ALASKA LEGISLATURE COMMITTEE FILES 1987-1988 8672
4544 HHES HB 277 (FILE 1)

POSITION PAPER/Department of Health & Social Services

3. Reporting of adverse reactions

7 AAC 27.005 currently requires health care providers to report "severe reactions to any vaccine" to the department. These reports are investigated according to strict protocol required by the national Centers for Disease Control. The investigation and reporting of adverse reactions to vaccinations are required as a condition of the immunization grant awards the department receives from the Centers for Disease Control. The department believes that the current regulatory language is sufficiently directive with regard to the reporting of adverse reactions and the statutory changes proposed in HB 277 are unnecessary.

In addition, Congress has recently adopted a federal vaccine liability law, and the federal government is currently writing regulations for its implementation. This law states: "The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."

This new law does not allow states to use any discretion regarding the reporting and investigation of reactions to vaccinations. This law also requires that each health care provider who administers a vaccine shall provide to any legal representative of any child to whom such provider intends to administer a vaccine a copy of written information about the vaccine.

Departmental Position

The department opposes this bill for three reasons: (1) Extending exemption from immunization requirements to individuals with philosophical opposition to such requirements will create a serious public health threat to Alaskan children. (2) HB 277's requirement to inform the parent or guardian of an immunization's risks and benefits is unnecessary, as this is already required by the department and by recently enacted federal law. (3) The department will be required to conform with the stringent new federal law governing reporting of adverse reactions. The statutory changes proposed in HB 277 are thus unnecessary and, if adopted, may have to be changed to meet the new federal requirements.

Recommended by: Elizabeth Ward
Elizabeth Ward, Director
Division of Public Health

Date: January 26 1988

Approved by: Myra M. Munson
Myra M. Munson, Commissioner
Department of Health and
Social Services

Date: Feb 10, 1988

STATE OF ALASKA
1988 LEGISLATIVE SESSION

BILL VERSION: HB 277
PUBLISH DATE: _____

FISCAL NOTE

REQUEST:

Revision Date: 4/29/87
Title: An Act relating to the immunization of minors.
Sponsor: _____
Requestor: Navarre

Agency Affected: Health & Social Services
BRU: State Health Services
Components: Section of Epidemiology

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 88	FY 89	FY 90	FY 91	FY 92	FY 93
PERSONAL SERVICES		45.2	46.9	48.7	50.5	52.4
TRAVEL		6.0	6.0	6.0	6.0	6.0
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING		51.2	52.9	54.7	56.5	58.4
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

GENERAL FUND		51.2	52.9	54.7	56.5	58.4
FEDERAL FUNDS						
OTHER						
TOTAL		51.2	52.9	54.7	56.5	58.4

POSITIONS:

FULL-TIME		1.0	1.0	1.0	1.0	1.0
PART-TIME						
TEMPORARY						

ANALYSIS: (Attach a separate page if necessary)

Personal services and travel costs are for one PFT Public Health Representative, range 16, to assure public information and reporting requirements are met. See attached.

Prepared by: Elizabeth Ward, Director
Division: Public Health
Phone: 465-3090
Date: 2-09-88

(R) Approved by Commissioner: Myra M Munson
Agency: Department of Health & Social Services
Date: 2-10-88

Distribution (by preparer):
Legislative Finance
Legislative Sponsor
Requestor
Office of Management and Budget
Impacted Agency(ies)

HB 277 Fiscal Note Analysis

To meet the requirements of Section 2 of HB 277, which requires individuals or facilities administering immunizations to provide detailed immunization information, a PFT Public Health Representative, range 16, will be needed. This person will be responsible for monitoring the individuals and agencies providing immunizations to assure compliance with the public information requirements of this bill. This person will educate providers on public information and reporting requirements, and will develop and maintain a centralized data bank regarding compliance.

The incumbent will also serve as the intial investigator for the proposed AS 18.15.310 and will develop the annual report for submission to the legislature.

This legislation will cause a reduction in immunization levels in Alaska. Increased disease outbreaks will follow, requiring additional staff time to perform follow-up investigations and outreach information services.

Position Title	No. of Positions	Range/Step	Barg. Unit
Public Health Representative	1	16B	GGU

Time Status	Staff Months	Location	Election District
PFT	12	Anchorage	HD 10/SD F

Type of Expenditure		Amount
1	2	3
Salary	33.6	
Benefits	11.6	
Premium Pay	0	
Other	0	
Total Personal Services		45.2
Travel		6.0
Contractual		
Commodities		
Equipment		
Other		
Total Cost		51.2

Funding Source for Total Cost		
Federal Receipts	1002	
G. F. Match	1003	
General Fund	1004	51.2
GF Program Receipts	1005	
Other		

Justification

A Public Health Representative, range 16, in Anchorage is necessary to assure compliance with the public information requirements of this legislation. This position will monitor the individuals and agencies providing immunizations and will educate them on public information and reporting requirements. The position will develop and maintain a centralized data bank on compliance. The incumbent will also be the initial investigator for the proposed AS 18.15.310 and will develop the annual report to the legislature.

Request For New Position

Agency: Health & Social Services

BRU: State Health Services

Component: Epidemiology

Revised Date

FY 89

From the Governor's Interim Commission on Children and Youth Report

1. Quality: *Health*

BACKGROUND RECOMMENDATION

Child Care Revolving Loan Fund: 31

Centers and homes that provide child care and education must be healthy for our children. But many programs are located in inadequate, makeshift spaces, sometimes poorly heated and often with minimal outdoor play space and equipment. When children spend so much of their time indoors, the space must be adequate for the number of children as well as well-lit, heated and maintained.

Child care is labor intensive and capital poor. Alaska used to have a Child Care Revolving Loan Fund for capital improvement. The maximum loan per facility was $50,000. By banking standards the loans were small. Loans were only available to property owners who often did not run the programs. These factors make it extremely difficult for child care programs to find needed capital to improve existing buildings and make them healthy places for children.

Alaska should reinstate the low interest Child Care Revolving Loan Fund, increase its previous level of funding and simplify the required paperwork. This loan program provides funding support so child care facilities can meet all codes and ensure a healthy environment for our children.

Child care is labor intensive and capital poor.

Comprehensive Health Screening: 32

Comprehensive health screenings assure parents and practitioners that the care for young children is appropriate to their needs. Screenings that check height and weight, blood pressure, teeth and include a random check for scoliosis promote normal growth and development. Regular attention to each child's physical health is essential to all children's well-being. The only funding presently available for comprehensive health screening of children in the Department of Health and Social Services is for children who have already been identified as developmentally disabled.

Required immunizations, adequate nutrition and access to medical, dental and mental health services are the right of all of Alaska's children and part of any quality early childhood system.

Comprehensive health screenings should be guaranteed to all Alaska's infants, toddlers, preschoolers and students, to identify problems as soon as possible to prevent more expensive treatment later.

Regular attention to each child's physical health is essential to all children's well-being.

Pertinent correspondence from State Health Dept. as referred to in Briefing Paper

STATE OF ALASKA

DEPT. OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH
SECTION OF COMMUNICABLE DISEASE CONTROL

May 1, 1986

The information you requested about DTP vaccine and whooping cough was not easily retrievable. The major reason being that I have only been on the job three months, therefore, I didn't know who to ask or where to look. However, this is what I have found.

1. There were five cases of whooping cough in 1984 and 30 cases in 1985.

2. Four of the five cases were confirmed in 1984 and nine of the 30 cases were confirmed in 1985.

3. A total of four of the 35 cases were hospitalized with no deaths.

4.

Age	1984	1985
unknown	0	4
<1	2	10
1	1	6
2	0	4
5-9	0	2
10-19	0	3
20-24	0	1
25-29	1	0
30-39	1	0

Approximately half of the cases had received pertussis vaccine at some point in their life , however, whether they were appropriately immunized for age I am unable to ascertain.

5. The parents/guardians of recipients who see a physician or who are hospitalized within one month of an immunization are supposed to notify the Alaska Immunization Program. When I receive notification of an adverse event following an immunization, I contact the parents/guardians, the immunization provider, and the attending physician. It is the physician's responsibility to determine whether or not the patient's problems are vaccine-related. All vaccine-related adverse reactions are documented on an official report form and sent to the Centers for Disease Control in Atlanta, Georgia.

I hope the enclosures are of help to you.

Sincerely,

Michael Klatt

Michael Klatt, Manager
Alaska Immunization Program

MK:db

BILL SHEFFIELD, GOVERNOR

DEPT. OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH
SECTION OF COMMUNICABLE DISEASE CONTROL

3601 "C" STREET, SUITE 576
POUCH 6333
ANCHORAGE, AK 99502-0333
(907) 561-4235

November 14, 1986

Ms. Shannon Kohler
Alaska Chapter-DPT
Box 1746
Soldotna, AK 99669

Dear Ms. Kohler:

Thank you for the information relative to the pertussis poster containing incorrect information. We are not aware of any state-wide department offices displaying such a poster.

The "Dear Health Care Provider" contains information which has been in existence for at least two years and is considered common knowledge by most health care providers who administer vaccine. However, it maybe appropriate to reiterate the information in an upcoming edition of the Epidemiology Bulletin (a news bulletin sent to health care providers and other interested parties). Also, we will be rewriting the immunization standing orders for the Public Health Nurses and, if not already part of their standing orders, we will include this important information.

The State does not have any specific regulations regarding the reporting of adverse reactions following immunizations. Health care provders who administer vaccines are encouraged to report possible adverse reactions to this office. This is a passive surveillance system which relies on the integrity of the health care providers to comply.

The answers to your remaining questions are as follows:

1. Report Gathering

   A. How are adverse reactions gathered from parents? from public health officials administering vaccine? from doctors?

      Parents are to notify the provider of the vaccine if the vaccinee visits a doctor, hospital, or clinic within 4 weeks of vaccination, as requested on every Important Information Form. A public provider who is made aware of a possible adverse reaction completes the MSAEFI report form and submits it to this office. A private physician who is made aware of a possible adverse reaction notifies this office and the MSAEFI Coordinator completes the MSAEFI report form.

B. What is the estimated rate of compliance?

C. How exactly is the rate of compliance determined?

No estimated rate of compliance is determined.

2. Handling Reports

A. Once a report is received, where and how is it recorded?

All submitted MSAEFI report forms are entered onto a MSAEFI report form log sheet by the MSAEFI Coordinator. All submitted MSAEFI report forms which meet the minimal criteria for submission to the Centers for Disease Control are forwarded.

B. Is the original or copy of report kept by State office?

A typed carbon copy is retained by the State office.

C. Is the original or copy of report sent to the National Center of Disease Control (CDC) in Atlanta Georgia?

A typed copy is forwarded to the CDC.

3. Approximately how many adverse reaction reports does your office receive per year from public health officials?

1985 - 12 (2 of which were military)
1986 - 9

from doctors?

1985 - 3
1986 - 1

from parents?

1985 - 0
1986 - 0

(The numbers listed above indicate adverse reaction reports forwarded to the CDC, not the number received by this office.)

B. What are the symptoms and diagnosis included in reports?

See enclosed MSAEFI report form.

And, finally, your last request to "send me a copy of the annual Alaska State reports regarding immunizations and reactions that were sent to Atlanta, Georgia CDC in 1984 and 1985," will have to be more specific.

There are no annual reaction reports, however, there a quite a few immunization reports sent to the CDC quarterly and annually by this office. If the specific information you want is available, we will send it to you.

Sincerely,

Michael Klatt, Manager
Alaska Immunization Program

Robert I. Fraser, M.D. Chief
Sec. of Comm. Disease Control

MK+RIF:ew

Enclosure

cc: Elizabeth Ward, Director
Division of Public Health

HB 277
REFERENCE MATERIALS
FROM
ALASKA DISSATISFIED PARENTS TOGETHER

TURNING POINT
Family Wellness Center

Edward H. Chapman, M.D.
Dolores Heeb, Reg. Ac.
Richard P. Ingrasci, M.D., M.P.H.
Richard Moskowitz, M.D.
Geri Schumacher, R.N.

November 25, 1987

Alaska State Legislature
Health Education and Social Affairs Committee
c/o Glenda Landua, Alaska DPT
39918 Dawn Avenue
Kenai, Alaska 99611

Dear Sir:

I am writing in support of House Bill No. 277, "An Act Relating to the Immunization of Minors."

I am a family physician and have been practising medicine for the past twenty years. During that time I have been impressed with the number and variety of chronic diseases that can be provoked or exacerbated by the various childhood vaccines in general use. My thoughts and observations on this subject are summarized in the articles enclosed herewith.

I am especially troubled by the fact that investigations of vaccine-related illness have generally been limited to acute complications occurring within thirty (30) days of the administration of the vaccine, thus excluding any condition occurring more gradually or not evident until months or years later.

Requiring all children to be vaccinated with foreign proteins or live viruses clearly presupposes the moral and legal obligation to prove both that the corresponding natural diseases constitute a serious public health hazard, and that the vaccines themselves are in no way detrimental to health. Furthermore, it implies full legal and financial liability for any illness or injury sustained by those vaccinated against their will.

Adequate investigation of chronic vaccine-related illness will necessarily be prolonged and difficult. It will require following large numbers of both vaccinated and unvaccinated children for at least a decade or more, to determine any differences in their overall health patterns, and in the incidence and severity of various chronic diseases (recurrent otitis media, asthma, epilepsy, behavior disorders, etc.).

Until these studies are completed, it would be reckless indeed to continue routine childhood vaccination on a compulsory or statutory basis. I personally favor making all vaccines completely optional, i.e., freely available to all who want them, and allowing parents to make the choice with and for their children, as is now being done in West Germany and many other countries. This practice will effectively reduce the liability of the state, if and when complications do occur. Furthermore, it will create a sizeable control group of unvaccinated children for the long-term studies that urgently need to be done.

For all of these reasons, I urge you to support H. B. 277, and to make it as simple as possible for parents not to vaccinate their children. I would suggest, for example, amending the opening section so as to allow parents to accept some vaccines, and to reject others, without having to give a reason, and without any discrimination or penalty. The term "religious or philosophical beliefs" implies a principled, across-the-board repudiation, while many parents actually prefer to obtain the tetanus and oral polio vaccines, for example, but not the others. The right to make such choices should perhaps be stated explicitly.

But, even in its present form, the proposed law is an important step forward, bringing Alaska abreast of the other states that have been most progressive in this respect. It deserves your full support.

Thank you.

Truly yours,

Richard Moskowitz, M.D.

The Nevada Clinic
6105 W. Tropicana Ave., Las Vegas, NV 89103
(702) 871-2700

January 13, 1988

Shannon Kohler, President
Alaska Dissatisfied Parents Together
Box 1746
Soldotna, Alaska 99669

Dear Shannon:

I have received your letter and am in complete sympathy with your efforts to modify the immunization laws as they exist in your state. Thank you very much for sending me a copy of the House Bill No. 277. I wish you all the success in the world in getting it passed.

I am enclosing a photocopy of a fairly recent article from the April, 1987 issue of the British Homeopathic Journal that deals with the use of pertussin as a prophylactic treatment to prevent whooping cough. As you can see from the articles enclosed, the battle goes on in other countries, as well as in various states in the United States.

I believe that homeopathy offers tremendous advantages over the standard and routine immunization programs, which have been pushed by allopathic medicine since the beginning of time (Pasteur's time, that is).

Our clinic has seen several infants and children who have not had a good response as a result of D.P.T. immunizations. I can recall three small children who developed "infantile spasms" and seizures as a result of the pertussin part of the D.P.T. immunization. Of course, none of the physicians who administered the injections, nor the company that made the serum, would in any way admit any kind of a connection between the immunization and the child's problems. Nevertheless, when treated homeopathically to remove the pertussin from the brains and nervous systems of these infants, they all have totally recovered without any further seizures or spasms.

There has not been a great deal of research done that I am aware of in this country with regards to an immunization program based on the treatments utilized by homeopathic physicians for the past 150 years. Nevertheless, these programs have proven very effective. In fact, during the 1917 flu epidemic in this country, the only patients who survived were those who were fortunate enough to find a homeopathic physician and be treated homeopathically.

I hope this information is of some help to you. There are obviously other journals and articles that could be sent, but I don't have them in hand at the present time.

Sincerely,

F. Fuller Royal, M.D.

FFR/elm

IMMUNIZATION COMPLIANCE RATES OF SCHOOL AGE CHILDREN (K-1ST GRADE) AND INCIDENCE OF VACCINE PREVENTABLE DISEASES (1986)

ALL STATES INCLUDED IN SURVEY HAVE PHILOSOPHICAL OBJECTION TO STATE MANDATED IMMUNIZATIONS IN STATUTES

	compliance rate:	reported cases of: measles	rubella	mumps	pertussis	tetanus	diptheria	polio
Michigan	91%	185	24	467	36	1	INA	INA
1971 (approx.) - mandatory law implemented 1971 (approx.) - philosophical objection allowed								
Utah	93%	13 [38.5%] {61.5%}	15	16	44 [65.9%] {34.1%}	0	0	0
197[illegible] - mandatory law implemented **1982 (approx.) - philosophical exemption allowed**								
Washington	95.7%	176 [65%] {35%}	15	30	163 [56%] {44%}	0	0	0
Missouri	98.3%	32	1	23*	32*	2(2)*	0	0
California	93.4%	497 [50%] {50%}	242	336	310 [40%] {60%}	3	0	1
1961-mandatory law implemented 1961-philosophical exemption allowed								
Pennsylvania	99.2%	28	1	63	52	1	0	0
Oklahoma	97.6%	39	0	INA	134	1	0	0
1976-mandatory law implemented 1976-philosophical exemption allowed								
Nebraska	96.5%	1	0	2	10	INA	INA	INA
1973-mandatory law implemented 1973-philosophical exemption allowed								
Indiana	97%	39	0	339	39	2	0	0
1976-mandatory law implemented 1976-philosophical exemption allowed								
Delaware	98%	35	INA	INA	INA	INA	INA	INA
1982-mandatory law implemented 1982-philosophical exemption allowed								

(6)

COMPLIANCE RATES CONT'D.

	compliance rate:	reported cases of: measles	rubella	mumps	pertussis	tetanus	diptheria	polio
Ohio	95%	1(0) [80%] {20%}	0	150	170	0	0	2
1959-mandatory law implemented **1970 (approx.)-philosophical exemption allowed**								
Arizona	95.1%	252	2	209	78	1	0	0
1976-mandatory law implemented **1981-philosophical exemption allowed**								
Minnesota	99%	50 [89%] {21%}	1	86 [88.8%] {11.2%}	50	0	0	0
1967-mandatory law implemented **1978-philosophical exemption allowed**								
Colorado	96.3%	11	1	17	84(2)	0	0	0
1974-mandatory law implemented **1979-philosophical exemption allowed**								
Maine	INFORMATION NOT AVAILABLE							
1977-mandatory law implemented 1977-philosophical exemption allowed								
Wisconsin	96.5%	287	1	325	111	0	0	0
1975-mandatory law implemented **1980-philosophical exemption allowed**								
Vermont	98%	0	1	6	5	0	0	0
1979-mandatory law implemented 1979-philosophical exemption allowed								

INA: information not available
*: immunization not mandatory in state
(n): fatalities
[n]: percent of ill fully immunized
{n}: percent of ill unimmunized

Data received from State Health Departments of states listed
22 states contacted - 17 states responded to date - January 20, 1988

All states implement exclusion of unimmunized children from school during vaccine preventable disease occurances.

13 of 17 states have mandatory disease reporting laws; 7 of those have penalties for non-reporting of contagious diseases

Data compiled by the Alaska Chapter of Dissatisfied Parents Together

(7)

Box 118
Columbus, Ohio 43266-0118

Telephone (614) 466-3543

RICHARD F. CELESTE
Governor

November 4, 1987

Shannon Kohler
Alaska Chapter-DPT
Box 1746
Soldotna, Alaska 99669

Dear Ms. Kohler:

I am responding to your July 27 letter regarding immunization exemptions. I am sorry for the delay, but the mail had apparently been misrouted.

While immunization exemptions are a concern, immunization-exempt children have not contributed to disease initiation or propagation in Ohio.

In Ohio immunization levels exceed 95 percent in schools; in fact, in kindergarten they are 97 percent or greater. Immunization exemptions have not exceeded Ø.3 percent - Ø.5 percent among children new to Ohio schools. (The table enclosed gives you information regarding immunization levels, exemptions and reported cases of the vaccine-preventable diseases you requested.)

The measles cases in Ohio (1Ø last year) can virtually all be attributed to importations and spread from importations among persons either inadequately vaccinated or vaccine failures, but not persons who are immunization exempt. In 1986, only two of the 1Ø cases were not previously vaccinated. Because of their small number, exemptions have not played a major part in outbreaks.

In 1986 Ohio reported 17Ø cases of pertussis. Of these we were able to determine the age and vaccine status of 115. Most of these cases were just too young to have completed a full series of DTP immunizations. While an analysis of immunization exemptions was not made, only two of the cases were of school age.

Mumps cases have been declining in Ohio since the inclusion of mumps in the school immunization law beginning in 1984. The 15Ø cases reported in 1986 can not be attributed to immunization exemptions.

I hope this answers most of your questions, please let me know if I can provide any further information.

Sincerely,

Thomas J. Halpin, M.D., M.P.H.
Chief
Bureau of Preventive Medicine

KOHLERLE.PRN
Enclosure:

(9)

November 12, 1987

SUMMARY OF SEVERE ADVERSE REACTIONS TO STATE MANDATED IMMUNIZATIONS

Data collected by: Dissatisfied Parents Together, Alaska Chapter

Dates of survey: October 1986-October 1987

Method used: Alaska "DPT" vaccine adverse reaction questionnaire

Number of subjects (reactions) - 25: 24 DPT
1 MMR

Range of survey: State of Alaska

1- College, AK.	1- Anchorage, AK.
1- Gustavis, AK.	1- Anchor Point, AK.
1- Sterling, AK.	1- Homer, AK.
4- Kenai, AK.	3- Fairbanks, AK.
2- Juneau, AK.	7- Soldotna, AK.
1- Palmer, AK.	2- Kasilof, AK.

Ages of subjects at date of response:

2- 4 months	1- 4 years
1- 6 months	2- 5 years
1-10 months	3- 6 years
1- 14 months	1- 8 years
1- 18 months	1- 17 years
5- 2 years	1- 20 years
4- 3 years	1- 23 years

Return to: Dissatisfied Parents Together (11)
Box 1746
Soldotna, AK 99669
Shannon Kohler 262-3825

DPT SHOT REACTION QUESTIONNAIRE

Directions: Please place an "X" before the answer(s) you select or fill in the spaces when appropriate.

1. Before your child received his DPT shot(s), did a health professional inform you of the possible serious reactions to the shot?

   5 Yes (1) 19 No (2) 1 Don't Know (3)

2. Did the health professional who gave your child the DPT shot(s) tell you to look for and report severe reactions such as a high temperature, excessive crying or high pitched screaming, excessive sleepiness, etc.?

   6 Yes (1) 18 No (2) 1 Don't Know (3)

3. Before giving your child the DPT shot(s) did a health professional tell you when the shot should not be given (i.e. if the child has an active infection or a fever, if the child reacted severely to a previous DPT shot, etc.)?

   6 Yes (1) 16 No (2) 3 Don't Know (3)

4. Did you sign a consent form containing information about the DPT shot and its possible reactions before your child received his DPT shot?

   2 Yes (1) 15 No (2) 8 Don't Know (3)

5. Before your child received his DPT shot(s), did a health professional question you about your family's and your child's medical history?

   ___ Yes (1) 23 No (2) 2 Don't Know (3)

6. Do you believe your child reacted severely to any of his DPT shots? (Answer yes only if the reaction was more serious than a low fever, mild crying, or slight redness or puffiness around the site of the shot)

   25 Yes (1) ___ No (2) ___ Don't Know (3)

If you answered yes to question #6, please answer the rest of the questionnaire. If you answered no to question #6, skip the rest of the questions and fill in your name, address and telephone number at the end of the questionnaire.

7. After the DPT shot that caused your child to react severely, did he have:
   most children had more than one symptom of reaction

   4 convulsions (1)
   16 fever of more than 103 degrees (2)
   13 excessive crying or high pitched screaming for long periods (3)
   6 extreme sleepiness (4)
   ___ collapse or shock (5)
   5 loss of muscle control (temporary or pemanent paralysis) (6)
   ___ death (7) 1-nerve damage deafness 1-severe allergies & eczema
   2-permanent partial paralysis 1-chronic cold sores
   ___ other (please explain) 1-severe congestion 1-whooping-like cough (8)
   1-limping 1-severe swelling of arm 1-severe leg swelling
   1-severe swelling of glands in head
   1-temporary loss of hearing 1-temporary fever blister

(12)

8. How long after the shot did the reaction begin to occur?

24 Within 24 hours after the shot (1)
1 24-48 hours after the shot (2)
___ 2 days - 7 days after the shot (3)
___ 1 week - 2 weeks after the shot (4)
___ more than 2 weeks after the shot (5)

9. After which DPT shot did your child react severely? Some children reacted to more than 1 shot

15 First shot (1)
4 Second shot (2)
3 Third shot (3)
2 Fourth shot (4)
___ Fifth shot (5)
1 all shots

10. How old was your child when he was given the DPT shot that caused the severe reaction?

8 2-3 months old (1)
6 4-5 months old (2)
4 6-7 months old (3)
3 8-12 months old (4)
1 13-18 months old (5)
1 19-24 months old (6)
___ 25 months - 3 years old (7)
___ over 3 years old (8)
1 all
1 Dont Know

11. How old is your child now?

See 1st page attachment

12. Did you report your child's severe reaction to the DPT shot to a health professional?

21 Yes (1) 4 No (2) ___ Don't Know (3)

13. If you did not report your child's severe reaction to the DPT shot, was it because you were not aware that the reaction was serious and should have been reported?

