ALASKA LEGISLATURE COMMITTEE FILES 1987-1988 8672
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VACCINATIONS—A TIME BORROWED DISEASE!

by LEE DeBILL

or many years now vaccines
ve been given to the public
h the claims of wiping out
ks, smallpox, diptheria,
shoid and other contagious
ases. Many believe, this is a
e statement and could not be
ther from the truth. Some
ieve it was the introduction of
sanitation and improved nutri-
s which reduced disease. Let
s review history for some far-
sight.

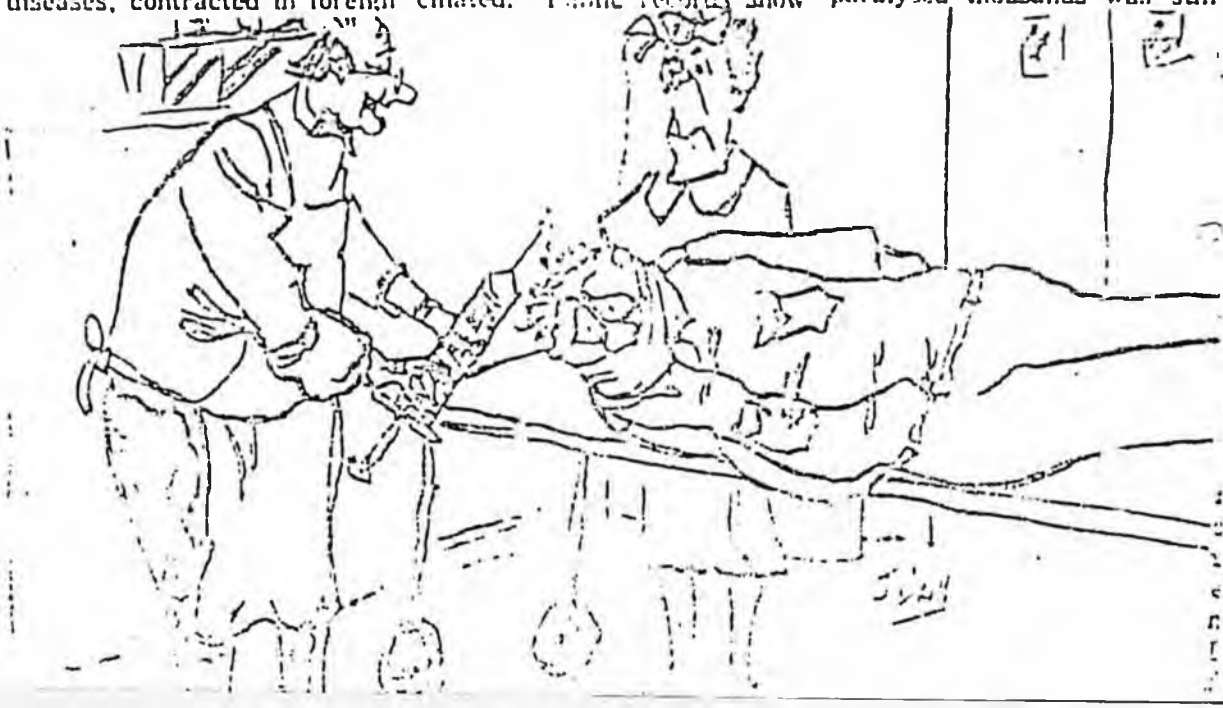
When the epidemics swept
rope in the 18th century, we
re taught to believe that they
re finally controlled by vac-
nation. Checking the records,
opposite situation can be
ld to be true, that these
lemics were actually caused
vaccination. Following, are a
medical reports of that time
iod.

ipan startedcompulsory vac-
ation in 1872 and continued
over 100 yearswithdisastrous
lts. Small pox was not
ed out as expected but in-
sed every year. By 1892 the
ords showed that 165,774
es of small pox had occurred
29,079 deaths, all of whom
e vaccinated. While in
tralia where they had no
pulsory vaccination, only 3
hs due to small pox were
rded in 15 years.

Germany at the beginning
W. II (1939) vaccination for
heria was made compulsory
the diptheria rate soared to
0 cases. All these cases
ere vaccinated. At the
back in history to that 1918 flu
period we will see that it suddenly struck just after W.W. I, when our soldiers were returning home from Europe. That was the first war that all known vaccines were forced on all servicemen. The drugs and proteins of which the vaccines were composed of caused such wide spread disease and death among the soldiers that it was common talk of the day that more of our men were being killed by medical shots than enemy shots. Theusands of men were quarantined to home or military hospitals as hopeless cases long before they ever saw a day of battle. The death and disease rate was four times higher than among unvaccinated civilians. At this same time, the civilians were told the soldiers were coming home with many dreaded diseases, contracted in foreign

The polio vaccination drive of 1954-1955 was a similar disaster. Records reveal thousands of previously healthy people were killed or paralyzed by vaccines (Salk and Sabin). Millions of dollars in damages were paid to the victims of that polio vaccine campaign, but most cases were hushed up by calling them another name or disease. During the vaccination disaster of 1954-1960 Morris A. Beale, a publisher and writer offered $50,000.00 to anyone who could prove that the polio vaccine was not a killer and a fraud. No one ever collected that $50,000.00. The lawsuits proved that the vaccine was deadly from the start.

There was a marked increase in polio among the vaccinated as compared to the unvaccinated. Public records show



and programs. Dr. James A. Shannon of the National Institute of Health stated "The only safe vaccine is a vaccine that is never used." The famous scientist Dr. Wm. F. Koch, M.D., Phd. stated "The injection of any serum, vaccine or even penicillin has shown a very marked increase in the incidence of polio, at least 400 percent.

"Statistics on this are so conclusive no one can deny it." Surgeon General Leonard Scheele, who was overseeing the countries largest polio drive told the A.M.A. convention in 1955 that "No batch of vaccine can be proved to be safe before it is given to children." Dr. Salk, the inventor of the polio vaccine admitted "No reliable test of safety to the vaccine is known." Yet this vaccine which killed and paralysed thousands was still

flu, measles, mumps and polio may actually be seeding humans with RNA to form pro viruses which will then become latent cells throughout the body. . .some of these latent pro viruses could be molecules in search of diseases' which under proper conditions become activated and cause a variety of diseases. . .(including rheumatoid arthritis, multiple sclerosis, lupus erythematosus, parkinson's disease and perhaps cancer)" (Report to Consumer, June 76-No. 127).

In 1968 a paper was published in Arch Intern Med which proved that Guillain-Barre paralysis was caused by vaccinations, not just in Isenza vaccine but other vaccines as well. In 1969 (Epid. Aspects of Imunization) another paper proved that blindness and brain damage was associated with innoculations.

In an article, published in Science (March 4, 1977) Jonas Salk was quoted "Live virus vaccines against influenza and paralytic poliomyelitis may in each instance produce the disease it intended to prevent. . .the live virus vaccine against measle and mumps may produce side effects as encephalitis (brain damage), and the killed virus vaccines against measles and the respitory syncitial virus have caused undesirable hypersensitivity reactions in individuals subsequently exposed to natural infections."

More recently, in 1976, the Swine Flu Vaccine program was enacted by President Ford. At that time there was not one

Ask Dr or nurse giving the shots:

Will you guarantee its safety and effectiveness?

way there were [illegible] 50 cases.

And in yet another country, the Netherlands (1929-1929), there were 129 cases of post-vaccinal encephalitis (inflamation of the brain from vaccine poisoning) and 40 deaths from it.

Two hundred and fifty years ago, in 1717, arm to arm vaccination was introduced into England and Europe. In 1796 Edward Jenner started the cowpox vaccination craze which increased the small pox epidemic to such an extent in 1838 that 22,681 people died from it.

Years later, in spite of absolute proof that vaccination had deadly effects a compulsory vaccination law was passed in [illegible] in 1853. The epidemics increased, and by 1872 the small pox epidemic of all time killed 44,840 people. The English people fought the vaccine promotors until they were able to abolish compulsory vaccines in England in 1948. They have had no epidemics in England since.

Our own U.S. Government staged a compulsory vaccine campaign in the Philippines which brought on the largest small pox epidemic in the history of that country with 162,502 cases and 71,153 deaths. All of these people were vaccinated. This occurred between 1917 and 1919.

Very few people even realize that the worst epidemic ever to hit America, The Spanish Influenza of 1918, was the after effect of a massive nation-wide vaccine campaign. If we check lands and that it was the patriotic duty of every man, woman and child to get protected by going to the vaccination centers and receiving all the shots.

The biggest tragedy here was that most people believed their doctors and government officials and did exactly what they said. The result was submission to shots without question. It was only hours later that people started dropping dead with a disease of such virulence that no one had ever seen before. These diseases all had the symptoms of the diseases they had been vaccinated against. The high fever, chills, pains, cramps, diarrhea of typhoid, the pneumonia congestion of diptheria, the hepatitis of jungle fever, sores from small pox plus paralysis from all the shots.

The doctors did not want this massive vaccine disease to reflect upon them so it was called Spanish influenza. 20 million people died from the flue epidemic. Greece and a few countries who did not except the vaccine, were the only ones who did not contract the flu.

