THE CONTINUING OVERSIGHT OF THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

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THE CONTINUING OVERSIGHT OF THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM

WEDNESDAY, SEPTEMBER 18, 2002

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

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

Present: Representatives Burton, Weldon, Duncan, Maloney, Norton, Kucinich, and Tierney.

Staff present: Kevin Binger, staff director; James C. Wilson, chief counsel; David A. Kass, deputy chief counsel; S. Elizabeth Clay, professional staff member; Allyson Blandford, assistant to chief counsel; Robert Briggs, chief clerk; Robin Butler, office manager; Nicholis Mutton, deputy communications director; Joshua E. Gillespie, deputy chief clerk; Michael Layman and Susie Schulte, legislative assistants; Blain Rethmeier, communications director; Leneal Scott, computer systems manager; Corinne Zaccagnini, systems administrator; Phil Barnett, minority chief counsel; Sarah Despres, minority counsel, Ellen Rayner, minority chief clerk; and Jean Gosa and Earley Green, minority assistant clerk.

Mr. BURTON. Good morning. 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. Without objection, so ordered.

I want to start off by saying that we have got a war that we are dealing with, and as a result, there are briefings going on the Hill from Donald Rumsfeld, the Secretary of Defense, and some of the other members of the administration. And as a result, a lot of the members are diverting their attention to those issues.

I don't want anybody to think that the information that is going to be discussed today will be not looked at very closely by this committee and the administration just because of the war. But I think everybody can understand that things being the way they are, things that are very important to us sometimes are put on the back burner or sidestepped while we get through the critical issues facing the country.

Over the last year, this committee has been overseeing the National Vaccine Injury Compensation Program. We have held two hearings and we have introduced legislation. Our concern has been that this program has become too adversarial and that people who have been injured aren't getting a fair shake. This program was intended to be less adversarial than civil litigation. It was intended by Congress to provide compensation quickly and easily to people who have suffered very serious injuries.

On close calls, the families are supposed to get the benefit of the doubt. Unfortunately, that doesn't seem to be happening.

We are going to look at the Rogers case today. It was a close call. The Special Master ruled in favor of the family. Instead of accepting that decision gracefully, the Government has filed appeal after appeal to try to overturn it; and I just think that's wrong. That's not how we intended this program to run.

While approximately 1,700 families have received compensation under this program, many families have seen their cases tied up for years in a system that has become too contentious. At last year's hearings, we heard from six different families. They all had a very difficult time getting through this program.

We asked two of those families to come back today and update us on their cases. The reason we did that is because almost 1 year later these cases are still not resolved. They've dragged on for 8 to 10 years; and if we want to figure out what's working and what isn't working with this program and try to fix the problems, then these are the kinds of cases we need to take a hard look at.

Janet Zuhlke is back with us today. Her daughter Rachel was severely injured after she received her prekindergarten vaccines in 1990. Today Rachel is mentally retarded. She has periodic bouts of blindness that are getting progressively worse. She has seizures. She's confined to a wheelchair. She will need around-the-clock care for the rest of her life.

A team of respected medical specialists diagnosed her case as a vaccine-related encephalopathy, which is a table injury. Table injuries are supposed to receive compensation quickly and without opposition. Unfortunately, Janet had to fight for 9 years to get compensation—9 years.

In July of last year, the Special Master ruled that Rachel was entitled to compensation over the strong opposition of the Justice Department and Health and Human Services. It has now been 14 months since then; and because this system has become so complex, Janet and Rachel still haven't received their compensation.

We are just a week or two away from the tenth anniversary of Ms. Zuhlke's filing her petition. To date, she has not received any compensation for the table injury her daughter suffered. Ten years to settle a table injury was not how Congress intended this program to operate.

I have been told that the Special Master is working very hard to move this case forward and get it finished. He deserves credit for that. In just the last 2 weeks, they had a hearing to try to resolve the remaining disputes.

I want to be clear on one thing. The purpose of this hearing is not to try to influence the Special Master's decisions. The Special

Masters have to be independent, and they have a tough job to do, and we should respect that independence.

What does bother me about this case is that the Justice Department and the Department of Health and Human Services are opposed to paying for the medical treatments that Rachel is receiving. She has a team of specialists. They prescribed a series of treatments for her to try to keep her condition from deteriorating. As I understand it, these treatments are helping, and the Government doesn't want to pay for them because they are too expensive.

For 9 years, they fought to deny the Zuhlkes compensation. And now for the last year, they've fought to deny her the medical treatments her doctors say will help her. For the life of me, I can't understand that.

As I mentioned earlier, the other case we are going to look at is the Rogers case. Thad Rogers came here last November from Alabama to testify on behalf of his wife Diane. We asked him to come back today, but she is too ill, and he couldn't leave. Ron Homer, who is the attorney for the Rogers family, will testify on their behalf. However, the family has sent a videotaped statement that we are going to watch.

Diane Rogers received a routine tetanus vaccination in February 1991. She rapidly developed MS-like symptoms. She's now bedridden. The Special Master determined in 2001 that Ms. Rogers is entitled to compensation under the program; it took 7 years to get to that point. Unfortunately, the Government does not want to concede on this case.

As I said before, the Justice Department has appealed this decision and they lost. They twice made motions for reconsiderations and then were rejected both times and now they are planning on appealing again. I just don't see the point of dragging this thing out. This family has been waiting for 8 years. It's time to stop fighting and give them what they deserve.

As a result of our investigation, we've introduced legislation to try to improve this program. It's a bipartisan bill. Congressman Waxman and Congressman Dave Weldon and over 40 of my colleagues have joined me in introducing H.R. 3741, the National Vaccine Injury Compensation Program Improvement Act of 2002. This bill does not address all of the flaws that I think exist in the program, but it's a good start.

[The information referred to follows:]

I

107TH CONGRESS
2D SESSION

H. R. 3741

To amend the Public Health Service Act with respect to the National Vaccine Injury Compensation Program.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 13, 2002

Mr. BURTON of Indiana (for himself, Mr. WAXMAN, Mr. WELDON of Florida, Mr. NADLER, Mr. GILMAN, Mr. HORN, Mr. DUNCAN, Mr. FROST, Mrs. MORELLA, Mr. KUCINICH, Mrs. JO ANN DAVIS of Virginia, and Mr. TOM DAVIS of Virginia) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act with respect to the National Vaccine Injury Compensation Program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Vaccine Injury Compensation Program Improvement Act of 2002".

SEC. 2. BASIS FOR CALCULATING PROJECTED LOST EARNINGS.

Section 2115(a)(3)(B) of the Public Health Service Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by strik-

1 ing all that follows "for loss of earnings" and inserting
2 the following: "determined on the basis of the annual esti-
3 mate of the average (mean) gross weekly earnings of full-
4 time wage and salary workers age 18 and over in the pri-
5 vate nonfarm sector (which includes all industries other
6 than agricultural production of crops and livestock), as
7 calculated annually by the Bureau of Labor Statistics
8 from the quarter sample data of the Current Population
9 Survey, or as calculated by such similar method as the
10 Secretary may prescribe by regulation, less appropriate
11 taxes and the average cost of a health insurance policy,
12 as determined by the Secretary.".

13 **SEC. 3. INCREASE OF AWARD IN THE CASE OF A VACCINE-**
14 **RELATED DEATH.**

15 Section 2115(a)(2) of the Public Health Service Act
16 (42 U.S.C. 300aa–15(a)(2)) is amended by striking
17 "$250,000" and inserting "$300,000".

18 **SEC. 4. ALLOWING COMPENSATION FOR FAMILY COUN-**
19 **SELING EXPENSES AND EXPENSES OF ESTAB-**
20 **LISHING GUARDIANSHIP.**

21 (a) FAMILY COUNSELING EXPENSES IN POST-1988
22 CASES.—Section 2115(a) of the Public Health Service Act
23 (42 U.S.C. 300aa–15(a)) is amended by adding at the end
24 the following:

1 "(5) Actual nonreimbursable expenses that have
2 been or will be incurred for family counseling deter-
3 mined to be reasonably necessary and that result
4 from the vaccine-related injury for which the peti-
5 tioner seeks compensation.".

6 (b) EXPENSES OF ESTABLISHING GUARDIANSHIPS IN
7 POST-1988 CASES.—Section 2115(a) of the Public Health
8 Service Act (42 U.S.C. 300aa–15(a)) is further amended
9 by adding at the end the following paragraph:

10 "(6) Actual and nonreimbursable expenses that
11 have been or will be incurred to establish and main-
12 tain a guardianship, conservatorship, or trust for an
13 individual who has suffered a vaccine-related injury,
14 including attorneys' fees and other costs incurred in
15 a proceeding to establish and maintain such a
16 guardianship, conservatorship, or trust.".

17 (c) CONFORMING AMENDMENT FOR CASES FROM
18 1988 AND EARLIER.—Section 2115(b) of the Public
19 Health Service Act (42 U.S.C. 300aa–15(b)) is
20 amended—

21 (1) in paragraph (2), by striking "and" at the
22 end of the paragraph;

23 (2) by redesignating paragraph (3) as para-
24 graph (5) and by inserting a closing parenthesis be-
25 fore the period in that paragraph; and

(3) by inserting after paragraph (2) the following paragraphs:

"(3) family counseling expenses (as provided in paragraph (5) of subsection (a)),

"(4) expenses of establishing and maintaining guardianships, conservatorships, or trusts (as provided in paragraph (6) of subsection (a)), and".

SEC. 5. ALLOWING PAYMENT OF INTERIM ATTORNEYS' FEES AND COSTS.

Section 2115(e) of the Public Health Service Act (42 U.S.C. 300aa–15(e)) is amended by adding at the end the following:

"(4) Upon completion of a conference required by Rule 5 of Appendix J of the Rules of the United States Court of Federal Claims, a special master may make an interim award of attorneys' fees and costs if—

"(A) the case involves a vaccine administered on or after October 1, 1988,

"(B) in tentative findings and conclusions, the special master determines that the petitioner's claim has a reasonable basis,

"(C) the award is limited to reasonable attorneys' fees and other costs (within the mean-

1 ing of paragraph (1)(B)) incurred in the pro-
2 ceeding, and
3 "(D) the petitioner provides documentation
4 verifying the expenditure of the amount for
5 which compensation is sought.
6 "(5) An interim award of attorneys' fees and
7 costs by a special master under paragraph (4) shall
8 be promptly paid by the Secretary pursuant to the
9 special master's order and without need of a judg-
10 ment. The special master's order for interim attor-
11 neys' fees and costs is not subject to review under
12 sections 2112(e) and 2112(f) until after the special
13 master has made a determination regarding an
14 award of attorneys' fees and costs under paragraph
15 (1).
16 "(6) The attorneys' fees and costs awarded as
17 compensation on a petition under paragraph (1)
18 shall be for the total attorneys' fees and costs in-
19 curred in any proceeding on such petition, less the
20 amount awarded for interim attorneys' fees and
21 costs. In determining fees and costs under para-
22 graph (1), a special master may reconsider and mod-
23 ify the amounts awarded for fees and costs under
24 paragraph (4).".

SEC. 6. PROCEDURE FOR PAYING ATTORNEYS' FEES.

Section 2115(e) of the Public Health Service Act (42 U.S.C. 300aa–15(e)), as amended by section 5, is amended by adding at the end the following:

"(7) When a special master or court awards attorneys' fees or costs under paragraph (1) or (4), it may order that such fees and costs be payable solely to the petitioner's attorney if—

"(A) the petitioner expressly consents, or

"(B) the special master or court, after affording to the Secretary and all interested persons the opportunity to submit relevant information, determines that—

"(i) the petitioner cannot be located or refuses to respond to a request by the special master or court for information, and there is no practical alternative means to ensure that the attorney will be reimbursed for such fees and costs expeditiously, or

"(ii) there are other exceptional circumstances and good cause for paying such fees and costs solely to the petitioner's attorney.".

1 **SEC. 7. EXTENSION OF STATUTE OF LIMITATIONS.**

2 (a) GENERAL RULE.—Section 2116(a) of the Public
3 Health Service Act (42 U.S.C. 300aa–16(a)) is
4 amended—

5 (1) in paragraph (2), by striking "36 months"
6 and inserting "6 years"; and

7 (2) in paragraph (3)—

8 (A) by striking "24 months" and inserting
9 "6 years"; and

10 (B) by striking "48 months" and inserting
11 "6 years".

12 (b) ADDITIONAL EXTENSION.—

13 (1) LIMITATION PERIOD.—Notwithstanding sec-
14 tion 2116(a) of the Public Health Service Act (42
15 U.S.C. 300aa–16(a)), in the case of a vaccine set
16 forth in the Vaccine Injury Table that is adminis-
17 tered after September 30, 1988, and before the date
18 of the enactment of this Act, if a vaccine-related in-
19 jury or death occurred as a result of the administra-
20 tion of such vaccine, the end of the limitation period
21 for filing a petition is the later of—

22 (A) the applicable date under section
23 2116(a) of the Public Health Service Act (42
24 U.S.C. 300aa–16(a)); or

25 (B) the date that is 2 years after the date
26 of the enactment of this Act.

1 (2) EFFECT OF PREVIOUS DISMISSAL.—Not-
2 withstanding section 2111(b)(2) of the Public
3 Health Service Act (42 U.S.C. 300aa–11(b)(2)), if a
4 petition is filed within the limitation period applica-
5 ble under paragraph (1), the petition may not be
6 dismissed on the basis of a previous dismissal for
7 untimely filing.
8 (c) CLAIMS BASED ON REVISIONS TO TABLE.—Sec-
9 tion 2116(b) of the Public Health Service Act (42 U.S.C.
10 300aa–16(b)) is amended by striking all that follows "file
11 a petition for such compensation" and inserting the fol-
12 lowing: "if—
13 "(1) the vaccine-related death or injury with re-
14 spect to which the petition is filed occurred no more
15 than 8 years before the effective date of the revision
16 of the table; and
17 "(2)(A) the petition satisfies the conditions
18 stated in subsection (a); or
19 "(B) the date of occurrence of the first symp-
20 tom or manifestation of onset of injury occurred
21 more than 4 years before the petition is filed, and
22 the petition is filed no more than 2 years after the
23 effective date of the revision of the table.".
24 (d) REPORTS.—

1 (1) TRANSMISSION.—The Secretary of Health
2 and Human Services shall transmit to the Congress
3 2 annual reports that shall each include the fol-
4 lowing:
5 (A) Identification of the number of peti-
6 tions filed for compensation under the National
7 Vaccine Injury Compensation Program that
8 would have been time-barred absent the limita-
9 tion period provided by subsection (b) .
10 (B) Describe the effects of subsection (b)
11 on the ability of the Secretary to administer the
12 National Vaccine Injury Compensation Program
13 and adjudicate petitions under such Program in
14 a timely manner.
15 (2) DATES OF SUBMISSION.—In carrying out
16 this subsection, the Secretary of Health and Human
17 Services shall transmit—
18 (A) the first report not later than 1 year
19 after the date of the enactment of this Act; and
20 (B) the second report not later than 2
21 years after the date of the enactment of this
22 Act.
23 **SEC. 8. ADVISORY COMMISSION ON CHILDHOOD VACCINES.**
24 (a) SELECTION OF INDIVIDUALS INJURED BY VAC-
25 CINES AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of

1 the Public Health Service Act (42 U.S.C. 300aa–
2 19(a)(1)(B)) is amended by striking all that follows the
3 comma and inserting the following: "of whom 1 shall be
4 the legal representative of a child who has suffered a vac-
5 cine-related injury or death, and at least 1 other shall be
6 either the legal representative of a child who has suffered
7 a vaccine-related injury or death or an individual who has
8 personally suffered a vaccine-related injury.".

9 (b) MANDATORY MEETING SCHEDULE ELIMI-
10 NATED.—Section 2119(c) of the Public Health Service Act
11 (42 U.S.C. 300aa–19(c)) is amended by striking "not less
12 often than four times per year and".

13 **SEC. 9. CONFORMING AMENDMENT TO TRUST FUND PROVI-**
14 **SION.**

15 Section 9510(c)(1)(A) of the Internal Revenue Code
16 of 1986 is amended by striking "(as in effect" and all
17 that follows through "for vaccine-related injury or death"
18 and inserting "(as in effect on the effective date of the
19 National Vaccine Injury Compensation Program Improve-
20 ment Act of 2002) for vaccine-related injury or death".

21 **SEC. 10. INCREASE IN LIMIT ON ADMINISTRATIVE EX-**
22 **PENSES.**

23 (a) INCREASE IN LIMIT ON ADMINISTRATIVE EX-
24 PENSES.—Section 9510(c)(1)(B) of the Internal Revenue
25 Code of 1986 is amended by striking "(but not in excess

1 of $9,500,000 for any fiscal year)" and inserting "(but
2 not in excess of $10,000,000 for any fiscal year)".
3 (b) ADMINISTRATIVE EXPENSES OF BUREAU OF
4 PUBLIC DEBT.—Section 9510(c)(1) of the Internal Rev-
5 enue Code of 1986, as amended by section 9 and sub-
6 section (a), is further amended—
7 (1) in subparagraph (A)(ii), by striking "or" at
8 the end;
9 (2) in subparagraph (B), by striking the period
10 at the end and inserting ", and"; and
11 (3) by adding at the end the following:
12 "(C) the payment of administrative and
13 personnel expenses that the Bureau of the Pub-
14 lic Debt incurs for financial services for the
15 Trust Fund.".
16 **SEC. 11. PUBLIC SERVICE ANNOUNCEMENT CAMPAIGN.**
17 Section 2110(c) of the Public Health Service Act (42
18 U.S.C. 300aa–10(c)) is amended by striking the period at
19 the end and inserting ", including by conducting a public
20 service announcement campaign.".
21 **SEC. 12. APPLICATION**
22 The provisions of and amendments made by sections
23 2, 3, 4, 5, 6, 7, and 9 apply to a petition filed under sec-
24 tion 2111 of the Public Health Service Act (42 U.S.C.

1 300aa–11) if the petition is pending on or filed after the
2 date of the enactment of this Act.

○

II

107TH CONGRESS
2D SESSION

S. 2053

To amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 21, 2002

Mr. FRIST introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

To amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 "Improved Vaccine Affordability and Availability Act".

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—STATE VACCINE GRANTS

Sec. 101. Availability of influenza vaccine.
Sec. 102. Program for increasing immunization rates for adults and adolescents; collection of additional immunization data.
Sec. 103. Immunization awareness.
Sec. 104. Supply of vaccines.

TITLE II—VACCINE INJURY COMPENSATION PROGRAM

Sec. 201. Administrative revision of vaccine injury table.
Sec. 202. Equitable relief.
Sec. 203. Parent petitions for compensation.
Sec. 204. Jurisdiction to dismiss actions improperly brought.
Sec. 205. Application.
Sec. 206. Clarification of when injury is caused by factor unrelated to administration of vaccine.
Sec. 207. Increase in award in the case of a vaccine-related death and for pain and suffering.
Sec. 208. Basis for calculating projected lost earnings.
Sec. 209. Allowing compensation for family counseling expenses and expenses of establishing guardianship.
Sec. 210. Allowing payment of interim costs.
Sec. 211. Procedure for paying attorneys' fees.
Sec. 212. Extension of statute of limitations.
Sec. 213. Advisory commission on childhood vaccines.
Sec. 214. Clarification of standards of responsibility.
Sec. 215. Clarification of definition of manufacturer.
Sec. 216. Clarification of definition of vaccine-related injury or death.
Sec. 217. Clarification of definition of vaccine.
Sec. 218. Conforming amendment to trust fund provision.
Sec. 219. Ongoing review of childhood vaccine data.
Sec. 220. Pending actions.
Sec. 221. Report.

TITLE I—STATE VACCINE GRANTS

SEC. 101. AVAILABILITY OF INFLUENZA VACCINE.

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

"(3)(A) For the purpose of carrying out activities relating to influenza vaccine under the immunization program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 and 2004. Such authorization shall be in

1 addition to amounts available under paragraphs (1) and
2 (2) for such purpose.
3 "(B) The authorization of appropriations established
4 in subparagraph (A) shall not be effective for a fiscal year
5 unless the total amount appropriated under paragraphs
6 (1) and (2) for the fiscal year is not less than such total
7 for fiscal year 2000.
8 "(C) The purposes for which amounts appropriated
9 under subparagraph (A) are available to the Secretary in-
10 clude providing for improved State and local infrastruc-
11 ture for influenza immunizations under this subsection in
12 accordance with the following:
13 "(i) Increasing influenza immunization rates in
14 populations considered by the Secretary to be at
15 high risk for influenza-related complications and in
16 their contacts.
17 "(ii) Recommending that health care providers
18 actively target influenza vaccine that is available in
19 September, October, and November to individuals
20 who are at increased risk for influenza-related com-
21 plications and to their contacts.
22 "(iii) Providing for the continued availability of
23 influenza immunizations through December of such
24 year, and for additional periods to the extent that
25 influenza vaccine remains available.

1 "(iv) Encouraging States, as appropriate, to de-
2 velop contingency plans (including plans for public
3 and professional educational activities) for maxi-
4 mizing influenza immunizations for high-risk popu-
5 lations in the event of a delay or shortage of influ-
6 enza vaccine.

7 "(D) The Secretary shall submit to the Committee
8 on Energy and Commerce of the House of Representa-
9 tives, and the Committee on Health, Education, Labor,
10 and Pensions of the Senate, periodic reports describing the
11 activities of the Secretary under this subsection regarding
12 influenza vaccine. The first such report shall be submitted
13 not later than June 6, 2003, the second report shall be
14 submitted not later than June 6, 2004, and subsequent
15 reports shall be submitted biennially thereafter.".

16 **SEC. 102. PROGRAM FOR INCREASING IMMUNIZATION**
17 **RATES FOR ADULTS AND ADOLESCENTS; COL-**
18 **LECTION OF ADDITIONAL IMMUNIZATION**
19 **DATA.**

20 (a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL
21 AND PREVENTION.—Section 317(j) of the Public Health
22 Service Act (42 U.S.C. 247b(j)), as amended by section
23 101, is further amended by adding at the end the fol-
24 lowing:

1 "(4)(A) For the purpose of carrying out activities to
2 increase immunization rates for adults and adolescents
3 through the immunization program under this subsection,
4 and for the purpose of carrying out subsection (k)(2),
5 there are authorized to be appropriated $50,000,000 for
6 fiscal year 2003, and such sums as may be necessary for
7 each of the fiscal years 2004 through 2006. Such author-
8 ization is in addition to amounts available under para-
9 graphs (1), (2), and (3) for such purposes.

10 "(B) In expending amounts appropriated under sub-
11 paragraph (A), the Secretary shall give priority to adults
12 and adolescents who are medically underserved and are
13 at risk for vaccine-preventable diseases, including as ap-
14 propriate populations identified through projects under
15 subsection (k)(2)(E).

16 "(C) The purposes for which amounts appropriated
17 under subparagraph (A) are available include (with re-
18 spect to immunizations for adults and adolescents) the
19 payment of the costs of storing vaccines, outreach activi-
20 ties to inform individuals of the availability of the immuni-
21 zations, and other program expenses necessary for the es-
22 tablishment or operation of immunization programs car-
23 ried out or supported by States or other public entities
24 pursuant to this subsection.

1 "(5) The Secretary shall annually submit to Congress
2 a report that—
3 "(A) evaluates the extent to which the immuni-
4 zation system in the United States has been effective
5 in providing for adequate immunization rates for
6 adults and adolescents, taking into account the ap-
7 plicable year 2010 health objectives established by
8 the Secretary regarding the health status of the peo-
9 ple of the United States; and
10 "(B) describes any issues identified by the Sec-
11 retary that may affect such rates.
12 "(6) In carrying out this subsection and paragraphs
13 (1) and (2) of subsection (k), the Secretary shall consider
14 recommendations regarding immunizations that are made
15 in reports issued by the Institute of Medicine.".
16 (b) RESEARCH, DEMONSTRATIONS, AND EDU-
17 CATION.—Section 317(k) of the Public Health Service Act
18 (42 U.S.C. 247b(k)) is amended—
19 (1) by redesignating paragraphs (2) through
20 (4) as paragraphs (3) through (5), respectively; and
21 (2) by inserting after paragraph (1) the fol-
22 lowing:
23 "(2) The Secretary, directly and through grants
24 under paragraph (1), shall provide for a program of re-

1 search, demonstration projects, and education in accord-
2 ance with the following:
3 "(A) The Secretary shall coordinate with public
4 and private entities (including nonprofit private enti-
5 ties), and develop and disseminate guidelines, toward
6 the goal of ensuring that immunizations are rou-
7 tinely offered to adults and adolescents by public
8 and private health care providers.
9 "(B) The Secretary shall cooperate with public
10 and private entities to obtain information for the an-
11 nual evaluations required in subsection (j)(5)(A).
12 "(C) The Secretary shall (relative to fiscal year
13 2001) increase the extent to which the Secretary col-
14 lects data on the incidence, prevalence, and cir-
15 cumstances of diseases and adverse events that are
16 experienced by adults and adolescents and may be
17 associated with immunizations, including collecting
18 data in cooperation with commercial laboratories.
19 "(D) The Secretary shall ensure that the enti-
20 ties with which the Secretary cooperates for pur-
21 poses of subparagraphs (A) through (C) include
22 managed care organizations, community-based orga-
23 nizations that provide health services, and other
24 health care providers.

1 "(E) The Secretary shall provide for projects to
2 identify racial and ethnic minority groups and other
3 health disparity populations for which immunization
4 rates for adults and adolescents are below such rates
5 for the general population, and to determine the fac-
6 tors underlying such disparities.".

7 **SEC. 103. IMMUNIZATION AWARENESS.**

8 (a) DEVELOPMENT OF INFORMATION CONCERNING
9 MENINGITIS.—

10 (1) IN GENERAL.—The Secretary of Health and
11 Human Services, in consultation with the Director of
12 the Centers for Disease Control and Prevention,
13 shall develop and make available to entities de-
14 scribed in paragraph (2) information concerning
15 bacterial meningitis and the availability and effec-
16 tiveness of vaccinations for populations targeted by
17 the Advisory Committee of Immunization Practices
18 (an advisory committee established by the Secretary
19 Health and Human Services, acting through the
20 Centers for Disease Control and Prevention).

21 (2) ENTITIES.—An entity is described in this
22 paragraph if the entity—

23 (A) is—

24 (i) a college or university; or

1 (ii) a prison or other detention facil-
2 ity; and
3 (B) is determined appropriate by the Sec-
4 retary of Health and Human Services.
5 (b) DEVELOPMENT OF INFORMATION CONCERNING
6 HEPATITIS.—
7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services, in consultation with the Director of
9 the Centers for Disease Control and Prevention,
10 shall develop and make available to entities de-
11 scribed in paragraph (2) information concerning
12 hepatitis A and B and the availability and effective-
13 ness of vaccinations with respect to such diseases.
14 (2) ENTITIES.—An entity is described in this
15 paragraph if the entity—
16 (A) is—
17 (i) a health care clinic that serves in-
18 dividuals diagnosed as being infected with
19 HIV or as having other sexually trans-
20 mitted diseases;
21 (ii) an organization or business that
22 counsels individuals about international
23 travel or who arranges for such travel;
24 (iii) a police, fire or emergency med-
25 ical services organization that responds to

1 natural or man-made disasters or emer-
2 gencies;
3 (iv) a prison or other detention facil-
4 ity;
5 (v) a college or university; or
6 (vi) a public health authority or chil-
7 dren's health service provider in areas of
8 intermediate or high endemnicity for hepa-
9 titis A as defined by the Centers for Dis-
10 ease Control and Prevention; and
11 (B) is determined appropriate by the Sec-
12 retary of Health and Human Services.

