648C	3		PO

SYMPTOM TEXT: 26AUG92 evening t102 lt arm tender & sore; 27AUG92 t39.9 lt arm extremely swollen w/yellow drainage;
OTHER MEDS: NONE
LAB DATA: BC-neg; CBC-nl;
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

45848
1.4 F 31-Aug-1992 Rx@ 10-Sep-1992 10 01-Oct-1992 NY PUB-NY92050 14-Sep-1999
COSTARTS: FEVER/INFECT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	LA	IM
	HIBV	LEDERLE(PRAXIS)	M145H	3	RA	IM
	MMR	MSD	M1754T	0	RA	SC
	OPV	LEDERLE	0653H	2		PO

SYMPTOM TEXT: pt began to be febrile to 102 on adverse onset date & temp to 104 inthe PM; mom administering APAP advised to contact MD: MD felt it was a viral infect per mom;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

45892
.2 M 31-Jul-1992 Rx@ 31-Jul-1992 0 05-Oct-1992 NJ PUB-NJ9224 14-Sep-1999
COSTARTS: FEVER/SCREAMING SYND/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	0	LL	
	HIBV	LEDERLE(PRAXIS)	M155HJ	0	RL	
	OPV	LEDERLE	0651E	0		PO

SYMPTOM TEXT: prolonged excessive crying-3hrs, t102 for 3 days;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

46020
.2 F 22-Sep-1992 Rx@ 08-Oct-1992 NY PVT- 14-Sep-1999
SERIOUS: Died
COSTARTS: REACT UNEVAL/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	0	RL	
	HEP	MSD	1062V	1	RA	
	HIBV	LEDERLE(PRAXIS)	M605JD	0	LL	
	OPV	LEDERLE	324938	0		PO

SYMPTOM TEXT: ? unk notified by CPS of pt's death;
OTHER MEDS: APAP
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

46084
5.0 F 08-Sep-1992 Rx@ 09-Sep-1992 1 12-Oct-1992 NY PUB-NY92054 14-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	4	RA	
MMR	MSD	0272V	1	RA	
OPV	LEDERLE	316946	3		PO

SYMPTOM TEXT: rt upper arm was swollen Wednesday & Thursday & today Friday is not swollen, but very warm to touch & red; mom not aware of fever;
LAB DATA: NONE
PREX ILLNESS: NKO

46376
.4 M 18-Sep-1992 Rx@ 18-Sep-1992 0 27-Oct-1992 TN PUB-TN92115 14-Sep-1999
COSTARTS: CONVULS/MYDRIASIS/STUPOR/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	IM
HIBV	LEDERLE(PRAXIS)	M605JD	0	RL	IM
OPV	LEDERLE	0661F	0		PO

SYMPTOM TEXT: 4 hrs p/vax mom noted pt to have dilated pupils, fixed gaze & was unresponsive; this lasted for about 1 minute; pt was taken to hosp where ER MD told mom the pt may have had a petit mal sz; no fever, no screaming;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

46378
2.5 F 28-Sep-1992 Rx@ 29-Sep-1992 1 27-Oct-1992 TN PUB-TN92117 14-Sep-1999
COSTARTS: FEVER/URTICARIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LL	IM

SYMPTOM TEXT: mom phoned in stating pt had whelps & t101 this AM; recvd DTP on 28SEP92; referred to pvt MD: uticara lasted 35 mins;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: allergic to Sulfa drugs, Augmentin, Erythromycin
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

47142
5.3 F 01-Oct-1992 Rx@ 21-Oct-1992 20 19-Nov-1992 NY PUB-NY92059 14-Sep-1999
COSTARTS: FEVER/INFECT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	4	LA	IM
	MMR	MSD	1754T	1	RA	SC
	OPV	LEDERLE	0648C	3		PO

SYMPTOM TEXT: recvd MMR #2 on 10OCT92 approx 3 wks post vax; pt sent home from school w/fever 103;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

47325
1.6 F 23-Oct-1992 Rx@ 23-Oct-1992 0 25-Nov-1992 ID PUB-ID92068 14-Sep-1999
COSTARTS: AGITATION/FEVER/SCREAMING SYND/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	1	RL	IM
	HIBV	LEDERLE(PRAXIS)	M135JA	1	LL	IM
	MMR	MSD	1371T	0	LL	SC
	OPV	LEDERLE	0657H	1		PO

SYMPTOM TEXT: pt cranky, non-stop crying when awake; has had 3 naps; t101; APAP for fever; 26OCT92 feeling much better; crying lasted approx 12 hrs; telephone consult w/pvt MD no interventions;
PREVIOUS VAX ILL: NA
OTHER MEDS: NA
LAB DATA: NA
HISTORY: NA
PREX ILLNESS: NA

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

47370
5.5 M 25-Aug-1992 Rx@ 25-Aug-1992 0 30-Nov-1992 TN PUB-TN92137 14-Sep-1999
COSTARTS: FEVER/INSOMNIA/MYALGIA/VOMIT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	4	RA	IM
	MMR	MSD	1898T	1	LA	SC
	OPV	LEDERLE	0659F	4		PO

SYMPTOM TEXT: pt recvd call on 26AUG92 from pt's cousin; stated starting fever not long p/leaving clinic then was up all noc w/vomiting & fever of 102; took pt to MD who prescribed an antispasmmodic & told them pt reacted to vax; pt rt arm was also sore;
PREVIOUS VAX ILL: NA
LAB DATA: UNK
HISTORY: NONE
PREX ILLNESS: NONE

47371
1.3 M 29-Sep-1992 Rx@ 29-Sep-1992 0 30-Nov-1992 TN PUB-TN92138 14-Sep-1999
COSTARTS: AGITATION/FEVER/HYSN INJECT SITE/MASS INJECT SITE/REACT AGGRAV/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3	LA	IM
	HIBV	LEDERLE(PRAXIS)	M210HK	3	LL	IM
	MMR	MSD	1898T	0	RA	SC
	OPV	LEDERLE	0658E	2		PO

SYMPTOM TEXT: mom states in about 3-4 hrs rt arm @ site of MMR became red & hard (1/2 dollar size) was fussy, but no elevated fever that noc; next day about 130 mom took pt to MD because of asthma attack; tx of ventolin was not helping; t101;
PREVIOUS VAX ILL: NA
OTHER MEDS: Intal, Ventolin
HISTORY: asthma
PREX ILLNESS: runny nose

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

47375
.2 M 29-Oct-1992 Rx@ 30-Oct-1992 1 30-Nov-1992 TN PUB-TN92142 14-Sep-1999
SERIOUS: Died
COSTARTS: EDEMA LUNG/LUNG DIS/SIDS/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	0	RL	IM
	HEP	MSD	1158V	0	LL	IM
	HIBV	LEDERLE(PRAXIS)	M155JA	0	LL	IM
	OPV	LEDERLE	0661D	0		PO

SYMPTOM TEXT: DTP/OPV/HIB/HBV were given 29OCT92 2PM pt found dead 30OCT92 approx 9AM of apparent crib death;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: had had MD exam 2 days prior;

47688
1.9 F 12-May-1992 Rx@ 13-May-1992 1 08-Dec-1992 TN PUB-TN92147 14-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/MASS INJECT SITE/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3		IM
	OPV	LEDERLE	0655H	3		PO

SYMPTOM TEXT: 13MAY92 devel redness @ site rt arm today is 2" in diameter; sl hard; hot to touch; used APAP w/hot & cold packs; no improvement today; advised to cont tx; 12AUG92 erythema & swelling cleared p/2-3 days;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NA

47689
.3 F 08-Jun-1992 Rx@ 08-Jun-1992 0 08-Dec-1992 TN PUB-TN92148 14-Sep-1999
COSTARTS: AGITATION/FEVER/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	1	LL	IM
	HIBV	LEDERLE(PRAXIS)	M155JA	1		IM
	OPV	LEDERLE	0652B	1		PO

SYMPTOM TEXT: prolonged crying consolable for short periods; PE neg; t100.3;
OTHER MEDS: Tempra
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

47690
.5 F 10-Jun-1992 Rx@ 10-Jun-1992 0 08-Dec-1992 TN PUB-TN92149 14-Sep-1999
COSTARTS: AGITATION/CRY ABNORMAL/EDEMA INJECT SITE/FEVER/HYSN INJECT SITE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	LL	IM
HIBV	LEDERLE(PRAXIS)	M210HK	1	RL	IM
OPV	LEDERLE	0655H	1		PO

SYMPTOM TEXT: p/vax recvd pt took a short nap woke up crying & cont screaming for 2 1/2 hrs; lt leg began to turn red & leg swelled 1 1/2 times; temp 103; mom called MD & was told to give DPH & APAP, applied warm pack to leg; fever & fussiness cont;
HISTORY: asthma-malabsorption
PREX ILLNESS: NONE

47691
5.4 F 28-Jul-1992 Rx@ 29-Jul-1992 1 08-Dec-1992 TN PUB-TN92150 14-Sep-1999
COSTARTS: EDEMA/HYSN INJECT SITE/PAIN INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	3	LA	IM
MMR	MSD	0456V	1	RA	SC
OPV	LEDERLE	0658E	3		PO

SYMPTOM TEXT: 29JUL 3AM awoke w/pain, redness & heat @ inject site of lt arm; w/in 12 hrs, redness swelling & heat extended down the arm; ?questionable area of abscess developing;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

47692
1.1 M 30-Jul-1992 Rx@ 31-Jul-1992 1 08-Dec-1992 TN PUB-TN92151 14-Sep-1999
COSTARTS: URTICARIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	LA	IM
OPV	LEDERLE	0656C	1		PO

SYMPTOM TEXT: w/in 24 hrs hive-like rash which was intermittent; no fever; no irritability; only lasted 24 hrs;
PREVIOUS VAX ILL: NA
HISTORY: NA
PREX ILLNESS: NA

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

47695
5.4 M 11-Aug-1992 Rx@ 12-Aug-1992 1 08-Dec-1992 TN PUB-TN92154 14-Sep-1999
COSTARTS: DIZZINESS/FEVER/HYSN INJECT SITE/PAIN INJECT SITE/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	4	RA	IM
	MMR	MSD	0456V	1	LA	SC
	OPV	LEDERLE	0658E	4		PO

SYMPTOM TEXT: dad states pt c/o dizziness on 12AUg92 was sent home from daycare that AM; subjective fever; rt upper arm red, warm to touch, tender; t100.8; Rx w/APAP;
OTHER MEDS: PPD by Connaught 232421
LAB DATA: NA
HISTORY: allergic PCN
PREX ILLNESS: NONE