The only people in the United States who escaped the influenza were there who refused the vaccinations.

that the vaccine did not wipe out polio but caused it.

In the Illinois Medical Journal (Aug. 1950 pp 61-63) a statement appeared by Dr. Langmuir (Head of Polio Surveillance of U.S. Public Health Service). After the nationwide polio drive of 1954 and 1955, he was quoted as saying "I will predict that by 1957 there will be less than 100 cases of paralytic polio in the United States." The record shows that within 4 years there were 5,694 cases of polio. The highest incidense of polio was in the five states that had compulsory shots.

1. North Carolina - 78 cases in 1958, 313 cases after the shots.
2. Connecticut - 45 cases in 1958, 123 cases after the shots.
3. Tennessee - 119 cases in 1953, 303 cases after the shots.
4. Ohio - 17 cases in 1958, 52 cases after the shots
5. Los Angeles California - 39 cases in 1958, 149 cases after the shots.

Note - In 1931 California enacted an escape clause for the shots.

Even though public records showed beyond shadow of doubt [illegible] caused the disease [illegible] promoted.

Casualties were also reported from the Sabin oral vaccine. Many of these cases were proven in court. Eleven cases of paralysis were reported September 15, 1961 in Syracuse, N.Y., and the vaccine promoters had to pay millions of dollars in damages. Failure of the vaccine, and the lawsuits brought about by it, caused four out of five companies producing it to drop out of the market. The fifth, Lederle, is still making the vaccine today, but will not give any guarantee of its effectiveness or safety. No doctor will guarantee safety or effectiveness either.

In October 1976 the Senate Committee heard testimony proving that the polio vaccine had caused all the reported cases of polio since 1961 and that the vaccine may be riskier than no vaccine at all. Since 1973 the Center for Disease Controll has admitted that over one half of all polio cases were vaccine associated. In July 1969 the International Medical Journal was advising the profession to "re-evaluate the principles, purposes, and hazards of immunization."

Dr. Robert W. Simpson of Rutgers N.J. stressed that "Mass immunization programs against

Dis was diagnosed as having Victorian Flu. But e swine flue had been fou vaccine would not have st it anyway. Dr. Anthony Mo noted vaccine experimen said that there was nev authentic swine flue va made, because there w swine flu to test it on. million was spent in advan the vaccine companies develop a vaccine for a existant disease. As of 23, 1979, 3,637 claims were for personal injury tot $3,351,065,797. 34 of these cl were for wrongful death t ing $344,908,214, and 1,045 cl werefor Guillian-Barre para totalling $952,549,317.

Many people who died were paralysed could have sparial if information had released as to the side effe any vaccine whether it be f flu, measles, mumps, whoo cough or diptheria.

Diptheria which is virt non-existant is still being cinated against even thoug percent of the people recei the vaccine contract the dis Upon vaccination for whoo cough, the possibility of fev convulsions and brain damag too high to ignore. Danger great that many p authorities prohibit the us the vaccine after the age o The Mumps vaccine exp children to the disease later in life after the vaccine wo [illegible] done by

(Continued on Page 5)

AS14.30.125 DOCUMENT= 1 OF 1 PAGE = 1 OF 2

CHAPTER = 14.30
SECTION = 14.30.125
TITLE = 14

HEADINGS TITLE 14.
Education.
CHAPTER 30.
Pupils and Educational Programs for Pupils.
ARTICLE 2.
Physical Examinations and Screening Examinations.

CITATION Sec. 14.30.125.

CATCH LINE
IMMUNIZATION.

TEXT If in the judgment of the commissioner of health and social services it is necessary for the welfare of the children or the general public in an area, the governing body of the school district shall require the children attending school in that area to be immunized against the diseases the commissioner of health and social services may specify.

HISTORY (Sec. 45 ch 98 SLA 1966; am sec. 2 ch 131 SLA 1967; am sec. 6 ch 104 SLA 1971)

(b) District boards shall determine which employees, if any, are exempt from the physical examination requirements.

(c) These regulations shall not be construed as exempting employees from taking physical examinations required by other regulations or law – i.e., food handlers, bus drivers, etc.

(d) Repealed 6/10/83.

(e) Each employee of a school district or private elementary or secondary school shall obtain a tuberculin skin test annually in the manner required by AS 18.15.145. (Eff. 10/9/66, Reg. 24; am 10/10/69, Reg. 29; am 5/30/71, Reg. 38; am 7/9/72, Reg. 42; am 10/4/73, Reg. 47; am 5/10/78, Reg. 66; am 6/10/83, Reg. 86; am 8/30/86, Reg. 99)

Authority: AS 14.07.020(7)
AS 14.07.060
AS 18.15.145

Editor's Note: The history note that appeared under 4 AAC 06.050 before Register 86 (July 1983) was found to be incorrect. With the distribution of that register, the note has been corrected.

4 AAC 06.055. IMMUNIZATIONS REQUIRED. (a) Prior to first entry in an Alaska public school district or nonpublic school offering pre-elementary education through the 12th grade, or any combination of these grades, a child shall be immunized against diphtheria, tetanus, polio, pertussis, measles and rubella, except that pertussis is not required in children over six and rubella is not required in children 12 years or older

(b) This section does not apply if the child

(1) has a valid immunization certificate defined as

(A) an international immunization certificate; or

(B) a statement by a physician listing the dates of immunizations; or

(C) a copy of clinic or health center record showing the immunization requirement has been fulfilled;

(2) has an affadavit signed by a physician (M.D.) or osteopath (D.O.) licensed to practice in Alaska affirming his opinion that immunization would be injurious to the health and welfare of the child or members of his family or household;

(3) has an affidavit signed by his parent or guardian affirming that immunization conflicts with the tenets and practices of the church or religious denomination of which the applicant is a member.

(c) A student registering in a school in a community where regular medical services are not available on at least a weekly basis and who does not have the required immunizations, may be provisionally admitted to a pre-elementary, elementary or secondary program for a reasonable period of time for the prevailing circumstances but not exceeding 90 days after

enrollment. No children will be provisionally admitted except in exceptional circumstances. Where exceptions are granted, they shall be reported to and discussed with the Communicable Disease Section of the Division of Public Health, Department of Health and Social Services, who will then be responsible for determining that the required immunizations are completed during the provisional period.

(d) If a parent or guardian is unable to pay the cost of immunization, or immunization is not available in the district or community, immunization shall be provided by state or federal public health services.

(e) Immunizations shall be recorded on each pupil's permanent health record form.

(f) School districts shall initiate action to exclude from school any child to whom this section applies but who has not been immunized as required by this section. (Eff. 1/13/73, Reg. 44; am 8/28/77, Reg. 63)

Authority: AS 14.07.020(7) and (8)
AS 14.30.125

4 AAC 06.060. SUSPENSION OR DENIAL OF ADMISSION. (a) In the district schools, the superintendent or principal may suspend pupils under the provisions of AS 14.30.045, and the pupils may be reinstated by the superintendent or principal or by the school board.

(b) Expulsion or denial of admission of a pupil shall be only upon the action of the governing school board in a district school.

(c) A pupil suspended or expelled under this section may appeal to the district board. (In effect before 7/28/59; am 9/24/65, Reg. 20; am 9/8/66, Reg. 24; am 1/9/68, Reg. 26; am 5/10/78, Reg. 66)

Authority: AS 14.30.045

4 AAC 06.070. ELEMENTARY COURSE OF STUDY. The Course of Study for the Elementary Schools in Alaska, reissued by the department in 1971, is officially adopted as the standard for elementary schools. (In effect before 7/28/59; am 5/30/71, Reg. 38)

Authority: AS 14.07.020(4)

4 AAC 06.075. HIGH SCHOOL GRADUATION REQUIREMENTS. (a) Each chief school administrator shall develop and submit to the district board for approval a plan consisting of district high school graduation requirements. The plan must require that, before graduation, a student must have earned at least 21 units of credit.

(b) Specific subject area units-of-credit requirements must be set out in each district plan and must require that, before graduation, a student must have completed at least the following:

(1) language arts – 4 units of credit;

(2) social studies – 3 units of credit;

(3) mathematics – 2 units of credit;

(4) science – 2 units of credit;

(5) health/physical education – 1 unit of credit.

(c) Districts which do not require 21 units of credit for graduation on June 16, 1984, must increase their requirements by at least one unit each school year until the number of units required attains or exceeds 21.

(d) Transfer students who have earned 13 units of credit while in attendance outside the district may, at the discretion of the district, be excused from the district subject area units-of-credit requirements.

(e) Districts which do not require the subject area units of credit for graduation required by (b) of this section on June 16, 1984, must increase their subject area units-of-credit requirements by at least one each school year until the number of units of credits required in each subject area attains or exceeds the requirements imposed by (b) of this section.

