ALASKA LEGISLATURE COMMITTEE FILES 1987-1988 8672
4545 HHES HB 277 (FILE 1) - HB 277 (FILE 2)

Official Business

COMMITTEE: HOUSE HESS

DATE: 2-11-88

SIGN-IN

Subject of meeting:
HB 277 Immunization of Minors
HCR 4 Children's Law Task Force
HB 332 Burn Injuries
HB 409 WAMI

NAME	ADDRESS	PHONE	REPRESENTING	DO YOU WANT TO TESTIFY? if yes, which one
CHRIS CLERK		2828	REP. COLLINS	HCR 4 ✓
Elizabeth A Ward	Box H-06 Juneau	5-3090	HSS	277 yes
Jan Maynard	Box FP	234	ACPE	no
Shannon Hohlo	Box 1746 Soldotna, AK	262-3825		YES 217 ✓
David B Alexander	9601 Prospect Anchorage 99516	346 2447	ASMA	HB @ 1:30 277 yes
Gayle Horetski	Box N Juneau 99811	465-4322	DPS	HB 332 yes
CHARLES STEINER Steiner	1001 Noble FBX AK	452-1611	Self, ASMA	HB277 Here @ 9:30 yes
Nina Keeler Kinney	Dept of Public Safety PO Box N Juneau 99811	465-4356	Dept. of Public Safety	HCR 4 Available for questions ✓
DAVID JOHNSON	3612 TONGASS AVE KETCHIKAN	225-5146	ALASKA STATE MEDICAL ASSOCIATION	YES HB 332
Commissioner Munson Yvonne Chrisel	Box H-05 Juneau	465-3030	DHSS	YES

English 111 Scott Manchee

December 10, 1987

"No Shots, No School"

Janet, a licenced practical nurse, took her two-month-old son. Ritchie, to the pediatrician for a check up. He was found to be in good health and was given his first DPT shot (diphtheria, pertussis, tetanus vaccine) and oral polio vaccine. By evening, the site of the injection was dark purple and spreading causing him to cry when it was touched. The next morning "`...he started screaming off and on. He sounded like a cat in pain. His scream was high and forceful, and then he would fall asleep,'" Janet remembers (Coulter 6). All through the day Ritchie's condition worsened. He had explosive diarrhea, stopped responding to voices and sweated excessively. "`When I picked him up, he was completely soaked through two receiving blankets. I have never seen a baby soaked like that. The order was musty and pungent, a smell I will never forget'" (6). As Janet and her husband were getting Ritchie ready to take to the hospital, he stopped breathing. Janet administered CPR until the ambulance came and took over. Thirty-three hours after his first DPT shot, Ritchie was dead. Ritchie's case is a classic example of some of the documented side effects of the DPT vaccine.

Deborah a new mother, began to cough. A month later her coughs made her feel like her insides were turning out (Coulter 154). About this time her new daughter, Sarah began to cough slightly. The doctors diagnosed a flu bug. Sarah's cough worsened to such an extent that she would turn blue

when she coughed. The doctors finally suspected pertussis or whooping cough, as it is commonly known and sent both of them to the hospital (155). Sarah was admitted to ICU (intensive care unit). They both were put on antibiotics to alleviate the secondary complications from whooping cough. Sarah continued to have fits of coughing and turning blue. After leaving ICU, Sarah stopped breathing once and was revived by the nurses (156). Ten days after entering the hospital Sarah was discharged the cough having become a shadow of itself. During Sarah's stay in the hospital, Deborah's other daughter Miriam developed a cough that cultured positive for whooping cough. Although she had whooping cough her case was mild and it was difficult to tell she was really sick (157). Sarah was too young to have received a vaccination against the disease but, Miriam had received four vaccinations and Deborah had received her full complement of five shot to be fully immunized against whooping cough (158).

Immunization is the process of protecting a population from plagues and epidemics of diseases such as pertussis. A vaccine is used to trick the immune system, causing antibodies to be released that remain in the system protecting us from a particular disease. Polio, rubella, diphtheria and many other dreaded diseases of the past have been virtually eliminated by using vaccines to immunize a population. Although, there are drawbacks to some vaccines. Many cases of polio today are caused by the vaccine rather than exposure to the disease itself. The most controversial of the vaccines today is the DPT shot, a combination of the diphtheria, pertussis and tetanus vaccines.

The controversy surrounding the DPT vaccine primarily focuses on the pertussis portion of the vaccine. The documented side effects range from

mild fever to death. "NO shots,no school," is a slogan used by local school districts to inform parents that DPT shots are required before admission to schools. This forms another controversy surrounding the shots. Parents should be allowed to weigh the risks of pertussis against the risks of the vaccine and base their decision on these risks, rather being forced into vaccinating their children so they can attend public schools.

Pertussis has been with us for centuries. The disease reached its highest levels in the nineteenth century. The overcrowding and poor sanitation in the cities of America and Europe contributed to the spread of pertussis and other diseases. The death rates from pertussis declined steadily from this point until the vaccine gained widespread use after World War II. There were 210 deaths per million in the 1870s in the U.S. dropping to 21 per million in 1940. European countries saw a similar decline. In Sweden during the five years prior to World War I, 800 children died annually from pertussis. The decline continued with 10 deaths between 1951 and 1955. Even though there is no cure for pertussis, the overall improved health of babies and the use of medical skills to alleviate the secondary complications from the disease, such as pneumonia, starvation, and suffocation has contributed to the decline in deaths from pertussis

The pertussis bacterium is very complex and unstable. It was not until 1906 when Jules Bordet and Octave Gengou of the Pasteur Institute announced they had isolated the toxic Bacterium. Today, there is still much to learn of the of B. pertussis bacterium (*Bordetella pertussis*, named after Jules Bordet). John Robbins M.D. of the FDA (Food and Drug Administration) stated, "'Unfortunately, we do not know the toxic component responsible for central nervous system injury in pertussis disease,'" in 1978 (Coulter 20).

Even though little was known about the Bacterium, once it was isolated, Jules Bordet and Octave Gengou were able to make a vaccine in 1912. They grew the bacteria in large pots, then killed the bacteria with heat, using formaldehyde to preserve it. This process is very similar today, creating the crudest vaccine produced today. Whole cell pertussis vaccine is termed crude because it is not known which part of the pertussis bacterium produces immunity, or causes brain damage, or if it is the same agent that causes both reactions. The pertussis vaccine in not completely effective. Gordon Stewart of the University of Glasgow, Rutchill Hospital (an infectious disease hospital), states that, "about 30% of cases of whooping cough have been confirmed in fully vaccinated children (Stewart 135)." There have been several cases of so called epidemics initially attributed to declines in vaccination, upon further investigations the cases were from babies under two months of age (first DPT shot given at two months of age in U.S) and from the immunized population.

The side effects from the DPT vaccine are numerous. In the CDC (Center for Disease Control, the federal agency that monitors the quality of vaccines and promotes immunization) pamphlet for parents about childhood immunization it states about possible side effects, "with DTP vaccine, most children will have a slight fever and will be irritable within two days after getting the shot. More than one half of children develop some soreness and swelling in the area where the shot was given. More serious side effects can occur. A temperature greater than 102°F may follow 1 of 20 DTP shots. Unusual high-pitched crying may occur after 1 in 1,000 shots. Convulsions or episodes of limpness and paleness may occur after 1 in 1,750 shots. Children who have previously had a convulsion may be more likely to have another

after pertussis shots. Rarely, about once in 110,000 shots, inflammation of the brain (encephalitis) may occur, and permanent brain damage may occur about once in 310,000 shots" (U.S. 6).

This excerpt from the CDC pamphlet doesn't tell the whole story of side effects of the pertussis vaccine. In Britain a pronounced local skin reaction is considered a contraindication (to make further treatment inadvisable) to further injections of pertussis vaccine. The product insert for the pertussis vaccine from Lerdle Laboratories and Connaught Laboratories (manufacturers of DPT vaccine) states that fever over 103°F contraindicates further pertussis vaccine (Coulter 55).

Vomiting and diarrhea are possible side effects, as one mother reported after her three month old daughter received her first DPT shot, "Once at home, she started having terrible gas. About every couple of minutes, she would have violent, explosive gas. I have never heard a human sound like that. Maybe a 300 pound pig in a barnyard, but never a human (Coulter 57)."

The CDC pamphlet fails to warn parents of some side effect and when serious side effects do occur, the DPT shots should be discontinued. Blood disorders, excessive sleepiness and the side effects listed by the CDC as excessive fever, convulsions and high pitched screaming are absolutely contraindicated by the makers of the DPT vaccine.

SIDS (sudden infant death syndrome) has been linked to the DPT vaccine in some cases. William C. Torch M.D., former director of Child Neurology, Department of Pediatrics, at University of Nevada School of Medicine, presented a paper linking SIDS and DPT vaccination. He states that out seventy cases of SIDS studied 6.5% died twelve hours after receiving DPT vaccination, 13% after twenty-four hours, 26% within three days. He found in

the non-DPT group deaths peaked at 2 months and in the DPT group deaths peaked at 2 and 4 months. He also discovered in the non-DPT group deaths occurred most often in the fall\winter season and in the DPT group deaths were nonseasonal (Coulter 94). With 1 in every 600 live births dying annually from SIDS (Mendelsohn 4) and 45% of SIDS cases occurring within 3 days of DPT vaccination (Coulter 94), using 3.7 million births per year (Funkhauser 1342) I conclude that approximately 2700 more deaths annually might be attributed to the DPT vaccine. Or, at the very least these deaths are misrepresented as SIDS deaths if not related.

In light of the SIDS statistics, let us take a closer look at the CDC figures in their pamphlet stating that 1 in 110,000 for encephlapathy and 1 in 330,000 for brain damage from the vaccine. These statistics were derived from the British National Childhood Encephalopathy Study (NCES). The study encompassed all cases of acute neurological illness in British children from two to thirty six months of age who were admitted to hospitals between 1976 and 1979. The NCES only included those patients admitted to a hospital and those who had a convulsion lasting 30 minutes or longer (Stewart 136). In the thirty-five cases receiving compensation, for 100% disability, caused by pertussis vaccinations, from the West German Health Authority there were six that had encephalopathy without convulsions and twenty-two with convulsion lasting less than 30 minutes. In comparing this data, we might assume that the NCES missed the 80% of the cases where brain damage occurred. In using the NCES figures, the CDC ignored that Britain uses a milder vaccine and British children are vaccinated at a older age. These discrepancies could raise the incidence of permanent brain damage much higher (Coulter 373).

The NCES study also gives us estimates of the incidence of damage

caused by whooping cough. The NCES estimated that acute encephalopathy occurred once every 300,000 cases of whooping cough. When compared to the NCES figures for damage from the vaccine, the chance of neurological damage from the vaccine and the disease are equal (Stewart 136).

In America the first DPT shot is given at two months of age, then four months, then six months, eighteen months, then a final shot between four and six years of age. This is in sharp contrast to other industrialized countries: Sweden and West Germany, without pertussis vaccinations; England, with shots starting at six months of age; Japan, DPT shots starting at two years of age. Between 1946 and 1957 the Medical Research Council in England conducted field trail of the pertussis vaccine involving 50,000 children between six months and eighteen months of age, with 80% fourteen months of age or older. There were 44 cases of convulsions reported during these tests. Even though these test were designed to test the effectiveness of the vaccine not the safety, the U.S. uses the data collected from Britain to justify the safety of the vaccine in newborns. George Dick M.D. asks, "'How did it come about that it was assumed that babies of only a few months of age would react the same way as babies twice their weight? Why was immunization with pertussis-containing vaccines recommended in babies a few moths of age with no adequate toxicity tests having being done? (Coulter 33)'"

The DPT issue is filled with may cases of reserchers omiting or discounting data, because of the source. A recent article in the Journal of American Medical Association (JAMA) estimates the effects of delaying the U.S. pertussis vaccination schedule to 8, 10 and 12 months of age. They concluded that the increased incidence of whooping cough in children under the age of two, would outweigh the risks from the vaccine in the same group.

In their conclusion they considered SIDS deaths as associated by chance with the pertussis vaccine, therefore not valid for their conclusion (Funkhauser 1345). They also discounted the Japanese experience of delaying the pertussis vaccination until children are two years old. They did not use this data for their conclusion, even though they stated it "might support use of the new schedule over the current one,(1346)" because the data was not "collected in a controlled clinical setting,"by the japanese compensation system and covered a different age group (1346). Instead they cited the NCES study as being "collected using carefully designed methods. (1346)" A related article in the same issue of JAMA recommends the use of acellular pertussis vaccine currently being used in Japan. When referring to possible under reporting by the Japanese compensation system they state the chances are minimal (Noble 1355).

In deciding whether to vaccinate their children parents must also consider Alaska statute. In Alaska all children entering school, public or private, are required to be vaccinated including the DPT vaccination. This law was implemented, as all laws are, for the common good of the public. This law was designed to protect the public through mandatory vaccination from epidemics of these diseases. But, are healthy, well fed children living in a clean, sanitary environment in Juneau at risk? We know the vast majority of pertussis cases occurring world wide are from third word countries with a low standard of living and primitive sanitary conditions. These same condition prevailed in the U.S. during the major pertussis epidemics of the 1870s.

With 30 cases (9 confirmed) of pertussis in 1985 and only 5 cases (4 confirmed) in 1985 reported in Alaska, there were only 4 cases hospitalized,

without any deaths (Klatt). There is not any regulations governing the reporting of reactions from the pertussis vaccine in Alaska (Klatt and Frazier). Without a larger group of cases in Alaska, we cannot fi[illegible]re the risks of the vaccine against the risks of the disease.

Just as there is not complete data in Alaska on whooping cough or the reactions from the vaccine, parents must make a decision for their children on incomplete or distorted information. There has not been a major clinical study of the risks of the vaccine or the risks to society from the disease, without flaws. The NCES study, from which our government bases it decision to promote the DPT vaccine, omits pertinent cases, causing the data to be flawed. Even if the data was not flawed, the NCES finds the incidence of permanent brain damage from the vaccine approximately equal to the incidence of permanent brain damage from pertussis. With all the conflicting data and controversy surrounding the DPT vaccine, for there to be statute requiring immunization is shameful. Parents should be allowed to choose whether their children brave the risks of the vaccine or the disease, without the education of their children held hostage.

MEMORANDUM State of Alaska

TO: Elizabeth Ward
Director, Division of Public Health

DATE: March 4, 1988

FILE NO:

TELEPHONE NO: 561-4406

FROM: Michael E. Jones
Medical Epidemiologist

SUBJECT: Review of MSAEFI Reports and Philosophical Exemptions to Immunization

I have reviewed all MSAEFI (Monitoring System for Adverse Events Following Immunization) reports submitted to the Section of Epidemiology during the three years from 1985 through 1987. During this period, there were eighty-one reports of adverse events occurring in persons vaccinated within the preceding 28 days. Of these events, twenty-seven (33%) were classified either as anaphylaxis or as one of the illnesses listed in subsections 7-15 of the MSAEFI form (attached); reports of such events require review by the Immunization Project physician to verify the clinical information.

The vaccines associated with these reported adverse events and the number of instances in which they were associated with such reactions were as follows: diphtheria-pertussis-tetanus (DPT) vaccine, 22 instances; oral polio vaccine (OPV), 7; measles-mumps-rubella (MMR) vaccine, 4; hepatitis B vaccine (Heptavax), 1; and Hemophilus influenzae type b (Hib) vaccine, 1. (Numbers total more than 27 because some individuals received two or more vaccines concurrently.) The disproportionate number of DPT-associated adverse events may be related in part to the fact that DPT is the most frequently administered vaccine in Alaska: a total of 5 doses of DPT vaccine are recommended for adequate immunization, compared with 4 doses of OPV and one dose of MMR vaccine.

The serious reactions reported, and the number of times they were associated with individual vaccines or with vaccine combinations, are listed in the table which follows:

TABLE 1

VACCINE(S) ADMINISTERED PRIOR TO ADVERSE EVENT

Adverse Event	DPT	DPT/OPV	DPT/OPV/Hib	MMR	Heptavax	Total
Convulsions/Seizures	7	-	-	4	-	11
Screaming Episodes	3	4	1	-	-	8
Hypotonic/Hyporesponsive Episodes ("Collapse")	3	-	-	-	-	3
Encephalitis (without residual defect)	-	1	-	-	-	1
Weakness of Extremities	-	1	-	-	-	1
Anaphylaxis	1	-	-	-	-	1
Infantile Spasms	1	-	-	-	-	1
Neonatal Apnea	-	-	-	-	1	1
All Adverse Events	15	6	1	4	1	27

None of these reactions was fatal. Except for one child who had persistent, mild weakness of his extremities one year following onset of the adverse event, all patients recovered fully.

It is important to remember that these adverse events are defined as being temporally related to vaccination (that is, they have occurred within 28 days following vaccine administration). It is not possible, in any individual case, to establish a cause-effect relationship between immunization and an adverse event, nor is it possible always to exclude such a relationship. Of the eleven individuals who had seizures, four (36%) had had histories of seizures prior to vaccine administration. The child with encephalitis was clinically diagnosed as having "viral meningoencephalitis" (an inflammatory brain condition caused by a virus). The child with persistent weakness of his extremities was examined by a neurologist who did not believe that his impairment was related to immunization. However, since the possibility that such adverse events are related to vaccination cannot be discounted, it is important that they be included in Alaska's MSAEFI reports and be analyzed with nation-wide data by the Centers for Disease Control.

Table 2 illustrates the frequency with which certain adverse events were reported to follow DPT vaccination in Alaska during the 3-year period, 1985-1987. Based on the number of doses (33,073) of DPT vaccine known to have been administered during 1987, it is estimated that a minimum of 99,000 doses of the vaccine were administered during that 3-year period. Thus, on average, seizure activity occurred following one of every 14,143 doses of DPT vaccine; a hypotonic/hyporesponsive episode (transient "collapse") after one in every 33,000 doses; and encephalitis following one of the 99,000 doses. It is evident from the data in table 2 that the reported frequency of these events in Alaska is less than, or approximately equal to, the published frequency with which such events can be expected to occur within very large populations. Of course, these frequency estimates depend upon the completeness of reporting of vaccine-associated adverse events by health care providers; and reporting of "severe reactions to any vaccination" has been required (7 AAC 27.005) in Alaska since at least 1975. It is not possible, from existing data, to estimate completeness of reporting.

The National Childhood Vaccine Injury Act of 1986 requires that each health care provider who administers a vaccine containing tetanus toxoid or diphtheria, pertussis, measles, mumps, rubella, or polio components shall record in a permanent record the date of administration of the vaccine, the vaccine manufacturer and lot number of the vaccine, the name and address of the health care provider administering the vaccine, and any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary of the Department of Health and Human Services. In addition, each health care provider and vaccine manufacturer are to report certain adverse events or reactions, set forth in a vaccine injury table, which occur within specified time intervals following vaccine administration. These adverse events, which

vary according to the vaccine(s) specified, include anaphylaxis or anaphylactic shock, encephalopathy (or encephalitis), shock-collapse or hypotonic-hyporesponsive collapse, residual seizure disorder, paralytic polio, or any acute complication or sequela (including death) of these illnesses, disabilities, injuries, or conditions. As of October, 1988, federal law, as well as existing state statutes, will require Alaska's health care providers to record information about the vaccines they administer and to report any adverse events following administration of vaccines.

Finally, there are no published reports which document the effects of philosophical exemptions from immunization in states which have such an exemption nor is any organized information about this issue available from the Centers for Disease Control's Immunization Division. The American Medical Association's recommendation (American Medical News, August 14, 1987) that both philosophical and religious exemptions be removed from statutes requiring mandatory immunizations was prompted, in part, by reports of two large outbreaks of measles which originated in, and were facilitated by, infection of persons with religious exemptions to immunization. These outbreaks resulted in three fatalities and affected individuals without such exemptions. Thus, the concern that vaccine-preventable diseases occurring in persons with exemptions from immunization might have deleterious effects on the general population is clearly more than a theoretical consideration. However, no body of data exists that would allow a reliable assessment of the public health impact of philosophical or religious exemptions.