13 **SEC. 104. SUPPLY OF VACCINES.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services, acting through the Director of the Cen-
16 ters for Disease Control and Prevention, shall prioritize,
17 acquire, and maintain a supply of such prioritized vaccines
18 sufficient to provide vaccinations throughout a 6-month
19 period.

20 (b) PROCEEDS.—Any proceeds received by the Sec-
21 retary of Health and Human Services from the sale of vac-
22 cines contained in the supply described in subsection (a),
23 shall be available to the Secretary for the purpose of pur-
24 chasing additional vaccines for the supply. Such proceeds
25 shall remain available until expended.

1 (c) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated for the purpose of car-
3 rying out subsection (a) such sums as may be necessary
4 for each of fiscal years 2003 through 2008.

5 TITLE II—VACCINE INJURY 6 COMPENSATION PROGRAM

7 SEC. 201. ADMINISTRATIVE REVISION OF VACCINE INJURY 8 TABLE.

9 The second sentence of section 2114(c)(1) of the
10 Public Health Service Act (42 U.S.C. 300aa–14(c)(1)) is
11 amended to read as follows: "In promulgating such regula-
12 tions, the Secretary shall provide for notice and for at
13 least 90 days opportunity for public comment.".

14 SEC. 202. EQUITABLE RELIEF.

15 Section 2111(a)(2)(A) of the Public Health Service
16 Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended by strik-
17 ing "No person" and all that follows through "and—" and
18 inserting the following: "No person may bring or maintain
19 a civil action against a vaccine administrator or manufac-
20 turer in a State or Federal court for damages arising
21 from, or equitable relief relating to, a vaccine-related in-
22 jury or death associated with the administration of a vac-
23 cine after October 1, 1988 and no such court may award
24 damages or equitable relief for any such vaccine-related
25 injury or death, unless the person proves present physical

1 injury and a timely petition has been filed, in accordance
2 with section 2116 for compensation under the Program
3 for such injury or death and—".

4 **SEC. 203. PARENT PETITIONS FOR COMPENSATION.**

5 Section 2111(a)(2) of the Public Health Service Act
6 (42 U.S.C. 300aa–(a)(2)) is amended—

7 (1) in subparagraph (B), by inserting "or (B)"
8 after "subparagraph (A)";

9 (2) by redesignating subparagraph (B) as sub-
10 paragraph (C); and

11 (3) by inserting after subparagraph (A) the fol-
12 lowing:

13 "(B) No parent or other third party may bring
14 or maintain a civil action against a vaccine adminis-
15 trator or manufacturer in a Federal or State court
16 for damages or equitable relief relating to a vaccine-
17 related injury or death, including but not limited to
18 damages for loss of consortium, society, companion-
19 ship or services, loss of earnings, medical or other
20 expenses, and emotional distress, and no court may
21 award damages or equitable relief in such an action
22 unless the action is joined with a civil action brought
23 by the person whose vaccine-related injury is the
24 basis for the parent's or other third party's action

1 and that person has satisfied the conditions of sub-
2 paragraph (A).".

3 **SEC. 204. JURISDICTION TO DISMISS ACTIONS IMPROP-**
4 **ERLY BROUGHT.**

5 Section 2111(a)(3) of the Public Health Service Act
6 (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the
7 end the following: "If any civil action which is barred
8 under subparagraph (A) or (B) of paragraph (2) is filed
9 or maintained in a State court, or any vaccine adminis-
10 trator or manufacturer is made a party to any civil action
11 brought in State court (other than a civil action which
12 may be brought under paragraph (2)) for damages or eq-
13 uitable relief for a vaccine-related injury or death associ-
14 ated with the administration of a vaccine after October
15 1, 1988, the civil action may be removed by the defendant
16 or defendants to the United States Court of Federal
17 Claims, which shall have jurisdiction over such civil action,
18 and which shall dismiss such action. The notice required
19 by section 1446 of title 28, United States Code, shall be
20 filed with the United States Court of Federal Claims, and
21 that court shall proceed in accordance with sections 1446
22 through 1451 of title 28, United States Code.".

23 **SEC. 205. APPLICATION.**

24 Section 2111(a)(9) of the Public Health Service Act
25 (42 U.S.C. 300aa–11(a)(9)) is amended by striking

1 "This" and inserting "Except as provided in subsection
2 (a)(2), this".

3 **SEC. 206. CLARIFICATION OF WHEN INJURY IS CAUSED BY**
4 **FACTOR UNRELATED TO ADMINISTRATION**
5 **OF VACCINE.**

6 Section 2113(a)(2)(B) of the Public Health Service
7 Act (42 U.S.C. 300aa–13(a)(2)(B)) is amended—
8 (1) by inserting "structural lesions, genetic dis-
9 orders," after "and related anoxia)";
10 (2) by inserting "(without regard to whether
11 the cause of the infection, toxin, trauma, structural
12 lesion, genetic disorder, or metabolic disturbance is
13 known)" after "metabolic disturbances"; and
14 (3) by striking "but" and inserting "and".

15 **SEC. 207. INCREASE IN AWARD IN THE CASE OF A VACCINE-**
16 **RELATED DEATH AND FOR PAIN AND SUF-**
17 **FERING.**

18 Section 2115(a) of the Public Health Service Act (42
19 U.S.C. 300aa–15(a)) is amended—
20 (1) in paragraph (2), by striking "$250,000"
21 and inserting "$350,000"; and
22 (2) in paragraph (4), by striking "$250,000"
23 and inserting "$350,000".

1 **SEC. 208. BASIS FOR CALCULATING PROJECTED LOST**
2 **EARNINGS.**

3 Section 2115(a)(3)(B) of the Public Health Service
4 Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by strik-
5 ing "loss of earnings" and all that follows and inserting
6 the following: "loss of earnings determined on the basis
7 of the annual estimate of the average (mean) gross weekly
8 earnings of wage and salary workers age 18 and over (ex-
9 cluding the incorporated self-employed) in the private non-
10 farm sector (which includes all industries other than agri-
11 cultural production crops and livestock), as calculated an-
12 nually by the Bureau of Labor Statistics from the quarter
13 sample data of the Current Population Survey, or as cal-
14 culated by such similar method as the Secretary may pre-
15 scribe by regulation, less appropriate taxes and the aver-
16 age cost of a health insurance policy, as determined by
17 the Secretary.".

18 **SEC. 209. ALLOWING COMPENSATION FOR FAMILY COUN-**
19 **SELING EXPENSES AND EXPENSES OF ESTAB-**
20 **LISHING GUARDIANSHIP.**

21 (a) FAMILY COUNSELING EXPENSES IN POST-1988
22 CASES.—Section 2115(a) of the Public Health Service Act
23 (42 U.S.C. 300aa–15(a)) is amended by adding at the end
24 to following:

25 "(5) Actual unreimbursable expenses that have
26 been or will be incurred for family counseling as is

1 determined to be reasonably necessary and that re-
2 sult from the vaccine-related injury from which the
3 petitioner seeks compensation.".

4 (b) EXPENSES OF ESTABLISHING GUARDIANSHIPS IN
5 POST-1988 CASES.—Section 2115(a) of the Public Health
6 Service Act (42 U.S.C. 300aa–15(a)), as amended by sub-
7 section (a), is further amended by adding at the end the
8 following:

9 "(6) Actual unreimbursable expenses that have
10 been, or will be reasonably incurred to establish and
11 maintain a guardianship or conservatorship for an
12 individual who has suffered a vaccine-related injury,
13 including attorney fees and other costs incurred in
14 a proceeding to establish and maintain such guard-
15 ianship or conservatorship.".

16 (c) CONFORMING AMENDMENT FOR CASES FROM
17 1988 AND EARLIER.—Section 2115(b) of the Public
18 Health Service Act (42 U.S.C. 300aa–15(b)) is
19 amended—

20 (1) in paragraph (2), by striking "and" at the
21 end;

22 (2) in paragraph (3), by inserting a closed pa-
23 renthesis before the period in that paragraph;

24 (3) by redesignating paragraph (3) as para-
25 graph (5); and

1 (4) by inserting after paragraph (2), the fol-
2 lowing:
3 "(3) family counseling expenses (as provided for
4 in paragraph (5) of subsection (a));
5 "(4) expenses of establishing guardianships (as
6 provided for in paragraph (6) of subsection (a));
7 and".

8 **SEC. 210. ALLOWING PAYMENT OF INTERIM COSTS.**

9 Section 2115(e) of the Public Health Service Act (42
10 U.S.C. 300aa–15(e)) is amended by adding at the end the
11 following:
12 "(4) A special master or court may make an interim
13 award of costs if—
14 "(A) the case involves a vaccine administered
15 on or after October 1, 1988;
16 "(B) the award is limited to other costs (within
17 the meaning of paragraph (1)(B)) incurred in the
18 proceeding; and
19 "(C) the petitioner provides documentation
20 verifying the expenditure of the amount for which
21 compensation is sought.".

22 **SEC. 211. PROCEDURE FOR PAYING ATTORNEYS' FEES.**

23 Section 2115(e) of the Public Health Service Act (42
24 U.S.C. 300aa–15(e)), as amended by section 205, is fur-
25 ther amended by adding at the end the following:

"(5) When a special master or court awards attorney fees or costs under paragraph (1) or (4), it may order that such fees or costs be payable solely to the petitioner's attorney if—

"(A) the petitioner expressly consents; or

"(B) the special master or court determines, after affording to the Secretary and to all interested persons the opportunity to submit relevant information, that—

"(i) the petitioner cannot be located or refuses to respond to a request by the special master or court for information, and there is no practical alternative means to ensure that the attorney will be reimbursed for such fees or costs expeditiously; or

"(ii) there are otherwise exceptional circumstances and good cause for paying such fees or costs solely to the petitioner's attorney.".

SEC. 212. EXTENSION OF STATUTE OF LIMITATIONS.

(a) GENERAL RULE.—Section 2116(a) of the Public Health Service Act (42 U.S.C. 300aa–16(a)) is amended—

(1) in paragraph (2) by striking "36 months" and inserting "6 years"; and

1 (2) in paragraph (3), by striking "48 months"
2 and inserting "6 years".
3 (b) CLAIMS BASED ON REVISIONS TO TABLE.—
4 Strike all of section 2116(b) of the Public Health Service
5 Act (42 U.S.C. 300aa–16(b)) and insert the following:
6 "(b) EFFECT OF REVISED TABLE.—If at any time
7 the Vaccine Injury Table is revised and the effect of such
8 revision is to make an individual eligible for compensation
9 under the program, where, before such revision, such indi-
10 vidual was not eligible for compensation under the pro-
11 gram, or to significantly increase the likelihood that an
12 individual will be able to obtain compensation under the
13 program, such person may, and must before filing a civil
14 action for equitable relief or monetary damages, notwith-
15 standing section 2111(b)(2), file a petition for such com-
16 pensation if—
17 "(1) the vaccine-related death or injury with re-
18 spect to which the petition is filed occurred not more
19 than 8 years before the effective date of the revision
20 of the table; and
21 "(2) either—
22 "(A) the petition satisfies the conditions
23 described in subsection (a); or
24 "(B) the date of the occurrence of the first
25 symptom or manifestation of onset of the injury

1 occurred more than 4 years before the petition
2 is filed, and the petition is filed not more than
3 2 years after the effective date of the revision
4 of the table.".

5 **SEC. 213. ADVISORY COMMISSION ON CHILDHOOD**
6 **VACCINES.**

7 (a) SELECTION OF PERSONS INJURED BY VACCINES
8 AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the
9 Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B))
10 is amended by striking "of whom" and all that follows
11 and inserting the following: "of whom 1 shall be the legal
12 representative of a child who has suffered a vaccine-re-
13 lated injury or death, and at least 1 other shall be either
14 the legal representative of a child who has suffered a vac-
15 cine-related injury or death or an individual who has per-
16 sonally suffered a vaccine-related injury.".

17 (b) MANDATORY MEETING SCHEDULE ELIMI-
18 NATED.—Section 2119(c) of the Public Health Service Act
19 (42 U.S.C. 300aa–19(c)) is amended by striking "not less
20 often than four times per year and".

21 **SEC. 214. CLARIFICATION OF STANDARDS OF RESPONSI-**
22 **BILITY.**

23 (a) GENERAL RULE.—Section 2122(a) of the Public
24 Health Service Act (42 U.S.C. 300aa–22(a)) is amended
25 by striking "and (e) State law shall apply to a civil action

1 brought for damages" and inserting "(d), and (f) State
2 law shall apply to a civil action brought for damages or
3 equitable relief"; and

4 (b) UNAVOIDABLE ADVERSE SIDE EFFECTS.—Sec-
5 tion 2122(b)(1) of the Public Health Service Act (42
6 U.S.C. 300aa–22(b)(1)) is amended by inserting "or equi-
7 table relief" after "for damages".

8 (c) DIRECT WARNINGS.—Section 2122(c) of the Pub-
9 lic Health Service Act (42 U.S.C. 300aa–22(c)) is amend-
10 ed by inserting "or equitable relief" after "for damages".

11 (d) CONSTRUCTION.—Section 2122(d) of the Public
12 Health Service Act (42 U.S.C. 300aa–22(d)) is
13 amended—

14 (1) by inserting "or equitable relief" after "for
15 damages"; and

16 (2) by inserting "or relief" after "which dam-
17 ages".

18 (e) PRESENT PHYSICAL INJURY.—Section 2122 of
19 the Public Health Service Act (42 U.S.C. 300aa–22) is
20 amended—

21 (1) by redesignating subsections (d) and (e) as
22 subsections (e) and (f), respectively; and

23 (2) by inserting after subsection (c) the fol-
24 lowing:

1 "(d) PRESENT PHYSICAL INJURY.—No vaccine man-
2 ufacturer or vaccine administrator shall be liable in a civil
3 action brought after October 1, 1988, for equitable or
4 monetary relief absent proof of present physical injury
5 from the administration of a vaccine, nor shall any vaccine
6 manufacturer or vaccine administrator be liable in any
7 such civil action for claims of medical monitoring, or in-
8 creased risk of harm.".

9 **SEC. 215. CLARIFICATION OF DEFINITION OF MANUFAC-**
10 **TURER.**

11 Section 2133(3) of the Public Health Service Act (42
12 U.S.C. 300aa–33(3)) is amended—

13 (1) in the first sentence, by striking "under its
14 label any vaccine set forth in the Vaccine Injury
15 Table" and inserting "any vaccine set forth in the
16 Vaccine Injury table, including any component or in-
17 gredient of any such vaccine"; and

18 (2) in the second sentence, by inserting "includ-
19 ing any component or ingredient of any such vac-
20 cine" before the period.

21 **SEC. 216. CLARIFICATION OF DEFINITION OF VACCINE-RE-**
22 **LATED INJURY OR DEATH.**

23 Section 2133(5) of the Public Health Service Act (42
24 U.S.C. 300aa–33(5)) is amended by adding at the end the
25 following: "For purposes of the preceding sentence, an

1 adulterant or contaminant shall not include any compo-
2 nent or ingredient listed in a vaccine's product license ap-
3 plication or product label.".

4 **SEC. 217. CLARIFICATION OF DEFINITION OF VACCINE.**

5 Section 2133 of the Public Health Service Act (42
6 U.S.C. 300aa–33) is amended by adding at the end the
7 following:

8 "(7) The term 'vaccine' means any preparation or
9 suspension, including but not limited to a preparation or
10 suspension containing an attenuated or inactive micro-
11 organism or subunit thereof or toxin, developed or admin-
12 istered to produce or enhance the body's immune response
13 to a disease or diseases and includes all components and
14 ingredients listed in the vaccines's product license applica-
15 tion and product label.".

16 **SEC. 218. CONFORMING AMENDMENT TO TRUST FUND PRO-**
17 **VISION.**

18 Section 9510(c)(1)(A) of the Internal Revenue Code
19 of 1986 is amended by striking "October 18, 2000" and
20 inserting "the effective date of the Improved Vaccine Af-
21 fordability and Availability Act".

1 **SEC. 219. ONGOING REVIEW OF CHILDHOOD VACCINE**
2 **DATA.**

3 Part C of title XXI of the Public Health Service Act
4 (42 U.S.C. 300a–25 et seq.) is amended by adding at the
5 end the following:

6 **"SEC. 2129. ONGOING REVIEW OF CHILDHOOD VACCINE**
7 **DATA.**

8 "(a) IN GENERAL.—Not later than 6 months after
9 the date of enactment of this section, the Secretary shall
10 enter into a contract with the Institute of Medicine of the
11 National Academy of Science under which the Institute
12 shall conduct an ongoing, comprehensive review of new sci-
13 entific data on childhood vaccines (according to priorities
14 agreed upon from time to time by the Secretary and the
15 Institute of Medicine).

16 "(b) REPORTS.—Not later than 3 years after the date
17 on which the contract is entered into under paragraph (1),
18 the Institute of Medicine shall submit to the Secretary a
19 report on the findings of studies conducted, including find-
20 ings as to any adverse events associated with childhood
21 vaccines, including conclusions concerning causation of ad-
22 verse events by such vaccines, together with recommenda-
23 tions for changes in the Vaccine Injury Table, and other
24 appropriate recommendations, based on such findings and
25 conclusions.

1 "(c) FAILURE TO ENTER INTO CONTRACT.—If the
2 Secretary and the Institute of Medicine are unable to
3 enter into the contract described in paragraph (1), the
4 Secretary shall enter into a contract with another qualified
5 nongovernmental scientific organization for the purposes
6 described in paragraphs (1) and (2).

7 "(d) AUTHORIZATION OF APPROPRIATIONS.—To
8 carry out this section, there are authorized to be appro-
9 priated such sums as may be necessary for each of fiscal
10 years 2003, 2004, 2005 and 2006.".

11 **SEC. 220. PENDING ACTIONS.**

12 The amendments made by this title shall apply to all
13 actions or proceedings pending on or after the date of en-
14 actment of this Act.

15 **SEC. 221. REPORT.**

16 Not later than 1 year after the date of enactment
17 of this Act, the Secretary of Health and Human Services
18 shall submit recommendations regarding how to address
19 the growing surplus in the Vaccine Trust Fund, and the
20 rationale for such recommendations to—

21 (1) the Health, Education, Labor and Pensions
22 Committee of the Senate;

23 (2) the Finance Committee of the Senate;

24 (3) the Energy and Commerce Committee of
25 the House of Representatives; and

1 (4) the Ways and Means Committee of the
2 House of Representatives.

○

I

107TH CONGRESS
2D SESSION

H. R. 5282

To amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2002

Mr. GREENWOOD (for himself and Mr. TOWNS) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act to improve immunization rates by increasing the distribution of vaccines and improving and clarifying the vaccine injury compensation program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 "Improved Vaccine Affordability and Availability Act".

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—STATE VACCINE GRANTS

Sec. 101. Availability of influenza vaccine.
Sec. 102. Program for increasing immunization rates for adults and adolescents; collection of additional immunization data.
Sec. 103. Immunization awareness.
Sec. 104. Supply of vaccines.

TITLE II—VACCINE INJURY COMPENSATION PROGRAM

Sec. 201. Administrative revision of vaccine injury table.
Sec. 202. Equitable relief.
Sec. 203. Parent petitions for compensation.
Sec. 204. Jurisdiction to dismiss actions improperly brought.
Sec. 205. Clarification of when injury is caused by factor unrelated to administration of vaccine.
Sec. 206. Basis for calculating projected lost earnings.
Sec. 207. Allowing compensation for family counseling expenses and expenses of establishing guardianship.
Sec. 208. Allowing payment of interim costs.
Sec. 209. Procedure for paying attorneys' fees.
Sec. 210. Extension of statute of limitations.
Sec. 211. Advisory commission on childhood vaccines.
Sec. 212. Clarification of standards of responsibility.
Sec. 213. Clarification of definition of manufacturer.
Sec. 214. Clarification of definition of vaccine-related injury or death.
Sec. 215. Clarification of definition of vaccine.
Sec. 216. Ongoing review of childhood vaccine data.
Sec. 217. Pending actions.
Sec. 218. Report.

TITLE I—STATE VACCINE GRANTS

SEC. 101. AVAILABILITY OF INFLUENZA VACCINE.

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

"(3)(A) For the purpose of carrying out activities relating to influenza vaccine under the immunization program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 and 2004. Such authorization shall be in

1 addition to amounts available under paragraphs (1) and
2 (2) for such purpose.
3 "(B) The authorization of appropriations established
4 in subparagraph (A) shall not be effective for a fiscal year
5 unless the total amount appropriated under paragraphs
6 (1) and (2) for the fiscal year is not less than such total
7 for fiscal year 2000.
8 "(C) The purposes for which amounts appropriated
9 under subparagraph (A) are available to the Secretary in-
10 clude providing for improved State and local infrastruc-
11 ture for influenza immunizations under this subsection in
12 accordance with the following:
13 "(i) Increasing influenza immunization rates in
14 populations considered by the Secretary to be at
15 high risk for influenza-related complications and in
16 their contacts.
17 "(ii) Recommending that health care providers
18 actively target influenza vaccine that is available in
19 September, October, and November to individuals
20 who are at increased risk for influenza-related com-
21 plications and to their contacts.
22 "(iii) Providing for the continued availability of
23 influenza immunizations through December of such
24 year, and for additional periods to the extent that
25 influenza vaccine remains available.

"(iv) Encouraging States, as appropriate, to develop contingency plans (including plans for public and professional educational activities) for maximizing influenza immunizations for high-risk populations in the event of a delay or shortage of influenza vaccine.

"(D) The Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, periodic reports describing the activities of the Secretary under this subsection regarding influenza vaccine. The first such report shall be submitted not later than June 6, 2003, the second report shall be submitted not later than June 6, 2004, and subsequent reports shall be submitted biennially thereafter.".

SEC. 102. PROGRAM FOR INCREASING IMMUNIZATION RATES FOR ADULTS AND ADOLESCENTS; COLLECTION OF ADDITIONAL IMMUNIZATION DATA.

(a) ACTIVITIES OF CENTERS FOR DISEASE CONTROL AND PREVENTION.—Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)), as amended by section 101, is further amended by adding at the end the following:

1 "(4)(A) For the purpose of carrying out activities to
2 increase immunization rates for adults and adolescents
3 through the immunization program under this subsection,
4 and for the purpose of carrying out subsection (k)(2),
5 there are authorized to be appropriated $50,000,000 for
6 fiscal year 2003, and such sums as may be necessary for
7 each of the fiscal years 2004 through 2006. Such author-
8 ization is in addition to amounts available under para-
9 graphs (1), (2), and (3) for such purposes.

10 "(B) In expending amounts appropriated under sub-
11 paragraph (A), the Secretary shall give priority to adults
12 and adolescents who are medically underserved and are
13 at risk for vaccine-preventable diseases, including as ap-
14 propriate populations identified through projects under
15 subsection (k)(2)(E).

16 "(C) The purposes for which amounts appropriated
17 under subparagraph (A) are available include (with re-
18 spect to immunizations for adults and adolescents) the
19 payment of the costs of storing vaccines, outreach activi-
20 ties to inform individuals of the availability of the immuni-
21 zations, and other program expenses necessary for the es-
22 tablishment or operation of immunization programs car-
23 ried out or supported by States or other public entities
24 pursuant to this subsection.

1 "(5) The Secretary shall annually submit to Congress
2 a report that—
3 "(A) evaluates the extent to which the immuni-
4 zation system in the United States has been effective
5 in providing for adequate immunization rates for
6 adults and adolescents, taking into account the ap-
7 plicable year 2010 health objectives established by
8 the Secretary regarding the health status of the peo-
9 ple of the United States; and
10 "(B) describes any issues identified by the Sec-
11 retary that may affect such rates.
12 "(6) In carrying out this subsection and paragraphs
13 (1) and (2) of subsection (k), the Secretary shall consider
14 recommendations regarding immunizations that are made
15 in reports issued by the Institute of Medicine.".
16 (b) RESEARCH, DEMONSTRATIONS, AND EDU-
17 CATION.—Section 317(k) of the Public Health Service Act
18 (42 U.S.C. 247b(k)) is amended—
19 (1) by redesignating paragraphs (2) through
20 (4) as paragraphs (3) through (5), respectively; and
21 (2) by inserting after paragraph (1) the fol-
22 lowing:
23 "(2) The Secretary, directly and through grants
24 under paragraph (1), shall provide for a program of re-

1 search, demonstration projects, and education in accord-
2 ance with the following:
3 "(A) The Secretary shall coordinate with public
4 and private entities (including nonprofit private enti-
5 ties), and develop and disseminate guidelines, toward
6 the goal of ensuring that immunizations are rou-
7 tinely offered to adults and adolescents by public
8 and private health care providers.
9 "(B) The Secretary shall cooperate with public
10 and private entities to obtain information for the an-
11 nual evaluations required in subsection (j)(5)(A).
12 "(C) The Secretary shall (relative to fiscal year
13 2001) increase the extent to which the Secretary col-
14 lects data on the incidence, prevalence, and cir-
15 cumstances of diseases and adverse events that are
16 experienced by adults and adolescents and may be
17 associated with immunizations, including collecting
18 data in cooperation with commercial laboratories.
19 "(D) The Secretary shall ensure that the enti-
20 ties with which the Secretary cooperates for pur-
21 poses of subparagraphs (A) through (C) include
22 managed care organizations, community-based orga-
23 nizations that provide health services, and other
24 health care providers.

"(E) The Secretary shall provide for projects to identify racial and ethnic minority groups and other health disparity populations for which immunization rates for adults and adolescents are below such rates for the general population, and to determine the factors underlying such disparities.".

SEC. 103. IMMUNIZATION AWARENESS.

(a) DEVELOPMENT OF INFORMATION CONCERNING MENINGITIS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop and make available to entities described in paragraph (2) information concerning bacterial meningitis and the availability and effectiveness of vaccinations for populations targeted by the Advisory Committee of Immunization Practices (an advisory committee established by the Secretary of Health and Human Services, acting through the Centers for Disease Control and Prevention).

(2) ENTITIES.—An entity is described in this paragraph if the entity—

(A) is—

(i) a college or university; or

1 (ii) a prison or other detention facil-
2 ity; and
3 (B) is determined appropriate by the Sec-
4 retary of Health and Human Services.
5 (b) DEVELOPMENT OF INFORMATION CONCERNING
6 HEPATITIS.—
7 (1) IN GENERAL.—The Secretary of Health and
8 Human Services, in consultation with the Director of
9 the Centers for Disease Control and Prevention,
10 shall develop and make available to entities de-
11 scribed in paragraph (2) information concerning
12 hepatitis A and B and the availability and effective-
13 ness of vaccinations with respect to such diseases.
14 (2) ENTITIES.—An entity is described in this
15 paragraph if the entity—
16 (A) is—
17 (i) a health care clinic that serves in-
18 dividuals diagnosed as being infected with
19 HIV or as having other sexually trans-
20 mitted diseases;
21 (ii) an organization or business that
22 counsels individuals about international
23 travel or who arranges for such travel;
24 (iii) a police, fire or emergency med-
25 ical services organization that responds to

1 natural or man-made disasters or emer-
2 gencies;
3 (iv) a prison or other detention facil-
4 ity;
5 (v) a college or university; or
6 (vi) a public health authority or chil-
7 dren's health service provider in areas of
8 intermediate or high endemnicity for hepa-
9 titis A as defined by the Centers for Dis-
10 ease Control and Prevention; and
11 (B) is determined appropriate by the Sec-
12 retary of Health and Human Services.