4 Yes (1) No ___ (2) ___ Don't Know (3)

* 14. If you did report your child's severe reaction to the DPT shot to a health professional, did that person report your child's severe reaction orally or in writing to: NO: 10

___ drug manufacturer (1)
___ federal government (2)
3 state health department (3)
___ any local health agency (4)
8 Don't Know (5) none of these parents had an official MSAEFI form completed

15. Was your child's severe reaction to the DPT shot written on his medical record?

6 Yes (1) 8 No (2) 11 Don't Know (3)

16. After your child reacted severely to a DPT shot, was he given another shot that contained the pertussis vaccine?

6 Yes (1) 17 No (2) 1 Don't Know (3) 1 n/a mmr shot

17. Was your child mentally and physically normal before he received the DPT shot to which he reacted severely?

25 Yes (1) ___ No (2) ___ Don't Know (3)

18. Prior to the DPT shot to which your child reacted severely, did your child have a history of convulsions or neurologic disease?

____ Yes (1) 24 No (2) 1 Don't know

19. Does your family have a history of convulsions or neurologic disease?

1 Yes (1) 23 No (2) 1 Don't Know (3)

20. Did you or your husband ever have whooping cough?

1 Yes (1) 22 No (2) 2 Don't Know (3)

21. Is there a significant history of allergies in your family or has your child ever been diagnosed as having allergies?

9 Yes (1) 12 No (2) 4 Don't Know (3)

22. If your child has allergies, were the allergies apparent before or after the DPT shot to which he reacted severely?

3 Before (1) 5 After (2) N/A 17

23. At the time your child had a severe reaction to the DPT shot, was he primarily bottle-fed?

9 Yes (1) 11 No (2) 5 Both

24. Has your child had a continuing physical or mental health problem since the DPT shot that caused the severe reaction?

12 Yes (1) 12 No (2) 1 dont know yet

If you answered yes to question #24, please answer the rest of the questions.

25. Is your child now:

1 experiencing motor delay
mentally retarded (1)

4 physicially handicapped (2)

3 experiencing convulsions (3)

4 exhibiting learning difficulties (4)

____ in an institution (5)

____ other (please explain) 1-nerve damage deafness 1-epilepsy 2-permanent partial paralysis 1-speech problem 2-cerebral palsy 1-severe allergies (6)

26. Has a physician confirmed your belief that your child's present health problems were caused by the DPT shot?

7 Yes (1) 7 No (2)

27. Has your child required special medical treatment, medicine, hospitalization, or therapy since the DPT shot that caused the severe reaction?

11 Yes (1) 14 No (2)

28. The cost of your child's special medical treatment is estimated to have been:

1 Under $2,000

10 $2,000 - $7,000

____ $7,000 - $12,000

____ $12,000 - $20,000 (4)

____ $20,000 - $40,000 (5)

____ Over $40,000 (6)

29. Please feel free to use the back of this page to tell us your story of what happened to your child as a result of his severe reaction to a DPT shot. Try to be as specific as possible, giving names, dates, and places.

Name: See next page for Emergency Treatment Information

Address: _____

Telepone Numbers: _____ (home) _____ (work)

Date: _____

(19)

4 visits to emergency room
2 telephone contact only

a) 1st parent
b) 2nd parent
c) 3rd parent
d) 4th parent
e) 5th parent
f) 6th parent

30. Emergency room treatment of adverse reaction, if applicable

a) What hospital did you go to?
a) Central Pen Gen. Hospital
B) Kenai Emergency medical Clinic
c) Central Peninsula Gen Hospital
D) Tanana, Alaska
e) Central Pen. Gen. Hospital
f) Homer South Peninsula Hospital

b) Did you call the emergency room?
5 yes a) B) C) D) e) 1 no f)

c) Did you go to the emergency room?
4 yes a) B) D) f) 2 no c) e)

d) How were you treated? (if more room needed, use back of sheet)
a) told not to worry; give cold bath & tylenol
B) O.K.
c) told not to worry; give cold bath & tylenol
D) hospital did not even record visit
e) Give cold bath & tylenol
f) good

e) Were you advised to tell your doctor of reaction?
___yes 6 no a) B) c) D) e) f)

f) Were you advised to tell Health Dept. of reaction?
___yes 6 no a) B) c) D) e) f)

31. Was your child hospitalized?
1 yes f) 5 no a) B) c) D) e)

a) Where? Homer South Peninsula General Hospital

b) For how long? 3 days

c) How was reaction treated? not treated as vaccine reaction

Attachment 3

COMPREHENSIVE CHILD CARE COMMITTEE

Public Comment
July 10, 1987

loyd Richmond, Executive Director of Women in Safe Homes, (WISH). ox 6552, Ketchikan, AK, 99901, 225-9474. Richmond expressed that the overnment has a role in providing freedom of choice to work outside the ome or in the home. This can only be achieved through a system of ffordable, qua ty child care. Note: Written testimony from Richmond s available by ontacting the office.

hannon Kohler, President of the Alaska chapter of Dissatisfied Parents ogether (DPT), Box 1746, Soldotna, AK 99669, 262-3825. Kohler poke on behalf of AK-DPT. This organization is actively working for he passage of HB 277, sponsored by Rep. Navarre. This legislation ould 1) require all public health officials to report all adverse eactions to immunizations, 2) require that prior to vaccination that ll parents are given accurate benefit/risk information with regard to accine safety, and 3) amend Alaska statues to allow a parent to enroll child in public schools with out vaccinating the child. Note: Written estimony and supporting documents presented by Kohler are available in he office.

Margeret Green, Tom Thumb Montessori Schools, 1901 Spenard Road, nchorage, AK 99503, 272-5033
n has b
een involved with this private school since 1956. Their rogram works with children from three years old through sixth grade. She attributes their success to emphasizing developmentally appropriate curriculum. Green shared that she is apprehensive about creating new statutes and regulations that would impact their successful program.

leather Heames, DPT, Box 73, Clam Gulch, AK 99568, 262-6287
leames is the mother of a child that suffered a severe reation to a DPT vaccine. She urged the Committee to do what it could from subjecting others to the problems that her child has faced.

Mary Wilson, Tom Thumb Montessori Schools, 1823 Beaver Pl., Anchorage, AK, 338-1669. Wilson is a teacher/supervisor at the Montessori school and is a certified elementary and montessori teacher. This school is self supporting. In response to questions it was calculated that the typical cost per child per month, for the full day program is $295.

Cheryl Rykaczewski, DPT, Box 311, Kasilof, AK. She is a parent concerned about vaccine safety. She urge the Committee to support the passage of HB 277- The Alaska Vaccine Reform Act.

Terry Victor, DPT, Box 1752, Fairbanks, AK 99708, 488-9531. Victor is the parent of a 15 month old child that suffered a severe reactio to a vaccine. She urged the Committee to support passage of HB 277, which ld require health care providers to report adverse reactions.

Mary Jo Hotchkiss, Instructor at Anchorage Community College, 2333 Providence Dr., 99508. She explained that in 1980 the University deleted their degree program in Early Childhood Education. This was a

(16)

result of there being few graduates in the program, which she attributed to the lack of incentives with in the field for pursuing a degree. She urged the Committee to support changes in the University that would establish training and possibly degrees in Early Childhood Education.

Regina Olszewski, 4003 Garfield , Anchorage, AK. She has a niece that suffered a stroke following a DPT vaccination. She urge the Committee to support the passage of HB 277.

Cecelia Bumanglage, Box 2708, Palmer, AK, 745-2528. She is the parent of a child that suffered a stroke following a DPT vaccination. Since there is no pediatric neurologist in Alaska, they have had to make medical trips to Seattle. The process of treating her now handicapped child is financially difficult. She urges the Committee to support the passage of HB 277, and possibly save one family this pain as the result of mandatory vaccination.

Susan Adams, Illilgaat Tupqaat, Inc., Box 1130, Kotzebue, AK, 442-3157. Adams is the Director of Illilgaat Tupqaat, a day care center. She agreed with the statements shared by Floyd Richmond of Ketchikan with regard to the State's responsibility in assisting in providing affordable, quality child care. She shared the story of a mother of four children, ages 4 months to 6 years, who wants to work outside the home, but can not afford a babysitter and does not qualify for day care assistance. Adams urged the Committee to assist the government in taking a leadership role in establishing quality day care in Alaska.

Carolyn Barnes, 5131 Hatcher, Anchorage, AK, 333-6028.
She is the parent of a child that became deaf after a DPT vaccine. She urged the Committee to support the passage of HB 277.

Dianne Gerber, DPT, St. Rt. 2, Box 560-Z, Kasiloff, AK 99610, 262-1714. She is the parent of a child that had severe reactions to the DPT vaccine and to the MMR vaccine. The child suffered fours days of high fever following the MMR vaccine. She urged the Committee to support the passage of HB 277.

Sharon Wells, 9340 Stratamore, Anchorage, AK, 243-4148. She is a medical foster parent for infants and premature babies. She is very concerned that many infants stay in foster care too long. Because of problems in the Indian Child Welfare Act, many infants that are adoptable stay in foster care past the point of being easily adoptable.

Kathy Boucha-Roberts, Director of Child Development at Providence Hospital, 3200 Providence Dr., Anchorage, AK, 99519, 261-3075. Roberts directs the corporate sponsored child care facility at Providence Hospital. The program cares for approximately 500 children and has a staff of 65. The fee for a child is based on age and the type of care, (i.e. daytime, night time, full time, drop in). They provide services 18 hours a day, 7 days a week, 365 days a year. This program also provides parenting education through classes taught at the hospital that provide interaction between parents and teachers.

Dee Ann Mueller, DPT, 501 Cole Dr., Kenai, AK 99611, 283-7459. She expressed her strong concern that parents should have a choice in deciding to vaccinate a child. Her child had adverse reactions to two DPT vaccines. She was not given any precautionary information, nor was the reaction reported. As a result of the vaccine her child now suffers with mild cerebral palsy.

Pertussis Whooping Cough

definition: an infectious disease typically of children marked by paroxysms of violent coughing followed by a shrill, whooping drawing in of breath. from: Nelson's Medical Dictionary

the following from: Vaccine Preventable Diseases - manual published by CDC

diagnosis: It has fastidious growth requirements that make it difficult to isolate with multiple serotypes. There are other causes of paroxysmal coughing that may also be confused with pertussis. These include bronchiolitis, bronchopneumonia, Bordetella parapertussis, B. bronchiseptica infections, adenovirus infections, chlymydia trachomatis, and others. Difficult to diagnose. Some success with swabs taken from posterior nasopharynx or immunoflourescent antibody testing.

treatment: erythromycin antibiotic of choice to decrease communicability and treat bacteriological secondary infections such as bronchopneumonia (most common and most severe secondary infection). Intensive nursing care essential. Pertussis immune globulin may help shorten illness.

complications: 10% of all pertussis cases may be hospitalized. 1982-1983 encephalopathy occurred in 371,000 cases, 2.5% of cases in children less than 1 year may have convulsion. Average of 6 deaths per year in United States due to pertussis.

Diptheria

definition: highly contagious bacterial disease spread by coughing and sneezing. Patches can be observed in throat that cause swelling, may obstruct breathing in severe cases and cause victim to choke to death.

diagnosis: usually made based on clinical presentation; swab of pharangeal area. variety of types: nasal, tonsillar, pharyngeal, laryngeal, etc.

treatment: antibiotics and antitoxin. respitory support and airway maintenance if needed

complications: respiratory diseases. 9% respiratory diptheria fatal. approx. 1 death per year in U.S. 1983; 5 cases, 0 deaths

Tetanus

definition: an acute infectious disease characterized by spasms of the muscles especially of the jaw caused by a baccillic toxin introduced through a wound. not contagious.

diagnosis: many medical conditions simulate tetanus. no laboratory findings characteristic of tetanus. Diagnosis is entirely clinical.

complications: spasms, coma, aspiration pneumonia. 20% of tetanus deaths attributed to tetanus toxoid. average 91 cases, 30 deaths per year in U.S. (no information as to vaccination rate of inflicted)

NOTES ABOUT TETANUS:
1) "...the mortality in reported cases of tetanus is higher in the U.S. than in developing countries." (Am J. Dis. Child, Vol 135, June 1981, pg. 571)
2) "nosocomial" (hospital acquired pneumonia) pneumonia is a major cause of death in these patients that come to autopsy." (J. Arkansas Med. Soc., Vol 80, No. 3, Aug. 1983, pg. 136)

(18)

GENERAL DPT (DIPTHERIA, PERTUSSIS, AND TETANUS) VACCINE INFORMATION

All vaccines come combined unless specifically requested separate via medical prescription. The following is from Lederle and Connaught manufacturer's inserts.

Ingredients: Lederle Co.: FORMALDEHYDE, potassium phosphate monobasic, sodium phosphate dibasis, glycine, THIMEROSAL (mercury derivative), sodium chloride, ALUMINUM, inactivated diptheria and tetanus toxoids, inactivated pertussis bacteria. Connought Co.: basically the same but no mention of formaldehyde.

Minor-Moderate Adverse Reactions: (See manufacturer's product insert for complete list)
1) local reactions, adscess formation at sight of injection, fretfulness, drowsiness, vomiting, anorexia

Severe Adverse Reactions: (See manufacturer's product insert insert for those recognized by manufacturer. Read large print under ADVERSE REACTIONS.)

ADVERSE REACTIONS

Local reactions manifested by erythema and induration with or without tenderness are common after administration of DTP. Such local reactions are usually self-limited and require no therapy. A nodule may be palpable at the injection site for a few weeks.

Abscess formation at the site of injection has been reported [illegible]. Cervical lymphadenopathy has been reported following DTP injections into the arm.

Mild to moderate temperature elevations frequently follow DTP administration and are often accompanied by fretfulness, drowsiness, vomiting, and anorexia. Approximately 50% of DTP recipients will develop temperature elevations > 38° C (100.4° F) after one or more doses of the series, approximately 6% > 39° C (102.2° F), and approximately 1.5% > 40° C (104° F). Some data suggest that febrile reactions are more likely to occur in those who have experienced such responses after prior doses.

SIGNIFICANT REACTIONS ATTRIBUTED TO THE PERTUSSIS VACCINE COMPONENT HAVE BEEN: HIGH FEVER OF 40.5° C (105° F), A TRANSIENT SHOCK-LIKE EPISODE, EXCESSIVE SCREAMING (PERSISTENT CRYING OR SCREAMING FOR THREE OR MORE HOURS DURATION), SOMNOLENCE, CONVULSIONS, AND ENCEPHALOPATHY. THESE REACTIONS HAVE BEEN REPORTED TO OCCUR RARELY FOLLOWING THE INJECTION OF THIS PRODUCT AND THEY MAY BE FATAL OR RESULT IN PERMANENT DAMAGE TO THE CENTRAL NERVOUS SYSTEM. PERTUSSIS VACCINE HAS BEEN ASSOCIATED WITH A GREATER PROPORTION OF ADVERSE REACTIONS THAN MANY OTHER CHILDHOOD IMMUNIZATIONS. SHOULD SYMPTOMATOLOGY REFERABLE TO THE CENTRAL NERVOUS SYSTEM DEVELOP FOLLOWING ADMINISTRATION, FURTHER IMMUNIZATION WITH THIS PRODUCT IS CONTRAINDICATED (SEE CONTRAINDICATIONS). SUCH REACTIONS ALMOST ALWAYS APPEAR WITHIN 24 TO 48 HOURS AFTER INJECTION, BUT HAVE BEEN THOUGHT TO OCCUR AFTER AN INTERVAL AS LONG AS SEVEN DAYS.

NEUROLOGICAL COMPLICATIONS FOLLOWING TETANUS TOXOID ADMINISTRATION, SUCH AS PARALYSIS OF THE RADIAL NERVE, RECURRENT PHARYNGEAL NERVE, COCHLEAR LESION, BRACHIAL PLEXUS NEUROPATHY, AND A CASE OF DIFFICULTY IN SWALLOWING, ACCOMMODATION PARESIS, AND EEG DISTURBANCES, HAVE BEEN REPORTED. IN THE DIFFERENTIAL DIAGNOSIS OF POLYRADICULONEUROPATHIES FOLLOWING ADMINISTRATION OF TETANUS TOXOID, TETANUS TOXOID SHOULD BE CONSIDERED AS A POSSIBLE ETIOLOGY.

CONTRAINDICATIONS

IMMUNIZATION SHOULD BE DEFERRED DURING THE COURSE OF ANY ACUTE ILLNESS. THE OCCURRENCE OF ANY TYPE OF NEUROLOGICAL SYMPTOMS OR SIGNS, INCLUDING ONE OR MORE CONVULSIONS (SEIZURES) FOLLOWING ADMINISTRATION OF THIS PRODUCT IS A CONTRAINDICATION TO FURTHER USE. USE OF THIS PRODUCT IS ALSO CONTRAINDICATED IF THE CHILD HAS A PERSONAL OR FAMILY HISTORY OF CENTRAL NERVOUS SYSTEM DISORDERS.

THE PRESENCE OF ANY EVOLVING OR CHANGING DISORDER AFFECTING THE CENTRAL NERVOUS SYSTEM IS A CONTRAINDICATION TO ADMINISTRATION OF DTP REGARDLESS OF WHETHER THE SUSPECTED NEUROLOGICAL DISORDER IS ASSOCIATED WITH OCCURRENCE OF SEIZURE ACTIVITY OF ANY TYPE.

The Committee on Infectious Diseases of the American Academy of Pediatrics recommends that pertussis vaccine should be withheld when a previous dose has been followed by convulsion, encephalitis, focal neurological signs or collapse. Nor should infants who experience excessive somnolence, excessive screaming (persistent crying or screaming for three or more hours duration) or temperature more than 105° F (40.5° C) receive additional doses of the vaccine.

The Immunization Practices Advisory Committee (ACIP) of the U.S. Public Health Service recommends that hypersensitivity to vaccine components, presence of an evolving neurologic disorder, or a history of a severe reaction (usually within 48 hours) following a previous dose all remain definitive contraindications to the receipt of pertussis vaccine. Severe reactions include collapse or shock, persistent screaming episode, temperature 40.5° C (105° F) or greater, convulsion(s) with or without accompanying fever, severe alterations of consciousness, generalized and/or focal neurologic signs, or systemic allergic reactions.

Immunosuppressive therapy, including irradiation, corticosteroids, antimetabolites, alkylating agents, and cytotoxic agents may result in aberrant responses to active immunization procedures. Administration should be deferred in individuals receiving such therapy.

The clinical judgement of the attending physician should prevail at all times.

Elective immunization of patients over the age of 6 months should be deferred during an outbreak of poliomyelitis.

PARTIAL LIST OF POSSIBLE SEVERE LONG-TERM ADVERSE REACTIONS TO DPT VACCINE (USUALLY PERTUSSIS COMPONENT IMPLICATED)

* article available from Alaska Dissatisfied Parents Together

*1) **Cervical lymphadenopathy** . Omokoku, B: "Post DPT inoculation caused lymphadenitis in children." N.Y. State Journa. ' 'cine 81:1667, 1981

2) **Thrombocytopenia** (blood disease). Connaught manufacturer's insert* Pertussis. Report of Committee on Infectious Diseases. AAP, Evanston, Illinois, p. 205. 1977

*3) **hemolytic anemia** (blood disease). Haneberg B.; "Acute hemolytic anemia related to DPT vaccination": ACTA Pae diatr. Scand. 67:347-350, 1978

*4) **death, encephalopathy, Reyes syndrome, tracheo bronchitis. convulsions with and without residual brain damage** . Griffith A.H: "Reactions after Pertussis vaccine; a manufacturer's experiences and difficulties since 1964", British Medical Journal: April 1, 1978, pg. 809-814

*5) **destructive encephalopathys, convulsions, hypsarrhythmia, shock, serious meningitis** . Incidence of neurological reactions 1:3,600 children. Strom, Justus M.D., "Further Experience of Reactions, Especially of a Cerebral Nature, in Conjunction w/Triple Vaccine: Swedish Study, 1959-1965", British Medical Journal, 1967, 320-323

*6) **recurrent seizures, severe developmental delays** . Murphy, Jerome. "Recurrent Seizures after DPT Vaccine Immunization", AJDC, Vol 138, Oct. 984

*7) **blindness, cerebral palsy, death, mental retardation, chronic convulsions** Byers, Randolph. "Encephalopathies Following Prophylactic Pertussis Vaccine", Pediatrics, Vol. 1, #4, April 1948.

*8) **recurring convulsions, paralysis, mental retardation, allergies** Berg, J.M "Neurological Complications of Pertussis Immunization", British Medical Journal, July 5, 1958

*9) **death, sudden death, convulsions, paresis, rhinopharyngitis, rapid mental deterioration, coma, cerebral palsy, deafness, epilepsy** Neurological reactions after vaccination-1 in 6,000 children; death or permanent defect-1 in 17,000. "Is Universal Vaccination Against Pertussis Always Justified?" Justus Strom, M.D., British Medical Journal. Oct. 22, 1960.

*10) **allergic form of encephalopathy, death** . "Encephalopathy Following Pertussis Vaccine Prophylaxis", Joseph H. Globus, M.D., J.A.M.A., October 22, 1949

*11) **cerebral degeneration, blindness** . "Neurological Complications of Pertussis Inoculation", M. Kulenkanpff, Archives of Disease in Children, 1974, pg. 46, 49

*12) **sudden death, seizures, convulsions, respiratory infection** . John A. Toomey, "Reactions to Pertussis Vaccine", J.A.M.A., February

13) "**Post vaccinal lymphadenitis developing into Hodgkins Disease**". Bichel, J. ACTA Med. Scand., 199:523, 1976

*14) **anaphylaxis** (extreme, sometimes fatal allergic reaction). Howard Orens, M.D. "Anaphylaxis due to vaccination in the Office". Can. Med. Assoc. Journal

*15) **paroxysmal supra ventricular tachycardia** . Joon M. Park, M.D. "Paroxysmal Supra ventricular tachycerdia precipitated by pertussis vaccine", Journal of Pediatrics, June 1983

SIDS AND DPT VACCINATION

STUDIES THAT SHOW CORRELATION BETWEEN SIDS/DPT

*1) BARAFF GRAPH. "Possible Temporal Association between DPT Vaccination and Sudden Infant Death" Pediatric Infectious Disease, 1983, 2,7-11

*2) TORCH STUDY summary & graph. DPT Immunization, a Potential Cause of the Sudden Infant Death Syndrome. Neurology 1982, 32 A No 3

(20)

*3) BERNIER STUDY GRAPH. "DTP Vaccination and SIDS in Tennessee." Journal of Pediatrics, 1982, 101:419-421
*4) "DTP Immunization and Sudden Infant Death Syndrome." Alexander M. Walker, et. al., AJPH, August 1987, Vol. 77, #8

TETANUS VACCINE REACTIONS (PARTIAL LIST)

1) "Abnormal T-Lymphocyte Subpopulations in Healthy Subjects After Tetanus Booster Immunization." Martha Eibe, New England Journal of Medicine, 310(3) 1307-1313, November 26, 1981. Report pointed out that similar drops in helper/suppressor ratio of T-lymphcytes are characteristic of AIDS.
2) **neuralgic amyotophy** . J. Neurology, Neurosurgy & Psych, Vol. 47; 320, March 1984
3) **transverse myelitis.** Br. Med Journal 1977; 1: 1430-1431
4) **demyelinating neuropathy** . J Neur. Sci. 1978; 37: 113-125
5) **peripheral neuropathy** . Arch Phys Med Rehab Vol 63, July 1982, 332-334. (detailing many cases)
6) **calcifying dermatomyositis** . Arch Int Med Vol 143, July 1983, 1457-8
7) **mono and polyneuritis** (22 cases). Int. Symnos. on Imm. Dev. Biol Stands, Vol. 43, pg. 25-32, 1979
8) **Guillain Barre Syndrome** . N.Z. Med J., Nov 11, 1981 , Akt Neurol 1980: 7;195-200
9) **hemolytic anemia** . Acta Pediatric Scand, May 1978
10) **anaphylactic shock** . Harefuah, Nov 1975 - Dtsch Med Wochenschr, Jan 1973 - Annals of Allergy, Vol 49, August 1982, pg 107
11) **nerve damage, inner ear** . Munch Med. Wochen Schr., Nov 1965
12) **foreign body granuloma** . Rocky Mountain Medical Journal, Jan, 1966
13) **seizure activity** . Neurol Neurochir Pol., Sept 1981
14) **recurrent abscess formatio n.** Pediatric, May 1985
15) **brachial plexus neuropathy** . Archives of Neurology, 1972
(which can lead to paralysis of the arm)

DIPTHERIA VACCINE REACTIONS

(all from Center of Disease Control Manual: "Vaccine Preventable Diseases; Epedemiology, Prevention and Control", pg 38-39.)