47696
1.0 F 21-Sep-1992 Rx@ 22-Sep-1992 1 08-Dec-1992 TN PUB-TN92155 14-Sep-1999
COSTARTS: RASH/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	2		IM
	HIBV	LEDERLE(PRAXIS)	M155JA	2		IM

SYMPTOM TEXT: nonspecific rash 1 day later; 17NOV92 unable to reach by phone & has not responded to letter;
OTHER MEDS: PPD by Connaught Lot# 233012
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

49887
2.7 F 11-May-1992 Rx@ 11-May-1992 0 16-Feb-1993 TN PUB-TN93008 14-Sep-1999
COSTARTS: HYPERKINESIA/MYDRIASIS/SCREAMING SYND/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	3		IM
	HIBV	LEDERLE(PRAXIS)	M210HK	0		IM
	MMR	MSD	1898T	0		SC
	OPV	LEDERLE	0655H	3		PO

SYMPTOM TEXT: upon leaving clinic thru to time of report (4 hrs) pt has been hyper, crying uncontrolled/unconsoled & eyes described as dilated; grandfather called in report for parent; unk if temp elevated; advised to seek medical f/u immed;
OTHER MEDS: PPd

VAERS ID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

50410
.2 F 14-Oct-1992 Rx@ 14-Oct-1992 0 02-Mar-1993 ID PUB-ID93011 14-Sep-1999
COSTARTS: CRY ABNORMAL/SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	IM
HIBV	LEDERLE(PRAXIS)	M135JA	0	RL	IM
OPV	LEDERLE	0666A	0		PO

SYMPTOM TEXT: pt had high pitched cry & unconsoleable for 3 hrs;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

50445
.2 M 19-Feb-1993 Rx@ 20-Feb-1993 1 03-Mar-1993 TN PVT- 14-Sep-1999
COSTARTS: ASTHENIA/CRY ABNORMAL/SCREAMING SYND/VOMIT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	
HIBV	LEDERLE(PRAXIS)	M195JF	0	RL	
OPV	LEDERLE	340917	0		PO

SYMPTOM TEXT: screaming & 4 1/2 hrs; vomited x 1; by time of phone call looked fine but tired;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

53598
.5 M 14-May-1992 Rx@ 14-May-1992 0 08-Jun-1993 ID PUB-ID93044 14-Sep-1999
COSTARTS: AGITATION/INJECT SITE REACT/SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	1	RL	IM
HIBV	LEDERLE(PRAXIS)	M660HH	1	LL	IM
OPV	LEDERLE	0645C	1		PO

SYMPTOM TEXT: following immun pt devel a large local reaction on rt thigh & very irritable & cried for several hrs;
OTHER MEDS: NONE
LAB DATA: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

54489
.6 F 23-Sep-1992 Rx@ 23-Sep-1992 0 12-Jul-1993 ID PUB-ID93046 14-Sep-1999
COSTARTS: RASH/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	2	LL	IM
	HIBV	LEDERLE(PRAXIS)	M135JA	2	RL	IM

SYMPTOM TEXT: pt recvd doses 2 & 3 of vax & devel red spots all over; not raised; no elevated temp but was given APAP; no other s/s; lasted couple of days; spots size of pencil head & bright red;
PREVIOUS VAX ILL: pt exp red spots all over @ 4mos w/DTP/HIB #2 doses;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

54490
1.0 F 01-Jun-1993 Rx@ 01-Jun-1993 0 12-Jul-1993 ID PUB-ID93047 14-Sep-1999
COSTARTS: HYSN INJECT SITE/URTICARIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	1		IM
	HIBV	LEDERLE(PRAXIS)	M22HL	1	LL	IM
	OPV	LEDERLE	06664	1		PO

SYMPTOM TEXT: mom called office & stated pt devel hives 50 mins p/vax from head to toe & had a welt @ the HIB site on the lt thigh; advised to see MD immed; mom refused monitered @ home & administered DPH on advise of MD;

55251
1.5 M 28-Apr-1993 Rx@ 29-Apr-1993 1 18-Aug-1993 TN PUB-TN93067 14-Sep-1999
COSTARTS: ABSCESS INJECT SITE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTP	LEDERLE	322914	1	LL	IM
	HIBV	LEDERLE(PRAXIS)	M210HK	1	RL	IM
	OPV	LEDERLE	0653B	1		PO

SYMPTOM TEXT: abscess @ site of inject; seen in hosp ER 2MAY92 & treated w/oral Cephalexin abscess @ lt thigh;
OTHER MEDS: APAP
LAB DATA: CBC & blood c/s done @ hosp;
HISTORY: wheezing MAR92 resolved;
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

56971
.5 M 16-Nov-1992 Rx@ 16-Nov-1992 0 08-Nov-1993 NJ PUB-NJ9233 14-Sep-1999
COSTARTS: AGITATION/FEVER/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	2	RL	
HIBV	LEDERLE(PRAXIS)	M140JB	2	LL	

SYMPTOM TEXT: fever of 105 & cont crying for 2 hrs;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

57691
.5 M 09-Nov-1992 Rx@ 09-Nov-1992 0 03-Dec-1993 ID PUB-ID93077 14-Sep-1999
COSTARTS: INTRACRAN HYPERTENS/SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	2	LL	IM
HIBV	LEDERLE(PRAXIS)	M135JA	2	RL	IM

SYMPTOM TEXT: crying 72 hrs; bulging fontanel;
PREVIOUS VAX ILL: NA
OTHER MEDS: ATB
LAB DATA: NONE
HISTORY: recurrent ear infections;
PREX ILLNESS: NONE

59361
.2 M 30-Jul-1992 Rx@ 30-Jul-1992 0 04-Feb-1994 ID PUB-ID93107 14-Sep-1999
COSTARTS: SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	IM
HIBV	LEDERLE(PRAXIS)	M575HJ	0	RL	IM
OPV	LEDERLE	0653H	0		PO

SYMPTOM TEXT: pt was inconsoleable for 4 hrs;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date
71900									
.2	M	28-Aug-1992	Rx@ 28-Aug-1992	0	08-Mar-1995		TN	PUB-TN95009	13-Sep-1999

SERIOUS: Life-threatening Extended-stay Hospitalized() Disability

COSTARTS: CONVULS/CONVULS GRAND MAL/DYSPNEA/EEG ABNORM/FEVER/SOMNOLENCE/STUPOR/TWITCH/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	LEDERLE	322914	0	LL	IM
HIBV	LEDERLE(PRAXIS)	M155JA	0		
OPV	LEDERLE	0653B	0		

SYMPTOM TEXT: pt dx w/sz disorder; pt lethargic & running mild temp; 14SEP92 c/o fever & being up all noc, congestion, yellow drainage, diff breathing & eating; pt was twitching; unaware of surroundings; EEG confirmed that pt was having szs; Grand mal sz

LAB DATA: PET SCANS, CAT scans, EEG's, MRI's, allergy tests;

HISTORY: NONE

PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

107944
.2 F 23-Feb-1998 Rx@ 25-Feb-1998 2 05-Mar-1998 NH PUB- 09-Sep-1999
COSTARTS: RASH/RASH MAC PAP/SKIN DISCOLOR/URTICARIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	0	LL	IM
HIBV	LEDERLE(PRAXIS)	M200RC	0	LL	IM
IPV	CONNAUGHT LTD	M0443	0	RL	SC

SYMPTOM TEXT: systemic rash: blotchy red rash-raised urticarial? some older fading to purple & becoming macular;
OTHER MEDS: NONE
HISTORY: NONE

108023
1,2 M 04-Mar-1998 Rx@ 04-Mar-1998 0 10-Mar-1998 GA PVT- 09-Sep-1999
COSTARTS: RASH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	3	LL	IM
HIBV	LEDERLE(PRAXIS)	M285RJ	3	LL	IM
MMR	MSD	0600E	0	LA	SC

SYMPTOM TEXT: gen rash all over vax given 9AM-rash noticed @ 430Pm;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

108127
.4 F 11-Feb-1998 Rx@ 15-Feb-1998 4 12-Mar-1998 NJ PVT- 09-Sep-1999
SERIOUS: Died
COSTARTS: FEVER/INFECT/SIDS/STUPOR/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	0	LL	IM
HIBV	CONNAUGHT LABS	0909960	0	RL	IM
OPV	LEDERLE	450848	0		PO

SYMPTOM TEXT: pt exp T102 & diarrhea on 10FEB98;11FEB98 pt afeb, well hydrated & nl PE;pt recv vax & devel fever;17FEB98 pt unresponsive @ 9AM taken to ER found to be dead on arrival autopsy performed dx SIDS;
LAB DATA: positive rotavirus in stool;
HISTORY: NONE
PREX ILLNESS: Gastroenteritis;T102 & diarrhea;

RSID

ge	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date
013									
5.0	F	19-Mar-1998	Rx@		09-Apr-1998		IN	PUB-IN98011	09-Sep-1999

TARTS: EDEMA INJECT SITE/HYSN INJECT SITE/VASODILAT/

DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	4		IM
OPV	LEDERLE	0772B	3		PO

PTOM TEXT: per mom arm was swollen from elbow to shoulder, reddened, warm to touch;occurred 48hr p/vax;mom gave DPH;

/IOUS VAX ILL: unk

TORY: pertussis as infant (5wk of age)

590

.3 F 25-Mar-1998 Rx@ 25-Mar-1998 0 16-Apr-1998 FL OTH-FL98011 04-Nov-1999

'ARTS: COUGH INC/ECZEMA/FEVER/RHINITIS/SCREAMING SYND/

DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	1	LL	IM
HIBV	MSD	1512E	1	LL	IM
IPV	CONNAUGHT LTD	N01463	1	RL	SC

'TOM TEXT: pt recv vax 25MAR98 & mom states pt has been crying throughout the day & noc;4 days later devel cough & congestion;had fever since vax;exam 1APR97 T100.5, eczema;URI, eczema;

'ORY: NONE

: ILLNESS: eczema

48

.7 F 23-Mar-1998 Rx@ 24-Mar-1998 1 16-Apr-1998 CA PUB-CA98035 09-Sep-1999

ARTS: EDEMA INJECT SITE/HYSN INJECT SITE/

DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	4	LA	IM
MMR	MSD	1600E	1	RA	SC
OPV	LEDERLE	0772B	4		PO

TOM TEXT: c/o red & swollen on lt upper arm;