MJ/jh
Attachment

TABLE 2

ANALYSIS OF SELECTED ADVERSE EVENTS ASSOCIATED
WITH DPT VACCINE, 1985-1987, ALASKA

Adverse Event	Number of Adverse Events Reported	Estimated Number of Doses of Vaccine Administered 1985-1987	Observed Incidence of Adverse Event	Expected Incidence of Adverse Event *
Seizure/Convulsion	7	99,000	1 in 14,143 Doses	1 in 1,750 Doses
Hypotonic/Hyporesponsive Episode	3	"	1 in 33,000 Doses	1 in 1,750 Doses
Encephalitis				
- Total	1	"	1 in 99,000 Doses	1 in 110,000 Doses
- With Residual Neurologic Defect	0	"	0	1 in 310,000 Doses

* Hinman and Koplan, JAMA 1984, 251:3109-3133

REPORT OF ADVERSE EVENT FOLLOWING IMMUNIZATION

FORM APPROVED
OMB NO. 0920-0039
EXP. DATE 9/87

PERSONAL IDENTIFIERS

Patient:	Form Completed By:	Vaccine Administered By:	Physician or Health Facility Visited for Treatment of Adverse Event:
Name	Name	Name	Name
Address	Address	Address	Address
Telephone No.	Telephone No.	Telephone No.	Telephone No.

REPORT OF ADVERSE EVENT FOLLOWING IMMUNIZATION
DEPARTMENT OF HEALTH & HUMAN SERVICES, PUBLIC HEALTH SERVICE, Centers for Disease Control, Atlanta, Georgia 30333

PATIENT ID

Immunization Project Area | State Code | Seq. No. | County Where Administered: | County Code | MSAEFI REPORT NO. FOR CDC USE ONLY

Date of Birth: Mo. Day Yr. | Sex: M F | Date of Initial Report: Mo. Day Yr. | Source of Information: MD/DO Nurse Family Other

VACCINE HISTORY

Date of Immunization: Mo. Day Yr.

Vaccine Administered By: Pub. Pvt. Mil. Other

Vaccine Purchased By: Pub. Pvt. Mil. Other

Enter Below All Vaccines Given on the Date of Immunization:

	Vaccine Type	Mfgr.	Lot Number	Route	Site	No. Prior Doses
A						
B						
C						
D						

CLINICAL DESCRIPTION OF PRESENT ILLNESS

SIGNS AND SYMPTOMS OF PRESENT ILLNESS

Onset of 1st Sign or Symptom: Mo. Day Yr.

	Yes	No	Unk
1. Fever: Temp ≥(100°F (37.8°C) (7806)			
Felt Hot, But Temperature Not Measured: (7806)			
Highest Measured Temperature ____ . ____ F/C			
2. Local Reaction: Site ____			
Pain, Swelling, Increased Warmth, Induration or Lump Without Abscess (9993)			
Abscess Formation — Required Drainage or Drained Spontaneously (6829)+(9993)			
Results of Culture ____			
3. Rash: Other Than at Injection Site (7823)			
4. Adenopathy:			
Local (Injection Site Area) (7856)			
Generalized (7856)			
5. Allergic Event: (9995)			
Hives (7060)			
Angioneurotic Edema (9951)			
Wheezing/Asthma (4939)			
Anaphylaxis (9994)			
If "Yes," Interval from Vaccination to Onset: < 30 min / 30 min-6 hrs / > 6 hrs			
Was Blood Pressure Measured?			
If "Yes," Lowest B.P. ___/___			
6. Arthralgia/Arthritis:			
Pain in Joints (7194)			
Inflammation of Joints (Redness, Swelling, Tenderness) (7169)			
7. Convulsions: (7803)			
If "Yes," How many Episodes Following Immunization			
8. Encephalitis and/or Encephalopathy: (3483)			
Abnormal Lumbar Puncture (Enter Results in Laboratory subsection) (7920)			
Signs of Increased Intracranial Pressure (3482)			
Focal Neurologic Signs (3499)			
Coma or Marked Alteration in Level of Consciousness (7800)			

	Yes	No	Unk
9. Guillain–Barré Syndrome: (3570)			
10. Reyo's Syndrome: (3318)			
11. Polio: (0459)			
12. Paralysis other than GBS, Reyo's Syndrome or Polio: (3449)			
13. Other Neurologic Symptoms and Diagnoses:			
Aseptic Meningitis (0479)			
Infantile Spasms (Hypsarrhythmia, drop seizures) (3456)			
Bell's Palsy (3510)			
Hearing Loss (3899)			
Neuritis, Neuralgia (7292)			
Paresthesias (7820)			
Screaming Episode (High-Pitched Abnormal Cry or Screaming Lasting ≥ 3 Hours) (7998)			
Neurologic Symptoms not cited above (specify) ____			
14. Miscellaneous:			
Hypotonic, Hyporesponsive Episode (7859)			
Idiopathic Thrombocytopenic Purpura			
If "Yes," Lowest Platelet count (2873) ____			
Pancreatitis (5770)			
Parotitis (5272)			
15. Death:			
Sudden Infant Death Syndrome (SIDS) (7980)			
Non–SIDS Death (7981)			
If "Yes," Cause(s): ____			

LABORATORY:	Performed Yes	Performed No	Performed Unk	Results Normal	Results Abnormal
EEG (7940)					
BRAIN SCAN (7940)					
LUMBAR PUNCTURE (7920)					

Results if Abnormal:
WBC's ____ Opening Pressure ____
Lymphs (%) ____ Culture Results ____
Glucose ____ Other ____
Total Protein ____

Other Pertinent Information:

Signature of MSAEFI Coordinator:

PAST HISTORY

Seen by Health Care Provider: Yes No Unk Number of Visits | Hospitalized Yes No Unk Number of Days

Previous Illness Following Immunization: Yes No If "Yes," Date: Mo. Day Yr.
Vaccine ____
Describe Illness ____

Previous Convulsions in Patient: Yes No Unk.
If "Yes," With Fever Without Fever

History of Convulsions in Siblings or Parents: Yes No Unk.
If "Yes," With Fever Without Fever

FOLLOWUP

SEVEN DAY FOLLOWUP: Mo. Day Yr.
If recovered, send to State Office

30 DAY FOLLOWUP:
If not recovered at 7 days, carry out 30 Day Followup and send to State Office

	Duration of Illness	Recovered	Partially Recovered*	Not Recovered*	Not Located	Dead
SEVEN DAY FOLLOWUP	Days					
30 DAY FOLLOWUP	Days					

* Comments ____

Reviewed By Immunization Physician (Items 7 - 15 and Anaphylaxis): Yes No Unk
Signature of Reviewing M.D.

CDC USE

Results of One-Year Followup: Recovered Partially Recovered* Not Recovered* Dead Not Located *Comments ____

This report is authorized by law (42 USC 247b; 42 CFR 51 b). Its submission is needed to monitor possible reactions to vaccination and is voluntary except when required as a condition of immunization grant awards.

CDC 71.19 REV. 9-85

CDC Copy

Please enter as testimony
3/10 - HHESS - HB277: IMMUNIZATION of MINOR

H. E. S. S. TELECONFERENCE

I support HB 277 which would provide more information on the benefits and risks if the D.P.T. program.

I as a parent am uninformed of the risks and benifits of these shots, manditory by the State with no garantee or liabelity by the State in case of mental, physical, or mortal damage to my child.

I as a parent have become alarmed to see the negative reaction my child has had from these D.P.T. shots.

I as a parent demand to know the risk factor of the diseases. Are they in remission, currently life threatning or readily treatable by modern medicine? Does the D.P.T. vaccine garantee safe protection or in fact cause illness itself ?

Please help answer these questions. SUPPORT HB 277.

Eastham

Sincerly Terry Eastham Nancy Eastham

Terry and Nancy Eastham

Soldotna

My name is Eileen Wagner. I am the parent of a 3 1/2 year old boy who has severe allergies which began right after his first DPT shot. I think the shot triggered the allergies. Doctors do not think so. Onset of allergies is not considered a contraindication to further shots. There is a great gray area of vaccine reactions, there are many children who don't collapse, die, or suffer brain damage from the shot, but who are "slightly" injured, and never reported.

John seemed to be a normal baby at the time of his first DPT shot at 3 1/2 months of age. As the public health nurse prepared the shot, I asked "Don't I have to sign something?" "oh no, we don't do that," she replied. I remember being surprised, since we had lived in Wisconsin when one of my older children was getting her shots, and each time I had had to read and sign a lengthy warning about vaccine risk. (I have 2 older fully vaccinated children.)

I was given no information of any kind. After the shot, John went to sleep for 16 hours It was a profound, deathlike sleep - he didn't move a muscle during that time, even when I felt his head for fever.

Within 2 weeks the skin trouble had started.

It was the beginning of a year of agony for my son. He itched intensely at all times, clawed himself bloody, even had hives on the soles of his feet. His nose and eyes ran constantly, his body was swollen all over. He writhed in my arms as I nursed him. He was completely breastfed, and exquisitely sensitive to the foods I was eating. Gradually we have learned what makes John tick, and he is now living a normal life, though his diet and environment are rigidly controlled. We carry an injection of epinephrine for emergencies. He still has occasional swelling of the windpipe, as well as many lesser allergic reactions.

The important thing for you to know is that the many doctors, both here and in Seatttle, I saw during that first year steadfastly denied any connection with the DPT shot. It was all so unbelievable to me that I began to do research at the State Library about vaccines, allergies, the immune system. I don't pretend to be an expert. But I found out enough to decide that further vaccination is too risky for John. And I found a Canadian doctor who had studied babies like John for 30 years. We had many phone conversations and during one he said that vaccination had triggered the allergies of many of the most severely allergic infants. "It's quite common, actually." The reason this doctor could level with me and admit that the shot triggered the allergies, whereas 4 American doctors denied it, is that Canada, although they recommend vaccination, does not mandate it.

The mandatory nature of the vaccine policy puts doctors in the position of having to deny a lot of reactions, to deny in their own minds as well as to the patient. When my dr. urged me to continue to vaccinate John, offering to withold the pertussis component, he said, "I'll admit I'll be biting my fingernails waiting to see if John has a reaction."
The fault does not lie with individual doctors but with the AAP, which provides doctors with guidelines.

I am uneasy about not having John vaccinated against tetanus and polio. I would really like to do it. I would like to be able to study state or national statistics and compare the number of children reported to have had allergic reactions after their DPT to the number of allergic reactions after DT, without pertussis. My question is, was it the pertussis component? or was it the shock of vaccination to a child who apparently had latent allergies? There is no way to get an answer to my question - no statistics exist. For this reason, I urge you to require health care providers to report <u>all</u> adverse reactions to vaccines.

There is a moral question here - can a free society require citizens to be injected with a toxic vaccine and continue to deny the full extent of risk involved? We look to you to get the facts out on the table. Only if we know the facts can we decide if the benefits really do outweigh the risks.

TESTIMONY BEFORE THE HOUSE H.E.S.S. COMMITTEE
March 10, 1988 by: Judy Ames, Box 824, Soldotna, Alaska 99669

I am a supporter of HB 277. This bill effectively addresses the vaccination issue so that I as a parent may try and raise my healthy child by known and safe health standards.

For this testimony, I would like to address one issue in particular - the questionable ingredients contained in these vaccines. Particularly, formaldehyde, mercury, and aluminum. These 3 ingredients are listed on the manufacturer's insert for the DPT vaccine with the exception of Connought Co. making no mention of formaldehyde. I am very particular about the substances I and my family consumes and I object to any level of formaldehyde, mercury or aluminum entering my child's body. It does not take many supposed or concrete findings to raise my objections to vaccinating my child with vaccines containing these potentially harmful toxins. Our state health dept. is not required to provide parents with a list of ingredients along with other vaccination information. The new Federal law, "National Childhood Vaccine Injury Act of 1986" under Sec. 2126 (c) Information Requirements, has no mention of requiring the manufacturer's product insert be presented to parents along with other pertinent vaccination information. Parents need to be informed of the ingredients entering their child's body at the time of vaccination. HB 277 would see to those requirements.

There are many uncertainties as to the rise and cause of certain diseases and immunological disorders in our society. For example, we are seeing an increase in allergies. In their article entitled "Bringing Vaccines into Perspective," Harold E. Buttram, M.D. and John Hoffmann suggest ..."current mass vaccination programs must be highly suspected as contributing to the increased incidence of allergic disorders. And from James Gibson's book, Formaldehyde Toxicity, "The characteristics of an allergic mechanism are that the response can be evoked in sensitized individuals with very small amounts of formaldehyde."

I am concerned about the possible link between aluminum (a cumulative carcinogen) and Alzheimer's disease, as reported in research entitled Physiological Behavior and Frontiers in Neurology and Neuroscience Research.

According to the Merck Index, ethylmercuric chloride used in preparation of thimerosal (another ingedient in the DPT vaccine) has a caution of being highly toxic.

I am concerned about the standards by which the ingredients used in vaccines are screened as in the monkey kidney cells used in growing the polio vaccine. Can we be guaranteed they contain no latent virus or disease harmful to the human body?

(1)

The list of questions and concerns goes on and on. The manufacturer claims the ingredients used in these vaccines are set at safe levels. What long term studies ON HUMAN BEINGS are being done to prove these safeties? If our own health department calls its vaccine reaction reporting system passive, what can be said about studies tracing the effect of the potential toxins being injected as part of our vaccines. How can any conclusive, concrete findings about the effect of these ingredients on infants and all human bodies be established when a system has obvious flaws?

From my point of view it appears that vaccine safety is not proven, however, the risks are substantial. Please consider this issue is full depth. Thank-you.

(2)

Deborah Gravel
Peter Dwyer
Rt. 2 Box 45
Ketchikan, Ak.99901

To Concerned Legislators,

We seriously question the safety of the DPT vaccine. We cannot ignore the dangers to our children's health that compulsory vaccinations represent. We feel that we must have a choice of whether to vaccinate our children or not.

We will not try to convince you of all the risks involved with vaccinations. We hope only that you will research this topic enough to acknowledge that there are good reasons to be concerned about the safety of children being vaccinated.

We feel that HB 277 is a beginning for concerned parents. We need a reporting system to document how children are reacting to the shots. Vaccines are administered with no guarantees as to their safety or effectiveness, Yet parents are urged to vaccinate despite the fact that Sudden Infant Death Syndrome, polio, encephalitis, and rheumatoid arthritis have been conclusively linked to vaccination.

We will not vaccinate our children. We are gravely concerned with their wellbeing and as responsible parents cannot take the risk to their health that vaccines represent.

We urge you to pass HB 277 as it is written. We feel it is our personal right to safe guard our children's health and we ask you to respect our rights.

Sincerely,

Deborah Gravel
Peter Dwyer

Alaska State Legislature

(1)

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

committee on HB 277 bill/subject, dated 3-10-88.

My Name is Cheryl Rykasaguski.

I am a supporter of HB277 for a variety of reasons. At this time, I will address one of these reasons.

It has been the experience of members of the Alaska Chapter of DPT that Doctors and Public Health Providers who administer vaccines refuse to admit that symptoms a child experiences after a vaccination can possibly be a reaction to that vaccine.

This fact leads me to Question the current system of voluntary reporting of adverse reactions first to the State Health Department and then on to the Center for Disease Control for the purpose of compiling statistics. It appears that there is a Conflict of Interest for a physician to diagnose a vaccine induced injury in a child whom they themselves vaccinated. How objective can they be when their Livlihood may be threatened

Signed: _____
Testifier

_____
Representing (Optional)

_____
Address

_____
Phone No.

Alaska State Legislature

(2)

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

committee on HB 277 , dated 3-10-88 .
bill/subject

by financial liability if a lawsuit occurs. Cont'd. The emotional repercussions of watching a child suffer as a result of a drug that they administered.

Now, Put yourself in the frightening position of a parent who has a child reacting to a vaccination. No one will even acknowledge the reaction or take responsibility for treating your childs reaction. Where do you turn?

The Alaska Vaccine Reform Legislation, HB 277, strives to correct these inconsistencies in the reporting of reactions. One long term benefit will be accurate statistics on adverse reactions to vaccinations.

Signed: Cheryl Rykaczewski (RYKACZEWSKI)
Testifier

Representing (Optional)

Box 311 KASILOF, AK 99610
Address

262-4937
Phone No.

Alaska State Legislature

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

committee on HB 277, dated 3-10-88.
bill/subject

Feel HB 277 unnecessary. Many dollars and much time spent in effort toward immunized population. Prevention important! Medical and religious exemptions in place. That is enough!

Signed: Beth Taeschner
Testifier

Self - Retired School Nurse. Former PHN
Representing (Optional)

P.O. Box 56 Soldotna, AK 99669
Address

262-4287
Phone No.

Teleconference

I support bill HB277

I believe parents have the right to free choice regarding the health of their children

I feel parents in Alaska are concerned enough and informed enough to make the choice that is best for their children.

I do not feel the medical community should take this choice away from parents.

Lee Conay
PO Box 3234
Soldotna, AK 99669

Jacqui Conduey

I believe that all parents have the responsibility to educate themselves and to use that knowledge in making decisions regarding their children's welfare. Society has demanded that all children be immunized. However most parents are unaware there are many risks associated with all vaccines. When my daughter received her first DPT shot she cried, a loud piercing cry for 2 days. In my ignorance, I just accepted it as an inevitable side effect of the vaccine. Later, as her second DPT was approaching, I started to question how anything that could affect my healthy 2 month old so strongly, could really be beneficial. So I began reading and learning about immunizations. I found that many parents and doctors agree that mass immunization ~~are~~ are neither a guaranteed preventative against the illnesses nor were they risk free. I also found that because of this many states and other countries do not require them. I was not informed by any health care worker of any of this information. Alaska does not require that this very pertinent information be shared with parents or allow exemptions based on this knowledge. It is time for this state to adopt HB 277.

Alaska State Legislature

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

committee on HB 277, dated 3/10/88.
bill/subject

I want to urge HB 277 NOT be passed. A philosophical exemption would endanger the health + lives of Alaskan children. As a society we chose to protect our children in various ways + I believe it's reasonable to continue to enforce mandatory immunization. I'm afraid many people have been lulled into complacency, forgetting the past + potential future ravages of vaccine-preventable diseases. Regarding the education component required in this bill — it's important for people to know that Public Health Nurses administer a large percentage of immunizations in the State + because of a required procedure of informing parents about risks, benefits, + adverse reactions, parents are well informed. I, too, empathize with parents + their testimony can sound convincing, however, it's important to for everyone to realize there's a big difference between temporal association of vaccine + reactions + proof of cause. The vaccines, unfortunately aren't all perfect, but a philosophical exemption is not the answer. Benefits of vaccination still outweigh risks.

Signed: Debbie Golden
Testifier

self
Representing (Optional)

P.O. Box 10533 Fairbanks, AK. 99710
Address

HM: 457-4022 WK: 452-1776
Phone No.

Alaska State Legislature

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

committee on Immunizations HB 277 bill/subject, dated 4/17/87.

I support HB 277 due to the personal experience with both of my children. My son was given the measles by his measles vaxination and my daughter received an "extreme allergic reaction" - as stated by her doctor from her DPT. She had a 105° F fever and was limp & lifeless for 10 days. This happened 2 times as when we moved to another state another DPT booster was required. Again she had the same reaction. The subject of immunization needs more investigation & the public needs to be informed. I have seen illnesses come and go. Could it be that by immunizing we → (over)

Signed: M. Suzanne Rich
Testifier

Representing (Optional)

1451 Flat Mtn. Rd.
Address

457-8086
Phone No.