13 **SEC. 104. SUPPLY OF VACCINES.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services, acting through the Director of the Cen-
16 ters for Disease Control and Prevention, shall prioritize,
17 acquire, and maintain a supply of such prioritized vaccines
18 sufficient to provide vaccinations throughout a 6-month
19 period.

20 (b) PROCEEDS.—Any proceeds received by the Sec-
21 retary of Health and Human Services from the sale of vac-
22 cines contained in the supply described in subsection (a),
23 shall be available to the Secretary for the purpose of pur-
24 chasing additional vaccines for the supply. Such proceeds
25 shall remain available until expended.

1 (c) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated for the purpose of car-
3 rying out subsection (a) such sums as may be necessary
4 for each of fiscal years 2003 through 2008.

5 TITLE II—VACCINE INJURY 6 COMPENSATION PROGRAM

7 SEC. 201. ADMINISTRATIVE REVISION OF VACCINE INJURY 8 TABLE.

9 Section 2114 of the Public Health Service Act (42
10 U.S.C. 300aa–14) is amended—
11 (1) in subsection (c), by striking paragraph (1)
12 and inserting the following:
13 "(1) In promulgating such regulations, the Sec-
14 retary shall provide for notice and for at least 9060
15 days opportunity for public comment."; and
16 (2) in subsection (d), by striking "90 days" and
17 inserting "60 days".

18 SEC. 202. EQUITABLE RELIEF.

19 Section 2111(a)(2)(A) of the Public Health Service
20 Act (42 U.S.C. 300aa–11(a)(2)(A)) is amended by strik-
21 ing "No person" and all that follows through "and—" and
22 inserting the following: "No person may bring or maintain
23 a civil action against a vaccine administrator or manufac-
24 turer in a State or Federal court for damages arising
25 from, or equitable relief relating to, a vaccine-related in-

1 jury or death associated with the administration of a vac-
2 cine after October 1, 1988 and no such court may award
3 damages or equitable relief for any such vaccine-related
4 injury or death, unless the person proves past or present
5 physical injury and a timely petition has been filed, in ac-
6 cordance with section 2116 for compensation under the
7 Program for such injury or death and—".

8 **SEC. 203. PARENT PETITIONS FOR COMPENSATION.**

9 (a) CIVIL ACTIONS.—Section 2111(a)(2) of the Pub-
10 lic Health Service Act (42 U.S.C. 300aa–(a)(2)) is
11 amended—

12 (1) in subparagraph (B), by inserting "or (B)"
13 after "subparagraph (A)";

14 (2) by redesignating subparagraph (B) as sub-
15 paragraph (C); and

16 (3) by inserting after subparagraph (A) the fol-
17 lowing:

18 "(B) No parent or other third party may bring
19 or maintain a civil action against a vaccine adminis-
20 trator or manufacturer in a State or Federal court
21 for damages or equitable relief relating to a vaccine-
22 related injury or death, including but not limited to
23 damages for loss of consortium, society, companion-
24 ship or services, loss of earnings, medical or other
25 expenses, and emotional distress, and no court may

1 award damages or equitable relief in such an action
2 unless—
3 "(i) the person who sustained the under-
4 lying vaccine-related injury or death upon which
5 such parent or third party's claim is premised
6 has, in accordance with section 2112, been
7 awarded compensation in a final judgment of
8 the United States Court of Federal Claims and
9 such judgment is subject to no further appeal
10 or review,
11 "(ii) such parent or other third party is
12 the parent, legal guardian or spouse of the per-
13 son who sustained the underlying vaccine-re-
14 lated injury and such parent, legal guardian or
15 spouse timely filed a derivative petition, in ac-
16 cordance with section 2116, and
17 "(iii)(I) the United States Court of Fed-
18 eral Claims has issued judgment under section
19 2112 on the derivative petition, and such par-
20 ent, legal guardian or spouse elects under sec-
21 tion 2121(a) to file a civil action, or
22 "(II) such parent, legal guardian or spouse
23 elects to withdraw such derivative petition
24 under section 2121(b) or such petition is con-
25 sidered withdrawn under such section.

1 Any civil action brought in accordance with this sub-
2 paragraph shall be subject to the standards and pro-
3 cedures set forth in section 2122 and 2123, regard-
4 less of whether the action arises directly from a vac-
5 cine-related injury or death associated with the ad-
6 ministration of a vaccine. Where the person who sus-
7 tained the underlying vaccine-related injury or death
8 upon which such parent, legal guardian, or spouse's
9 civil cause of action is premised elects under section
10 2121(a) to receive the compensation awarded, such
11 parent or third party may not bring a civil action for
12 damages or equitable relief, and no court may award
13 damages or equitable relief, for any injury or loss of
14 the type set forth in section 2115(a) or that might
15 in any way overlap with or otherwise duplicate com-
16 pensation of the type available under section
17 2115(a).".

18 (b) APPLICABILITY.—Section 2111(a)(9) of the Pub-
19 lic Health Service Act (42 U.S.C. 300aa–11(a)(9)) is
20 amended by inserting before the period the following: "and
21 to a parent or other third party to the extent such parent
22 or other third party seeks damages or equitable relief re-
23 lating to a vaccine-related injury or death sustained by
24 a person who is qualified to file a petition for compensa-
25 tion under the Program".

1 (c) PETITIONERS.—Section 2111(b) of the Public
2 Health Service Act (42 U.S.C. 300aa–11(b)) is
3 amended—
4 (1) in paragraph (1)—
5 (A) in subparagraph (A), by striking "(B)"
6 and inserting "(C)";
7 (B) by redesignating subparagraph (B) as
8 subparagraph (C); and
9 (C) by inserting after subparagraph (A)
10 the following:
11 "(B) Except as provided in subparagraph (C),
12 any parent, legal guardian or spouse of a person—
13 "(i) who has sustained a vaccine-related in-
14 jury or death,
15 "(ii) who has filed a petition for compensa-
16 tion under the Program (or whose legal rep-
17 resentative has filed a petition as authorized in
18 subparagraph (A)), and
19 "(iii) who has, in accordance with section
20 2112, been awarded compensation in a final
21 judgment of the United States Court of Federal
22 Claims that is subject to no further appeal or
23 review,

1 may, if such parent, legal guardian or spouse meets
2 the requirements of subsection (d) of this section,
3 file a derivative petition under this section."; and
4 (2) in paragraph (2)—
5 (A) by inserting after "filed" the following:
6 "by or on behalf of the person who sustained
7 the vaccine-related injury or death"; and
8 (B) by adding at the end the following:
9 "No parent, legal guardian, or spouse may file
10 more than one derivative petition with respect
11 to each administration of a vaccine.".
12 (d) DERIVATIVE PETITIONS.—Section 2111 of the
13 Public Health Service Act (42 U.S.C. 300aa–11) is
14 amended—
15 (1) by redesignating subsections (d) and (e)
16 and subsections (e) and (f), respectively; and
17 (2) by inserting after subsection (c) the fol-
18 lowing subsection:
19 "(d) DERIVATIVE PETITIONS.—If the parent, legal
20 guardian, or spouse of the person who sustained the vac-
21 cine-related injury or death seeks compensation under the
22 Program, such parent, legal guardian or spouse shall file
23 a timely derivative petition for compensation under the
24 Program in accordance with this section. Such a derivative
25 petition shall contain—

1 "(1) an affidavit, and supporting documenta-
2 tion, demonstrating that—
3 "(A) the child, ward, or spouse of such
4 person was, in accordance with section 2112,
5 previously awarded compensation for the under-
6 lying vaccine-related injury or death upon which
7 such parent's, legal guardian's, or spouse's de-
8 rivative claim is premised in a final judgment of
9 the United States Court of Federal Claims and
10 such judgment is subject to no further appeal
11 or review,
12 "(B) the derivative petition was filed no
13 later than 60 days after the date on which such
14 judgment became final and subject to no fur-
15 ther appeal or review,
16 "(C) such parent, legal guardian or spouse
17 suffered a loss compensable under section
18 2115(b) as a result of the vaccine-related injury
19 or death sustained by such person's child, ward,
20 or spouse, and
21 "(D) such parent, legal guardian or spouse
22 has not previously collected an award or settle-
23 ment of a civil action for damages for such loss,
24 and

1 "(2) records establishing such parent's, legal
2 guardian's, or spouse's legal relationship to the per-
3 son who sustained the vaccine-related injury or
4 death.".

5 (e) DETERMINATION OF ELIGIBILITY AND COM-
6 PENSATION.—Section 2113(a)(1) of the Public Health
7 Service Act (42 U.S.C. 300aa–13(a)(1)) is amended—

8 (1) in subparagraph (A), by inserting before ",
9 and" the following: "or, where applicable, section
10 2111(d)"; and

11 (2) in subparagraph (B), by inserting before
12 the period the following: "or, as applicable, that the
13 injury or loss described in the derivative petition is
14 due to factors unrelated to the vaccine-related injury
15 or death".

16 (f) COMPENSATION.—Section 2115 of the Public
17 Health Service Act (42 U.S.C. 300aa–15) is amended—

18 (1) by redesignating subsections (b) through (j)
19 as subsections (c) through (k), respectively; and

20 (2) by inserting after subsection (a) the fol-
21 lowing:

22 "(b) DERIVATIVE PETITIONS.—Compensation
23 awarded under the Program to a parent, legal guardian,
24 or spouse who files a derivative petition under section
25 2111 for a loss sustained as a result of a vaccine-related

1 injury or death sustained by such petitioner's child, ward,
2 or spouse shall include compensation for loss of consor-
3 tium, society, companionship or services, in an amount not
4 to exceed the lesser of $250,000 or the total amount of
5 compensation awarded to the person who sustained the
6 underlying vaccine-related injury or death.";
7 (3) in subsection (e), by inserting ", (3), and
8 (4)" after "(2)" and by inserting "and subsection
9 (b) of this section," following "section,";
10 (4) in subsection (g)(4)(B), by striking "sub-
11 section (j)" and inserting "subsection (k)";
12 (5) in subsection (j)(1), by striking "(j)" and
13 inserting "(k)";
14 (6) in subsection (j)(2), by inserting ", or to a
15 parent or spouse of a person who sustained a vac-
16 cine-related injury or death," following "death"; and
17 (7) in subsection (k), by striking "subsection
18 (f)(4)(B)" and inserting "subsection (g)(4)(B)".
19 **SEC. 204. JURISDICTION TO DISMISS ACTIONS IMPROP-**
20 **ERLY BROUGHT.**
21 Section 2111(a)(3) of the Public Health Service Act
22 (42 U.S.C. 300aa–11(a)(3)) is amended by adding at the
23 end the following: "If any civil action which is barred
24 under subparagraph (A) or (B) of paragraph (2) is filed
25 or maintained in a State court, or any vaccine adminis-

1 trator or manufacturer is made a party to any civil action
2 brought in State court (other than a civil action which
3 may be brought under paragraph (2)) for damages or eq-
4 uitable relief for a vaccine-related injury or death associ-
5 ated with the administration of a vaccine after October
6 1, 1988, the civil action may be removed at any time be-
7 fore final judgment by the defendant or defendants to the
8 United States Court of Federal Claims, which shall have
9 jurisdiction over such civil action, and which shall dismiss
10 such action. The notice required by section 1446 of title
11 28, United States Code, shall be filed with the United
12 States Court of Federal Claims, and that court shall, ex-
13 cept as provided herein, proceed in accordance with sec-
14 tions 1446 through 1451 of title 28, United States Code.".

15 **SEC. 205. CLARIFICATION OF WHEN INJURY IS CAUSED BY**
16 **FACTOR UNRELATED TO ADMINISTRATION**
17 **OF VACCINE.**

18 Section 2113(a)(2)(B) of the Public Health Service
19 Act (42 U.S.C. 300aa–13(a)(2)(B)) is amended—

20 (1) by inserting "structural lesions, genetic dis-
21 orders," after "and related anoxia)";

22 (2) by inserting "(without regard to whether
23 the cause of the infection, toxin, trauma, structural
24 lesion, genetic disorder, or metabolic disturbance is
25 known)" after "metabolic disturbances"; and

1 (3) by striking "but" and inserting "and".

2 **SEC. 206. BASIS FOR CALCULATING PROJECTED LOST**
3 **EARNINGS.**

4 Section 2115(a)(3)(B) of the Public Health Service
5 Act (42 U.S.C. 300aa–15(a)(3)(B)) is amended by strik-
6 ing "loss of earnings" and all that follows and inserting
7 the following: "loss of earnings determined on the basis
8 of the annual estimate of the average (mean) gross weekly
9 earnings of wage and salary workers age 18 and over (ex-
10 cluding the incorporated self-employed) in the private non-
11 farm sector (which includes all industries other than agri-
12 cultural production crops and livestock), as calculated an-
13 nually by the Bureau of Labor Statistics from the quarter
14 sample data of the Current Population Survey, or as cal-
15 culated by such similar method as the Secretary may pre-
16 scribe by regulation, less appropriate taxes and the aver-
17 age cost of a health insurance policy, as determined by
18 the Secretary.".

19 **SEC. 207. ALLOWING COMPENSATION FOR FAMILY COUN-**
20 **SELING EXPENSES AND EXPENSES OF ESTAB-**
21 **LISHING GUARDIANSHIP.**

22 (a) FAMILY COUNSELING EXPENSES IN POST-1988
23 CASES.—Section 2115(a) of the Public Health Service Act
24 (42 U.S.C. 300aa–15(a)) is amended by adding at the end
25 the following:

1 "(5) Actual unreimbursable expenses that have
2 been or will be incurred for family counseling as is
3 determined to be reasonably necessary and that re-
4 sult from the vaccine-related injury from which the
5 petitioner seeks compensation.".

6 (b) EXPENSES OF ESTABLISHING GUARDIANSHIPS IN
7 POST-1988 CASES.—Section 2115(a) of the Public Health
8 Service Act (42 U.S.C. 300aa–15(a)), as amended by sub-
9 section (a), is further amended by adding at the end the
10 following:

11 "(6) Actual unreimbursable expenses that have
12 been, or will be reasonably incurred to establish and
13 maintain a guardianship or conservatorship for an
14 individual who has suffered a vaccine-related injury,
15 including attorney fees and other costs incurred in
16 a proceeding to establish and maintain such guard-
17 ianship or conservatorship.".

18 (c) CONFORMING AMENDMENT FOR CASES FROM
19 1988 AND EARLIER.—Section 2115(c) of the Public
20 Health Service Act (42 U.S.C. 300aa–15(c)) is
21 amended—

22 (1) in paragraph (2), by striking "and" at the
23 end;

1 (2) in paragraph (3), by inserting a closed pa-
2 renthesis before the period in that paragraph, and
3 by striking "(e)" and inserting "(f)";
4 (3) by redesignating paragraph (3) as para-
5 graph (5); and
6 (4) by inserting after paragraph (2), the fol-
7 lowing:
8 "(3) family counseling expenses (as provided for
9 in paragraph (5) of subsection (a));
10 "(4) expenses of establishing guardianships (as
11 provided for in paragraph (6) of subsection (a));
12 and".

13 **SEC. 208. ALLOWING PAYMENT OF INTERIM COSTS.**

14 Section 2115(f) of the Public Health Service Act (42
15 U.S.C. 300aa–15(f)) is amended by adding at the end the
16 following:
17 "(4) A special master or court may make an interim
18 award of costs if—
19 "(A) the case involves a vaccine administered
20 on or after October 1, 1988;
21 "(B) the special master or court has determined
22 that the petitioner is entitled to compensation under
23 the Program;

"(C) the award is limited to other costs (within the meaning of paragraph (1)(B)) incurred in the proceeding; and

"(D) the petitioner provides documentation verifying the expenditure of the amount for which compensation is sought.".

SEC. 209. PROCEDURE FOR PAYING ATTORNEYS' FEES.

Section 2115(f) of the Public Health Service Act (42 U.S.C. 300aa–15(f)), as amended by section 205, is further amended by adding at the end the following:

"(5) When a special master or court awards attorney fees or costs under paragraph (1) or (4), it may order that such fees or costs be payable solely to the petitioner's attorney if—

"(A) the petitioner expressly consents; or

"(B) the special master or court determines, after affording to the Secretary and to all interested persons the opportunity to submit relevant information, that—

"(i) the petitioner cannot be located or refuses to respond to a request by the special master or court for information, and there is no practical alternative means to ensure that the attorney will be reimbursed for such fees or costs expeditiously; or

1 "(ii) there are otherwise exceptional cir-
2 cumstances and good cause for paying such fees
3 or costs solely to the petitioner's attorney.".

4 **SEC. 210. EXTENSION OF STATUTE OF LIMITATIONS.**

5 (a) GENERAL RULE.—Section 2116(a) of the Public
6 Health Service Act (42 U.S.C. 300aa–16(a)) is
7 amended—

8 (1) in paragraph (2) by striking "36 months"
9 and inserting "6 years"; and

10 (2) in paragraph (3), by striking "48 months"
11 and inserting "6 years".

12 (b) EFFECT OF AMENDMENT ON PREVIOUSLY UN-
13 TIMELY CLAIMS.—Section 2121 of the Public Health
14 Service Act (42 U.S.C. 300aa–21) is amended by adding
15 at the end the following:

16 "(d) PREVIOUSLY UNTIMELY CLAIMS.—Notwith-
17 standing subsection (a), (b), or (c) of this section, if a
18 petition is filed under section 2111(a), and such petition
19 would have been untimely under the statute of limitations
20 set forth in section 2116, as in effect prior to the effective
21 date of this subsection, the special master shall dismiss
22 the petition if the special master determines that the peti-
23 tioner did not sustain a vaccine-related illness, disability,
24 injury or condition as listed on the Vaccine Injury Table.".

1 (c) CLAIMS BASED ON REVISIONS TO TABLE.—
2 Strike all of section 2116(b) of the Public Health Service
3 Act (42 U.S.C. 300aa–16(b)) and insert the following:
4 "(b) EFFECT OF REVISED TABLE.—If at any time
5 the Vaccine Injury Table is revised and the effect of such
6 revision is to make an individual eligible for compensation
7 under the program, where, before such revision, such indi-
8 vidual was not eligible for compensation under the pro-
9 gram, or to significantly increase the likelihood that an
10 individual will be able to obtain compensation under the
11 program, such person may, and must before filing a civil
12 action for equitable relief or monetary damages, notwith-
13 standing section 2111(b)(2), file a petition for such com-
14 pensation if—
15 "(1) the vaccine-related death or injury with re-
16 spect to which the petition is filed occurred not more
17 than 8 years before the effective date of the revision
18 of the table; and
19 "(2) either—
20 "(A) the petition satisfies the conditions
21 described in subsection (a); or
22 "(B) the date of the occurrence of the first
23 symptom or manifestation of onset of the injury
24 occurred more than 4 years before the petition
25 is filed, and the petition is filed not more than

1 2 years after the effective date of the revision
2 of the table.".
3 (d) DERIVATIVE PETITIONS.—Section 2116 of the
4 Public Health Service Act (42 U.S.C. 300aa–16) is
5 amended by adding at the end the following:
6 "(d) DERIVATIVE PETITIONS.—No derivative petition
7 may be filed for compensation under the Program after
8 the expiration of 60 days after the date on which the
9 United States Court of Federal Claims has entered final
10 judgment and the time for all further appeals or review
11 has expired on the underlying claim of the person who sus-
12 tained the vaccine-related injury or death upon which the
13 derivative petition in premised.".
14 (e) TIMELY RESOLUTIONS OF CLAIMS.—
15 (1) SPECIAL MASTER DECISION.—Section
16 2112(d)(3)(A)(ii) of the Public Health Service Act
17 (42 U.S.C. 300aa–12(d)(3)(A)(ii)) is amended by
18 adding at the end the following: "For purposes of
19 this provision, the petition shall be deemed filed on
20 the date on which all petition contents and sup-
21 porting documents required under section 2111(c)
22 and, when applicable, section 2111(d) and the Vac-
23 cine Rules of the United States Court of Federal
24 Claims, including an affidavit and supporting docu-
25 mentation, are served on the Secretary and filed

1 with the clerk of the United States Court of Federal
2 Claims.".
3 (2) COURT OF FEDERAL CLAIMS DECISION.—
4 Section 2121(b)(2) of the Public Health Service Act
5 (42 U.S.C. 300aa–21(b)(2) is amended by adding at
6 the end the following: "For purposes of this provi-
7 sion, the petition shall be deemed filed on the date
8 on which all petition contents and supporting docu-
9 ments required under section 2111(c) and, when ap-
10 plicable, section 2111(d) and the Vaccine Rules of
11 the United States Court of Federal Claims, includ-
12 ing an affidavit and supporting documentation, are
13 served on the Secretary and filed with the clerk of
14 the United States Court of Federal Claims.".

15 **SEC. 211. ADVISORY COMMISSION ON CHILDHOOD VAC-**
16 **CINES.**

17 (a) SELECTION OF PERSONS INJURED BY VACCINES
18 AS PUBLIC MEMBERS.—Section 2119(a)(1)(B) of the
19 Public Health Service Act (42 U.S.C. 300aa–19(a)(1)(B))
20 is amended by striking "of whom" and all that follows
21 and inserting the following: "of whom 1 shall be the legal
22 representative of a child who has suffered a vaccine-re-
23 lated injury or death, and at least 1 other shall be either
24 the legal representative of a child who has suffered a vac-

1 cine-related injury or death or an individual who has per-
2 sonally suffered a vaccine-related injury.".

3 (b) MANDATORY MEETING SCHEDULE ELIMI-
4 NATED.—Section 2119(c) of the Public Health Service Act
5 (42 U.S.C. 300aa–19(c)) is amended by striking "not less
6 often than four times per year and".

7 **SEC. 212. CLARIFICATION OF STANDARDS OF RESPONSI-**
8 **BILITY.**

9 (a) GENERAL RULE.—Section 2122(a) of the Public
10 Health Service Act (42 U.S.C. 300aa–22(a)) is amended
11 by striking "and (e) State law shall apply to a civil action
12 brought for damages" and inserting "(d), and (f) State
13 law shall apply to a civil action brought for damages or
14 equitable relief"; and

15 (b) UNAVOIDABLE ADVERSE SIDE EFFECTS.—Sec-
16 tion 2122(b)(1) of the Public Health Service Act (42
17 U.S.C. 300aa–22(b)(1)) is amended by inserting "or equi-
18 table relief" after "for damages".

19 (c) DIRECT WARNINGS.—Section 2122(c) of the Pub-
20 lic Health Service Act (42 U.S.C. 300aa–22(c)) is amend-
21 ed by inserting "or equitable relief" after "for damages".

22 (d) CONSTRUCTION.—Section 2122(d) of the Public
23 Health Service Act (42 U.S.C. 300aa–22(d)) is
24 amended—

1 (1) by inserting "or equitable relief" after "for
2 damages"; and
3 (2) by inserting "or relief" after "which dam-
4 ages".
5 (e) PRESENT PHYSICAL INJURY.—Section 2122 of
6 the Public Health Service Act (42 U.S.C. 300aa–22) is
7 amended—
8 (1) by redesignating subsections (d) and (e) as
9 subsections (e) and (f), respectively; and
10 (2) by inserting after subsection (c) the fol-
11 lowing:
12 "(d) PRESENT PHYSICAL INJURY.—No vaccine man-
13 ufacturer or vaccine administrator shall be liable in a civil
14 action brought after October 1, 1988, for equitable or
15 monetary relief absent proof of past or present physical
16 injury from the administration of a vaccine, nor shall any
17 vaccine manufacturer or vaccine administrator be liable in
18 any such civil action for claims of medical monitoring, or
19 increased risk of harm.".

20 **SEC. 213. CLARIFICATION OF DEFINITION OF MANUFAC-**
21 **TURER.**

22 Section 2133(3) of the Public Health Service Act (42
23 U.S.C. 300aa–33(3)) is amended—
24 (1) in the first sentence, by striking "under its
25 label any vaccine set forth in the Vaccine Injury

1 Table" and inserting "any vaccine set forth in the
2 Vaccine Injury table, including any component or in-
3 gredient of any such vaccine"; and
4 (2) in the second sentence, by inserting "includ-
5 ing any component or ingredient of any such vac-
6 cine" before the period.

7 **SEC. 214. CLARIFICATION OF DEFINITION OF VACCINE-RE-**
8 **LATED INJURY OR DEATH.**

9 Section 2133(5) of the Public Health Service Act (42
10 U.S.C. 300aa–33(5)) is amended by adding at the end the
11 following: "For purposes of the preceding sentence, an
12 adulterant or contaminant shall not include any compo-
13 nent or ingredient listed in a vaccine's product license ap-
14 plication or product label.".

15 **SEC. 215. CLARIFICATION OF DEFINITION OF VACCINE.**

16 Section 2133 of the Public Health Service Act (42
17 U.S.C. 300aa–33) is amended by adding at the end the
18 following:
19 "(7) The term 'vaccine' means any preparation or
20 suspension, including but not limited to a preparation or
21 suspension containing an attenuated or inactive micro-
22 organism or subunit thereof or toxin, developed or admin-
23 istered to produce or enhance the body's immune response
24 to a disease or diseases and includes all components and

1 ingredients listed in the vaccines's product license applica-
2 tion and product label.".

3 **SEC. 216. ONGOING REVIEW OF CHILDHOOD VACCINE**
4 **DATA.**

5 Part C of title XXI of the Public Health Service Act
6 (42 U.S.C. 300a–25 et seq.) is amended by adding at the
7 end the following:

8 **"SEC. 2129. ONGOING REVIEW OF CHILDHOOD VACCINE**
9 **DATA.**

10 "(a) IN GENERAL.—Not later than 6 months after
11 the date of enactment of this section, the Secretary shall
12 enter into a contract with the Institute of Medicine of the
13 National Academy of Science under which the Institute
14 shall conduct an ongoing, comprehensive review of new sci-
15 entific data on childhood vaccines (according to priorities
16 agreed upon from time to time by the Secretary and the
17 Institute of Medicine).

18 "(b) REPORTS.—Not later than 3 years after the date
19 on which the contract is entered into under paragraph (1),
20 the Institute of Medicine shall submit to the Secretary a
21 report on the findings of studies conducted, including find-
22 ings as to any adverse events associated with childhood
23 vaccines, including conclusions concerning causation of ad-
24 verse events by such vaccines and other appropriate rec-
25 ommendations, based on such findings and conclusions.

1 "(c) FAILURE TO ENTER INTO CONTRACT.—If the
2 Secretary and the Institute of Medicine are unable to
3 enter into the contract described in paragraph (1), the
4 Secretary shall enter into a contract with another qualified
5 nongovernmental scientific organization for the purposes
6 described in paragraphs (1) and (2).