IOUS VAX ILL: ca980035

R MEDS: APAP

DATA: HCT nl

ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

110524
5.1 F 29-Apr-1998 Rx® 29-Apr-1998 0 12-May-1998 IL PVT- 09-Sep-1999
COSTARTS: EDEMA FACE/HYPOTHERMIA/HYPOVENTIL/RHINITIS/TACHYCARDIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	HBHEPB	MSD	0992E	1	RA	IM
	HEP	SMITHKLINE	839A2	1	LA	IM
	MMR	MSD	1235E	0	RA	IM
	OPV	LEDERLE	201ND10	1		PO

SYMPTOM TEXT: pt recv vax & T97.1, P88, R22, Ht 44;1110AM parent reported edema to face & eyes along congestion, P146, R16;epi given;P146, R16;
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NKA
PREX ILLNESS: NONE

110633
5.4 F 27-Apr-1998 Rx® 15-May-1998 OH PVT- 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/NAUSEA VOMIT/SERUM SICK/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	839A2		LA	
	OPV	LEDERLE	450134			PO

SYMPTOM TEXT: +local rxn of erythema & swelling 5cm x 3cm 48hr;+ system reaction nausea/vomit 48hr;
HISTORY: NONE
PREX ILLNESS: NONE

110686
.4 F 24-Apr-1998 Rx® 24-Apr-1998 0 11-May-1998 IL PVT- 09-Sep-1999
SERIOUS: Hospitalized(4)
COSTARTS: ANOMALY CONGEN/BRAIN SYND CHRON/DEHYDRAT/FEBRILE SEIZURE/HYPOXIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	1	LL	IM
	HIBV	MSD	0079H	1	LL	IM
	IPV	CONNAUGHT LTD	M1070	1	RL	IM

SYMPTOM TEXT: pt had a fever & sz approx 12hr post vax;pt rehydrated & had to be intubated;transferred to hosp; EEG & MRI done results pending;
OTHER MEDS: APAP
LAB DATA: electrolytes nl;Ca 9.9-PO4 5.7;Mg 1.6;
HISTORY: NONE
PREX ILLNESS: rhinitis

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

110795
5.3 M 27-Apr-1998 Rx@ 28-Apr-1998 1 22-May-1998 IL PUB-IL98047 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/PAIN INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	3	LA	IM
MMR	MSD	1235E	1	RA	SC
OPV	LEDERLE	0782A	3		PO

SYMPTOM TEXT: lt arm became swollen, red & hot to touch p/DTAP;appeared @ inj. now more swollen;no fever, no pain elsewhere in body;area on lt arm is tender to touch seen by pvt MD & placed on ATB;
PREVIOUS VAX ILL: NA
LAB DATA: NA
HISTORY: NONE
PREX ILLNESS: NONE

110987
.3 M 30-Apr-1998 Rx@ 02-May-1998 2 28-May-1998 CA PUB-CA980072 09-Sep-1999
COSTARTS: CRY ABNORMAL/HYPOTONIA/HYPOXIA/PALLOR/SHOCK/SOMNOLENCE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	839A2	1		
HIBV	LEDERLE(PRAXIS)	1483E			
OPV	LEDERLE	0769E			PO

SYMPTOM TEXT: high pitched cry, face red, then limp;required brief CPR w/breaths;drowsy for a short time then returned to nl activity over 30-60min not sure if pale;(shock-collapse rxn);
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

111200
5.3 M 18 May 1998 Rx@ 18-May-1998 0 01-Jun-1998 CA OTH 09-Sep-1999
COSTARTS: HYSN INJECT SITE/RASH MAC PAP/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2		LA	IM
MMR	MSD	1595E	1	LA	SC
OPV	LEDERLE	0772K	5		PO

SYMPTOM TEXT: local redness to rt deltoid & a papule;
PREVIOUS VAX ILL: NA
OTHER MEDS: PPD given 18MAY98
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

111295
1.3 M 11-May-1998 Rx@ 19-May-1998 8 04-Jun-1998 IL PUB-IL98034 09-Sep-1999
COSTARTS: FEVER/INSOMNIA/RASH/RHINITIS/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	3	LA	
	HIBV	LEDERLE(PRAXIS)	0318H	3	A	
	MMR	MSD	1235E		A	

SYMPTOM TEXT: fever began 19MAY98 101;20MAY98 T105 fever in AM & rash neck, side of underarm, temp went down w/APAP;T101 & 102 21MAY98;sleeplessness;no fever 22OCT98;clear runny nose 19MAY98, 20MAY98;
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

111537
5.2 M 19-May-1998 Rx@ 20-May-1998 1 10-Jun-1998 CA PUB- 09-Sep-1999
COSTARTS: FEBRILE SEIZURE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	4		
	MMR	MSD	1595E	1		
	OPV	LEDERLE	0787D	3		PO

SYMPTOM TEXT: febrile sz w/in 24hr of vax-no other illness noted;taken to ER; nl exam;
LAB DATA: CBC nl
HISTORY: unk
PREX ILLNESS: NONE

111833
4.3 M 14-May-1998 Rx@ 15-May-1998 1 16-Jun-1998 IL PVT- 09-Sep-1999
SERIOUS: Hospitalized(4)
COSTARTS: CELLULITIS/EDEMA INJECT SITE/HYSN INJECT SITE/MASS INJECT SITE/PAIN INJECT SITE/SKIN DISCOLOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	0	A	IM
	MMR	MSD	0995D	1	LA	SC
	OPV	LEDERLE	447929	3		PO

SYMPTOM TEXT: rt upper arm is very swollen 7 inches tenderness +induration, hard like rock w/yellowish central coloration;acute cellulitis rt upper arm;adm to hosp for observation;
OTHER MEDS: TB
HISTORY: NA
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

111863
5.2 M 28-Feb-1998 Rx@ 06-Mar-1998 6 18-Jun-1998 WI PUB-WI98016 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYPOTHERMIA/HYSN INJECT SITE/PAIN INJECT SITE/PRURITUS/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	OPV	LEDERLE	0731A	1		PO
	DTAP	SMITHKLINE	839A2	1	LL	IM
	HEP	SMITHKLINE	2498A2	0	LA	IM
	MMR	MSD	1020E	0	A	SC

SYMPTOM TEXT: day of & day p/vax had sl swelling & tenderness @ site of DTAP;over night devel redness, swelling & itching @ site;mom brought pt to clinic;pt had 12cm by 9.5cm red, raised, hot, swollen, tender & itchy area on lt thigh @ site;T98.4;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: born w/fused skull-surgery to correct
PREX ILLNESS: NONE

111880
5.2 M 19-May-1998 Rx@ 20-May-1998 1 18-Jun-1998 IL PVT- 09-Sep-1999
COSTARTS: ALLERG REACT/CELLULITIS/NODULE SKIN/RASH/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	0	LA	IM
	MMR	MSD	0995D	0	A	SC
	OPV	LEDERLE	447929	3		PO

SYMPTOM TEXT: lt arm +induration 3-4inch;+erythema;no abscess formation;allerg rxn to DTAP in lt arm;cellulitis in lt arm;ice & dph & duricef;
OTHER MEDS: TB tine test given 19MAY98
HISTORY: NA
PREX ILLNESS: NONE-well child visit

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

111990
4.3 M 19-May-1998 Rx@ 20-May-1998 1 23-Jun-1998 CA PUB-CA980057 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/FEVER/HYSN INJECT SITE/MASS INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	1	LA	
MMR	MSD	1600E	1	A	
OPV	LEDERLE	450851	3		PO

SYMPTOM TEXT: mom states pt had fever the following day p/vax given @ 9AM but does not have a thermometer-only felt warm;also lt arm became red & swollen;21MAY98 lt arm redness & indurated measures 5 11/2cm in length & 4cm in width;
PREVIOUS VAX ILL: pt exp red, swollen leg @ 2mo 28MAR94 unk vax dose 1;pt sibling exp red swollen
OTHER MEDS: Triaminic
HISTORY: NONE
PREX ILLNESS: NONE

112079
.5 M 13-Apr-1998 Rx@ 13-Apr-1998 0 25-Jun-1998 FL UNK-FL98024 09-Sep-1999
COSTARTS: AGITATION/FEVER/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
HEP	SMITHKLINE	2425A2	2	RL	IM
HIBV	MSD	1512E	1	RL	IM
IPV	CONNAUGHT LTD	N01463	1	LL	SC
DTAP	SMITHKLINE	839A2	1	LL	IM

SYMPTOM TEXT: pt recv vax & had a fever & was irritable for almost a week;
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

112233
.2 M 13-May-1998 Rx@ 13-May-1998 0 01-Jul-1998 IL PUB-IL98037 09-Sep-1999
COSTARTS: AGITATION/COUGH INC/FEVER/FLU SYND/RHINITIS/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	0	RL	IM
HIBV	MSD	0029H	0	LL	IM
IPV	CONNAUGHT LTD	M10702	0	LL	SC

SYMPTOM TEXT: cough w/thick white mucous 3-6hr p/vax;per mom pt devel thick mucous (white) cough has dec daily since vax;started 3-6hr p/vax;T101 w/APAP q 4-6hr;irritable & had crying spells;devel isolate flu like episode w/T103 20MAY98 in late PM;
PREVIOUS VAX ILL: NONE
LAB DATA: NA
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

112369
1.3 M 18-Jun-1998 Rx® 28-Jun-1998 10 07-Jul-1998 IL PUB-IL98050 09-Sep-1999
COSTARTS: ANOREXIA/RASH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	UNCLASSIFIED	839A2	3	LL	IM
HIBV	MSD	0318H	3	RL	IM
MMR	MSD	0999D	0	RL	SC
OPV	LEDERLE	0778A	2		PO

SYMPTOM TEXT: light rash arms, bilat anterior & posterior torso, legs bilat;began 28JUN98 in PM dec appetite began 27JUN98 (mom attributed to heat);
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

112477
.2 M 27-Apr-1998 Rx® 14-Jul-1998 IL PUB-IL98041 27-Sep-1999
COSTARTS: AGITATION/EDEMA INJECT SITE/HYSN INJECT SITE/STUPOR/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	0		IM
HBHEPB	MSD	1206E			IM
OPV	LEDERLE	0778A	0		PO

SYMPTOM TEXT: mom reports 18JUN98 that p/vax 27APR98 pt cried inconsolable, had glazed eyes & red swollen leg;taken to ER;mom states ER MD stated was d/t colic;PCP according to mom thinks it was d/t pertussis & pt should recv DTAP;
HISTORY: premature
PREX ILLNESS: NONE

112868
1.0 F 21-Apr-1998 Rx® 21-Apr-1998 0 28-Jul-1998 CO PUB-CO98029 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/MASS INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	839A2	3	RA	
HIBV	LEDERLE(PRAXIS)	7D91848	3	LL	
MMR	MSD	1230E	0	LA	
VARCEL	MSD	09576	0	LA	