Alaska State Legislature

Please enter into the record my testimony to the H&SS
committee name

committee on HB 277 , dated 03/10/88
bill/subject

there is a growing body of scientific evidence indicating that animal retro-viruses may have contaminated the live vaccines with which we have all been inoculated for the past 30 yrs. these animal viruses, injected into the human body, may have combined with human genetic material to form the AIDS virus. one of the retro viruses only 4) have been identified, all in domestic animals - is apparently the closest virus to AIDS yet discovered. we've pumped live viruses into millions of people over 3 decades, to believe there's no downside is naive. the AIDS virus is widely believed to have begun in Africa where massive small pox vaccinations were conducted from late 60s to 80-81. the standard method for developing the vaccine in Africa was to grow the pox in the bellies of cows. Most cow herds are taught to contain retro-viruses.

Signed: _____
Testifier

Dave Jones
Representing (Optional)

Box 81785
Address

456 2871
Phone No.

9/86 Legislative Information Office

Alaska State Legislature

Please enter into the record my testimony to the H.E.S.S.
committee name

committee on HB277 Vaccinations, dated 3/10/88.
bill/subject

I support HB277. The power of the state should not be used to compel people to medicate themselves or their children against their will. This is a civil rights issue.

The long-term effects of vaccines are not known. There has been a large increase in chronic degenerative diseases in countries with widespread vaccination programs. Some authorities argue that this is due to weakened immune systems in vaccinated persons.

The situation is much like that of radiation. Thirty years ago we knew little about long-term effects radiation, especially at low levels. Until medical science asks the question: what are the long term effects of vaccinations?, there will be no answers. We have asked this question about radiation, and we are beginning to get the answers now (and they are rather grim, the victims say).

People should have the right to examine the pros and cons of this issue, and make an informed choice.

Signed: Ed Berg — graduate student in biology at UAF and a parent
Testifier

Representing (Optional)

2682 Goldhill Rd, Fairbanks AK 99709
Address

479-3796
Phone No.

Alaska State Legislature

Please enter into the record my testimony to the H.E.S.S.
committee name

committee on HB 277 - Immunizations, dated 3/10/88.
bill/subject

There is a school of medical science called Natural Hygiene. The following discussion against immunizations is from an Australian physician Alex Burton's (MD, D.A.D.F.) speech taped at the July 1987 Natural Hygiene Society's international conference at St. Catharines, Ontario.

At this conference, Burton said that generally disease is thought of as an "attack" of an "invader" - and that the physician is supposed to destroy this "attacker" or "conquer the disease." A natural hygiene physician conversely sees a disease not as something negative, but positive: disease is seen as the process of the body healing itself. For example, if you say that "on Monday I was well, but on Tuesday I was sick," the Natural Hygienist would say that on Monday you were sick and on Tuesday you were getting well.

The concept of immunization - ie. to make someone immune, →

Signed: Linda Redman LINDA REDMAN
Testifier

Representing (Optional)

21682 Goldhill Rd.
Address

479-3796
Phone No.

Municipality of Anchorage

P.O. BOX 196650
ANCHORAGE, ALASKA 99519-6650
(907) 343-4674

Tom Fink
MAYOR

MUNICIPAL HEALTH & HUMAN SERVICES COMMISSION

March 9, 1988

Representative Johnny Ellis, Chair
House Health, Education and
Social Services Committee
Alaska State Legislature
POB V
Juneau, Alaska 99811

Dear Representative Ellis,

The Municipal Health and Human Services Commission can not support HB277. In fact, HB277 is entirely contrary to sound public health policy. The Municipal Health and Human Services Commission is, therefore, opposed to changes in current state policy regarding immunizations. The effects of many infectious diseases, such as whooping cough, are contagious and can be devastating. Current state policy protects the public's health by attempting to prevent an outbreak through immunization.

We do, however, see the merits of reporting adverse reactions to immunizations and maintaining records of the vaccine manufacturer and lot number. We would like to recommend such measures are taken as a means of protecting the consumer.

If you have any questions, please feel free to call me (562-2828) or our staff (343-4674).

Sincerely,

Gari B. Andreini, Chair
Municipal Health and Human Services Commission

cc: Representative Mike Navarre, Sponsor
House HESS Committee
Myra Munson, Commissioner, Department of Health and Social Services, State of Alaska
Anchorage Municipal Assembly
Tom Fink, Mayor, Municipality of Anchorage
Ron Garzini, Manager, Municipality of Anchorage
Robert A. (Bert) Hall, Director, Department of Health and Human Services, Municipality of Anchorage

SJ4/dPD20

CORRECTION

THIS DOCUMENT
HAS BEEN REPHOTOGRAPHED
TO ASSURE LEGIBILITY

Alaska State Legislature

Please enter into the record my testimony to the H.E.S.S
committee name

committee on HB 277 - Immunizations, dated 3/10/88 .
bill/subject

There is a school of medical science called Natural Hygiene. The following discussion against immunizations is from an Australian physician Alex Burton's (MHO, D.O.D.F.(2)) speech taped at the July 1987 Natural Hygiene Society's international conference at St. Catharines, Ontario.

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The concept of immunization - ie. to make someone immune, →

Signed: Linda Redman LINDA REDMAN
Testifier

Representing (Optional)

21082 Goldhill Rd.
Address

479-3796
Phone No.

implies that a person can have the freedom to do as he or she pleases without any consequences. Nature is not like that, Burton says. He continued, disease has three stages: the cause, the process of healing, & the effect. Immunization suspends causality.

Immunization relates to certain foreign substances that gain entrance to the body. These foreign substances are often protein substances and are called "antigens." The body's means of resisting these antigens is to produce substances by lymphocytes called "antibodies."

[As a side note, according to Natureal Hygiene, prevention of disease is possible by optimum nutrition. Intaking "high octane-type fuels" and maximizing fitness will keep the body's energy reserve level overflowing and thus can help prevent disease. If disease occurs a high health and energy level can help the process of disease to successfully repair the body.]

The theory of auto immune disease says that the body no longer recognizes itself, and the antibodies attack the body's own tissue, destroying it. Dr. Burton continues, says that this is a process that results from a long time of ignoring causes and supressing disease. The cause of auto immune deficiency for example is that a person's body is so toxemic and enervated (from poor nutrition, and thus a low vital force) that the result is an almost total collapse of the body's mechanisms to heal itself...

Basically, I believe immunization tends to override the body's own immune system. There is growing concern that many medicines serve to inhibit the body's natural defense mechanisms and supress the full healing process thus allowing the later onset of immune deficient diseases such as cancer and AIDS. I support HB 277 as I believe people in this state should have the very important choice of deciding what to put in or keep out of their bodies.

Municipality of Anchorage

P.O. BOX 196650
ANCHORAGE, ALASKA 99519-6650
(907) 343-4674

Tom Fink
MAYOR

MUNICIPAL HEALTH & HUMAN SERVICES COMMISSION

March 9, 1988

Representative Johnny Ellis, Chair
House Health, Education and
Social Services Committee
Alaska State Legislature
POB V
Juneau, Alaska 99811

Dear Representative Ellis,

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If you have any questions, please feel free to call me (562-2828) or our staff (343-4674).

Sincerely,

Gari B. Andreini, Chair
Municipal Health and Human Services Commission

cc: Representative Mike Navarre, Sponsor
House HESS Committee
Myra Munson, Commissioner, Department of Health and Social Services,
State of Alaska
Anchorage Municipal Assembly
Tom Fink, Mayor, Municipality of Anchorage
Ron Garzini, Manager, Municipality of Anchorage
Robert A. (Bert) Hall, Director, Department of Health and Human Services,
Municipality of Anchorage

SJ4/dPD20

HB

277

file 2

MEMORANDUM State of Alaska

TO: John Katz, Special Counsel
Office of the Governor
Washington, D.C.

DATE: March 3, 1988

FILE NO: SD:3

TELEPHONE NO: 465-3030

THRU:

SUBJECT: Supplemental Funding for Vaccine Purchases

FROM: Myra M. Munson
Commissioner
Department of Health and Social Services

The federal Immunization Compensation Bill (ICB) recently signed into law by President Reagan imposes a federal excise tax on vaccines. As a result, vaccine manufacturers have announced substantial price increases for vaccines effective January 1, 1988. As the following table shows, these price increases have serious budget implications for Alaska's immunization program in FY 89.

Vaccine	Old Price Per Dose	New Price Per Dose	Difference		Doses Needed/Yr.		Extra Cost/Yr.
DPT	$7.6933	$9.623[1]	$1.9297	x	60,000	=	$115,782
MMR	$10.67	$17.78[2]	$7.11	x	15,000	=	106,650
OPV	$1.363	$1.363[3]	--	x	54,000	=	--
Ped DT	$.13	$.19[4]	$.06	x	2,500	=	150
Adult TD	$.096	$.156[4]	$.06	x	25,000	=	1,500
Mumps	$5.97	$11.90[2]	$5.93	x	500	=	2,965
						Total	$227,047

DPT = diphtheria, pertussis, tetanus; MMR = measles, mumps, rubella; OPV = oral polio vaccine; Ped DT = pediatric diphtheria/tetanus; Adult TD = adult tetanus/diphtheria

[1]Includes per dose federal excise tax of $4.56
[2]Includes per dose federal excise tax of $4.44
[3]Includes per dose federal excise tax of $ .29
[4]Includes per dose federal excise tax of $ .06

New prices are current as of January 27, 1988 (MMR and mumps are estimates based on manufacturer's announcement February 18, 1988).

The manufacturers of DPT and OPV have adjusted their base prices to reflect their reduced liability as a result of the ICB. The manufacturer of our MMR and mumps vaccines has just announced a possible 25% increase in price, effective February 25, 1988, in addition to the federal excise tax. This is reflected in the prices shown in the table.

Vaccine prices generally increase every year, and we anticipate this in our budget requests. Before the ICB was signed, we had already asked for an FY 89 budget increment of $125,000 for vaccine purchases. The $227,047 shown in the table as the total extra cost per year represents a projected FY 89 deficit beyond the $125,000 already anticipated and requested.

It is my understanding that the ICB contains language allowing for an appropriation of federal funds to help states pay the expected higher vaccine costs. This assistance is crucial to Alaska.

I request your assistance in encouraging the Alaska delegation, the sponsors of the bill, and the key members of the relevant finance and budget committee to appropriate sufficient funds in the coming federal budget to provide financial assistance for vaccine purchases to states requiring such assistance.

cc: Representative Mark Boyer
Representative Johnny Ellis
Representative Steve Frank
Representative Cliff Davidson

Dissatisfied Parents Together
Alaska Chapter
Box 1746
Soldotna, Alaska 99669
262-3825

Representative Johnny Ellis
Co-Chairman
House H.E.S.S. Committee
Juneau, Alaska 99811

March 17, 1988

Dear Representative Ellis;

Thank you and the H.E.S.S. committee for sponsoring the teleconference of March 10th to hear HB 277 again. I took part in the teleconference in Soldotna and became quite frustrated during Dr. Middaugh's testimony. For some reason that the legislative liason could not correct, we could not discern what Dr. Middaugh was saying about 95% of the time. So until I am able to review his testimony in writing, I can't comment on his testimony in this correspondence.

What I would like to address is the legislative process that HB 277 is involved in now. I understand that it has been referred to a H.E.S.S. subcommittee for possible reconstruction in order to avoid conflict with the impending enactment of the National Childhood Vaccine Injury Compensation Act.

I have compared both bills and after discussing the situation with other members of AK-DPT have prepared a written presentation that outlines what we feel must be retained in HB 277 to best serve the health interest of Alaskan children.

Ideally, we want some major improvements in the immunization program mandated before the legislature adjourns this spring. Since I am unsure of the legislative process and time allowances required to finalize this legislation, I would appreciate it if you would contact me as soon as possible to discuss what may or may not happen with HB 277 this year.

Thanks again,

Shannon Kohler

Shannon Kohler
President

cc; Pat Malone
Lisa McClaren

HB 277, AN ACT RELATING TO THE IMMUNIZATION OF MINORS

Alaska Dissatisfied Parents Together (AK-DPT) recommendations as to how bill could be reconstructed to comply with National Childhood Vaccine Injury Compensation Act (N.C.V.I.C.A.), to facilitate legislative progress, and to serve the health interests of Alaskan children.

Recommendations will be referred to according to page number and line number of HB 277.

Page 1. Section 1, lines 8-17; as refers to philosophical objection to vaccinations.

AK-DPT wishes to retain this portion of HB 277; however, it is open for discussion.

Page 1. Article 3A, Section 18.15.300 Immunization Information, lines 26-28 (2); as refers to manufacturer's product insert being required to be given to parents

AK-DPT stresses that this section must be retained for the simple reason that this is the only material that lists the ingredients of the vaccine it accompanies. Ingredients need to be known for a variety of reasons, the most important is to identify and avoid allergic reactions. The federal N.C.V.I.C.A. does not address ingredients as required parental information. Also, since manufacturers vary on occassion (as does accompanying data) parents should as a matter of course be presented whatever insert is applicable for vaccine being administered that day, week, or month, etc. Also, contraindications and adverse reaction listings can vary. Providing the manufacturer's insert will help parents to discern what the manufacturer recognizes as a contraindicating reaction to a vaccine and thus facilitate parental communication with health care providers so that health care providers will be able to effectively and accurately comply with page 12, Part C of the N.C.V.I.C.A: Assuring a Safer Childhood Vaccination Program in the U.S., "Recording and Reporting of Information", Section 2125(B)

Page 2, lines 7-9 (b); as refers to hospital provided parental information.

Since the State Health Department does already provide some material at birth, this section should remain to insure that the manufacturer's product insert also be presented.

Page 2, Section 18.15.310: Adverse Reaction Reports, lines 14-21

AK-DPT stresses that the wording of this section must remain as such. The N.C.V.I.C.A. does mandate that "health care providers" report serious adverse reaction, but only if they administer vaccines. See page 14 of federal bill, "Definitions", Section 2133 (1).

HB 277 requires that all health care providers comply, because more of them will see reaction than those that administer vaccines. i.e. physicians, emergency room personnel. It also mandates that a form be constructed so parents can also report a reaction. (See attachment of Maryland model parental form.)

Since HB 277 requires more specific reporting, its reconstruction needs to mandate that all reports (copies of federal reports) need to be sent to the Alaska Public Health Department, so that accurate Alaska statistics, follow-up, and legislative reporting may occur. Specifics to follow.

Page 2. lines 26-29 (c) Long Term Follow-up

The N.C.V.I.C.A. does not address long term follow-up of all adverse events. This must be done in at least our state to obtain an accurate benefit/risk ratio involving vaccinations. This also must be done to detail the effects of vaccination on individual children. Every statistic is a person and their developing problems must be chronicled.

Page 3. lines 1-5 (c) Long Term Follow-up (cont'd.)

An annual report prepared by the Health Department and presented to legislators is essential for the reasons stated in bill. This report would then be available to public. This is necessary for public awareness.

"TRIAL

"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

: USC
00aa-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.

Alaska needs to have this exception

"VACCINE [illegible]ATION

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

REPORT OF: SERIOUS ADVERSE REACTION FOLLOWING RECEIPT OF PERTUSSIS VACCINE.

Patient's Name and Address _____ Sex _____ Age _____ Phone _____

Describe Reaction (Include date vaccine was administered and type of vaccine)

_____

_____

_____

Hospitalized? _____ Name of hospital _____

CUT ALONG THIS LINE

If your child has a serious reaction following pertussis vaccine, this information must be reported to the health authorities. Normally, this will be done by your doctor or clinic once they have knowledge of the event. You also may file a report by completing the form above and submitting it to your respective local health department listed below.

NAMES, ADDRESSES AND PHONE NUMBERS OF MARYLAND'S LOCAL HEALTH DEPARTMENTS

Allegany, Box 1745, Willowbrook Road, Cumberland, 21502	777-5600
Anne Arundel, Health Services Bldg., 6 Harry S. Truman Pkwy., Annap., 21401	224-7095
Baltimore, New Courts Bldg., 401 Bosley Ave., Towson, 21204	494-2724
Calvert, P.O. Box 980, Prince Frederick, 20678	535-5400
Caroline, Box 10, 411 Franklin St., Denton, 21629	479-0556
Carroll, Box 845, 540 Washington Rd., Westminster, 21157	857-5000
Cecil, Court House Annex, 2nd Floor, Elkton, 21921	398-5100
Charles, Box 640, LaPlata, 20646	934-9577
Dorchester, Rt. 50 & Woods Rd., Box 519, Cambridge, 21613	228-3223
Frederick, 12 E. Church St., Frederick, 21701	694-1700
Garrett, Garrett Co. Medical Center, Oakland, 21550	334-8111
Harford, 119 Hays St., Box 191, Bel Air, 21014-0191	838-3047
Howard, 3450 Court House Dr., Box 476, Ellicott City, 21043	992-2333
Kent, College Ave., Ext., Box 359, Chestertown, 21620	778-1550
Montgomery, 100 Maryland Ave., Rockville, 20850	681-5000
Prince George's, Hospital Rd., Cheverly, 20785	386-0300
Queen Anne's, 206 N. Commerce St., Centreville, 21617	758-0720
St. Mary's, Tudor Hall Dr., P.O. Box 316, Leonardtown, 20650	475-8921
Somerset, Box 129, Dr. Robert Johnson Health Center, Westover, 21871	651-0822
Talbot, 100 S. Hanson St., Box 480, Easton, 21601	822-2292
Washington, 1302 Pennsylvania Ave., P.O. Box 2067, Hagerstown, 21740	791-3200
Wicomico, 300 W. Carroll St., Salisbury, 21801	749-1244
Worcester, P.O. Box 249, Snow Hill, 21863	632-1100
Baltimore City, 111 N. Calvert St., Baltimore, 21202	396-4187
State Health Dept., 201 W. Preston St., Baltimore, 21201	225-6677

Turn page for more→

IMPORTANT INFORMATION AVAILABLE TO YOU

Each time your child is given a DTP shot, the following information is recorded in a permanent record and is available to you from your doctor or clinic upon request.

- the date and time of day the vaccine was given,
- the DTP dose number,
- the name and title of the person who gave the shot,
- the vaccine manufacturer name, and
- the vaccine lot number.

You should keep information concerning the dates of any vaccine given to your child in a permanent immunization record plus the details of any reactions that may occur until your child enters school. The Maryland Department of Health and Mental Hygiene, Division of Immunization, 201 W. Preston Street, Baltimore, MD 21201, provides a personal Maryland Immunization Record for this purpose.

IMMUNIZATION REQUIREMENTS FOR ENTRY TO SCHOOL

There is a law in Maryland that requires children to have certain immunizations in order to enroll in a public or private school. Before a child is allowed to attend school, proof of immunization must be shown. Proof of immunization consists of a written record showing the month, day and year of each immunization, along with the signature of the person or clinic which administered each dose.

The following immunizations are currently required in Maryland.

- DTP — 4 doses for pupils less than 7 years of age,
- DT/Td — 3 doses for pupils 7 years of age and older,
- Polio — 3 doses for pupils less than 18 years of age.
- Measles — 1 dose of live virus vaccine on or after the first birthday, or a blood titer of at least 1:4, and
- Rubella — 1 dose of live virus vaccine on or after the first birthday, or a blood titer of at least 1:8.

As with pertussis, there are medical reasons that could exempt some children from mandated immunizations, the law allows a religious exemption, also.

SUMMARY

You have the right to receive and understand the information contained in this booklet. If you don't understand any part of it, ask to discuss it before your child receives pertussis vaccine.

Maryland law requires that most children receive, among other vaccines, pertussis vaccine in order to attend school. However, your child could be exempted temporarily or permanently from this mandate if he or she meets the appropriate conditions for such exemptions that are outlined in this booklet.