(f) As used in this section, "unit of credit" means the credit that a student is awarded for achieving a passing grade in a course of study consisting of at least 8,100 minutes of class time during the school term. (Eff. 3/1/78, Reg. 65;

TRUTH BULLETIN # 25:
A M.D. who was an AMA employee for 10 years and who called himself "Sore Throat," sent copies of secret AMA documents and memos to various outsiders that revealed that the powerful doctors' union "will stop at nothing to increase its own power" and increase the flow of money to itself and the drug makers. The documents showed that the AMA used every method it could to get AMA members placed in government positions, that it "'laundered' AMA money so it could be secretly given to politicians who would look out for AMA interests," that it managed to avoid $21 million in taxes on money made from massive drug ads in its journals, that some of the "Sore Throat" material indicated'"the AMA is involved in a kind of conspiracy with the federal government, the purpose of which is the elimination of drugless healing in the United States.'" The AMA defines "quackery" to mean "anything that the AMA doesn't agree with."[From: PREVENTION, Feb.,1976,"Things Here and There,"by M. Bricklin, pp.89-90]

TRUTH BULLETIN # 26:
Americans swallow more than 80 million aspirin tablets every day; that's 29 billion tablets each year. Few realize that aspirin can kill; a small overdose(about 30 tablets) can be fatal to adults, and aspirin disguised as candy for children poses a real menace. Too much aspirin depresses the brain's respiratory system, causing the victim to stop breathing, but even a standard 1-3 tablet dose can have serious side effects. In conjunction with alcohol, aspirin can cause ulcers. Large amounts of aspirin taken for long periods cause ear ringing and even deafness, may damage the lungs' lining, and in pregnant females influences the fetus.[From: SCIENCE DIGEST, June,1986,"Aspirin The Newest Wonder Drug," by S. Shapiro, pp.50-55]

TRUTH BULLETIN # 27:
"Immunization programs against flu, measles, mumps and polio," said Robert Simpson, M.D. of Rutgers University,"may actually be seeding humans with RNA to form proviruses, which will then become latent cells throughout the body...whichunder proper conditions become activated and cause a variety of diseases...including rheumatoid arthritis, multiple sclerosis, lupus, Parkinson's disease and perhaps cancer."[From:THE SPOTLIGHT, "Researchers Rap Vaccinations as Cause, Not Cure of Diseases,"by G. Deal,Ph.D,D.C., March 3,1986,pp.26-27]

TRUTH BULLETIN # 28:
'"Never in modern history has the medical profession been weaker. To a great extent, physicians are becoming seen as highly successful businessmen who are functioning with the business ethic rather than the professional ethic,'" wrote Dr. George Lundberg in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION.

Doctors, wrote Dr. Peter H. Gott recently, have "...become more conspicious in thei devotion to money.""I think," he said,"that conspicious avarice is a major character flaw in many of today's M.D.'s"We doctors could not have predicted during our training period"...the many wavs in which financial concerns corrupt our altruism,"Gott said. [From:THE ORANGE COUNTY REGISTER,May 7,1986,"Doctors Can Treat Image by Choosing Caring Over Money,"by P.H.Gott,M.D.]

TRUTH BULLETIN # 29:
"The AMA gives generously to key congressmen and senators. And the AMA has a lot of special interest legislation in the hopper at any given time."[From: HEALTH FREEDOM NEWS, Editorial response to a Letter to the Editor, April,1986,p.30]

TRUTH BULLETIN # 30:
"According to Norman Shumway,chairman of the department of cardiovascular surgery at Stanford Medical Center, the artificial heart is a 'dangerous' device and a'gimmick to get a donor.'"[From: SCIENCE DIGEST,"Artificial Heart:A Gimmick?"June,1986,p.16]

THE FIRST TRUTH BULLETIN HAS 12 WEEKLY ITEMS. THIS SECOND MAILING HAS 18 more, WHICH will CARRY OUR CAMPAIGN TO THE END OF NOVEMBER. GODWIN.

STATE OF ALASKA
Immunization Program
IMPORTANT INFORMATION LOG SHEET

MOA C/D. 3/27/87.

Clinic/Provider Identification

I have read the information contained in the "Important Information" form(s) about the disease(s) and the vaccine(s). I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of the vaccine(s) and request that the vaccine(s) indicated below be given to me or to the person named below for whom I am authorized to make this request.

IMPORTANT INFORMATION ABOUT MEASLES, MUMPS, AND RUBELLA AND MEASLES, MUMPS, AND RUBELLA VACCINES

WHAT IS MEASLES? Measles is the most serious of the common childhood diseases. Usually it causes a rash, high fever, cough, runny nose, and watery eyes lasting 1 to 2 weeks. Sometimes it is more serious. It causes an ear infection or pneumonia in nearly 1 out of 10 children who get it. Approximately 1 child out of every 1,000 who get measles has an inflammation of the brain (encephalitis). This can lead to convulsions, deafness, or mental retardation. About 2 children in every 10,000 who get measles die from it. Measles can also cause a pregnant woman to have a miscarriage or give birth to a premature baby.

Before measles vaccine shots were available, there were hundreds of thousands of cases and hundreds of deaths each year. Nearly all children got measles by the time they were 15. Now, wide use of measles vaccine has nearly eliminated measles from the United States. However, if children are not vaccinated they have a high risk of getting measles, either now or later in life.

WHAT IS MUMPS? Mumps is a common disease of children. Usually it causes fever, headache, and inflammation of the salivary glands, which causes the cheeks to swell. Sometimes it is more serious. It causes a mild inflammation of the coverings of the brain and spinal cord (meningitis) in about 1 child in every 10 who get it. More rarely, it can cause inflammation of the brain (encephalitis) which usually goes away without leaving permanent damage. Mumps can also cause deafness. About 1 out of every 4 adolescent or adult men who get mumps develops painful inflammation and swelling of the testicles. While this condition usually goes away, on rare occasions it may cause sterility.

Before mumps vaccine shots were available, there were more than 150,000 cases each year. Now, because of the wide use of mumps vaccine, the number of cases of mumps is much lower. However, if children are not vaccinated, they have a high risk of getting mumps.

WHAT IS RUBELLA? Rubella is also called German measles. It is a common disease of children and may also affect adults. Usually it is very mild and causes a slight fever, rash, and swelling of glands in the neck. The sickness lasts about 3 days. Sometimes, especially in adult women, there may be swelling and aching of the joints for a week or two. Very rarely, rubella can cause inflammation of the brain (encephalitis) or cause a temporary bleeding disorder (purpura).

The most serious problem with rubella is that if a pregnant woman gets this disease, there is a good chance that she may have a miscarriage or that the baby will be born crippled, blind, or with other defects. The last big rubella epidemic in the United States was in 1964. Because of that epidemic, about 25,000 children were born with serious problems such as heart defects, deafness, blindness, or mental retardation because their mothers had rubella during the pregnancy.

Before rubella vaccine shots were available, rubella was so common that most children got the disease by the time they were 15. Now, because of the wide use of rubella vaccine, the number of cases of rubella is much lower. However, if children are not vaccinated, they have a high risk of getting rubella and possibly exposing a pregnant woman to the disease. If an unvaccinated woman later becomes pregnant and catches rubella, she may have a defective baby.

Since rubella is a mild illness, many women of childbearing age do not recall if they had rubella as a child. A simple blood test can show whether a person is immune to rubella or is not protected against the disease. Overall, about one in five women of childbearing age is not protected against rubella.

MEASLES, MUMPS, AND RUBELLA VACCINES: The vaccines are given by injection and are very effective. Ninety percent or more of people who get the shot will have protection, probably for life. Since protection is not as likely to occur if the vaccines are given very early in life, these vaccines should be given to children after their first birthday; measles vaccine should be given at 15 months of age or older. Measles, mumps, and rubella vaccines can be given one at a time or in a combined vaccine (measles-rubella [MR], measles-mumps-rubella [MMR]) by a single shot. If they are given in combined vaccine, they should be given at 15 months of age or older.

Experts recommend that adolescents and adults—especially women of childbearing age—who are not known to be immune to rubella should receive rubella vaccine (or MMR if they might also be susceptible to measles or mumps). Women should not receive the shot if they are pregnant or might become pregnant within 3 months. There is no known risk in being vaccinated against any or all three of these diseases if you are already immune to any of them.

POSSIBLE SIDE EFFECTS FROM THE VACCINES: About 1 out of every 5 children will get a rash or slight fever lasting for a few days, 1 or 2 weeks after getting measles vaccine. Occasionally there is mild swelling of the salivary glands after mumps vaccination.

About 1 out of every 7 children who get rubella vaccine will get a rash or some swelling of the glands of the neck 1 or 2 weeks after the shot. About 1 out of every 20 children who get rubella vaccine will have some aching or swelling of the joints. This may happen anywhere from 1-3 weeks after the shot. It usually lasts only 2 or 3 days. Adults are more likely to have these problems with their joints—as many as 1 in 4 may have them. Other temporary side effects, such as pain, numbness, or tingling in the hands and feet have also occurred but are very uncommon.

Although experts are not sure, it seems that *very rarely* children who get these vaccines may have a more serious reaction, such as inflammation of the brain (encephalitis), convulsions with fever, or nerve deafness.

With any vaccine or drug, there is a possibility that allergic or other more serious reactions or even death could occur.