SYMPTOM TEXT: immed p/vax lt arm @ inj site became angry red-pink penny sized blister-appearing spot in center;hand knot noted size of marble entire area around inj site edematous & warm;(approx tennis-ball size are);ice to site;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

112900
1.6 M 02-Jul-1998 Rx@ 03-Jul-1998 1 31-Jul-1998 IL PUB-IL98045 09-Sep-1999
COSTARTS: CONVULS/FEBRILE SEIZURE/FEVER/LAB TEST ABNORM/LYMPHOCYTOSIS/STUPOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	0	LL	
	HIBV	MSD	0318H	3	RL	
	MMR	MSD	1235E	0	RL	

SYMPTOM TEXT: pt w/ c/o acute sz;pt devel fever p/vax;pt showed tonic clonic sz approx 30seconds;T102.1, alert & oreinted;MD impression acute febrile seizure;mom states pt may have had fever @ time of vax;pt cut molars 7JUL98 5 days p/vax;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: rapid strep test negative for group A beta hemolytic strep;chem reveal sodium 136, K+ 4.0, chloride 102, co@ 20, BUN 9, creatinine 0.3, glucose 107;CBC 10.4 w/53% segs, 43% lymphs, 3% monocytes, 1% eosinophils, hgb & hct 11.7 & 35.7;
HISTORY: heart murmur-no problems w/condition
PREX ILLNESS: NONE

113492
.4 F 08-Jul-1998 Rx@ 08-Jul-1998 0 19-Aug-1998 IL PUB-IL98054 01-Feb-2000
COSTARTS: CYANOSIS/INFECT/STUPOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	1	RL	IM
	HIBV	MSD	0079H	1	LL	IM
	OPV	LEDERLE	0785H	1		PO

SYMPTOM TEXT: mom indicates that around 3:30 pt turned blue & started blanking out;all blood test that were done were nl results;ER felt pt may have had infect;no further vax containing pertussis;
HISTORY: NONE
PREX ILLNESS: NONE

113660
5.3 F 27-Jul-1998 Rx@ 30-Jul-1998 3 28-Aug-1998 WI PUB- 09-Sep-1999
COSTARTS: FEVER/INSOMNIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	4	LA	IM
	MMR	MSD	0741D	1	RA	SC
	OPV	LEDERLE	450032	3		PO

SYMPTOM TEXT: pt recv vax 27JUL98 & 30JUL woke up during noc w/fever of 101.6 axillary;no other specific complaints-mom gave APAP but fever cont through next day;
OTHER MEDS: NONE
LAB DATA: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

114300
.4 U 21-Aug-1998 Rx@ 23-Aug-1998 2 25-Sep-1998 CA PUB-CA980090 08-Sep-1999
COSTARTS: CRY ABNORMAL/DIARRHEA/FEVER/OPISTHOTONOS/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	1	LL	IM
	HIBV	LEDERLE(PRAXIS)	6K81422	1	RL	IM
	IPV	CONNAUGHT LTD	M12941	1	LL	SC

SYMPTOM TEXT: 2 days p/vax pt devel mild fever, diarrhea & high pitched unconsolable cry, arched back;this lasted on & off over a week;when upset crys & arches back, otherwise acting nl;
PREVIOUS VAX ILL: NONE
OTHER MEDS: denies any
LAB DATA: urine negative;stool sample negative;
HISTORY: denies any
PREX ILLNESS: denies any but states teething

114863
.6 U 08-Apr-1998 Rx@ 09-Apr-1998 1 19-Oct-1998 AR PUB-AR9857 08-Sep-1999
COSTARTS: FEVER/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	SMITHKLINE	839A2	1	RL	IM
	HEP	SMITHKLINE	2428A2	1	LL	IM
	HIBV	LEDERLE(PRAXIS)	0077H	1	LL	IM
	IPV	CONNAUGHT LTD	M0843	1	RL	SC

SYMPTOM TEXT: mom states the noc p/vax pt had T104 & was taken to ER;11SEP98 hosp states no ER records only have xray report;
PREVIOUS VAX ILL: NA
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

116973
.7 M 27-Oct-1998 Rx@ 27-Oct-1998 0 07-Dec-1998 CA PUB- 08-Sep-1999
COSTARTS: AGITATION/FEVER/RASH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2		RL	
HBHEPB	MSD	0239H		LL	

SYMPTOM TEXT: Pt recv vax on 10/27/98; on same day pt exp crying, fever (104); tx=Motrin; 10/28/98 pt exp rash on legs, arms & trunk
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: UNK
HISTORY: NONE
PREX ILLNESS: Diaper rash

117907
.4 F 15-Dec-1998 Rx@ 18-Dec-1998 3 06-Jan-1999 WI PVT- 08-Sep-1999
SERIOUS: Hospitalized(2)
COSTARTS: AGITATION/CSF ABNORM/FEVER/HYPOKINESIA/LAB TEST ABNORM/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	SMITHKLINE	839A2	1	RL	IM
HIBV	LEDERLE(PRAXIS)	361503A	1	LL	IM
IPV	MERIEUX INST	NO2922	1	LL	SC

SYMPTOM TEXT: Pt recv vax on 12/15/98; on 12/18/98 pt exp fever (105), irritability, rigidness, immobile
PREVIOUS VAX ILL: UNK
OTHER MEDS: Tylenol
LAB DATA: CBC, WBC-17.1, UA-neg, CSF 380, Seg 38, 6 Bands, 29 Lymph, 5 neu, 4 E
HISTORY: Dacryostenosis
PREX ILLNESS: NONE

VAERSID

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date
120256									
4.5	M	08-Apr-1998	Rx@ 21-Apr-1998	13	16-Mar-1999		CA	PVT-	08-Sep-1999

SERIOUS: Hospitalized(3) Disability

CONTAINS: AMNESIA/APHASIA/BRAIN SYND CHRON/CONVULS/DEPRESSION/DIZZINESS/EMOTION LABIL/GAIT ABNORM/HEADACHE/HOSTILITY/HYPERKINESIA/INCONTIN FECAL/INCONTIN URIN/MENTAL RETARD/NEUROSIS/PREV REACT/SCREAMING SYND/SPASM GENERAL/SPEECH DIS/TWITCH/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	LEDERLE	839A2	4		
MMR	MSD	0734E	1		
OPV	LEDERLE	0765	4		

SYMPTOM TEXT: pt exp fever, h/a, dizzy x 13 days;13th day pt began twitching uncontrollably, head & mouth mainly;loss coherency;pt cont twitching, jerking, spasms;could not walk w/o falling;loss memory;urinate & soil self;dx ADHD & OCD;brain damage

PREVIOUS VAX ILL: pt & brother exp twitching staring, twitching @ 2&6mo w/DTP dose 1&2;

OTHER MEDS: NONE

LAB DATA: 2MRI's, 1 spinal tap, 1EEG, 1 spect scan, extensive blood workup

HISTORY: NONE

PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

96750
1.9 M 03-Apr-1997 Rx@ 03-Apr-1997 0 09-Apr-1997 FL PVT- 10-Sep-1999
SERIOUS: Life-threatening
COSTARTS: ASTHMA/DYSPNEA/EDEMA FACE/URTICARIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	2	LL	IM
	HEP	SMITHKLINE	2206A2	2	RL	IM

SYMPTOM TEXT: urticaria, facial swelling, wheezing, resp distress;given susprin, ventolin, prelone, DPH;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

97360
5.0 M 24-Apr-1997 Rx@ 25-Apr-1997 1 07-May-1997 MA PVT- 10-Sep-1999
COSTARTS: EDEMA PERIPH/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	4	LA	
	MMR	MSD	0989D	1	RA	
	OPV	LEDERLE	441228	4		PO

SYMPTOM TEXT: approx 23hr p/vax presented w/non tender swelling & redness of upper arm just below shot area of darker redness 9cm x 6cm, total redness 9cm x 10cm;swelling <9x6cm;no fever;no systemic sx;
OTHER MEDS: mult vits w/fluoride
LAB DATA: NONE
HISTORY: RAD
PREX ILLNESS: NONE

99141
.2 M 11-Jun-1997 Rx@ 11-Jun-1997 0 25-Jun-1997 NC PVT-NC97054 10-Sep-1999
SERIOUS: Hospitalized()
COSTARTS: HYPERVENTIL/HYPOTONIA/PALLOR/SOMNOLENCE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	0	RL	IM
	HEP	SMITHKLINE	227A2	1	LL	IM
	HIBV	LEDERLE(PRAXIS)	M305PN	0	RL	IM
	IPV	MERIEUX INST	MD443	0	LL	SC

SYMPTOM TEXT: approx 2min p/all 4 immun pt stopped crying became limp & pale;seen by MD immed, HR 132, R40 easy 02 sat 97%;fell asleep approx 30min;lethargy VS stable sent to hosp for observation overnoc;
OTHER MEDS: NONE
HISTORY: low birth wt-term;
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

99361
1.1 F 13-Jun-1997 Rx@ 17-Jun-1997 4 01-Jul-1997 OH PVT- 10-Sep-1999
SERIOUS: Hospitalized()
COSTARTS: APNEA/CYANOSIS/EYES GAZE UPWARD/FEBRILE SEIZURE/HYPERTONIA/LEUKOCYTOSIS/RASH VESIC BULL/VOMIT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	2	RL	
HEP	MSD	1434D	2	LL	
HIBV	LEDERLE(PRAXIS)	M350PN	2	LL	
OPV	LEDERLE	760E6	2		PO

SYMPTOM TEXT: pt recv vax & devel sz assoc w/fever;body stiff, eyes rolled back in head;dx febrile sz;pt had another sz & cyanosis, apnea, emesis x2;vesicular pharyngitis;WBC 18.6;pt fussy, jaw shaking up & down, lethargic;pt recv OPV & 3 other unk vax;
OTHER MEDS: Amoxicillin
LAB DATA: CBC shows a WBC count 20.7, platelete 406, segs 39, bands 22, lymphs 23, monos 16, eosinophils 1;chem-7 panel show sodium 137, K 4.2, chloride 103, co@ 22, BUN 7, glucose 123;magnesium 1.9;
HISTORY: father hx of sx febrile;
PREX ILLNESS: URI, red throat,BM8

99827
.2 M 24-Jun-1997 Rx@ 25-Jun-1997 1 10-Jul-1997 NY PUB- 06-Jul-1998
SERIOUS: Hospitalized(5)
COSTARTS: AGITATION/ANOREXIA/FEVER/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507			IM
HEP	SMITHKLINE	2250A2			IM
HIBV	MSD	138SD			IM
IPV	MERIEUX INST	M40938			IM