1) local reactions, abscess at the site of injection
2) arthus-type hypersensitivity reactions, characterized by severe local reactions
3) severe systemic reactions such as generalized urticaria (allergic rash and hives), anaphylaxis, neurological complications

DPT VACCINE INGREDIENTS

*data available from Alaska Dissatisfied Parents Together

FORMALDEHYDE

"Formaldehyde (ingredient in Lederle DPT vaccine) is also mutagenic in bacteria, viruses, fungi, insects and mouse lymphoma cells with or without metabolic activation. It induces chromosomal recombination in yeast, insects, and cultured mammalian cells, as well as cellular transformation in mouse Balb/C 3T3 cells (Griesemer, et al., 1980). These results indicate that formaldehyde is capable of binding to, and altering, genetic material."
Formaldehyde: Review of Scientific Basis of EPA's Carcinogenic Risk Assessment Peter W. Preuss Ph. D., May 20, 1987 page 21-

"Immunologic. (physiological effect): The characteristics of an allergic mechanism are that the response can be evoked in sensitized individuals with very small amounts of formaldehyde. Symptoms usually develop some time after the initial exposure rather than on initial contact. Usually only a proportion of the exposed will be affected. In the documented cases there is typically a delayed response, although there may be a brief immediate reaction as well (dual response), and the late reaction may be prolonged." Formaldehyde Toxicity, James E. Gibson, 1983*

"Carcinogenic Effect: Of additional concern is the carcinogenic potential of formaldehyde in humans. This concern is based on metabolism, mutagenicity, and carcinogenicity studies which were reviewed in the Report of the Federal Panel on Formaldehyde, Griesemer, et. al., 1980. In brief, the panel reported that these studies showed that formaldehyde reacts readily with biological chemical, including proteins and nucleic acids." page 395, Formaldehyde: Review of Scientific Basis of EPA's Carcinogenic Risk Assessment, May 20, 1982*

Aluminum

(another ingredient in all DPT vaccines)

"...In Canada (researchers) found that after a latent period of 10 to 20 days, animals receiving a single intracerebral injection of aluminum incurred a progressive decline in learning and memory." Physiol Behav, Crapper DR, Dalton AJ, 1973

"Crapper also found that aluminum accumulates preferentially on the chromatin of various cell nuclei, including brain cell nuclei from patients with SDAT... (Senile Dementia of the Alaheimer's Type)." Frontiers in Neurology and Neuroscience Research, "Dementia: Recent observations on Alzheimer's disease and experimental aluminum encephalopathy." Crapper, Dr., 1974

Thimerosal (mercury derivative)

definition: prepared by reacting ethylmercuric chloride (or ethymercuric hydroxide) with thiosalicylic acid. The Merck Index, 1983*

ethylmercuric chloride: caution: Highly toxic. causes skin burns, is absorbed through the skin, chronic exposure has caused permanent injury to brain, applied at 2% strength as a fungicide for treating seeds. The Merck Index, 1983*

the following from: "Epidemiology & Toxicology of Mercury" The Environmental Mercury Problem*

"Furthermore, the vast majority of the organomercurial poisonings are due to alkylmercurials such as methyl or ethylmercury."

"Therefore while it is important to recognize that all forms of mercury are powerful poisons, the akylmercurials are many times more effective poisons than either the inorganic or arylmercurials."

"...the organic mercury compounds, especially the alkymercurials (ethymercury) are more toxic than the other kinds of mercury compounds because the human body absorbs more and excretes less of them."

"Several alkylmercury poisoning epidemics have been recorded." Guatamala, Pakistan, Iraq: "In 1960 many farmers were poisoned and 221 patients were admitted to hospital in Baghdad, Iraq. Other patients were known to have been stricken by ETHYLMERCURIC CHLORIDE

POLIO

definition : a viral disease marked by inflammation of the nerve cells of the spinal cord, deformity, and paralysis. 95% of all polio infections are inapparent or subclinical, but may still be able to transmit infection to others (CDC Manual)

diagnosis : A) 4%-8% nonspecific illness of influenza-like illness B) 1%-2% of polio infections result in major illness w/complete recovery C) 0.1%-0.2% of all polio infections result in flaccid paralysis. Many persons w/paralytic polio recover completely. Deathrate: 2-5% in children 15-30% in adults

treatment : 1) early ambulation 2) muscular relaxation 3) controlled and prolonged medical observation 4) special nutrition program Virginia Medical Monthly, June 1956, Nutrition; "Nutrition as Treatment for Polio Victims", Prevention, November 1960

complications: See diagnosis

POLIOVIRUS VACCINE

all information from manufacturer's product insert unless specified

Ingredients: mixture of 3 types of attenuated polioviruses propagated in cercopithecus MONKEY KIDNEY CELLS, amino acids, antibiotics, CALF SERUM, sorbitol, streptomycin, NEOMYCIN

CONTRAINDICATION MUST NOT BE ADMINISTERED TO PATIENTS WITH IMMUNE DEFICIENCY

Question: Since no mechanisms are employed by health care providers to determine immune deficiency (especially public health providers who have never seen 2 month old infants before vaccine clinics), how is this to be determined?

ALL PERSONS WITH ALTERED IMMUNE STATUS SHOULD AVOID CLOSE HOUSEHOLD-TYPE CONTACT WITH RECIPIENTS FOR AT LEAST 6-8 WEEKS.

Question: Most people aren't aware of the health status of everyone their child comes in contact with (especially other infants in day care), so how is this to be accomplished and what are the other health implications?

Adverse Reactions: 1) paralytic disease, vaccine associated paralysis in healthy vaccines, susceptible family members, and other close personal contacts 2) transverse myletis (inflammation of spinal cord or bone marrow) "Transverse myletis after diptheria, tetanus, and polio immunization." case history British Medical Journal, June 4, 1977

NOTES:

1) "Many physicians and health workers will be surprised to learn that the Sabin vaccine is now the chief cause of polio in the world today and that it was introduced without any controlled field trials." J. and D. Salk, Science 4/4/77

2) Current Trends: Average of 10 cases per year reported 1980-1985, no wild virus cases since 1979; one imported case per year. REMAINING CASES IN VACCINE RECIPIENTS OR CONTACTS. page 88, CDC manual Note: speaker at seminar Neil Livengood stated that no "natural cases" of polio have occurred in U.S. since 1979

(2-4)

3) "A defect either in the humoral (B-cell) mediated (T-cell) system appears to increase the risk of vaccine associated polio myelitis. T-cell dysjunction from any cause must therefore be assumed to confer greater risk for vaccine related poliomyelitis." Elena Nightengale, Ph. D, et al, Committee for the Study of Poliomyelitis Vaccines, Institute of Medicine. Correspondence New England Journal of Medicine, Dec. 8, 1977

4) "The poliovirus isolated from a patient with paralytic disease may not always be the virus causing the patients disease." Lancet, Dec. 8, 1984, pg 1315

*5) "The DBS (Division of Biological Sciences) requires monkey kidney cells used in growing polio vaccine be held for only 28 days in order to ensure that they contain no SV 40 virus According to A. Girandi of the Wistar Institute SV 40 may remain latent for up to 35 days. Nor does the DBS require monkey kidney cells to be screened for chromosomal abnormalities - a possible indicator of cancerous tendencies - a test they would probably fail in large numbers." "The Boat That Never Rocked", Science, March 17, 1977

CONTRAINDICATIONS

Under no circumstances should this vaccine be administered parenterally

Administration of the vaccine should be postponed or avoided in those experiencing an acute illness and in those with any advanced debilitated condition or persistent vomiting or diarrhea

ORIMUNE *must not* be administered to patients with immune deficiency diseases such as combined immunodeficiency, hypogammaglobulinemia and agammaglobulinemia. It would also be prudent to withhold ORIMUNE from siblings of a child known to have an immunodeficiency syndrome. Further, ORIMUNE *must not* be administered to patients with altered immune states such as those occurring in thymic abnormalities, leukemia, lymphoma or generalized malignancy or by lowered resistance from therapy with corticosteroids, alkylating drugs, antimetabolites or radiation. All persons with altered immune status should avoid close household-type contact with recipients of the vaccine for at least 6-8 weeks. IPV is preferred for immunizing all persons in this setting.[2,3,4,6,7]

PRECAUTIONS

Other viruses (including poliovirus and other enterovirus) may interfere with the desired response to this vaccine since their presence in the intestinal tract may interfere with the replication of the attenuated strains of poliovirus in the vaccine

It would seem prudent not to administer TOPV shortly after Immune Serum Globulin (ISG) unless such a procedure is unavoidable, for example, with unexpected travel to or contact with epidemic areas or endemic areas. If TOPV is given with or shortly after ISG, the dose probably should be repeated after three months if immunization is still indicated.[8] However, ISG may not interfere with immunization with TOPV.[9]

The vaccine is not effective in modifying or preventing cases of existing and/or incubating poliomyelitis.

ADVERSE REACTIONS

Paralytic disease following the ingestion of live poliovirus vaccines has been, on rare occasion, reported in individuals receiving the vaccine, (see for example CONTRAINDICATIONS) and in persons who were in close contact with vaccinees.[2,3,4,10,11,12,13] The vaccine viruses are shed in the vaccinee's stools for at least 6 to 8 weeks as well as via the pharyngeal route. Most reports of paralytic disease following ingestion of the vaccine or contact with a recent vaccinee are based on epidemiological analysis and temporal association between vaccination or contact and the onset of symptoms. Most authorities believe that a causal relationship exists.[2,10,14,15]

The risk of vaccine-associated paralysis is extremely small for vaccinees, susceptible family members and other close personal contacts.[7] However, prior to administration of the vaccine, the attending physician should warn or specifically direct personnel acting under his authority to convey the warnings to the vaccinee, parent, guardian or other responsible person of the possibility of vaccine-associated paralysis. The Centers for Disease Control report that during the years 1969 through 1980 approximately 290 million doses of TOPV were distributed in the United States. In the same 12 years, 25 "vaccine-associated" and 55 "contact vaccine-associated" paralytic cases were reported. Twelve other "vaccine-associated" cases have been reported in persons (recipients or contacts) with immune deficiency conditions.[7] These statistics do not provide a satisfactory basis for estimating these risks on a per person basis."[14]

When the attenuated vaccine strains are to be introduced into a household with adults who have not been adequately vaccinated or whose immune status cannot be determined, the risk of vaccine-associated paralysis can be minimized by giving these adults three doses of IPV a month apart before the children receive ORIMUNE.[7] The CDC reports that no paralytic reactions to IPV are known to have occurred since the 1955 cluster of poliomyelitis cases caused by vaccine that contained live polioviruses that had escaped inactivation.[7]

The Immunization Practices Advisory Committee of the U.S. Public Health Service states:

"Because of the overriding importance of ensuring prompt and complete immunization of the child and the extreme rarity of OPV-associated disease in contacts, the Committee recommends the administration of OPV to a child regardless of the poliovirus-vaccine status of adult household contacts. This is the usual practice in the United States. The responsible adult should be informed of the small risk involved. An acceptable alternative, if there is strong assurance that ultimate, full immunization of the child will not be jeopardized or unduly delayed, is to immunize adults according to the schedule outlined above before giving OPV to the child."[7]

The Immunization Practices Advisory Committee has concluded that "Oral polio vaccine remains the vaccine of choice for primary immunization of Children

from: How to Raise a Healthy Child in Spite of Your Doctor, Dr. Robert Mendelsohn

MUMPS

definition and diagnosis: relatively innocous viral disease, usually experienced in childhood, causes swelling of one or both of the salivary glands. Symptoms; temp of 100-104 degrees, appetite loss, headache, back pain. Infection confers lifetime immunity.

treatment: does not require medical treatment - bed rest, lots of fluids, ice packs to reduce swelling.

complications: very rarely in adult males with mumps infection, orchitis (mumps condition that affects testicles) may occur. Orchitis rarely causes sterility and when it does usually only one testicle is affected

In 1981, 1,491 cases in U.S..; 1 death (MMWR 1983 summary)

MEASLES

definition and diagnosis: rubeola, contagious viral disease that can be contracted by touching an object used by infected person, slight fever at first to high (103-104 degrees) in few days-sometimes small white spots occur inside mouth - rash occurs below hairline and spreads downward to cover body in about 36 hours

treatment: bedrest, fluids, Calamine lotion or cornstarch to relieve itching, may be light sensitive (darken room), Vitamin A supplements in malnourished. "Vitamin A Supplements and Mortality Related to Measles: A Randemised Clinical Trial", Andrew J.G. Barclay, British Medical Journal, Jan. 31, 1987, Volume 294

RUBELLA

definition and diagnosis: non-threatening disease in children that does not require medical treatment- fever, slight cold w/sore throat - rash appears on face and spreads to body, spot do not run together (as in measles), confers lifetime immunity

treatment: rest and fluids

complications: none to child. Threat posed by rubella is the possibility it may cause damage to fetus if a women contracts disease during first three months of pregnancy

In 1981, 2,077 cases of rubella in U.S.; 5 deaths (MMWR 1983 Summary)

(26)

MEASLES, MUMPS, RUBELLA (MMR)
VACCINE INFORMATION AND ADVERSE REACTIONS

NOTE: Since all three vaccines in combined shot, it's difficult to ascertain what vaccine causes what reaction. Any live virus vaccine is capable of producing the same syptoms, reactions, etc. as the virus.

Ingredients: CELL CULTURES OF CHICK EMBRYO (measles and mumps), HUMAN DIPLOID CELL culture (rubella), neomycin, sorbitol, hydorlized gelatin.
Adverse Reactions: (from Manufacturer's insert)

CONTRAINDICATIONS

Do not give M·M·R II to pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy must be avoided for three months following vaccination.

Hypersensitivity to neomycin (each dose of reconstituted vaccine contains approximately 25 mcg of neomycin).

Any febrile respiratory illness or other active febrile infection.

Active untreated tuberculosis.

Patients receiving therapy with ACTH, corticosteroids, irradiation, alkylating agents or antimetabolites. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

Individuals with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems.

Primary immuno-deficiency states, including cellular immune deficiencies, hypogammaglobulinemic and dysgammaglobulinemic states.

HYPERSENSITIVITY TO EGGS, CHICKEN, OR CHICKEN FEATHERS

This vaccine is essentially devoid of potentially allergenic substances derived from host tissues (chick embryos).* However, because the attenuated measles and mumps viruses in this vaccine are propagated in cell cultures of chick embryo, there is a potential risk of hypersensitivity reactions in patients allergic to eggs, chicken or chicken feathers. Widespread use of the vaccine for more than a decade has resulted in only rare, isolated reports of minor allergic reactions attributed to allergens of this kind, possibly related to the vaccine. Significantly, when children with known allergies to eggs, chicken and chicken feathers were given a similarly prepared vaccine in a clinical study,[20] none experienced reactions other than those reactions previously observed in non-allergic children.

PRECAUTIONS

Administer M·M·R II subcutaneously; *do not give intravenously.*

Epinephrine should be available for immediate use in case an anaphylactoid reaction occurs.

M·M·R II may be given simultaneously with monovalent or trivalent poliovirus vaccine, live, oral. M·M·R II should not be given less than one month before or after administration of other live virus vaccines.

Due caution should be employed in administration of M·M·R II to children with a history of febrile convulsions, cerebral injury or any other condition in which stress due to fever should be avoided. The physician should be alert to the temperature elevation which may occur 5 to 12 days following vaccination.

Vaccination should be deferred for at least 3 months following blood or plasma transfusions, or administration of human immune serum globulin.

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7-28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are in contact with the vaccinated individuals. Consequently, transmission, while accepted as a theoretical possibility, is not regarded as a significant risk.**

There are no reports of transmission of live attenuated measles or mumps viruses from vaccinees to susceptible contacts.

It has been reported that live attenuated measles, mumps and rubella virus vaccines given individually may result in a temporary depression of tuberculin skin sensitivity. Therefore, if a tuberculin test is to be done, it should be administered either before or simultaneously with M·M·R II.

As for any vaccine, vaccination with M·M·R II may not result in seroconversion in 100% of susceptible subjects given the vaccine.

ADVERSE REACTIONS

Because of the slightly acidic pH (6.2-6.6) of the vaccine, patients may complain of burning and/or stinging of short duration at the injection site.

The adverse clinical reactions associated with the use of M·M·R II are those expected to follow administration of the monovalent vaccines given separately. These may include malaise, sore throat, headache, fever, and rash; mild local reactions such as erythema, induration, tenderness and regional lymphadenopathy; parotitis; orchitis; thrombocytopenia and purpura; allergic reactions such as wheal and flare at the injection site or urticaria; and arthritis, arthralgia and polyneuritis.

Moderate fever (101-102.5°F [38.3-39.4°C]) occurs occasionally, and high fever (above 103°F [39.4°C]) occurs less commonly. On rare occasions, children developing fever may exhibit febrile convulsions. Rash occurs infrequently and is usually minimal, but rarely may be generalized.

Clinical experience with live attenuated measles, mumps and rubella virus vaccines given individually indicates that encephalitis and other nervous system reactions have occurred very rarely. These might occur also with M·M·R II.

Experience from more than 80 million doses of all live measles vaccines given in the U.S. through 1975 indicates that significant central nervous system reactions such as encephalitis and encephalopathy, occurring within 30 days after vaccination, have been temporally associated with measles vaccine approximately once for every million doses. In no case has it been shown that reactions were actually caused by vaccine. The Center for Disease Control has pointed out that "a certain number of cases of encephalitis may be expected to occur in a large childhood population in a defined period of time even when no vaccines are administered". However, the data suggest the possibility that some of these cases may have been caused by measles vaccines. The risk of such serious neurological disorders following live measles virus vaccine administration remains far less than that for encephalitis and encephalopathy with natural measles (one per thousand reported cases).

There have been isolated reports of ocular palsies and Guillain-Barre syndrome occurring after immunization with vaccines containing live attenuated measles virus. The ocular palsies have occurred approximately 3-24 days following vaccination. No definite causal relationship has been established between either of these events and vaccination.

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 5-10 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Center for Disease Control suggest that the overall affect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.

Local reactions characterized by marked swelling, redness and vesiculation at the injection site of attenuated live measles virus vaccines have occurred in children who received killed measles vaccine previously. M·M·R II was not given under this condition in clinical trials.

Transient arthritis, arthralgia and polyneuritis are features of natural rubella and vary in frequency and severity with age and sex, being greatest in adult females and least in prepubertal children. This type of involvement has also been reported following administration of MERUVAX II (Rubella Virus Vaccine, Live, MSD). In children, joint reactions are rare and of brief duration if they do occur. In women, incidence rates for arthritis and arthralgia are generally higher than those seen in children (children: 0-3%; women: 12-20%),[21] and the reactions tend to be more marked and of longer duration. Rarely, symptoms may persist for a matter of months. In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and in adult women. Even in older women (35-45 years), these reactions are generally well tolerated and rarely interfere with normal activities.

NOTES:

MEASLES

1) subacute scleros panencephalitis "SSPE" (fatal hardening of brain) Modern Medicine, 1/7/74 and "Occurence of Measles in Previously Vaccinated Individuals, 1979", American Society for Microbiology meeting at Ft. Detrick, Md., April 27, 1987

*2) toxic epidermal nercrolysis (dying of skin "scalded skin") also reported to occur secondary to polio, diptheria, and tetanus vaccinations. "Toxic Epidermal Nercrolysis Following Measles Vaccination", Robert G. Shoss, M.D. Arch Dermatol, Vol 110, Nov. 1974

*3) ataxia (inability to coordinate muscle movements), mental retardation, aseptic meningitis, seizure disorders, hemiparesis (paralysis affecting one side of body), multiple sclerosis, Reyes syndrome, juvenile-onset diabetes. How to Raise a Healthy Child In Spite of Your Doctor, Robert S. Mendelsohn, M.D., 1984, Contemporary Books, Inc.

RUBELLA

*1) thrombocytopenia (blood clotting problem) "Thrombocytopenia Associated With Rubella Vaccination", Henry R. Bartos M.D., F.A.C.P; New York State Journal of Medicine, Feb. 15, 1972

2) arthritis and arthralgia. In United States, 87 cases of congenital rubella syndrome were reported, 12 in New Jersey. 17% of all children vaccinated in N. Jersey developed arthritis and arthralgia. Science, March 26, 1977

(29)

Boffins claim the cure can kill

By HARRY NELSON

ST PETERSBURG, (Florida).— New findings about the way viruses ebave once more point to their possible role in causing cancer — and, perhaps diseases such as arthritis and multiple sclerosis.

The findings, reported here at a seminar for science writers spnsored by the American Cancer Society, raise questions about the possible harmful effects of immunization programmes to prevent influenza, measles and polio.

The new findings came from Dr Robert W. Simpson, of Rutgers University in New Jersey, and Dr Wendell D. Winters, a University of California at Los Angeles virologist now working at the University of Texas in San Antonio.

Last year, the Nobel Prize for medicine was given to David Baltimore and Howard Temin for discovering that viruses that cause cancer in animals are equipped with a very special enzyme called reverse transcriptase.

The viruse that carry the enzyme are called RNA viruses. Possession of the enzyme allows the RNZ viruses to form strands of DNA, thus enabling them to become cftegrated with the DNA of the cells they infect.

It is this integration of the DNA transcribed by the virus with the cell's DNA that somehow triggers cancer, at least in animals.

(The genetic material of all living things, includin viruses, is either RNA (ribonucleic acid) or DNA (deoxyribonucleic acid). Before the discovery of reverse transcriptase, which enables RNA viruses to transcribe their genetic material into a DNA form, scientists had trouble understanding how RNA cancer viruses could transform DNA cells.)

in cells without expressing themselves in any way.

Simpson raised the question whether immunization programmes against flu, measles, mumps and polio may actually be seeding humans with RNA to form proviruses which will then becme latent in cells throughout the body.

He said some of these latent proviruses could be "molecules in search of disease" which under proper conditions become activated and cause a variety of diseases.

Of diseases that could be caused in this manner, the chief possibilities are rheumatoid arthritis, multiple sclerosis, lupus erythematosus, Parkinson's disease and, perhaps cancer.

Winters, the UCLA virologist, has added a new dimension to the subject of viruses being a possible cause of human cancer.

Cells grown

He has been working in the laboratory with tumour cells removed frm UCLA surgery patients. The cells were then grown in dishes.

When he added a common respiratory virus known as Adenovirus 5 to the cells, the Adenovirus caused large numbers of latent RNA particles to be released.

It is possible but not proven that the RNA particles were the cause of the human tumours. Perhaps they are also the seeds released into the bloodstream which float to other parts of the body where they infect cells and start cancer viruses into action.— Los Angeles Times service.

More recently, Simpson has found that RNA viruses which do not cause cancer also can form DNA, even though they lack reverse transcriptase.

DNA formed in this way from an RNA virus is called a provirus.

No effect

It is known from earlier work that some non-cancerous viruses have a tendency to exist as proviruses for long periods of time in cells without causing any apparent disease.

Some examples of common RNA viruses that do not cause cancer but may have the capacity to form proviruses are influenza, measles, mumps and polio viruses.

Simpson showed in laboratory experiments that proviruses derived from the measles virus and the respiratory syncytial virus (a cause of respiratory disease in newborn babies) can exist

30

Expert links AIDS to bovine viruses

By PHILIP M. BOFFEY
New York Times

WASHINGTON — Jeremy Rifkin, an outspoken critic of genetic engineering and other biotechnologies, Monday asked three federal agencies to determine whether cattle viruses play a role in causing AIDS.

In a petition submitted to the Agriculture Department, the Federal Centers for Disease Control and the National Institutes of Health, Rifkin called the cattle viruses "an extraordinary potential threat to public health."

Rifkin speculated in an interview that the AIDS virus might have evolved from cattle viruses, or that the cattle viruses might themselves play a role in the development of acquired immune deficiency syndrome in humans.

The petition cited scientific papers indicating a "close correlation" between the HIV, or human immunodeficiency virus, that causes AIDS in humans, and a virus found in cattle called bovine visna-like virus or bovine immunodeficiency-like virus. The petition warned that a range of viruses "exist in domestic animal herds in the U.S. and thus could pose a potential health hazard."

It also speculated that the cattle virus, BIV, might have infected cell cultures used to make some human vaccines, perhaps thereby contributing to the global spread of AIDS.

However, two of the scientists whose papers were cited by Rifkin expressed doubt in interviews that the cattle viruses played any role in causing AIDS.

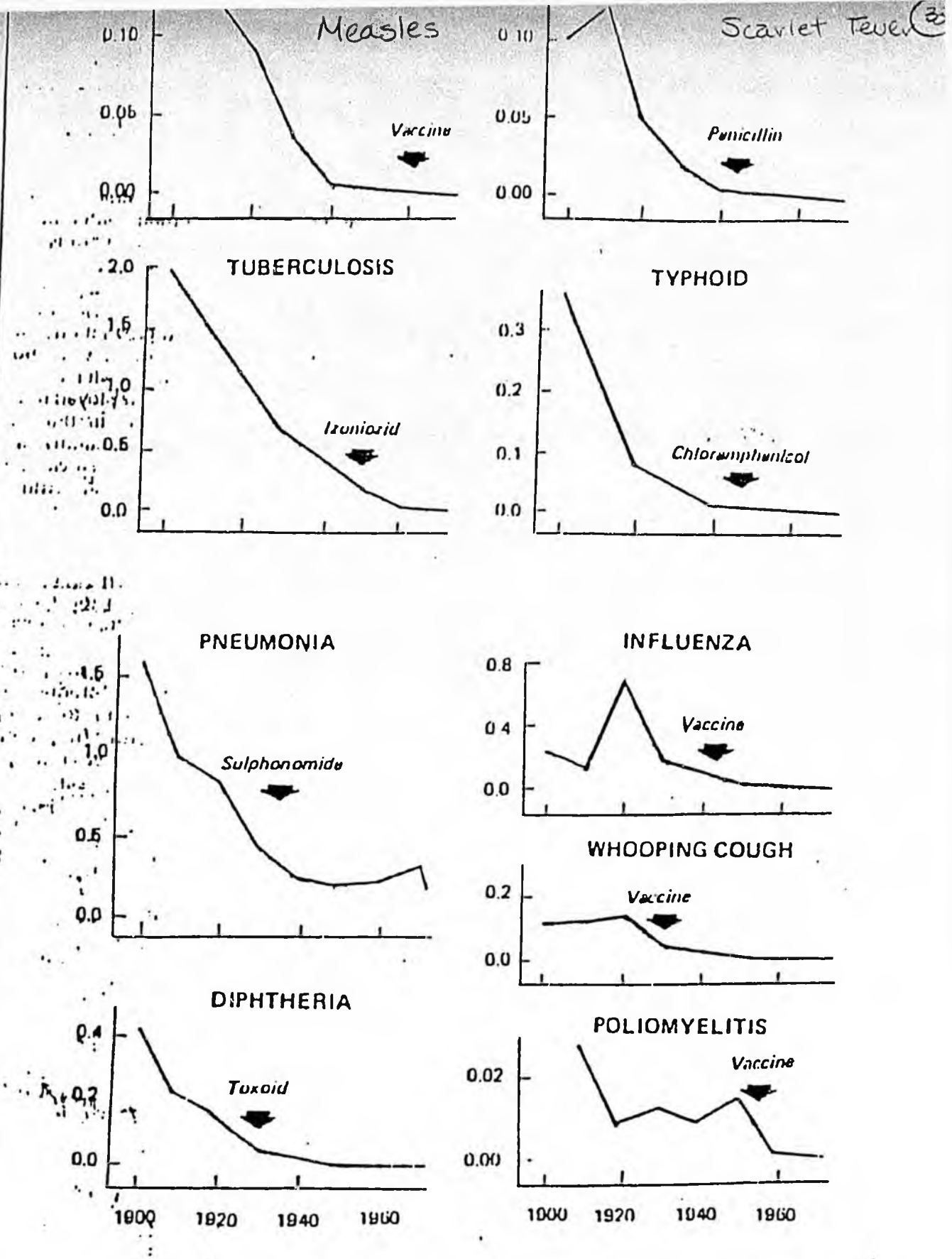
One of them, Dr. Matthew A. Gonda, a virus expert who has performed detailed studies of the structural and genetic makeup of BIV as compared to the AIDS virus, said that the two were close enough to be considered members of the same family of viruses, called lentiviruses.