WARNING—SOME PERSONS SHOULD *NOT* TAKE THESE VACCINES WITHOUT CHECKING WITH A DOCTOR:

- Anyone who is sick right now with something more serious than a cold.
- Anyone who had an allergic reaction to eating eggs so serious that it required medical treatment (does not apply to rubella vaccine).
- Anyone with cancer, leukemia, or lymphoma.
- Anyone with a disease that lowers the body's resistance to infection.
- Anyone taking a drug that lowers the body's resistance to infection (such as cortisone, prednisone or certain anticancer drugs)
- Anyone who has received a gamma globulin (immune globulin) within the preceding 3 months.
- Anyone who had an allergic reaction to an antibiotic called neomycin so serious that it required medical treatment.

PREGNANCY: Measles, mumps, and rubella vaccines are not known to cause special problems for pregnant women or their unborn babies. However, doctors usually avoid giving any drugs or vaccines to pregnant women unless there is a specific need. To be safe, pregnant women should not get these vaccines. A woman who gets any of these vaccines should wait 3 months before getting pregnant.

Vaccinating a child whose mother is pregnant is not dangerous to the pregnancy.

QUESTIONS: If you have any questions about measles, mumps, or rubella vaccination, please ask us now or call your doctor or health department before you sign this form.

REACTIONS: If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic in the 4 weeks after vaccination, please report it to the facility which provided the vaccine.

PLEASE KEEP THIS PART OF THE INFORMATION SHEET FOR YOUR RECORDS

IMPORTANT INFORMATION ABOUT DIPHTHERIA, TETANUS, AND PERTUSSIS AND DTP, DT, AND Td VACCINES

Please read this carefully

DTP 2/1/86

WHAT IS DIPHTHERIA? Diphtheria is a very serious disease which can affect people in different ways. It can cause an infection in the nose and throat which can interfere with breathing. It can also cause an infection of the skin. Sometimes it causes heart failure or paralysis. About 1 person out of every 10 who get diphtheria dies of it.

WHAT IS TETANUS? Tetanus, or lockjaw, results when wounds are infected with tetanus bacteria, which are often found in dirt. The bacteria in the wound make a poison which causes the muscles of the body to go into spasm. Four out of every 10 persons who get tetanus die of it.

WHAT IS PERTUSSIS? Pertussis, or whooping cough, causes severe spells of coughing which can interfere with eating, drinking, and breathing. In the United States, more than 75 percent of reported pertussis cases occur in children younger than 5 years. Pertussis is a more serious disease in young children and more than half of the children less than 1 year of age reported to have pertussis are hospitalized. In recent years, an average of 1,700 cases of pertussis have been reported each year in the United States. Complications occur in a substantial proportion of reported cases. Pneumonia occurs in one of every four children with pertussis. For every 1,000 reported pertussis cases, 22 develop convulsions and/or have more severe problems of the brain. In recent years, an average of eight deaths due to pertussis occurred annually.

Before vaccines were developed, these three diseases were all very common and caused a large number of deaths each year in the United States. If children are not vaccinated, the risk of getting these diseases will go back up again.

DTP, DT, AND Td VACCINES: Immunization with DTP vaccine is one of the best ways to prevent these diseases. DTP vaccine is actually three vaccines combined into one shot to make it easier to get protection. The United States Public Health Service and the American Academy of Pediatrics recommend DTP vaccine be used in children up to their seventh birthday. The vaccine is given by injection starting early in infancy. At least three shots are needed to provide initial protection. Young children should get three doses in the first year of life and a fourth dose at about 18 months of age. A booster shot is important for children who are about to enter school and should be given between their fourth and seventh birthdays. The vaccine is very effective at preventing tetanus—over 95 percent of those who get the vaccine are protected if the recommended number of shots is given. Although the diphtheria and pertussis parts of the vaccine are not quite as effective, they still prevent most children from getting disease and they make the disease milder for those who do get it.

Because pertussis is not very common or severe in older children, those 7 years of age and older should take a vaccine that does not contain the pertussis part. Also, because reactions to the diphtheria part of the vaccine may be more common in older children, those 7 years of age and older should take a form of the vaccine that has a lower concentration of the diphtheria part. This vaccine which contains no pertussis part and a lower concentration of the diphtheria part is called Td vaccine. Boosters with the Td vaccine should be received every 10 years throughout life.

(PLEASE READ OTHER SIDE)

DEFERRAL OF DTP IMMUNIZATION: Children who have had a serious reaction to previous DTP shots should not receive additional pertussis vaccine (see WARNING). A preparation called DT vaccine is available for them which does not contain the pertussis part. Also, children who have previously had a convulsion or are suspected to have a problem of the nervous system should not receive DTP vaccine until a full medical evaluation has been made.

POSSIBLE SIDE EFFECTS FROM THE VACCINE: With DTP vaccine, most children will have a slight fever and be irritable within 2 days after getting the shot. 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 of 105°F or greater may follow 1 out of 330 DTP shots. Continuous crying lasting 3 or more hours may occur after 1 in every 100 shots and unusual, high-pitched crying may occur after 1 in every 900 shots. Convulsions or episodes of limpness and paleness may each occur after 1 in every 1,750 shots. Children who have previously had a convulsion may be more likely to have another one after pertussis shots. Rarely, about once in every 110,000 shots, other more severe problems of the brain may occur, and permanent brain damage may occur about once in every 310,000 shots. Side effects from DT or Td vaccine are not common and usually consist only of soreness and slight fever. As with any drug or vaccine, there is a rare possibility that allergic or more serious reactions or even death could occur.

Although some people have questioned whether DTP shots might cause Sudden Infant Death Syndrome (SIDS), in careful studies DTP shots have not been shown to cause SIDS.

PREGNANCY: Babies born under unsanitary conditions to unimmunized women have a risk of developing tetanus during the newborn period (neonatal tetanus). Neonatal tetanus can be prevented by immunization of adult women. Women who have not received Td earlier and who are thought to be at risk of delivering their babies under unsanitary conditions should be immunized during pregnancy. Td is not known to cause special problems for pregnant women or their unborn babies. Doctors usually do not recommend giving any drugs or vaccines to pregnant women unless there is a specific need. Pregnant women who need Td should receive it, preferably during the second and/or third trimesters.

WARNING—SOME PERSONS SHOULD *NOT* TAKE THESE VACCINES WITHOUT CHECKING WITH A DOCTOR:

- Anyone who is sick right now with something more serious than a cold.
- Anyone who has had a convulsion or is suspected to have a problem of the nervous system.
- Anyone who has had a serious reaction to DTP, DT, or Td shots before, such as: an allergic reaction to any vaccine component; a temperature of 105°F or greater; an episode of limpness and paleness; prolonged continous crying; an unusual, high-pitched cry; or a convulsion or other more severe problem of the brain.
- Anyone taking a drug or undergoing a treatment that lowers the body's resistance to infection, such as: cortisone, prednisone, certain anticancer drugs, or irradiation.

QUESTIONS: If you have any questions about diphtheria, tetanus, or pertussis or DTP, DT, or Td vaccination, please ask us now or call your doctor or health department before you sign this form.

REACTIONS: If the person who received the vaccine develops a temperature of 105°F or greater, continuous crying lasting 3 or more hours, an unusual high-pitched cry, a convulsion, an episode of limpness and paleness, or a severe problem of the brain, the person should be evaluated promptly by a doctor.

If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic in the 4 weeks after vaccination, please report it to the facility which provided the vaccine.

PLEASE KEEP THIS PART OF THE INFORMATION SHEET FOR YOUR RECORDS

IMPORTANT INFORMATION ABOUT POLIO AND ORAL POLIO VACCINE

Please read this carefully

OP 3/1/83

WHAT IS POLIO? Polio is a virus disease that may cause permanent crippling (paralysis) and occasionally death. There used to be thousands of cases and hundreds of deaths from polio every year in the United States. Because of the widespread use of polio vaccines, which became available beginning in the mid-1950's, polio disease has nearly been eliminated from the United States. Although thousands of cases continue to occur each year in the rest of the world, in the United States during the past 5 years there have been only 67 cases of polio reported, an average of 13 cases per year. Our success in preventing the spread of wild polio virus has been so great that most of the recent cases (approximately nine per year) have resulted from the rare side effects of oral polio vaccine (see below). Because of this fact, some people have asked why we should continue to use polio vaccine. The reason is that, even though we may not have much wild polio virus spreading here now, there is so much of it in the rest of the world that there is a great risk of its being reestablished if our children are not vaccinated.

ORAL LIVE POLIO VACCINE: Immunization with oral live polio vaccine (OPV) is one of the best ways to prevent polio. It is given by mouth starting in early infancy. Several doses are needed to provide good protection. Young children should get two or more doses in the first year of life and another dose at about 18 months of age. An additional dose is important for children when they enter school or when there is a high risk of polio, for example, during an epidemic or when traveling to a place where polio is common. The vaccine is easy to take and is effective in preventing the spread of polio. In over 90 percent of people, OPV gives protection for a long time, probably for life. Because OPV viruses live for a time in the intestinal tract of the person who is vaccinated, some of the viruses pass in the stool and can spread from the vaccinated person to those in close contact (usually household members). This may help to immunize these persons and is one of the advantages of OPV. The Immunization Practices Advisory Committee of the Public Health Service and the American Academy of Pediatrics recommend oral live polio vaccine as the preferred polio vaccine for people up to the 18th birthday.