SYMPTOM TEXT: temp 105 1 day following inj;pt was irritable, feeding poor;r/o sepsis w/up;CSF, blood cult negative;CBC negative;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

100217
.4 F 01-Jul-1997 Rx@ 02-Jul-1997 1 16-Jul-1997 NY PVT- 10-Sep-1999
SERIOUS: Died
COSTARTS: SIDS/STUPOR/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	RL	IM
HEP	SMITHKLINE	2250A2	1	LL	IM
HIBV	CONNAUGHT LABS	7A91570	1	RL	IM
OPV	LEDERLE	766C1	1		PO

SYMPTOM TEXT: pt found unresponsive in crib 3JUL97 230PM;
OTHER MEDS: NONE
LAB DATA: Autopsy: SIDS
HISTORY: nONE
PREX ILLNESS: NONE

100464
4.7 F 13-Jun-1997 Rx@ 13-Jun-1997 0 28-Jul-1997 OH PVT-OH97051 10-Sep-1999
COSTARTS: AGITATION/HYSN INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	4	LA	IM
MMR	UNCLASSIFIED	1237D	1	RA	SC
OPV	LEDERLE	0757F	3		PO

SYMPTOM TEXT: warm/redness @ site of inj;anxiety;Ibuporfen & DPH;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: allergy to sulfa med;
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

100761
1.8 F 23-Jun-1997 Rx@ 29-Jun-1997 6 29-Jul-1997 CA PUB-CA970056 10-Sep-1999
COSTARTS: AGITATION/FEVER/HYSN INJECT SITE/PAIN INJECT SITE/URTICARIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	RA	IM
HEP	MSD	0079E	1	LA	IM
HIBV	LEDERLE(PRAXIS)	M350PN	1	LA	IM
OPV	LEDERLE	0755C	1		PO

SYMPTOM TEXT: onset 29JUN of hives & tenderness @ inj site & fever 101.9;RD nickel sized bumpy red spot, sl faded by 30JUN;LD nickel size 29JUN-quarter size 30JUN, bumpy irregular shape;pt cranky teething;DPH w/o relief;
PREVIOUS VAX ILL: pt devel rxn @2mo w/DTP/HIB/HBV dose 1;sibling exp hives, breathing @6mo w/pertu
OTHER MEDS: APAP
LAB DATA: NA
HISTORY: prematurity, apnea
PREX ILLNESS: NONE

101575
.2 M 21-Jul-1997 Rx@ 24-Jul-1997 3 18-Aug-1997 NC PUB-NC97071 10-Sep-1999
COSTARTS: STUPOR/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	LL	
HEP	MSD	16270	1	LL	
HIBV	LEDERLE(PRAXIS)	M305PN	0	LL	
IPV	CONNAUGHT LTD	M0443	0	LL	

SYMPTOM TEXT: mom states that the pt closed eyes & would not open them for 25min;denies pt sleeping;no tx @ ER-pt was responsive in ER & alert;dx was made as acute adverse drug reaction;pt released to see MD 22JUL97;
PREVIOUS VAX ILL: NONE
OTHER MEDS: APAP
LAB DATA: CBC-WBC 8.1;RBC 3.90 low;HGB 10.7-low;HCT 31.6 low;MCV 80.9-low;RDW 13.5;MCH 27.5-low;MCHC 34.0;PLTS 448;
HISTORY: NONE
PREX ILLNESS: NONE

101631
.4 M 22-Jul-1997 Rx@ 22-Jul-1997 0 25-Aug-1997 MA PVT- 10-Sep-1999
COSTARTS: AGITATION/FEVER/SCREAMING SYND/VOMIT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	LL	IM

SYMPTOM TEXT: crying & irritable x 3 days;t100R;no swelling @ inj site;spitting up more than usual;
LAB DATA: NONE
PREX ILLNESS: thrush

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

101812
.3 M 25-Apr-1997 Rx@ 25-Apr-1997 0 26-Aug-1997 MD PVT-897135016L 10-Sep-1999
COSTARTS: PHARYNGITIS/RHINITIS/URTICARIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	LL	IM
HIBV	LEDERLE(PRAXIS)	M035PE	1	RL	IM
IPV	CONNAUGHT LTD	M0843	1	LA	SC

SYMPTOM TEXT: pt recv vax & devel gen hives approx 30min later;pt was treated w/DPH & hives resolved;additional info 9JUN97 indicated that pt devel cold sx later that evening;pt recovered;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

102079
.2 F 18-Aug-1997 Rx@ 18-Aug-1997 0 05-Sep-1997 NC PVT- 09-Sep-1999
COSTARTS: AGITATION/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	RL	IM
HIBV	LEDERLE(PRAXIS)	M350PN	0	LL	IM
IPV	CONNAUGHT LTD	M0845	0	LL	SC

SYMPTOM TEXT: excessive crying x 9hr;not quite non stop
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

102141
.5 M 13-Aug-1997 Rx@ 13-Aug-1997 0 04-Sep-1997 VA PVT- 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/PAIN INJECT SITE/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	2	RL	IM
HEP	MSD	0515D	2	LL	IM
HIBV	CONNAUGHT LABS	7C91688	2	RL	IM

SYMPTOM TEXT: inj site red, swollen, & tender rt upper thigh for 8-10cm diameter most of anterior thigh;cold compresses & DPH;
OTHER MEDS: Tri-vi-flor vitamins
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

102173
.3 F 19-Aug-1997 Rx@ 19-Aug-1997 0 09-Sep-1997 MA PVT- 09-Sep-1999
COSTARTS: SOMNOLENCE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	1	L	
	HIBV	UNCLASSIFIED		1	L	
	IPV	UNCLASSIFIED		1	L	

SYMPTOM TEXT: pt had change in sleep pattern slept >4hr x/for feeding;no fever-fine p/24hr;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
PREX ILLNESS: NONE

102507
5.3 F 04-Aug-1997 Rx@ 04-Aug-1997 0 16-Sep-1997 NC PUB-NC97079 09-Sep-1999
COSTARTS: EDEMA PERIPH/FEVER/MYALGIA/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	4	LA	IM
	MMR	MSD	1006D	1	RA	SC
	OPV	LEDERLE	07590	3		PO

SYMPTOM TEXT: 7AUG97 lt arm red, hot, swollen & tender;had fever, hot to touch since 4AUG97;gave Ibuprofen;seen @ clinic 7AUg97;no fever today;lt arm felt better p/warm compress;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
HISTORY: nONE
PREX ILLNESS: NONE

102509
5.3 F 13-Aug-1997 Rx@ 13-Aug-1997 0 16-Sep-1997 NC PUB-NC97078 09-Sep-1999
COSTARTS: RASH MAC PAP/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	5	LA	IM
	MMR	MSD	10060	1	RA	SC
	OPV	LEDERLE	0759D	3		PO

SYMPTOM TEXT: 13AUG97 mom reported noticed pt face looked splotchy in car on way to school; principal said to take child home & watch;rash-splotchy red spread to abd, back, arms;went to MD office given DPh for 1hr;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

102561
5.3 M 11-Sep-1997 Rx@ 13-Sep-1997 2 19-Sep-1997 TX PVT- 09-Sep-1999
COSTARTS: EDEMA PERIPH/RASH/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	4	LA	IM
OPV	LEDERLE	0769M12	4		PO

SYMPTOM TEXT: pt recv vax 11SEP97 seen 13SEP97 for swollen & red acid on lt arm 4x6cm area of erythema w/o pain;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

102813
.6 M 22-Sep-1997 Rx@ 22-Sep-1997 0 01-Oct-1997 IL PVT- 09-Sep-1999
COSTARTS: AGITATION/CONVULS/HYPERTONIA/HYPOTONIA/SOMNOLENCE/STUPOR/TONGUE DIS/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTP	CONNAUGHT LABS	7H81507	2	RL	IM
HIBV	CONNAUGHT LABS	7B91590	2	LL	IM
OPV	LEDERLE	0771B	2		PO

SYMPTOM TEXT: pt recv vax 22SEP97 approx 30-60min p/that time;pt started screaming p/nap;felt hot;10 second episode of tongue thrusting w/body tensing x8;mouth dragged open;eyes glassy;pt slept in car during transit;dx sz;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: MD exam only
HISTORY: NONE
PREX ILLNESS: NONE

102881
3.0 M 10-Sep-1997 Rx@ 18-Sep-1997 8 06-Oct-1997 IL PVT- 09-Sep-1999
COSTARTS: FEVER/PAIN ABDO/PAIN BACK/RASH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	2	RL	IM
HEP	SMITHKLINE	2320A2	0	RL	IM
MMR	MSD	0470E	0	LL	IM
OPV	LEDERLE	448166	2		PO

SYMPTOM TEXT: high fever 102.7; pinpoint rash 9 days p/vax;nonspecific abd & back pain;no apparent source of fever otherwise;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

102987
5.0 M 17-Jun-1997 Rx@ 08-Oct-1997 MA PVT- 09-Sep-1999
SERIOUS: Hospitalized()
COSTARTS: FLU SYND/HYPOXIA/MALAISE/MOVEMENT DIS/PARALYSIS/POLIOMYELITIS/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	4	LA	
	OPV	LEDERLE	760H4	3		PO

SYMPTOM TEXT: child recv vax & child's grandma became ill w/flu like sx on 23JUL97;seen by MD 24JUL97 hosp-ICU;first felt to be GBS by final dx polio;hosp x1mo;grandma paralyzed from waist up;trach still on ventilator;
OTHER MEDS: NONE
LAB DATA: tests & date in England;
PREX ILLNESS: NONE

103029
.4 F 18-Jul-1997 Rx@ 09-Oct-1997 FL PUB-FL97070 09-Sep-1999
SERIOUS: Died
COSTARTS: ASPHYXIA/INJURY ACCID/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	0	LL	IM
	HEP	MSD	0358E	1	RL	IM
	HIBV	LEDERLE(PRAXIS)	M005PF	0	RL	IM
	IPV	MERIEUX INST	M0443	0	LL	SC

SYMPTOM TEXT: died of asphyxia;compression of neck & chest according to death certificate;
OTHER MEDS: unk

103125
.2 F 06-Oct-1997 Rx@ 06-Oct-1997 0 20-Oct-1997 NY PVT- 09-Sep-1999
COSTARTS: CRY ABNORMAL/HYPOTONIA/PALLOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	0	RL	IM
	HBHEPB	MSD	1655D	0	LL	IM
	IPV	MERIEUX INST	N0031	0	RA	SC