7 "(d) AUTHORIZATION OF APPROPRIATIONS.—To
8 carry out this section, there are authorized to be appro-
9 priated such sums as may be necessary for each of fiscal
10 years 2003, 2004, 2005 and 2006.".

11 **SEC. 217. PENDING ACTIONS.**

12 The amendments made by this title shall apply to all
13 actions or proceedings pending on or after the date of en-
14 actment of this Act unless a court of competent jurisdic-
15 tion has entered judgment (regardless of whether the time
16 for appeal has expired) in such action or proceeding dis-
17 posing of the entire action or proceeding.

18 **SEC. 218. REPORT.**

19 Not later than 1 year after the date of enactment
20 of this Act, and annually thereafter, the Advisory Commis-
21 sion on Childhood Vaccines shall report to the Secretary
22 of Health and Human Services regarding the status of the
23 Vaccine Trust Fund, and shall make recommendations to

1 the Secretary regarding the allocation of disbursements
2 from the Fund.

○

Mr. BURTON. Unfortunately, I've been told that the administration is opposed to the bill, and that's very disappointing to me. It's unfortunate that the pharmaceutical companies have so much influence over the Government of the United States. I just don't understand it.

The Victims' Compensation Fund was set up for the express purpose of protecting the pharmaceutical companies and at the same time making sure that people who are injured from vaccinations and vaccination-related instances got compensation for that. And it was supposed to be nonadversarial. That was the intent of Congress; everybody was supposed to be better off. The pharmaceutical companies were supposed to be free from litigation, product liability litigation, and the victims were supposed to be compensated.

And what we have now is, we have the vaccine companies urging legislators and people in the administration to oppose legislation that would make it easier for people to get compensation. And to me, that's just dead wrong.

We took as our starting point a series of recommendations from an advisory committee. Some of them were good and some were not so good, and we took what we thought were the best recommendations and we built on those. We expanded on them because we want this program to be as effective as possible.

But everything in this bill is bipartisan, everything is reasonable; and I can't see why the administration should oppose this. We doubled the statute of limitations from 3 to 6 years, and the pharmaceutical companies don't want that. We increased the amount of death benefits from 250,000 to 300,000, and it hasn't been increased for more than a decade. Inflation alone would require that change, and they don't want that.

We allow the program to pay interim attorneys' fees and costs. These provisions are of major importance for improving the ability of families and their lawyers to move these cases through the program fairly.

Imagine how difficult it is for families when the Government can bring in any number of expert witnesses that they have, and an unlimited budget to do so, and the witnesses get paid right away; but families like the Zuhlkes and the Rogers have to wait 10 years to be reimbursed for the same expenses.

And we are not talking about super-wealthy families here. Thad Rogers is a factory worker. He works in a Michelin tire plant. Janet Zuhlke is a single mom, and she works part-time in a doctor's office.

We have to level the playing field. Their lawyers have gone without payment while incurring tremendous expenses. And that is one of the reasons why people can't bring suits and try to get compensation for their injuries. They can't afford the lawyers, and the lawyers can't afford to work for nothing. Of course, that impacts their ability to represent their clients. All too often the Government is dragging out these cases for 5, 6 years.

And we have also included a one-time look-back provision. It allows for families who couldn't file claims because they missed the statute of limitations a 2-year period to file their claim. This provision has provoked stronger opposition than anything else in the bill; and I think that's really unfortunate because it would do so

much to help families who just didn't know much about the program and didn't file on time, and those families really need help.

I have a personal issue that bothers me, and it applies to thousands and thousands of people across this country. We have gone from 1 in 10,000 children that are autistic in America—used to be 1 in 10,000; now it is more than 1 in 250. We have an absolute epidemic of autism.

These other vaccination-related injuries are all important—all of them are important. But we have an absolute epidemic of autism. And these—1 in every 250 children are autistic, and those kids are going to grow up and many of them are going to be unable to go out in the work force and earn a living. They are going to be dependent on society and the Government for their existence.

And what really bothers me is, we just don't have any foresight. The administration and the Government of this country ought to be thinking about these things and thinking about how to solve the problem now, not just compensation from the Vaccine Compensation Fund, but in making sure that these vaccines are tested and tested and tested again before they start using them on children. Many of these vaccines contain thimerosal or mercury. And there are aluminum and other substances in these that are preservatives that it is believed by many scientists around the world are causing these injuries.

In addition to the Vaccine Compensation Program we are talking about today, the Government and the administration and health agencies need to get on with double-checking these vaccinations before they take place. And parents ought to be informed about the risks, and they ought to read the inserts before they give these kids these vaccinations.

I mean, we're going to have to pay for all that. It just scares me to death when I think about the long-term financial impact that's going to have on the United States. I will be dead and gone when this happens. But the future generations and young folks in this audience are saying, how in the world are we going to pay for all this? Where are we going to put all these people?

And as far as the Vaccine Injury Compensation Program, I got a letter from my daughter yesterday; and I try to help her as much as I can. But my grandson is autistic, and they have received tremendous bills to take care of my grandson Christian, who became autistic 2 days after getting vaccinated; and a lot of people have suffered the same kinds of problems.

And they have gone bankrupt once, even though I helped them. And they are in dire straits again. And now we found out, just about 2, 3 months ago—I know you didn't want to be bored with my personal problems, but I think it's interesting to find out that Members of Congress have similar problems to what people across the country are having.

My granddaughter received a vaccination when she was about 6 months old for 6-month olds, for hepatitis B, and she quit breathing within just a matter of a few hours; and they rushed her to the hospital. And they saved her life, and she's been a very normal child, but now she's suffering from a mild form of epilepsy, and we wonder how that happened. There's nothing else that we can think

of that could have caused it. There's no history in our family of anything like that.

And these are things that our health agencies really need to take a hard look at. In addition to my grandson now being an undue burden on the family because of the medical expenses, now our granddaughter has to get special treatment, as well, for her condition. And I am not a poor fellow. I think I can afford to help them quite a bit, but I don't know how people across this country that are of average income, who don't have a lot of assets, can handle this.

And the media has written about this in the past, but unfortunately it seems to be lost on the Government leaders. And it really, really bothers me not because of our family situation, because we'll figure out a way to get by, but 1 in 250 kids is autistic.

People aren't getting compensated for their medical expenses from these vaccine compensation funds. And the pharmaceutical companies are fighting it, and the administration—for what reason, I don't know—is opposed to some of these changes. And I just get totally frustrated.

But I will tell you this, as long as I am active in Congress and chairman of the committee that is dealing with—and I will be chairman of the committee, or a member of the committee that's dealing with this, we are going to continue to put pressure every place we can and try to illuminate the issue through the press and through the media to the American people. And 1 day—I am very hopeful and I believe we will get their attention.

If nothing else happens, they are going to get the attention pretty quick when all these medical bills start coming in for all these kids across the country that are becoming autistic and other people that are suffering from other related vaccine injuries.

Well, I got that off my chest. The record will be open until October 2 for the Members who are not here today, and I am sure that my colleagues will be looking at the record and looking at the testimony and entering their own statements in the record.

And I want to say that Mr. Waxman and I have had a lot of differences, but he and I see eye to eye on this adjustment to the Vaccine Compensation Program.

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

Opening Statement

Chairman Dan Burton

Committee on Government Reform

September 18,2002 Hearing

Continuing Oversight of the

National Vaccine Injury Compensation Program

2154 Rayburn House Office Building

Washington, D.C.

10:00 a.m.

Good morning, a Quorum being present, the Committee on Government Reform will come to order. I ask unanimous consent that all Members' and witnesses' written and opening statements be 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.

Good morning. Over the last year, this Committee has been overseeing the National Vaccine Injury Compensation Program. We've held two hearings. We've introduced legislation. Our concern has been that this program has become too adversarial and that people who've been injured aren't getting a fair shake.

This program was intended to be less adversarial than civil litigation. It was intended by Congress to provide compensation quickly and easily, to people who have suffered very serious injuries. On close calls, the families are supposed to get the benefit of the doubt. Unfortunately, that doesn't seem to be happening. We're going to look at the Rogers case today. It was a close call. The Special Master ruled in favor of the family. Instead of accepting that decision gracefully, the government has filed appeal after appeal to try to overturn it. I just think that's wrong. That's not how we intended this program to run.

While approximately 1,700 families have received compensation under this program, many families have seen their cases tied up for years in a system that has become too contentious.

At last year's hearings, we heard from six different families. They all had a very difficult time getting through this program. We asked two of those families to come back today and update us on their cases. The reason we did that is because almost one year later, these cases are still not resolved. They have dragged on for eight and ten years. If we want to figure out what's working and what isn't working with this program and try to fix the problems, these are the kinds of cases that we need to look at.

Janet Zuhlke is back with us today. Her daughter, Rachel was severely injured after she received her pre-kindergarten vaccinations in 1990. Today Rachel is mentally retarded. She has periodic bouts of blindness that are getting progressively worse. She has seizures. She is confined to a wheelchair. She will need round the clock care for the rest of her life.

A team of respected medical specialists diagnosed her case as a vaccine-related encephalopathy, which is a table injury. Table injuries are supposed to receive compensation quickly and without opposition. Unfortunately, Janet had to fight for nine years to get compensation. **Nine years**.

In July of last year, the Special Master ruled that Rachel was entitled to compensation over the strong opposition of the Justice Department and HHS. It's now been 14 months since then, and because this system has become so complex, Janet and Rachel still haven't received their compensation.

We are just a week or two away from the tenth anniversary of Mrs. Zuhlke filing her petition. To date, she has not received any compensation for the table injury her daughter

suffered. Ten years to settle a table injury was not how Congress intended this program to operate.

I've been told that the special master is working very hard to move this case forward and get it finished. He deserves credit for that. Just in the last two weeks they had a hearing to try to resolve the remaining disputes. I want to be clear on one thing. The purpose of this hearing is not to try to influence the special master's decisions. The special masters have to be independent. They have a tough job to do and we should respect that independence.

What does bother me about this case is that the Justice Department, and the Department of Health and Human Services are opposed to paying for the medical treatments that Rachel is receiving. She has a team of specialists. They've prescribed a series of treatments for her to try to keep her condition from deteriorating. As I understand it, these treatments are helping. And the government doesn't want to pay for them because they're too expensive. For nine years, they fought to deny the Zuhlkes compensation, and now for the last year, they've fought to deny her the medical treatments her doctors say will help her.
For the life of me, I can't understand that.

As I mentioned earlier, the other case we're going to look at today is the Rogers case. Thad Rogers came here last November from Alabama to testify on behalf of his wife, Diane. We asked him to come back today, but she's too ill, and he couldn't leave. Ron Homer, who is the attorney for the Rogers Family, will testify on their behalf. However, the family has sent a videotaped statement that we're going to watch.

Diane Rogers received a routine tetanus vaccine in February 1991. She rapidly developed MS-like symptoms. She is now bedridden. The Special Master determined in 2001 that Mrs. Rogers is entitled to compensation under the program.

It took seven years to get to that point. Unfortunately, the Government does not want to concede this case. As I said before, the Justice Department has appealed this decision and lost. They've twice made motions for reconsideration and been rejected both times. And now they're planning on appealing again. I just don't see the point of dragging this thing out. This family has been waiting for eight years. Its time to stop fighting and give them what they deserve.

As a result of our investigation, we've introduced legislation to try to improve this program. Congressman Waxman, Congressman Dave Weldon and over 40 of our colleagues have joined me in introducing H.R. 3741, the National Vaccine Injury Compensation Program Improvement Act of 2002. This bill doesn't address all of the flaws I think exist in this program. But it's a good start. Unfortunately, I've been told that the Administration is opposed to our bill. That is very disappointing to me.

We took as our starting point a series of recommendations from an advisory committee. Some of them were good, some were not so good. We took what we thought were the best recommendations, and we built on those. We expanded on them because we want this program to be as effective as possible. But everything in this bill is bipartisan. Everything is reasonable. I can't see any reason why the Administration should oppose this.

- We double the statute of limitations from three to six years.

- We increase the amount of death benefit from $250,000 to $300,000. It hasn't been increased in more than a decade.
- We allow the program to pay interim attorney's fees and costs.

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We have also included a one time look-back provision. It allows, for families who couldn't file claims because they missed the statute of limitations, a two-year period to file their claim. This provision has provoked stronger opposition than anything else in the bill. I think that's really unfortunate because it would do so much to help families who just didn't know much about the program and didn't file on time. Those families really need help.

These are all issues we're going to discuss today with our witnesses. I want to thank all of our witnesses for being here today. The hearing record will remain open until October 2.

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

Mr. BURTON. With that, let me welcome our first panel. We are going to hear testimony from the first panel, which includes Ms. Janet Zuhlke, whom I mentioned earlier, and Ron Homer.

And I appreciate you coming here today to testify once again to bring us up to date on the situations we just talked about. So would you please rise and be sworn?

[Witnesses sworn.]

Mr. BURTON. We will let Ms. Zuhlke, lovely lady, go first.

STATEMENTS OF JANET ZUHLKE, PARENT OF A VACCINE-INJURED CHILD; AND RON HOMER, ATTORNEY FOR THAD AND DIANE ROGERS

Ms. ZUHLKE. Again, good morning. Thank you for your words. My name is Janet Zuhlke and I am pleased to have been invited back here today. I gave testimony last year in November regarding my daughter Rachel Anne. I was invited here today to provide an update on her case through the National Vaccine Injury Compensation Program and to discuss my most recent experiences with the Life Care Planning Process.

When I testified last year, I departed this room feeling that this committee had a better understanding of the difficulties, expenses and frustrations that families like mine have had to undergo in order to meet the criteria for this program; and you heard it not only from me, but also from other families.

Further, I believed the future process would become more expeditious, friendlier to the families, and that the outcome would be more favorable toward meeting the needs of the injured children. And I regret that my testimony today may be a disappointment for the committee.

For reference, the key points of my testimony last year were the onerous costs associated with presenting a case, including in my Rachel's needs, the repetitive and expensive production of documents and radiologic films, the delays and extensions of deadlines caused mostly by the fact that, as petitioners, we are not given any interim costs to help us pay the expenses of this litigation and also caused by the DOJ repeatedly seeking delays to get updated medical records for their experts to review; the litigious and adversarial attitude of the DOJ throughout the entire process.

A synopsis of the activities in my family's life since November is, one, although Rachel was declared eligible for compensation in July 2001 as a "table injury victim," no compensation or interim payments have been awarded.

Two, the Life Care Planning Process for my Rachel remains the area of contention. There is no agreement with the DOJ on the level of care and/or cost. The Special Master must now make a determination on compensating my family and for meeting Rachel's needs for the rest of her life. The past 10 months have been a continuation of the adversarial process that I described last year.

As you'll recall, approximately 10 years ago—and as you stated, it will be 10 years at the end of this month that have been spent making the determination of Rachel's eligibility for compensation. All of her treating physicians were unanimous in their decision about causation. It was the DOJ whose experts were called in to read her medical records and to testify that Rachel's immunol-

ogists, neurologists, neurophthalmologists and pediatricians were all inaccurate. This debate went on for far too, too long.

I need to explain to you about the Life Care Planning Process. It's been the focus of the post-determination activity to resolve this case. It is important to understand the role of the Life Care Planning Process used to formulate and agree upon its contents.

An expert, referred to as a "Life Care Planner," evaluates the medical status and prognosis of the victim. They're paid to project the level of medical care and living support needed for the individual's expected life span. They make these assessments by speaking directly to the attending physicians to clearly understand the future needs of the child. These needs include all medications, doctor visits, treatments, hospitalizations, mobility aids, special appliances and residency needs. The total cost of all life care needs determines the amount of money to be placed in trust for the victim.

It's important to remember that once the amount is finalized, there's no renegotiating. It's a done deal. If the amount agreed upon was inadequate to meet Rachel's needs, we'd have no ability to go back to the program for additional funds.

These Life Care Plans are provided—in my experience, have been provided separately to the Special Master. First, Rachel's Life Care Planner, which I will refer to now as an LCP, did her preliminary work-up. It was submitted to the Department of Justice for inspection.

They, in turn, hired their LCP to oversee this plan and to submit their own with the necessary changes made that they were not in agreement with.

Then Rachel's LCP goes through the process all over again to argue the point differences. That is referred to at this point as the final Life Care Plan.

The plan is submitted to the DOJ to again look over and again bring in their LCP to do the same thing. Then at this point, both final plans are submitted to the Special Master for his review.

You would anticipate that the two plans would have similar outcomes. In Rachel's case, the two were very different. It was brought to my attention that this program may be practiced in this manner to alleviate any issues or concerns that were not brought forth by the petitioner. If I had overlooked something with the LCP, too bad. Therefore the respondent would not have to acknowledge or address any outside speculative information. Again, I find this unacceptable in trying to meet the victim's needs.

Without going into detail, let me just say that her condition has deteriorated since I was here in November. And if you have questions about it, I will be happy to elaborate on it. Again, I went over this with you last year and things aren't any better; they are worse.

So if you have questions, I will be happy to answer them, but I am not going to go into them at this point.

Mr. BURTON. Thank you. We appreciate you coming back. And I might just say before we go to Mr. Homer that that is just indicative—this is just one example of thousands of cases and problems across this country that people are dealing with. And these are the ones that know about the program.

Mr. Homer.

Mr. BURTON. Are you not finished? I'm sorry, I thought you were finished.

Ms. ZUHLKE. I am not a public speaker. I will try to be brief, but I do have other issues that I would like to address. Thank you, sir.

The two main issues, as far as the DOJ is concerned referring to the compensation, are contesting and arguing about the appropriateness of a medicinal regime prescribed by her treating physicians to control further degradation of my daughter's health; and two, disagreement about the nature of Rachel's long-term care and the cost.

I would like for all of you to understand that my daughter's life expectancy should be to reach the age of 25 or 30. Again, she'll turn 18 on December 16 of this year and she's been ill since the age of 5.

Last week, I flew into D.C. for the final hearing dates of September 4 and 5 to conclude this compensation effort for my child. It turned out that it had to be continued another day in length, until September 6, because of the arguments on the table concerning meeting Rachel's future needs.

Concerning the first issue I just stated, about her receiving a medication not approved of by the DOJ, is a medication called IVIG. The DOJ litigated the appropriateness of the treatment, challenging the judgment of her physicians by hiring experts who have not lived with Rachel's case over the years and who were paid extensive fees by our Government to dispute Rachel's medications. It's proven itself to be beneficial to my daughter's care.

An argument that the DOJ brought forth is that this medication is not a needed medicinal requirement for Rachel, and I believe that this issue is totally cost related. I think they are just not receptive to the cost of the medication and, therefore, unwilling to accept the medicinal benefits that it provides to my child.

The other issue concerns placing Rachel in a life care facility that is specifically qualified to meet her medical needs. Rachel needs 24-hour care. Her placement will be expensive, not an argument; it is my goal to keep my daughter home for as long as is possible. I am aware of the fact that I can die in a car wreck, or something tomorrow, and God takes my life away; and in that, I need to make sure my daughter is taken care of.

Eventually, the level of care that Rachel will need requires onsite medical staff that can resuscitate and administer emergency medications. The Government disagrees, believing that aide workers—and in the State of Florida, their health aides have no skills. They have nothing that—as an LPN or RN—they are not allowed to do anything other than call 911 whenever an emergency occurs. This is not only unacceptable for my daughter; it raises the question in my heart, would these officials feel comfortable with this minimal care for their own children?

Also of concern to me is the fact that during last week's final hearing for compensation, the court reporter somehow inadvertently recorded over Rachel's testifying, treating physicians. It's not available to the Court to be transcribed. It's gone. Everything else for the Department of Justice and their arguments are available. The Special Master must now rely on his memory of the testimony given.

As I stated, all other statements of testimony are preserved. And in a case of this magnitude and importance, how could such a monumental and catastrophic error occur?

I'd like to take a moment to especially thank Special Master Hastings. He has made a strong effort to expedite this case for my daughter. From the time he took over Rachel's case, he was obviously committed to making a difference, to pushing this matter to a conclusion as expeditiously as possible; and I am very thankful for that, because I'm tired. I'm done. My daughter's dying, and I need help; and somebody's actually getting it. And I'm trying to be patient, and I know that—again, I give him tremendous praise. He's making a wonderful effort in bringing closure for my family.

I would like to say some things in general about the Vaccine Compensation Program. Now I've been told that Congress, when they passed this statute, intended for this to be a relatively simple, nonadversarial procedure. My experience is not at all consistent with that intention. As I saw the program, it is highly adversarial, and in my opinion, very unfair.

All of Rachel's treating doctors agreed she had a reaction to her vaccination. The Government went to extraordinary lengths to try to prove them wrong. I've been forced to borrow money to pay for voluminous medical records and radiology films.

It seemed like every time we got close to a hearing date, Rachel was hospitalized and the Government insisted on getting updated records, apparently hoping to find something that would help them disprove causation.

My lawyer is Cliff Shoemaker, and he has stuck with me and my daughter through all of these years. He has received no pay for his time or reimbursement of his expenses for over 10 years, and he's still not been paid. It will be months before he ever sees the first penny, while the Government experts are paid promptly upon billing the Government.

Experts who testified for me and my family not only risked the wrath of the Government, but they had to wait years to be paid. One of the Government's experts last week in the recent 2½ day hearing testified that he normally bills $500 an hour, but he's agreed to testify for the Government for a mere $200 an hour. It's obvious to me that there's a lot of value to be derived by these experts who agree to testify on behalf of the Government.

And let me put it to you this way, no doctors are going to be applying to my lawyer for any grants. So when he asks them to defer their fees until the end of the case, they've got to be really dedicated to do the right thing.

Mr. Chairman, I've had the opportunity to look at and discuss the provisions of H.R. 3741, a bill which you and Congressman Waxman have coauthored and which numerous other Congressmen and -women on both sides of the aisle have agreed to cosponsor; and as I understand it, this bill does three very important things.

First, it changes the statute of limitations. While I was lucky enough to get to an attorney and file a claim within 3 years of the onset of Rachel's symptoms, there are way too many parents who have not been so fortunate. And again, I strongly encourage Congress to remedy this problem.

Second, H.R. 3741 allows for interim fees and costs. It is critical that the dedicated lawyers who are involved in these cases be compensated for their time and expenses on an ongoing basis. It is clearly not fair to ask parents like myself to pay these costs of litigation as well as our medical expenses. And it's not fair to ask lawyers who have dedicated their lives to this program to defer their fees and expenses. This is not a program where petitioners' lawyers are making a lot of money, but somebody is.

Finally, H.R. 3741 makes it clear that this program is what Congress originally intended it to be, a remedial compensation program. It should not be considered a waiver of sovereign immunity where everything is narrowly construed in favor of the Government and against the petitioners.

I would like to see this bill go further, but at least I have made this one statement. And thank you. I know I'm over my time. I am just thankful that you have given me the opportunity and the voice to speak from my heart concerning these issues. My daughter Rachel and I hope that what I have spoken about today will have meaning and will help the families that will follow behind me. Thank you.

[The prepared statement of Ms. Zuhlke follows:]

Testimony of Mrs. Janet Zuhlke
Before for the Committee on Government Reform
September 18, 2002

Hearing
Continuing Oversight of the
National Vaccine Injury Compensation Program

Good Morning,

My name is Janet Zuhlke, and I am pleased to have been invited back today. I gave testimony last year in November, regarding my daughter Rachel Anne. I was invited here today to provide an update on her case through the National Vaccine Injury Compensation Program (NVICP) and to discuss my most recent experiences with the Life Care Planning Process.

When I testified last year, I departed this room feeling that this committee had a better understanding of the difficulties, expenses, and frustrations those families like mine have had to undergo in order to meet the criteria for this program. You heard it not only from me, but also from other families. Further, I believed the future process would become more expeditious, and friendlier to the families and that the outcome would be more favorable towards meeting the needs of the injured children.

I regret that my testimony today may be a disappointment for the Committee.

For reference, the key points of my testimony last year were:

- The onerous costs associated with presenting a case, including, in Rachel's case, the repetitive, and expensive production of documents and radiology films.
- The delays and extensions of deadlines, caused mostly by the fact that, as petitioners, we are not given any interim costs to help us pay the expenses of this litigation, and also caused by the DOJ repeatedly seeking delays to get updated medical records for their experts to review.
- The litigious and adversarial attitude of the DOJ throughout the ENTIRE process.

Here is a synopsis of the activity since last November.

1. Although Rachel was declared eligible for compensation in July of 2001 as a "table injury" victim, NO compensation or interim payments have been awarded.
2. The Life Care Plan for Rachel remains the area of contention. There is no agreement with the DOJ on the level of care and cost.
3. The Special Master must now make a determination on compensating my family and for meeting Rachel's needs for the rest of her life.

The past 10 months have been a continuation of the adversarial process I described last year.

As you will recall approximately 10 years were spent making the determination of Rachel's eligibility for compensation. All of her treating physicians were unanimous in their decision about causation. It was the DOJ whose "experts" were called in to read her medical records and to testify that Rachel's Immunologist, Neurologist, Neuro-Opthamologist, and Pediatrician were all inaccurate. This debate went on far, far too long.

Now I would like to tell you about the Life Care Planning process, which has been the focus of the post determination activity to resolve this case.

It is important to understand the role of the life care plan and the process used to formulate and agree upon its contents.

An expert, referred to as a Life Care Planner, evaluates the medical status and prognosis of the victim. They are paid to project the level of medical care and living support needed for the individuals expected life span. They make these assessments by speaking directly to the attending physicians to clearly understand the future needs of the child. These needs include all medications, doctor visits, treatments, hospitalizations, mobility aids, special appliances and residency needs. The total cost of all Life Care needs determines the amount of money to be placed in trust for the victim. It is important to remember that once the amount is finalized, there is not renegotiating, if the amount agreed upon was inadequate to meet Rachel's needs, we have no ability to go back to the program for additional funds.

These Life Care plans are provided separately to the Special Master. First Rachel's Life Care Planner (LCP) did her preliminary work-up. It was submitted to the DOJ for inspection. They in turn hired their LCP to oversee this plan and to submit their own with the necessary changes made that they were not in agreement with. Then Rachel's LCP goes through the process all over again to argue the point differences. That is referred to as the Final Life Care Plan. The plan is submitted to the DOJ to again look over and again bring in their LCP to do the same thing. Then at that point these final plans are submitted to the Special Master for his review.

You would anticipate that the two plans would have similar outcomes. In Rachel's case the two were very different. It was brought to my attention that this program may be practiced in this manner to alleviate any issues or concerns that were not brought forth by the petitioner. Therefore the respondent would not have to acknowledge or address any outside speculative information. Again I find this unacceptable in trying to meet the victim's needs.

Without going into detail let me just say that her condition has deteriorated. If you have questions please ask me to elaborate on that issue if you feel compelled to do so.

The two main issues, as far as the DOJ is concerned, referring to the compensation are:

1.Contesting and arguing about the appropriateness of a medicinal regime prescribed by her treating physicians to control further degradation of her health and
2. Disagreement about the nature of Rachel's long-term care and the cost.