POSSIBLE SIDE EFFECTS FROM THE VACCINE: OPV very rarely (once in about every 8.1 million doses of OPV distributed) causes paralytic polio in the person who is vaccinated. The risk may be slightly higher in adults being vaccinated and substantially higher in persons with abnormally low resistance to infection. Also very rarely (once in about every 5 million doses of OPV distributed) paralytic polio may develop in a close contact of a recently vaccinated person. Even though these risks are very low, they should be recognized. The risk of side effects from the vaccine must be balanced against the risk of the disease, both now and in the future.

(PLEASE READ OTHER SIDE)

PREGNANCY: Polio vaccine experts do not think oral polio vaccine can cause special problems for pregnant women or their unborn babies. However, doctors usually avoid giving any drugs or vaccines to pregnant women unless there is a specific need. Pregnant women should check with a doctor before taking oral polio vaccine.

WARNING—SOME PERSONS SHOULD NOT TAKE ORAL POLIO VACCINE WITHOUT CHECKING WITH A DOCTOR:

- Anyone with cancer, leukemia, or lymphoma.
- Anyone with a disease that lowers the body's resistance to infection.
- Anyone taking a drug that lowers the body's resistance to infection, such as cortisone or prednisone.
- Anyone who lives in the same household with anyone who has one of the conditions listed above.
- Anyone who is sick right now with something more serious than a cold.
- Pregnant women.
- Most persons age 18 and older because adults have a slightly bigger risk of developing paralysis from oral polio vaccine than children (However, if the risk of polio is increased-as may occur, for example, when there is an outbreak in your community-most polio experts recommend that unprotected persons receive oral polio vaccine regardless of age.)

NOTE ON INJECTABLE (KILLED) POLIO VACCINE: Besides the oral polio vaccine (OPV), there is also a killed polio vaccine (IPV) given by injection which protects against polio after several shots. This killed polio vaccine has no known risk of causing paralytic polio. Because OPV may provide lifetime protection, seems to provide stronger immunity in the intestinal tract (where infection first occurs), is simpler to administer, and is more effective in preventing the spread of polio virus than IPV, most polio experts feel that oral vaccine is more effective for controlling polio in the United States. Injectable polio vaccine is recommended for persons needing polio vaccination who have low resistance to serious infections or who live with persons with low resistance to serious infections. It may also be recommended for previously unvaccinated adults who plan to travel to a place where polio is common or for previously unvaccinated adults whose children are to be vaccinated with OPV. It is not widely used in this country at the present time, but it is available. If you would like to know more about this type of polio vaccine, or wish to receive this vaccine, please ask us.

QUESTIONS: If you have any questions about polio or polio vaccination, please ask us now or call your doctor or health department before you sign this form.

REACTIONS: If the person who received the vaccine gets sick and visits a doctor, hospital, or clinic in the 4 weeks after vaccination, please report it to the facility which provided the vaccine.

PLEASE KEEP THIS PART OF THE INFORMATION SHEET FOR YOUR RECORDS

Parents suing for child's ills

The parents of a 5-year-old boy who allegedly suffered permanent injuries from a DTP vaccination received a few months after birth has filed suit against the vaccine manufacturer and the state of Washington.

James and Joan Dunn claim in the suit filed Wednesday in Spokane County Superior Court that their son, Christopher, continues to suffer severe convulsions and seizures caused by the vaccination.

Listed along with the state as a defendant in the suit are Lederle Laboratories Division of American Cyanamid Co. and Connaught Labs Inc.

The companies are described as foreign corporations which manufacture and distribute the Tri-Immunol vaccine, commonly referred to as DTP vaccine, for immunization against diptheria, tetanus and pertussis.

The suit says the couple's son was born June 23, 1979, and received his first DTP vaccination Sept. 10, 1979, at the Spokane County Health District.

It claims the vaccine has caused the child severe neurological and physiological damages which render him permanently disabled.

The suit contends the manufacturer was negligent in failing to adequately test the vaccine for possible severe adverse reactions or to warn the medical profession or the public about its potential for causing such reactions.

The state of Washington is negligent for distributing the "defective and unreasonably dangerous" vaccine to the Spokane County Health District and other municipal entities, the suit claims.

SPOKANE CHRONICLE June 6, 1985 p. C1 6

Boy's not shots

Family Doctor

By DR. ROBERT MENDELSOHN

DEAR DR. MENDELSOHN: Please help me with this problem. We apparently are going to be required by law to immunize our school-age children. I have put off getting rubella and mumps shots for our 12-year-old daughter in the hope that she would get these illnesses naturally, but she has not. I read in the July and August 1975 issues of Today's Health that rubella immunization is not very long-lasting, with 25 percent of those immunized losing protection within five years after innoculation.

When my daughter was immunized against red measles at the age of 18 months, she became very ill, and her eyes were crossed for years afterward because of the high fever she had developed. The daughter of a friend of mine suffered from arthritis after being immunized against German measles, and she still has the condition—10 years later. I looked this up in the Physicians' Desk Reference and discovered that in my daughter's age group, there is a 5 to 10 percent chance of joint pain, swelling, stiffness and, rarely, encephalitis after rubella immunization.

Is it best to get these shots or not?—Mrs. B. C., Spokane, Wash.

DEAR MRS. B. C.: You are a smart lady! Even though medical societies, the pharmaceutical industry and government agencies are pushing these shots, each mother and father still has the ultimate responsibility of examining both sides of the story in order to decide whether to place their child in the line forming for immunizations.

Of course, vaccine enthusiasts advocate their product on the grounds that, while they certainly produce complications, they are safer than the disease itself. Nevertheless, the adverse reactions listed in the prescribing information for measles vaccine include encephalitis and encephalopathy occurring within 30 days after vaccination, as well as sub-acute sclerosing panencephalitis in children who had no history of natural measles but who did receive measles vaccine.

Listed under adverse reactions for rubella (German measles) vaccine are arthritis, arthralgia (painful joints) and polyneuritis. "Symptoms relating to joints (pain, swelling, stiffness, etc.) and to peripheral nerves (pain, numbness, tingling, etc.) occurring within approximately two months after vaccination should be considered as possibly vaccine related."

The Journal of the American Medical Association, Jan. 23, 1978, reported that of the 18 cases of polio in 1977, three of the patients were persons who were in the United States, but not residents, and two of the other 15 victims apparently contracted the disease abroad. Three cases occurred in recent vaccine recipients, and 10 cases had been in close contact with recently immunized people. Only three cases occurred in persons without known vaccine associations.

As far as the whooping cough vaccine (a component of the triple DPT baby shots) is concerned, Dr. Edward B. Shaw, a distinguished University of California physician, has stated (JAMA, March 1975): "I doubt that the decrease in pertussis (whooping cough) is due to the vaccine, which is a very poor antigen and an extremely dangerous one, with many very serious complications. . . the decline in pertussis began long before the widespread use of vaccine." Dr. Shaw then proceeds to question the conventional view that the decrease in polio is a result of the polio vaccine.

These negative aspects and views on immunizations abound in the medical literature, and this column will continue, as it has in the past, to make this information available to those who do not have ready access to these publications. The information you gathered on the pros and cons of current immunizations will also help you when you are faced with the vaccines currently being developed for chicken pox and venereal disease.

From the letters reaching me from all parts of the country, I am aware that many school authorities have decided to exclude unimmunized children from classes. Thus, vaccination, once a medical matter, now has become a political issue.

As a case in point, some Alaskan chiropractors had sought to excuse healthy children in their practices from compulsory immunization. A Superior Court ruling that only M.D.s and D.O.s have the right to decide when a child's health will be harmed by a vaccination is now being appealed to the Alaska Supreme Court.

As with all political issues, the question of immunization will be resolved by lawyers, by elected representatives and, ultimately, by informed public opinion. ©

(Dr. Mendelsohn welcomes questions from readers. While he cannot reply to them all individually, he will answer those of general interest in his column. Write to Dr. Mendelsohn in care of this newspaper.)

HEALTH

School Shots: More Harm than Good?

By Michael D'Antonio


Elena Amity

DPT. The letters stand for diphtheria, pertussis and tetanus, three diseases that were often lethal for children of past generations. Today the DPT vaccine — a series of five shots administered between 3 months of age and school entry — has all but eliminated the risk of these childhood nightmares. But some doctors are starting to wonder if the vaccine for pertussis, commonly known as whooping cough, is more risky than the actual disease.

In Britain, West Germany and some Scandinavian countries, parents are no longer required to have children vaccinated against pertussis before they enter school. Medical authorities in Europe have isolated the pertussis component in the DPT inoculation, blaming it for serious brain damage and lesser brain-related conditions — such as shock and convulsions — found in thousands of vaccinated children. Millions of European children have not been vaccinated.

In the U.S., school systems in most states still require the DPT series. In fact, every year hundreds of unvaccinated 6-year-olds are sent home on the first day of class and barred from school until they bring proof of vaccination. Court cases have upheld laws requiring the shots, and for more than a generation parents have routinely sought the inoculations. In most cases, the shots are harmless. But recent media focus on the exceptions — cases of crippled and brain-damaged children — now has many parents alarmed about the DPT vaccine.