SYMPTOM TEXT: 12hr p/vax became pale, somewhat limp for estimated 102min;lips lost color color returned w/o any intervention;also had harsh whiny cry prior to event;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

103258
1.2 M 08-Sep-1997 Rx@ 08-Sep-1997 0 24-Oct-1997 CA PUB- 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	LA	

SYMPTOM TEXT: immed swelling & redness of lt arm;IM DPH given immed;redness & swelling subsided w/in 15min;discharged w/DPH;
PREVIOUS VAX ILL: pt febrile rxn @ lyr old w/MMR/HIB/Varicella dose 1;
LAB DATA: NONE
HISTORY: febrile reaction to MMR/HIB & or varicella;
PREX ILLNESS: NONE

103338
1.2 F 25-Aug-1997 Rx@ 26-Aug-1997 1 27-Oct-1997 NY PVT-NY97042 09-Sep-1999
COSTARTS: HYSN INJECT SITE/URTICARIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1		IM
HEP	SMITHKLINE	2293A2	1		IM
HIBV	LEDERLE(PRAXIS)	M330PL	1		IM
OPV	LEDERLE	445208	1		PO

SYMPTOM TEXT: urticaria @ site of 1 of 3 vax & on trunk;rx DPH;
PREVIOUS VAX ILL: unk
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: malnutrition
PREX ILLNESS: NONE

104000
5.6 F 17-Apr-1997 Rx@ 18-Apr-1997 1 03-Nov-1997 PA OTH- 09-Sep-1999
COSTARTS: EDEMA PERIPH/INJECT SITE REACT/NODULE SKIN/RASH/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	4	LA	IM
OPV	LEDERLE	438121	3		PO
VARCEL	MSD	0081E	0	RA	SC

SYMPTOM TEXT: 18APR97 ER rt upper arm red & swollen, 11x11cm erythema, induration non tender;dx local rxn to varicella vax;19APR97 swelling worse today;dx local rxn immunization;
PREVIOUS VAX ILL: pt exp rxn @ age 1yr w/MMR dose 1;
HISTORY: PCN, erythro, zinacef, sulfa, ceclor

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

104356
1.0 M 05-Sep-1997 Rx@ 09-Sep-1997 4 12-Nov-1997 NC PUB-NC97110 09-Sep-1999
COSTARTS: FEVER/LAB TEST ABNORM/OTITIS MED/RASH/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	3	LL	IM
	HIBV	LEDERLE(PRAXIS)	M350PN			
	MMR	MSD	1006D	0	RL	SC
	VARCEL	MSD	0544E		RL	SC

SYMPTOM TEXT: pt recv vax 5SEP97 & 9SEP97 mom called & stated pt had 101.6 temp 10SEP97;@ clinic 100.9 dx ROM & rx amoxicillin;19SEP97 returned for check up & has a rash over entire body starting feet to face & on palms;
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
LAB DATA: 19SEP97 serum tiger top tube drawn for measles titer acute & 30CT97 #2 tube drawn for convalescent titer results 19SEP97 <8 30CT97 64;the state lab stated that illness on recent vax causes the titer to be 4x >baseline;
HISTORY: maternal PIH/Pre-eclampsia/IUGR born @ 36 3/7wk
PREX ILLNESS: NONE

104377
.3 M 02-Oct-1997 Rx@ 02-Oct-1997 0 12-Nov-1997 LA PUB-LA971004 09-Sep-1999
COSTARTS: AGITATION/ANOREXIA/CRY ABNORMAL/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	1	LL	IM
	HIBV	CONNAUGHT LABS	7C91704	1	LL	IM
	IPV	MERIEUX INST	M09381	1	LL	SC

SYMPTOM TEXT: pt recv vax 920AM on 20CT97 @ 210Pm pt began crying & was inconsolable;APAP & myoflex administered p/vax; no fever;mom reports never cried like this before;no sz by report infant wouldn't eat;
PREVIOUS VAX ILL: NONE
OTHER MEDS: APAP & myoflex p/shot
LAB DATA: CBC
HISTORY: nONE
PREX ILLNESS: NONE

104992
4.0 F 01-Oct-1997 Rx@ 01-Oct-1997 0 02-Dec-1997 UK UNK- 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/MASS INJECT SITE/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507		LA	IM

SYMPTOM TEXT: pt recv vax 10CT97 & devel 4" in diameter round red hot hard, very swollen area;given ATB;30CT97 now 2" in diameter very swollen remains hard & warm;70CT97 still 2", sl swollen, red not as warm or hard;
LAB DATA: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

104993
.2 F 02-Oct-1997 Rx@ 02-Oct-1997 0 02-Dec-1997 UK UNK- 09-Sep-1999
COSTARTS: CRY ABNORMAL/EDEMA INJECT SITE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507		RL	IM

SYMPTOM TEXT: rt upper leg puffy where got DTAP that day pt squealing;leg better next day-no lump or redness only sl swollen;smiling next day;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

105078
.2 M 17-Nov-1997 Rx@ 18-Nov-1997 1 04-Dec-1997 MD PVT- 09-Sep-1999
COSTARTS: RASH MAC PAP/RASH VESIC BULL/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	RL	
HIBV	CONNAUGHT LABS	7D91905	0	RL	
IPV	CONNAUGHT LTD	N0031	0	LL	

SYMPTOM TEXT: woke the AM p/vax given w/rash on trunk & inner aspects of knees & elbows;rash appeared symmetric;small vesicles, single on trunk & clustered on knees, elbows;looks like heat rash;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

105135
5.8 F 17-Nov-1997 Rx@ 18-Nov-1997 1 05-Dec-1997 PA PUB- 09-Sep-1999
COSTARTS: HYSN INJECT SITE/PAIN INJECT SITE/PRURITUS/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	3	RA	IM
HEP	MSD	0399E	0	LA	IM
MMR	MSD	0464E	1	RA	SC
OPV	LEDERLE	444061	3		PO

SYMPTOM TEXT: local rxn site red, hot, itching, painful;
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
HISTORY: NA
PREX ILLNESS: NA

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

105473
.2 M 22-Aug-1997 Rx@ 22-Aug-1997 0 12-Dec-1997 NV PUB-NV97024 09-Sep-1999
COSTARTS: AGITATION/CRY ABNORMAL/HYSN INJECT SITE/INSOMNIA/SCREAMING SYND/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	LL	IM
HIBV	CONNAUGHT LABS	7A91621	0	RL	IM
OPV	LEDERLE	0767D	0		PO

SYMPTOM TEXT: 1230PM inconsolable high pitched cry for 3hr, irritable for 2 days-insomnia, notes sl redness of inj site;mom talked to MD;
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

105722
4.2 F 12-Nov-1997 Rx@ 14-Nov-1997 2 18-Dec-1997 PA PUB-PA9768 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/EDEMA PERIPH/SKIN DISCOLOR/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507		LA	IM
HEP	MSD	0115E	2	RA	IM

SYMPTOM TEXT: approx 36hr p/vax mom noticed a difference in arm size when holding child;when checked lt upper arm was swollen, warm tot ouch w/dark reddish coloring from inj site to elbow approx 3-4:;
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

105762
5.0 M 10-Nov-1997 Rx@ 17-Nov-1997 7 19-Dec-1997 LA PUB- 09-Sep-1999
COSTARTS: FEVER/HYSN INJECT SITE/LYMPHADENO/RASH/URTICARIA/VASODILAT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	3	LA	IM
MMR	MSD	0744E	0	RA	SC
OPV	LEDERLE	0770A	2		PO

SYMPTOM TEXT: 17NOV97 rash on face & ears were red & swelling behind one ear lasted approx 2 1/2hr then hives on chest for 1hr;18NOV febrile 104 temp ax-spoke w/MD & saw MD;19NOV rash fever & hives intermittently;12NOV redness & swelling @ site of MMR
OTHER MEDS: NONE
LAB DATA: strep test @ MD 18NOV97 test was negative;
HISTORY: sl asthma, hx of hives d/t allergies w/fever
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

105959
1.0 M 03-Nov-1997 Rx@ 10-Nov-1997 7 07-Jan-1998 TN PUB-TN97053 09-Sep-1999
COSTARTS: INFECT/NO DRUG EFFECT/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	3	LA	
HIBV	CONNAUGHT LABS	7H81507	3	LA	
MMR	MSD	0014E			
OPV	LEDERLE	0757F			
VARCEL	MSD	0536E			

SYMPTOM TEXT: devel chickenpox 10 days p/vax;no known exposure to chickenpox;
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: URI

106325
.2 F 09-Jan-1998 Rx@ 11-Jan-1998 2 14-Jan-1998 MO PVT- 09-Sep-1999
SERIOUS: Died
COSTARTS: REACT UNEVAL/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	LL	IM
HIBV	CONNAUGHT LABS	7D91713	0	RL	IM
IPV	CONNAUGHT LTD	M0359	0	LL	IM

SYMPTOM TEXT: found dead in bed approx 06:00 11JAN98;
PREVIOUS VAX ILL: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

106657
.1 F 08-Dec-1997 Rx@ 09-Dec-1997 1 21-Jan-1998 TN PUB-TN97055 09-Sep-1999
SERIOUS: Died
COSTARTS: SIDS/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	LL	IM
HEP	SMITHKLINE	2292A2	1	LL	IM
HIBV	LEDERLE(PRAXIS)	M195RF	0	RL	IM
IPV	CONNAUGHT LTD	M0938	0	RL	IM

SYMPTOM TEXT: Medical examiner reported pt was pronounced dead @ 136PM 9DEC97;autopsy to be performed;
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

107094
3.3 M 21-Oct-1997 Rx@ 21-Oct-1997 0 12-Feb-1998 MN PVT-897343001L 09-Sep-1999
COSTARTS: HYPOKINESIA/PALLOR/STUPOR/VOMIT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	3	LL	IM
	HEP	MSD	0079E	2	RL	IM
	OPV	LEDERLE	0761E	2		PO

SYMPTOM TEXT: 30min p/vax pt became pale, vomited twice, then exp dry heaving;then noted to be hypoactive;seen by MD who sent pt to ER;became unresponsive in ER; p/ 2.5 hr returned to nl status & was sent home;
OTHER MEDS: Claritin;Albutero Nebulizer;
HISTORY: asthma, biaxin allergy
PREX ILLNESS: NONE

107424
1.3 M 10-Jan-1998 Rx@ 10-Jan-1998 0 13-Feb-1998 MO PVT- 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/FEVER/HYSN INJECT SITE/MASS INJECT SITE/PAIN INJECT SITE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	3	RA	
	HIBV	LEDERLE(PRAXIS)	165RH	3	LA	