Under Maryland law, if your doctor decides that your child should not get the vaccine, his judgment is final. It cannot be reversed by the State or Local Health Department or by school officials. Except in an emergency, your child cannot be kept out of school because of the doctor's decision not to give your child the vaccine.

DHMH PPAAP
REV 01/90/87

IMPORTANT INFORMATION ABOUT PERTUSSIS AND PERTUSSIS VACCINE

Prepared for you by:

The Maryland Department of Health and Mental Hygiene
The Medical and Chirurgical Faculty of the State of Maryland
The Maryland Chapter of the American Academy of Pediatrics

INTRODUCTION

This booklet is intended to answer some of the questions you may have about pertussis (whooping cough) and pertussis vaccine. You should read this information before your child receives the DTP vaccine.

Pertussis or whooping cough can be a serious disease. In some persons, especially very young children, it can cause permanent brain damage or even death. In order to protect persons from whooping cough, Maryland law requires most children to get four DTP shots before they go to school.

However, not all children have to get pertussis vaccine. In some cases, the "P" part of the DTP vaccine can cause serious reactions, including permanent brain damage or even death. So some children should not get the "P" part of the DTP vaccine at all. Also, for some children the series of pertussis vaccine should be delayed.

So it is very important to read and to understand this information about the disease and the pertussis vaccine to protect your child's health. If there is something in this booklet you don't understand, ask the person who gave you the booklet to explain it.

WHAT IS PERTUSSIS (WHOOPING COUGH)?

Pertussis, also known as whooping cough, is a highly contagious disease caused by the bacteria, *Bordetella pertussis*, and is spread through the air to others. The disease starts with cold symptoms and progresses to repeated, violent coughing spells which can interfere with eating, drinking and breathing. The coughing spells may be accompanied at the end by a "whooping" sound while the victim struggles to inhale. The disease will normally last for one-to-two months.

WHAT ARE THE RISKS OF GETTING WHOOPING COUGH?

According to the Centers for Disease Control (CDC), in the past ten years an average of 1,800 cases of pertussis have been reported each year in the U.S. Since many cases go unrecognized or unreported, the real numbers could be much higher.

Over half of the reported cases occur in children under 1 year of age. Most reported cases of whooping cough involve children under 5 years of age. This is why vaccination in early life is so important. Older children and adults.. even those who have been vaccinated can also contract the disease and are believed in many cases to be the source of infection in the younger children.

Although there is some disagreement about how effective the vaccine is, most children who receive the series of pertussis vaccine are protected from whooping cough. The disease is often milder in vaccinated children who do become ill with the disease.

WHAT ARE THE POSSIBLE DANGERS OF WHOOPING COUGH?

In the U.S. over the last ten years, an annual average of 8 deaths has occurred following the disease. While fatality is low, almost all deaths are among children under 1 year of age, most in those under 6 months.

While there is no specific treatment for pertussis, prompt medical attention and supportive care can be successful in reducing the severity and complications of the disease.

WHAT ARE THE POSSIBLE DANGERS OF THE PERTUSSIS PART OF DTP VACCINE?

Most U S doctors and public health officials believe that the benefits of pertussis vaccine outweigh the risk of reactions to the vaccine for most children. Most children have only a low fever, some crying and/or soreness after a DTP shot. Some have no reaction at all.

Some children, however, have serious reactions to the "P" part of the DTP vaccine. These reactions may include convulsions, seizures, shock-collapse (turning blue or pale, limp, non-responsive), a fever of 105 degrees F. or more, high-pitched unusual cries, unusually long sleeping with great difficulty waking the child, or crying which lasts more than 3 hours and cannot be stopped. Any of these signs should be reported to your doctor or clinic at once.

In some cases serious reactions to the vaccine can involve long-term uncontrolled seizure disorders, brain damage, and even death.

There is a great deal of disagreement over how often these serious reactions happen. The pertussis vaccine is known to cause serious reactions more often than other vaccines. An effective test to screen the pertussis vaccine for its potential to cause reactions is not available. It is not known how many children die or get long lasting disabilities after the DTP shot is given, yet clearly children who get DTP shots are at somewhat greater risk of serious reactions than those who get DT shots, without the "P".

This is why parents, doctors, and clinics need to give careful consideration before giving this vaccine and need to be alert to possible serious reactions which may occur.

DOES THE LAW REQUIRE ME TO GET PERTUSSIS VACCINE FOR MY CHILD?

Maryland law requires most children to receive several different immunizations before they can enter school – pertussis vaccine is one of them. In order to enter school, a minimum of 4 doses of DTP is required, 5 are recommended.

Not all children are required to get DTP shots. Maryland law allows some children not to have the "P" part of these shots if:

- the child has any condition listed in the following section ("Which Children Should Not Receive Pertussis Vaccine?").
- the parents object due to their good faith religious beliefs and practices (in which case the objections must be universal and not for pertussis vaccine alone), or
- the doctor decides that because of your child's particular situation, the risks of the vaccine outweigh the benefits to the child and the public. For instance, if a parent, brother, or sister of the child to be given the vaccine has epilepsy, seizures, or other diseases of the central nervous system, or has had a severe reaction to a DTP shot, the doctor may choose not to give the vaccine.

WHEN SHOULD A CHILD'S DTP SHOTS BE DELAYED?

A child's DTP shots should be delayed if he or she:

- has a fever or ear or chest infection or is sick at the proposed time for vaccination, or has not completely recovered from a past illness,
- has had a previous convulsion, seizure, or nervous system illness, until it can be determined that no more seizures are happening and the condition is stable and under control, or
- is receiving chemotherapy or radiation treatments which may reduce the immune response of the child to vaccines.

A child's shots can be continued after he or she is well.

WHICH CHILDREN SHOULD NOT RECEIVE PERTUSSIS VACCINE?

It is generally agreed that some children should not get the "P" part of the DTP vaccine. The pertussis vaccine should not be given to your child if:

- he or she has an underlying neurologic or seizure disorder which is getting worse or is uncontrolled;
- he or she is seven years of age or older, or
- he or she has already had an earlier DTP shot and had any of the following reactions after the shot:
  - a measured fever of 105 degrees F. or greater (some manufacturers believe a temperature of 103 degrees F. or greater is a contraindication, therefore, this also should be reported to your doctor),
  - a severe allergic reaction,
  - collapse or shock-like state,
  - persisting, inconsolable crying lasting 3 hours or more, or an unusual high-pitched cry,
  - convulsion(s) with or without fever occurring within 7 days, or
  - other severe problems of the brain occurring within 7 days, this includes prolonged sleeping and inability to wake child, unusual twitching of the body or unusual staring.

Some vaccine manufacturers state that a family history of central nervous system disorders is an absolute reason not to get whooping cough vaccine (the P part of the DTP vaccine). However, the Centers for Disease Control and the American Academy of Pediatrics disagree with the manufacturers on this issue. Therefore, any family history of central nervous system problems should be considered carefully with your doctor before vaccination.

Your child should not need further pertussis shots if he or she has had laboratory confirmed whooping cough. This also should be considered with your doctor.

If a child should not receive pertussis vaccine, he or she can still be protected against diphtheria and tetanus by receiving DT vaccine rather than DTP.

ARE CERTAIN CHILDREN MORE LIKELY TO HAVE A SERIOUS REACTION TO DTP VACCINE THAN OTHERS?

The medical experts do not agree on the reasons why reactions following vaccination happen, nor can they predict in which children serious reactions will occur. But there are some factors which may make children more likely to have serious reactions.

A child may be at higher risk of a serious reaction to the "P" part of the DTP vaccine if he or she:

- has had a serious reaction to a previous DTP shot;
- has a neurologic illness, including seizures or convulsions, the severity of which is changing or uncontrolled, or
- has a fever or infection or is sick when the shot is given.

HOW TO REDUCE THE RISK OF A SERIOUS REACTION TO PERTUSSIS VACCINE

It is important that a child's medical history be provided to the doctor or clinic before he or she receives the pertussis vaccine. Such a history should include, but not necessarily be limited to, the following information:

- major birth problems,
- your child's and family's history of convulsion (seizure) or neurological illness,
- any allergy,

- recent or present illness;
- medicines or treatment currently taking; and
- your child's and family's history of previous vaccine reactions.

Besides providing your doctor with your child's medical history, there are other things which can be done to reduce the risk of a serious vaccine reaction. One thing you can do is take your child's temperature before he or she is vaccinated to make sure he or she has no fever. Another is to make sure your child has no obvious signs of infection at the time vaccine is given. If your child's throat is red or the child has been pulling his or her ears, this may be a sign of infection and should be discussed with your doctor.

WHAT SIGNS TO LOOK FOR IN A SERIOUS REACTION TO VACCINE

It is important to observe your child carefully at periodic intervals after vaccination, particularly during the first 72 hours. If your child has any of the following symptoms after a DTP shot, write down the details on this form to help you report the correct information to your doctor or clinic:

SYMPTOM	DATE	TIME	DURATION	DESCRIPTION
Measured fever nearing 105 degrees F				
High-pitched, unusual crying				
Persistent, inconsolable crying (3 or more hours)				
Inability to wake child, unusually prolonged sleeping				
Shock or collapse, loss of muscle control, turning white, blue or gray, limpness				
Convulsion, seizure, unusual repeated twitching, jerking, startling, or staring spells				
Loss of sensory or muscle control, paralysis, limping, loss of speech, hearing or sight				
Difficulty or stoppage of breathing				
Severe local reaction, large red, blue or purple coloring with extended swelling near where the shot was given				

If any of these events happen after your child gets a DTP shot, call your doctor or clinic at once. Tell them about the shot, when it was given, and about your child's reaction. *Arrange for a prompt examination at the doctor's office, clinic, or emergency room.* When things settle down, write down in detail exactly what happened.

MEMORANDUM State of Alaska

TO: Elizabeth Ward
Director, Division of Public Health

DATE: March 4, 1988

FILE NO:

TELEPHONE NO: 561-4406

FROM: Michael E. Jones
Medical Epidemiologist

SUBJECT: Review of MSAEFI Reports and Philosophical Exemptions to Immunization

I have reviewed all MSAEFI (Monitoring System for Adverse Events Following Immunization) reports submitted to the Section of Epidemiology during the three years from 1985 through 1987. During this period, there were eighty-one reports of adverse events occurring in persons vaccinated within the preceding 28 days. Of these events, twenty-seven (33%) were classified either as anaphylaxis or as one of the illnesses listed in subsections 7-15 of the MSAEFI form (attached); reports of such events require review by the Immunization Project physician to verify the clinical information.

The vaccines associated with these reported adverse events and the number of instances in which they were associated with such reactions were as follows: diphtheria-pertussis-tetanus (DPT) vaccine, 22 instances; oral polio vaccine (OPV), 7; measles-mumps-rubella (MMR) vaccine, 4; hepatitis B vaccine (Heptavax), 1; and Hemophilus influenzae type b (Hib) vaccine, 1. (Numbers total more than 27 because some individuals received two or more vaccines concurrently.) The disproportionate number of DPT-associated adverse events may be related in part to the fact that DPT is the most frequently administered vaccine in Alaska: a total of 5 doses of DPT vaccine are recommended for adequate immunization, compared with 4 doses of OPV and one dose of MMR vaccine.

The serious reactions reported, and the number of times they were associated with individual vaccines or with vaccine combinations, are listed in the table which follows:

TABLE 1

VACCINE(S) ADMINISTERED PRIOR TO ADVERSE EVENT

Adverse Event	DPT	DPT/OPV	DPT/OPV/Hib	MMR	Heptavax	Total
Convulsions/Seizures	7	-	-	4	-	11
Screaming Episodes	3	4	1	-	-	8
Hypotonic/Hyporesponsive Episodes ("Collapse")	3	-	-	-	-	3
Encephalitis (without residual defect)	-	1	-	-	-	1
Weakness of Extremities	-	1	-	-	-	1
Anaphylaxis	1	-	-	-	-	1
Infantile Spasms	1	-	-	-	-	1
Neonatal Apnea	-	-	-	-	1	1
All Adverse Events	15	6	1	4	1	27

None of these reactions was fatal. Except for one child who had persistent, mild weakness of his extremities one year following onset of the adverse event, all patients recovered fully.

It is important to remember that these adverse events are defined as being temporally related to vaccination (that is, they have occurred within 28 days following vaccine administration). It is not possible, in any individual case, to establish a cause-effect relationship between immunization and an adverse event, nor is it possible always to exclude such a relationship. Of the eleven individuals who had seizures, four (36%) had had histories of seizures prior to vaccine administration. The child with encephalitis was clinically diagnosed as having "viral meningoencephalitis" (an inflammatory brain condition caused by a virus). The child with persistent weakness of his extremities was examined by a neurologist who did not believe that his impairment was related to immunization. However, since the possibility that such adverse events are related to vaccination cannot be discounted, it is important that they be included in Alaska's MSAEFI reports and be analyzed with nation-wide data by the Centers for Disease Control.

Table 2 illustrates the frequency with which certain adverse events were reported to follow DPT vaccination in Alaska during the 3-year period, 1985-1987. Based on the number of doses (33,073) of DPT vaccine known to have been administered during 1987, it is estimated that a minimum of 99,000 doses of the vaccine were administered during that 3-year period. Thus, on average, seizure activity occurred following one of every 14,143 doses of DPT vaccine; a hypotonic/hyporesponsive episode (transient "collapse") after one in every 33,000 doses; and encephalitis following one of the 99,000 doses. It is evident from the data in table 2 that the reported frequency of these events in Alaska is less than, or approximately equal to, the published frequency with which such events can be expected to occur within very large populations. Of course, these frequency estimates depend upon the completeness of reporting of vaccine-associated adverse events by health care providers; and reporting of "severe reactions to any vaccination" has been required (7 AAC 27.005) in Alaska since at least 1975. It is not possible, from existing data, to estimate completeness of reporting.

The National Childhood Vaccine Injury Act of 1986 requires that each health care provider who administers a vaccine containing tetanus toxoid or diphtheria, pertussis, measles, mumps, rubella, or polio components shall record in a permanent record the date of administration of the vaccine, the vaccine manufacturer and lot number of the vaccine, the name and address of the health care provider administering the vaccine, and any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary of the Department of Health and Human Services. In addition, each health care provider and vaccine manufacturer are to report certain adverse events or reactions, set forth in a vaccine injury table, which occur within specified time intervals following vaccine administration. These adverse events, which

vary according to the vaccine(s) specified, include anaphylaxis or anaphylactic shock, encephalopathy (or encephalitis), shock-collapse or hypotonic-hyporesponsive collapse, residual seizure disorder, paralytic polio, or any acute complication or sequela (including death) of these illnesses, disabilities, injuries, or conditions. As of October, 1988, federal law, as well as existing state statutes, will require Alaska's health care providers to record information about the vaccines they administer and to report any adverse events following administration of vaccines.

Finally, there are no published reports which document the effects of philosophical exemptions from immunization in states which have such an exemption nor is any organized information about this issue available from the Centers for Disease Control's Immunization Division. The American Medical Association's recommendation (American Medical News, August 14, 1987) that both philosophical and religious exemptions be removed from statutes requiring mandatory immunizations was prompted, in part, by reports of two large outbreaks of measles which originated in, and were facilitated by, infection of persons with religious exemptions to immunization. These outbreaks resulted in three fatalities and affected individuals without such exemptions. Thus, the concern that vaccine-preventable diseases occurring in persons with exemptions from immunization might have deleterious effects on the general population is clearly more than a theoretical consideration. However, no body of data exists that would allow a reliable assessment of the public health impact of philosophical or religious exemptions.

MJ/jh
Attachment

TABLE 2

ANALYSIS OF SELECTED ADVERSE EVENTS ASSOCIATED
WITH DPT VACCINE, 1985-1987, ALASKA

Adverse Event	Number of Adverse Events Reported	Estimated Number of Doses of Vaccine Administered 1985-1987	Observed Incidence of Adverse Event	Expected Incidence of Adverse Event *
Seizure/Convulsion	7	99,000	1 in 14,143 Doses	1 in 1,750 Doses
Hypotonic/Hypore-sponsive Episode	3	"	1 in 33,000 Doses	1 in 1,750 Doses
Encephalitis				
- Total	1	"	1 in 99,000 Doses	1 in 110,000 Doses
- With Residual Neurologic Defect	0	"	0	1 in 310,000 Doses

* Hinman and Koplan, JAMA 1984, 251:3109-3133

REPORT OF ADVERSE EVENT FOLLOWING IMMUNIZATION

FORM APPROVED OMB NO. 0920-0039 EXP DATE 9-87

PERSONAL IDENTIFIERS

Patient:	Form Completed By:	Vaccine Administered By:	Physician or Health Facility Visited for Treatment of Adverse Event:
Name	Name	Name	Name
Address	Address	Address	Address
Telephone No.	Telephone No.	Telephone No.	Telephone No.

REPORT OF ADVERSE EVENT FOLLOWING IMMUNIZATION
DEPARTMENT OF HEALTH & HUMAN SERVICES, PUBLIC HEALTH SERVICE, Centers for Disease Control, Atlanta, Georgia 30333

PATIENT ID

Immunization Project Area | State Code | Seq. No. | County Where Administered: | County Code | MSAEFI REPORT NO. | FOR CDC USE ONLY

Date of Birth (Mo. Day Yr.) | Sex M F | Date of Initial Report (Mo. Day Yr.) | Source of Information: MD/DO Nurse Family Other

VACCINE HISTORY

Date of Immunization (Mo. Day Yr.)

Vaccine Administered By: Pub. Pvt. Mil. Other

Vaccine Purchased By: Pub. Pvt. Mil. Other

Enter Below All Vaccines Given on the Date of Immunization:

	Vaccine Type	Mfgr.	Lot Number	Route	Site	No. Prior Doses
A						
B						
C						
D						

CLINICAL DESCRIPTION OF PRESENT ILLNESS

SIGNS AND SYMPTOMS OF PRESENT ILLNESS

Onset of 1st Sign or Symptom: (Mo. Day Yr.)

	Yes	No	Unk
1. Fever: Temp ≥(100°F (37.8°C) (7806)			
Felt Hot, But Temperature Not Measured: (7806)			
Highest Measured Temperature ____ F/C			
2. Local Reaction: Site ____			
Pain, Swelling, Increased Warmth, Induration or Lump Without Abscess (9993)			
Abscess Formation — Required Drainage or Drained Spontaneously (6629)+(9993)			
Results of Culture ____			
3. Rash: Other Than at Injection Site (7821)			
4. Adenopathy:			
Local (Injection Site Area) (7856)			
Generalized (7856)			
5. Allergic Event: (9995)			
Hives (7060)			
Angioneurotic Edema (9951)			
Wheezing/Asthma (4939)			
Anaphylaxis (9994)			
If "Yes," Interval from Vaccination to Onset: <30 min 30 min-6 hrs >6 hrs			
Was Blood Pressure Measured?			
If "Yes," Lowest B.P. ___/___			
6. Arthralgia/Arthritis:			
Pain in Joints (7194)			
Inflammation of Joints (Redness, Swelling, Tenderness) (7169)			
7. Convulsions: (7803)			
If "Yes," How many Episodes Following Immunization			
8. Encephalitis and/or Encephalopathy: (3483)			
Abnormal Lumbar Puncture (Enter Results in Laboratory subsection) (7920)			
Signs of Increased Intracranial Pressure (3482)			
Focal Neurologic Signs (3499)			
Coma or Marked Alteration in Level of Consciousness (7800)			

	Yes	No	Unk
9. Guillain-Barré Syndrome: (3570)			
10. Reye's Syndrome: (3318)			
11. Polio: (0459)			
12. Paralysis other than GBS, Reye's Syndrome or Polio: (3449)			
13. Other Neurologic Symptoms and Diagnoses:			
Aseptic Meningitis (0479)			
Infantile Spasms (Hypsarrhythmia, drop seizures) (3456)			
Bell's Palsy (3510)			
Hearing Loss (3899)			
Neuritis, Neuralgia (7292)			
Paresthesias (7820)			
Screaming Episode (High-Pitched Abnormal Cry or Screaming Lasting ≥3 Hours) (7998)			
Neurologic Symptoms not cited above (specify) ____			
14. Miscellaneous:			
Hypotonic, Hyporesponsive Episode (7859)			
Idiopathic Thrombocytopenic Purpura			
If "Yes," Lowest Platelet count (2873)			
Pancreatitis (5770)			
Parotitis (5272)			
15. Death:			
Sudden Infant Death Syndrome (SIDS) (7980)			
Non-SIDS Death (7981)			
If "Yes," Cause(s): ____			

LABORATORY:

	Performed Yes	No	Unk	Results Normal	Abnormal
EEG (7940)					
BRAIN SCAN (7940)					
LUMBAR PUNCTURE (7920)					

Results if Abnormal:

WBC's ____ Opening Pressure ____

Lymphs (%) ____ Culture Results ____

Glucose ____ Other ____

Total Protein ____

Other Pertinent Information:

Signature of MSAEFI Coordinator:

Seen by Health Care Provider: Yes No Unk Number of Visits | Hospitalized Yes No Unk Number of Days

PAST HISTORY

Previous Illness Following Immunization: Yes No If "Yes," Date: (Mo. Day Yr.)