I would like for all of you to understand that my daughter's life expectancy should be to reach the age of 25 or 30. Again she will turn 18 on December 16th of this year. She has been ill since the age of 5. Last week I flew into D.C. for the final hearing dates of September 4 and 5 to conclude this compensation effort for my child. It turned out that it had to be continued another day in length, into Sept.6th, because of the arguments on the table concerning meeting Rachel's future needs.

Concerning the first issue I just stated about her receiving a medication not approved of by the DOJ is a medication called I.V.I.G. The DOJ litigated the appropriateness of the treatment challenging the judgment of her physicians, by hiring "experts" who have not lived with Rachel's case over the years, and who were paid extensive fees by the government to dispute Rachel's medications.

It has proven itself to be beneficial to my daughter's care. An argument that the DOJ brought forth is that this medication is not a needed medicinal requirement for Rachel. I believe that this issue is totally cost related. I think that they are just not receptive to the cost of the medication and therefore unwilling to accept the medicinal benefits that it provides to my child.

The other issue concerns placing Rachel in a life care facility that is specifically qualified to meeting her medical needs. Rachel needs 24 hour care. Her placement will be expensive. It is my goal to keep Rachel home as long as possible. Eventually the level of care that Rachel will need requires on sight medical staff that can resuscitate and administer emergency medications. The government disagrees, believing aid workers can call 911 whenever an emergency occurs. This is not only unacceptable for my daughter it raises the question in my mind, would these officials feel comfortable with this minimal care for their own children.

Also of concern to me, is the fact that during last weeks final hearing for compensation the court reporter somehow inadvertently recorded over Rachel's treating physicians testimony. It is no longer available to the courts for transcription. The Special Master must now rely on his memory of the testimony given. All other statements of testimony are preserved. In a case of this magnitude and importance, how could such a monumental and catastrophic error occur?

I would like to take a moment to especially thank Special Master Hastings again for his strong effort to expedite this case. From the time he took over Rachel's case, he was obviously committed to pushing this matter to a conclusion as expeditiously as possible.

I would like to say some things in general about the Vaccine Compensation Program. I have been told that Congress, when they passed this statute, intended for this to be a relatively simple, non-adversarial procedure. My experience is not at all consistent with that intention. As I saw the program, it is highly adversarial and, in my opinion, very unfair. All of Rachel's treating doctors agreed she had a reaction to her vaccination. The government went to extraordinary lengths to try to prove them wrong. I was forced to borrow money to pay for voluminous medical records and radiology films. It seemed like every time we got close to a hearing date, Rachel was hospitalized, and the government insisted on getting updated records, apparently hoping to find something that would help them disprove causation. My lawyer, who stuck with

us through all these years, received no pay for his time or reimbursement of his expenses for over ten years. He still has not been paid, and it will be months before he sees the first penny. While Government experts were paid promptly upon billing the government, experts who testified for me not only risked the wrath of the government, but they have had to wait years to be paid. One of the government experts, in the recent two and a half day damages hearing, testified that he normally bills $500 an hour, but he has agreed to testify for the government for $200 an hour. It is obvious to me that there is a lot of value to be derived by these experts who agree to testify on behalf of the government. Let me put it this way - no doctors are going to be applying to my lawyer for any grants, so when he asks them to defer their fees to the end of the case, they have to be really dedicated to doing the right thing.

Mr. Chairman, I have had the opportunity to look at and discuss the provisions of HR 3741, a bill which you and Congressman Waxman have co-authored and which numerous other Congressmen on both sides of the aisle have agreed to co-sponsor. As I understand it, that bill does three very important things:

First, it changes the statute of limitations. While I was lucky enough to get to an attorney and file a claim within three years of the onset of Rachel's symptoms, there are way too many parents who have not been so fortunate. I strongly encourage Congress to remedy this obvious problem.

Secondly, HR 3741 allows for interim fees and costs. It is critical that the dedicated lawyers who are involved in these cases be compensated for their time and expenses on an ongoing basis. It is clearly not fair to ask parents like me to pay these costs of litigation, and it is not fair to ask lawyers who have dedicated their lives to this program to defer their fees and expenses. This is not a program where petitioners' lawyers are making a lot of money.

Finally, HR 3741 makes it clear that this program is what Congress originally intended it to be - a remedial compensation program. It should not be considered a waiver of sovereign immunity where everything is narrowly construed in favor of the government and against the petitioners. I would like to see the bill go further, but at least make this one statement.

Again I am thankful you have given me the opportunity and the voice to speak from my heart concerning the issues surrounding my daughter Rachel Anne. I hope that what I have spoken about today will have meaning and help the families that will follow behind me.

Mr. BURTON. Thank you, Ms. Zuhlke, and we will have some questions for you in a minute. And as one who has had that kind of a problem in our family, not to the degree that you have, I understand; and we will continue to fight to try to get some positive changes.

Mr. Homer.

Mr. HOMER. Good morning, Mr. Chairman and others.

Vaccines are an important part of our Nation's health policy. In 1986, vaccine manufacturers threatened to stop manufacturing vaccines because of civil lawsuits against them. In response to the crisis, Congress established the vaccine program.

Congress created this program for two reasons. One was to protect the vaccine manufacturers from civil lawsuits so they would continue to manufacture vaccines. Congress accomplished this goal by requiring that all new claims for vaccine-related injuries be filed in the vaccine program. The second reason was to compensate individuals who could show they were injured by vaccines.

The vaccine program was Congress's first real attempt at tort reform. It created a new forum to resolve vaccine claims. However, Congress was also reluctant to abrogate the State's rights of injured persons. Therefore, Congress decided if a person's claim for compensation was denied in the vaccine program, or if the reward was too small, the individual could opt to reject the decision of the vaccine program and proceed as before with traditional litigation against a manufacturer.

Obviously, Congress did not want this to happen. It wanted all claims to be resolved in the vaccine program. Therefore, Congress tried to make the program extremely attractive to claimants. It tried to make the program expeditious and fair. It tried to remove the difficult determinations of causation and negligence. It tried to create a no-fault compensation program under which awards could be made to vaccine-injured persons quickly, easily and with generosity.

Indeed, Congress fully expected that the speed of the compensation program, the low transaction costs, the no-fault nature and the relative certainty and generosity of the program's awards would divert a significant number of potential plaintiffs from litigation and compensate many persons presently without a remedy under current tort law.

I believe many of the goals of Congress have been accomplished. I believe America can be proud of the vaccine program. For example, I am aware of no cases where a person has lost a claim in the vaccine program, then prevailed against a manufacturer in a civil lawsuit. I am aware of no case where a person has rejected a vaccine program award as too small, then obtained more money in a civil lawsuit against a manufacturer.

To my knowledge, there continues to be a sufficient supply of vaccines. In addition, a far greater number of vaccine-injured persons are now receiving compensation. In my opinion, because of the creation of the program, hundreds of persons previously without a civil tort remedy, persons who would never have previously been compensated, have received substantial benefits from the program. This is good. It is consistent with congressional intent.

Are there serious problems with the program? Yes, there are several. I wish to briefly discuss two problems, two problems which I see as the most significant and the most dangerous.

In 1991, over 11 years ago, my client, Diane Rogers, was devastated by a tetanus vaccine. It caused her an MS-like illness which has left her bedridden. She filed a claim in the vaccine program in 1994, over 8 years ago.

Her treating doctors concluded her injuries were likely due to her tetanus vaccine. In addition, several expert witnesses testified that Diane's illness was likely caused by her tetanus vaccine. A Special Master determined Diane's injuries were due to the vaccine. A judge at the Federal claims court has agreed.

However, Diane has not received any compensation. In fact, 11 years after her injury and 8 years after she filed the claim, the end is not in sight. Given her health, she may not live to see the end.

Why has it taken so long for the program to resolve her claim? Although the reasons are many, I would like to highlight two. First, the Department of Health and Human Services and the expert witnesses it chooses to evaluate claims frequently requires scientific certainty before it will concede an injury has been caused by a vaccine. This was certainly not the intention of Congress. All Congress required is a showing, based on good science, that the vaccine is the likely cause of the injury.

Second, since proof of scientific certainty in these cases is almost never available, any expert testimony offered by any expert from either side is subject to valid attack. Accordingly, the Secretary, with its requirement for scientific certainty, can and does make proceedings in the vaccine program as adversarial as any civil, traditional, tort litigation.

Congress never intended for this to happen. It intended for claims to be resolved in the program with a showing that the vaccine was the likely cause of the injury, not the certain cause of the injury. In Diane's case, the Secretary has required scientific certainty. Since she has been unable to prove her case with scientific certainty, Diane's case has been as adversarial as any in the history of the program.

The Secretary initially denied Diane's claim. When after two evidentiary hearings, the Special Master found in favor of Diane, the Secretary requested that the Special Master reconsider her opinion. When the Court of Claims agreed with the Special Master, the Secretary asked the judge to reconsider his opinion. When the judge declined to do so, the Secretary appealed the case to the Federal Circuit or at least noticed to the Federal Circuit that they will appeal.

All this fighting in a case where the Special Master called the evidence overwhelming, where Diane's treating doctors and experts agreed that the vaccine caused the injury, where the Secretary's experts who were unable to even offer some other likely cause of the injury.

To date, the program's been a success. However, the Secretary's requirement for scientific certainty and the resultant adversarial nature of the Secretary's defenses in the program do not bode well for the program's future. Success may soon evolve into failure.

Recently, hundreds of cases have been filed in the program alleging vaccine-caused autism. Countless civil attorneys across the Nation now point to the high level of proof required in the program. They point to the adversarial nature of the program. They tell their clients they can leave this program after 240 days. For the first time, the success of the program is in jeopardy if, in fact, these clients go on and pursue civil litigation.

In my opinion, a return to the old days would be a disaster. To prevent this, Diane and others like her must be compensated. The program must be fair, but expeditious and generous as Congress intended.

The program is not about scientific truth. It's about compensating persons who are likely injured by a vaccine. It's about the resolution of claims, not perpetual litigation and appeals. It's about preserving the vaccine supply so we can continue to protect our children from devastating disease. It's about working together to find an acceptable balance for the competing needs of our open society.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Homer follows:]

Testimony of Ron Homer
On Behalf of Thad and Diane Rogers

Before for the Committee on Government Reform

September 18, 2002

Hearing
Continuing Oversight of the
National Vaccine Injury Compensation Program

Good Morning

Vaccines are an important part of our nation's health policy. In 1986, vaccine manufacturers threatened to stop manufacturing vaccines because of civil lawsuits against them. In response to this crisis, Congress established the National Vaccine Injury Compensation Program.

Congress created this Program for two reasons. One was to protect vaccine manufacturers from civil lawsuits, so they would continue to manufacture vaccines. Congress accomplished this goal by requiring that all new claims for vaccine-related injuries be filed in the Vaccine Program. The second reason was to compensate individuals who could show they were injured by vaccines.

The Vaccine Program was Congress's first real attempt at "tort-reform." It created a new forum to resolve vaccine claims. However, Congress was also reluctant to abrogate the states' rights of injured persons. Therefore, Congress decided, if a person's claim for compensation was denied in the Vaccine Program, or if the award was too small, the individual could opt to reject the decision of the Vaccine Program, and proceed, as before, with traditional litigation against a manufacturer.

Obviously, Congress did not want this to happen. It wanted all claims to be resolved in the Vaccine Program. Therefore, Congress tried to make the Program extremely attractive to claimants. It tried to make the Program "expeditious and fair." It tried to remove the "difficult determinations of causation" and "negligence." It tried to create a "no

fault compensation program under which awards [could] be made to vaccine-injured persons quickly, easily, and with generosity." Indeed, Congress fully expected that "the speed of the compensation program, the low transaction costs. . . the 'no fault' nature. . . and the relative certainty and generosity of the Program's awards [would] divert a significant number of potential plaintiffs from litigation," and compensate many persons "presently without a remedy under current tort law."

I believe many of the goals of Congress have been accomplished. I believe America can be proud of its Vaccine Program. For example, I am aware of no cases where a person has lost a claim in the Vaccine Program, then prevailed against a manufacturer in a civil lawsuit. I am aware of no case where a person has rejected a Vaccine Program award as too small, then obtained more money in a civil lawsuit against the manufacturer. To my knowledge, there continues to be a sufficient supply of vaccines.

In addition, a far greater number of vaccine-injured persons are now receiving compensation. In my opinion, because of the creation of the Program, hundreds of persons previously without a civil tort remedy, persons who would never have previously been compensated, have received substantial benefits from the Program. This is good. It is consistent with Congressional intent.

Are there any serious problems with the Program? Yes, there are several. I wish to briefly discuss two such problems, two which I see as the most significant and the most dangerous. .

In 1991, over 11 years ago, my client Diane Rogers was devastated by a tetanus vaccine. It caused her an MS-like illness which has left her bed-ridden. She filed a claim in the Vaccine Program in 1994, over 8 years ago. Her treating doctors concluded her injuries were likely due to her tetanus vaccine. In addition, several expert witnesses testified that Diane's illness was likely caused by her tetanus vaccine. A special master determined Diane's injures were due to the vaccine. A Judge at the Federal Claims Court agreed. However, Diane has not received any compensation. In fact, 11 years after her injury and 8 years after she filed a claim, the end is not in sight. Given her health, she may not live to see the end.

Why has it taken so long for the Program to resolve her case? Although the reasons are many, I would like to highlight two.

First, the Department of HHS, and the expert witnesses it chooses to evaluate claims, frequently requires **scientific certainty** before it will concede an injury has been caused by a vaccine. This was certainly not the intention of Congress. All Congress required is a showing, based on good science, that the vaccine is the **likely** cause of the injury.

Second, since proof of scientific certainty in these cases is almost never available, any expert testimony offered by any expert, from either side, is subject to valid attack. Accordingly, the Secretary, with its requirement for scientific certainty, can –and does- make proceedings in the Vaccine Program as **adversarial** as any traditional civil tort litigation. Congress never intended for this to happen. It intended for claims to be resolved in the Program, with a showing that the vaccine was the likely cause of the injury, not the certain cause of the injury.

In Diane's case, the Secretary has required scientific certainty. Since she has been unable to prove her case with scientific certainty, Diane's case has been as **adversarial** as any in the history of the Program. The Secretary initially denied Diane's claim. When, after two full evidentiary hearings, the special master found in favor of Diane, the Secretary requested that the special master reconsider her opinion. When the Court of Federal Claims agreed with the special master, the Secretary asked the Judge to reconsider his opinion. When the Judge declined to do so, the Secretary appealed the case to the Federal Circuit. All this fighting in a case where the special master called the evidence "overwhelming." Where Diane's treating doctors and experts agreed the vaccine caused the injury. Where the Secretary's experts were unable to even offer some other likely cause of the injury.

To date, the Program's been a success. However, the Secretary's requirement for scientific certainty and the resulting adversarial nature of the Secretary's defenses in the Program do not bode well for the Program's future. Success may soon evolve into failure.

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In my opinion, a return to "the old days" would be a disaster. To prevent this, Diane, and others like her, must be compensated. The Program must be fair, but expeditious and generous,- as Congress intended. The Program is not about scientific truth. It's about compensating persons who were likely injured by a vaccine. It's about the resolution of claims, not perpetual litigation and appeals. It's about preserving the vaccine supply, so we can continue to protect our children from devastating disease. It's about working together to find an acceptable balance for the competing needs of our open society.

Mr. BURTON. We understand we have a video. Since they couldn't be here, we would like to see that now.

[Videotape shown.]

Mr. BURTON. I wish everybody in the Congress could hear that kind of testimony. I think it would have a positive impact.

Mr. Homer, let me just start off by saying that you said that a lot of lawyers in the case of the autism epidemic are now filing, or getting together and filing, a joint suit against the Government, which could lead to a destruction of the program.

Mr. HOMER. It's a very likely scenario, sir.

Mr. BURTON. I just want to say this. I am a Congressman and I helped create the program—and I hope the Justice Department and health agencies hear this—but if destruction of the program is what it takes to get these peoples' attention, then I will testify in open court on these cases. I mean, I cannot understand why the Justice Department appeals and appeals and appeals these cases when they aren't doctors and they are not experts, and they go on and on and on; and you've got these people who are suffering these huge medical expenses, and their wives and their kids are suffering and they're going bankrupt. And the Government creates this fund to help solve the problem, to help protect the pharmaceutical companies, and it just doesn't work for so many of these people. Granted, a lot of people have been helped, but it's not supposed to be as adversarial as it is.

And I think the lady in the bed, who was making that comment there, Ms. Rogers, I think she makes a very good point. If it is adjudged that somebody should get compensation from the fund and the Justice Department and our health agencies decide to appeal it, during the appeal process, they ought to be compensated. And the lawyers' fees ought to be paid, because how else are they going to get help?

I have a personal experience with this, and I am talking to everybody now, especially the people who are going to be on the next panel. My son-in-law and my daughter have filed bankruptcy once. They can't do it again for 7 years. They've got medical bills out the kazoo for my grandson, who's autistic, and now they've got them for my granddaughter. And I'm going to help them, but a lot of these people can't do that.

What do they do? What do they do? What is this fund all about?

And so I really mean this, and I'll tell the lawyers who are paying attention to this, if you need somebody to testify at the case, especially in the autism cases, if you need somebody to testify about the shortcomings of this program and why this program needs to be corrected—and if the Congress of the United States and the administration will not correct it, and we have legislation to do that, then I think these civil suits should be pursued. And if it causes the program to fall apart and for us to have to revisit it after it falls apart, then so be it. These people should not have to suffer like that.

You've got 1 out of 250 kids in the country that are autistic. It's a 40fold epidemic, and we're not doing anything about it with an awful lot of these cases.

And a lot of these people haven't found out about it until the time has run out on them being able to file a suit, file a case. And

the look-back provision makes some sense, but the pharmaceutical companies are against it and they swing a big axe in this town.

Well, let me just ask a few questions, Ms. Zuhlke. How many medications does Rachel receive in any given month?

Ms. ZUHLKE. Well, sir, on a daily basis, she's receiving seven oral medications. I give her injections every other night of another medication. And she is currently going into the hospital for 5 days every month for the infusion of the IVIG.

Mr. BURTON. So she gets an IV, as well, for 5 days?

Ms. ZUHLKE. Yes, sir.

Mr. BURTON. How do you pay for all this?

Ms. ZUHLKE. I look at it as making a car payment or anything else, sir.

Mr. BURTON. Are you in debt?

Ms. ZUHLKE. Yes.

Mr. BURTON. Can you tell us how much it has put you in debt?

Ms. ZUHLKE. At this point I still do have insurance on my Rachel, which is a blessing, but I am thousands of dollars in debt to Shands Hospital, to Wuesthoff Hospital, which is our local facility, and that's where I am able to take her every month.

I've got it worked out now that instead of having to take her to Shands for these infusions, I'm able to have this taken care of through her pediatrician, Dr. Rick O'Hern, locally. That way I can spend the night with my daughter and get up and go to work in the morning. Otherwise, I'd be missing work, because Shands is 3 hours from my home. So I don't have loss of income anymore, which is great.

Mr. BURTON. Since you were last here, have you seen any difference in the way the Government lawyers have handled the case? Have they tried to be more sympathetic or more helpful?

Ms. ZUHLKE. No, not at all, except with the Special Master who is in charge of this case; I think he has done an exceptional job.

I did have issues before, which I will not go into today; and again not with this individual. The adversarial process is still an ongoing issue. As I stated before, the Life Care Planning Process has been a back and forth; we can't agree on anything about the care, on the costs of treatments. It's just nothing.

And it's been months and months of going back and forth with these life care planners in trying to formulate, you know, to meet Rachel's needs.

Mr. BURTON. But your daughter's injury was what they call a table injury.

Ms. ZUHLKE. That's correct.

Mr. BURTON. And so it should have been a very simple process.

Ms. ZUHLKE. You would think so, wouldn't you, sir?

Mr. BURTON. As complex as your daughter's case is, and as long as you have been dealing with these particular doctors, do you think Rachel's doctors would have prescribed an expensive IV medication unless she absolutely needed it?

Ms. ZUHLKE. Absolutely not. And I as a parent—a point that was made to me during last week's hearing with the DOJ is, you know, how could you subject to putting your daughter into the hospital for 5 days every month? I mean, how cruel.

Well, excuse me. It is what is necessary to do for my child. I feel that strongly, or I would not subject my child.

Mr. BURTON. But your doctor has said that that was what she needs.

Ms. ZUHLKE. All of them. All of them.

Mr. BURTON. And the Justice Department inferred that you were being cruel because you were doing that?

Ms. ZUHLKE. That's absolutely correct.

Mr. BURTON. But you were following doctor's orders.

Ms. ZUHLKE. OK.

Mr. BURTON. OK.

Dr. Weldon.

Dr. WELDON. The IVIG is very expensive.

Ms. ZUHLKE. Yes, it is.

Dr. WELDON. And that is the bone of contention between you and the Justice Department.

Ms. ZUHLKE. Apparently, that's correct. That's my belief.

Dr. WELDON. Who prescribed the IVIG initially?

Ms. ZUHLKE. Initially it would have been her neuroophthalmologist, which was Dr. John Guy at the University of Florida Shands Hospital. And the reason that it was prescribed is that Rachel has a condition referred to as optic neuritis. She has been blind twice. And with the IVIG treatment in conjunction with another medication called IV solumedrol, which is a high-dose steroid, it has reduced the inflammatory process to the optic nerve, which has restored her sight. She is again in the throes of optic neuritis, and the IVIG is being administered, and again, once—once the optic nerve is diseased, there is retardation. There is no regeneration, if you will, at all. There is scarring.

Dr. WELDON. I'm familiar with what optic neuritis is.

Ms. ZUHLKE. OK. Yes, you're a medical doctor.

Dr. WELDON. You remember, I'm a medical doctor.

Ms. ZUHLKE. I apologize.

Dr. WELDON. I know Dr. O'Hern. And, by the way, thank you for coming again.

The IVIG, is that considered experimental?

Ms. ZUHLKE. No, sir, Not as far as Rachel's physicians are concerned. If you want to label it as experimental, it would be in trying to find the appropriate aggressive medications to work for my daughter.

Dr. WELDON. Have you—how long have they been giving the IVIG for?

Ms. ZUHLKE. She has been receiving it for almost a year now.

Dr. WELDON. And how long do they anticipate that she will continue to need that?

Ms. ZUHLKE. There is no answer to that. And I will be the first to tell you that Rachel had been on it previously—this was over 2 years ago—and she started failing neurologically, and by that I mean not being able to go to the bathroom, not being able to walk, not being able to speak, grand mal seizures, etc. We switched over to another medication called Avonex, which is something which I had to inject; it was an I M injection for my daughter. She was on that for 1 year. She started to feel neurologically again, just the same issues.

Then we went over to a drug called Betaseron, which is one that she is on now which is a "subcu" injection that I give her every other night. The Betaseron was working very well for the child, but now again, with the involvement of the optic neuritis, the IVIG was reintroduced as of Tuesday. I took her back to Shands to see Dr. Bahti, who works in conjunction with Dr. Guy, neuroopthalmology. The child's vision is maintaining itself, the stability, if you will. Her vision has improved, and 3 months ago when we were there, it was at a 2,200. Previously it had been 2,300 in one eye, 2,200 in the other. Three months ago it was 2,200 again. When I took her back last Tuesday, the vision is stable. It's at 2,200 in both eyes. That's phenomenal. And, again, the treatment is the IVIG.

Dr. WELDON. Have you seen—just as a parent, not based on the medical evaluations and what the doctors are telling you—a response to these IVIG?

Ms. ZUHLKE. Absolutely. Yes, I have.

Dr. WELDON. What have you be able to perceive as the benefits of it?

Ms. ZUHLKE. One thing—and again, I don't know how to explain this to the committee, but a lightness in my daughter's spirit. She seems to be a happier person. She is able to walk better. She is able to converse and communicate more. Her life functioning skills improve, and I'm not the only one that notices it. And besides the physicians, when I take her into the hospital every month, the nurses are aware of it and this last go-around made a comment about, you know, it's amazing when she comes in, within 2 to 3 days you can see a difference in Rachel. And by the time we come back in for the monthly infusion to be reinstated, you can see the deterioration in the child.

So there is absolutely a change for the better for my daughter.

Dr. WELDON. And I just want to clarify. The attorneys for the Federal Government accused you of being cruel to your daughter by your giving her this treatment?

Ms. ZUHLKE. Yeah. Yes, sir.

Dr. WELDON. What exactly did they say?

Ms. ZUHLKE. Well, there was—again, you know, how can you subject to child to the 5-day course and this? And, again, this was coming from the expert that has been hired by the DOJ that was in the presence of the court during that time that—it was just, you know, how can you do this? And you are not seeing—what he—he kept referring to risk and benefit factors, and, again, you know, markers that could be obtained that they are not seeing, etc.

So again, sir, I can't give it to you verbatim, but I am telling you the truth. And the transcriptions should be available to you if you would like to look them over.

Dr. WELDON. Mr. Chairman, we have described this as adversarial. I would describe it as abusive. I wouldn't describe it as adversarial. I mean, this is—you know, I know some of the doctors involved with her care. These are respected physicians in the community, these are not crackpot physicians that are looked on with disrepute. I mean, Dr. O'Hern is one of the most well-respected pediatricians in the entire country. And that's abusive. I don't know how else to describe it.

I mean, this woman is not a physician, and she is following the directions. She is going to Shands Hospital. Shands Hospital is the hospital attached to the University of Florida. This is one of the most prestigious research institutions in the entire State of Florida, if not the Southeast. It receives a tremendous amount of NIH granting. There are—some of the top brains in the country are at this institution, and these people are prescribing this. And we have attorneys for the Justice Department describing this as child abuse?

Mr. Chairman, this is totally unacceptable, and I am really looking forward to the testimony from the Justice Department because I am in shock. I don't know what else to say. I yield back.

Mr. BURTON. Thank you, Dr. Weldon.

Judge Duncan.

Mr. DUNCAN. Well, thank you very much, Mr. Chairman. And I want you to know I appreciate your continuing to bulldog this issue and to do everything you can in regard to the problems that have occurred. And I appreciate the work that Dr. Weldon has done.

As I have mentioned before in here, I knew nothing about this problem until a woman whose son had received a D P T shot that went bad, a perfectly healthy boy of approximately a year old, and at the time she came to see me, he was 21 years old and weighed 22 pounds and had continual convulsions and projectile vomiting and all kinds of horrible problems. And then a couple years ago, I had another family in my district who brought me their 6-year-old son who had a similar occurrence and having terrible problems. And so I've been very interested in the testimony that we have heard at these hearings.

And, Mrs. Zuhlke, I can say this: As a lawyer I handled a wide variety of cases, and then for the last 7—for 7½ years before I came to the Congress, I was a circuit court judge in Tennessee, a State trial judge, and I can tell you I think it is totally ridiculous that you have had an injury that occurred 12 years ago and a petition that was filed 10 years ago, and still, you still haven't received compensation after all this time. And I do know that most government lawyers don't have nearly as many cases to handle as lawyers in private practice, and so they often try to drag things out, but this is pitiful. This is terrible to drag these kinds of cases out all these years.

Mr. Homer said he didn't think his client was—I think you said you didn't know whether your client was going to live to see the conclusion of this case.