SYMPTOM TEXT: marked redness & swelling to muscle w/pain-itching @ inj site;ice applied & temp-golf ball size to grape size resolved completely in 4 days only in rt deltoid;
OTHER MEDS: Augmentin x 5 days;APAP
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: mild skin eczema on thighs

107742
.1 M 22-Jan-1998 Rx@ 07-Feb-1998 16 20-Feb-1998 NC PUB-NC98005 09-Sep-1999
SERIOUS: Died
COSTARTS: ISCHEMIA CEREBR/SIDS/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	0	LL	IM
	HEP	MSD	2251A2	1	RL	IM
	HIBV	LEDERLE(PRAXIS)	M305NP	0	RL	IM
	OPV	LEDERLE	0766H	0		PO

SYMPTOM TEXT: death per reporter death certificate states cerebral anoxia & SIDS;
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
LAB DATA: unk
HISTORY: NONE
PREX ILLNESS: rash under neck & face

VAERSID

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date
107797									
.4	M	10-Feb-1998 Rx@ 10-Feb-1998		0	25-Feb-1998		NJ	PUB-NJ982	09-Sep-1999

COSTARTS: CRY ABNORMAL/FEVER/URTICARIA/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1		SC
HIBV	LEDERLE(PRAXIS)	M305PN	1		SC
OPV	LEDERLE	0767L	1		PO

SYMPTOM TEXT: pt suddenly broke out in hives approx 8-10hr p/vax; temp was 102 ear;pt had high pitched cry 15-20min;phone call to ER felt may be allerg rxn; aunt called 911 seen in ER T100.8 no other signs pt release T99 that noc;

PREVIOUS VAX ILL: NA

OTHER MEDS: NONE

LAB DATA: NA

HISTORY: cradle cap

PREX ILLNESS: NONE

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date
107885									
5.0	F	16-Jan-1998 Rx@ 17-Jan-1998		1	03-Mar-1998		PA	PUB-PA9808	09-Sep-1999

COSTARTS: AGITATION/EDEMA INJECT SITE/HYSN INJECT SITE/PAIN INJECT SITE/PRURITUS/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	LA	IM
HEP	MSD	0358E	0	RA	IM
MMR	MSD	0736E	1	LA	SC
OPV	LEDERLE	444061	3		PO

SYMPTOM TEXT: itching, swelling, redness edema @ lt arm inj site in AM of 17JAN98 lessened by AM of 18JAN98;pt screamed for 45min on 19JAN98 PM, & had inc in itching, c/burning @ site PM of 19JAN98;itching & burning cont 21JAN98;

OTHER MEDS: NONE

LAB DATA: NA

HISTORY: NONE

PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

107886
1.3 M 25-Nov-1997 Rx@ 30-Nov-1997 5 03-Mar-1998 PA PUB-PA9809 17-Nov-1999
COSTARTS: CONVULS/TWITCH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	3	LL	IM
MMR	MSD	0464E	0	LA	SC

SYMPTOM TEXT: 16DEC97 on scheduled return visit to clinic pt mom reported a 10min episode of twitching involving head, eyes & arms 5th day p/prev visit;mom denies sz hx-no med attention was sought as of 16DEC97;28JAN98 pt neuro does not feel sz r/t vax
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: EEG negative on 24DEC79;
HISTORY: encephalopathy-undetermined etiology
PREX ILLNESS: NONE

107920
1.6 F 11-Feb-1998 Rx@ 11-Feb-1998 0 05-Mar-1998 NY PVT- 09-Sep-1999
COSTARTS: URTICARIA/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	3	RL	IM
HIBV	LEDERLE(PRAXIS)	M200RC	3	LL	IM
MMR	MSD	0157E	0	LL	SC

SYMPTOM TEXT: 11Feb98 pt recv 1st dose vax. 11Feb98 pt exp hives & swelling on abdomen,face,ears,thighs & eyes swollen shut. No further info.
OTHER MEDS: unknown
HISTORY: unknown

107971
1.2 F 05-Feb-1998 Rx@ 16-Feb-1998 11 09-Mar-1998 MO PUB-MO98006 09-Sep-1999
COSTARTS: FEVER/RASH/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	3	LA	IM
HIBV	LEDERLE(PRAXIS)	M195RC	3	RL	
IPV	MERIEUX INST	L1217	2	LL	SC
MMR	MSD	1012F	0	RA	SC

SYMPTOM TEXT: pt devel temp 102 on 16FEB98 followed by rash on trunk & limbs was seen by MD who felt this was side effect from vax;
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

108088
2.2 F 19-Feb-1998 Rx@ 19-Feb-1998 0 12-Mar-1998 MO PUB-MO98007 09-Sep-1999
COSTARTS: HEM/INFECT URIN TRACT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H815C7	3	RL	IM
	HEP	MSD	1434D	2	LL	IM
	HIBV	LEDERLE(PRAXIS)	M195RC	3	LL	IM

SYMPTOM TEXT: approx 10hr p/vax pt had pink in diaper, went to ER did UA & was + for blood dx w/UTI tx w/septra x 10 days;pt had been on augmentin for ear infect w/last dose of med taken on 18FEB98 AM;
OTHER MEDS: augmentin last dose take 18FEB98 AM;
LAB DATA: UA test +blood
HISTORY: mild cerebral hypotonia
PREX ILLNESS: recovering from ear infect;

108098
1.2 F 18-Feb-1998 Rx@ 12-Mar-1998 PA PVT- 09-Sep-1999
COSTARTS: RASH/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	3	RL	IM
	HIBV	CONNAUGHT LABS	M350PN	3	LL	IM
	MMR	MSD	0464E	0	RL	SC

SYMPTOM TEXT: generalized rash;
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
LAB DATA: NA
HISTORY: NONE
PREX ILLNESS: NONE

108785
.3 M 02-Feb-1998 Rx@ 03-Feb-1998 1 24-Mar-1998 NY PVT- 09-Sep-1999
SERIOUS: Life-threatening Hospitalized(4)
COSTARTS: DYSPHAGIA/DYSPNEA/HYPOXIA/NEUROPATHY/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	0	RL	
	HEP	SMITHKLINE	2293A2	0	LL	
	HIBV	LEDERLE(PRAXIS)	M260ORJ	0	RL	
	IPV	CONNAUGHT LTD	M1294	0	LL	

SYMPTOM TEXT: pt devel resp distress & had to be supported by ventilator for several hr-via trach tube;
HISTORY: severe hypoxia/severe neuro defiate/trachiotomy-occurred @ birth severely impaired;
PREX ILLNESS: severe hypoxia/severe neuro defiate/trachiotomy

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

108812
.5 M 10-Mar-1998 Rx@ 10-Mar-1998 0 25-Mar-1998 MN OTH- 09-Sep-1999
COSTARTS: EDEMA FACE/URTICARIA/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	2	LL	IM
	HEP	SMITHKLINE	2513A2	1	RL	IM
	HIBV	LEDERLE(PRAXIS)	M215RD	2	RL	IM

SYMPTOM TEXT: pt recv vax 1015AM 10MAR98 & approx 1PM pt devel hives on lt eyelid then gen edema of lt eyelid;
OTHER MEDS: APAP gtts
HISTORY: NONE
PREX ILLNESS: NONE

108943
5.0 M 26-Jan-1998 Rx@ 26-Jan-1998 0 03-Apr-1998 PA PUB-PA9812 09-Sep-1999
COSTARTS: ALLERG REACT/ASTHMA/EDEMA FACE/FEVER/PHARYNGITIS/PRURITUS/REACT AGGRAV/URTICARIA/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	MMR	MSD	0014E	1	RA	SC
	DTAP	CONNAUGHT LABS	7H81507	3	LA	IM

SYMPTOM TEXT: 26JAN98 c/o sore throat & wheezy @ 930PM;28JAN98 redness on lt arm moving up shoulder to neck;29JAN98 1AM woke up itchy, welts;smaller mosquito like area on extremities;fever-felt hot;eyes & face & neck swollen;allerg react'
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
LAB DATA: NA
HISTORY: pt croupy & wheezed;
PREX ILLNESS: NONE

108945
.6 M 13-Jan-1998 Rx@ 13-Jan-1998 0 03-Apr-1998 PA PUB-PA9816 09-Sep-1999
COSTARTS: AGITATION/ANOREXIA/CRY ABNORMAL/FEVER/HYPERTONIA/HYPOKINESIA/SOMNOLENCE/SPEECH DIS/STUPOR/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	2	LL	IM
	HIBV	LEDERLE(PRAXIS)	M350PN	2	RL	
	IPV	CONNAUGHT LTD	M0359	1	RL	

SYMPTOM TEXT: mom reported pt woke up from nap w/unusual high pitched scream on 31OCT97;pt 'spacey', fussy & had fever;APAP given;pt slept a lot;when pt not sleeping either fussy or crying;would not nurse;vomit;
PREVIOUS VAX ILL: pt exp rxn 31JUN98 @ 4mo w/DTAP dose 2;
OTHER MEDS: APAP
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

108949
.6 F 11-Dec-1997 Rx® 13-Dec-1997 2 03-Apr-1998 PA PUB-PA9820 09-Sep-1999
COSTARTS: HYSN INJECT SITE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	2	RL	IM
HEP	MSD	0358E	2	LL	IM
HIBV	LEDERLE(PRAXIS)	M350PN	2	LL	IM
OPV	LEDERLE	077OH	2		PO

SYMPTOM TEXT: 13DEC97 raised, red, bumpy rash like little pimples on legs where recv shots;16DEC97 legs improved, whitehead type bumps where each shot was given & scabs @ inj site;31DEC97 rash cleared 1wk ago, still has scabs where needle entered;
PREVIOUS VAX ILL: pt exp pimple like red bumps past second set of immun;
OTHER MEDS: NONE
LAB DATA: NA
HISTORY: NONE
PREX ILLNESS: NONE

109385
.3 F 08-Dec-1997 Rx® 12-Dec-1997 4 14-Apr-1998 TN PUB-TN98002 09-Sep-1999
COSTARTS: ECCHYMOSIS/HYSN INJECT SITE/MASS INJECT SITE/PAIN INJECT SITE/
VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	RL	IM
HEP	MSD	0457E	1	LL	IM
HIBV	MSD	1112E	1	LL	IM
IPV	MERIEUX INST	M10702	1	LA	SC

SYMPTOM TEXT: 4 1/2cm induration-hard & moveable & tender on lt thigh 1-2cm raised bruise located over induration;
PREVIOUS VAX ILL: NONE
OTHER MEDS: APAP PRN-dosage by weight q4hr PRN
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: seborrheic dermatitis of brows & scalp (cradle cap)