Vaccine ____

Describe Illness ____

Previous Convulsions in Patient: Yes No Unk.

If "Yes," With Fever Without Fever

History of Convulsions in Siblings or Parents: Yes No Unk.

If "Yes," With Fever Without Fever

FOLLOWUP

SEVEN DAY FOLLOWUP: (Mo. Day Yr.) If recovered, send to State Office

30 DAY FOLLOWUP: If not recovered at 7 days, carry out 30 Day Followup and send to State Office

	Duration of Illness	Recovered	Partially Recovered*	Not Recovered*	Not Located	Dead
SEVEN DAY FOLLOWUP	Days					
30 DAY FOLLOWUP	Days					

* Comments ____

Reviewed By Immunization Project Physician (Items 7 - 15 and Anaphylaxis): Yes No Unk Signature of Reviewing M.D.

FOR CDC USE

Results of One-Year Followup: Recovered Partially Recovered* Not Recovered* Dead Not Located *Comments ____

POSITION PAPER/Department of Health & Social Services

Position Paper

HB 277

For an Act entitled: "An Act relating to the immunization of minors."

HB 277 proposes the following changes in statutes pertaining to the immunization of minors in Alaska:

1. Section 1 amends AS 14.30.125 by removing the requirements for immunization against specific diseases as a condition for admission to schools, preschools, nurseries, or day care or child care when a parent or legal guardian states that immunization is contrary to the parent's or guardian's philosophical beliefs. (The Alaska Administrative Code currently exempts children whose parents object to immunizations because of religious beliefs.)

2. Section 2 requires that an individual or facility administering vaccine must provide the following information to the parent or guardian prior to the immunization: (a) a written explanation of the risks and benefits associated with the immunization; (b) a copy of the product insert required by the Food and Drug Administration; (c) a list of symptoms of adverse reactions to the immunization; and (d) a copy of the pertinent legislation and regulations. Moreover, the person who administers the immunization must ascertain that the parent or guardian has received and understands the materials provided.

3. Proposed Section AS 18.15.310 requires that health care providers submit and the Department of Health and Social Services investigate any reports of adverse reactions to immunizations and requires the department to report annually to the legislature on the incidence of infectious disease and the incidence of serious reactions and permanent or long-term damage to minors that results from immunization.

4. Proposed Section AS 18.15.320 requires that records of lot numbers and vaccine manufacturers be maintained for three years after immunization.

The first three of these provisions are discussed below.

1. <u>Exemption from mandatory immunization requirements based on philosophical beliefs of parent or guardian</u>

AS 14.30.125 authorizes the Department of Health and Social Services to require that children entering school be immunized against diseases

specified by the commissioner. Currently, regulations (7 AAC 50.255) require immunizations against diphtheria, tetanus, polio, measles, rubella, and if the child is under seven years of age, pertussis. Regulations allow a child to be exempted from immunization requirements if receiving the immunization is contrary to the religious beliefs of the parent or guardian or if there are medical reasons to exempt the child. 7 AAC 50.255, adopted under the authority of AS 47.35.030, requires that a child receive immunizations "appropriate to his age as prescribed in the Alaska Division of Public Health's schedule for active immunization" as a condition of admission to day care.

Although "childhood diseases" are commonly thought to be benign, complications do occur and can be severe. For example, inflammation of the heart muscle can complicate diphtheria; pneumonia is one of the chief complications of both measles and pertussis; and neurological damage can occur with diphtheria, measles, mumps, and pertussis. Rubella can cause a wide spectrum of congenital disorders when acquired by the mother during pregnancy. The goal of rubella immunization programs is to assure immunity of all females before they reach childbearing age and to limit the accidental exposure of pregnant women to the virus.

Vigorous immunization efforts aimed particularly at very young children have virtually eliminated most of the vaccine-preventable diseases, as seen in the following table:

	Diphtheria	Measles	Mumps	Pertussis	Rubella
1976	8	14	39	0	2
1977	2	60	35	5	1
1978	3	1	15	18	8
1979	0	17	15	10	4
1980	0	6	15	5	12
1981	1	0	20	1	1
1982	0	1	6	0	1
1983	0	1	10	0	0
1984	0	0	8	3	1
1985	0	0	10	30	1
1986	0	0	8	5	0

Unfortunately, vaccines are not perfect. Vaccines are not 100 per cent effective, and therefore some people who are immunized may not be protected. Also, vaccines are not perfectly safe, and some people who receive them may be damaged by them. The question is one of balancing the benefits to the individual receiving the vaccine and the benefits to society in general against the risk of damage.

In recent years, debate on benefit v. risk has centered on the pertussis vaccine. (Pertussis is a component of the DPT vaccine, one of the "baby shots.") Reactions to the vaccine are relatively common since about 40 per cent of vaccinated children develop minor redness, swelling, and pain at the site of injection. Fever, vomiting, and drowsiness occur in about 20 per cent of vaccines. Convulsions or collapse with complete recovery occur at a rate of about one episode per 1,750 vaccine doses given. Encephalitis occurs at a rate of one case per 110,000 doses

given, and encephalitis with residual defect at a rate of one case per 310,000 doses administered. Sudden infant death syndrome is not related to pertussis vaccine use.

Given the relatively low incidence of pertussis, the adverse effects associated with the vaccine seem prominent. However, for perspective, the effects of the disease itself should be considered. The death rate from pertussis for previously unvaccinated patients who develop the disease is one in 1,000; among affected children less than one year of age, the death rate is one per cent. Permanent brain damage from whooping cough afflicts one child in 10,000 cases. Consensus among health authorities is that the benefit from immunization outweighs the risk. This view has been expressed by the American Medical Association, the Public Health Service, the American Academy of Pediatrics, and the American Public Health Association.

The department believes that because the proposed exemption includes individuals with philosophical objections to immunization, a serious health threat for many Alaskan children will be created. There will be increased risk for those whose parents or guardians elect to exclude them from immunization. There will be increased risk to very young children in other families who have not had a chance to complete the entire series of injections. There will be increased risk to the 10 to 20 per cent of completely immunized children who are incompletely protected because the vaccine is not 100 per cent effective. The decision not to immunize has effects that extend beyond the individual.

Since the decision not to immunize is likely to be unevenly distributed across the population, it is thought that there will be geographic areas in which significant numbers of children will be unimmunized and where the likelihood of disease occurrence will be great.

The recent upswing in reported cases of pertussis in Alaska is directly attributable to the nonimmunized or inadequately immunized status of the cases.

2. Immunization Information

Much of the intent of this portion of the proposed bill is already required by the department as a part of its agreement with the federal Centers for Disease Control, through whom the state's vaccine supply is purchased. The department provides the major portion of vaccines used in the state, with the exception of vaccines used by the military. A written explanation of risks and benefits called the Important Information Statement is used in the public sector. By signing the statement, the parent or guardian states that he or she has read the statement and has had an opportunity to ask questions of the person administering the vaccine. The manufacturer's name and vaccine lot number are recorded and retained. Private physicians who receive vaccine from the state can use the Important Information Statement system or exercise their professional judgement in informing parents or guardians of the risks and benefits of immunization. Written descriptions of potential adverse reactions are also provided. Copies of applicable statutes and regulations are not distributed or discussed.

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 A. 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 — Phone: 465-3090
Division: Public Health — Date: 2-09-88

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

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

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.

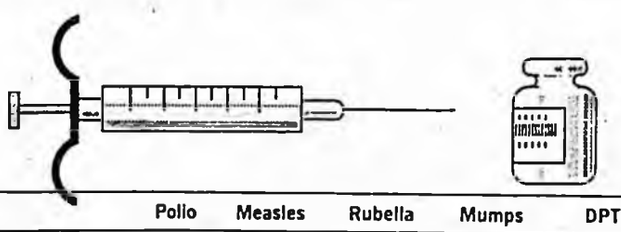
The final appropriation for the program in fiscal 1988 has been set at $86 million, $8 million below the full authorization level. That figure is slightly higher than current levels, but the price per dose of vaccine for measles, mumps and rubella has risen sharply over the past decade from $2.42 in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

Daniel S. Strickler

Vaccinations And Immune Malfunction

Harold E. Buttram, M.D. and John Chriss Hoffman

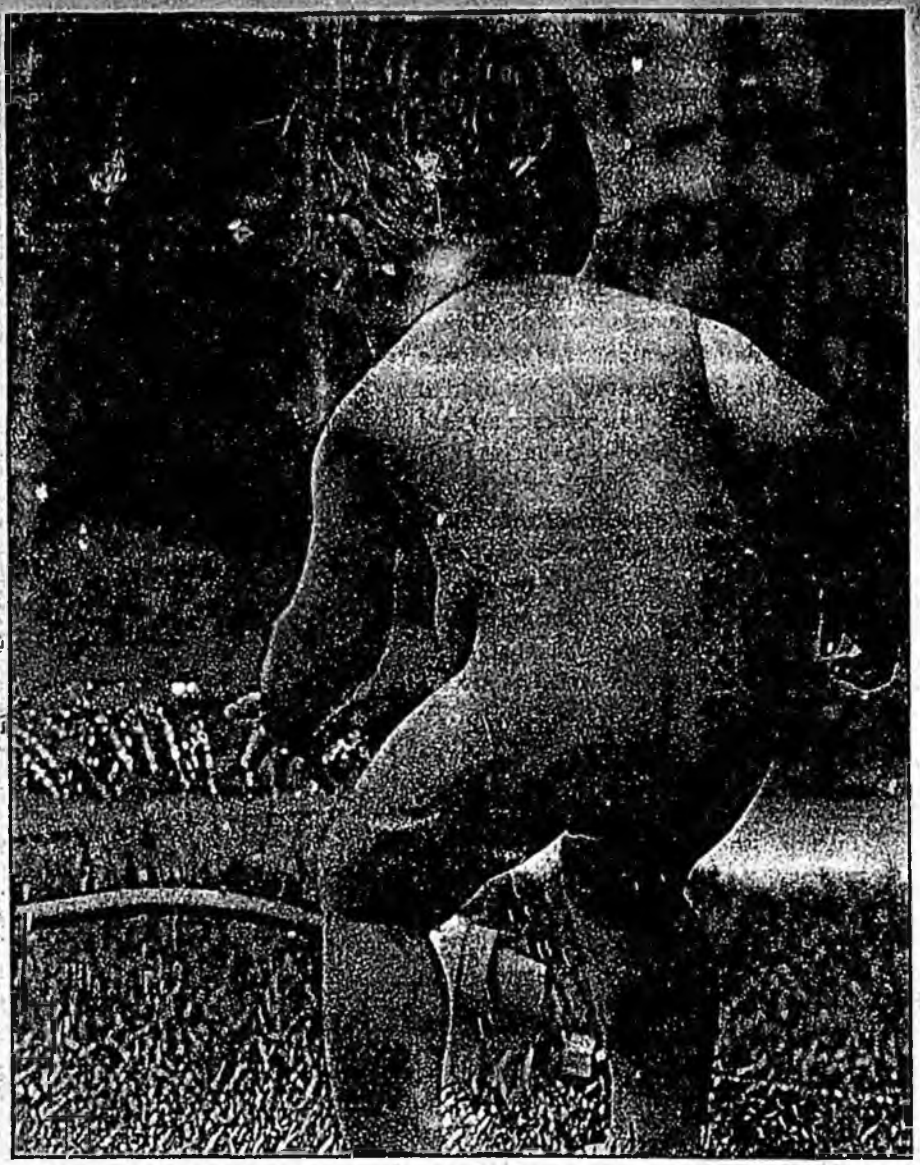
One of the fundamental issues concerning current vaccination programs can be summarized in the following question: **Is there a significant difference between the immunity acquired in the natural course of a disease, such as mumps or measles, and the immunity gained from vaccines?** There do appear to be fundamental differences.

Natural immunity in a healthy person is based on a series of body defenses, much as the defense of a medieval fortified castle. Vaccinations, on the other hand, inject massive amounts of vaccine preparations directly into the body, thus by-passing the outer defenses.

By way of illustration, let us assume that a child is born with a total immune capacity of 100 units. According to the one cell/one antibody rule, once an immune body (plasma cell or lymphocyte) becomes committed to a given antigen, it becomes incapable of responding to other antigens or challenges. Again, let us assume that a hypothetical child twenty or more years ago passed through the usual childhood diseases of former decades (measles, mumps, chicken pox, and so on) with relatively minor and uncomplicated illnesses. Consider-

ing the extreme efficiency of "natural immunity" we may make an educated guess that permanent immunity was gained to these diseases by utilizing only 3 to 7 percent of the total immune capacity. In the case of the routine childhood vaccines, in contrast, it is likely that a higher percentage of the total immune capacity becomes committed, perhaps something on the order of 30 to 70 percent. It should be emphasized that, once an immune body becomes committed to a specific antigen, it becomes inert and incapable of responding to other challenges.

If the reserve capacity of children is being reduced by current vaccinations in this manner, what will be the consequences? No one knows for certain at this time, but it is possible that these consequences could be seen as an increased susceptibility to viruses, to other infections, and to various forms of allergies. The consequences may be seen as immunologic disorders in the form of autoimmune diseases, which are increasingly recognized in modern times. Finally, there is indisputable evidence that many instances of mental and nervous disorders are caused by immunologic aberrations.[2-6] The relationship of these disorders to vaccinations remains speculative at this time, but there is a substantial and growing body of evidence that modern vaccines can result in immune malfunction.



Susan Peace

THE EVIDENCE

For many years immunologists have been aware of a state of *anergy* (immunological unresponsiveness) folowing vaccinations. For example, live-virus vaccines have been shown to transiently suppress tuberculin sensitivity.[7,8]

One of the most extensively documented studies of the indirect effects of vaccines is to be found in the book, *The Hazards of Immunization,*[9] by Sir Graham Wilson, formerly of the Public Health Laboratory Service, England and Wales. In his chapter entitled, "Indirect Effects: Provocation Disease," Dr. Wilson provides a number of documented historical examples in which vaccination against one disease seemed to provoke another. As one example, a physician in London first drew attention to the relation between inoculation against diptheria or pertussis and attacks of poliomyelitis when he de ed fifteen cases he had seen between 1944 and 1949. Paralysis came on, as a rule, seven to twenty-one days after injection and affected the left arm, into which injections were usually given, four times as often as the right. In describing this type of occurrence, Wilson stated:

> *"When a vaccine is injected into the tissues during the incubation period of a disease or during the course of a latent infection, it may bring on an acute attack of the disease. That is to say, the incubation period is shortened, or a latent infection that might have given rise to no manifest illness is converted into a clinical attack. The two diseases in which this so-called provocation effect has been most studied are typhoid fever and poliomyelitis, but evidence exists to show that it may be operative in other diseases . . ."*

An important investigation into the role of malnutrition and vaccination as causative factors in immune dysfunction has been in progress among the Australian aborigines since the early 1970's by Archie Kalokerinos, M.D. of New South Wales, Australia (later aided by Glenn Dettman, Ph.D., Orthomolecular Medisearch, of Mentone, Australia).

One of the first published reports of large-scale immune malfunction following the conventional childhood vaccines is to be found in the book, *Every Second Child,*[10] by Archie Kalokerinos. In this book, Dr. Kalokerinos describes his work as a physician in the 1960's and 1970's among Australian aborigines. In

early work with these peoples, he was appalled by the high infant mortality rate — death rates in some areas having soared to 50 percent.

The Australian aborigines were a unique population: They lacked the natural resistance to many infectious diseases to which the Caucasian race has been exposed through the centuries. Also the aborigines lived in relative poverty on a diet consisting mostly of highly refined and denatured food products, a diet deficient in many vital nutrients.

Dr. Kalokerinos determined that many of the aboriginal infants suffered from acute ascorbic acid (vitamin C) deficiency. He postulated that a compromised immune resistance due both to a diet lacking in essential nutrients, especially vitamin C, and to the presence of infectious illness placed many infants in a dangerous state of health. In many children the injection of vaccine, further challenging an already crippled immune system, was enough to bring on death.

Working on the assumption that these deaths were the result of an interaction of the vaccinations with malnutrition, he instituted an improved nutrition program with regular ascorbic acid supplementation. In addition, he screened infants to avoid giving vaccines during minor illnesses. As a result, infant mortality was virtually abolished. For two years, not one infant under his care died.