Scott Grant is one of the exceptions. Vaccinated in 1961, Scott suffered a severe reaction to the shot. "He literally wilted before our eyes," his mother, Marge Grant, sadly remembers. The brain damage, which Scott's doctors say was caused by the vaccine, has left him immobile and mentally retarded.

What makes the DPT controversy a quandary for parents is the danger of pertussis. The disease starts with symptoms similar to the common cold. But as weeks go by, the cough and congestion get so bad that children struggle to breathe (the inhalation of air sounds like a whoop). And the bronchial system becomes so irritated from coughing that pneumonia is easily contracted. Before the DPT vaccine was developed in the 1930's, whooping cough was a killer. And some survivors suffered brain damage and convulsions.

"It is tragic that events such as brain damage may occur as a result of pertussis vaccination," says Dr. William H. Foege, director of the Federal Government's Centers for Disease Control in Atlanta. "However, we must all remember that pertussis itself causes complications more severe than these and may cause death."

The scientists studying the pertussis vaccine have little conclusive evidence of its side effects. For years, crying spells that develop on the day the shot is given were considered insignificant. Today some doctors believe they are evidence of a neurological reaction to the shot. And the manufacturers of the vaccine now recommend that children with such reactions do not receive further shots.

A study on DPT effects by researchers at the University of California, the first such study to be done in the U.S. in 25 years, found that one in 13 vaccinated children suffers persistent, piercing crying spells the day after receiving a DPT injection. Because the first three shots are given to children when they are still under 1 year old, they can't explain the exact nature of their distress. However, the crying is usually accompanied by a fever and drowsiness. Some experts theorize the crying is due to slight damage to the nervous system, but the connection has not been proven.

The statistics developed by studies here and abroad are critical in the DPT debate. The study cited above also found that one in 700 children who received the vaccine suffered convulsions or went into shock. Foreign studies found that serious brain damage, causing severe retardation and motor disability, occurs in one of every 50,000 recipients. Britain and Japan now have national programs to compensate thousands of children who suffered serious side effects due to DPT. The State of California has now begun its own compensation program, but so far only one child has been compensated.

The statistics related to whooping cough are also frightening. In 1934 more than a million cases of the disease were reported, and more than 7,500 children were killed by it. Final figures have not been compiled, but the Government estimates there were fewer than 2,000 cases of pertussis last year, and six deaths. Proponents of the vaccine say that without it the nation risks a return to whooping cough epidemics and deaths. There is still no specific treatment for pertussis — except intravenous fluids to prevent dehydration and respiratory care (antibiotics are not effective).

Britain's recent experience should be a warning to America, insists Dr. Vincent Fulginiti of the American Academy of Pediatrics. Following a decline in use of the pertussis vaccination, that country has suffered an epidemic of more than a hundred thousand cases of whooping cough and 28 deaths. "The United States is in potential danger of a similar assault," he says, if DPT is abandoned.

But public concern about DPT is rising. In the metropolitan Washington area, a parents group has organized to study the problem and lobby for a change in the laws making the shots mandatory. Inoculations without the pertussis component have fewer side effects, and the parents want to be free to choose whether their children get the full DPT vaccine or not.

The Government and the drug industry are working on safer vaccines, and new ones are expected in the next few years. In the meantime, Congress has scheduled hearings to investigate the controversy, and individual members of Congress, led by Senator Paula Hawkins (R.-Fla.), are calling on the Government and doctors to warn parents of the risks of both the vaccine and the shot, to screen children susceptible to side effects and to develop better vaccines.

Until new, exhaustive studies are completed, parents will have to consult with their family doctors before making their own decision about DPT.

Michael D'Antonio is a freelance writer.

Warning for Parents

Possible side effects from DPT vaccine include: high fever, convulsions, shock, excessive crying and loss of awareness. Consult your pediatrician if they occur. The American Academy of Pediatrics and DPT manufacturers say a child who suffers serious side effects should not receive additional inoculations.

This ad appeared in the newspaper in Anchorage.

Nurse Position

Full-time, Bethel, AK. Exceptional opportunity to work on an ongoing vaccine efficacy trial conducting well-baby assessments, administering vaccine and conducting disease surveillance and related research. Frequent travel to villages. Prefer public health or similar experience. Send resume to: Centers for Disease Control, 225 Eagle St., Anchorage, AK 99501 or call 271-4011.

persons may call: (907)842-5201 ext. 331 for more information.

NURSE POSITION

Full-time, Bethel, AK. Exceptional opportunity to work on an ongoing vaccine efficacy trial conducting well-baby assessments, administering vaccine and conducting disease surveillance and related research. Frequent travel to villages. Prefer public health or similar experience. Send resume to: Centers for Disease Control, 225 Eagle St. Anchorage, AK 99501 or call 271-4011.

ORTHODONIC ASSISTANT

P/T Employment, Monday through Thursday afternoons.

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Your

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Current

Concerning House Bill 277,

I support this bill because I think parents should have freedom of choice concerning immunizations. Parents are ultimately responsible for their childrens health, and I think provided with all the facts they can make wise choices about all aspects of health care.

I believe that most parents will make the choice to have their children immunized, the important factor being that it is parents choice. If parents do not have a choice and their child has an adverse reaction to a vaccine, they then feel victimized. If they themselves made the decision to immunize knowing all the pros and cons, they are more willing to accept any adverse reactions because they were fully informed about the possibilities.

Kaye Kanne
116 Wire Street
Juneau, Alaska 99801

TURNING POINT
Family Wellness Center

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

November 25, 1987

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

Dear Sir:

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

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

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

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

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

(2)

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

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

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

Thank you.

Truly yours,

Richard Moskowitz, M.D.

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

(3)

January 13, 1988

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

Dear Shannon:

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

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

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

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

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

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

Sincerely,

F. Fuller Royal, M.D.

FFR/erm

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

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

	compliance rate:	reported cases of: measles	rubella	mumps	pertussis	tetanus	diptheria	polio
Michigan	91%	185	24	467	36	1	INA	INA
1971 (approx.) - mandatory law implemented 1971 (approx.) - philosophical objection allowed								
Utah	93%	13 [38.5%] {61.5%}	15	16	44 [65.9%] {34.1%}	0	0	0
1975 - mandatory law implemented **1982 (approx.) - philosophical exemption allowed**								
Washington	95.7%	176 [65%] {35%}	15	30	163 [56%] {44%}	0	0	0
Missouri	98.3%	32	1	23*	32*	2(2)*	0	0
California	93.4%	497 [50%] {50%}	242	336	310 [40%] {60%}	3	0	1
1961-mandatory law implemented 1961-philosophical exemption allowed								
Pennsylvania	99.2%	28	1	63	52	1	0	0
Oklahoma	97.6%	39	0	INA	134	1	0	0
1976-mandatory law implemented 1976-philosophical exemption allowed								
Nebraska	96.5%	1	0	2	10	INA	INA	INA
1973-mandatory law implemented 1973-philosophical exemption allowed								
Indiana	97%	39	0	339	39	2	0	0
1976-mandatory law implemented 1976-philosophical exemption allowed								
Delaware	98%	35	INA	INA	INA	INA	INA	INA
1982-mandatory law implemented 1982-philosophical exemption allowed								

COMPLIANCE RATES CONT'D.

	compliance rate:	reported cases of: measles	rubella	mumps	pertussis	tetanus	diptheria	polio
Ohio	95%	10 [80%] {20%}	0	150	170	0	0	2
1959-mandatory law implemented **1970 (approx.)-philosophical exemption allowed**								
Arizona	95.1%	252	2	209	78	1	0	0
1976-mandatory law implemented **1981-philosophical exemption allowed**								
Minnesota	99%	50 [89%] {21%}	1	86 [88.8%] {11.2%}	50	0	0	0
1967-mandatory law implemented **1978-philosophical exemption allowed**								
Colorado	96.3%	11	1	17	84 (2)	0	0	0
1974-mandatory law implemented **1979-philosophical exemption allowed**								
Maine	INFORMATION NOT AVAILABLE							
1977-mandatory law implemented 1977-philosophical exemption allowed								
Wisconsin	96.5%	287	1	325	111	0	0	0
1975-mandatory law implemented **1980-philosophical exemption allowed**								
Vermont	98%	0	1	6	5	0	0	0
1979-mandatory law implemented 1979-philosophical exemption allowed								

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

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

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

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

Data compiled by the Alaska Chapter of Dissatisfied Parents Together

(7)

[illegible]
[illegible] Box 118
[illegible]mbus, Ohio 43266-0118

Telephone (614) 466-3543

RICHARD F. CELESTE
Governor

November 4, 1987

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

Dear Ms. Kohler:

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

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

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

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

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

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

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

Sincerely,

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

KOHLERLE.PRN
Enclosure:

(9)

November 12, 1987

SUMMARY OF SEVERE ADVERSE REACTIONS TO STATE MANDATED IMMUNIZATIONS

Data collected by: Dissatisfied Parents Together, Alaska Chapter

Dates of survey: October 1986-October 1987

Method used: Alaska "DPT" vaccine adverse reaction questionnaire

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

Range of survey: State of Alaska

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

Ages of subjects at date of response:

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

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

DPT SHOT REACTION QUESTIONNAIRE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 convulsions (1)
16 fever of more than 103 degrees (2)
13 excessive crying or high pitched screaming for long periods (3)
6 extreme sleepiness (4)
____ collapse or shock (5)
5 loss of muscle control (temporary or pemanent paralysis) (6)
____ death (7) 1-nerve damage deafness 1-severe allergies & eczema 2-permanent partial paralysis 1-chronic cold sores
____ other (please explain) 1-severe congestion 1-whooping-like cough (8)
1-limping 1-severe swelling of arm 1-severe leg swelling
1-severe swelling of glands in head
1-temperature for 1 week 1-temperature for 10 days

(12)

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

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

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

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

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

8 2-3 months old (1)
6 4-5 months old (2)
4 6-7 months old (3)
3 8-12 months old (4)
1 13-18 months old (5)
1 19-24 months old (6)
___ 25 months - 3 years old (7)
___ over 3 years old (8)
1 Don't Know
1 all

11. How old is your child now?

See 1st page attachment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 Yes (1) 12 No (2) 1 don't know yet

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

25. Is your child now:

1 experiencing motor delay mentally retarded (1)

4 physicially handicapped (2)

3 experiencing convulsions (3)

4 exhibiting learning difficulties (4)

____ in an institution (5)

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

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

7 Yes (1) 7 No (2)

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

11 Yes (1) 14 No (2)

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

1 Under $2,000

10 $2,000 - $7,000

____ $7,000 - $12,000

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

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

____ Over $40,000 (6)

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

Name: See next page for Emergency Treatment Information

Address: _____

Telepone Numbers: _____(home) _____(work)

Date:

(14)

4 visits to emergency room
2 telephone conduct only

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

30. Emergency room treatment of adverse reaction, if applicable.

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

b) Did you call the emergency room?
5 yes a) B) C) D) e) 1 no f) e) Central Pen. Gen. Hos

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

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

e) Were you advised to tell your doctor of reaction?
___ yes 6 no a) B) C) D) e) f)

f) Were you advised to tell Health Dept. of reaction?
___ yes 6 no a) B) C) D) e) f)

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

a) Where? Homer South Peninsula General Hospital

b) For how long? 3 days

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

Attachment 3

COMPREHENSIVE CHILD CARE COMMITTEE

Public Comment
July 10, 1987

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Pertussis (Whooping Cough)

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

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

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

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

complications: 10% of all pertussis cases may be hospitalized. 1982-1983 encephalopathy occurred in 3/1,000 cases, 2.5% of cases in children less than 1 year may have convulsion Average of 6 deaths per year in United States due to pertussis.

Diptheria

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

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

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

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

Tetanus

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

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

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

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

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

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

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

Minor-Moderate Adverse Reactions: (See manufacturer's product insert for complete list)

1) local reactions, adscess formation at sight of injection, fretfulness, drowsiness, vomiting, anorexia

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

ADVERSE REACTIONS

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

Abscess formation at the site of injection has been reported.[1,2,3] Cervical lymphadenopathy has been reported following DTP injections into the arm.[4]

Mild to moderate temperature elevations frequently follow DTP administration and are often accompanied by fretfulness, drowsiness, vomiting, and anorexia.[1,2,3,5] Approximately 50% of DTP recipients will develop temperature elevations > 38° C (100.4° F) after one or more doses of the series, approximately 6% > 39° C (102.2° F), and approximately 1.5% > 40° C (104° F). Some data suggest that febrile reactions are more likely to occur in those who have experienced such responses after prior doses.[6]

SIGNIFICANT REACTIONS ATTRIBUTED TO THE PERTUSSIS VACCINE COMPONENT HAVE BEEN: HIGH FEVER OF 40.5° C (105° F), A TRANSIENT SHOCK-LIKE EPISODE, EXCESSIVE SCREAMING (PERSISTENT CRYING OR SCREAMING FOR THREE OR MORE HOURS DURATION), SOMNOLENCE, CONVULSIONS, AND ENCEPHALOPATHY. THESE REACTIONS HAVE BEEN REPORTED TO OCCUR RARELY FOLLOWING THE INJECTION OF THIS PRODUCT AND THEY MAY BE FATAL OR RESULT IN PERMANENT DAMAGE TO THE CENTRAL NERVOUS SYSTEM. PERTUSSIS VACCINE HAS BEEN ASSOCIATED WITH A GREATER PROPORTION OF ADVERSE REACTIONS THAN MANY OTHER CHILDHOOD IMMUNIZATIONS.[7,8] SHOULD SYMPTOMATOLOGY REFERABLE TO THE CENTRAL NERVOUS SYSTEM DEVELOP FOLLOWING ADMINISTRATION, FURTHER IMMUNIZATION WITH THIS PRODUCT IS CONTRAINDICATED (SEE CONTRAINDICATIONS). SUCH REACTIONS ALMOST ALWAYS APPEAR WITHIN 24 TO 48 HOURS AFTER INJECTION, BUT HAVE BEEN THOUGHT TO OCCUR AFTER AN INTERVAL AS LONG AS SEVEN DAYS.

NEUROLOGICAL COMPLICATIONS FOLLOWING TETANUS TOXOID ADMINISTRATION, SUCH AS PARALYSIS OF THE RADIAL NERVE,[9] RECURRENT PHARYNGEAL NERVE,[10] COCHLEAR LESION,[11] BRACHIAL PLEXUS NEUROPATHY,[12,13] AND A CASE OF DIFFICULTY IN SWALLOWING, ACCOMMODATION PARESIS, AND EEG DISTURBANCES[14] HAVE BEEN REPORTED IN THE DIFFERENTIAL DIAGNOSIS OF POLYRADICULONEUROPATHIES FOLLOWING ADMINISTRATION OF TETANUS TOXOID. TETANUS TOXOID SHOULD BE CONSIDERED AS A POSSIBLE ETIOLOGY.[15]

CONTRAINDICATIONS

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

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

The Committee on Infectious Diseases of the American Academy of Pediatrics recommends that pertussis vaccine should be withheld when a previous dose has been followed by convulsion, encephalitis, focal neurological signs or collapse. Nor should infants who experience excessive somnolence, excessive screaming (persistent crying or screaming for three or more hours duration) or temperature more than 105° F (40.5° C) receive additional doses of the vaccine.[16]

The Immunization Practices Advisory Committee (ACIP) of the U.S. Public Health Service recommends that hypersensitivity to vaccine components, presence of an evolving neurologic disorder, or a history of a severe reaction (usually within 48 hours) following a previous dose all remain definitive contraindications to the receipt of pertussis vaccine. Severe reactions include collapse or shock, persistent screaming episode, temperature 40.5° C (105° F) or greater, convulsion(s) with or without accompanying fever, severe alterations of consciousness, generalized and/or focal neurologic signs, or systemic allergic reactions.[17]

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

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

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

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

* article available from Alaska Dissatisfied Parents Together

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

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

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

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

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

*6) **recurrent seizures, severe developmental delays** . Murphy, Jerome. "Recurrent Seizures after DPT Vaccine Immunization", AJDC, Vol 138, Oct. 1984

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

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

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

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

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

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

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

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

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

SIDS AND DPT VACCINATION

STUDIES THAT SHOW CORRELATION BETWEEN SIDS/DPT

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

*2) TORCH STUDY summary & graph "DPT Immunization: a Potential Cause of the Sudden Infant Death Syndrome." Neurology 1982, 32 A 169

(20)

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

TETANUS VACCINE REACTIONS (PARTIAL LIST)

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

DIPTHERIA VACCINE REACTIONS

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

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

DPT VACCINE INGREDIENTS

*data available from Alaska Dissatisfied Parents Together

FORMALDEHYDE

"Formaldehyde (ingredient in Lederle DPT vaccine) is also mutagenic in bacteria, viruses, fungi, insects and mouse lymphoma cells with or without metabolic activation. It induces chromosomal recombination in yeast, insects, and cultured mammalian cells, as well as cellular transformation in mouse Balb/C 3T3 cells (Griesemer, et al., 1980). These results indicate that formaldehyde is capable of binding to, and altering, genetic material."
Formaldehyde: Review of Scientific Basis of EPA's Carcinogenic Risk Assessment Peter W. Preuss Ph. D., May 20, 1983., page 91

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

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

Aluminum

(another ingredient in all DPT vaccines)

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

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

Thimerosal (mercury derivative)

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

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

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

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

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

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

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

CORRECTION

THIS DOCUMENT
HAS BEEN REPHOTOGRAPHED
TO ASSURE LEGIBILITY

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POLIO

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

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

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

complications: See diagnosis

POLIOVIRUS VACCINE

all information from manufacturer's product insert unless specified

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

CONTRAINDICATION : MUST NOT BE ADMINISTERED TO PATIENTS WITH IMMUNE DEFICIENCY.