And when you talk about scientific certainty, in the face of overwhelming evidence—you know, there are very few things in this life that can be proven to scientific certainty. I can give you all kinds of examples of that. But you can find many leading scientists that tell you with great certainty that global warming is occurring, and then you can find other leading scientists who say just the opposite. And there is very few significant types of cases that could be proven to a scientific certainty, but the evidence is overwhelming, that should be—that should be enough.

But, Mrs. Zuhlke, since you last testified before our committee, how have you be treated by the opposing lawyers? What's been their reaction?

Ms. ZUHLKE. Well, sir, again, I haven't seen any change in how I've been treated, which is, again, as I stated when I was here before, I believed that there would be changes. And again, I'll consider this because I'm here, because where I am, that this is considered a high-profile case possibly. So I would think that people would have really been a little more helpful, nonadversarial, and that is not what has occurred, and I was shocked by that. I still am.

Again, the only thing that I can say is that I have someone involved now—meaning the special master—that has proven himself to me at this point to moving things along. I'm hoping to hear within the next couple of weeks that compensation will be forthcoming. I am afraid that the DOJ will appeal it. It would not surprise me. I'm ready for it.

Mr. DUNCAN. Well, I hope that they don't—that you don't suffer repercussions because of your testimony here, although I wouldn't be surprised.

If there was—if there was one change you could make in this program, what would it be? What do you think?

Ms. ZUHLKE. One change. That's very difficult, sir. Again, the money issue, outstanding medical bills, and, again, no sort of compensation, no interim help of any kind. It's very, very difficult. It would be—I would just be grateful to have been financially helped at this point.

I think that the biggest problem for me is the adversarial issues, where Rachel's physicians are all unanimous in what they think; and here I have individuals that don't know my daughter, are not treating her, they are reading something on a piece of paper and making judgments and assessments on their own. And I just—I find that unacceptable. I mean, if there were issues to begin with, you know, nonagreement again between the physicians involved, you know, then speculation of it's—that this was not an accurate assessment about causation, I could understand that. But for this blatant, long-term, here we go over and over and over again, that's——

Mr. DUNCAN. My time has expired, so let me just ask very quickly. Mr. Homer, you said that you knew of no cases that—in which somebody had prevailed after they had been denied compensation under the program. Are there many cases that have been filed after somebody's been denied? I would assume that there would be—after somebody fights through this program for years, I would assume that not many people can afford to file these types of cases. How many cases have there been of this nature?

Mr. HOMER. How many cases?

Mr. DUNCAN. How many cases have there been where somebody's been denied, where they have gone all through the program, and then they filed a suit in Federal court? Do you have any rough guess?

Mr. HOMER. I don't, sir. We don't handle civil litigation post-program. But I am aware of cases out there; I'm not aware of many cases.

Mr. DUNCAN. I think they would be extremely rare just because of the money and the time involved. Almost nobody besides the

government has deep pockets enough to keep fighting this for years and years and years.

All right. Thank you, Mr. Chairman.

Mr. BURTON. I think we will ask just a few more questions. I have some more questions I would like to ask, and if you would like to ask a few more, we will be happy to grant that.

Let me ask one more question, Ms. Zuhlke. We have a 2-year look-back provision. This means that if a family whose child was injured by a vaccine after 1988 did not know about the program and they missed a filing deadline, they would get 2 years in which to file a claim. Now, the Justice Department opposes this. I'm talking about our legislation now. Here is one of their reasons. "The provision would have the inequitable effect of penalizing those who pursued their rights in a timely fashion and promptly adjudicated their claims."

Now, you pursued your rights in a timely fashion, and you promptly adjudicated your claim. How would you feel about giving families who missed the statute of limitations a 2-year look-back or a short period of time to file a claim? Do you think that would be unfair to you?

Ms. ZUHLKE. No, sir. I—again, in addressing that, I knew within 6 hours of my daughter's immunization that there was a problem. So—and again, it was her pediatrician that shared with me—I didn't even know that this program was available to families.

Mr. BURTON. But there are certain families that may not be aware of the program and may have a problem that occurs later on.

Ms. ZUHLKE. I think the statute of limitations should be extended.

Mr. BURTON. And you don't think it would be unfair to you?

Ms. ZUHLKE. No, sir.

Mr. BURTON. OK. Thank you.

Let me ask you a couple questions, Mr. Homer.

Mr. HOMER. Yes, sir.

Mr. BURTON. You have litigated a lot of these cases, haven't you?

Mr. HOMER. Yes. I would say I have brought to conclusion anywhere from 250 to 300 cases, and presently my law firm has about 300 active cases.

Mr. BURTON. And you have been fairly satisfied with the result of the program?

Mr. HOMER. Yes. I think that's a fair statement. Yes.

Mr. BURTON. But you do see some inequities and some problems with the program, as in the case of the Rogers.

Mr. HOMER. Yes, sir.

Mr. BURTON. Tell me about these class-action suits that are being filed like by the families of autistic children. And there's thousands of them across the country that are going to be getting together to file this class-action suit.

Mr. HOMER. Yes, sir.

Mr. BURTON. What do you think would happen if they prevailed in court? What would that do to the pharmaceutical companies?

Mr. HOMER. I think it would be devastating. I think it would be very similar to what happened to the asbestos companies that eventually made many of them go bankrupt.

Mr. BURTON. And what do you think that would do to the companies that are providing very important vaccines in this country if they went belly up?

Mr. HOMER. Well, then we are back to what I refer to as the old days, where vaccine manufacturers can no longer produce vaccines which——

Mr. BURTON. Because of the risk.

Mr. HOMER. Yes.

Mr. BURTON. So it could lead—at a time when we have a war going on and we need to have vaccines for smallpox and other things, it could lead to a very serious shortfall if some of these companies down the road went bankrupt because these lawsuits prevailed and were upheld in an appeal.

Mr. HOMER. It's a reality. Yes.

Mr. BURTON. That's why I don't understand why our government is so short-sighted, both our health agencies and our Justice Department, because if they don't realistically look at these things—I mean, maybe you would disagree, and you are welcome to express yourself. It seems to me that they would try to be realistic and look at these cases, and try to adjudicate them as quickly as possible so that they don't have this kind of a problem with class-action lawsuits that might prevail, because I, quite frankly, think if this goes before a court, and the overwhelming evidence is that, you know, Thimerosal and mercury and—mercury and vaccines and other substances have led to a lot of these cases, I think there is scientific evidence from Europe and elsewhere that this has been a problem, I think that courts will rule in their favor, and if they do and they appeal it—it may take some time before the appeals process takes place, but ultimately it appears to me that there is a very good likelihood that the pharmaceutical companies could take it on the chin, and this would have a reverberating bad impact over the entire country, don't you think?

Mr. HOMER. Yes, I agree. And I think, up to this point in time, that was not so much of a concern, but now recently, with the possibility of vaccines causing autism, you have a lot of interested civil litigators all throughout the country interested in this, and they see that not—they are looking at the program as more of an obstacle. And what will happen if they—you will see that many of these civil litigators are not filing in the program to begin with, which could present a problem ultimately, but if they are forced to—and they will be by the State courts and Federal courts, they will file in the program—if it's as adversarial—if it's as difficult to put a case through this program as it is civilly, then why go through the program? Just put it in, pull it out after 240 days, and let's get a class action going. That is what's going on out there.

Mr. BURTON. Well, you are a trial lawyer, are you not?

Mr. HOMER. My practice is actually specifically with the vaccine program.

Mr. BURTON. Do you do any trial work?

Mr. HOMER. Not outside the vaccine program.

Mr. BURTON. Well, as a lawyer who has dealt with this, what do you think the probability is that a class-action suit like this would be successful?

Mr. HOMER. Well, actually I'm part of an alliance with—and part of that alliance, there are civil litigators involved, and we are actually working with them attempting to put these cases through the program, specifically the autism cases. And if the result through the program is not acceptable, they're—you know, they are ready to bring these civilly.

Mr. BURTON. I know. What do you think the prospect is of them being successful in court and making their case?

Mr. HOMER. I think if they brought a case today, they would not be successful, but I think with the ongoing studies and a year, 2 years' time, I think there will be enough evidence where these civil litigators will be successful in courts.

Mr. BURTON. So you think short term, maybe not, but you think long term they will be successful?

Mr. HOMER. Yes, sir.

Mr. BURTON. And the resulting costs to the pharmaceutical industry in the country would be huge?

Mr. HOMER. Absolutely.

Mr. BURTON. OK. As I understand it, your contention is that Mrs. Rogers had a genetic predisposition to multiple sclerosis, and that the tetanus shot triggered the illness; is that correct?

Mr. HOMER. Yes.

Mr. BURTON. Is it fair to say that this was a fairly complicated case, and that it was a pretty close call for the special master?

Mr. HOMER. Yes. I think the science is very complicated, especially at the first hearing in 1997. The second hearing, more—new evidence was available. I think it clarified some of the medical issues. But, yes, I think it was a very complicated case medically.

Mr. BURTON. And you think the special master has been fair in this case?

Mr. HOMER. Oh, yes. I think she has done a very good job.

Mr. BURTON. In August 2001, the Rogers family was awarded about $1 million, and this came about a year after the special master granted them entitlement. About 1 month later the Justice Department appealed to the Court of Federal Claims. The government isn't allowed to appeal until after the award is determined and accepted. Were you surprised that they appealed?

Mr. HOMER. I was surprised. And just to clarify that, she was awarded $1 million, and that would be a lump sum payment. There was additional—additionally, there is an annuity that would pay out about $100,000 a year for the rest of her life.

But answering your question, was I surprised? I was surprised. I didn't see this case as—an issue in this case that, once resolved, would have a wide effect on other cases. If there was an issue here that, say, it was resolved in favor of the respondent, then that would affect, you know, 30, 40 other cases. This was a very narrow issue. It only applies to the Rogers case: Diane Rogers; MS may be triggered by a tetanus vaccine. It's very fact-specific to each case. I don't think the special master was saying tetanus causes MS.

Mr. BURTON. I understand.

Let me just ask one more question, and then I will yield to Dr. Weldon.

There was an appeal.

Mr. HOMER. Um-hmm.

Mr. BURTON. The appeals court rejected the appeal, and the Justice Department then didn't say OK. They are going on with another appeal, correct?

Mr. HOMER. Yes. They have noticed the Federal circuit that they may—well, noticed the Federal circuit that an appeal may be filed, and I think that would be due, I think, the 27th of this month.

Mr. BURTON. Why do you think that's happening?

Mr. HOMER. You know, you try to look at these cases from the other side, and I truly am trying to look at it as a Department of Justice attorney or from employees of HHS, and I really can't get a grasp on it, what is the significant issue here in this particular case that is so important that it's going up to the circuit. I wish I could. Then it would be—I could explain that to my client.

Mr. BURTON. We will let them try to explain that in just a little bit.

Dr. Weldon. We have a vote on after you conclude your questions. Unless you have more questions, I will excuse this panel, and we will get to the government people when we come back.

Dr. WELDON. I just have a few questions, Mr. Chairman.

Mr. BURTON. Sure.

Dr. WELDON. Janet, I understand the special master in your case was asking that the case be resolved by the end of this month, which is the 10-year anniversary of filing the case.

Ms. ZUHLKE. That's correct.

Dr. WELDON. Do you think that's likely, that you will be able to resolve this?

Ms. ZUHLKE. Yes, I do. And the reason I do is that during his closing statements at the hearing last week, he had even made a comment to me that apparently the court reporter and—transcriptions that are made from those records normally would take 30 days. He told me he had specifically requested that it be done in 5 days, and that he wanted those materials set before him promptly, and that this was a top priority for him, and that he wanted very strongly to have closure to this before the 10th anniversary at the end of this month. So I believe his words, sir.

Dr. WELDON. But as I understand it—and maybe, Mr. Homer, you can comment on this; you are a legal expert. The government can appeal to the circuit court even if the special master makes a decision here?

Mr. HOMER. Yes. The procedure is that the parties can appeal to, the first appeals, to the Court of Federal Claims. The next level is the Federal circuit. And then, of course, they can petition the Supreme Court for certiorari.

Dr. WELDON. In the Rogers case would you say that the special master has been fairly conscientious in the way that she's handled this case?

Mr. HOMER. Yes, I think she has. I think she—in the sense that in 1997 she did write a decision in which she found against Mrs. Rogers, but, in all fairness, she entertained additional medical evidence and took additional testimony, and was, I think, large enough to say, hey, with this new evidence I have to reverse myself. And I think that's very difficult for any judge to do, but she did.

Dr. WELDON. Now, I understand when she reconsidered and reversed herself, the Justice Department then asked her to reconsider her decision.

Mr. HOMER. Yes. As we asked her to reconsider her first decision, they asked her to reconsider her second.

Dr. WELDON. Now, evidently she made some comments about the Justice Department lawyer—and this isn't the first time I've seen the special masters complain about the Justice Department lawyers. She said, this is not the first time respondent has attempted to circumvent the rules by introducing postdecision expert testimony. And she went on to say, in the strongest words possible, this court finds that the respondent's method of supplementing a closed record constitutes extremely bad practice, sets bad precedents, and is getting to be a bad habit. The court and the legal profession have vested interests in encouraging closure rather than imposing further delays and multiple responsive motions ad nauseam.

Is this true?

Mr. HOMER. Well, I would like to clarify that. Remember, I don't think this is necessarily one particular trial attorney we are talking about. I don't know what the marching orders are from higher up for these trial attorneys about filing posthearing evidence.

Dr. WELDON. Well, I'm just asking you, did the special master say those things I just quoted?

Mr. HOMER. Yes, sir.

Dr. WELDON. Now, you have—this is going on 10 years. You said you have handled like 300 of these cases over the years.

Mr. HOMER. I've brought about 300 to conclusion. I have about 300 pending.

Dr. WELDON. What's the average length of time that you spend on these cases?

Mr. HOMER. Interesting question, because recently I had to—for another hearing on attorney's fees, I had to prepare for that information. I took all the—we resolved 20 cases last year in my firm, so I used those 20 cases as—to format a response, and I found that on average, those 20 cases, from the time of filing until we receive our attorney's fee check, there was an average of 7 years. And nine of those cases we voluntarily dismissed. We got the medical records, we summarized them, we realized that there was not a case. There was a reasonable basis to investigate, but there was no reason to go further. Those cases took about 2 years. Cases that went through entitlement hearing and then went on to damages, it took an average of 7 years.

Dr. WELDON. Mr. Chairman, I yield back.

Mr. BURTON. Let me just say, we will excuse this panel, and we will go to the government witnesses when we come back. We have to go vote on the floor right now. We should be back in about 15 minutes.

But let me just say that I don't know how people of moderate income with a sick child can wait 7 years for that kind of a decision. It just—I just don't know how they do it.

And with that, thank you both for testifying. I hope you can stick around to hear the government respond to some of the questions. We will be back in just a few questions.

[Recess.]

Mr. BURTON. Could we have the government witnesses, Mr. Paul Harris, Sr., Deputy Associate Attorney General, U.S. Department of Justice, who is accompanied by Mr. John Euler; and Mr. William Hobson, Director of the Office of Special Programs at H H—Health Services Research Administration, Department of Health and Human Services, who is accompanied by Dr. Tom Balbier. So would you please all—are you all here? Is everybody here? OK. Would you please rise, and raise your right hand, please.

[Witnesses sworn.]

Do any of you have an opening statement you would like to make? Mr. Harris?

STATEMENTS OF PAUL CLINTON HARRIS, SR., DEPUTY ASSOCIATE ATTORNEY GENERAL, U.S. DEPARTMENT OF JUSTICE, ACCOMPANIED BY JOHN EULER; AND WILLIAM HOBSON, DIRECTOR, OFFICE OF SPECIAL PROGRAMS, HEALTH SERVICES RESEARCH ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY TOM BALBIER

Mr. HARRIS. Good morning, Mr. Chairman. I do have an opening statement.

Chairman Burton, members of the committee, I want to thank you for the opportunity to appear before you today, and I am pleased to return on behalf of the administration to talk about the National Vaccine Injury Compensation Program.

Over the past several years, this committee has proven its dedication to this important program, praising it for certain accomplishments and suggesting improvements where the program has not worked as effectively as possible.

I would like to emphasize that we at the Department of Justice share your dedication to this program. In creating the program, Congress sought 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. Other positive results of the V I C P include the protection of the Nation's supply of life-saving vaccines and the research and development of new, better, and safer vaccines.

We recognize that the success of the program is an integral part of the achievement of these interrelated goals and the overall success of our Nation's immunization program. We therefore take very seriously the program's effective administration.

In my prior appearances before this committee, I provided lengthy written testimony. So as to limit my remarks this afternoon, I ask that my written statement for today's hearing as well as the written statements from the November 1, 2001, and December 12, 2001, hearings be incorporated into the record for this hearing.

Mr. BURTON. It will, without objection.

Mr. HARRIS. Similarly, I ask that the Department's letter containing our detailed views of your bill, Mr. Chairman, H.R. 3741, be included in the record as well.

Mr. BURTON. As well.

Mr. HARRIS. In your letter of invitation, you requested that I address several areas of program administration with which you have expressed concern in the past. We, too, are concerned that there are examples of cases that have taken too long to resolve, that there are individuals who are displeased with the manner in which their case has been processed, and that some perceive the program as too adversarial. However, I think it is important to emphasize that these are the exceptions and not the rule. We continually look for ways to address concerns such as these.

I believe that the Department of Justice and the Department of Health and Human Services have made improvements in the manner in which we process program cases. I would like to share with you examples of positive developments in the program.

One means to lessen the potentially adversarial nature of the proceedings can be the use of settlement techniques such as alternative dispute resolution, or ADR, to resolve cases informally without the need for court hearings. I am pleased to report this afternoon that our reliance on ADR continues to grow. In the past 8 months alone, we have attempted ADR in almost as many cases as it was used in the first 10 years of the program's existence.

The prompt processing of petitions continues to be a major focus of the program. I am pleased to report the success of an initiative initiated this year to resolve the program's oldest cases. In the beginning of the year, we identified all pending cases that had been filed in 1997 or earlier and redoubled our efforts to resolve these cases as quickly as possible. Eighty-six cases fell into that category, but as of last week 67 cases, or 78 percent of these cases, have been resolved on the merits.

Of course, all program participants would like to see cases resolved in the shortest time possible; however, we are mindful that speedy and efficiency—speed and efficiency oftentimes may be inconsistent with the compensatory principles of the program. 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 much greater importance. Yet 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 the most complicated cases, despite the best efforts of all parties, lengthy proceedings are unlikely to be eliminated. Mr. Chairman, you have identified two such cases involving the Zuhlke and Rogers families. Last year, when I appeared before this committee on November 1, 2001, I listened to both Mrs. Zuhlke and Mr. Rogers describe their experiences in this program. I have deep sympathy for the suffering that Rachel Zuhlke and Helen Rogers have experienced and the pain that their family members have also endured. One troubling aspect of each of these cases was that both involved complicated medical and legal issues, with the result that their cases had been pending for many years. Unfortunately, these cases remain pending, and thus, as before, I am unable to discuss specific details about either case. Nevertheless, I would like to describe what procedures have taken place in each case since last No-

vember to assure you and this committee that diligent efforts have been under way to resolve these issues.

With regard to Mrs. Zuhlke's case, the special master issued a decision last July 2001 finding that Rachel suffered a vaccine injury. The process of determining the amount of compensation that Rachel should receive for her injury was initiated in August 2001. As of 2 weeks ago, a hearing was completed, and the case is now pending a decision from the special master. Over the past 14-month period that the parties worked to resolve the issues of compensation, efforts were concentrated on obtaining necessary documents through the issuance of subpoenas to physicians, filing exhibits with the court, including the all-important life care plans, and participating in monthly, then weekly, status conferences with the special master. The Zuhlkes filed their life care plan on March 29, 2002, setting forth the items they sought for Rachel's care, and the responsive life care plan was filed on behalf of the government approximately 3 months later on July 3, 2002.

To resolve the differences in the parties' opinions as to Rachel's future needs, a hearing was scheduled for September 4 and 5, 2002. In the meantime, the parties participated in an ADR in July in an attempt to settle the matter sooner. Unfortunately, those efforts were not successful, and 6 weeks later the parties presented the issues to the special master for decision at a hearing during the first week of September. We now look forward to receiving a decision from the court.

I agree that the Zuhlke case has taken too long, and I understand that this has been a frustrating experience for the Zuhlke family. Fortunately, the process is now nearly complete. While I unfortunately cannot share the specific reasons why this length of time was necessary in this particular case, I can state that our goal in such cases is to fashion compensation that is both appropriate and fair for the injured person's needs and is consistent with the requirements of the act.

The statute specifically identifies permissible types of compensation that may be awarded under the act. Included are reasonable projected unreimbursable expenses that, "result from the vaccine injury" and are, "determined to be reasonably necessary for medical and other rehabilitative care."

Part of our mission includes a duty to support both the medical and fiscal integrity of this program. Each settlement in the program, whether it results from informal negotiation or ADR methods, is approached with this balance in mind.

In evaluating requests for compensation, the Department relies heavily upon the expertise of doctors, nurses, and other rehabilitative experts to assess the claimant's needs and recommend items and services to meet those needs. Determining adequate and appropriate lifetime medical compensation takes time, and it is incumbent upon the parties to ensure that it is done properly the first time. Once the award is in place, it cannot be changed.

I would also like to address the chronology of events that have occurred in the case involving Ms. Rogers, one of very few vaccine cases the Department has appealed. First, I would like to state that we are not insensitive to the personal tragedies that all claimants such as the Rogers family have endured, and understand that

awaiting the outcome of the appeal process is frustrating. For these very reasons the government's decision to appeal in a particular case is exercised infrequently and with much caution. 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.

Some criticize that appeals cause unnecessary delay in reaching a final case disposition. Of course, appeals do add additional time. However, appellate rights, which are authorized by the statute, have predominantly been exercised by claimants, not the government. The government infrequently appeals program decisions of the special master and even more rarely to the U.S. Court of Appeals for the Federal Circuit.

Moreover, the number of appeals filed by either party has decreased in recent years. For example, since January 2002, this year, claimants have filed appeals in five cases to the Court of Federal Claims; the government has appealed only one. In the Federal circuit, petitioners have filed two appeals this year, and the Department has filed one, and that one case is the case involving Mrs. Rogers. I would like to note that since 1993, the Department has appealed only one other case to the Federal circuit, and that occurred 4 years ago in 1997.

The specific procedures of Mrs. Rogers' case are as follows: In August 2001, the special master issued a decision awarding compensation to Ms. Rogers. For reasons I am prevented from discussing in detail, we filed a motion for review of this decision the following month, a procedure that is authorized by the act. Five months later, in February 2002, the reviewing judge remanded the case to the special master, sent the case back to the special master. As evident from the decision, the judge instructed the special master to provide additional information that established a basis for her conclusion that the vaccine administered to Ms. Rogers caused her injury.

On April 24, 2002, the special master issued another decision confirming her conclusion, which the reviewing judge accepted on May 7, 2002, even though, as he noted, the special master's decision referenced evidence that was not contained in the evidentiary record.

The Department sought reconsideration of the judge's order on May 21, 2002, which was denied on May 29, 2002. In accordance with the court's rules, a notice of appeal was filed at the Federal circuit on July 15, 2002. The government's brief setting forth the basis for the appeal is due September 27, 2002, although a decision on whether to appeal has not been made by the Department at this time.

We regret that an appeal prolongs a family's involvement in this case and, if the government's appeal is unsuccessful, will have the unintended affect of delaying delivery of compensation. We are mindful 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 mandate, preserve the integrity of the program, and promote its overall goals. Unfortunately, such is the case with Ms. Rogers' claim.

I want to assure the committee again today that the Department is dedicated in its resolve to continually improve program operations. To help us meet this goal, we remain committed to working further with Congress, HHS, the court, and other interested groups such as the ACCV and petitioner's bar. And I will be pleased and happy to answer any questions that you may. And thank you.

[The prepared statement of Mr. Harris follows:]

Department of Justice

STATEMENT

OF

PAUL CLINTON HARRIS
DEPUTY ASSOCIATE ATTORNEY GENERAL

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES

CONCERNING

VACCINE INJURY COMPENSATION

PRESENTED ON

SEPTEMBER 18, 2002

STATEMENT OF
PAUL CLINTON HARRIS
DEPUTY ASSOCIATE ATTORNEY GENERAL

BEFORE THE COMMITTEE ON GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2002

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 return on behalf of the Administration to talk about the National Vaccine Injury Compensation Program ("Program" or "VICP").

Over the past several years, this Committee has proven its dedication to this important Program, praising it for certain accomplishments, and suggesting improvements where the Program has not worked as effectively as possible. I would like to emphasize that we at the Justice Department share your dedication to this Program. In creating the Program, Congress sought 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. Other positive results of the VICP include the protection of the Nation's supply of life-saving vaccines, and the

research and development of new, better and safer vaccines. We recognize that 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. We therefore take very seriously the Program's effective administration.

In my prior appearances before this Committee, I provided the Committee with lengthy written testimony. So as to limit my remarks this afternoon, I ask that my written testimony from the November 1, 2001, and December 12, 2001, hearings be incorporated into the record of this hearing.

In your letter of invitation, Mr. Chairman, you stated that one of the issues of particular interest to the Committee is the proposed amendments to the Vaccine Act. The Department was pleased to review your bill, H.R. 3741, containing several important legislative improvements to the VICP. A detailed description of the Department's views on this bill is contained in the Department's letter, attached hereto, and I ask that a copy be included in the record of these proceedings. In particular, H.R. 3741 contains several 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, all of which would constitute improvements to the Program. We compliment you and your

staff for endorsing these improvements and hope these provisions receive favorable consideration by the Congress. In addition, we look forward to an opportunity to work further with the Congress regarding other legislative initiatives.

In addition, Mr. Chairman, in your letter of invitation you requested that I address several areas of Program administration with which you have expressed concern in the past. We, too, are concerned that there are examples of cases that have taken too long to resolve, that there are individuals who are displeased with the manner in which their case has been processed, and that the Program is sometimes perceived as too adversarial. We continually look for ways to address concerns such as these.

I believe that the Department of Justice and the Department of Health and Human Services have made improvements in the manner in which we process Program cases. I would like to share with you examples of positive developments in the Program. One means to lessen the potentially adversarial nature of proceedings can be the use of settlement techniques such as Alternative Dispute Resolution ("ADR") to resolve cases informally without the need for court hearings. I recognize that the use of ADR in the Program has been of particular interest to this Committee. I am pleased to report that our reliance on ADR continues to grow. In the past eight months, ADR has been attempted in fifteen cases. In contrast, in the entire ten year period prior to 1999, these types of ADR

proceedings had been instituted in almost the same number of cases (just 17). As part of the Vaccine Group's policy of encouraging informal resolution of disputed issues, we have conducted office-wide, in-house training in negotiating complex claims, including use of ADR. Most recently, five attorneys in the Vaccine Group have received ADR training over the past year to further enhance their settlement skills.

The prompt processing of petitions continues to be a major focus of the Program. We acknowledge that sometimes the process of adjudicating cases has taken too long, and we, too, would like to see cases processed more quickly. In this regard, I am pleased to report the success of an initiative instituted this year to resolve the Program's oldest cases. In the beginning of the year, we identified all pending cases that had been filed in 1997 or earlier, and redoubled our efforts to resolve these cases as quickly as possible. Out of approximately 750 cases then pending, 86 cases fell into that category. I am happy to announce that as of last week, 67 cases, or 78%, have been resolved on the merits. In particular, as of January 1, 2002, thirteen "retrospective" cases were pending. More than half have been resolved, leaving just six such cases. We continue to press for resolution of the remaining pending cases.