Besides diseases of an acute nature, chronic degenerative diseases have also been reported to follow vaccination. Numerous German authors have described the occurrence of multiple sclerosis following administration of vaccines against small pox, typhoid fever, paratyphoid fever, tetanus, poliomyelitis, tuberculosis, influenza, and rabies.[11] Systemic lupus erythematosis has been reported to occur following vaccination.[18]

Burton Waisbren posed the following question concerning the apparent immune system-mediated diseases of multiple sclerosis and Guillain-Barre syndrome — notorious due to its tragic occurrence after the ill-fated swine flu vaccine program:

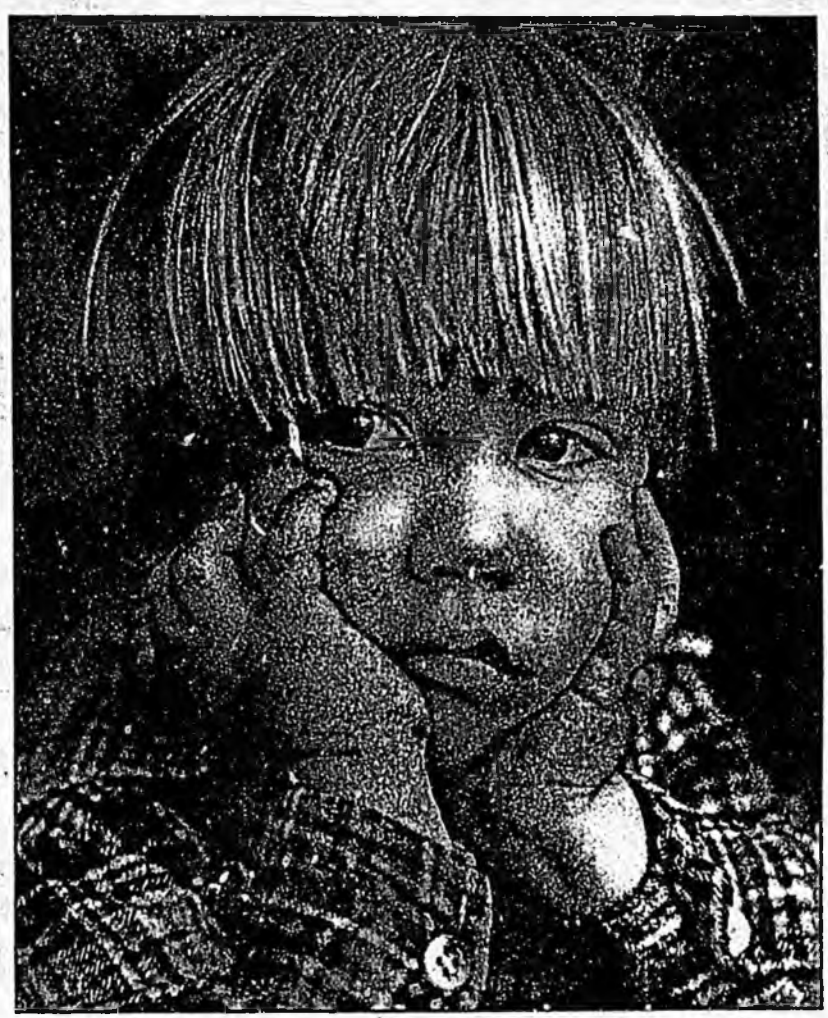
> *"Is it possible that an antigen in the swine-influenza vaccine evokes in some patients an immune response to myelin basic proteins; those that surround the peripheral nerves in patients who developed Guillain-Barre syndrome, and those around the central nerves in patients who developed a disorder similar to multiple sclerosis?"*[12]

Dr. Robert Couch, Baylor University, Houston, Texas, testified before the U.S. Public Health Service Immunization Practices Advisory Committee in January, 1982, that after flu vaccination of elderly persons who had history of chronic disorders, six of seven persons with allergies reported their allergies to worsen; one of twenty with hypertension noted increased blood pressure; one of nine with diabetes and two with gout developed a cold, a gout attack, and increased blood sugar; one on therapy for Parkinson's Disease noted increased clumsiness.[13]

In a study of the diptheria-pertussis-tetanus (DPT) vaccine, only 7% of those receiving the vaccine had no untoward reactions; 54% had fevers and 32% exhibited behavioral changes.[19]

SUMMARY AND CONCLUSIONS

At the present time an overwhelming majority of the members of the American medical community accept and approve current vaccination programs for children. It should be obvious that this period of early infancy with an immature immune system is one of extreme vulnerability and susceptibility to



Lucia Jenkins

Current research . . . is arrested by the system of compulsory vaccination for school children. If vaccinations are made optional . . . medical research can move ahead in search of other workable solutions . . .

vaccinations, especially in the earliest months following birth. Only a handful of physicians and lay-persons throughout the decades have objected to these vaccination programs because of suspected adverse side effects. In some instances their arguments have lacked substance due to the fact that they have sought to demonstrate direct toxicities from the vaccines.

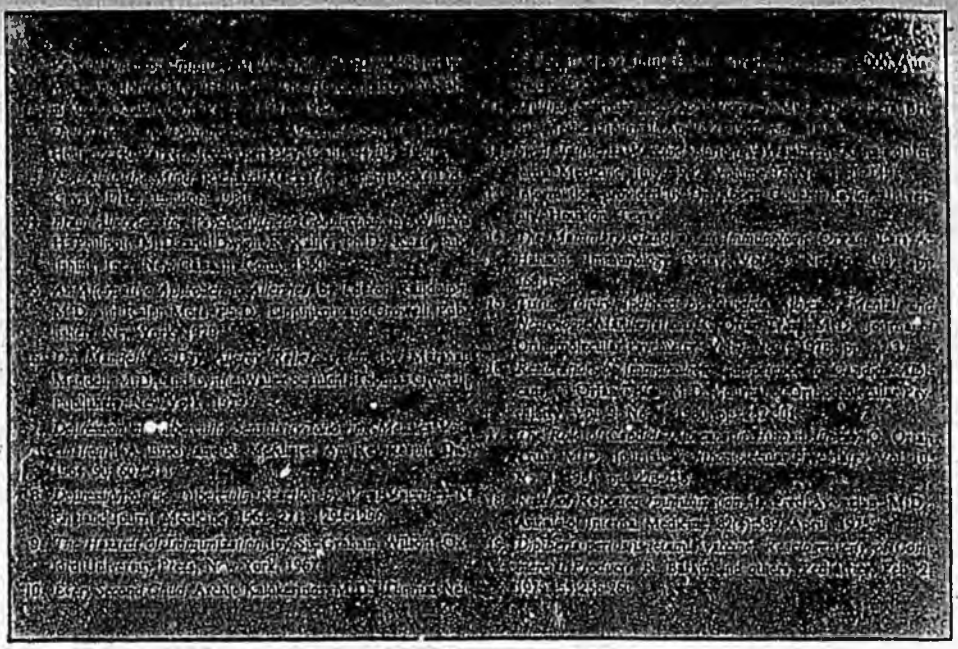
Direct toxicities do occur, but they appear to be relatively uncommon. Most authorities today consider these occasional incidents as an acceptable risk. They believe that the benefits from the vaccines, in terms of control gained over infectious diseases, far outweigh the danger of toxicities.

The real danger appears to be an indirect effect with impairment and malfunction of the immune system. Since this effect is often delayed, indirect, and masked, its true nature is seldom recognized.

Within the United States few persons have braved the wrath of orthodoxy by pointing out the probability of widespread and unrecognized immune system malfunctions, which are vaccine-induced, and the need for scientific investigation of these effects. In our opinion there is now sufficient evidence of immune malfunction following current vaccination programs to anticipate a growing public demand for research investigation into alternative methods for prevention of infectious diseases.

The one change that could bring immediate and far-reaching results is to allow absolute freedom-of-choice in accepting or rejecting vaccines for every individual and every parent. Like the Mississippi River steamboat that is grounded on a sand-bar, current research in the prevention of infectious diseases is arrested by the current system of compulsory, mandated vaccination for school children. If vaccinations are made optional, the situation will become unfrozen. Medical research can then move ahead in search of other workable solutions.

In an enlightened free society such as America, there are inherent checks and balances in a system which allows free choice to the individual in matters which concern his or her personal welfare. Nothing else works quite so well.



Harry Camp

VACCINATIONS AND INDIVIDUAL FREEDOM

Vicki Giles

The Center for Disease Control (CDC) in Atlanta, Georgia has recently made recommendations concerning Wyoming immunization laws in an attempt to *increase* the number of school children who are "properly immunized." This number is currently 98.1 percent of Wyoming public school children, according to the CDC.

There can be no doubt that any medicine that is potent enough to do good has at least some potential for toxicity as well. Parents should be aware of the following precautionary steps when dealing with routine vaccinations:

- **Do not allow your child to be immunized if he or she has been ill or has had a cold or runny nose within the last 48 hours.** Vaccinations provide immunity by going directly into the bloodstream, and an immune system that is already taxed is more likely to react badly to immunization. Vaccinations also affect the lymphatic system which may already be stressed by a cold or runny nose.

- **If you wish to have your child vaccinated, consider beginning at six months rather than six weeks. If your child was small for gestational age or was born prematurely, consider waiting even longer.**

Although most physicians would recommend that immunizations be started at six weeks because the risk of pertussis, for example, is greater in infancy, there have never been any controlled studies done to determine whether or not an infant under six months of age can actually build immunity when immunized. Booster shots became popular to protect against the possibility that early immunity may not develop through immunization.

In Great Britain, vaccinations are started at six months of age. Why do we start them so much sooner in the United States? The major reasoning for beginning vaccinations so early comes from a study conducted by Parke-Davis in 1962, which concluded that it is more likely that children will receive the entire series of vaccinations if they are begun early in infancy. And, since most babies visit the doctor at four to six weeks for a check-up, it is more convenient for the health practitioner to start the series of immunizations at this time.

- **If you have a family history of central nervous system disease, deafness, blindness, convulsions, or life-threatening allergies, the pertussis vaccine may be contraindicated for your child.** The pertussis, or "P" part of the DPT vaccine is considered quite crude. The "whole-cell" pertussis vaccine which American children are given has not been separated; the child receives the part of the pertussis cell which generates immunity to the disease along with the part which causes toxic reactions. Current research may be able to isolate the toxic element.

- **If one child in your family has had a serious reaction to the pertussis vaccine, the child's siblings should probably not receive the vaccine.** Children in the same family tend to react similarly to the pertussis vaccine. The reason for this is not clear.

- **If your child has exhibited a severe reaction to the pertussis vaccine, immediately find a physician who will verify the reaction and write in your child's permanent medical record that he or she should never again receive a pertussis shot.**

Once a particular child has reacted seriously, additional doses will frequently cause more serious reactions. A serious reaction to vaccination may include any of the following: excessive, high-pitched screaming (the high-pitched scream is suggestive of central nervous system irritation); severe swelling or redness at the site of the injection; fever lasting several days; collapse or extreme lethargy; grayish skin color and cool extremities; or convulsions.

If your child exhibits any of these symptoms, be sure to report this to your health professionals and urge

Photo: James Ewing

them to report the reaction to the CDC along with the lot and batch number of the vaccination given. Some physicians might not consider local swelling and fever for several days to be severe reactions; but there have been cases of children who have exhibited swelling and fever reactions to a first immunization and more severe reactions to a second one, so even swelling and fever should not be minimized.

Some practitioners suggest a half dose followed by another half dose for children who have exhibited a toxic reaction to the vaccine. All available evidence indicates that giving the child a half dose of DPT, followed one week later by another half dose, does *not* lessen the potential for toxic reaction.

• **Always write down the batch and lot number of any vaccine that your child is given.** Be sure to look carefully at the vial whenever your child is given a vaccination. It is possible for a person to make a mistake and give your child the wrong vaccine.

If for any reason your child becomes ill enough to be hospitalized within two weeks following a vaccination, fully describe the course of illness to the health center where the child was given the vaccination. Urge the healthcare professionals to report the reaction and the batch and lot number to the CDC. This will help the CDC statistically analyze whether the batch is particularly reactive or whether your child is overly sensitive to vaccination.

Many, perhaps most, doctors do not consistently report adverse reactions to vaccines. Consequently, the CDC lacks clinical figures for how often a particular vaccine is reactive.

• **For about two weeks after receiving the "live" polio vaccine, keep your child away from anyone who is not fully immunized against polio, anyone who has an immune deficiency (for example, Acquired Immune Deficiency Syndrome or a deficiency due to chemotherapy)—for their own protection.**

The "live" polio vaccine, a live virus, is contagious. Because the disease is carried in the bodily excretions, it is especially important to refuse to allow people who have an immune deficiency to change your baby's diapers.

Be aware that most doctors recommend not giving your child aspirin following the live polio vaccine, because aspirin use has been associated with Reye's syndrome when a child is ill with a virus. A "killed" polio vaccine is also available, but it is not thought to be as effective as the live vaccine.

"Herd immunity" is based on the belief that if *most* people in a community are immune to a disease, an epidemic can be prevented. Those in favor of 100 percent vaccination do not seem to recognize the fact that not *everyone* who receives a vaccine for a particular disease will be totally immune to this disease. The belief that "allowing one person to be free from immunity will endanger everyone" is without validity.

Medical care is an individual question in a free country. Medical practice has a tendency to follow traditions long after they are useful. Vaccinations should be a question for each *individual* to answer. Only then will we be free to be healthy.

the People's Doctor
A MEDICAL NEWSLETTER FOR CONSUMERS by Robert S. Mendelsohn, MD

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IN THIS ISSUE: **AIDS: LINKAGE TO SMALLPOX VACCINE**
Condoms Aren't Foolproof . . . Blaming the Victim . . .
Tests Aren't Reliable

AIDS linked to smallpox vaccine

Have you read anything in your newspaper which links the AIDS epidemic with vaccinations? Have you seen or heard any television or radio reports on the subject? I haven't, and as you know, I've been following the AIDS epidemic very carefully.

Have you heard Dr. Robert Gallo, the U.S. expert who first identified the AIDS virus, talk about AIDS and vaccines? I haven't. But, Dr. Gallo did tell the London Times (May 11, 1987), "The link between the WHO programme [the World Health Organization effort to eradicate smallpox in Third World countries] and the [AIDS] epidemic in Africa is an interesting and important hypothesis. I cannot say that it actually happened, but I have been saying for some years that the use of live vaccine such as that used for smallpox can activate a dormant infection such as HIV."

Has Dr. Gallo been making these speculations "for some years" to only the British press? Or, if he and Surgeon General Koop and the experts from the Centers for Disease Control have mentioned this to U.S. reporters, have their words been drowned in the cacophony of statements telling people that it's their own fault if they get AIDS?

Government scientists have been quick to point the finger at peoples' lifestyles--"You don't have the right sexual partners," "You don't wear enough condoms," etc. But nowhere on the front pages of U.S. newspapers has there been a hint that the doctors may have played at least as important a role in spreading AIDS as have the people.

Look how quick government doctors are to blame drug addicts for spreading AIDS by sharing needles. But have they told you that, in the recent WHO smallpox vaccination campaign, needles were re-used 40 to 60 times? The main method of "sterilization" was waving the needle across a flame. Doctors are quick to play the game of "blame the victim," but what if it turns out that doctors themselves are responsible for the victims' plight?

WHO information indicates that the AIDS table of Central Africa matches the concentration of smallpox vaccinations, i.e., the greatest spread of HIV infection coincides with the most intense immunization programs. Thus, Zaire, at the top of the AIDS list, had 36,000,000 people immunized with the smallpox vaccine. Next is Zambia, with 19 million, followed by Tanzania with 15 million, Uganda with 11 million, Malawai with 8 million, Ruanda with 3.3 million and Burundi with 3.2 million. Brazil, the only South American country covered by the smallpox eradication campaign, has the highest incidence of AIDS in that part of the world.

This theory--that the AIDS epidemic in Africa may have been triggered by the smallpox immunization program--has sparked intense debate among scientists. You may not have heard about this debate, but an urgent call for evidence to support the idea has been demanded by the World Health Organization. This theory was discussed by WHO officials last autumn. No follow-up data are available from the smallpox eradication campaign because no systematic studies of the complications produced by the mass immunization have been done(!).

According to Professor Oswald Jarrett, an AIDS researcher at the University of Glasgow (Scotland): "We need to know whether the virus was spread from a small to a large group of people through the immunization programme." And Dr. Laurence Gerlis, a clinical AIDS researcher, states, "Previous circumstantial evidence looks more persuasive alongside the latest research that shows AIDS can be stimulated by smallpox vaccination."

Here's what the unnamed WHO advisor who disclosed the problem to the Times had to say: "I thought it was just a coincidence until we studied the latest findings about the reactions which can be caused by vaccinia. Now I believe the smallpox vaccine theory is the explanation to the explosion of AIDS."

This theory also provides an explanation of how AIDS infection is spread more evenly between males and females in Africa than in the West.

Further evidence of the link between AIDS and the smallpox vaccine comes from the Walter Reed Army Medical Center in Washington, D.C., where routine smallpox vaccination of a 19-year-old army recruit was the trigger for the stimulation of dormant HIV virus into full-blown AIDS. This discovery was made by a medical team working with Dr. Robert Redfield at Walter Reed. The recruit developed AIDS two-and-a-half weeks after being immunized against smallpox, and he died shortly thereafter.

While in no way diminishing the role certain lifestyles play in AIDS causation, isn't it high time that we turn the spotlight on the possibility that modern medical miracles--immunizations included--can help cause modern medical plagues?

AIDS and hepatitis B vaccine

The safety of the hepatitis B vaccine (a human blood product) has been questioned in the Journal of the American Medical Association (January 16, 1987). Albert L. Meric of Metairie, Louisiana, disagrees with other researchers who insist that the AIDS virus has been physically removed from the hapatitis vaccine. He points out that just because hepatitis vaccine recipients did not develop antibodies to the AIDS virus does not mean the AIDS virus is not present in the hepatitis vaccine. Or, to use his own words, "It does not rule out the physical presence of AIDS virus antigen in the vaccine." Meric concludes that the presence of AIDS virus in Heptavax-B remains an open question.

If your doctor recommends this vaccine, ask him if he has read this important article.

Q

As a result of your work and that of others, I have decided not to immunize our 18-month-old son against most childhood diseases. My only concern is with the tetanus vaccine. Although I hesitate to give it because of the various immune and chronic disease risks which seem to accompany it, it does seem to be important: If my son receives a deep tissue injury and has not been previously immunized, the treatment includes an injection of tetanus immune globulin, a pooled blood product which carries with it the risk of AIDS and other contagion.

What is your advice? Are such globulin injections really necessary and, if so, in what sorts of injuries?--S.F.

QualityCare Insights

Vol 2 No. 1 | *For Today's Healthcare Decision-Maker* | Spring 1988

Candidates' Representatives Talk About Health Issues

Representatives of seven presidential candidates met at a Washington, D.C. forum January 29 to explain each candidate's view on health issues in this election year to an audience of health policy planners, analysts, managers and practitioners.

The setting was the fourth annual health agenda conference cosponsored by the Washington Business Group on Health and the National Association of Manufacturers.

Present were representatives of Vice President George Bush and Sen. Robert Dole (KS) on the Republican side and Massachusetts Gov. Michael Dukakis, Sen. Paul Simon (IL), Rep. Richard Gephardt (MO), Rev. Jesse Jackson and Sen. Albert Gore, Jr. (TN) on the Democratic side.

Speaking for the Bush campaign, Deborah Steelman, a Washington lawyer, said the Vice President supports more money for AIDS research, education and demonstration treatment programs. He opposes mandatory blood testing and special benefits for AIDS patients. He does favor, however, routine blood testing for AIDS with ensured confidentiality.

On other issues, Steelman said Bush opposes any new federal programs for long-term care that would be funded by additional payroll taxes. She said he sees long-term care as a family responsibility. Steelman also noted the Vice President feels the Medicaid program is in need of change.

Lynn Drake, a health policy fellow in Dole's Senate office, cited Dole's work on the catastrophic health insurance bill, calling it a "giant step" toward addressing the acute care needs of the elderly. She said Dole favors educating employers and consumers so people understand what the bill covers and what it does not.

Drake said Dole encourages a better dialogue between employees and employers to help solve the uninsured and underinsured problem. He also wants more information on

(See "*Candidates*," page 6)

27 New Drugs Approved In 1987, Research Funds Up Even More

The U.S. Food and Drug Administration (FDA) approved 21 new drugs and six important new biological products in 1987, the same year the pharmaceutical industry reported spending a record $5.4 billion on research and development.

Among the most significant new drugs approved in 1987 were:

- zidovudine or AZT (sold under the trade name Retrovir). Previously known as azidothymidine, AZT is the first drug approved for treating patients with AIDS and AIDS-related complex.
- lovostatin (Mevacor), which lowers blood cholesterol levels and thus reduces the risk of a heart attack;
- ciprofloxacin (Cipro), an oral antibiotic that patients can take at

(See "*Drug Approvals*", page 3)

WHAT'S INSIDE

SpeakingOut

The pharmaceutical industry is achieving breakthroughs in drug discovery that were barely imaginable a few years ago. This progress is possible because of powerful new tools of research and insights into human physiology. For example, scientists can use molecular modeling by computer and other means to conduct more targeted, rational research. New understanding of biology at the molecular level is leading to the discovery of superior new therapies in areas like heart disease.

At the same time, these scientific advances have made drug discovery an increasingly complex and resource-intensive process. An enormous investment of time and money is necessary to bring the promise of these new technologies to fruition. It takes some 10 years to bring a new drug from clinical trials to regulatory approval, while the cost of R&D per new drug marketed is now estimated at $125 million, more than twice the cost for a drug approved a decade ago.

But the investment is worth it in terms of results. Drug therapy is the least invasive way to treat diseases. It is also highly cost-effective. There are many examples. The new anti-ulcer drugs that act on the histamine-H_2 receptor site replace or reduce the need for more expensive treatments, like surgery. Another example: studies have found that using beta blockers to prevent second heart attack can save up to $3 billion per year.