In fact, Gonda and his colleagues at Program Resources, Inc., which conducts research for the National Cancer Institute in Frederick, Md., have proposed that the cattle virus be used as a model for studying the AIDS virus. But the cattle virus is not close enough to be considered the progenitor of the AIDS virus or the cause of AIDS, Gonda said.

"I don't think that BIV could cause AIDS in humans," he said. "I don't want people to say this is an AIDS virus. It's not something that somebody should be afraid will jump into humans or that should make people fear cows."

The second expert, Dr. Martin J. Van der Maaten, of the Agriculture Department's National Animal Disease Laboratory in Ames, Iowa., who first isolated BIV from cattle, said he believed there was "very little chance of it infecting humans."

[redacted]



The Fall in the Standardized Death Rate (per 1,000 Population) for Nine Common Infectious Diseases in Relation to Specific Medical Measures, for the United States, 1900-1977.

From "Contribution of Medical Measures to Mortality Decline", by John B. McKinlay and Sonja M. McKinlay

Children's Diseases Increase As Vaccinations Decline

Officials are worried about minor problems becoming major

By Michael Specter
Washington Post Staff Writer

Cases of measles, mumps and whooping cough have risen steadily over the past several years while the percentage of young children receiving vaccines has dropped, according to a recent report by the Children's Defense Fund.

Public health officials have become worried that if the trend continues, childhood diseases that are now considered minor problems in the United States could return in force.

"Anytime you have a disease that can be prevented by a vaccine, the effort of the nation should be to eliminate it," says Surgeon General C. Everett Koop. "Compare the cost of the vaccine—in pain as well as money—to the cost of the disease. We need to reach the children we are missing."

Health experts say that diminished federal funds have been responsible for at least part of the problem. As funds have been cut during the past five years, it has become increasingly difficult for poorer children to gain access to vaccines, according to the report.

The surgeon general has set as a health objective for 1990 that at least 90 percent of the nation's children have vaccines before they are 2 years old. But general levels of immunization for preschool children declined between 1980 and 1985, according to federal statistics.

Progress toward the surgeon general's vaccination goals slowed or fell off for most major childhood diseases in the past five years, the Children's Defense Fund report says. For polio, measles, rubella, mumps and DPT (diphtheria, pertussis and tetanus), the percentage of children under 2 who received full immunization declined between 1980 and 1985.

During those years, the last for which there are complete statistics, the proportion of 1- to 4-year-olds receiving no doses of polio vaccine rose by 40 percent for children of all races and 80 percent for nonwhite children, according to the report. In addition, cases of mumps rose in 1986 after a 15-year decline, and in 1985 there were 3,589 reported cases of whooping cough, or pertussis, the highest number since 1970.

"This is becoming a very serious problem," says Dr. Richard Narkewicz, president of the American Academy of Pediatrics. "The immunization program in this country is a bulwark for the future health of our children. It has been built over years and it is beginning to erode."

Narkewicz cites several reasons for the drop in the percentage of children seeking immunization. The liability risks have driven the costs of vaccines up and pushed many drug companies out of the business. Also, because vaccines pose an inherent—but incredibly small—risk to children under 2, some parents decide to avoid them.

"Many American pediatricians have never even seen whooping cough," Narkewicz says. "Because the disease is so rare a certain complacency begins to settle in. But as long as the disease is still out there, it cannot be ignored."

Many health officials believe that parental fears about bad reactions to vaccines have been blown out of proportion. Nearly 11 million children are immunized in America each year and about 30 to 50—at most one out of 220,000—have reactions that cause permanent damage.

But health officials agree that benefits of vaccines far outweigh possible risks. The Children's Defense Fund report, which used figures compiled by the federal Centers for Disease Control, says the number of measles cases reported has risen dramatically since 1983 and that more than 80 percent could have been prevented through adequate immunization.

The development of successful vaccines for most major childhood diseases has been regarded as a hallmark of modern medicine. Vaccines routinely protect children against seven diseases: polio, measles, mumps, rubella, diphtheria, tetanus and pertussis.

Statistics suggest that the decline in vaccinations can be attributed at least partially to access problems rather than parental decisions to avoid the shots. Poor and minority children consistently had the biggest drop in vaccination rates.

Vaccines against DPT give some illustration of the small but growing problem. The percentage of children from 1 to 4 years old with no reported dosages rose only slightly from 0.7 to 0.8 percent between 1980 and 1985, according to the report.

Complete protection requires a series of shots. The number of children younger than 1 only partially immunized against DPT climbed by 10 percent, from 15.8 to 17.3, while the percentage of nonwhite infants not fully immunized climbed 68 percent from 21.0 to 35.2 percent.

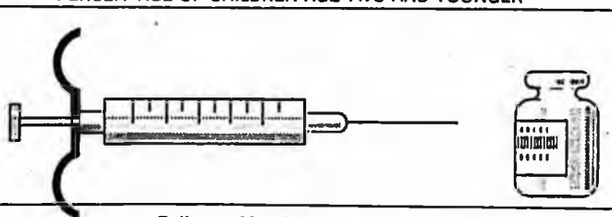
The final appropriation for the program in fiscal 1988 has been set at $86 million, $8 million below the full authorization level. That figure is slightly higher than current levels, but the price per dose of vaccine for measles, mumps and rubella has risen sharply over the past decade from $2.42 in 1975 to $8.47 last year, according to the report.

"By 1986 it took three times as many federal immunization grant dollars to purchase the same number of vaccine doses that were purchased in 1981," the report says.

The number of children younger than 6 has also increased over the past several years, from 18.8 million in 1979 to 21.7 million in 1986, and the number of poor and uninsured children rose dramatically. Between 1982 and 1985 the number of uninsured children increased by more than 16 percent. "It all boils down to dollars," Narkewicz says. "But this makes sense economically as well as medically." ■

HOW MANY CHILDREN ARE IMMUNIZED?

PERCENTAGE OF CHILDREN AGE TWO AND YOUNGER



Year	Polio	Measles	Rubella	Mumps	DPT*
1980	80.7%	83.0%	83.2%	80.2%	87.0%
1981	80.9	81.5	83.9	79.1	87.6
1982	78.6	84.3	81.1	79.0	88.4
1983	78.6	83.9	81.9	78.1	88.4
1984	74.2	81.7	76.7	78.4	85.8
1985	76.7	81.7	77.3	78.9	85.8
1990 Objective	90.0	90.0	90.0	90.0	90.0

*Diphtheria, pertussis and tetanus
NOTE: Full immunization for DPT and polio at this age is defined as three or more vaccinations.
SOURCE: Centers for Disease Control

THE WASHINGTON POST

Diphtheria-Tetanus-Pertussis Immunization and Sudden Infant Death Syndrome

ALEXANDER M. WALKER, MD, DrPH, HERSHEL JICK, MD, DAVID R. PERERA, MD, MPH, ROBERT S. THOMPSON, MD, AND THOMAS A. KNAUSS, MD, PhD

Abstract: We compared the recency of diphtheria-tetanus-pertussis (DTP) immunization in healthy children with birthweights greater than 2500 gms who died of sudden infant death syndrome (SIDS) to that of age-matched reference children, using a modified case-control analysis. Focusing on very narrow time intervals following immunization, we found the SIDS mortality rate in the period zero to three days following DTP to be 7.3 times that in the period beginning 30 days after immunization (95 per cent confidence interval, 1.7 to 31). The mortality rate of non-immunized infants was 6.5 times that of immunized infants of the same age (95 per cent CI, 2.2 to 19). The latter result and to some extent the former appear to be ascribable to known risk factors for SIDS. Although the mortality ratios for SIDS following DTP, as estimated from this study, are high the period of apparently elevated risk was very short, so that only a small proportion of SIDS cases in infants with birthweights greater than 2500 gms could be associated with DTP. (*Am J Public Health* 1987; 77:945–951.)

Introduction

Sudden infant death syndrome (SIDS) has been reported as a possible complication of pertussis immunization on a number of occasions and despite studies which have been interpreted as unsupportive of the idea, a causal relation has not been ruled out.[1–7] There is some *a priori* credibility to the hypothesis that pertussis vaccination might induce a fatal disorganization of respiratory control in susceptible infants. Minor systemic reactions are common,[8] and pertussis vaccine is thought to have rare but serious neurologic sequellae.[9] Neither vital statistics on infant death nor case reports are entirely helpful for the elucidation of a link between SIDS and pertussis vaccine, since the period of highest risk for SIDS coincides in the United States with the recommended dates for the first two diphtheria-tetanus-pertussis (DTP) immunizations. Formal analyses must moreover contend with the potential distortive effect of risk factors for SIDS that in themselves influence pertussis immunization schedules: poverty and low birthweight[10] are prominent in this category.

The present study was designed to re-examine the hypothesis that DTP vaccine might be associated with an increased risk of SIDS in the first year of life. We have been fortunate in having access to complete medical records and notifications of death in a well-defined population. In order to clarify the examination of an outcome thought to have many possibly independent causes,[10] we further focused attention on children possessing no obvious medical risk factors for SIDS.

Methods

Group Health Cooperative of Puget Sound (GHC) is a consumer-owned health maintenance organization founded in 1945 which provides its members with full coverage for virtually all aspects of outpatient and inpatient medical care. According to internal surveys, the GHC population is 90 per cent non-Hispanic White; 92 per cent of members over the age of 18 have completed high school, and two-thirds have had *more* than 12 years of education. Unemployment among GHC members was 4 per cent in 1985. GHC maintains its own clinics, hospitals, and a centralized pharmacy to serve its membership, which now exceeds 309,000 persons. Since 1972, all hospital discharges have been recorded in a machine-readable format and can be linked with GHC's membership file and with computerized death records from the State of Washington. All pharmacy prescriptions and refills have been recorded since July 1976 and can be similarly linked to the other GHC data bases. Coded abstracts of GHC's computerized files, including archival records, are maintained by the Boston Collaborative Drug Surveillance Program to facilitate joint research.

The study population for the present report consists of all apparently healthy infants of birthweight greater than 2500 grams born in GHC hospitals from 1972 to 1983, who were subsequent users of GHC services, and for whom all medical records were retrievable in 1985 and 1986, the period during which this investigation was carried out. There were 35,581 deliveries at GHC hospitals during the period of study. An analysis of a random sample of records (see below) indicates that 75 per cent of these deliveries were of infants eligible for the present investigation. The surveyed population experience thus comprises the immunization and mortality of approximately 26,500 infants. These infants remained under surveillance, and therefore in the study population, for the duration of their families' membership in GHC.

All deaths occurring from 1972 through 1983 among GHC members from 30 to 365 days of age were identified by linkage of GHC membership files to State records. These deaths were reviewed in a two-step process. First, all deaths which on the basis of death certificate diagnosis, hospital discharge data, and pharmacy use taken together could be clearly ascribed to causes not related to immunization were excluded. All remaining records were then abstracted in order to determine cause of death in cases in which computerized data left room for doubt. Copies of death certificates and autopsy results were sought whenever cause of death was not evident from attending physicians' notes.

SIDS was defined as any death for which no cause could be discerned among infants of normal birthweight and without predisposing medical conditions born at GHC hospitals in the years 1972 through 1983. The case series consisted of all 29 SIDS deaths, so defined. Although an autopsy compatible with SIDS was not required for eligibility for this study, all but one of the eligible cases had been autopsied, and the

Address reprint requests to Alexander M. Walker, MD, DrPH, Boston Collaborative Drug Surveillance Program, Boston University Medical Center, 300 Totten Pond Road, Waltham, MA 02154. He is also with the Department of Epidemiology, Harvard School of Public Health, Boston. Dr. Jick is also with the Boston Collaborative Drug Surveillance Program; Drs. Perera, Thompson, and Knauss are with Group Health Cooperative of Puget Sound, Seattle, WA. This paper, submitted to the Journal December 16, 1986, was revised and accepted for publication March 1, 1987.
Editor's Note: See also related editorial p 925 this issue.

autopsy diagnosis was in every case SIDS. An additional 14 deaths certified as SIDS occurred among GHC members over the age of 30 days. These have been retained for some of the descriptive material, as described below, and are presented in some detail in the Appendix, but they did not enter into formal analyses.

The overall incidence of SIDS was estimated by dividing the number of deaths (including low birthweight and medically predisposed cases) by the number of infant years at risk in the age range 30 to 365 days.

The timing of DTP administration was determined for the case group by abstracting each infant's lifetime outpatient record. The timing of immunization in the population giving rise to the cases was estimated by examining 262 records of infants with birthweight >2500 grams, without medical conditions placing them at high risk for SIDS, and receiving their primary medical care at GHC during the period under review. These reference records were the complete set of eligible records identified out of 350 randomly selected records of children born at GHC hospitals. (The list of 350 records reviewed comprised 50 records identified at random from computerized files of children born in each of the years 1972, 1974, 1976, 1978, 1980, 1982 and 1984.) The sampled target population may be estimated to constitute about 75 per cent (262/350) of all births at GHC. Most of the first two DTP immunizations were accompanied by oral polio vaccine (OPV) through 1979. From 1980 the first OPV appears to have been given often in conjunction with the second DTP. All DTP and OPV administrations took place in a GHC clinic.

Each case was compared to all the reference children born in the calendar year closest to the case's date of birth, and immunization status was evaluated from the primary medical record for the case and all of the corresponding reference children as of the case's age in days at death. Immunization status was categorized as "No pertussis vaccine to date," "Last immunization within the past three days," "Last immunization within four to seven days," "Last immunization within eight to 29 days," and "Last immunization 30 or more days earlier." Split vaccine doses were counted as separate immunizations.

Variation in mortality from SIDS in relation to DTP immunization status was calculated by means of a matched case-control analysis[11] performed in GLIM,[12] using Whitehead's[13] algorithm. All analyses were carried out both with and without matching on calendar period, with essentially identical results. Analyses presented in what follows retain the period matching. Since no SIDS victim studied was born after June 30, 1983, the 1984 reference group was not invoked for the period-matched analyses, and the reference series used in the period-matched analyses numbered 225 infants. All reference series children were counted for the graphical displays.

Confidence intervals for the relative mortalities in the crude analyses of Tables 2 through 4 were derived by considering pairs of case counts to be distributed as binomial variables and obtaining the binomial counterpart of Cornfield's[14] limits, without continuity correction. A product-limit estimate[15] was used to calculate the cumulative probability of immunization in children excluded from the study.

Results

Case Characteristics

Some details of the 29 case histories are listed in Table 1. Corresponding data for 14 deaths ascribed to SIDS in GHCmembers who were not part of the study population are listed in Appendix Table A1. Thirty-nine of the total 43 cases identified on their death certificates as SIDS occurred in children born at GHC hospitals, during a period that encompassed 27,940.8 infant years of observation, giving an overall mortality of 1.4 cases per 1,000 infant years at risk.

Never Immunized Infants

Six of the 29 infants had not received pertussis vaccine at the time of their death (Table 1). This proportion is compared to that expected (1.56 out of 29) and further analyzed in Table 2. The relative mortality can be approximated by the cross product of Table 2, giving $(6 \times 27.44)/(23 \times 1.56) = 4.6$. The formal matched analysis yields an estimate of 6.5 fold increase in mortality of never-immunized over ever-immunized infants (95 per cent CI 2.2 and 19).

At the time of their deaths, all but one of the non-immunized had passed the 95th percentile of the population distribution of age at first DTP (Figure 1). In order to determine whether any common circumstances related to risk of SIDS affected their immunization schedules, we reabstracted the charts of the non-immunized SIDS victims for data on social characteristics and utilization of medical care. Four out of six mothers were single parents, three of whom were unemployed, and two of whom were receiving public assistance. Physical abuse, at least of the mother, appears to have characterized one other family.

Although at least five of these infants who died before recorded DTP immunization (and/or their mothers) appeared to be using GHC services in the interval between delivery and the infant's death, it is conceivable that the mother might have sought infant immunizations elsewhere. We identified and contacted all well child clinics operating near the homes of these children or near the homes of other possible caretakers listed in the chart, such as grandparents. None of these clinics had any record of visits of any kind by any of the children in question.

Immunized Children

We analyzed SIDS mortality among immunized children by a procedure analogous to that above, except that non-immunized cases were deleted and non-immunized reference group members were omitted from every matched set. There was an important decline in SIDS mortality rates over the days following immunization (Table 3). Four infants died within three days of DTP (three following the first immunization, one following the second) yielding an estimated age- and period-adjusted relative mortality rate of 7.3 (95 per cent CI 1.7 to 31) by comparison to children immunized at least 30 days earlier. Age-adjusted mortality declined gradually over the four weeks following immunization. It should be noted that the confidence intervals for relative mortality in the fourth through 29th days following immunization extend well below one and therefore into the range of a mortality deficit. The overall mortality in the period 0 to 29 days following DTP was 2.9 times that in the period 30 or more days after immunization; the 95 per cent CI was 0.93 to 9.1. The data therefore do not rule out the possibility of a compensatory decline in SIDS mortality after a brief post-immunization rise.

Reabstraction of the medical records of the four children dying soon after immunization for indications of non-medical risk factors for SIDS was not productive of the kinds of indicators of risk found with the non-immunized cases. However, an indirect indicator of postnatal care, the date of first DTP immunization, was somewhat delayed in three of

TABLE 1—SIDS Deaths in Children without Predisposing Medical Conditions Born at Group Health Cooperative of Puget Sound

Patient #	Sex	Race[a]	Birth Weight	Month/Year of Death	Age at Death (days)	Days Since Last DTP	No. of DTPs Preceding Death	Autopsy Diagnosis	Observations
1	F	W	2982	8/72	160	—	0	(SIDS)[b]	post mature
2	M	W	3863	10/72	167	6	3	SIDS[c]	
3	F	W	3579	12/72	102	3	2	(SIDS)	
4	F	W	3124	1/74	117	25	2	(SIDS)	
5	F	A	3323	1/74	60	14	1	SIDS	
6	M	W	3295	10/74	78	25	1	(SIDS)	twin
7	M	W	3380	11/74	133	20	2	(SIDS)	history of fracture of right humerus. ?child abuse
8	M	W	3240	12/75	52	5	2	SIDS	
9	F	B	3039	12/76	87	—	0	SIDS	
10	M	W	3721	4/77	80	14	1	SIDS	
11	M	W	4346	7/77	77	49	1	SIDS	
12	F	W	2897	11/77	87	42	1	SIDS	
13	M	W	3607	12/77	115	44	1	SIDS	
14	M	W	3493	2/78	175	28	1	SIDS	
15	F	W	2812	7/78	56	13	1	SIDS	
16	F	W	3636	8/78	277	137	2	SIDS	
17	F	W	3437	12/79	60	31	1	SIDS	
18	F	AI	3266	2/80	78	—	0	SIDS	fever, vomiting, 2 days before death
19	M	W	4090	4/80	84	—	0	SIDS	
20	M	W	3238	6/80	114	72	1	SIDS	
21	M	W	3266	7/80	81	37	1	Refused	
22	F	W	3550	8/80	134	—	0	(SIDS)	
23	M	W	3777	8/81	58	2	1	SIDS	
24	M	W	3181	11/81	59	—	0	SIDS	
25	M	W	4573	1/82	103	2	1	SIDS	
26	M	W	3181	7/82	134	95	1	SIDS	
27	M	W	3493	8/82	46	0	1	SIDS	family disruption
28	F	A	2925	9/82	53	9	1	SIDS	
29	M	W	4402	1/83	178	45	2	SIDS	

[a]Race: A—Asian, AI—American Indian, B—Black, W—White
[b](SIDS) autopsy performed and recorded on Death Certificate as supportive of diagnosis of SIDS, but original documentation no longer available.
[c]SIDS full autopsy results available and supportive of diagnosis.

TABLE 2—SIDS Mortality in Relation to DTP

	DTP Immunization Status		
	Never	Ever	Total
Observed Case Distribution	6	23	29
Age- and Period-Matched Expected Case Distribution[a]	1.56	27.44	29
Relative Mortality			
Crude Analysis[b]	4.6	1.0	
95% Confidence Limits	(1.9,11)		
Matched Analysis[c]	6.5	1.0	
95% Confidence Limits	(2.2,19)		

[a]Based on immunization histories in a random sample of children born at Group Health Hospitals.
[b]Calculated as: (6/1.56)/(23/27.44) = 4.6.
[c]Age- and period-matching accounted for in analysis (see text).

these children (including Case 3, whose death followed the second DTP administration). Figure 1 plots these ages at first DTP and those of the remaining SIDS infants.

Three of the cases dying shortly after immunization did so during a 13-month span beginning in August 1981. For these children, it was possible to identify the lot numbers of the vaccines used. The infants had each received vaccine from a different lot; the lots came from two different manufacturers. Of the four children dying shortly after DTP, only Case 3 had had a concurrent OPV.

Discussion

The major finding of the present study is an apparent 7.3 fold elevation in the risk for SIDS in the first four days following immunization with DTP in the first year of life. In addition, children without any DTP immunization had a SIDS mortality more than six times higher than those who had been immunized. All of the children who died without immunization had already passed the normal ages of first DTP immunization at Group Health, as had a majority of those children who died within a few days of immunization.

Delay in immunization of high-risk infants might lead both to an elevated risk in the never-immunized and to a foreshortening of the interval between immunization and SIDS in the immunized. Both phenomena could operate in the absence of any causal connection between immunization and risk of SIDS death, and could account at least in part for the results obtained here. Review of the individual non-immunized cases suggested a high prevalence of factors that might well lead to a delay in immunization and which are known to predispose to SIDS. Although these elements are not in themselves entirely sufficient to explain the observed risk elevation, both the pattern itself (high risk of SIDS associated with absence of immunization) and probable confounding by socioeconomic factors have been observed previously.[4,6] Data reported from a prospective study of SIDS in Sheffield, United Kingdom,[4] yield a crude SIDS

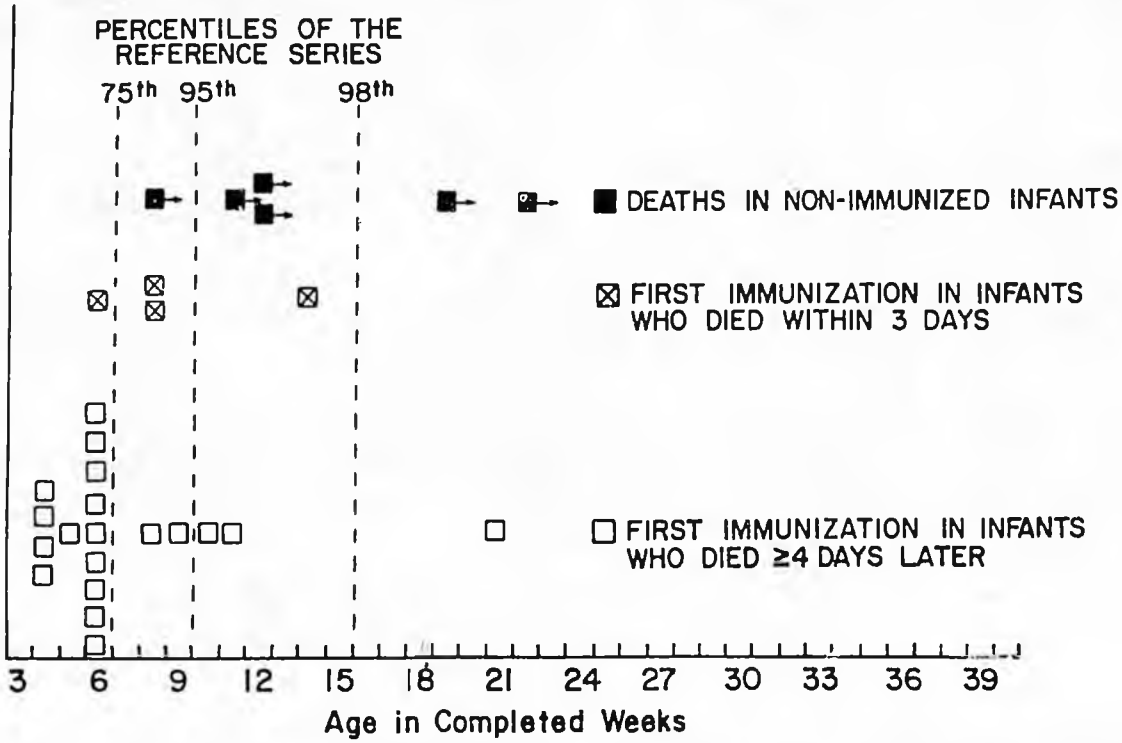


FIGURE 1—Timing of first DTP in immunized SIDS cases, and of death in the non-immunized. Arrows are on the non-immunized to emphasize that date of first DTP would have been later than the date indicated for death. Vertical lines give the percentiles of the cumulative distribution of age at first DTP in the reference series. Time of first DTP serves here as an index of timeliness of postnatal care. The proportions of cases beyond the 75th percentile of the reference distribution are: non-immunized, 100%; recently immunized, 75%; others, 26%. The first two categories of infants experienced delays in their postnatal care.