The prompt adjudication of newly filed cases is equally important, and we are pleased with these results as well. For example, of the cases filed in the year 2000,

approximately 40% have already been resolved on the merits.

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. 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. 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.

Yet, 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 the most complicated cases, despite the best efforts of all parties, lengthy proceedings are unlikely to be eliminated.

Finally, although improvements can, and should, be made, we must not overlook the Program's undeniable accomplishments. More than 1,760 families and individuals have received compensation for vaccine injuries, and more than $1.35 billion has been

paid to claimants. The VICP provides a viable avenue for compensation for vaccine-injured claimants who would have stood little, if any, chance of obtaining awards in the traditional tort system.

I want to assure the Committee again today that the Department is dedicated in its resolve to continually improve Program operations. 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. Mr. Hobson, do you have a statement?

Mr. HOBSON. Yes, Chairman Burton.

Mr. BURTON. Would you pull the mike a little closer, sir, and turn it on.

Mr. HOBSON. Yes.

Mr. HOBSON. Chairman Burton, my name is William Hobson. I was recently assigned to be the Director of the Office of Special Programs in the Health Resources and Services Administration. Currently I have been serving in that position for a little less than 2 months. Joining me today is Mr. Tom Balbier, who has worked with the Vaccine Injury Compensation Program Division of our office for approximately 11 years.

I am happy to appear before you today to discuss the National Vaccine Injury Compensation Program. As you know, the program is administered jointly by the Departments of Health and Human Services, Department of Justice, and the U.S. Court of Federal Claims. As the Director of the Office of Special Programs at HHS's Health Resources and Services Administration, I am very eager to work with you to ensure that the program is both expeditious and fair and operates as Congress intended.

In your September 11th letter of invitation, you asked that I be prepared to discuss two things: The cases that were presented by the previous witnesses, as well as the National Vaccine Injury Compensation Improvement Act of 2002, H.R. 3741.

To address your first request, because these cases are currently pending in Federal court, I cannot discuss them specifically, but, as you suggested in your letter, I can comment generally.

On the human level I express my very deepest sympathy to anyone who suffered a painful and debilitating injury and to the people who love and who are responsible for caring for those injured individuals. Such occurrences are surely among the most difficult that any of us has to face.

At the level of someone who works with the program, I know the diligence and dedication of my coworkers who have been charged with carrying out the National Vaccine Injury Compensation Program as established by Public Law 99660. Our job at HHS is to do the best we can operating within the program as established by law. Each case is handled individually; each case is subject to the same scrutiny.

To address your second request, I know that you, Chairman Burton, and Ranking Minority Member Waxman have both been working to modify and improve the National Vaccine Injury Compensation Program through H.R. 3741, which was introduced in February of this year. There are many provisions in the legislation that the Department of Health and Human Services supports. Many of them also have the support of the Advisory Commission on Childhood Vaccines. I think you know that we work closely with that advisory committee, which meets regularly and includes health professionals, parents of the injured children, attorneys, including a representative of the vaccine manufacturers, and nonvoting Federal personnel. The group advises the Secretary of the Department of Health and Human Services on the implementation of the program.

Some of the provisions supported by the advisory committee and the Department include adding additional family counseling as a compensable expense—that's in Section 4(a); changing the procedures for the payment of attorney's fees to allow payment directly to the petitioner's attorney under some circumstances—that's in section 6; and slightly altering the compensation and meeting schedule of the advisory committee—that's covered in section 8.

The Department would support additional provisions if they were modified. We support with modification section 2, which addresses the basis for calculating projected lost earnings. We feel the exclusionary language, excluding the incorporated self-employed, should be a part of this section to prevent possible misinterpretation. Since the Bureau of Labor Statistics says that it does not and cannot tabulate the average earnings of incorporated self-employed individuals, we feel this group should be specifically excluded from the calculation. Without this exclusion, this section would invite further litigation.

The advisory committee felt that section 11, public service announcement campaign, would be more useful if it were structured as a general publicity effort. They suggested that such publicity include research on the best communication methods and other outreach activities to increase the public's, the attorneys' and health care providers' awareness of the Vaccine Injury Compensation Fund. Thus we support section 11 with modification.

The Department has real concerns with section 3 of the bill, which would raise the death benefit from $250,000 to $300,000. The Department has concerns about provisions to increase noneconomic award payments significantly in the bill. In light of other provisions, that will expand the program's coverage and trends toward more claims being filed in the Vaccine Injury Compensation Program. These provisions collectively might lead to higher vaccine budget costs that are not sustainable.

There are some provisions of H.R. 3741 that the Department does not support. Section 5 provides that a special master make an interim award for attorney's fees and costs upon completion of the Rule 5 conference. We support a single payment of interim costs, but oppose the payment of interim attorney's fees for several reasons. First, the Rule 5 conference is the first substantive status conference in a case, and, in our view, occurs too early for such a determination for interim fees or costs to be made. In addition, focusing on requests for interim fees diverts time and resources from the prompt resolution of petitions. H.R. 3741 also does not impose any limit on the amount of attorney's fees that may be awarded on an interim basis. Not imposing a cap would result in excessive awards and invite collateral litigation. For these reasons the Department does not support interim attorney's fees and only supports the payment of interim costs with modifications to section 5 as currently written.

Although the Department supports section 7(a) of the bill, the general rule for the statute of limitations exclusion, we oppose section 7(b) which would allow a broad extension of the statute of limitations, enabling a filing of any claims arising from vaccines administered over the past 14 years. This provision of the bill would allow a look-back period of 14 years for claimants who either never

filed with the National Vaccine injury Compensation Program, or whose claims were dismissed by the court for not being filed in a timely manner.

Thousands of new litigants would cause significant administrative burdens at the Department of Health and Human Services, at the Department of Justice, and on the Federal court, based on program experience in the 1990's when approximately 4,000 claims were filed over a 2-year period, more than a quarter of which were nonmeritorious and eventually dismissed by the court without medical review. A similar outcome might be expected should section 7(b) be enacted. The Department sees that outcome as harmful in that it would lead to long delays in pending and future claims adjudication. This provision, along with others, could significantly expand the Vaccine Injury Compensation Program, and the Department is concerned about the implication of this to the overall costs of the program. For these reasons, we cannot support H.R. 3741 as currently drafted.

Our first choice would be, of course—would, of course, be that no child is ever injured in the attempt to protect him or her through vaccination. However, because some children do suffer injury as a result of vaccine administration, we who work in the National Vaccine Injury Compensation Program are dedicated to making compensation as fair and as expeditious as possible.

I would be happy to answer any questions that you have, and look forward to working with you and your staff to achieve our common goal of a well-administered National Vaccine Injury Compensation Program. Thank you very much.

Mr. BURTON. Thank you.

[The prepared statement of Mr. Hobson follows:]

Testimony of

William Hobson

Director, Office of Special Programs
Health Resources and Services Administration

before the

Committee on Government Reform

United States House of Representatives

September 18, 2002

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

I am happy to appear before you today to discuss the National Vaccine Injury Compensation Program. As you know, the Program is administered jointly by the Department of Health and Human Services, the Department of Justice, and the U.S. Court of Federal Claims. As the Director, Office of Special Programs at HHS's Health Resources and Services Administration, I am eager to work with you to ensure a Program that is expeditious and fair, as Congress intended.

In your September 11th letter of invitation, you asked that I be prepared to discuss two things: the cases that were presented by the previous witnesses and the bill, H.R. 3741, the "National Vaccine Injury Compensation Improvement Act of 2002."

To address your first request: Because these cases are currently pending in Federal court, I cannot discuss them specifically. But, as you suggested in your letter, I can comment generally. On the human level, I express my deepest sympathy to anyone who has suffered a painful and debilitating injury and to the people who love and are responsible for caring for the injured person. Such occurrences are

surely among the most difficult that any of us ever has to face. At the level of someone who works with the Program, I know the diligence and dedication of my co-workers who are charged with carrying out the National Vaccine Injury Compensation Program as established by Public Law 99-660. Our job at HHS is to do the best we can operating within the Program as established by law. Each case is handled individually; each case is subject to the same scrutiny.

To address your second request: I know that Chairman Burton and Ranking Minority Member Waxman have been working to modify and improve the National Vaccine Injury Compensation Program through H.R. 3741, which they introduced in February of this year. There are many provisions in the legislation that the Department of Health and Human Services supports– many of them also have the support of the Advisory Commission on Childhood Vaccines. I think you know that we work closely with the ACCV, which meets regularly and includes health professionals, parents of injured children, attorneys (including a representative of the vaccine manufacturers), and non-voting Federal personnel. The group advises the Secretary of HHS on the implementation of the Program. Some of the provisions supported by the ACCV and the Department include: adding family counseling as a compensable expense (section 4(a)); changing the

procedures for the payment of attorney fees to allow payment directly to the petitioner's attorney under some circumstances (section 6); and slightly altering the composition and meeting schedule of the ACCV (section 8).

The Department would support additional provisions if they were modified. We support with modifications section 2, which addresses the basis for calculating projected lost earnings. We feel the exclusionary language, "excluding the incorporated self-employed" should be a part of this section to prevent possible misinterpretation. Since the Bureau of Labor Statistics says that it does not and cannot tabulate the average earnings of the incorporated self-employed, we feel this group should be specifically excluded from the calculation. Without the exclusion, this section could invite future litigation. The ACCV felt that section 11, "Public Service Announcement Campaign" would be more useful if it were structured as a general publicity effort. They suggested that such publicity include research on the best communication methods and other outreach activities to increase the public's, attorneys', and health care providers' awareness of the VICP. Thus, we support section 11 with modification.

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attorneys' fees and only supports the payment of interim costs with modification to section 5 as written.

Although the Department supports section 7(a) of the bill, the general rule for the statute of limitations extension, we oppose section 7(b), which would allow a broad extension of the statute of limitations, enabling the filing of any claims arising from vaccines administered over the past 14 years. This provision of the bill would allow a look-back period of 14 years for claimants who either never filed with the National Vaccine Injury Compensation Program or whose claims were dismissed by the Court for not being filed in a timely manner. Thousands of new litigants would cause significant administrative burdens at the Department, at the Department of Justice, and on the Court. Based on Program experience in the 1990s, when 4000 claims were filed over a 2-year period, more than one-quarter of which were non-meritorious and eventually dismissed by the Court without medical review, a similar outcome is expected should section 7(b) be enacted. The Department sees that outcome as harmful in that it would lead to long delays in pending and future claims adjudication. This provision, along with the others, could significantly expand the VICP and the Department is concerned about the

implication of this to the overall cost of the program. For these reasons, we cannot support H.R. 3741 as currently drafted.

Our first choice would of course be that no child is ever injured in the attempt to protect him or her through vaccination. However, because some children do suffer injury as a result of vaccine administration, we who work in the National Vaccine Injury Compensation Program are dedicated to making compensation as fair and expeditious as possible.

I would be happy to answer any questions you have and look forward to working with you and your staff to achieve our common goal of a well-administered National Vaccine Injury Compensation Program.

Mr. BURTON. Let me start the questions with Mr. Harris. I would like to ask you a few questions about the Rogers case. I know you can't comment about some of the specifics while it's being litigated, but I would like for you to try to address these issues in a general sense if you can.

I know the law created an appeals process, and I know that you have the right to appeal these cases if you lose, but that doesn't mean that you have to. Is there some great principle at stake here that's compelling you to appeal this all the way to the appeals court?

Mr. HARRIS. Mr. Chairman, as I indicated in my opening statement, we take very seriously cases that we review for appeal. Obviously, this would be one of them. There is a mandate that the Congress gave to the Department and to the Department of Health and Human Services in administering this program. That mandate is to make sure that compensation is paid when the medical evidence is sustainable and it's mainstream medical evidence, that there is a preponderance of the evidence that supports compensation for injuries. That is at tension with the idea that these claims should be processed as efficiently and as quickly as possible.

We are mindful of both of those requirements in the act, and so whenever we decide to take an appeal, you can bet that it's because we feel very strongly that there are either medical or legal or in some cases medical and legal reasons that would necessitate us taking appeal.

Mr. BURTON. Well, I know you can't comment, but this is a case that's dragged on for 8 years. This is a family that doesn't have a lot of money, modest means. She is so ill, she can't even get out of bed. And when you make a decision on whether or not to appeal a case, do you take into consideration the situation of that family?

Mr. HARRIS. In every case.

Mr. BURTON. You do. OK. Well, let me just go forward then.

You asked the special master to reconsider her decision. She turned you down. You appealed to the Court of Federal Claims, and that was rejected. You asked the Court of Federal Claims to reconsider. The judge turned you down. Now, how far do you keep going with this thing? I mean, you know, the woman may be dead before you get this thing resolved. The family's suffered. The husband and the daughter are spending a lot, an inordinate amount of their time taking care of her, and they are incurring huge medical bills.

The master's turned you down, the judge has turned you down, the judge rejected, you know, the reconsidering motion. I mean, to go forward after all that, it just seems like it's harassment, you know, harassing somebody when they are down. It's pretty bad.

Mr. HARRIS. Well, I would first have to reject any notion that this is harassment.

Mr. BURTON. Well, what do you call it? You just continue to appeal. I mean, you have got doctors that have given evidence to the special master, and that evidence has been appealed to the judge. The judge has reviewed it. The judge has rejected your position. Now, you know, at what point do you say, hey, let's just pay these people?

Mr. HARRIS. Well, we have a responsibility, as I said before, to make sure that in administering this program we protect the integrity of the program.

Mr. BURTON. Well, you know, excuse me, sir, I helped get this program put into place, and I can remember the discussion and debate about it. Henry Waxman was one of the primary authors of that. I don't think any of us ever envisioned this kind of dragging things on for 7, 8 years while somebody is bedridden. And even though the special master's made a decision, the court has rejected your position not once, but a couple of times, for you just to keep this up. And you talk about protecting the integrity of the program, that wasn't what we envisioned in the first place.

Mr. HARRIS. Well, everything that we—all of our actions under this program are totally and completely consistent with the act that this Congress passed.

Mr. BURTON. And if we try to correct the act, we get a letter back from you saying, well, we don't think you ought to do that; and we get a letter back from the health agency saying they don't agree with some of these provisions that we think ought to be put in there to correct the situation. So, you know, it's a Catch–22 situation not only for the Congress, but for the people that are suffering. They can't get their money.

The Congress sees the problem that you guys are—you know, you have gotten into the legalese of this thing. You say we have got to take it all the way down the road to the very nth degree. And, if Congress wants to correct that so we can make this as noncombative as possible, you guys say you don't want to do that because you want to protect the integrity of the program and the money that's in it. It sounds like you want to protect the interests of the pharmaceutical companies for whom we came up with this program in the first place.

Mr. HARRIS. Well, that would be your interpretation, Mr. Chairman, and I respect your interpretation, but the fact is that in the Rogers case, I believe that there were several iterations of special master decisions that this is a very complicated situation, it is not clear-cut, and to prove that, I would just like to read a line from this order from the special master—from Judge Hodges rather, and it recognizes that this is a difficult case. It is a difficult case not only for legal reasons, which some might view as legalese, but it's a difficult case for medical reasons as well.

The judge writes in the order dated February 22nd, after we had petitioned the court for review on this, that "This case represents an unusually close question both legally and factually, as the special master recognizes."

In May 2002, after the court had accepted the special master's decision, which we asked for reconsideration on, the judge again wrote that the government—I'm quoting—the government has understandable concern with respect to this case.

So it is not as if we are haphazardly taking on appeals in these cases without any legal or medical basis for doing so.

Mr. BURTON. But the fact of the matter——

Mr. HARRIS. It's been recognized by the judge.

Mr. BURTON. OK. But the fact of the matter——

Mr. HARRIS. And so any characterization of our taking appeals that are not consistent with the mandate that Congress gave us to protect the legal and medical integrity of the program is simply false.

Mr. BURTON. Well, let my just say from a nonlawyer's point of view, the special master has made a decision after reviewing this very thoroughly and the medical records. The judge has reviewed it twice and has come to the conclusion that it should be paid. You are not a doctor, you are a lawyer, and you guys are doggedly going on with this thing. And it seems to me that a decision has been made by people who have some expertise and have looked at this case as thoroughly as you have, and the woman is suffering, and for you to go on and on and on with this makes absolutely no sense to me. But, of course, you guys are at the Justice Department, and you can do pretty much what you darn well please.

Now, when we try to correct the situation with legislation that we think would make it easier for people to make claims as—and this was supposed to be a nonadversarial solution to the problem that the pharmaceutical companies face—it just doesn't happen; it's just not happening in these cases, and it really is troubling.

Mr. HARRIS. We do not, I must say for the record, reject all of the suggestions that you have made in your proposed legislation. There are many provisions in your legislation that we, in fact, support, and we have made that clear to you, Mr. Chairman.

Mr. BURTON. But you don't like to look at——

Mr. HARRIS. But we don't like all of the provisions.

Mr. BURTON. You don't like the look-back provision, which would——

Mr. HARRIS. No, we do not like the look-back provision.

Mr. BURTON. Well, and the reason, because it would be more cases.

Mr. HARRIS. No. In fact, we don't like the 14-year look-back provision that is proposed in 3741, and to buttress our case for supporting a look-back provision of 6 years, we have expressly stated that in our views letter that was sent to this committee. So it is not fair or accurate to say that we don't support a look-back provision because it would add new cases. We, in fact, do support a look-back provision of 6 years.

We think a 14-year look-back does not inure to the benefit of the program, because then individuals who had filed cases and had those cases adjudicated would be able to refile, and there would more than likely be a rush of new cases filed, as evidenced by experience with the first statute of repose where we had 4,234 cases, I believe, come into the program as a result; that it would substantially burden the program and severely hamper our ability to effectively administer these programs. Then once, as time goes on, medical records are lost, witnesses lose the memory of what happened 14 years ago, is not as accurate or full, as complete as we would like to have so that we can efficiently process these claims. And the devotion of scarce resources and attention to these kinds of cases, many of which result in being dismissed because they lack substantial foundation——

Mr. BURTON. What about the 2-year look-back provision that's in there?

What about the 2-year look-back provision that's in there?

Mr. HARRIS. We support a 6-year look-back provision. That's greater than 2 years.

Mr. BURTON. We're talking about a 2-year timeframe for post-'88 cases.

Mr. HARRIS. We support the provision in the bill that would allow anyone who experienced an onset of injury as far back as 1996 to come into the program.

Mr. BURTON. Let me review that.

Dr. Weldon.

Dr. WELDON. Didn't come up with that out of thin air, you know. What we're interested in—the 14 years, OK?

You know, what we are interested in doing is what is right for the American people. We are not, per se, interested in protecting your agency from being overwhelmed. We're not trying to look out for a "program." We're trying to do what is best for the public, the public interest. And the reason why we selected 14 years is, there are cases out there that go back that far.

I mean, we took testimony here in this committee from a doctor who has a meritorious case in my opinion, but he was making so much money he just paid all the bills himself, and he didn't even know about the program.

I mean, this thing was so badly not publicized properly. And, Mr. Hobson, you said in your testimony there were 4,000 claims and one-quarter were nonmeritorious the last time you had a look-back provision. So that tells me three-quarters of them, 3,000, were meritorious. That's our concern.

There are thousands of people out there with meritorious claims. And when you draw a line of 6 years, you're telling a lot of people with meritorious claims, sorry, we have to protect the integrity of the program, we've got to do this, we've got to do that, we can't be overwhelmed. And so you're stuck.

I mean, what do we say to these constituents of ours? What do you recommend that we do? I mean, we are in charge, the Congress, of the purse strings of the Federal budget. That's according to my reading of the Constitution. And we vetted this bill with both sides of the aisle. It's the Burton-Waxman bill, OK?

So you've got Democrats and Republicans supporting it. You've got conservatives and liberals. And I'm sorry, I don't feel 6 years is adequate. I mean, if you want to talk about some language to help you more easily deal with cases that have already been reviewed and dismissed, I'm very, very open to that, but I don't think 6 years is adequate to address the nature of the problem that is out there.

Mr. HARRIS. Well, Mr. Chairman, you described it being the case that with a 6-year statute of limitations that some individuals with valid claims might be "stuck," using your words. And that is a consideration that Congress, I'm sure, undertakes every time it imposes a statute of limitations, which Congress does on a regular basis; and that is, it involves a weighing of what is, in fact, the public interest with what might be the best procedure or mechanism to effectively establish and administer a program that meets the interest that Congress has designed.

With the 6-year look back, we think that that is a—that reaches the balance of allowing petitioners additional time to file claims, which is an interest that members of this committee have expressed. But it does not go so far, we think, as to work an unfairness against petitioners who, in the past, filed their claims within the established statute of limitations, had their claims processed and awards paid under the compensation program, especially——

Dr. WELDON. Reclaiming my time.

Mr. HARRIS. If some of the other changes take place, such as the family counseling provision, the guardianship provision, and if there's an increase in the pain and suffering awards, as has been proposed in the legislation, it is very difficult for me to see how that is fair to the public interest for those petitioners who did file their claims. Given the trauma that these families go through, as you have identified yourself, it just seems a little bit unfair that that would be the case.

Dr. WELDON. I do not—I cannot conceive how us extending the look-back provision for 14 years is any unfairness to those who filed their claims in a timely fashion when the people who have those claims outstanding, that go beyond 6 years, report to us that they were not aware of the existence of the program.

And when you specifically testify that there are thousands of cases that could potentially be brought, to me, you're making the case for what we want to do. It suggests that there are thousands of cases out there when you say that.

You know, I feel very strongly—I am specifically involved in that decision of 14 years. And that, as I said was not pulled out of thin air. There are people out there that have been brought to my attention that—on looking at their cases, that their cases have merit; and they are going to be excluded when you go to 6 years.

I have another question, though, and I really want to get into this a little bit with you——

Mr. BURTON. Can I interrupt for a second? Let me just say that you make a valid point when you talk about us creating legislation that has a statute of limitations, and we know what that statute of limitations is, and we've set that. But usually when we set a statute of limitations, it's on some kind of an issue where there's no harm done to an individual.

We're talking about people here that have been injured by vaccines, and they may not have been aware of the program; and so we created this program to be—to show a human face of government, as well as protect the pharmaceutical companies from liability suits. And we're not talking about a 7-year statute of limitations, for instance, where someone commits a criminal act and beyond that time they can't be prosecuted because we didn't get them soon enough.

We're talking about someone who may be injured for life because of a vaccine that wasn't administered properly, or had some kind of an adverse impact on that person, or maybe it wasn't properly produced or properly tested. And it's an entirely different kettle of fish from the other kinds of statutes of limitations that you're talking about, so I don't think you can throw that into the mix.

When we came up with this program, we came up with a program that we thought was going to be nonadversarial, that was

going to help people get compensation for an injury. We didn't anticipate that people would be injured and not be aware of the program, and find out 10, 12 years later that they could have gotten compensation and now they can't because the statute has run out on it.

And so the reason we put that in, as Dr. Weldon explained, is that a lot of these people out there deserve compensation, and we're saying, no, because they didn't find out about the program quickly enough; and we want to create—correct that inequity.

Go ahead, Dr. Weldon.

Dr. WELDON. I understand, Mr. Harris, that you are trying to protect the program and you're trying to comport yourself and your office consistent with the guidelines as set forth in the act by the Congress of the United States. But I found the testimony of Janet Zuhlke regarding assertions that what she was doing with her daughter were cruel, to be inappropriate as put forth by a Justice Department attorney in the hearing that was held a few days ago.

Did you hear her testimony?

Mr. HARRIS. Yes, I did. And I believe I heard her correct her testimony, to state that the statements she was referring to were made by the expert witness, that a Justice Department attorney, in fact, did not make those statements and that the statement was made by an expert witness in the context of expressing the risks and benefits to the treatment that——

Dr. WELDON. Expert witness called by the Department of Justice.

Mr. HARRIS. Correct.

That a balancing of the risks and benefits of the treatment being weighed ought to be discussed. And there were some questions with regard—there were certain risks with regard to the treatment that, in fact, outweighed the benefits.

And I can understand, as a parent, how having a child in this traumatic situation may have been interpreted as Ms. Zuhlke had interpreted it. But it was not made by a Justice Department lawyer nor would we make such a statement.

Dr. WELDON. Well, I understand that and maybe I stand corrected, but it's a Justice Department witness called by your attorneys. And, you know, perhaps maybe you have no control over every word that is going to come out of their mouths. And I understand that from a scientific perspective, there's some controversy associated with the treatment that this child is receiving, but this is not the first time that we have been receiving complaints from citizens, from constituents that go through the program, that complain that the nature of these evidentiary hearings are very adversarial; and it was not the intent of the authors of the legislation for them to be conducted in that fashion.

And I would be most appreciative if you would keep that in context as you continue to function in your capacity.

Mr. HARRIS. I can assure you, Mr. Congressman, that I will do that and that our lawyers have been following that guidance as a matter of professionalism in the administration of the program.

I would—I have no hesitancy at all in coming to any conclusion that a Department of Justice lawyer would not engage in that kind of inflammatory or offensive exchange with someone who is coming to this program, especially since we truly understand the traumatic

nature of the program in working with these cases on a day-to-day basis.

And the suggestion, otherwise, I think is out of place, and I would welcome any showing that you may have that, in fact, our Department attorneys have, you know, been offensive to someone in this program.

We addressed this issue the last time I testified. If there are cases where it is shown that a Department lawyer has, in fact, been offensive, we will take appropriate and corrective action. In the Zuhlke case, that has not been brought to our attention.

Mr. BURTON. May I ask a couple of questions here, Doctor?

Dr. WELDON. I will yield to the gentleman.

Mr. BURTON. We will come back to you in just a couple minutes.

You talk about not being offensive. Let me just say, when a person has somebody in the family—a child or a wife—that's incapacitated and going down hill and may die, dragging a case out may not be analogous to asking them offensive questions face to face, but it certainly is offensive to those people because they are suffering and they consider the Government's—what they would consider to be harsh action by dragging that out, when they know it's a vaccine-related injury, would be offensive to them.

And I think that is what I got from Ms. Zuhlke's testimony; just dragging this out, asking for more and more documents after you had documents, and going over and over again, even though you may think it's necessary, to her was an offensive act.

Now let me ask you a couple of questions. The Department supports the doubling of the statute of limitations from 3 to 6 years for both injuries and death cases?

Mr. HARRIS. Correct. There will be a doubling to 6 years in both cases.

Mr. BURTON. The Department attempts to pose one claimant against another in the rejection of our look-back provision. When the program had 4,000 claims filed in 1 year, the program developed assistants to take on a specific number of pre-1988 cases at a time, and notified petitioners where on the waiting list they were.

If you were inundated with thousands of cases now, wouldn't you take a similar approach, so the existing current cases would continue to move forward?

Mr. HARRIS. They would continue to move forward, but they would move forward at a much, much slower pace, which is one of the primary concerns of this committee. In fact, we have been up here before to testify about the first statute of repose and the lengthy delays that statute of repose resulted in with regard to pending cases that were post-'88 cases.