Gerald D. Laubach, Ph.D.
President, Pfizer, Inc.

The advances of recent years are ultimately a response to an undiminished public demand for medical progress against disease. As far as we have come against diseases like heart disease, cancer, and diabetes, for example, much remains to be done—and the public clearly wants it to be done. According to polls cited by the *New England Journal of Medicine*, the public gives medical research the highest priority on the national research agenda. The threat of AIDS is now placing enormous additional pressure on biomedical research, and it is clear that our best hope for containing this epidemic will come from vaccines and drugs.

Almost equally important are the quality of life advances offered by new drug therapy. There is a growing demand for drugs that can improve the quality of life by increasing mobility and convenience and by lessening sexual dysfunction and pain.

The resources are clearly available to make further progress against disease, and public demand for such progress is strong. The major uncertainty concerns the diffusion of new drug products. Will these drugs be accessible to patients who need them? Will they be paid for at a level that reflects ever increasing costs of research?

These questions will be answered by the myriad of drug access and reimbursement decisions that are going to be made by those beyond the physician now involved in drug product selection: pharmacists, third-party payers, health plan administrators, and formulary committees—all of whose importance has rapidly increased. Their role in holding down costs is well known.

What is less appreciated is the equally important role they will necessarily play in pharmaceutical innovation—and thus in medical progress. Questions of access and payment will inevitably affect the resources available for research. A statesmanlike approach is called for to see that short-term cost savings do not obscure the long-term public interest in new and better therapies. All the relevant parties will have to work together to make certain that patient needs continue to be met—both now and in the future.

QualityCare Insights

Quality Care Insights is a quarterly newsletter provided by the Pharmaceutical Manufacturers Association, 1100 Fifteenth Street, N.W., Washington, D.C. 20005.

From The Editor's Desk

With this issue ***Quality Care Insights*** starts its second year. From the beginning we have sought to keep you informed about developments in health policy, planning and practice affecting the quality of care.

This issue reports on two significant developments. One concerns a conference on biomedical research that examined the partnership between government, academia, private industry and voluntary organizations. The second involves findings that, at least for now, early hospital discharges under Medicare's DRG system is disrupting community health services for the elderly.

Many readers have written to say how much they value ***Quality Care Insights*** and we appreciate that. In addition, we want to hear how you are dealing with quality of care issues in your community, company, agency or care setting. Information of that kind will be of value to all our readers.

("*Drug Approvals*," from page 1)

home to treat conditions that formerly required intravenous antibiotics; and

- lisinopril (Prinivil or Zestril), a once-a-day hypertensive drug.

The most visible new biological product is alteplase (Activase) or tissue plasminogen activator (TPA). When given to a heart attack victim within hours after the attack, alteplase can dissolve clots blocking coronary arteries.

In 1987, FDA approved eight orphan drugs—drugs for diseases that afflict relatively few people and thus are often unprofitable to develop without FDA aid. Eight is the most the agency has approved in a single year since Congress passed the Orphan Drug Act in 1983.

"These new drug approvals will save lives, enhance the quality of life and save money, thereby helping the health care system in general," said Gerald J. Mossinghoff, president of the Pharmaceutical Manufacturers Association, the trade group representing research-based drug companies.

The record $5.4 billion U.S. drug makers spent to find and develop more new pharmaceuticals in 1987 represents a 15 percent increase in R&D investments over the $4.7 billion in 1986. It also roughly equals what the National Institutes of Health (NIH) spend on all biomedical research.

"The country no longer needs to depend solely on taxpayers and the government to carry on medical research," Mossinghoff noted. "It is highly significant that the private sector continues to shoulder a substantial and growing share of the nation's medical research."

"We have seen at FDA in recent years a concerted effort to upgrade performance of the agency and the (drug-approval) system," Mossinghoff said.

Before approving new drugs for consumer use, FDA requires the pioneering manufacturer to submit massive research data showing the drug is safe and effective, and may ask for additional tests if unanswered questions remain. PMA estimates it takes about 10 years to bring a new drug from concept to FDA approval. Studies have shown the average cost of bringing a new drug to market is $125 million.

New Drugs & Biologicals Approved By FDA In 1987

NAME	MANUFACTURER	CATEGORY
Drugs		
Bactroban *(mupirocin)*	Beecham Laboratories	Antibiotic
Cefmax *(cefmenoxime HCl)*	Tap Pharmaceuticals	Antibiotic
Choletec *(technetium Tc-99m mebrofenin)*	Squibb Diagnostics	Imaging Agent
Cipro *(ciprofloxacin HCl)*	Miles Inc.	Antibiotic
Deursil *(ursodiol)*	Gipharmex S.P.A./CIBA-GEIGY Corporation	Gallstones
Elocon *(mometasone furoate)*	Schering-Plough Corporation	Dermatologic
Hytrin *(terazosin HCl)*	Abbott Laboratories	Cardiovascular
Iopidine *(apionidine HCl)*	Alcon Laboratories, Inc.	Ophthalmologic
Levatol *(penbutolol sulfate)*	Eli Lilly and Company	Cardiovascular
Mevacor *(lovastatin)*	Merck Sharp & Dohme	Cardiovascular
Novantrone *(mitoxantrone)*	Lederle Laboratories	Cancer
Parathar *(teriparatide acetate)*	Rorer Group Inc.	Diagnostic
Primacor *(milrinone lactate)*	Sterling Drug Inc.	Cardiovascular
Prinivil* *(lisinopril)*	Merck Sharp & Dohme	Cardiovascular
Prozac *(fluoxetine HCl)*	Eli Lilly and Company	Anti-depressant
Retrovir *(zidovudine)*	Burroughs Wellcome Company	Anti-viral
Rimadyl *(carprofen)*	Hoffmann-La Roche Inc.	Anti-arthritic
Rowasa *(mesalamine)*	Reid-Rowell	Gastrointestinal
Spectamine *(iofetamine HCl)*	Medi-Physics, Inc.	Imaging Agent
Terazol 7 *(terconazole)*	Ortho Pharmaceutical Corp.	Gynecologic
Ucephan *(sodium benzoate/sodium phenylacetate)*	Kendall McGaw Laboratories	Hyperammonemia
Biologicals		
Activase *(alteplase, recombinant)*	Genentech, Inc.	Cardiovascular
HIV Western Blot Test Kit	Biotech Research Laboratories/Dupont	Diagnostic for AIDS
Poliovirus Vaccine Inactivated	Connaught Laboratories, Inc.	Polio Vaccine
Monoclate *(factor VIII: C)*	Armour Pharmaceutical Co.	Anti-hemophilic
Prohibit *(haemophilus b conjugate vaccine)*	Connaught Laboratories, Inc.	Bacterial Meningitis Vaccine
Prolastin *(alpha$_1$-proteinase inhibitor)*	Cutter Biological of Miles Inc.	Emphysema

*Also being marketed by Stuart Pharmaceuticals under the brand name of Zestril.

Focus

HSR's Robert Rubin

Dr. Robert Rubin, M.D., is president of Health and Sciences Research Inc. (HSR), a Washington, D.C. consulting firm. He was assistant secretary for planning and evaluation at the Department of Health and Human Services from 1981 to 1984. HSR recently delivered a report on the quality of health care to the National Committee for Quality Health Care. The following excerpts were taken from a longer interview with ***Quality Care Insights.***

QCI: What is the state of health care in the United States today?

Rubin: Overall, good. There is neither a national nor a regional quality crisis today. But there is a potential for both if certain trends we identified in the report are not averted. Those trends are signposts signifying problems on the horizon. In some cases, the problems are here today.

QCI: What are the problems you see?

Rubin: There are a series of red flags concerning potential problems. One is a clearly growing nursing shortage. There are not enough nurses to care properly for all patients in many hospitals. Some Maryland hospitals have a 20 percent nursing shortage. At the same time, nursing school enrollments are down. We either have to train someone else to do that work or make nurses' salaries competitive with other fields young women can choose to go into.

There is also a malpractice crisis that is making it too expensive for some physicians to practice medicine. Twenty percent of obstetricians in Massachusetts are no longer delivering babies. That is creating access problems. In fact, access in general is becoming more difficult for the most vulnerable people in our society—the poor, pregnant women and those living in rural or inner city areas where hospitals have closed.

QCI: Have changes in health care brought about by cost-saving pressures affected quality?

Rubin: My concern with cutting health care costs is that many people suppose you can cut indefinitely without affecting quality. That is not the case. There is certainly waste, but there is not an infinite pool of fraud, abuse or inefficiency. The problem is no one today is really talking about preserving quality in any meaningful way.

QCI: Where should our first priority be?

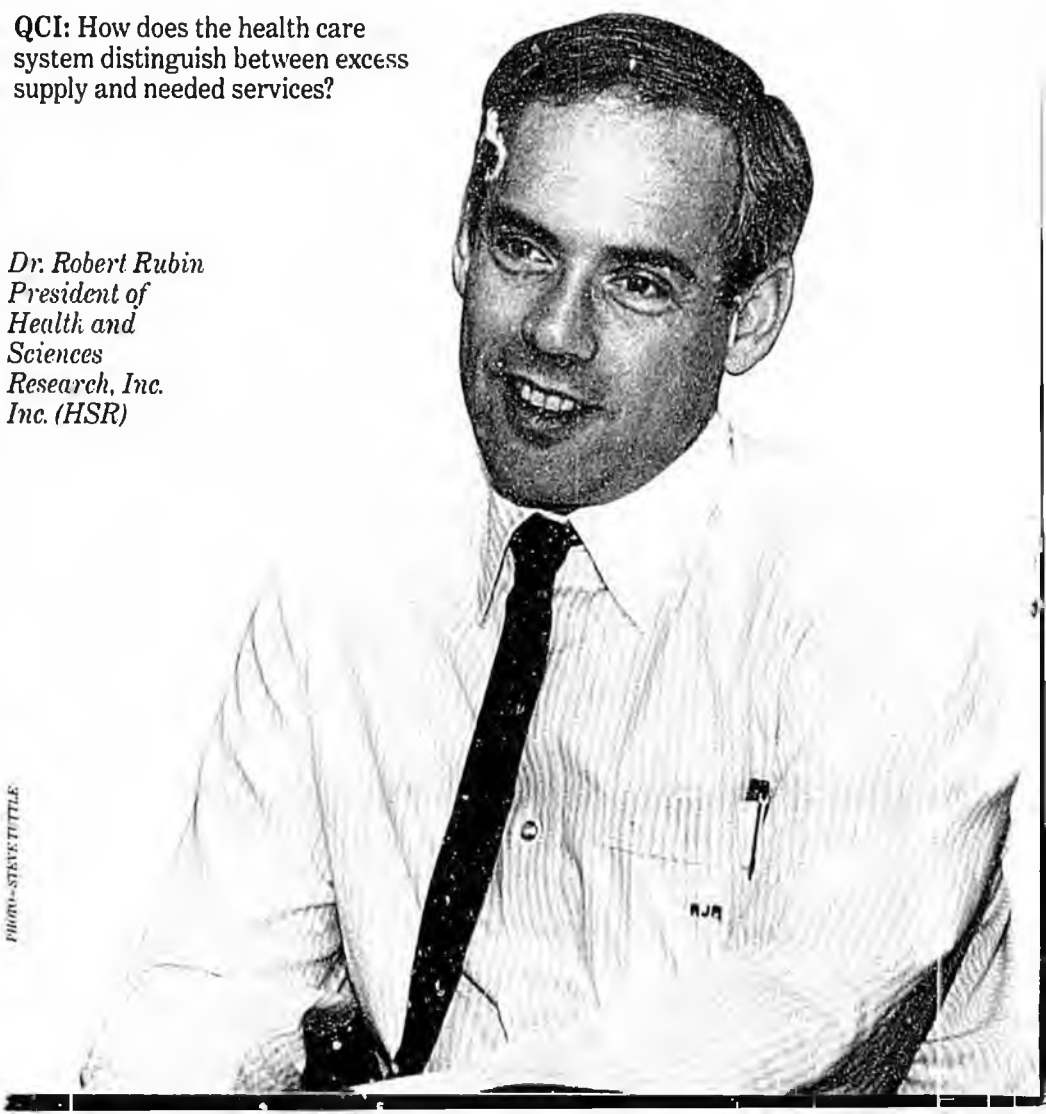
Rubin: The first priority ought to be access to quality health care. To come back to cost-cutting or savings, we should really be talking about cost-effectiveness. That is a better term for the kind of health care system I would like to see in place. The dilemma is whether we are willing to spend the money to develop new cost-effective health technologies that will improve quality care.

QCI: How does the health care system distinguish between excess supply and needed services?

Rubin: Badly. That is the most difficult question in the health care arena. Nobody doubts there is an oversupply of hospital beds, but figuring out which ones to eliminate is very difficult. When the extra bed is in your community it is no longer an extra bed. The local hospital, especially in rural communities, is a symbol as well as a provider of care.

QCI: How do we as a society balance the often-conflicting goals of access, quality and cost?

Rubin: There needs to be an acceptable level of access to high quality care at a reasonable price. The problem is some people want almost instantaneous access to the highest quality care at the lowest possible price. That's where we get into questions of how many tests to order or



Dr. Robert Rubin President of Health and Sciences Research, Inc. Inc. (HSR)

PHOTO—STEVE TUTTLE

what procedures to perform on whom or the role of government. We are willing to pay any price to treat ourselves or our families, yet collectively we may not be willing to pay for the same level of care for everyone in society.

QCI: Is there a role for pharmaceuticals and pharmaceutical companies in ensuring access to quality care at reasonable prices?

Rubin: Yes. Pharmaceutical companies are beginning to hold down costs as a major marketing tool. They are looking for more cost-effective ways of delivering drugs. They achieve this by making the drugs longer acting or administering them in more cost-effective ways. This is just one example of how pharmaceutical companies are providing better drugs at lower prices through research.

QCI: Has Medicare's prospective payment system, as some critics allege, contributed to a decline in quality?

Rubin: The DRG (diagnosis related group) system has not adversely affected quality. It did what we set out for it to do. Whatever the problems, they are not widespread or directly related to quality. The problem is that Medicare has been used as a vehicle for balancing the budget rather than caring for people who need medical services.

QCI: Beyond addressing such problems as a nursing shortage or malpractice crisis, how do we ensure quality care?

Rubin: First, we need to educate private and government payers as to what constitutes quality care. Next, we have to balance concerns for quality with those for cost-cutting. In doing so, we have to reconsider what level of health care we want, remembering that we will have to pay for that level of quality either directly or indirectly. That is why this Administration and I favor a marketplace approach with an eye to preserving access.

DRG-Linked Hospital Discharges... Problems For Community Services

A new survey of 191 randomly selected home health agencies shows that the early discharge of Medicare patients from hospitals is causing major problems for and changes in community health services for the elderly.

"The DRG (diagnosis related groups) system has placed lots of new demands on relatively few resources," said Linda Bergthold, assistant professor of social and behavioral sciences and project director at the Institute for Health and Aging, University of California, San Francisco. "Things are very chaotic right now," she added.

Bergthold told the American Public Health Association that DRGs are causing a shift of patients from hospitals to outside programs, thereby straining the latter's ability to provide quality care and threatening the elderly's access to it.

In particular, Bergthold said, 91 percent of the home health agencies surveyed reported DRGs affecting their patients. Further, 95 percent of the agencies said their newly-discharged patients from hospitals were sicker than before DRGs were adopted by the federal government in 1984.

Of eight home health agencies that shifted status in the past three years, all have changed from public or non-profit agencies to for-profit ones, she reported. "That is a large change," Bergthold observed.

Bergthold also said that more than two-thirds of community mental health centers surveyed reported being affected by DRGs. The finding was surprising, she said, because most hospital psychiatric care is exempt from Medicare's early discharge policies and because the elderly usually do not use community mental health centers. More than half the centers said their patients were arriving older, sicker and in need of more care than before.

Similarly, nursing homes surveyed said they have more elderly patients requesting care than before DRGs. They also reported patients were waiting longer to get care. More than two-thirds of 198 nursing homes surveyed had a waiting list and more than half said the list had grown in the past two years.

One of the most significant changes found, Bergthold said, was in the hospital discharge planning function. Previously, most hospital staffs did not need to know much about the community programs and services available for the elderly.

Now, hospitals are finding they have to help their elderly patients find post-hospital care.

Bergthold said for-profit hospitals were more likely to use registered nurses as discharge planners and that nonprofits were more likely to spend more and have larger discharge planning staffs.

For health policy analyst Bergthold, the changes brought to light by the survey are disturbing. "We may be creating again a two-tiered health care system where those who can afford it get care at home and those who cannot afford it must go into a hospital or nursing home" she said. "The elderly poor and those without insurance will be affected most. We may wind up paying more for them if they cannot be cared for at home."

The survey showed that planners should think more about the whole health care system rather than just part of it, Bergthold added. "We found that major changes in the acute-care setting have had major ramifications for out-patient services," she said. "You cannot cut costs in one sector because those costs merely shift to another."

Research Partnership Praised At NHC-PMA Conference

An unprecedented partnership among government, academia, private industry and voluntary organizations has helped spark major biomedical research advances since World War II, but has shown signs of strain in recent years, participants at a November conference on America's medical research were told.

The conference, which was cosponsored by the National Health Council and the Pharmaceutical Manufacturers Association, also examined the contribution of pharmaceuticals to the litany of medical advances as well as the outlook for new and more effective therapeutic agents.

"The private sector wants to produce new drugs," said prizewinning scientist Paul Janssen, president of Janssen Research Foundation Worldwide. "There is more money and manpower being devoted to the search for new drugs by the private sector than ever before. But policy makers are devoting more energy to cost containment than to biomedical research."

That theme was also touched on by Sen. Lowell Weicker (R-Conn.), the conference's keynote speaker. Weicker warned that continuing cuts for science and education in the name of reducing budget deficits "won't keep the United States on top" in a competitive world.

"Government's task is to provide a consistency of funding for basic biomedical research and to encourage young people to go into research," Weicker said. "This nation can and should speak out on the priority of life. The business of life has to be translated into the national budget and national policy."

Seconding Weicker's words was Robert Bolan, vice president of the National Health Council and executive vice president of the American Diabetes Association. Bolan warned that an inadequate supply of new researchers, a growing obsolescence of equipment and facilities, a heightened uncertainty over public funding and a rising competition from foreign research centers are threatening U.S. leadership in health and medicine.

"We need to heighten public and congressional concern for the cause of medical research," he said. "We need to convince them that nothing can increase our nation's gross national product more and contribute to our everyday lives than to encourage medical research."

On the subject of research itself, all basic biomedical studies today begin with deoxyribonucleic acid or DNA, said George Poste, vice president for worldwide research at SmithKline & French Laboratories.

"Our ability to move genes around gives us an ability to control their expression," Poste added. "That will lead to new molecular weight pharmaceuticals in amounts impossible by traditional means. That, in turn, will allow us to target cellular molecules for drug action rather than just cell surface receptors."

(See "*Conference*", page 8)

("*Candidates*," from page 1)

home health care services for AIDS patients and block grants to states so they have flexibility in dealing with the disease, she said. In the long run, Drake said, Dole favors prevention as the way to reduce health care costs.

The most important health issue today is that of equity, said Karen Smith, assistant director of health policy in Massachusetts' Office of Human Services. Speaking for Gov. Dukakis, Smith cited his work with the business community to develop a plan to provide health care to the uninsured. She said Dukakis favors a more creative approach so that small and marginal businesses can afford to buy health insurance for their employees. Dukakis also wants an approach to long-term care that lets elderly people who can, stay at home with their families, she said.

Jack Bresch, Sen. Simon's campaign manager in Montgomery County, Maryland, said a national health policy is needed to resolve where this country wants to go in providing health services to its people. Bresch said Simon wants the government to ensure health care coverage for everyone as a right.