TABLE 3—SIDS Mortality among the Immunized in Relation to Post-Immunization Interval

	Days Since Last DTP				
	0–3	4–7	8–29	30+	Total
Observed Case Distribution	4	2	8	9	23
Age- and Period-Matched Expected Case Distribution[a]	1.36	1.56	8.23	11.85	23
Relative Mortality					
Crude Analysis[a]	3.9	1.7	1.2	1.0	
95% Confidence Limits	(1.3,12)	(0.41,6.9)	(0.51,3.2)		
Matched Analysis[a]	7.3	3.1	1.9	1.0	
95% Confidence Limits	(1.7,31)	(0.52,19)	(0.53,6.9)		
		2.9			
		(0.93,9.1)			

[a]Non-immunized excluded from reference series.

relative risk of 2.4 for never immunized as compared to age-matched immunized children. The NICHD Cooperative Epidemiological Study of Sudden Infant Death Syndrome[6] found crude relative risks of about two for SIDS in unimmunized infants compared to those who had received DTP in both Whites and Blacks.

All candidate explanations for the observation of increased risk of SIDS in nonimmunized infants hinge on an artifact of some sort. SIDS rates in the UK did not rise and fall with the mass abandonment of pertussis vaccination, nor with the ensuing epidemics of pertussis.[17] It seems therefore unlikely that pertussis immunization protects against SIDS, as for example by aborting an idiosyncratic, fatal reaction to *Bordetella pertussis*.

Several factors mitigate also against acceptance of the data on immunized children (Table 3) as evidence for a simple causal association. A delay in the immunization schedule among high-risk infants could produce an increase in the number of short intervals between immunizations and death, if immunizations were postponed from an age of lower risk (six weeks) to one of higher risk (eight to 16 weeks). The relatively small number of SIDS cases in the present study also admits the possibility of substantial random error.

Preceding investigations of the relation between SIDS and DTP have been subject to a variety of interpretations, partly because of differences in methodology. Table 4 presents an attempt to abstract elements common to this earlier work. For various time intervals following immunization, Table 4 gives the number of SIDS cases reported and the durations of the intervals. A crude relative mortality has been calculated in Table 4 as the ratio of two ratios: (deaths in interval/duration of interval) divided by (deaths in last reported interval/duration of last reported interval). The rationale for this comparison is that the number of child days at risk in the populations giving rise to the SIDS cases in various time intervals must be, to a very close approximation, proportional to the length of the interval. Thus, for example, Baraff, *et al*,[6] reported five cases in the 3.5-day period 0–3 days following DTP and nine cases in the 22-day period 8–29 days following DTP. If the number of children at risk is N, then the ratio of SIDS daily mortality rates in the two periods is $[5/(3.5 \times N)]/[9/(22 \times N)] = (5/3.5)/(9/22) = 5.4$. To the extent that immunizations occur in periods of declining risk for SIDS, the comparisons in Table 4 are somewhat biased toward higher relative mortality in the earlier intervals. Two of the studies tabulated were undertaken in response to reported deaths; the index deaths and the mortality ratios obtained by the inclusion of the deaths that

TABLE 4—Case Series of SIDS Preceded by Pertussis Vaccine Relative Mortality Inferred from Ratios of Cases to Days-at-Risk

Source	Period I			Period II			Period III		
	Definition	Duration[a]	Cases	Definition	Duration	Cases	Definition	Duration	Cases
ner, et al. (ref 2)									
sla	0–3 days	3.5	3(+4)[c]	4–7 days	4	5	8–29 days	22	11
lative Mortality[b]		1.7 (4.0)			2.5			1.0	
% CI		0.52–5.7 (1.6–10)			0.91–6.9				
(ref 3)									
a	0–3 days	3.5	9(+3)	4–7 days	4	5	8–21 days	14	16
tive Mortality		2.3 (3.0)			1.0			1.0	
CI		1.0–5.0 (1.4–6.2)			0.37–2.5				
n et al. (ref 4)									
	24 hours	1	2	1–14 days	14	33			
ve Mortality		0.85			1.0				
CI		0.23–3.2							
and Emery (ref 5)									
	0–2 days	2.5	1	3–7 days	5	0	8–28 days	21	3
ve Mortality		2.8			0			1.0	
CI		0.41–20			0–5.4				
et al. (ref 6)									
	0–3 days	3.5	9	4–7 days	4	8	8–28 days	21	10
ve Mortality		5.4			4.2			1.0	
CI		2.3–13			1.7–10				
(ref 7)									
	0–3 days	3.5	4	4–7 days	4	11	8–28 days	21	38
ve Mortality		0.63			1.5			1.0	
CI		0.24–1.7			0.79–2.9				
Study									
	0–3 days	3.5	5	4–7 days	4	2	8–29 days	22	9
ve Mortality		3.5			1.4			1.0	
CI		1.2–9.9			0.33–5.7				

[a] 0 counted as 0.5 days unless authors state to contrary.
[b] ative mortality [(deaths in interval) (days in interval)] [(deaths in last interval) (days in last interval)]
[c] ers in parentheses are based on inclusion of additional cases that prompted the investigation in question.
[d] e entries derived from percentages reported in the original.
[e] e entries derived from graphical presentation in the original.

ipted the studies are given in parentheses. In the line sponding to the present study, the otherwise eligible s who were excluded for not having been born at a GHC ital are reintroduced.

The studies presented in Table 4 vary enormously in the tail of data acquisition and in the thoroughness of analysis, rmation which is not reflected in the table. Although, fortunately, the full text of Solberg's[7] report has had only ited distribution in English (in the form of an NIH Library anslation), its negative result should be given especially erious consideration. Of all the investigations listed, only at one is comparable to the present study in that: 1) analysis the DTP-SIDS relation was a primary initial objective of e research; 2) case identification and exposure ascertainent were based on medical and vital statistics data of a latively standard format and accessibility for all the popuation covered; and 3) the data have been fully reported (i.e., t only in an abstract or letter form).

While the results of the present study are worrisome, ey do not constitute an appropriate basis for any specific tion other than a thorough examination of data from other urces. First, the study is confined to children at a low seline risk for SIDS. There were not enough births at GHC permit an approach to the question of vaccine risks in low rthweight or ill children, but the sparse data available do not dicate an elevated risk in that group (see the Appendix). ven if all the SIDS occurring within three days after mmunization were due to DTP, immunization practice ould not have accounted for more than about 10 per cent of SIDS cases at GHC. The possibility of compensatory decline in mortality after an initial rise cannot be ruled out.

In the absence of infant immunization programs there would have been a substantial risk of pertussis itself,[18] a serious illness requiring hospitalization for the great majority of infected children under six months of age and resulting in death for about one infant in a hundred.[19] Even a six-month postponement in the currently recommended US schedule for DTP immunizations is thought to entail serious potential consequences.[20]

The present study was one whose logistics were not complex, given the health maintenance organization (HMO) in which it was carried out. It should be replicable in any population with a defined infant membership, clear immunization records, linked death files, and reasonably complete autopsy data on children. Since many HMOs and governmental programs meet these minimal criteria, it should be possible to organize routine administrative data into vaccine surveillance systems capable of addressing the questions raised here.

Reevaluation of the immunization status of a single reference group at different ages for different cases produces a variant of case-control studies which has been termed a "case-cohort" design, since the evolving exposure status of the reference series mirrors that of the underlying cohort.[11] When the cases are few by comparison to the size of the reference series or when the exposure status at one time is a weak predictor of exposure status at another time, the appropriate analysis is just that of a matched case-control

TABLE A1—Sudden Unexplained Death In GHC Infants Who Were Not Members of the Study Population

Patients	Sex	Race[a]	Birth Weight	Month/Year of Death	Age at Death (days)	Days Since Last DTP	No. of DTPs Preceding Death	Death Certificate Diagnosis	Autopsy Diagnosis	Reason for Ineligibility
x1	F	AI	1647	10/73	161	—	0	SIDS	SIDS[b]	Low birthweight
x2	M	W	1619	8/74	93	—	0	SIDS	(SIDS)[c]	Low birthweight
x3	M	W	2727	5/77	76	—	0	SIDS	SIDS	Failure to thrive, PDA, hospitalized for pneumonitis × 22 days, discharged 2 days before death
x4	M	B	2101	10/78	47	18	1	SIDS	SIDS	Low birthweight
x5	F	W	n/a	12/78	182	3	3	SIDS	Refused	Not born GHC
x6	M	W	1220	10/80	52	—	0	SIDS	Not performed	Low birthweight
x7	F	W	2100	12/80	228	78	1	SIDS	SIDS	Low birthweight
x8	F	W	n/a	1/81	217	148	2	SIDS	Not available	Not born GHC
x9	M	W	n/a	10/81	124	71	1	SIDS	Not available	Not born GHC
x10	M	W	n/a	11/81	64	17	1	SIDS	SIDS	Not born GHC
x11	M	W	2868	12/81	88	45	1	SIDS	SIDS	Severe birth asphyxia, Neonatal Group B strep sepsis
x12	F	B	2073	3/82	76	34	1	SIDS	SIDS	Low birthweight
x13	M	W	1350	5/82	77	49	1	SIDS	Not performed	Low birthweight
x14	F	W	2329	9/83	91	43	1	SIDS	SIDS	Low birthweight

[a]Race: AI = American Indian, B = Black, W = White
[b]SIDS full autopsy results available and supportive of diagnosis.
[c](SIDS) autopsy performed and recorded on Death Certificate as supportive of diagnosis of SIDS, but original documentation no longer available.

study (R. L. Prentice, personal communication). The variance of estimates arising from a case-cohort study tend to be smaller than those of more traditional designs. In the present instance, however, all error estimates were determined principally by the relatively small numbers of cases, and so the advantage was small.

APPENDIX

SIDS Deaths in Children Not Members of the Study Population

Fourteen GHC members who were not from the study population were certified as having died of SIDS at age 30 days or older during the years 1972–83. Eight had birthweights below 2500 grams, two had life-threatening medical conditions, and four were not born at GHC hospitals. Although these children could not be entered into the formal comparisons, some of their case data are presented in Table A1 in order to provide a complete portrait of SIDS at GHC.

The prevalence of immunization among the SIDS cases excluded for medical reasons exceeded 50 per cent only at 150 days of life. This observation tends to confirm the anticipated relation between medical risk factors for SIDS and delay in immunization. As a group, very high-risk infants may therefore not be exposed to pertussis vaccine at an age comparable to that of lower risk children. None of the 10 high-risk children who died of SIDS at GHC had had a DTP in the two weeks preceding death.

The four cases ineligible because of not having been born at a GHC hospital (cases x5, x8, x9 and x10) had unremarkable DTP immunization histories. The intervals between DTP and death in these children (3, 17, 71, and 148 days) were similar to those of the eligible cases, and addition of these deaths to the case series would have strengthened the associations documented in Table 3.

ACKNOWLEDGMENTS

The authors benefited from advice and criticism provided by an advisory committee consisting of James D. Cherry, MD, UCLA School of Medicine; Harriet Kiltie, MD, Lederle Laboratories; John A. Livengood, MD, and Harrison C. Stetler, MD, Centers for Disease Control; Edward A. Mortimer, Jr., MD, Case Western Reserve University School of Medicine; Karin B. Nelson, MD, National Institute of Neurological Disease and Stroke; Donald R. Peterson, MD, MPH, University of Washington School of Public Health. This acknowledgment should not be construed as an endorsement of the study or its results by the advisory committee members or the institutions to which they belong. The findings and conclusions of this study do not necessarily represent the views of Group Health Cooperative of Puget Sound.

The Boston Collaborative Drug Surveillance Program is supported by the Food and Drug Administration (Cooperative Agreement FD-U-000071-04) and by grants from: Burroughs Wellcome Co., Ciba-Geigy, Glaxo Inc., Hoffmann-La Roche Inc., Lederle Laboratories, Lilly Research Laboratories, McNeil Pharmaceuticals, Merck Sharpe and Dohme Research Laboratories, Pfizer Inc., Winthrop-Breon Laboratories.

Dr. Walker is supported by awards from the Burroughs Wellcome Foundation and from the Mellon Foundation.

REFERENCES

1. Stewart GT: Infection and immunization. Scot Med J 1979; 24:47–52.
2. Bernier RH, Frank JA, Dondero TJ, Turner P: Diphtheria-tetanus toxoids-pertussis vaccination and sudden infant deaths in Tennessee. J Pediatr 1982; 101:419–421.
3. Torch WC: Diphtheria-pertussis-tetanus (DPT) immunization: A potential cause of the sudden infant death syndrome (SIDS). Abstract. Neurology 1982; 32:A169–170.
4. Hoffman HJ, Hunter JC, Hasselmeyer EG: SIDS and DTP. *In:* Proceedings of the 17th Immunization Conference, Atlanta, GA, May 1982.
5. Taylor EM, Emery JL: Immunization and cot deaths (letter). Lancet 1982; 2:721.
6. Baraff LJ, Ablon WJ, Weiss RC: Possible temporal association between diphtheria-tetanus toxoid-pertussis vaccination and sudden infant death syndrome. Pediatr Infect Dis 1983; 2:7–11.
7. Solberg LK: DPT vaccination, visit to child health center and sudden infant death syndrome (SIDS): Evaluation of DPT vaccination. Oslo Health Council 1985. NIH Library Translation NIH-85-152. Distributed by CR Manclark. Laboratory of Pertussis, Food and Drug Administration, Bethesda, MD.
8. Cody CL, Baraff LJ, Cherry JD, March SM, Manclark CR: Nature and rates of adverse reactions associated with DTP and DT immunizations in infants and children. Pediatrics 1981; 68:650–660.
9. Miller DL, Ross EM, Aldershade R, Bellman MH, Rawson NSB: Pertussis immunization and serious acute neurological illness in children. Br Med J 1981; 282:1595–1599.
10. Peterson DR: Evolution of the epidemiology of sudden infant death syndrome. Epidemiol Rev 1980; 2:97–112.
11. Prentice RL: A case-cohort design for epidemiologic cohort and disease prevention trials. Biometrika 1986; 73:1–11.
12. GLIM Working Party: The generalized linear interactive modeling system, Release 3.77. Numerical Algorithms Group Ltd., Oxford.
13. Whitehead J: Fitting Cox's regression model to survival data using GLIM. Appl Stat 1980; 29:268–275.
14. Cornfield J: A statistical problem arising in retrospective studies. *In:*

Neyman J (ed): Proceedings of the Third Berkeley Symposium, IV, Berkeley, University of California Press, 133–148.
15. Kaplan EL, Meier P: Nonparametric estimation from incomplete observations. J Am Stat Assoc 1958; 53:457–481.
16. Pharoah POD, Morris JN: Postneonatal mortality. Epidemiol Rev 1979; 1:170–183.
17. Swansea Research Unit of the RCGP: Effect of a low pertussis vaccination uptake on a large community. Br Med J 1981; 282:23–26.
18. Hinman AR, Koplan JP: Pertussis and pertussis vaccine: reanalysis of benefits, risks and costs. JAMA 1984; 251:3109–3113.
19. Miller CL, Fletcher WB: Severity of notified whooping cough. Br Med J 1976; 1:117–119.
20. Funkhouser AW, Wassilak SGF, Orenstein WA, Hinman AR, Mortimer EA: Estimated effects of a delay in the recommended vaccination schedule for diphtheria and tetanus toxoids and pertussis vaccine. JAMA 1987; 257:1341–1346.

Unique AIDS Library Available on Colleague

Since this Journal went "on-line" with the electronic publishing activity called Colleague in July 1985—one of the first journals to be included in the BRS/Saunders Colleague Program—the program has expanded greatly and now includes over 60 professional journals and health-related periodicals.

To assist those who are trying to keep up with the literature and latest information on AIDS (acquired immunodeficiency syndrome), Colleague is developing a comprehensive library of databases devoted exclusively to AIDS. The AIDS Library includes:

LIBRARY DATABASES	LABEL
AIDS Abstracts from the Bureau of Hygiene and Tropical Diseases	AIDD
AIDS Articles from Colleague's Complete Text Library	AACC
Medical and Psychological Previews	PREV
MEDLINE References on AIDS	MRAI
PDQ Cancer Information	PDQC
PDQ Protocols	PDQP

BRS has *created* two of these files, AACC and MRAI, and is the only place you can find these unique collections:

- *AIDS Articles from Colleague's Complete Text Library (AACC)* is a collection of full text articles on AIDS taken from the Colleague Journal Collection—JOUR. AACC is exclusively devoted to the subject of AIDS.
- *MEDLINE References on AIDS (MRAI)* consists of citations and abstracts from MESH which deal with all aspects of AIDS.
- *AIDS Abstracts from the Bureau of Hygiene and Tropical Diseases (AIDD)* is produced by the Bureau of Hygiene and Tropical Diseases in the United Kingdom. The Bureau scans the published literature on AIDS and then creates the records for AIDD. Only articles that represent good work and that are new, important and relevant are fully abstracted.

The *AIDS KNOWLEDGE BASE*, a unique, new database on AIDS from San Francisco General Hospital, to be available this summer online on BRS, is designed for use by clinicians, researchers, nurses, public health personnel, hospital administrators, educators, and others working to combat AIDS. The *AIDS KNOWLEDGE BASE* will evolve through continuous updating as new developments and practices emerge in this rapidly changing area, allowing users to keep current with all aspects of clinical practice and research.

For further information about this or other Colleague Program activities, contact BRS Colleague, BRS Information Technologies, 555 East Lancaster Avenue, St. Davids, PA 19087, or check the newsletter *On Call*, published bimonthly at BRS/Colleague, 1350 Avenue of the Americas, New York, NY 10019.

DTP and SIDS: When Data Differ

The question of the possible relationship of certain serious events and the administration of diphtheria and tetanus toxoids and pertussis vaccine (DTP) to infants has resulted in considerable consternation among parents and health professionals, particularly in the United Kingdom, Japan, and the United States. Resolution of these questions is not easily achieved, and all of the answers are not available in spite of considerable effort. The questions in particular revolve around the reactivity of the pertussis component of DTP. The probable reason for this reactivity is that pertussis vaccine is not as refined as one would like, largely because the relationship of the organism's biologic anatomy to immunity in man eluded investigators for many years, and only recently shows prospects of being elucidated. It is to be anticipated that a more refined vaccine, limited to those components of the organism that are responsible for immunity, will ameliorate some of the concerns about DTP.[1]

Reports of severe neurologic damage and death associated with the administration of DTP date back many years.[2] To most physicians during the early years of pertussis vaccine these reported events were probably deemed to be a small price to pay for protection from a disease of high mortality and morbidity. Only as the disease has nearly disappeared in the United States and other developed countries, largely because of the vaccine, have these untoward reactions loomed larger in importance.

The occasional untoward events temporally associated with DTP that have been of greatest concern are acute encephalopathy with permanent brain damage and the sudden infant death syndrome (SIDS).[3] For three reasons, sorting out of cause and effect relationships between these disorders and DTP has been most difficult epidemiologically.

- First, seizures with or without permanent brain damage in infancy occur for many reasons, known and unknown. Because the vast majority are not related to DTP, to determine whether a small fraction may be attributable to the vaccine is a complex task. The same may be said for SIDS; the vast majority of these unfortunate events clearly bear no relationship to DTP, and determining that a very few are due to the vaccine, if such is the case, is very difficult.
- Second, DTP is given to infants at 2, 4 and 6 months of age, a time in life when inherent, underlying neurologic disorders often become apparent or manifest as the child's neurologic development proceeds or fails to proceed. The peak age-specific incidence of SIDS is also between 2 and 4 months.
- Third, it is possible that fever and other systemic effects of DTP may prematurely induce inevitable manifestations of underlying central nervous system disease, such as seizures.

Several attempts to answer these questions have been made in recent years. The remarkable National Childhood Encephalopathy Study (NCES), conducted in Britain in 1976–79, compared the frequency of receipt of DTP in the recent past in 1,182 children with acute encephalopathy with the frequency in a group of matched control children.[4] During the week prior to onset of encephalopathy, there was a slight excess of affected children who had received DTP compared to the control group. Because the study population included all children in Britain and because the numbers of doses of DTP distributed were known, the investigators were able to estimate that encephalopathy with permanent brain damage occurred approximately once in a third of a million doses administered. However, in this study there was also a small excess of encephalopathy following DT and a deficit of encephalopathy one to four weeks following DTP. Although neither of these achieved statistical significance, they do suggest that at least some of the episodes of acute encephalopathy associated with DTP comprised the premature precipitation of inevitable manifestations of an underlying disorder. Further, because the final risk estimates were based on only four children who may have had other unrecognized causes for their disorders, the authors concluded that encephalopathy resulting from DTP, if it ever occurs, is extremely rare.[5]

The NCES also shed light on the possible relationship of DTP to infantile spasms.[6] This disorder strikes approximately 1,200 children in the United States annually: its onset is usually between 2 and 8 months of age. The NCES clearly demonstrated that DTP either brings out, or attracts the parents' attention to, the characteristic symptoms of infantile spasms a week or two earlier than they otherwise would have occurred, but does not cause the problem.

Similar approaches to the possible relationship of DTP to SIDS have been undertaken. In the US for each of the three years, 1982–84, an average of 5,276 SIDS deaths occurred, for a rate of 1.44 per 1,000 live births.[7] Because the peak age incidence for SIDS is 8–10 weeks of age, it is to be expected that a proportion would occur in temporal proximity to receipt of DTP by simple chance. Nonetheless, although SIDS existed long before DTP, it is reasonable to suppose that in some instances SIDS might be precipitated by a systemic effect of DTP, a supposition that is not easily studied.

Other than anecdotal evidence there have been reports of five prior studies of this question;[8–12] a sixth by Walker, *et al*, appears in this issue of the Journal.[13] Two of the first five reports showed a relationship between SIDS and DTP. However, that of Torch is available only as an abstract and the data cannot be independently analyzed. Moreover, the report suggests considerable potential for ascertainment and/or recall bias. That of Baraff, *et al*, has also been discounted because of potential recall bias, plus the fact that the data were not adjusted for week by week changes in the age incidence of SIDS.[14] The other three studies, if anything, show a reverse association of DTP with SIDS, i.e., infants who experienced SIDS are less likely to be immunized than control infants, perhaps in part due to socioeconomic factors.

The most recent of these is a large, multicenter case-control study conducted by the National Institute of Child Health and Human Development (NICHHD).[12] The purpose of this study was to pursue clues as to the etiology of SIDS, including vaccine administration. In this study each of 757 infants succumbing to SIDS was matched with two control infants, one matched by birth date (control A), and one by birth date, birth weight and race. The results of this large study showed no relationship between DTP and SIDS:

indeed, if anything, SIDS infants were less likely to have been immunized in the recent past or at any time than controls.

The present report by Walker, *et al.* suggests a small but significant excess of SIDS in the three days following DTP. How can the disparity between the results of this study and those of others, particularly the large cooperative study conducted in the US, be explained? This is an important question, given the legal issues involved and the fact that DTP, like fluoridation, receives the blame for a great many of our woes in certain circles. Three possibilities exist, all noted by the authors:

- The first is that DTP does, in rare instances, trigger SIDS.
- The second and most likely is that of simple random chance, given the fact that the number of infants succumbing to SIDS within three days of DTP is only four.
- The third relates to delay in immunization in higher-risk infants for socioeconomic reasons and consequent administration of DTP at the peak age of SIDS incidence.

As these authors note,[13] even in the extreme their results are compatible with only 10 per cent of SIDS cases being attributable to DTP, but this would implicate DTP in up to 500 infant deaths annually, all occurring within three days of receiving the vaccine. It is difficult to believe that such would not have been recognized in the NICHHD study. In that study, five (0.7 per cent) of 757 SIDS deaths occurred within 24 hours and 12.9 per cent within two weeks of receiving DTP. In this regard, using age-specific SIDS rates[15] and assuming 80 per cent of infants receive DTP on schedule, among the average of 5,276 deaths from SIDS observed annually, 1982–84, 48 (0.09 per cent) and 679 (12.9 per cent) would have been expected by chance alone within 24 hours and 14 days respectively following DTP. Thus, in the context of other data, if DTP causes SIDS, it must do so sufficiently infrequently to be nearly immeasurable.

The authors of the present study are appropriately cautious. They advise no change in immunization policy on the basis of their data and note the established benefits of DTP. Instead, they suggest pursuit of similar information from other sources. We should heed that advice.