VAERSID

Age	Sex	Vacc Date	Onset Date	(days)	Status Date	Birth Date	State	MFR Report ID	Last Edit Date

109997

.4 M 02-Feb-1998 Rx@ 02-Feb-1998 0 27-Apr-1998 PA OTH-PA9824 09-Sep-1999

COSTARTS: AGITATION/ANOREXIA/FEVER/MALAISE/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	0	LL	IM
HBHEPB	MSD	1176E	0	RL	IM
OPV	LEDERLE	450032	0		PO

SYMPTOM TEXT: pt recv vax & was not right for 1 week afterwards per mom- cried, high fever 102, only took grape juice for 1 wk nothing else;

PREVIOUS VAX ILL: NA

OTHER MEDS: NONE

LAB DATA: NONE

HISTORY: NONE

PREX ILLNESS: NONE

110367

1.1 M 05-Feb-1998 Rx@ 12-Feb-1998 7 04-May-1998 NJ PUB-NJ989 09-Sep-1999

COSTARTS: AGITATION/ALLERG REACT/DIARRHEA/FEVER/PRURITUS/RASH/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	RL	IM
HEP	SMITHKLINE	2210A2	1	LL	IM
HIBV	CONNAUGHT LABS	7C9168B	1	LL	IM
IPV	CONNAUGHT LTD	M0844	1	RA	SC
MMR	MSD	1004D	0	LA	SC

SYMPTOM TEXT: 5 days p/vax broke out in rash, severe itching, fever 101, diarrhea & child uncontrollable screaming;pt broke out all over in a rash 12FEB98;pt went to ER calamine lotion suggested;15FEB98 returned to ER called it allerg rxn, itching;

PREX ILLNESS: NONE

110586

1.6 F 11-Feb-1998 Rx@ 11-Feb-1998 0 14-May-1998 NY PVT-NY98004 09-Sep-1999

COSTARTS: URTICARIA/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
MMR	MSD	0157E	0	LL	SC
DTAP	CONNAUGHT LABS	7H81507	3	RL	IM
HIBV	LEDERLE(PRAXIS)	M200RC	3	LL	IM

SYMPTOM TEXT: w/in 1 1/2hr of vax pt began developing mosquito bite size hives all over body, eventually all blended together;abd, face, ears & thigh the worst;tx w/DPH;in ER & cont for 24hr;

OTHER MEDS: Tempera;Poly vi flor

HISTORY: NONE

PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

110888
1.7 M 30-Apr-1998 Rx@ 03-May-1998 3 27-May-1998 MO PUB-MO98022 09-Sep-1999
COSTARTS: FEVER/RASH VESIC BULL/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	1	LL	IM
	HEP	MSD	0745E	1	RL	IM
	HIBV	LEDERLE(PRAXIS)	M195RC	1	LL	IM
	IPV	CONNAUGHT LTD	MD0443	1	RA	SC
	MMR	MSD	1012E	1	LA	SC

SYMPTOM TEXT: 3MAY pt ran a fever of 104 for 2 days & had fever blisters;pt fever today 100 & had MD appt 6MAY98;MD office feels fever is unrelated to immun;
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

111194
5.7 F 04-May-1998 Rx@ 05-May-1998 1 01-Jun-1998 MO PUB-MO98025 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/HYSN INJECT SITE/MASS INJECT SITE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	3	LL	IM
	HEP	MSD	1308D	1	LL	IM
	MMR	MSD	1012E	1	RL	SC
	OPV	LEDERLE	0769C	3		PO

SYMPTOM TEXT: 5MAY98 small pink area lt thigh reported by mom;6MAY98 raised red area;7MAY98 edema & red;
PREVIOUS VAX ILL: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

111543
5.2 M 08-May-1998 Rx@ 15-May-1998 7 10-Jun-1998 MN PVT- 09-Sep-1999
COSTARTS: URTICARIA/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	0	LA	IM
	OPV	LEDERLE	449087			PO

SYMPTOM TEXT: hives 2" x 1 1/4" warm to touch, reddened;mom noticed evening of 15MAY98-gone 16MAYY98;
PREVIOUS VAX ILL: NA
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

111866
5.4 M 02-Feb-1998 Rx® 09-Feb-1998 7 18-Jun-1998 WI PUB-WI98005 09-Sep-1999
COSTARTS: EDEMA INJECT SITE/EDEMA PERIPH/ERYTHEMA MULT/HYSN INJECT SITE/RASH/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	4	LA	IM
	MMR	MSD	0623E	1	A	SC
	OPV	LEDERLE	0769C	4		PO
	VARCEL	MSD	1321E	0	LA	SC

SYMPTOM TEXT: pt recv vax 2FEB98 & 3FEB98 & 4FEB98 lt arm had redness & mild swelling from elbow to shoulder;no rash 5FEB98;930AM 9FEB98 mom noticed rash beginning on ankles;big circular rash to knees;erythema multiforme;
PREVIOUS VAX ILL: NONE
OTHER MEDS: flouride tablet
LAB DATA: NONE
HISTORY: sensitivity to sulfa as an infant
PREX ILLNESS: NONE

112242
5.2 F 15-Sep-1997 Rx® 17-Sep-1997 2 02-Jul-1998 MN PUB-MN98010 09-Sep-1999
COSTARTS: HYSN INJECT SITE/PRURITUS/VASODILAT/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	4	RL	IM
	OPV	LEDERLE	444062	3		PO

SYMPTOM TEXT: 2 days p/vax leg where recv DTAP was reddened, inflamed & itched;mom stated it had improved from the day before-the inflammation was from the top of the knee to the upper thigh groin area;no tx given
PREX ILLNESS: NONE

113644
1.3 F 18-Jun-1998 Rx® 25-Jun-1998 7 27-Aug-1998 OK PUB-OK9818 21-Sep-1999
COSTARTS: CONVULS GRAND MAL/FEBRILE SEIZURE/FEVER/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	3	LA	
	HIBV	CONNAUGHT LABS	6K81378	3	RA	
	MMR	MSD	1316E	0	RA	SC
	VARCEL	MSD	6687E	0	LA	SC

SYMPTOM TEXT: devel fever 25JUN98-had grand mal sz for approx 2-3min;taken to ER;CXR negative;UA negative;fever cont for 2 wk p/episode, was told by MD was caused by vaccine;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: UA, CXR, blood, CBC WNL;no other studies;
HISTORY: allergies PCN
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

113814
5.6 M 17-Apr-1998 Rx@ 11-Aug-1998 116 04-Sep-1998 MO PUB-MO98044 09-Sep-1999
COSTARTS: ATROPHY MUSCLE/ECCHYMOSIS/HYPERTONIA/PAIN/PAIN INJECT SITE/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	4	LA	IM
	MMR	MSD	0108E		RA	SC
	OPV	LEDERLE	0786A	3		PO

SYMPTOM TEXT: pt c/o pain @ vax site, immed p/vax;next day c/o pain, tenderness & stiffness in arm;4mo later mom noticed bruising & a 1 1/2" by 1" wide indentation 1/8" depth;the bruise was purple in color;
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

115092
1.6 F 23-Jul-1997 Rx@ 14-Oct-1998 448 21-Oct-1998 NC PVT- 08-Sep-1999
COSTARTS: INFECT/NO DRUG EFFECT/RASH/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	3		IM
	OPV	LEDERLE	0766H	2		PO
	VARCEL	MSD	0536E	0		SC

SYMPTOM TEXT: onset of chickenpox 14OCT98 mild case, afeb, rash;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
LAB DATA: NONE
HISTORY: NONE
PREX ILLNESS: NONE

116990
.6 M 29-Aug-1997 Rx@ 29-Aug-1997 0 09-Dec-1998 KY UNK-KY980042 08-Sep-1999
COSTARTS: EAR DIS/FEVER/NERVOUSNESS/RASH/STOMATITIS/

VAX DETAIL:	Type	Manufacturer	Lot	Doses	Site	Route
	DTAP	CONNAUGHT LABS	7H81507	1	RL	
	HIBV	LEDERLE(PRAXIS)	M195RC	1	LL	
	IPV	CONNAUGHT LTD	M0461	1	RL	

SYMPTOM TEXT: grandma accompanied child today & stated child devel fever, rash & irritability p/vax AUG97;taken to ER;had ear infect along w/side effects of vax;inc rash & sores in mouth;seen by MD;
PREVIOUS VAX ILL: NONE
OTHER MEDS: NONE
HISTORY: NONE
PREX ILLNESS: NONE

VAERSID
Age Sex Vacc Date Onset Date (days) Status Date Birth Date State MFR Report ID Last Edit Date

118579
.6 M 27-Aug-1997 Rx® 27-Aug-1997 0 09-Feb-1999 PA UNK- 08-Sep-1999
SERIOUS: Life-threatening Disability
COSTARTS: AUTISM/FEVER/HYPERACUSIS/HYPERESTHESIA/HYPOTONIA/INSOMNIA/LAB TEST ABNORM/PALLOR/PARESTHESIA/PHOTOSENSITIVITY/SALIVA INC/SPEECH DIS/STUPOR/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	1	LL	IM
HEP	MSD	0115E	2	RL	IM
HIBV	LEDERLE(PRAXIS)	ML50PN	0	RL	IM
OPV	LEDERLE	443665	1		PO

SYMPTOM TEXT: Pt recv vax on 8/27/97; on same day pt exp fever (103), pale color, limp, staring, drooling; tx=Tylenol
OTHER MEDS: NONE
LAB DATA: Pt being evaluated for autism
HISTORY: NONE
PREX ILLNESS: NONE

127407
1.2 F 26-Jun-1997 Rx® 01-Jul-1997 5 24-Aug-1999 NY PVT- 03-Dec-1999
SERIOUS: Hospitalized()
COSTARTS: AGITATION/BRAIN STEM DIS/DYSPHAGIA/ENCEPHALITIS/HYPOKINESIA/REFLEXES DEC/

VAX DETAIL:

Type	Manufacturer	Lot	Doses	Site	Route
DTAP	CONNAUGHT LABS	7H81507	3	LA	IM
HIBV	CONNAUGHT LABS	7A91562	3	LA	IM
MMR	MSD	0284E	0	RA	SC

SYMPTOM TEXT: p/vax pt out of country; began to lose major motor milestones; stopped cruising; stopped bearing weight; lost ability to sit-up; could not roll over; difficulty swallowing; areflexia; poor head control; irritable; tx: IV Immunoglobulin
OTHER MEDS: none
LAB DATA: blood count; chem, MRI, neuro work-up, nerve conduct all nl;
HISTORY: strabismus surgery
PREX ILLNESS: none