On specific issues, Bresch said Simon favors an emphasis on children's health, more money for biomedical research and voluntary testing, education and a caring and compassionate approach to AIDS victims and blood testing.

Speaking for Gephardt, Joanne Symons, a campaign consultant on loan from the American Nurses Association, called the health care system a "crazy quilt" of little programs that are out of control. She said Gephardt favors affordable, accessible health care. He sees prevention, education and more home care as ways to cut costs and make more care more accessible to more people.

Symons also said Gephardt favors programs that encourage competition in the health care arena so people and companies can choose among plans, providers and physicians. One problem Gephardt is most concerned with, she said, was our "hideous" infant mortality rate, an issue the candidate wants to address.

Returning to the uninsured and underinsured issue, Dr. Vincent Navarro, a professor of health policy at Johns Hopkins University, said Jackson is outraged that 38 million Americans lack health insurance and 25 million more are underinsured. Jackson favors a comprehensive, universal national health service, with coverage for everyone ensured by the federal government. Navarro said Jackson sees this as a moral rather than just a health issue.

Navarro said universal health insurance can be paid for "if we want to do it." He said Jackson would increase taxes for the wealthy and cut defense spending to reduce federal budget deficits and pay for health care. He also said the government can manage health care programs better than private industry.

Health care costs concern Gore, said Jerry Mande, the Senator's legislative assistant. Mande said Gore thinks money can be saved by investigating FDA practices, creating a national data base for malpractice cases, and promoting prevention and screening programs nationwide. He also said Gore favors cutting out "unnecessary and inappropriate" treatments as a way to cut costs and finance other services, such as organ transplants.

Hospital Data Release Produces Comment, Controversy and Action

The release of mortality data for Medicare patients in hospitals nationwide by the Department of Health and Human Services in December generated a storm of controversy as well as an opportunity for the public to take a first good look at one measure of hospital quality.

The information is contained in a seven-volume report weighing some 30 pounds. It includes data on 735,000 deaths of Medicare patients either in, or within 30 days after discharge from, 5,971 hospitals in 1986. The data, which is accompanied by comments from individual hospitals, is adjusted by age, sex, medical condition upon admission or transfer, and prior hospitalizations.

The result is a range of expected death rates for each of 16 diagnostic categories plus an overall range of expected deaths for each hospital. The report showed some 585 hospitals or 10 percent had death rates at the top of the spectrum and another 146 hospitals or 2.5 percent had rates above their expected range.

The meaning of such findings raised considerable comment and controversy. "The information is potentially misleading," said James Marriman, director of federal agency affairs at the American Hospital Association. "People will assume that mortality data relates to hospital quality, but you can't make that assumption."

Similarly, the American Medical Association warned that use of the information could be harmful. "Distributing this data provides no meaningful value to patients," said Dr. James Sammons, AMA executive vice president. "It will cause irreparable damage to physician-patient relationships."

On the other hand, consumer groups welcomed the data's release. "We have long encouraged government agencies to get hospital mortality data into the hands of consumers," said Craig Tanio of the Public Citizen Health Research Group. "We want to see more data become publicly available."

Agreeing was Vita Ostrander, immediate past president of the American Association of Retired Persons. The data, she said, "will build the patient's overall understanding of medical treatment, including an understanding of the difficulty of measuring and predicting quality."

To better measure and predict quality, the AHA's Marriman said, mortality rates should be adjusted for severity of illness. He said AHA is looking at existing severity indices to see how they might be used to interpret the data better. Marriman also said pilot studies are needed to examine the relationship between mortality data and hospital quality.

The Health Care Financing Administration, which runs the Medicare program, is likewise working to develop severity indices. Stephen Jencks, a senior physician in HCFA's office of research, said the agency is collecting and analyzing data on deaths from stroke, pneumonia, heart attack and congestive heart failure from five states.

The data will be used to give a likelihood of death for any individual or group of patients that can then be compared with what actually happened to those patients. Severity will be adjusted for, Jencks said, on the basis of some 30 physical and medical history measurements taken at admission. HCFA's severity index should be available by fall so hospitals and consumers can use it to analyze the agency's 1988 hospital mortality data release, he added.

Public Citizen advises the 1987 mortality data be used to ask questions of physicians and hospital administrators. The questions include what, if any, changes a hospital made regarding individual physicians and departments as a result of the data. "If there are no reasonable explanations, then you might consider going to a different hospital with a lower mortality rate," the consumer advocacy group said in its newsletter.

But, individual consumers might find HHS's seven-volume report difficult to obtain, costly ($69) to buy and hard to plow through. Help is on the way, however, said Robert Krughoff, president of Consumers' Checkbook, a Washington, D.C.-and San Francisco-based group. Consumers' Checkbook will publish a one-volume, 200-page condensed version in April.

The Consumer's Checkbook report will explain how to use the hospital mortality data, show whether each hospital is affiliated to a university medical school and/or has a residency program, and its type (nonprofit, community, for-profit) of ownership. It will also show the group's own surveys of patients, nurses and physicians of hospital quality in Washington,D.C. and San Francisco.

The condensed report will be available for $10 from Consumer's Checkbook, Suite 925, 806 15th Street, N.W., Washington. D.C., 20005.

Government Roundup

Statehouse Report . . . **Delaware** has decided to drop its Medicaid incentive fee program to encourage generic drug substitution. The state Department of Health and Social Services said it could not show cost savings were achieved by the program. Any savings that were achieved might have been achieved without paying the incentive fee, it added. The program was a one-year pilot study begun in October 1985. A report on the program found generic substitutions increased only 12.7 percent during the incentive fee year. Meanwhile, a bill to create a similar incentive fee program for generic substitution under Medicaid has been dropped in **South Carolina**. The South Carolina bill was introduced in 1987, but has now been withdrawn. It cannot be reconsidered for two years . . . A new bill to provide "universal" health care in **Massachusetts** is being drafted. A bill passed the state Senate in 1987, but failed to pass the House before it adjourned. The 1987 bill would have required all businesses to provide health insurance benefits to employees or pay $1,680 per employee to a state health insurance fund. The Massachusetts bill also provided tax incentives for businesses to offer health care coverage to employees . . . Massachusetts is not the only state considering or actually adopting some form of universal health insurance. **Oregon** enacted a voluntary, employer-provided health care insurance program in 1987 that offers businesses with 25 or fewer employees a tax credit equal to 50 percent of their contributions to health insurance for their workers. In **Michigan**, the Robert Wood Johnson Foundation is sponsoring a demonstration project in which the state, employers and employees share equally in paying for insurance coverage. A similar Johnson Foundation-sponsored plan was adopted in **Arizona**. **Washington** state passed a bill in 1987 to provide health care coverage to 30,000 low-income people in five pilot project locations. And **Hawaii** has for 10 years required employers to provide health insurance to employees . . . Davidson County (Nashville), **Tennessee**, has proposed to tax six nonprofit hospitals in the Nashville area. The county assessor says the hospitals' charges are similar to those of local proprietary ones, even though the former do not provide appreciably more charity care. A similar proposal to tax nonprofit hospitals is being considered in Chattanooga.

. . . The **New York** State Department of Social Services issued a final regulation regarding reimbursement for brand name drugs under the Medicaid program. The regulations, scheduled to be effective on March 1, would deny full reimbursement for a brand name product even if the physician indicates on the prescription form that a particular brand name product should be dispensed. In promulgating this regulation, the state in effect has allowed a physician override for brand name products but will not provide full reimbursement . . . In January, Delegates White and Wells introduced **West Virginia** House Bill 4242, a bill which would assess hospitals, long-term care facilities, home health agencies, pharmacies, durable medical equipment companies and certain group homes in order to raise revenue to repay the state's consolidated investment fund. This fund is used to pay for the state's Medicaid program. The bill has now been dropped in Conference Committee, and $30 million from the State's Black Lung Fund will be used to fund the Medicaid program . . . **Utah** state Senate bill 75, a bill that prohibits the use of a restricted drug list for the Medicaid program in that state, has passed both the House and Senate and is waiting the Governor's signature.

Sources

• Project Hope has issued a pamphlet on "Buying Quality Health Care." The pamphlet is designed to help health care purchasers, whether individuals or companies, better understand the many new options available. It lists questions to ask and points to consider in selecting a health care plan, physician or hospital. *Copies can be obtained by writing the Center for Health Affairs, Project Hope, Suite 500, Two Wisconsin Circle, Chevy Chase, Maryland 20815.*

• Lewin and Associates has prepared a report for Pfizer Inc. summarizing the objectives, methodology and status of major research and other projects in progress relating to quality of care issues. The report discusses projects on measurements of quality and outcomes research, employer and consumer information, managed care and the Medicare prospective payment system. *Copies can be obtained by writing Paul Meyer, Ph.D., Pfizer, Inc., 235 East 42nd Street, New York, New York 10017.*

• The Food and Drug Administration has published a special report entitled "New Drug Development in the United States." It includes articles from the agency's magazine on how drugs are developed, tested and approved, on FDA's attempts to improve the process and on drugs for the desperately ill or rare diseases, among others. *Copies can be obtained by writing the Office of Public Affairs, HFI-1, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857.*

("*Conference.*" from page 6)

Where is research going? Marvin Jaffe, senior vice president at Merck Sharp & Dohme Research Laboratories, noted the graying of America's population and said new drugs are needed to control such body functions as heart rate, breathing and metabolism, all of which change with age. Jaffe also urged studies of how drugs work in different life stages and in different combinations.

Another look at the future was offered by Humphrey Taylor, president of Louis Harris and Associates. Using his firm's opinion surveys of health researchers and professionals, Taylor predicted a growing emphasis on preventive medicine, less invasive surgical and treatment methods, new drugs to treat neurological and viral disorders, and better nutrition to prevent and/or treat diseases such as osteoporosis.

Alaska State Legislature

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State Senate

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February 12, 1988

Honorable Ted Stevens
United States Senate
522 Hart Building
Washington D.C. 20510

Dear Senator Stevens,

Please consider this letter recommendation for the appointment of Shannon Kohler to the Advisory Commission on Childhood Vaccines.

Shannon has been active in Alaska Dissatisfied Parents Together (DPT) for a number of years. During this time she has completed extensive research with regard to vaccine safety and efficacy. She has been instrumental in the introduction of HB 277, a copy of which is enclosed, and the improvement of the vaccination program within the State of Alaska. Many of these concerns need to be addressed at the Federal level especially in regard to National Childhood Vaccine Injury Act of 1986.

Shannon has expressed a willingness to serve on the Commission. Taking into consideration her background, dedication, and motivation she would be an asset to the Commission.

Thank you for your time and consideration.

Cordially,

Paul

Senator Paul A. Fischer

PAF/ssw

Alaska State Legislature
House of Representatives
COMMITTEE ON HEALTH, EDUCATION
AND SOCIAL SERVICES

OFFICIAL BUSINESS

POUCH V
JUNEAU, AK 99811
465-3759

March 8, 1988

Honorable Ted Stevens
United State Senate
522 Hart Building
Washington, D.C. 20510

Dear Senator Stevens:

As the Co-Chairs of the Alaska House Health, Education, and Social Services Committee, we would like to recommend Shannon Kohler be appointed to the federal Commission being created in conjunction with the National Childhood Vaccine Injury Compensation Act.

Ms Kohler has a strong viewpoint on the subject of mandatory immunization and has put considerable effort into researching and organizing around it. We believe the federal Commission to be an appropriate place for someone with her concerns to serve. She would undoubtedly make a hard working member of such a commission.

It is our understanding that Shannon is also being recommended by the Alaska Department of Health and Social Services, by the Senate HESS Chair, Senator Paul Fischer, and by Representative Mike Navarre.

Thank you for your attention to this matter. We will continue to monitor discussions around the subjects of immunization and public health.

Sincerely,

Rep. Niilo Koponen, Co-Chair

Rep. Johnny Ellis, Co-Chair

CC: Shannon Kohler
NK/JE/ljm

Alaska State Legislature

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CHAIR, RULES COMMITTEE

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DISTRICT 5

Representative Mike Navarre

March 1, 1988

Honorable Ted Stevens
United States Senate
522 Hart Building
Washington, D.C. 20510

Dear Senator Stevens:

As I am sure you are aware, the National Childhood Vaccine Injury Act of 1986 deals with compensation for adverse vaccine reactions. In addition, the legislation calls for the creation of the Advisory Commission on Childhood Vaccines.

Three members of the nine member commission are to be from the general public, two of whom will be legal representatives of children who have suffered vaccine-related injury or death.

I strongly feel that one of the public members should be from Alaska, and would like to suggest Mrs. Shannon Kohler of Soldotna.

Shannon Kohler is the president of the Alaska Chapter of Dissatisfied Parents Together (DPT), a national organization dedicated to vaccine safety. I have worked closely with Shannon on vaccine legislation in Alaska, and she has testified before the House Committee on Health, Education and Social Services.

Because of Mrs. Kohler's intense dedication to elimination of vaccine-related injuries, she has become extremely knowledgeable about vaccines - as knowledgeable as many health care professionals are. In addition to this impressive knowledge, she demonstrates a real concern that the issue of vaccine-related injuries be addressed in a logical and fair manner.

In summary, I feel Shannon Kohler is highly qualified, and would prove to be a very valuable addition to the commission. I recommend her without reservation.

If you have further questions, feel free to contact me, or Mrs. Kohler directly at Box 1746, Soldotna, AK 99669. Her phone number is (907) 262-3825.

Thank you for your consideration.

Sincerely,

Mike Navarre
State Representative

cc: Shannon Kohler

ALASKA STATE LEGISLATURE
HOUSE OF REPRESENTATIVES
RESEARCH AGENCY

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January 28, 1988

MEMORANDUM

TO: Representative Mike Navarre

FROM: Patricia Brawley
Legislative Analyst

RE: **Personal Exemption from Mandatory Immunization**
Research Request 88.075 (Supplemental Information)

You requested that we provide information about personal exemptions from mandatory immunization laws in Colorado, Wisconsin and Utah. Specifically, you wanted to know the following:

1. Historically, how did this personal exemption come about in those states, and what was the reason for the change in existing law?

2. What happened to the vaccination compliance rate as a result of these waivers? What is the current compliance rate?

3. What is the before and after frequency of the "serious seven" diseases in those states, and in what percentage of cases, if any, were the persons vaccinated?

4. Do parents have the opportunity to "pick and choose" which vaccinations their children will receive, or is it an "all or nothing" proposition?

The Center for Disease Control in Atlanta indicates that all states have mandatory immunization laws. The following exemptions have been incorporated into law: every state allows a medical exemption; every state, except Mississippi and West Virginia, allows a religious exemption; and 22 states allow a philosophical (personal) exemption. Responses to your specific questions concerning Colorado, Wisconsin and Utah follow.

COLORADO

According to Judy Canner, Immunization Program Director, Colorado Department of Health, the state's mandatory immunization law was in place by 1975. The original version covered only kindergartners, transfer students through grade 6, and child care facility enrollees. An amendment in 1978 extended coverage to all students in public schools and added the personal exemption. The push for inclusion of a personal exemption was based on the argument that the law was an infringement of personal rights. Colorado officials believe that the amendment would not have passed without the addition of the personal exemption.

The Colorado Department of Health does not consider the personal exemption to have significantly affected compliance rates. Statistics showing percentage of compliance and percentage of personal exemptions suggest, however, that the compliance rate is in a slight downward trend while the personal exemption rate is climbing.

School Year	Compliance Rate (%)	Personal Exemption Rate (%)
78-79	90	0.3
79-80	97.7	0.5
80-81	unavailable	unavailable
81-82	97.4	0.6
82-83	97.8	0.7
83-84	97.4	0.8
84-85	97.2	0.8
85-86	97.4	0.8
86-87	97.1	0.9

There is little correlation between the personal exemption and the frequency of disease outbreak. Frequency has continued to decline during the last decade, except in the case of pertussis (whooping cough), which has been on the increase. This is a reflection of the law rather than the exemption, however, because Colorado does not require immunization against pertussis. Colorado currently has a an outbreak of measles in a college community; most of the involved individuals had been vaccinated. While this year's incidence far exceeds the frequency typical of the last decade, it is still considered to be "well within the five percent failure rate common in vaccines, and is typical of measle transmission."

Parents are allowed to choose which vaccines their children will be exempt from taking. In practice, parents generally object to all vaccines if they object to any.

WISCONSIN

Craig Leutzinger, Immunization Program Director, Wisconsin Department of Public Health, indicated that Wisconsin's mandatory immunization law included medical and religious exemptions when it was instituted in 1975. It was ineffective in that it covered only kindergartners, and the wording did not require parents to have children vaccinated. Amendments in 1980 expanded coverage to grades K - 12 (to be implemented gradually), changed the wording to require vaccinations, and added the personal exemption. In spite of Department of Health opposition, the exemption was included through lobbying efforts of a group known as Dissatisfied Parents Together (DPT), which was led by a woman whose son had been severely injured by the DPT vaccine.

Immunization is a widely accepted practice in Wisconsin as reflected by a 99 percent compliance rate. Since 1977, the total percentage of exemptions has remained constant at 0.8 percent to one percent. Prior to 1980, the one percent reflected equal numbers of religious and medical exemptions; since 1980, religious and medical exemptions have dropped to 0.1 percent each while personal exemptions have remained steady at 0.6 percent. It appears that individuals who might previously have claimed religious exemptions now call their objections philosophical rather than religious.

In spite of the high compliance rate, Wisconsin had the highest state rate of mumps in 1987. The incidence of measles in Wisconsin was also high (284 in Wisconsin compared to 12 in Colorado). This does not necessarily correlate to the personal exemption, however, because Wisconsin's mandatory immunization law was set up to be implemented in stages. For example, vaccination for mumps was required beginning in 1982, and only grades K - 4 are currently covered; if an unvaccinated fifth-grader from another state enters a Wisconsin school, there is no requirement that the child be vaccinated against mumps. Another important factor in the high incidence of disease in Wisconsin is that until 1987 there was a strong reluctance on the part of schools to exclude unvaccinated individuals from school during disease outbreaks, even though the law allowed for it. In 1987, during an outbreak of measles, the need to protect unvaccinated children and to interrupt the transmission cycle overcame that reluctance. Since then, exclusion from school has become widely accepted. Outbreaks have "certainly included uncovered children," but no statistics are available on the percentages.

As in Colorado, parents have the right to select which vaccinations their children will be exempt from taking; however, generally there is an all or nothing attitude.

UTAH

According to Rick Crankshaw, Immunization Program Coordinator, Utah Department of Health, Utah's mandatory immunization law included only entering kindergartners when it was enacted in 1976. An amendment in 1982 expanded the coverage to grades K - 12, included all licenced child care facilities, and incorporated the personal exemption. The inclusion of the personal exemption was based on other states' experience with the DPT controversy over vaccinations for pertussis--which sometimes causes extremely serious adverse reactions.

The compliance rate in Utah is very high; exemptions during the last several years have been approximately one percent. Of that, 0.8 percent are personal exemptions and the other 0.2 percent are medical exemptions. No statistics directly comparing compliance rates before and after incorporation of the personal exemption are available.

No statistics are available on the frequency of disease before and after incorporation of the personal exemption. Because of the law, Utah schools now have an accurate tracking system so that each school can make an immunization assessment. During an outbreak of disease, the Department of Health orders that any unprotected children be excluded from school until the outbreak is over.

As in Colorado and Wisconsin, parents can choose individual vaccinations to which they are philosophically opposed. In practice, however, parents generally object to all vaccinations or to none.

According to the results of this sample, and the Center for Disease Control, the availability of the personal exemption appears to have had relatively little significance. Feared problems have not materialized; the philosophical exemption does, however, weaken the force of immunization laws inasmuch as it provides some potential for sustaining transmission of disease.

I have requested a copy of the Center for Disease Control's most recent update of State Immunization Requirements, which I will forward to you.

I hope you find this information useful. Please contact me if you have any questions.