REFERENCES

1. Robbins FC, Robbins JB: Current status and prospects for some improved and new bacterial vaccines. Ann Rev Public Health 1986;7:105–125.
2. Cherry JD: The epidemiology of pertussis and pertussis vaccine in the United Kingdom and the United States: a comparative study. *In:* Lockhart JD (ed): Current Problems in Pediatrics. Chicago: Year Book Medical Publishers, 1984; 14(2): 78 pp.
3. Fenichel GM: The pertussis vaccine controversy. The danger of case reports. Editorial. Arch Neurol 1983; 40:193–194.
4. Miller DL, Ross EM, Alderslade R, Bellman MH, Rawson NSB: Pertussis immunisation and serious acute neurological illness in children. Br Med J 1981; 282:1595–1599.
5. Ross E, Miller D: Risks and pertussis vaccine. Correspondence. Arch Dis Child 1986; 61:98–99.
6. Bellman MH, Ross EM, Miller DL: Infantile spasms and pertussis immunisation. Lancet 1983; 1:1031–1034.
7. National Center for Health Statistics: Advance Report of Final Mortality Statistics, 1982. Monthly Vital Statistics Report 1984; 33 (suppl): 1–44. For 1983: Ibid 1985; 34 (suppl 2): 1–44. For 1984: Ibid 1986; 35 (suppl 2): 1–44.
8. Torch WC: Diphtheria-pertussis-tetanus (DPT) immunization: a potential cause of the sudden infant death syndrome (SIDS). (Abstract) J Pediatr 1982; 101:169–170.
9. Baraff LJ, Ablon WJ, Weiss RC: Possible temporal association between diphtheria-tetanus toxoid-pertussis vaccination and sudden infant death syndrome. Pediatr Infect Dis 1983; 2:7–11.
10. Taylor EM, Emery JL: Immunisation and cot deaths. Letter. Lancet 1982; 2:721.
11. Solberg LK: DPT vaccination, visit to child health center and sudden infant death syndrome (SIDS): Evaluation of DPT vaccination. Oslo Health Council 1985; 131 pp.
12. Hoffman HJ, Hunter JC, Damus K, Pakter J, Peterson DR, van Belle G, Hasselmeyer EG: Diphtheria-tetanus-pertussis immunization and sudden infant death: results of the National Institute of Child Health and Human Development study of sudden infant death syndrome risk factors. Pediatrics 1987; 79:598–611.
13. Walker AM, Jick H, Perera DR, Thompson RS, Knauss TA: DTP immunization and the sudden infant death syndrome. Am J Public Health 1987; 77:945–951.
14. Mortimer EA Jr, Jones PK, Adelson L: DTP and SIDS. Pediatr Infect Dis 1983; 2:492–493.
15. Funkhouser AW, Wassilak SGF, Orenstein WA, Hinman AR, Mortimer EA Jr: Estimated effects of a delay in the recommended vaccination schedule for diphtheria and tetanus toxoids and pertussis vaccine. JAMA 1987; 257:1341–1346.

EDWARD A. MORTIMER, JR., MD

Address reprint requests to Dr. Edward A. Mortimer, Jr., Elisabeth Severance Prentiss Professor and Vice Chairman, Department of Epidemiology and Biostatistics, and Professor of Pediatrics, Case Western Reserve University, School of Medicine, Cleveland, OH 44106.

People

Klatt urges parents to immunize children

By JANET HEVLY
Staff Writer

Parents who aren't immunizing their children because of concern about the safety of the pertussis vaccine are encouraged to consider the risks of the disease, says Michael Klatt, manager of the Alaska Immunization Program.

"The real risks of the pertussis disease far outweigh the theoretical risks of the pertussis vaccine," Klatt said in a recent interview. "The best way to protect your child and society from the disease is to immunize your child on schedule."

Pertussis, also called whooping cough, can be a fatal disease for children. According to information Klatt provided from various medical journals, the disease claims an estimated 600,000 lives a year throughout the world. The vast majority of these fatalities are children under six months of age.

For children, whooping cough is characterized by a distinctive wheezing gasp for air in coughing episodes that can last several minutes. The gasp is coupled by a choking build-up of thick mucus — appearing as a froth from the nose and mouth — that restricts the child's ability to breathe. Children may turn blue from lack of oxygen.

Several epidemics of whooping cough were reported in 1985, resulting in 30 reported cases of the disease in Alaska. During that year, 18 cases were reported in the Kenai-Soldotna area, with 13 of those cases occurring in children under the age of five, Klatt said.

Of the 13 preschoolers, four of the children were less than six months old, four were between the ages of six and 12 months, and five were reported in children between one and five years of age.

Klatt said 11 of the 13 children afflicted with the disease had not been properly immunized. Those children either hadn't received any immunizations, or hadn't been immunized according to the mandated immunization schedule. State and federal laws require children in public schools, in state day-care centers and in the federally funded Headstart program to be immunized at two, four and six months, and between 15 and 18 months of age. A booster shot is also recommended before entering school.

Klatt said five cases of whooping cough were reported in 1986, and three cases have been reported so far this year.

Many of the parents who aren't immunizing their children are worried about the adverse effects of the pertussis vaccine. Klatt said 15 adverse reactions were reported in Alaska in 1985. An adverse reaction is defined as anything more than a fever or minor reaction at the site of the injection.

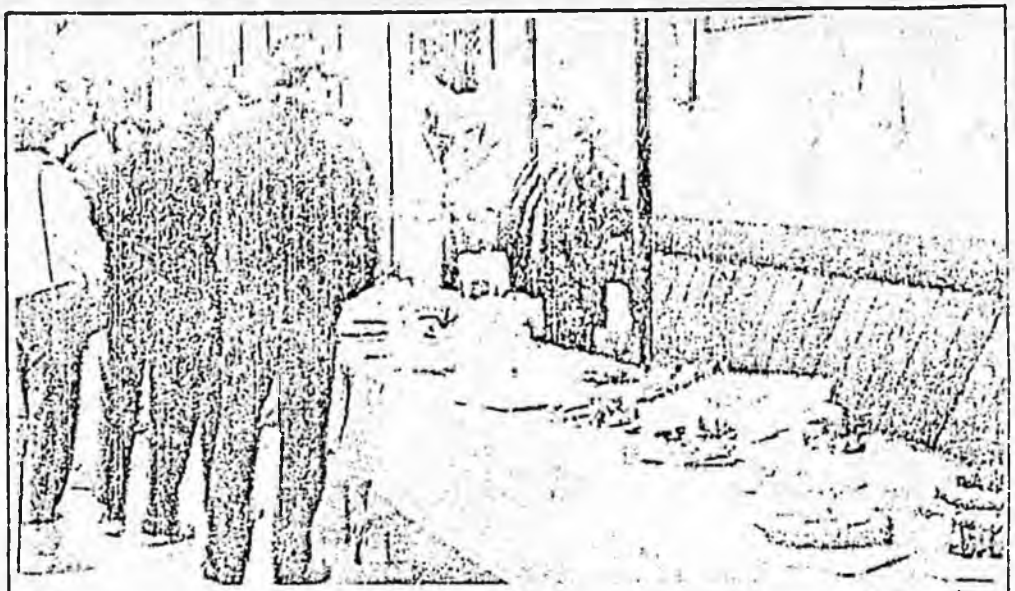
He acknowledges that the reaction reporting system hasn't been effective in the past, and that many parents may not have associated illnesses occurring after a vaccination as related to the vaccine. "I have no doubt that the adverse reactions were under-reported," Klatt said.

As of mid-1986, Klatt said the state is using vaccines purchased from the federal government which require parents to receive written information about the potential hazards of the vaccines. Parents must sign a form stating they understand the possible adverse reactions, and that any adverse reactions should be reported to the health-care provider.

Prior to the written warnings, parents having their children immunized only received verbal warnings about the potential adverse reactions to the shots, Klatt said.

"I anticipate an increase in reported adverse reactions," Klatt said, "And that's good because we want accurate reporting."

According to information from Klatt's medical journals, whooping cough is an extremely contagious disease. The odds indicate that if one of your children brings it home, the rest of the kids will get it. Recovery takes weeks; the Japanese name for whooping cough is translated to "the hundred-days cough."



Neva Black, a judge in the 4-H Council's Chocolate Lovers Contest, talks to passersby who were looking at entries to the contest this weekend at the Kenai Mall. (Photo by Nicky Donald)

Children have about a 50-50 chance of developing minor redness, swelling and pain at the site of the DTP injection. Fever, vomiting and drowsiness after a DTP vaccination occur about one in five times. One in 310,000 vaccinated children suffers brain damage, according to information supplied by Klatt. Despite the alarming number of side affects, he emphasized that a study in the United States indicates that SIDS victims were no more likely than non victims to have received a DTP vaccine.

Parents who delay having their children immunized until after six months of age are actually missing their prime opportunity to immunize against pertussis when it is most effective, Klatt said. Whooping cough is most fatal to children under six months of age.

Klatt said public health nurses are receiving an increasing number of requests for just a DT vaccine, without the "P" for pertussis. "They won't honor that request unless they have a written request from a physician," Klatt said. Only a private physician will give just a DT vaccine because a parent philosophically objects to the pertussis vaccine.

A more safe pertussis vaccine may be introduced in the near future, Klatt said. The United States is currently helping finance a study being conducted in Sweden on an acellular pertussis vaccine. The pertussis vaccine administered here is a whole cell vaccine, using all parts of the pertussis bacteria, Klatt said. The acellular vaccine separates the bacteria, attempting to use just the immune qualities of the bacteria and eliminate the other ingredients that may be causing the adverse reactions, he explained.

"The study should be done by the end of the summer, and the results written up by the end of the year," Klatt said. "If it is determined to be as effective at protecting against pertussis with less side affects, I would assume the U.S. would go for that vaccine."

Klatt said he obtained his information from articles on pertussis in Public Health Reports, Journal of the American Medical Association, the American Journal of Diseases of Children, the John Hopkins University School of Hygiene and Public Health and Mothers Today.

Letters to the editor

DPT parent responds to report on interview of health official

To the editor:

This is in regard to the article, "Klatt urges parents to immunize children," by Janet Hevly, Jan. 18.

I am president of the Alaska chapter of Dissatisfied Parents Together (DPT), parents concerned with vaccine safety, efficacy and awareness. We are not anti-vaccine, but stress that each parent should be educated as to all the risks as well as the benefits of any vaccine to be administered to their child. We also stress that each parent should be allowed to choose what vaccines their child is to receive without threat of exclusion from public school.

I wish to clarify and comment on several of the misleading statemets made by Mr. Klatt, so that local parents will not fall prey to the scare tactics so willingly employed by our public health department.

As it is true that the pertussis disease can be fatal, the high death rate (600,000 yearly worldwide) does not exist in developed countries. In Sweden and West Germany, where mandatory pertussis vaccinations have been discontinued due to high reaction rates, the death rate is virtually nonexistent. According to the official Annual Summary 1983 of Morbidity and Mortality Weekly Report, distributed by the U.S. Department of Health and Human Services, only six fatalities due to the pertussis disease occurred in the U.S. in 1981. According to this publication, six deaths per year due to pertussis is the average in our country. An interesting note: the only part of Europe where pertussis vaccination is universally imposed is in the communist countries, such as the Soviet Union, East Germany, Poland and Czechoslovakia.

In regards to the 1985 whooping cough epidemic, I have correspondence from Michael Klatt stating that only 9 of the 30 reported whooping cough cases were actually confirmed pertussis. Approximately half had received pertussis vaccinations. There were no deaths. According to this letter and future correspondence, Mr. Klatt stated that he "was unable to ascertain the immunization histories, because immunization histories were not gotten (for whatever reasons) for all reported cases." How did he manage to come up with the in-depth information then for his interview with Ms. Hevly?

While our group of concerned parents is glad to see that the health department is finally allowing that their adverse-reaction reporting system is inefficient and has been underreporting both immediate severe reactions and long-term illnesses suffered from vaccinations, it is not heartening to realize that this same health department expects parents to disregard these facts and keep on injecting our children with this highly reactive pertussis vaccine. Also, Mr. Klatt failed to mention that his office does not accept an adverse-reaction form unless it meets minimum criteria. One of these is that the reaction must have been severe enough to require a visit to a doctor, health-care facility or hospital. None of these places are required to report any reaction, however.

If a report form does not include this visit, it is shredded. According to the 1987 Goals and Objectives, published by our health department, this criteria is not scheduled to change.

In regard to the statistics Mr. Klatt quoted in relation to reported adverse reactions, they are not only questionable because they are admittedly underreported, but they do not begin to address the long-term damage associated with many immediate adverse reactions; epilepsy, chronic blood diseases, deafness, blindness, cerebral palsy, severe retardation, death, etc.

Our organization finds it amazing that though there have been four studies published in the 1980s in the Unites State showing a direct causal relationship between DPT vaccinations and SIDS, our government and public officials (e.g., Mr. Klatt) have chosen to disregard these findings in favor of another study that shows only a temporal relation. I have correspondence from our Alaska Health Department that states that no vaccine information is collected on SID victims, supposedly because such information is too hard to analyze!

Also, Mr. Klatt failed to mention that the DPT vaccination series is not effective until all three shots of that first series are completed at the age of six months (if the vaccination schedule is strictly adhered to), so by the time child is "protected," he's already out of the danger zone. "Whooping cough is most fatal to children under six months of age," Klatt, quoted from Clarion article.

As a last comment, I'd like to let Alaskan parents know that there is legislation being drafted to require mandatory adverse-reaction reporting by all sectors, to require accurate parent information, extensive long-term followup and to allow Alaskan parents to object to any or all state mandated vaccines without exclusion from public school is allowed in 22 other states.

Shannon Kohl
Soldotna

PEDIATRIC CONSULTANTS OF ALASKA, INC.
Clinton B. Lillibridge, M.D., F.A.A.P.
Peter H. Michelson, M.D., F.A.A.P.

December 10, 1987

Representative Kay Brown
3111 C Street, Suite 435
Anchorage, Alaska 99503

RE: HOUSE BILL 277 (Amendment to immunization regulations, making them optional)

Dear Kay:

I am terribly upset at the amount of misinformation and emotionalism exhibited by the proponents of this bill. The facts which are pertinent have been ignored. Specifically, pertussis, diphtheria, and tetanus organisms are widespread throughout the community and are easily caught. The rate of death for even something as simple as pertussis is about 10%. One out of a thousand children who catch pertussis will survive, but be permanently brain-damaged. The shot itself causes brain-damage in 1 out of 310,000 people. There have been six infants in Alaska this year who caught whooping cough (they were not immunized) and nearly died. The parents had huge hospital bills because of that, but luckily their children survived.

I strongly urge you to do everything you can to work against House Bill 277.

Sincerely,

Clint

Clinton B. Lillibridge, M.D.
Pediatrician

CBL:pm

1200 Airport Heights Drive, Suite 230 • Anchorage, Alaska 99508
Telephone (907) 276-5517

May 3, 1987

Representative Kopanen
Alaska State Legislature
Pouch V (MS 3100)
Juneau, Alaska 99811

Dear Representative Kopanen:

I am writing to you to let you know how important I feel House Bill 277 is.

I support House Bill 277 and I would like you to support it too.

I had know idea of the problems that could arise from the DPT shots until I contacted my local Chapter of Dissatisfied Parents Together. I was very thankful for the information I received because my daughter did have a reaction to the shot and I was able to know what to look out for and stop any damage that could have been done.

It seems a shame that we carry these children so carefully for 9 months; we eat well, take vitamins, and watch out for hazards in our environment that might affect them, and then we turn around and inject them with something that can cause so much harm.

Please pass House Bill 277 through the committee without change.

Sincerely,

Kika Hutto
3955 Nichols
Soldotna, Alaska 99669

Alaska State Legislature

Please enter into the record my testimony to the HHS
committee name

committee on House Bill No. 277, dated 11 Feb 88.
bill/subject

I would like to respond to several points. Number one, I agree that better information could be made available to parents. I spend many hours adding to the information parents have.

Many studies are available showing both the long Term effects of no vaccinations and also the great value of immunizations. The incidence of severe effects of measles such as subacute sclerosing panencephalitis has fallen remarkably since measles vaccine became available. The issue of whether boosters are needed is still uncertain, but since giving the vaccine to children aged 15 months rather than 9 months should make immunity more certain. This will need continuing study.

Signed: Richard C. Reem, M.D.
Testifier

Representing (Optional)

1001 Noble Street, Fairbanks
Address

452-1611
Phone No.

It has been demonstrated over and over that the more pertusis vaccine one has had, the milder is the disease. Whooping cough is unheard of in children who have had all doses of the vaccine.

No doubt, vaccines need improvement, especially pertussis vaccine. New vaccines are needed such as vaccine against Hemophyllus influenza, AIDS, and other diseases.

MY NAME IS JUDY AMES, BOX 824, SOLDOTNA

I am a concerned parent who takes health issues very seriously. We all know there are new findings happening daily concerning all aspects of the human body, particularly the immune system. After receiving all the information regarding vaccinations provided by a health care provider, I am left feeling very unassured and helpless. My additional research on this issue has given me more reason to doubt a "safe" system. I want the personal choice of taking charge of my child's health care and am looking forward to a change in the present immunization system.

Please take a positive approach to hb 277.

Judy Ames
2-11-88

Alaska State Legislature

(1)

Please enter into the record my testimony to the Health Education & Social Services + Judiciary committee name committee on House Bill No. 277 bill/subject, dated February 11, 1988.

"An act relating to the immunization of minors"

As a concerned citizen and currently employed as a Public Health nurse I am opposed to House Bill No 277 because:

1) a child who is not required to be immunized before entry into school, preschool, nursery or day care facility puts the public at risk for increase of incidence of disease & will create a serious health problem for Alaska students.
2) The state of Alaska already requires informed parental consent before administering vaccines.
   ie: Parent (important) information forms plus parental signature
   Also at the time of birth, all new parents receive a booklet called - "Parents Guide to Immunizations."
3) The current alaska immunization Program requires health professionals to report any adverse reactions to vaccines.
4) Adverse reactions secondary to administration of vaccines is rarely fatal.
5) Communities should become more involved in public awareness of the benefits vs risks of vaccination.

Signed: Leslie Callaway (Travis)
Testifier

Representing (Optional)

PO Box 1125 Kotzebue AK 99752
Address

442-2608
Phone No.

udget cuts add to girl's whooping cough

He baby was only 5 weeks old

INIE CHAPPELL
ws reporter

ER — Sabrina Kvas- is no longer gasping ith or coughing so vio- that the tiny blood in her eyes burst. Her doesn't worry any bout her choking to n her own vomit. The spasms that left her is shade of blue have

worst is over. After a the hospital, she has returned to her home village of Port Graham.

Sabrina suffers from pertussis, a highly infectious, sometimes fatal respiratory disease that is commonly known as whooping cough. She is also the victim of state budget cuts that kept her from getting a vaccine that could have prevented her from contracting the disease.

Lydia Kvasnikoff tried to have her daughter innoculated.

"We were unable to get the shot because the state had cut the travel budget of the public health nurse," she said.

The nurse, based in Homer, used to visit Port Graham on a monthly basis to administer shots, render prenatal care to pregnant women and see to other needs beyond the ability of the village health aide.

That changed when the price of oil plummeted.

Now the nurse gets to the village about six times a year. She was there in October when Kvasnikoff first inquired about having her daughter innoculated. Sabrina, who was then 6 weeks old, was too young for the shot.

In Alaska, children receive three DPT (diptheria, pertussis and tetanus) shots. The first is administered at age 2 months, the second at 4 months and the third at 6 months.

The nurse didn't return to Port Graham in November or December. In January, she tried to fly into the village, but was weathered out. By then, Sabrina, had started to cough.

"This particular case is very tragic," said Almeda Amoureux, regional supervisor for the public health nurses who work in southcentral Alaska. "I wish the baby had been two weeks older when we were there. It would have made so much difference in her life. It was just a quirk of fate that the child was too young that first time."

Amoureux acknowledges that her nurses are traveling less. Several were laid off in the aftermath of a drastic budget cut in 1986 and visits to many villages had to be curtailed. Some of that money was restored by the legislature in 1987, but there still isn't enough to resume monthly visits to the villages around Kachemak Bay.

So Amoureux and the nurses who work for her are forced to ration their services.

See Page C-3, COUGH

COUGH: Cuts add

Continued from Page C-1

Villages with large numbers of infants and pregnant women receive the most attention. The schedule for Port Graham was established to allow immunization clinics every two months, she said.

For Sabrina, however, that wasn't enough.

Her sickness "began like a regular cold," said Kvasnikoff, who has two other children. "We waited about a week but she never got over it. She kept getting worse. The health aide gave us medicine, but it didn't help. We kept her in a mist tent and everything. She just couldn't catch her breath."

By late January, Sabrina was making the whooping sound for which the disease is known. Kvasnikoff flew to Homer to see a doctor. Three days later, lab tests confirmed that the baby girl was suffering from pertussis.

Sabrina was admitted to South Peninsula General Hospital and put in respiratory isolation. She lived in an oxygen tent.

After a difficult week her symptoms subsided. Dr. Paul Raymond sent Sabrina home Tuesday after ascertaining that she was no longer capable of infecting others.

In the meantime, public health officials have been scrambling to contain an outbreak of the highly contagious disease. As soon as Sabrina's diagnosis was confirmed, a nurse flew to Port Graham and to English Bay to check the vaccination records of every child in both villages and to innoculate those who needed shots. The nurse also contacted everyone who came in contact with Sabrina.

Village health aides have been instructed to report everyone who complains of a persistant cough and fever.

"The big concern we have is that a lot of families have not got DPT shots," said Dr. Paul Eneboe. "So now there is a pool of susceptible children in the villages around Kachemak Bay has declined, Eneboe said.

who eigh- early w, a

(4) Hold hearings, in accordance with section 205(a), in areas of the United States with high infant mortality rates.

(b) RECOMMENDATIONS.—The Commission shall—

(1) recommend a national policy designed to reduce and prevent infant mortality, including recommendations concerning populations at risk of high infant death rates and recommendations concerning appropriate roles for the Federal Government, States, local governments, and private sector;

(2) recommend to the Congress and the President the specific changes needed within Federal laws and Federal programs to achieve an effective Federal role in preventing infant mortality, including the programs specified in subparagraphs (A) and (B) of subsection (a)(1);

(3) recommend to the Congress and the President the specific changes needed to improve the national vital statistics registration system with respect to infant death statistics; and

(4) present such recommendations to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Finance and Governmental Affairs of the Senate no later than one year after enactment of this Act.

42 USC 285g note.

SEC. 205. POWERS OF THE COMMISSION.

(a) HEARINGS.—The Commission, or at its direction, any subcommittee or member thereof, may for the purpose of carrying out the provisions of this title, hold such hearings, sit and act at such times and places, take such testimony, receive such evidence and administer such oaths, as the Commission or such subcommittee or member may deem advisable. Any member of the Commission may administer oaths or affirmations to witnesses appearing before the Commission, subcommittee, or member thereof.

(b) INFORMATION.—The Commission may secure directly from any Federal department or agency such information as may be necessary to enable the Commission to carry out this title. Upon request of the Chairman of the Commission, the head of such department or agency shall furnish such information to the Commission.

(c) CONTRACTS.—To carry out this title, the Commission may enter into such contracts and other arrangements to such extent or in such amounts as are provided in appropriation Acts, and without regard to the provisions of section 3709 of the Revised Statutes (41 U.S.C. 5). Contracts and other arrangements may be entered into under this subsection with or without consideration or bond.

(d) APPLICABILITY OF FEDERAL ADVISORY COMMITTEE ACT.—The provisions of the Federal Advisory Committee Act shall not apply to the Commission.

5 USC app.

42 USC 285g note.

SEC. 206. COMMISSION STAFF.

(a) EXECUTIVE DIRECTOR.—The Chairperson and Vice Chairperson of the Commission shall appoint an executive director. The employment of such executive director shall be subject to confirmation by the Commission.

(b) OTHER PERSONNEL.—The Commission may appoint and terminate the executive director selected under subsection (a) and such other personnel as it considers appropriate to assist in the performance of its duties under this title, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and may pay such executive director and other personnel without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, except that the rate of pay for such executive director and other personnel may not exceed the rate payable for GS-18 of the General Schedule under section 5332 of such title.

(c) APPLICABILITY OF OTHER FEDERAL LAWS.—Service of an individual as a member of the Commission or employment of an individual by the Commission on a part-time or full-time basis and with or without compensation shall not be considered as service or employment bringing such individual within the provisions of any Federal law relating to conflicts of interest or otherwise imposing restrictions, requirements, or penalties in relation to the employment of persons, the performance of services, or the payment or receipt of compensation in connection with claims, proceedings, or matters involving the United States. Service as a member of the Commission or as an employee of the Commission, shall not be considered service in an appointive or elective position in the Government for purposes of section 8344 of title 5, United States Code, or comparable provisions of Federal law.

(d) EXPERTS AND CONSULTANTS.—Subject to such rules as may be prescribed by the Commission, the Chairman of the Commission may procure temporary and intermittent services under section 3109 of title 5, United States Code, at rates for individuals not to exceed the daily rate payable for GS-18 of the General Schedule under section 5332 of such title.

SEC. 207. SUNSHINE PROVISION.

The Commission shall establish procedures to ensure its proceedings are open to the public to the maximum extent practicable.

SEC. 208. TERMINATION OF THE COMMISSION.

Ninety days after the Commission submits its recommendations as required by section 204(b)(4) the Commission shall terminate.

SEC. 209. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to the Commission such sums as may be necessary. Amounts appropriated under this section shall remain available until the day on which the Commission terminates under section 208.

TITLE III—VACCINE COMPENSATION

SEC. 301. SHORT TITLE.

This title may be cited as the "National Childhood Vaccine Injury Act of 1986".

PART A—VACCINES

SEC. 311. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.