Mr. BURTON. How many lawyers do you have over there that work on this stuff?

Mr. HARRIS. I am not sure of the exact number, but I can get that information for you.

Mr. BURTON. We have about $1.3 billion or $1.4 billion in the victim's compensation fund—1.7 billion in the Vaccine Compensation Fund. It seems to me that if the Justice Department needs more people, lawyers and analysts to process more cases, they ought to tell us that, because you should not turn down somebody's claim, or the review of someone's claim who has a legitimate claim, simply

because the process would be slowed down and you don't have enough personnel to deal with it.

The victim's compensation program was set up not to coincide with the number of attorneys there are over at the Justice Department who can deal with it. It was set up to take care of people who were injured or the families that were injured. So it kind of bothers me that you say, well, if we had this kind of provision in there, there would be a lot more cases and it would slow down the process. The process shouldn't be slowed down. It should be brought to the Congress' attention that you need more personnel to deal with the increasing number of cases.

As I said earlier, 1 out of 250 children, according to HHS, is autistic. There's a growing body of scientific evidence around the world that that tremendous increase is caused in large part because of vaccinations and reactions to vaccinations. Now, if you have 1 in 250 kids in this country that have been damaged by vaccinations, or even three-fourths of that, or even half of that, think of the tremendous number of claims you are going to have in the future. You're simply going to have to have more people to deal with it.

So when you say it will slow down the process, and I deduce from that you don't have enough people to deal with the cases, then you're just going to have to get more.

Given that you don't support the look-back provision that we're talking about, the 14-year, do you then support a clarification in existing law to provide the opportunity for families who have missed their opportunity in this program to be allowed to file their claim in a civil court and not have the VICP statute of limitation act against them in other courts?

Let's say somebody misses the limitation period, and they find that they have a vaccine-related injury; they ought to have some recourse. They shouldn't have to sit back and say, my gosh, my husband, child or wife was injured by a vaccine; we're sure of that. Because we missed the statute of limitations, because we didn't know about it or some other reason, shouldn't we have the right to go to a civil court to try to get money from the pharmaceutical company that produced the product?

Mr. HARRIS. Mr. Chairman, I am not aware that this issue has been presented to the administration. And as you know, I don't make these decisions myself.

Mr. BURTON. Would you support that?

Mr. HARRIS. I am not in a position to say this morning whether the administration would support that position, but if you would like to present that question to us, we'd certainly consider it.

Mr. BURTON. What do you think personally? Don't you think they should have some avenue of recourse?

Mr. HARRIS. Well, I'm not here to testify personally. I'm here to testify on behalf of the administration.

Mr. BURTON. So you don't have an opinion on that?

Mr. HARRIS. I have an opinion on just about everything, but this is not the appropriate forum for me to express my opinions.

Mr. BURTON. Are you refusing to answer on constitutional grounds?

Never mind. I'm just kidding.

Mr. HARRIS. I just don't want to be fired.

Mr. BURTON. In New Jersey, a precedent has been set that would preclude families that opportunity if they missed the deadline in the VICP. A provision in the Frist bill would make that Federal law.

Do you guys support the Frist bill?

Mr. HARRIS. We have reviewed the Frist bill, as well as other legislation proposed by Mr. Greenwood and Mr. Towns, I believe. But I—again, I am not here this morning to express the administration's views on that legislation.

Mr. BURTON. But that legislation is important, and you're here to review the issue.

Have you read the Frist bill?

Mr. HARRIS. Yes, I have read it.

Mr. BURTON. What do you think about that?

Mr. HARRIS. I am not here to testify about that. We came here prepared to address the chairman's bill and the provisions within that bill that we support and the provisions that we are not able to support at this time.

And I would add, with regard to the 14-year look back that you propose that this is not one of the provisions that has been supported by the Advisory Council on Childhood Vaccines as well. They have not supported the 14-year look back.

Mr. BURTON. Dr. Weldon?

Dr. WELDON. I don't have any more questions, Mr. Chairman.

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

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Rep. Dave Weldon, M.D. Calls For Reforms of a Broken Vaccine Injury Compensation Program

Washington, D.C.-- The House Government Reform Committee convened a hearing today to highlight the shortcomings in the current Vaccine Injury Compensation Program (VICP)—the program designed to compensate individuals who suffer serious adverse reactions to vaccines. Today's hearing has been called to address the overly litigious nature of the program and the seemingly endless appeals of cases brought by the program administrators.

"I continue to be amazed at the lengths the administrators of this program will go to deny an injured party a claim," said Rep. Dave Weldon. "The Zuhlke case has been going on for 10 years. The administrators of the program have twice lost, but they have appealed the Rogers case for a third time. It was my understanding from earlier discussions on this issue that the VICP program administrators where going to work to try to make this process less adversarial. I'm not sure they are capable of such compassion."

Late last year, Rep. Weldon joined with Chairman Dan Burton, Ranking Member Henry Waxman, Rep. Jerrold Nadler and several other members in introducing H.R. 3741. This legislation would make significant improvements in the operation of the VICP. H.R. 3741 would:

- Increase the compensation for vaccine-related deaths to $300,000;

- Make the compensation for lost earnings more generous;
- Allow compensation for the costs of family counseling and creating a guardianship;
- Allow for the payment of interim attorneys fees and costs while a case is under review;
- Extend the statute of limitations for filing a petition to six years; and
- Establish a two-year window for families to file a petition if they were previously excluded from the program by the existing two-year statute of limitations.

"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. "These 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 to these families. We have an obligation to bend over backwards in these cases and ensure that these claims are considered with compassion and that the benefit of the doubt goes to the injured child."

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.

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Mr. BURTON. Let's talk real quickly about the interim attorneys' fees. This is very important to level the playing field. You opposed our proposal because you said it's too early in the process. What we do is, we authorize interim legal fees after the rule 5 conference, which is a point by which all claims that don't have a reasonable basis are weeded out.

In your letter to us, you stated that a determination that a claim has a reasonable basis isn't made until the end of the process when eligibility is determined. However, reasonable basis and eligibility are two completely different things.

Can you point to a single instance in which a case was thrown out because it did not have a reasonable basis after a rule 5 conference?

Mr. HARRIS. Mr. Chairman, the criteria that the courts look to in deciding whether a petitioner is entitled to compensation is the two-pronged approach, whether the petitioner has a reasonable basis and whether it's filed in good faith. At the end of the process, when it comes to awarding attorneys' fees, those are the same criteria that the courts look to in awarding attorneys' fees.

The reason we opposed the interim attorneys' fee provisions of H.R. 3741 are that the award of attorneys' fees would come before the rule 5 conference, that this is a very early stage of the process, and that the litigation that would result from an agreement on what the attorneys' fees ought to be would detract attention from scarce resources in the program in addressing some other claims.

This is a collateral issue that would——

Mr. BURTON. Scarce resources? There's $1.7 billion in the program.

Mr. HARRIS. We have 18 attorneys in the program. There have been 6,890 claims filed in that program; about 5,557 have been adjudicated. So resources are a combination of the money that's in the trust fund as well as the attorneys we have to process the claims.

But this would be the issue of addressing the issue of attorneys' fees even before a Special Master has determined that the petition which was filed in good faith on a reasonable basis, would not inure to the benefit to those who have claims in the program.

Mr. BURTON. Isn't it true that at that point in the proceedings, extensive medical records and legal briefs have been submitted by both sides?

Mr. HARRIS. Correct. Right. But a decision on whether entitlement would not have been made at that point in the program——

Mr. BURTON. I know, but put yourself in the place of a mother, a single mother, who has a child that's been injured, and she can't afford to take care of the medical expenses of her child as well as the legal fees. What is she supposed to do?

She's gotten all the medical records that you have required up to that point. She's gotten an attorney to file the legal briefs up to that point. What is she supposed to do? How is she supposed to proceed? How can an average citizen proceed?

Mr. HARRIS. Mr. Chairman, these are the rules that Congress established.

Mr. BURTON. That's what I'm asking about changing this. This is one of the things that we talked about.

Mr. HARRIS. We support the changes that would allow——

Mr. BURTON. Interim legal fees?

Mr. HARRIS. Interim costs.

Mr. BURTON. Including legal fees?

Mr. HARRIS. No. And we have expressly opposed the payment of interim legal fees.

Mr. BURTON. OK.

Well, then I go back to my question, if you oppose that, how does an average mother who has this kind of a problem, who's paying the medical bills, how does she deal with that? How does she pay the legal fees?

Lawyers don't work for nothing. The three cardinal rules for most lawyers is get the money up front, get the money up front, get the money up front.

Mr. HARRIS. I can assure you that some lawyers work for nothing.

Mr. BURTON. You have legal staffs being paid by the Government. And it becomes, in many cases, an adversarial situation. She can't afford a lawyer. What is she supposed to do?

Mr. HARRIS. The payment of interim costs associated with processing the claims, which is something that the ACCV supports and something that the administration supports, because we are cognizant of the fact that obtaining the medical records and other nonreimbursables, that there ought to be some interim payment for those types of costs.

Now, within this program, as opposed to civil litigation—the litigation risks are not as high within this program as one would find in the civil justice system, so much so that the attorneys that process claims in this program are virtually assured a payment at the end of the road. That is not true in your civil litigation context with respect to medical malpractice claims, for example.

Dr. WELDON. Could the gentleman yield?

Mr. HARRIS. To the extent that the burden would be eased by the Government paying the costs at an interim phase, we would support that. The payment of interim attorneys' fees with no limitation on what those fees ought to be, with the provision that it's not allowed for any review of the Special Master's decision, makes for a scheme that we can't support because it would——

Mr. BURTON. What if there was a ceiling put on the fees?

Mr. HARRIS. I haven't seen one.

Mr. BURTON. If there were, would that change the Justice Department's position?

Mr. HARRIS. We would certainly consider that, but I have not seen it has been proposed.

Mr. BURTON. Instead of writing back saying you opposed that, it seems it would have been reasonable to say, if reasonable fees are set, and give us a figure so we can change that in the legislation. That's not something that we would look at with a jaundiced eye. We just don't want the single mother or these people of moderate income that can't afford it to not be able to pursue a valid claim.

And let me say one more thing, and then I'll yield to my colleague. The main reason, as I understand it from my staff, that cases get thrown out, they are thrown—the main reason cases get thrown out on a reasonable basis ground is because the vaccine

isn't covered by the program, No. 1; or No. 2, because the family missed the statute of limitations.

Those cases are weeded out long before—the point before we would award interim legal fees. So when we were talking about interim legal fees, we were talking about, in the bill we proposed, when medical records have been given, when a legal brief has been filed, and you are there with them. I mean, we are not talking about something where there hasn't been a lot of research done.

Mr. HARRIS. Mr. Chairman, two things: One, an argument that the parents somehow are disadvantaged by our position of not paying interim attorneys' costs, I would just urge the committee to keep in mind that the parents are not paying the legal fees while the case is being processed. And the attorneys might prefer to have some sort of payment on an interim basis, but it does not in any way work a hardship on the parents who are processing the claims through the program.

Mr. BURTON. Let me just tell you this. My grandson is autistic, OK? And the attorneys do take cases on a contingency basis, but there are very few attorneys that will take these cases because they take so long, and they don't know how long it's going to take or whether or not they'll be recognized, whatsoever. And they do—many of these attorneys do ask for funds up front in addition to a contingency agreement.

So don't tell me these people don't have to take money out of their pockets, because you can't find attorneys in many of these cases because these cases drag on for so long.

You anticipate that they are going to be able to go out and find an attorney who'll say, my child is autistic; and he looks at the record, and he's the guy who has worked on this thing, and he says, this case may take 6 or 8 years and I may never get anything. To find some attorney that is going to do that is asking him to do pro bono work for a long, long period of time, and most of them aren't going to do that without some money up front, at least the ones who specialize in this stuff.

Mr. HARRIS. Mr. Homer testified several hundred cases to conclusion within the program; and to my knowledge, there has not been any showing that there is a shortage of attorneys who are willing to come into the program.

And I would add that the compensation for attorneys, I think, has improved over the last decade. The average compensation for an attorney processing a claim under our program in 1990 was $12,500. Now it's about $37,000 and in 2000–2001, the highest awards that were paid to attorneys for attorneys' fees were $301,000, $239,000 respectively.

Mr. BURTON. For 7 years of work?

Mr. HARRIS. Not for 7 years of work. The average processing time period for a claim under this program is about 2 years.

We are talking about cases this morning that are, as I said in my written testimony, the exception, not the rule. So no one should walk away from this hearing thinking that the average case in this program takes 7 years of processing—2 years.

Mr. BURTON. We had an attorney before us just a few minutes ago, and he said many of the cases take 7 years. You recall that?

Mr. HARRIS. I don't. I don't recall it.

Mr. BURTON. You weren't listening then, because he did say that.

Let me just tell you that you say there are a lot of attorneys out there that will take these cases, and these people don't have any problem. I don't know if you listened to any of the witnesses we have had here last year and this year, but we have had witnesses here that have talked about the problems with finding proper legal counsel to deal with their children's problems. And for you to say that that's not a problem for them is just not correct.

They will tell you that they have had a difficult time. My daughter has had a difficult time. And so if you want to start recommending attorneys that will take these cases on a long-term basis for no fee until the resolution of the case, give me a call, will you, because I don't think that's correct.

And the Justice Department has a battery of attorneys over there that are on the Federal payroll, that can work long hours refuting these cases. And the poor moderate-income person who can't find an attorney to deal with that because of the uncertainty of the case and the length of the case, they're out of luck; and that's the problem.

And we wanted this program to be a program with a heart. We wanted it to be a program with a heart. So if a woman like that woman we saw in bed was incapacitated, or a child was injured by a vaccine, that would be a nonconfrontational settlement of the case, this was supposed to be great for the pharmaceutical companies and great for the legal system and great for the person who was injured; and it ain't working out that way in many, many cases. And we wanted to correct that, at least in part with this legislation; and what we're getting back is opposition to a lot of it that we think is very important.

That look-back provision for 14 years, Dr. Weldon came up with it because of the reasons he stated. And, you know, I just don't understand the Government being so recalcitrant about that.

Mr. HARRIS. I would just reiterate that the Government is not being recalcitrant about the 14-year look-back provision without some well-founded reasons, some of which I have been able to discuss this morning.

And I would just add again that this is a conclusion that is concurred with by the ACCV, which is comprised of parent representatives, petitioners' counsel and medical experts. And this body of this diverse group of stakeholders in this system does not support a 14-year look back.

Mr. BURTON. Do you have pharmaceutical people on that board as well?

Mr. HARRIS. It's a nine-member board, and the members are parent representatives, medical experts and attorneys.

Mr. BURTON. And no representatives of the pharmaceutical industry?

Mr. HARRIS. Not to my knowledge.

I am told there is one attorney on the ACCV from a pharmaceutical company.

Mr. BURTON. There is a representative of the industry on the board as well.

Let me ask just a couple more questions of Mr. Hobson, and then we'll wrap this thing up. There's been a lot of discussion over the

last year about whether or not an injury caused by the preservative thimerosal is supposed to be filed in the NVICP or in civil courts.

Would you clarify if thimerosal injuries are covered in the program or not?

Mr. HOBSON. Just a second. Mr. Chairman, I would like to confer.

Mr. BURTON. You can bring one of your staff people up there if you like.

Mr. HARRIS. I may be able to help you with that. We filed a statement of interest on behalf of the Government in consultation with Department of Health and Human Services in a class action suit that was filed in Oregon on the thimerosal issue, the issue being whether thimerosal is a part of the vaccine, and therefore falling within the broad scope of the Vaccine Injury Compensation Program; or whether thimerosal is an adulterant to the vaccine, and therefore outside of the program.

We filed a statement of interest in the Federal Court in Oregon and the case is now remanded to the State court for determination on that legal issue.

Mr. BURTON. So right now there is no determination?

Mr. HARRIS. Our position was that the thimerosal class action should be within the Vaccine Injury Compensation Program, which is a view I think you would support.

Mr. BURTON. So—OK. In reviewing published research on thimerosal—and incidentally, for those who aren't familiar with thimerosal, it is a preservative that also includes mercury, and mercury is toxic to the human body, and we have been injecting our children with this substance for a long, long time even though it's been taken out of all topical dressings.

In reviewing published research on thimerosal, we have learned that in addition to concerns about the toxicity of mercury, that the TSA component in the preservative of thimerosal is highly allergic to as much as 35 percent of the population.

How is the VICP staff preparing to handle cases involving thimerosal? I am talking to health agencies, but if you want to respond——

Mr. HARRIS. I thought you asked about the administration of claims that might be brought under thimerosal.

Mr. BURTON. OK, go ahead.

Mr. HARRIS. The class action involves some—a class of, I believe—180 million plaintiffs in the class and as few as 30 million in the Oregon case in the class.

So even a small fraction of those who are in the civil action—if a small fraction were to pursue a claim under our program, obviously that would put a tremendous burden on the program, but it would be a burden we would have to staff up to meet, because we believe those claims ought to be brought into the program based on the mandate from Congress.

Mr. BURTON. Mr. Balbier can come up to the table with you. He was sworn, as well, and he has been before the committee as well.

Mr. HOBSON. We are aware that some issues have been raised with regard to preservatives in vaccines, but I am informed we are in the very early stages at this point in time in investigating the causality associated with those preservatives.

Mr. BURTON. Well, thimerosal has been used in vaccines, I think, since the 1930's.

Mr. HOBSON. I was not referring specifically to thimerosal, but to the other ones that I think you mentioned. I think you mentioned TSA; is that correct?

Mr. BURTON. Right. Where are you? Have you started testing? Are you doing studies on that?

Mr. BALBIER. The only aspect of the thimerosal litigation that we're involved in is the adjudication of claims. And we have had a number of claims filed alleging that thimerosal has caused injuries, but none of those cases have gone forward yet. So we don't know what theories are being proposed in terms of the cause—of how thimerosal has caused injuries. We don't know what those theories are yet.

Mr. BURTON. You were here, I believe, when we had the tape from Canada that showed what happened to brain cells when a small amount of mercury is introduced into close proximity to those brain cells. Do you remember that?

Mr. BALBIER. I don't think I was at that hearing, sir.

Mr. BURTON. Do we have a copy of that tape? I want you to see that, because it shows pretty conclusively what happens to brain cells the minute they're—when mercury of any kind is introduced to them. They shrivel up and start dying immediately.

Seems like, to me, that if Canada has done some testing on this and these are medical people in Canada, that the FDA would have started doing some research studies on animals or something else. You have not yet started doing that?

Mr. BALBIER. Research is not something that comes under the authority we have for administration of the program. We don't necessarily sponsor research.

Mr. BURTON. I understand, but there's been no request from our health agencies to test whether or not the mercury in thimerosal is causing damage to brain cells?

Mr. BALBIER. I can't comment on that.

Mr. BURTON. Is there anybody here from HHS that could answer that? No?

Is measles encephalitis a table injury?

Mr. BALBIER. Yes, it is.

Mr. BURTON. Is subacute sclerosing panencephalitis a recognized vaccine injury?

Mr. BALBIER. I'm sorry. What was the question again?

Mr. BURTON. I'm going to let my staff tell you what that is.

Ms. CLAY. Subacute sclerosing panencephalitis.

Mr. BALBIER. No. That's not a table injury.

Mr. BURTON. Is it a recognized vaccine injury?

Mr. BALBIER. No.

Mr. BURTON. Individuals who join the military are required to get routine immunization such as DTaP, MMR, hepatitis B, etc. If an active duty military member suffered an injury from one of the covered vaccines, would they be eligible to file for compensation in the NVICP program?

Mr. BALBIER. Yes, they would.

Mr. BURTON. In your written testimony, you state that you don't support section 2 of our vaccine bill, which addresses the basis for

calculating projected lost earnings. You state that the Bureau of Labor Statistics says it is not and cannot tabulate the average earnings of the incorporated self-employed.

In fact, Mr. Hobson, our staff worked extensively with the Bureau and learned that they do have the ability to include in the tabulation the average earnings of the incorporated self-employed. This provision, in fact, would reduce litigation on the settling of lost earnings because it is more fair and more generous since it would include professionals such as doctors and lawyers who are often incorporated and self-employed.

If the ability to include these earnings in the tabulation is possible, does this mean that the Department would support this provision?

Mr. HOBSON. I think that we should, at this point in time, revisit our consultation with the Department of Labor statistics on this issue, Mr. Chairman, if indeed you have information contrary to what I provided in my written testimony. We would be happy to get back to you after we make that contact and try to clarify the situation. It had been our information that basically that there would be problems with essentially coming up with that computation for the incorporated self-employed.

Mr. HARRIS. And if we were to have that data, I believe, at least in some small measure, conflicts with the other provision in the legislation that would require that the computation be based on the gross average or mean weekly earnings of full-time employees, because self-employed persons are, by definition, not full-time.

Mr. BURTON. Subacute sclerosing panencephalitis—I'll go to SSPE since I can say that easier—is a progressive neurological disorder characterized by inflammation of the brain, encephalitis. The disease may develop due to a reactivation of the measles virus or an inappropriate immune response to the measles virus. SSPE usually develops 2 to 10 years after the original viral attack. Initial symptoms may include memory loss, irritability, seizures, involuntary muscle movements and/or behavioral changes leading to neurological deterioration.

Now the question, this is for professor—this is from Indiana University, Bloomington Center. Can this occur from a measles vaccine or the MMR vaccine?

It cannot?

Mr. BALBIER. Our view is that it cannot.

Mr. BURTON. I wish Dr. Weldon was still here. We had a doctor here that had taken a sample from the spinal cord of 18 or 20 children who were suffering from autism, and they showed in the spinal fluids the measles virus as well as—what was the other substance that was in there, do you recall?

Anyhow, there was a very strong indication that that measles MMR vaccine had caused that, and he's trying to get that study published right now. Are you familiar with that?

Mr. BALBIER. No, I am not familiar with that study. I can't say that I have. It sounds like it's an unpublished study.

Mr. BURTON. It was brought up in a hearing. You may have been present.

Mr. BALBIER. I wasn't at the hearing.

Mr. BURTON. Here is a published study from 1997 regarding the measles, mumps, Rubella vaccine and this disease. A particular case of SSPE is described in a 13-year-old girl who had been immunized against all childhood diseases, receiving the MMR vaccine at the age of 9 months. The girl's intellectual functioning, until development of the illness, had been very good. After illness developed, the child verbalized little and was socially inappropriate. Her memory and thinking were impaired as she grew.

The authors concluded that SSPE was engendered as a delayed adverse effect, as a result of the measles vaccine. The authors note that other cases of SSPE have been induced by the attenuated measles vaccine. This was published in 1997 by R.B. Belgamwar. Are you familiar with that?

Mr. BALBIER. No, sir.

Mr. BURTON. This is another published study here?

I think we have pretty much covered everything we wanted to cover today. I have some other questions that we would like you to answer and submit for the record. And could you get those back to us, and we'll distribute those to the other members of the committee.

I would like to take a look at the legal fees. If you could get back to us also, if there was a stated amount or some kind of a limit on those legal fees, if you could let us know if that would be something that you guys could live with in the legislation that we are talking about.

Mr. HARRIS. In fact, in the views letter that we sent to your office, it is stating—and I will read directly from the views letter—"Imposition of a reasonable cap on interim awards would both protect the program and significantly reduce the likelihood of collateral litigation surrounding the determination of the appropriate interim award." That is in the letter that we sent to your office.

Mr. BURTON. Let me ask just—my staff keeps giving me these questions.

Mr. Hobson or Mr. Balbier, do you agree with the decision to appeal the Rogers case?

Mr. HOBSON. Once again, Mr. Chairman, we are technically not supposed to comment because it is still in litigation.

Mr. BURTON. Given this has gone on for 8 years now and given that the Special Master and the Federal judge has ruled that this family deserves compensation, you are not going to give me an answer?

Mr. HARRIS. With regard to the premise of the question, we have not made a decision on whether we are going to appeal that case. We filed a notice of appeal, but we have not made a decision.

Mr. BURTON. When will you make a decision? You can tell me that, can't you?

Mr. HARRIS. Very soon, probably within the next week or two, but don't hold me to that. I am more comfortable with saying "very soon." It's not in my control to decide whether we appeal this case or not.

Mr. BURTON. Since you can't talk about it, I guess I will have to write a letter to John Ashcroft, the Attorney General, and ask him to put this baby to bed, and see if he's willing to do that; because 8 years seems to be enough. If that means I am interfering with

an ongoing case, then so be it. But I think these people have gone through enough.

The dictionary defines compassion as, "the deep feeling of sharing the suffering of another and the inclination to give aid or support or to show mercy." Just thought you'd like to know that.

Thank you very much. We are adjourned.

[Whereupon, at 1:30 p.m., the committee was adjourned.]

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

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STATEMENT OF REP. HENRY A. WAXMAN
RANKING MINORITY MEMBER
COMMITTEE ON GOVERNMENT REFORM
SEPTEMBER 18, 2002

Today we are holding another hearing on an important federal program: the Vaccine Injury Compensation Program. Fifteen years ago, when I chaired the Health and the Environment Subcommittee, I was the principal author of the legislation that established the Vaccine Injury Compensation Program.

The Vaccine Injury Compensation Program was established as part of the 1987 Vaccine Injury Compensation Act. It had several goals. The program was intended to be a no-fault system for compensating people who suffer from the rare but sometimes serious side effects of vaccines. At the same time, the program was supposed to reduce the number of lawsuits against vaccine manufacturers in order to encourage them to stay in the vaccine business. The program was also supposed to allay parents' concerns about vaccine safety, so that parents would continue to vaccinate their kids against potentially deadly and debilitating diseases like whooping cough or diphtheria.

In general, the program is working. However, during the course of this Committee's investigation, we have heard complaints about the program. Specifically parents have raised concerns 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.

Today we will hear the stories of two families who have faced great difficulty in getting the compensation the program's special masters have said they are entitled to. I appreciate their willingness to testify today. This is Mrs. Zuhlke's second appearance before us today. I know that it is very difficult for her to take time away from caring for her daughter, so I especially thank her for making the trip to testify again.

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I am also pleased that we will be hearing today from the Administration. Because the cases are ongoing, the Administration will not be able to comment on the specifics of the Zuhlke and the Rogers cases. However, I am looking forward to hearing the Administration's views on pending legislation regarding the program. These bills include legislation offered by Chairman Burton and myself, as well as a bill offered by Sen. Frist and his House companion, Mr. Greenwood.

It is clear that there are changes that need to be made to the program, including increasing the statute of limitations, allowing for interim payments for petitioners' litigation costs, and allowing the program to pay for family counseling expenses. While there is general agreement that these changes need to be made, the Burton/Waxman approach is different in certain respects from the approach that Senator Frist and Mr. Greenwood have taken. I hope we will learn the Administration's opinions about these differing approaches.

The discussion of the Vaccine Injury Compensation program cannot be separated from a discussion of vaccine supply. The United States is only now pulling out of very severe vaccine shortages. The General Accounting Office has just released a report that I and others in Congress requested about current vaccine supplies. According to the GAO, while the most recent vaccine supply crisis has largely been resolved, the vaccine supply continues to remain vulnerable. As we consider the future of the Vaccine Injury Compensation Program, we must always be mindful that ensuring a stable vaccine supply was one of the major purposes of the program.

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

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