(a) NEW TITLE.—The Public Health Service Act is amended by redesignating title XXI as title XXIII, by redesignating sections 2101 through 2116 as sections 2301 through 2316, respectively, and by inserting after title XX the following new title:

"TITLE XXI—VACCINES

"Subtitle 1—National Vaccine Program

"ESTABLISHMENT

42 USC 300aa-1. "SEC. 2101. The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

"PROGRAM RESPONSIBILITIES

42 USC 300aa-2. "SEC. 2102. (a) The Director of the Program shall have the following responsibilities:

"(1) VACCINE RESEARCH.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

"(2) VACCINE DEVELOPMENT.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

"(3) SAFETY AND EFFICACY TESTING OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

"(4) LICENSING OF VACCINE MANUFACTURERS AND VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 353.

42 USC 263a.

"(5) PRODUCTION AND PROCUREMENT OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

"(6) DISTRIBUTION AND USE OF VACCINES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the Centers for Disease Control and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

"(7) EVALUATING THE NEED FOR AND THE EFFECTIVENESS AND ADVERSE EFFECTS OF VACCINES AND IMMUNIZATION ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

"(8) COORDINATING GOVERNMENTAL AND NON-GOVERNMENTAL ACTIVITIES.—The Director of the Program shall, through the plan issued under section 2103, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

"(9) FUNDING OF FEDERAL AGENCIES.—The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 2103 funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the plan.

"(b) In carrying out subsection (a) and in preparing the plan under section 2103, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

"PLAN

42 "SEC. 2103. The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 2102. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

"REPORT

42 "SEC. 2104. The Director shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than January 1, 1988, and annually thereafter on the implementation of the Program and the plan prepared under section 2103.

"NATIONAL VACCINE ADVISORY COMMITTEE

42 USC 300aa-5.

"SEC. 2105. (a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

"(b) The Committee shall—

"(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

"(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

"(3) advise the Director of the Program in the implementation of sections 2102, 2103, and 2104, and

"(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104.

"AUTHORIZATIONS

42 USC 300aa-6.

"SEC. 2106. (a) To carry out this subtitle other than section 2102(9) there are authorized to be appropriated $2,000,000 for fiscal year 1987, $2,500,000 for fiscal year 1988, $3,000,000 for fiscal year 1989, $3,500,000 for fiscal year 1990, $4,000,000 for fiscal year 1991.

"(b) To carry out section 2102(9) there are authorized to be appropriated $20,000,000 for fiscal year 1987, $22,500,000 for fiscal year 1988, $25,000,000 for fiscal year 1989, $27,500,000 for fiscal year 1990, $30,000,000 for fiscal year 1991.

"Subtitle 2—National Vaccine Injury Compensation Program

"PART A—PROGRAM REQUIREMENTS

"ESTABLISHMENT OF PROGRAM

42 USC 300aa-10.

"SEC. 2110. (a) PROGRAM ESTABLISHED.—There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

"(b) ATTORNEY'S OBLIGATION.—It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

"PETITIONS FOR COMPENSATION

42 USC 300aa-11.

"SEC. 2111. (a) GENERAL RULE.—

"(1) A proceeding for compensation under the Program for vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition with the United States district court for the district in which the petitioner resides or in which the injury or death occurred.

"(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless—

"(i) a petition has been filed, in accordance with section 2116, under subsection (b) for compensation under the Program for such injury or death,

"(ii) a district court of the United States has issued a judgment under section 2112 on such petition, and

"(iii) such person elects under section 2121(a) to file such an action.

"(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 2116, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

"(3) No vaccine manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle.

"(4) If in a civil action brought against a vaccine manufacturer before the effective date of this subtitle damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

"(5)(A) A plaintiff who on the effective date of this subtitle has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this title or before judgment, whichever occurs first, elect to withdraw such action without prejudice and file a petition under subsection (b) for such injury or death.

"(B) If a plaintiff who on the effective date of this subtitle had pending a civil action for damages for a vaccine-related injury or death does not withdraw the action under subparagraph (A), such person may not file a petition under subsection (b) for such injury or death.

"(6) If a person brings a civil action after the effective date of this subtitle for damages for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subtitle, such person may not file a petition under subsection (b) for such injury or death.

"(7) If in a civil action brought against a vaccine manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

"(b) PETITIONERS.—

"(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may file a petition for compensation under the Program.

"(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this subtitle if compensation has been paid under this subtitle for 3500 petitions for such injuries or deaths.

"(2) Only one petition may be filed with respect to each administration of a vaccine.

"(c) PETITION CONTENT.—A petition for compensation under the Program for a vaccine-related injury or death shall contain—

"(1) an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

"(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

"(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

"(I) received the vaccine in the United States or in its trust territories,

"(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

"(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

"(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

"(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

"(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

"(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

"(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 1 year after the administration of the vaccine, (ii) incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000, or (iii) died from the administration of the vaccine, and

"(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

"(2) all available relevant medical records (including autopsy reports, if any) relating to the person who suffered such injury or who died from the administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and

"(3) appropriate assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

"COURT JURISDICTION

"SEC. 2112. (a) GENERAL RULE.—The district courts of the United States shall have jurisdiction (1) over proceedings to determine if a petitioner under section 2111 is entitled to compensation under the Program and the amount of such compensation, and (2) to issue and enforce such orders as the courts deem necessary to assure the prompt payment of any compensation awarded.

"(b) PARTIES.—

"(1) The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 2111(b). Except as provided in paragraph (2), no other person may intervene in any such proceeding.

"(2) Within 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

"(A) relating to the existence of the evidence described in section 2113(a)(1)(B), or

"(B) relating to any allegation in a petition with respect to the matters described in section 2111(c)(1)(C)(ii).

"(c) SPECIAL MASTERS.—

"(1) Following receipt of a petition under subsection (a), the district court of the United States in which the petition is filed shall designate a special master to carry out the functions authorized by paragraph (2).

"(2) A special master shall serve as an adjunct to the court and may—

"(A) require such evidence as may be appropriate for the preparation of proposed findings of fact and conclusions of law with respect to whether compensation is to be provided

under the Program and the amount of any such compensation,

"(B) require the submission of such information as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

"(C) require the testimony of any person and the production of any document as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

"(D) conduct such hearings as may be appropriate, and

"(E) prepare and submit to the court proposed findings of fact and conclusions of law.

Information submitted to a special master in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express, written consent of the person who submitted the information. There may be no discovery in a proceeding on a petition other than the discovery required under this paragraph.

"(d) ACTION BY THE COURT.—

Records.

"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed.

"(e) ADMINISTRATION OF AWARD.—The Program shall administer the payments of such compensation. The Program shall audit the payments of compensation under a judgment. A petitioner awarded compensation shall notify the Program of any changes which significantly affect the compensation to be paid.

"(f) REVISION OF AWARD.—

"(1) If the court issues a judgment awarding to a petitioner compensation described in section 2115(a)(1)(A) for unreimbursable expenses and the compensation is insufficient to meet such expenses, such petitioner may petition the court to (A) review such award, and (B) increase the award to make it sufficient to meet such expenses or amend the periodic payment schedule established under section 2115, or both.

"(2) If an audit conducted under subsection (e) discloses the improper use of compensation awarded under a judgment or the termination of a need for an item of compensation, the Program shall petition the court which awarded the compensation to make an appropriate revision in the compensation.

"(g) APPEALS.—The findings of fact and conclusions of law of a district court of the United States on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the circuit in which the court is located upon petition filed with such court of appeals.

"DETERMINATION OF ELIGIBILITY AND COMPENSATION

Cod
Rep
42 U
300a

"SEC. 2113. (a) GENERAL RULE.—

"(1) Compensation shall be awarded under the Program to a petitioner if the court finds on the record as a whole—

"(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1), and

"(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

"(2) For purposes of paragraph (1), the term 'factors unrelated to the administration of the vaccine'—

"(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

"(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

"(b) MATTERS TO BE CONSIDERED.—

Cod
Rep

"(1) In determining whether to award compensation to a petitioner under the Program, the court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

"(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

"(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the court.

"(2) The court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condi-

tion, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

"(c) RECORD DEFINED.—For purposes of this section, the term 'record' means the record established by a distict court of the United States in a proceeding on a petition filed under section 2111.

"VACCINE INJURY TABLE

42 USC 300aa-14.

"SEC. 2114. (a) INITIAL TABLE.—The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

"VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (c)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	C. Residual seizure disorder in accordance with subsection (c)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not apolicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

"(b) QUALIFICATIONS AND AIDS TO INTERPRETATION.—The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

"(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

"(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

"(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

"(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

"(3)(A) The term 'encephalopathy' means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high

pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

"(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 2111(b) for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

"(4) For purposes of paragraphs (2) and (3), the terms 'seizure' and 'convulsion' include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

"(c) ADMINISTRATIVE REVISION OF THE TABLE.—

gulations.

"(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

"(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

"(A) receipt of any recommendation of the Commission, or

"(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

"(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

"(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

"(d) ROLE OF COMMISSION.—Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

"(e) RECOMMENDATION.—The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table.

"COMPENSATION

"SEC. 2115. (a) GENERAL RULE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle shall include the following:

"(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

"(i) result from the vaccine-related injury for which the petitioner seeks compensation,

"(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

"(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

"(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 2111(c)(1)(D)(ii).

"(B) Subject to section 2116(a)(2), actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

"(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

"(ii) were incurred by or on behalf of the person who suffered such injury, and

"(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 2111(c)(1)(D)(ii).

"(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

"(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning

capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

"(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

"(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum.

"(b) VACCINES ADMINISTERED BEFORE THE EFFECTIVE DATE.—Compensation awarded under the Program to a petitioner under section 2111 for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this subtitle shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a).

"(c) RESIDENTIAL AND CUSTODIAL CARE AND SERVICE.—The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

"(d) TYPES OF COMPENSATION PROHIBITED.—Compensation awarded under the Program may not include the following:

"(1) Punitive or exemplary damages.

"(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

"(e) ATTORNEYS' FEES.—

Courts, U.S.

"(1) The judgment of a court on a petition filed under section 2111 awarding compensation shall include an amount to cover—

"(A) reasonable attorneys' fees, and

"(B) other costs,

incurred in any proceeding on such petition. If the judgment of a court on such a petition does not award compensation, the court may include in the judgment an amount to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action was brought.

"(2) If the petitioner, before the effective date of this title, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and elected under section 2111(a)(4) to withdraw such action and to file a petition for compensation under the Program, the judgment of the court on such petition may include an amount limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this subtitle in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

"(3) No attorney may charge any fee for services in connection with a petition filed under section 2111 which is in addition to any amount included under paragraph (1) in a judgment on such petition.

"(f) PAYMENT OF COMPENSATION.—

"(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 2121(a) to receive compensation.

"(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the district court of the United States under section 2112 awarding the compensation. Such compensation may not be paid after an election under section 2121(b) to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

"(3) Payments of compensation shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985.

"(f) PROGRAM NOT PRIMARILY LIABLE.—Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity which provides health services on a prepaid basis.

"(g) LIABILITY OF HEALTH INSURANCE CARRIERS, PREPAID HEALTH PLANS, AND BENEFIT PROVIDERS.—No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

"(1) no State, and

"(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program.

"LIMITATIONS OF ACTIONS

"SEC. 2116. (a) GENERAL RULE.—In the case of—

"(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this title, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 24 months after the effective date of this title,

"(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this title, if a vaccine-related injury occurred as a result of the administration of such

vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

"(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this title, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

"(b) EFFECT OF REVISED TABLE.—If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, such person may file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

"(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

"(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

"(c) STATE LIMITATIONS OF ACTIONS.—If a petition is filed under section 2111(b) for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date a final judgment is entered on the petition.

"SUBROGATION

42 USC 300aa–17.

"SEC. 2117. (a) GENERAL RULE.—

"(1) Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

Courts, U.S. Records. Claims.

"(2) In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 2115 for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1).

"(b) DISPOSITION OF AMOUNTS RECOVERED.—Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in the trust fund which has been established to provide compensation under the Program.

"SEC. 2118. The compensation under subsections (a)(2) and (a)(4) of section 2115 and the civil penalty under section 2127(b) shall, effective December 1 of each year beginning 1 year after the effective date of this title, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this section, the term 'base quarter', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

"ADVISORY COMMISSION ON CHILDHOOD VACCINES

"SEC. 2119. (a) ESTABLISHMENT.—There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

"(1) Nine members appointed by the Secretary as follows:

"(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

"(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

"(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

"(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of the effective date of this subtitle. The members of the Commission shall select a Chair from among the members.

"(b) TERM OF OFFICE.—Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

"(c) MEETINGS.—The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission.

"(d) COMPENSATION.—Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the

5 USC 5332.

Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule for each day (including travel time) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, title 5, United States Code, for employees serving intermittently.

"(e) STAFF.—The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

"(f) FUNCTIONS.—The Commission shall—

"(1) advise the Secretary on the implementation of the Program,

"(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

"(3) advise the Secretary in implementing the Secretary's responsibilities under section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

"(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

"(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this subtitle.

"PART B—ADDITIONAL REMEDIES

"AUTHORITY TO BRING ACTIONS

2 USC 300aa-21.

"SEC. 2121. (a) ELECTION.—After the judgment of a district court of the United States under section 2111 on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—

"(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

"(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the entry of the court's judgment with respect to which the election is to be made. If a person required to file an election with a court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of a court or is deemed to have accepted the judgment of a court, against a vaccine manufacturer for damages for a vaccine-related injury or death for which the judgment was entered.

"(b) LIMITATIONS OF ACTIONS.—A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 2111 shall, except as provided in section 2116(c), be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

"STANDARDS OF RESPONSIBILITY

"SEC. 2122. (a) GENERAL RULE.—Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

"(b) UNAVOIDABLE ADVERSE SIDE EFFECTS; WARNINGS.—

"(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

"(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

"(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2), or

"(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

"(c) DIRECT WARNINGS.—No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

"(d) CONSTRUCTION.—The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

"(e) PREEMPTION.—No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle.

"TRIAL

42 USC 300aa-23.

"SEC. 2123. (a) GENERAL RULE.—A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle which is not barred by section 2111(a)(2) shall be tried in three stages.

"(b) LIABILITY.—The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 2122.

"(c) GENERAL DAMAGES.—The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

"(d) PUNITIVE DAMAGES.—

"(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 2122 shall be required to pay.

and.

"(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

21 USC 301 note.
42 USC 201 note.

"(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 351,

42 USC 262.

"(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

fety.

"(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

"(e) EVIDENCE.—In any stage of a civil action, the Vaccine Injury Table, any finding of a district court of the United States or a master appointed by such court in a proceeding on a petition filed under section 2111 and the final judgment of a district court of the United States on such a petition shall not be admissible.

"PART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

"RECORDING AND REPORTING OF INFORMATION

42 USC 300aa-25.

"SEC. 2125. (a) GENERAL RULE.—Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

"(1) the date of administration of the vaccine,

"(2) the vaccine manufacturer and lot number of the vaccine,

"(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

"(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

"(b) REPORTING.—

"(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

"(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 2114(b) which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

"(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

"(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this subtitle. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

"(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

"(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this subtitle.

"(c) RELEASE OF INFORMATION.—

"(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, United States Code, or otherwise, to any person except—

"(A) the person who received the vaccine, or

"(B) the legal representative of such person.

"(2) For purposes of paragraph (1), the term 'information which may identify an individual' shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

"(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

"VACCINE INFORMATION

"SEC. 2126. (a) GENERAL RULE.—Not later than 1 year after the effective date of this subtitle, the Secretary shall develop and

of this section. Such materials or other information shall be provided prior to the administration of such vaccine.

"MANDATE FOR SAFER CHILDHOOD VACCINES

"SEC. 2127. (a) GENERAL RULE.—In the administration of this subtitle and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

"(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this subtitle and promote the refinement of such vaccines, and

"(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

"(b) REPORT.—Within 2 years after the effective date of this subtitle, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

"MANUFACTURER RECORDKEEPING AND REPORTING

"SEC. 2128. (a) GENERAL RULE.—Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after the effective date of this subtitle—

"(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

"(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

"(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

"(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

Fraud.

"(b) SANCTION.—Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

"(1) be subject to a civil penalty of up to $100,000 per occurrence, or

"(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

"PART D—GENERAL PROVISIONS

"CITIZEN'S ACTIONS

42 USC 300aa-31.

"SEC. 2131. (a) GENERAL RULE.—Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this subtitle.

"(b) NOTICE.—No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

Courts, U.S.

"(c) COSTS OF LITIGATION.—The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such award is appropriate.

"JUDICIAL REVIEW

Regulations. 42 USC 300aa-32.

"SEC. 2132. A petition for review of a regulation under this subtitle may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

"DEFINITIONS

42 USC 300aa-33.

"SEC. 2133. For purposes of this subtitle:

"(1) The term 'health care provider' means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

"(2) The term 'legal representative' means a parent or an individual who qualifies as a legal guardian under State law.

"(3) The term 'manufacturer' means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 2128, such

ered by that section. The term 'manufacture' means to manufacture, import, process, or distribute a vaccine.

"(4) The term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

"(5) The term 'vaccine-related injury or death' means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

"(6)(A) The term 'Advisory Commission on Childhood Vaccines' means the Commission established under section 2119.

"(B) The term 'Vaccine Injury Table' means the table set out in section 2114.".

(b) CONFORMING AMENDMENTS.—

(1) Sections 217(c), 465(f), and 497 of the Public Health Service Act (42 U.S.C. 218(c), 286(f), 289(f)) are each amended by striking out "2101" and inserting in lieu thereof "2301".

(2) Section 305(h) of such Act (42 U.S.C. 242c(h)) is amended by striking out "2113" each place it occurs and inserting in lieu thereof "2313".

SEC. 312. RELATED STUDIES.

(a) REVIEW OF PERTUSSIS VACCINES AND RELATED ILLNESSES AND CONDITIONS.—Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under subsection (e)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions:

(1) Hemolytic anemia.
(2) Hypsarrhythmia.
(3) Infantile spasms.
(4) Reye's syndrome.
(5) Peripheral mononeuropathy.
(6) Deaths classified as sudden infant death syndrome.
(7) Aseptic meningitis.
(8) Juvenile diabetes.
(9) Autism.
(10) Learning disabilities.
(11) Hyperactivity.
(12) Such other illnesses and conditions as the Secretary may choose to review or as the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act recommends for inclusion in such review.

The review under this subsection shall include notice and opportunity for a public hearing, consideration of written information submitted by the public, and consultation with such Advisory Commission.

(b) FINDINGS WITH RESPECT TO PERTUSSIS.—Not later than 3 years after the effective date of this title, the Secretary shall make, and publish in the Federal Register, the following specific findings:

(1) Whether each of the illnesses or conditions set forth in subsection (a) can reasonably be determined in some circumstances to be caused or significantly aggravated, by pertussis-containing vaccines.

(2) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), the circumstances under which such causation or aggravation can reasonably be determined to occur.

(3) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), and for each illness or condition set forth in the Vaccine Injury Table under section 2114 of the Public Health Service Act, the time periods within which the first symptom or manifestation of onset or aggravation of each such illness or condition can reasonably be determined to occur after pertussis vaccination.

Ante, p. 3764.

Regulations.

(c) REVISION OF TABLE WITH RESPECT TO PERTUSSIS VACCINES.—At the same time the Secretary publishes in the Federal Register findings under subsection (b), the Secretary shall propose regulations to amend the Vaccine Injury Table under section 2114 of the Public Health Service Act as a result of such findings. Not later than 42 months after the effective date of this title, the Secretary shall promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

(d) REVIEW OF MMR VACCINES AND RELATED ILLNESSES AND CONDITIONS.—Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review similar to the review conducted under subsection (a) with respect to the potential relationship between vaccines containing rubella (including MMR) and radiculoneuritis. The review under this subsection shall include notice and opportunity for a public hearing, consultation with the Advisory Commission on Childhood Vaccines and consideration of written information submitted by the public. Not later than 3 years after the effective date of this title, the Secretary shall make and publish in the Federal Register findings similar to those required by subsection (b) and shall, if appropriate, propose similar regulations (and thereafter promulgate such regulations) to those required by subsection (c), with respect to compensation under the National Vaccine Injury Compensation Program established under section 2110 of the Public Health Service Act for radiculoneuritis caused, contributed to, or significantly aggravated by vaccines containing rubella.

Federal Register, publication.

Ante, p. 3758.

(e) PERTUSSIS AND MMR STUDIES.—

(1) In order to assist the Secretary in making the findings required under subsections (b) and (d), the Secretary shall, in accordance with subparagraph (B), arrange for the conduct of studies of—

(A) the relationship between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the illnesses or conditions set forth in paragraphs (1) through (11) of subsection (a),

(B) the relationship between vaccines containing pertussis and any other illnesses and conditions, as selected by the Secretary or the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act, and

Ante, p. 3771.

(C) the relationship between vaccines containing rubella (including MMR) and radiculoneuritis.

(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the studies required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in paragraph (3).

(C) The Institute of Medicine or other group or association conducting the studies required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act.

(3) Reports on the results of the studies required by paragraph (1) shall be completed and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary not later than 32 months after the effective date of this title. Upon submission to the Secretary, the reports shall be made available to the public.

(4) There are authorized to be appropriated such sums as are necessary for the purpose of making payments for the conduct of the studies required under this subsection.

(f) DEFINITIONS.—For purposes of this section:

(1) The term "medical and scientific information" includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature or official Government publications, as well as relevant unpublished information, data, studies, and observations.

(2) The term "MMR" means a vaccine containing material intended to prevent or confer immunity against measles, mumps, and rubella disease.

SEC. 313. STUDY OF OTHER VACCINE RISKS.

(a) STUDY.—

(1) Not later than 3 years after the effective date of this title, the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act—

(A) arrange for a broad study of the risks (other than the risks considered under section 102) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act, and

(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

(i) the circumstances under which any such vaccine should not be administered,

(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act.

Ante, p. 3771.

(b) REVISION OF GUIDELINES.—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

Federal Register, publication.

(c) FACTORS AFFECTING GUIDELINES.—Guidelines under subsection (a) shall take into account—

(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

(2) the medical and other characteristics of such potential recipients, and

(3) the risks to the public of not having such vaccines administered.

(d) DISSEMINATION.—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

Physicians. Hospitals. Nurses. State and local governments.

(1) physicians and other health care providers,

(2) professional health associations,

(3) State and local governments and agencies, and

(4) other relevant entities.

42 USC 300aa-1 note.

SEC. 314. REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION.

Not later than 1 year after the effective date of this title and after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act and with other appropriate entities, the Secretary of Health and Human Services shall review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 2114 of the Public Health Service Act and shall by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines. If the Secretary determines that any such warning, instruction, or information is inadequate for such purpose in any respect, the Secretary shall at the same time require the manufacturers to revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title.

Ante, p. 3764.

SEC. 315. RECALL AUTHORITY.

Subsection (d) of section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) by inserting "(1)" after "(d)", and

(2) by adding at the end thereof the following new paragraph:

"(2)(A) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

"(B) Any violation of subparagraph (A) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this subparagraph shall, effective December 1 of each year beginning 1 year after the effective date of this subparagraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this subparagraph, the term 'base quarter', as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.".

SEC. 316. STUDY OF IMPACT ON SUPPLY OF VACCINES.

On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate—

(1) an assessment of the impact of the amendments made by this title on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act, and

(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children.

PART B—MISCELLANEOUS

SEC. 321. WAIVER OF PAPERWORK REDUCTION.

Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this title and implementing the amendments made by this title.

SEC. 322. NONSEVERABILITY.

If any provision of this title or the application of any provision of this title to any person or circumstance is held invalid by reason of a violation of the Constitution, the entire title shall be considered invalid.

SEC. 321. EFFECTIVE DATE.

(a) GENERAL RULE.—Subtitle 1 of title XXI of the Public Health Service Act shall take effect on the date of the enactment of this Act and Subtitle 2 of such title and this title shall take effect on the effective date of a tax enacted after the date of the enactment of this Act to provide funds for compensation paid under such subtitle 2.

Ante, p. 3756.
Ante, p. 3758.

Claims.

(b) INSUFFICIENCY OF FUNDS.—If at any time there are insufficient funds to pay all of the claims payable under subtitle 2 of title XXI of the Public Health Service Act for 180 days, such subtitle shall cease to be in effect until sufficient funds to pay all of the claims under such subtitle become available.

TITLE IV—ENCOURAGING GOOD FAITH PROFESSIONAL REVIEW ACTIVITIES

Health Care Quality Improvement Act of 1986.

42 USC 11101 note

SEC. 401. SHORT TITLE.

This title may be cited as the "Health Care Quality Improvement Act of 1986".

42 USC 11101.

SEC. 402. FINDINGS.

The Congress finds the following:

(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.

(2) There is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance.

(3) This nationwide problem can be remedied through effective professional peer review.

(4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.

(5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review.

PART A—PROMOTION OF PROFESSIONAL REVIEW ACTIVITIES

42 USC 11111.

SEC. 411. PROFESSIONAL REVIEW.

State and local governments.

(a) IN GENERAL.—

(1) LIMITATION ON DAMAGES FOR PROFESSIONAL REVIEW ACTIONS.—If a professional review action (as defined in section 431(9)) of a professional review body meets all the standards specified in section 412(a), except as provided in subsection (b)—

(A) the professional review body,

(B) any person acting as a member or staff to the body,

(C) any person under a contract or other formal agreement with the body, and

(D) any person who participates with or assists the body with respect to the action,

shall not be liable in damages under any law of the United States or of any State (or political subdivision thereof) with respect to the action. The preceding sentence shall not apply to damages under any law of the United States or any State relating to the civil rights of any person or persons, including the Civil Rights Act of 1964, 42 U.S.C. 2000e, et seq. and the Civil Rights Acts, 42 U.S.C. 1981, et seq. Nothing in this paragraph shall prevent the United States or any Attorney General of a State from bringing an action, including an action under section 4C of the Clayton Act, 15 U.S.C. 15C, where such an action is otherwise authorized.

(2) PROTECTION FOR THOSE PROVIDING INFORMATION TO PROFESSIONAL REVIEW BODIES.—Notwithstanding any other provision of law, no person (whether as a witness or otherwise) providing information to a professional review body regarding the competence or professional conduct of a physician shall be held, by reason of having provided such information, to be liable in damages under any law of the United States or of any State (or political subdivision thereof) unless such information is false and the person providing it knew that such information was false.

(b) EXCEPTION.—If the Secretary has reason to believe that a health care entity has failed to report information in accordance with section 423(a), the Secretary shall conduct an investigation. If after providing notice of noncompliance, an opportunity to correct the noncompliance, and an opportunity for a hearing, the Secretary determines that a health care entity has failed substantially to report information in accordance with section 423(a), the Secretary shall publish the name of the entity in the Federal Register. The protections of subsection (a)(1) shall not apply to an entity the name of which is published in the Federal Register under the previous sentence with respect to professional review actions of the entity commenced during the 3-year period beginning 30 days after the date of publication of the name.

(c) TREATMENT UNDER STATE LAWS.—

(1) PROFESSIONAL REVIEW ACTIONS TAKEN ON OR AFTER OCTOBER 14, 1989.—Except as provided in paragraph (2), subsection (a) shall apply to State laws in a State only for professional review actions commenced on or after October 14, 1989.

(2) EXCEPTIONS.—

(A) STATE EARLY OPT-IN.—Subsection (a) shall apply to State laws in a State for actions commenced before October 14, 1989, if the State by legislation elects such treatment.

(B) STATE OPT-OUT.—Subsection (a) shall not apply to State laws in a State for actions commenced on or after October 14, 1989, if the State by legislation elects such treatment.

(C) EFFECTIVE DATE OF ELECTION.—An election under State law is not effective, for purposes of subparagraphs (A) and (B), for actions commenced before the effective date of the State law, which may not be earlier than the date of the enactment of that law.

SEC. 412. STANDARDS FOR PROFESSIONAL REVIEW ACTIONS.

(a) IN GENERAL.—For purposes of the protection set forth in section 411(a), a professional review action must be taken—

Name: Michael E. Jones, M.D.

Title: Medical Epidemiologist
State of Alaska Department of Health and Social Services,
Division of Public Health, Section of Epidemiology, Immunization Program

Subject: Testimony Presented to the House HESS Committee on February 11, 1988, in Opposition to House Bill 277

Many of us consider the vaccine-preventable diseases of childhood a thing of the past; some of us may think they no longer exist. Except for smallpox, which was eradicated from the world in 1977, those diseases do still exist, but in relatively small numbers. The decline in the incidence rates of childhood diseases is largely attributable to the development of effective vaccines. For example, 21,000 cases of paralytic polio were reported in the USA in 1952; in 1986, only 2 cases were reported. Cases of diphtheria peaked at 207,000 cases in 1921; no cases were reported in 1986. We forget not only how common those diseases were, but also how serious they were and are. As many as 20 percent of children under 5 years of age died after contracting respiratory diphtheria. Measles can be complicated by pneumonia, convulsions, or an inflammatory brain disease. For whooping cough (also known as pertussis), the death rate for children under 6 months of age is 1%.

Although vaccines are extremely effective in preventing certain diseases and their complications, they are not without side effects. The side effects, or adverse events, associated with vaccine administration may be mild or severe. However, permanent, serious adverse events associated with vaccines are quite rare. In order for a vaccine to be useful, its benefits must outweigh its risks. For example, pertussis disease is complicated by encephalopathy--an inflammatory brain condition--once in every 250 cases. Although pertussis vaccine is associated with encephalopathy once in every 110,000 doses, the use of this vaccine has resulted in a 93% decline in the number of cases of this potentially fatal disease during the past 50 years. The vast majority of United States scientists, physicians, and public health officials believe that the benefits of immunization far outweigh the risks, and that the savings outweigh the costs.

In order to collect detailed information about vaccine-associated side-effects, the Alaska Immunization Program uses the Monitoring System for Adverse Events Following Immunization, or MSAEFI, established by the Centers for Disease Control in late 1978. This monitoring system is used to collect reports from public and private providers of publicly funded vaccines concerning adverse events following immunization.

Under MSAEFI, each parent or guardian of a child who receives publicly funded vaccine is to be instructed to report any illness that occurs within 28 days of receiving vaccine and that is severe enough to require a visit to a doctor, clinic, or hospital. This instruction is accomplished in the public medical sector by a notice in writing on every Important Information Statement. Important Information Statements (developed by the Centers for Disease Control) are to be given to all parents/guardians of children who receive an immunization in a public medical facility as a condition for receipt of publicly funded vaccine.

Important Information Statements discuss the risks and benefits of the specific vaccine and the risks of the specific vaccine-preventable disease. By signing the Statement the parent/guardian states that they have read the Important Information Statement and have had an opportunity to ask questions of the health care provider administering the vaccine. Signed Important Information Statements must be kept 10 years beyond the end of the calendar year in which the signature was obtained.

In addition to the parent's/guardian's signature, the vaccine manufacturer's name, the vaccine lot number, the date of the Important Information Statement, and the date of the immunization are documented and retained. Private providers of publicly funded vaccines can either use the Important Information Statement system or use their professional medical judgment to inform parents/guardians of the risks and benefits of the vaccines. Reporting of adverse events following immunization by health care providers has been required in Alaska by regulation since 1974.

Reports of adverse events following immunization which meet minimum reporting criteria are investigated by the Alaska Immunization Program and the pertinent information forwarded to the Centers for Disease Control in Atlanta. A one year follow-up is conducted by the Alaska Immunization Program to determine the health status of the vaccinee.

An integral component of the Alaska Immunization Program is the hospital-based maternal education/immunization program for new mothers. New mothers are to be given a Parents Guide to Immunization (some hospitals distribute their own immunization literature) either during prenatal classes or at the time of discharge. Not only are all of Alaska's hospitals with OB/GYN services part of a maternal education/immunization program, but so are Alaska's lay midwives.

The Alaska Immunization Program has mechanisms in place for informing in print the parents/guardians of the risks and benefits of vaccine(s), ascertaining that the parents/guardians receive and understand the vaccine information, documenting the vaccine manufacturer's name and the vaccine lot number, reporting and investigating adverse events following immunization, and educating mothers of newborns about immunizations.

The current Immunization Program in Alaska traces its roots to the epidemics of diptheria and measles in Alaska in 1975 and 1977. Investigation of the measles epidemic in 1977 revealed that it occurred because Alaska's school immunization law was not being enforced and children were not being vaccinated. A massive, state-wide vaccination campaign was effective in stopping the measeles epidemic. Since March 1, 1977, the daycare and school immunization regulations have been enforced with great success. Cases of rubella and pertussis have been documented in Alaska among individuals who were not appropriately vaccinated or who have recently arrived in Alaska bringing the diseases with them. For 10 years our program has worked well, has achieved our goals of preventing these diseases among Alaskans, and has been accepted by almost all Alaskans.

My name is Cheryl Rykaczewski, I am a concerned parent and a member of the Alaska Chapter of Dissatisfied Parents Together.

I support HB277 because I am concerned about the risk of adverse reaction that we take when we are required to immunize our children. Currently parents are not given enough information about the diseases that can occur as a long term result of an adverse reaction. This bill requires that extensive information be given to parents well in advance of the date of immunization, allowing them to examine their child's and their family's health history and decide whether their child could have a serious reaction to the immunization.

Only a philosophical objection allowance will give parents the confidence and right to exclude their child from immunization if they are at serious risk.

Thank you,

Cheryl Rykaczewski
Box 311
Kasilof, AK 99610
262-4937

Testimony before the Alaska House Committee on Health, Education, and Social Services
February 11, 1988

Shannon M. Kohler, President
Alaska Dissatisfied Parents Together (AK-DPT)

Rep. Koponen, Rep. Ellis and members of the committee:

My name is Shannon Kohler. I am President of the Alaska Chapter of Dissatisfied Parents Together and am here on behalf of that group. AK-DPT is part of a national, non-profit educational organization consisting of parents concerned with vaccine safety and efficacy. We are not anti-vaccine. Alaska DPT has four simple goals that are effectively addressed in H.B. 277, sponsored by Rep. Mike Navarre at the request of Alaska DPT.

Before I go into a quick and concise presentation of some of the supporting data for H.B. 277, I'd like to express my sincere appreciation for the convening of today's hearing (especially since it was arranged to be as convenient as possible for my situation.) I'd also like to convey my and the Alaska DPT group's thanks to Rep. Mike Navarre for sponsorship of this bill, thus giving us the chance to bring to light many of the problems existing in the state's current vaccine program.

I do understand the limited time available for this hearing and the need to lay factual groundwork for this bill. Many parents are willing to tell their stories and express their support of H.B. 277 and have asked me to convey their desire for a statewide teleconference. AK DPT did participate in a teleconference sponsored by The Governors Interim Commission on Youth in July 1987. A copy of that testimony is included in the packets I have distributed.

I would also like to add that it is not the intention of AK-DPT to dismantle the AK Immunization Program. Alaska Law currently mandates that each child receive 5 DPT (Diptheria, Pertussis and Tetanus) shots, recommended at 2,4, 6 & 15 months and 5 years. It mandates 3 oral live polio vaccines recommended at 2,4,and 18 months and one Measles, Mumps and Rubella shot recommended at 15 months. We view the major parts of HB 277 (i.e. Sections 2,3 & 4) as desperately needed information and accountability improvements to the existing program. The first section which relates to choice I will discuss now.

House Bill 277, An Act Relating to the Immunization of Minors
Section I: Philosophical Objection

As H.B. 277 is constructed the first section refers to parental choice (philosophical objection) to vaccination. I will discuss this briefly, then since the remainder of the bill also adds support to this concept, I will return to summarize the necessity of this section.

To allow a parent to choose whether their child is to be vaccinated with a variety of bacteria, viruses, preservatives, additives, etc. should ideally be a simple matter of CHOICE. But since many view choosing not to vaccinate as negligence, I view my task here as one that shows some of the reasons why a responsible loving parent may choose not to vaccinate. It is not my intention or the intention of AK-DPT, to convince parents to vaccinate or not, but in this instance to advocate a choice. Currently state law allows for exemption on medical or religious grounds. It seems ironic that people may currently object to vaccines if they are a member of a religious organization whose beliefs forbid immunizations (i.e. it is their "GOD GIVEN RIGHT" to refuse to immunize their child) but it is unacceptable legally to say "I read 25 articles in medical journals, three newspaper articles, and saw on 20/20 that pertussis vaccine has serious side effects and for this reason I don't want my child to have pertussis vaccine." This statement is not reason enough to refuse to immunize your child against pertussis, at least it is not currently acceptable by law. This is one of the most serious problems with immunization policy: in order to legally refuse any single immunization it is necessary to be opposed to all immunizations on religious grounds.

Alaska DPT has written letters to the twenty-two states that already allow a philosophical objection or parental discretion to vaccination. We asked a variety of questions, including questions about their rates of compliance and rates of disease. Seventeen of the states responded. We have compiled a chart that shows the pertinent data they provided. Please open your packet to this chart. Note that 6 of the 17 states have added a philosophical exemption since 1970, most since 1979, and all have very high vaccine compliance rates. This data should effectively address the possible argument that if AK allows for choice that parents may become lazy or disinterested and discontinue vaccination. This **has not** occurred in the 17 states on this chart, why should it happen in Alaska? This chart also shows that we would not be setting a precedent, we would be joining a growing list of states that obviously decided personal choice in this matter is a distinct priority.

(Discuss disease rates: Vaccinated/Unvaccinated)

Please note the letter from the State of Ohio stating that exemptions cause no disease implication concern there.

Section II. IMMUNIZATION INFORMATION

A) Safety of Vaccines

Though the AK Immunization Program does provide parent information handouts written by the National Center of Disease Control, our group stresses that this information is not nearly adequate at addressing the spectrum of adverse events that may follow routine vaccination. This Immunization Program material never mentions the ingredients contained in any vaccine. Since the state provides the vaccines, it follows that the state should make every effort to give complete information about the ingredients, contraindications (who should not be vaccinated and why), as well as recognized adverse reactions. This requirement could easily be met by providing parents with the manufacturers product insert from each vaccine. Also in this section of H.B. 277 is the provision that hospitals provide all vaccination information to parents of newborns. This is to insure that the parents have ample time to ingest this information before vaccination time 2 months later.

We have heard the argument from health care providers that giving people information will frighten them, that the risks should be minimized, not accentuated. That the benefits out weigh the risks. We have compiled a lot of information that points to the contrary. That pertussis is no longer the dread disease of the early 1900's. That it had declined in frequency by 70% by the time the vaccine was introduced in 1940 [from Pertussis Immunization: Problems, Perspectives, Prospects, Edward A Mortimer Jr. Case Western Reserve Univ., Hospital Practice, Oct 1980, pp103] There is increasing medical evidence and opinion that the vaccine may cause more encephalopathy (and consequent brain damage) than could be expected from the disease itself. [Vaccine Roulette, Dr. Robert Mendelsohn & Dr. Gordon Stewart, Vaccination Against Whooping-Cough, Efficacy versus Risks, Gordon T. Stewart, The Lancet, January 29, 1977, pp237] We realize that this is all currently controversial and do not put ourselves before you as experts, only as people who have a valid concern. We contend that parents as well as health care professionals should be as informed as possible to help initially screen for high risk infants who otherwise might slide through the screening process. No one knows a child's or family's history better than the parent. Information about adverse side effects is also very important to the child who has exhibited a serious reaction with a prior immunization and may be at (in the instance of Pertussis vaccine) substantially increased risk of brain damage. We have experience with parents who didn't realize that the reaction their child had should have been considered serious (because they were not provided information on what constitutes a "serious" reaction or because the seriousness was denied or minimized by their health care provider) and subsequent shots actually did permanent damage. If the reporting of reactions to the shots were encouraged and taken seriously, these children would not be dealing with life long disability today. [See Testimony of Gov. Interim

Commission on Youth, and the Summary of Severe Adverse Reactions.]

Also in the packet provided, AK DPT has prepared a list of severe adverse reactions that may occur after vaccination all with references as to source from medical literature. I must stress that these listings are partial. **[READ SOME OF LISTINGS]**

New information as to the possible long term effects of vaccination is surfacing all the time. Also in these packets are descriptions of some of the ingredients in these vaccines. Did you know that formaldehyde, thimerosal (mercury derivative) and aluminum are ingredients found in the DPT vaccine? As described in your packet, formaldehyde is a highly suspected carcinogen and worse. Thimerosal is made of ethymercuric chloride which happens to belong to the alkylmercuric family which is the most poisonous of mercury families. This mercury is easily absorbed by the body and not easily excreted. It causes brain damage. Aluminum toxicity has been associated with the occurence of Altzheimer's disease. I am not saying that these vaccine ingredients are the only source of these contaminants in our world. Nonetheless, due to the route of exposure (i.e. frequent injection) and time of exposure (early infancy and youth) they can not be discounted as having no possible affect on the general and long term health of our children.

As regards live virus vaccines; measles, mumps, rubella, polio, there are many questions as to the long term implications of their use. I have included a newspaper clipping in your packets that addresses this. In summary this article states that live virus vaccines may be seeding humans with RNA to form proviruses which will then become latent in cells throughout the body. These proviruses could under proper conditions become activated and cause rheumatoid arthritis, multiple sclerosis, allergies and perhaps cancer. I have many medical articles with me that describe the variety of other problems that may exist with the use of live virus vaccines. One very interesting tidbit of info is found on page 25 of the handbook "Surgeon Generals Report on AIDS" provided to all United States households. Under Testing of Military Personnel: I quote about AIDS testing of military recruits: "...They also need to protect new recruits (who unknowingly may be AIDS virus carriers) from receiving live virus vaccines. These vaccines could activate disease and be potentially life-threatening to the recruits."

Question: What other as yet unknown virus may be activated by live virus vaccines?

The fact that there are an infinite number of viruses in the world and these are constantly mutating leads to another question: What kinds of undetected viruses are included in these live virus vaccines that should not be injected into humans? Such an incident was discovered to be occurring in 1961. Simion virus 40, a monkey virus occuring in the monkey kidney ingredient of the polio vaccine, was found to be contaminating the

polio vaccines being injected world wide. Simion virus 40 is known to cause leukemia and cancerous tumors in hamsters. [Division of Biologics Standards. The Boat that Never Rocked; March 1972 Science. Near Disaster With The Salk Vaccine Dec 1963 Science Digest; Development of S and T Antigens and Oncogenicity in Hamster Embryonic Cell Lines Exposed to SV40 Virology 34 1968.] It was reported in the Survey of Childhood Malignancies, Feb 1962 *that children, between the ages of 2 and 4, were being adversely affected by an unfavorable trend of leukemia mortality in technically advanced countries.* [Survey of Childhood Malignancies" Alice Stewart M.D. Public Health Reports Vol 77, No. 2, Feb 1962]

I have the articles describing these incidents and others. Another quote about live virus vaccines from Van Nostrand's Scientific Encyclopedia' Fifth Edition; part of the defintion of virus:

"Phage: Bacteriophages are viruses that invade bacterial cells and are replicated within the bacterial cells. The presence of phage in live virus vaccines has precipitated concern among some authorities. It has been established that phage are introduced into vaccines when viruses for the vaccines are grown in tissue culture... It has been suggested that it is in the realm of possibility for phage to transmit genes to human cells and thus cause cancer or degenerative disease in humans".

VACCINE EFFICACY

According to the vaccine compliance chart we looked at earlier, on the average during a pertussis epidemic 50% of those stricken are vaccinated; 50% are not. During measles outbreaks usually more are vaccinated than are not.

More Facts:

*Some 90% of the pertussis patients whose immunization status was known, appear to have been adequately vaccinated" From the Vaccine Bulletin, Feb 1987, pp11-12, Center for Disease Control publication in regard to the 1986 pertussis outbreak of 1300 cases in Kansas.

*Approximately half of the cases of pertussis (whooping cough) in 1984/85 epidemic had received pertussis vaccine at some point in their life (from correspondence of May 1, 1986 with the AK Public Health Dept.)

Measles:

**Nationally, of the 1,051 affected with measles who were between the ages of 16 months and 28 years of age, 842 (80.1%) had been vaccinated on or after their first birthday which is the currently recommended timetable for measles vaccination".* (from Morbidity and Mortality Weekly, CDC Report, Jan 10, 1986)

The following measles and rubella quotes are from "The 'New' Epidemiology of Measles and Rubella", by James D. Cherry M.D., Univ of Calif, L.A., published in Hospital Practice July 1980, pp49-57.

Direct Quote from Cherry article " *Both Diseases have been effectively controlled in the pediatric population that, in the prevaccine era, harbored them. However, with the shift in prevalence to adolescents and young adults, it is possible the diseases may be "time bombs".*

Spring 1977- outbreak of measles on the UCLA campus. "When 506 students underwent serologic screening 9% had HIA titers of less than 5 and thus, presumably, were susceptible to measles: in other words, the outbreak had developed in a population that appeared to be 91% immune".

Testing done in 1976 and 1977 in Los Angeles County and also on the UCLA campus suggest that booster shots might not have any lasting effect on waning measles immunity.

RUBELLA:
Since 1969 Rubella activity has declined about 70% (aprox administration of 83 million doses). But as with measles there has been a shift in age groups susceptible to rubella. Before rubella immunization less than 25% of reported rubella involved patients 15 or older. By 1975 62% was in the 15 or older age group and by 1976 and 1977 70% was in 15 and older age group (with 15-19 yrs having the highest incidence) Direct Quote from Cherry: *"The decline in congenital rubella is curious because the number of infections in women of child bearing age has remained the same. Anyway, it is clear that the apparent stability in the control of congenital rubella is precarious".*

Along with the problem of waning immunity which leaves an older, more vulnerable age group at risk for serious illness from childhood diseases there is also the problem of Atypical measles. According to James Cherry M.D., in the 1980 article 'The 'New' Epidemiology of Measles and Rubella, atypical measles started showing up in 1965 and were traced to the Killed measles vaccine. It was a serious illness that led into pneumonia and because of the atypical symptoms proved to be a diagnostic challence for physicians. Quote: *"Since "only" about 1.8 million doses of killed vaccine were distributed between 1963 and 1967, and since "only" an estimated 600,000 to 900,00 children received two or three doses of killed vaccine in those years, it was expected in the early 1970's that the problem would disappear quickly. Eventually (If its pathogenesis involves killed vaccine) it will, but in the meantime, atypical measles is still very much with us. It is a disease of significant morbidity in young adults and some adolescents..."*

Vaccinations apparent effect on mortality rates occurring from measles, diptheria, polio can be questioned via another chart in your packet: "Contribution of Medical Measure to Mortality Decline". Vaccination in these instances were introduced when mortalities from these diseases

were already steadily declining.

SECTION III: Adverse Reaction Reports

HB277 would mandate that **all** health care providers report to the Public Health Dept. **all** occurences of serious adverse reactions to vaccinations and also asks for long term follow-up investigations.

A major problem with the federal MSAEFI reporting system is that a report is not accepted if the parent and child do not physically visit a clinic or hospital within 4 weeks of vaccination to report an adverse event or seek treatment. Here is an often occuring scenario: The child receives their shot of vaccine at the Public Health Department, eight hours later is suffering from a high fever and prolonged high pitched screaming. The health department is closed, their doctor is gone for the day so the parent calls the emergency room and is told to give the child Tylenol and is reassured that this is not an unusual reaction to a shot. The child is never seen by a doctor or health professional. This serious adverse reaction just slipped through the reporting system. By the next morning, or whenever next the parent can get in to see the family doctor the child appears to be better. The health dept. does not hear about the reaction, the hospital nor the doctor report the reaction and although the parent and health provider need to carefully consider whether giving additional doses of the vaccine is a good idea, no one catches that. Obviously, loopholes abound! What about a convulsion and or high fever that occurs during the night and apparently resolves itself by morning... perhaps a Saturday morning when clinics and doctors offices are closed? What about a parent who can't necessarily afford an emergency room or doctor visit to seek treatment? Accessability and affordability play key roles here. All reactions should be reported to accurately ascertain just what is happening to our children after vaccination both immediately and in the long term. Parents should be believed and encouraged to report regardless of time elapsed and professional assistance sought.

The State's apparent attitude as regards adverse reaction reporting can be summed up in one statement from correspondence with AK Public Health Dept. *"The State does not have any specific regulations regarding the reporting of adverse reactions following immunizations. Health care providers who administer vaccines are encouraged to report possible adverse reactions to this office. This is a passive surveillance system that relies on the integrity of the health care providers to comply"* correspondence with Michael Klatt, manager AK Immunization Program, Nov 14, 1986

Add this quote to the apparent lack of health care provider integrity shown in the summary of adverse reactions (in your packet) Page 2 of the questionnaire shows that of the 21 who reported the adverse reaction to a health care provider 18 never had a MSAEFI form completed for them (This means they were not effectively reported if they were reported at all)

(NOTE - Discuss Summary)
This system must be improved now! Alaskan children are reacting to these vaccinations! They are not, however being counted in vaccine safety statistics. It is ironic to me that that health providers quote statistics on the safety of the vaccines when statistics are something that are currently so poorly kept. How will the problems with the vaccines ever be defined and resolved if they continue to be ignored and denied? Just look at this summary and at the testimony at the children's commission for the specifics!

IV. IMMUNIZATION RECORDS

This part of HB 277 is to insure that the vaccination manufacturer and lot number be kept on file for at least three years and to insure that any severe reaction be recorded in the minors permanent record. Obviously this section is necessary to avoid dangerous revaccination of any adversely affected child, even if location of administration varies. It will also help determine tainted batches of vaccine should they occur.

This all brings us full circle back to the first section of HB277.
I have talked about how other states have been adding this exemption without undue loss of vaccine compliance, and without apparent disease implications. I have shown this committee that the short term and long term safety of all of these vaccines is indeed questionable. More questions and uncertainties arise almost daily especially as regards live virus vaccines and the ingredients of all vaccines. I have shown this committee how vaccination does not guarantee immunity from these diseases. I have shown, too, the variety of other known and suspected ailments that can be contracted via vaccination. I feel I have provided the evidence necessary to show this committee why a responsible parent might intelligently question vaccination. Because one parent may choose not to vaccinate should not reflect on another parents right to choose immunization. AK-DPT does not want to imply that we advocate against the immunization program. We do not wish to interfere with the accessibility and affordibility of the vaccine program but rather wish to encourage the safest and most effective program that can be made available. We are asking quite simply for accountability.

I end this testimony feeling frustrated because I have barely touched the tip of the iceberg as regards this issue. The time element and repect for this committee's already overloaded agenda does not allow me to expound any further. All the material I have referred to, if not already in your individual packets, will be on file as reference material with the chairmen

or available by request from AK-DPT. Within your packets, the materials with asterisks are available from me on request.

I will be in Juneau through Saturday Feb 13 and available to discuss this further. Copies of this testimony are at the end of your packets for easy reference.

I and the members of Alaska's DPT chapter urge you to support HB277.

I'd like to finish with this quote by Edward Bradley who is a researcher with the Cetus Corporation: *"We probably know as little about the immune system now as Columbus knew about the Americas after his first voyage."* Edward Bradley researcher, Cetus Corporation from the article: Our Immune Systerm: The Wars Within, National Geographic magazine June 1986:

Once again I thank you for your time and consideration of this important matter.