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

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

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

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

NOTES:

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

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

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

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

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

CONTRAINDICATIONS

Under no circumstances should this vaccine be administered parenterally

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

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

PRECAUTIONS

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

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

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

ADVERSE REACTIONS

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

The risk of vaccine-associated paralysis is extremely small for vaccinees, susceptible family members and other close personal contacts.[2] However, prior to administration of the vaccine, the attending physician should warn or specifically direct personnel acting under his authority to convey the warnings to the vaccinee, parent, guardian or other responsible person of the possibility of vaccine-associated paralysis. The Centers for Disease Control report that during the years 1969 through 1980 approximately 290 million doses of TOPV were distributed in the United States. In the same 12 years, 25 "vaccine-associated" and 55 "contact vaccine-associated" paralytic cases were reported. Twelve other "vaccine-associated" cases have been reported in persons (recipients or contacts) with immune deficiency conditions.[3] These statistics do not provide a satisfactory basis for estimating these risks on a per person basis.[14]

When the attenuated vaccine strains are to be introduced into a household with adults who have not been adequately vaccinated or whose immune status cannot be determined, the risk of vaccine-associated paralysis can be minimized by giving these adults three doses of IPV a month apart before the children receive ORIMUNE.[2] The CDC reports that no paralytic reactions to IPV are known to have occurred since the 1955 cluster of poliomyelitis cases caused by vaccine that contained live polioviruses that had escaped inactivation.[2]

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

"Because of the overriding importance of ensuring prompt and complete immunization of the child and the extreme rarity of OPV-associated disease in contacts, the Committee recommends the administration of OPV to a child regardless of the poliovirus-vaccine status of adult household contacts. This is the usual practice in the United States. The responsible adult should be informed of the small risk involved. An acceptable alternative, if there is strong assurance that ultimate, full immunization of the child will not be jeopardized or unduly delayed, is to immunize adults according to the schedule outlined above before giving OPV to the child."[2]

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

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

MUMPS

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

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

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

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

MEASLES

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

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

RUBELLA

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

treatment: rest and fluids

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

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

(26)

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

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

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

CONTRAINDICATIONS

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

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

Any febrile respiratory illness or other active febrile infection.

Active untreated tuberculosis.

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

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

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

HYPERSENSITIVITY TO EGGS, CHICKEN, OR CHICKEN FEATHERS

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

PRECAUTIONS

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

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

Moderate fever [101-102.9°F (38.3-39.4°C)] occurs occasionally, and high fever (above 103°F (39.4°C)) occurs less commonly. On rare occasions, children developing fever may exhibit febrile convulsions. Rash occurs infrequently and is usually minimal, but rarely may be generalized.

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

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

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

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

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

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

NOTES:

MEASLES

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

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

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

RUBELLA

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

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

(29)

Boffins claim the cure can kill

By HARRY NELSON

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

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

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

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

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

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

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

in cells without expressing themselves in any way.

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

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

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

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

Cells grown

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

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

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

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

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

No effect

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

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

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

(31)

Expert links AIDS to bovine viruses

By PHILIP M. BOFFEY
New York Times

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

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

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

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

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

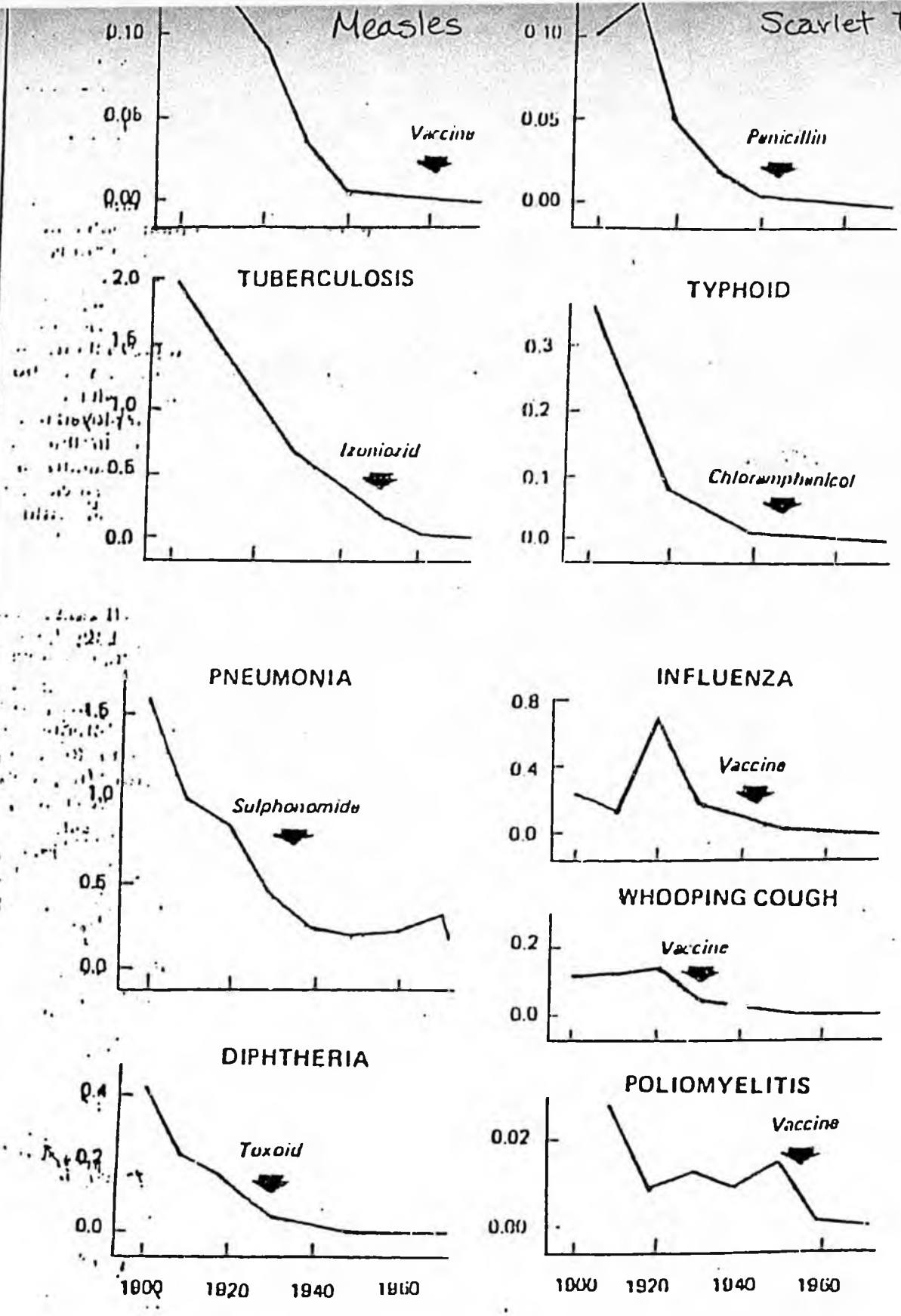
However, two of the scientists whose papers were cited by Rifkin expressed doubt in interviews that the cattle viruses played any role in causing AIDS.

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

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

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

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



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

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

(For Adult Use) is recommended.[1-4]

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

HOW SUPPLIED

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, Aluminum Phosphate Adsorbed, is available in vials of 7.5 ml. Product 1948-33

STORAGE

Keep between 2 and 8° C (35-46° F). DO NOT FREEZE.

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LEDERLE LABORATORIES DIVISION
American Cyanamid Company, Pearl River, N.Y. 10965

REV. 11/84

16042
DX12

DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE ADSORBED TRI-IMMUNOL®

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed, TRI-IMMUNOL®, Lederle, is a combination of *Purogenated* Diphtheria Toxoid Aluminum Phosphate-Adsorbed, *Purogenated* Tetanus Toxoid Aluminum Phosphate-Adsorbed, and Pertussis Vaccine.

DESCRIPTION

The diphtheria toxin is produced according to the method of Mueller and Miller and is detoxified by use of formaldehyde. The tetanus toxin is produced by the method of Mueller and Miller and is detoxified by the use of formaldehyde. The toxoids are refined by the Pillemer alcohol fractionation method and are diluted with a solution containing potassium phosphate monobasic, sodium phosphate dibasic, glycine, and thimerosal (mercury derivative) as a preservative. Pertussis Vaccine is prepared by growing Phase I *B. pertussis* in a modified Cohen-Wheeler broth containing acid hydrolysate of casein. The *B. pertussis* culture is harvested, inactivated, and then suspended in a solution containing potassium phosphate monobasic, sodium phosphate dibasic, sodium chloride, and thimerosal (mercury derivative) as a preservative and is then combined with the refined Diphtheria and Tetanus Toxoids in physiological saline (NaCl) diluent containing thimerosal (mercury derivative) as a preservative. The final concentration of thimerosal (mercury derivative) in the combined vaccine is 1:10,000. The aluminum content of the final product does not exceed 0.80 mg per 0.5 ml dose.

The total immunizing dose contains 12 units of pertussis vaccine.

The primary immunization against diphtheria, tetanus, and pertussis consists of four 0.5 ml doses when administered as recommended.[1-4]

CLINICAL PHARMACOLOGY

Simultaneous immunization against diphtheria, tetanus, and pertussis during infancy and childhood has been a routine practice in the United States since the late 1940's. It has played a major role in markedly reducing the incidence of cases and deaths from each of these diseases.

Diphtheria is primarily a localized and generalized intoxication caused by diphtherial toxin, an extracellular protein metabolite of toxinogenic strains of *Corynebacterium diphtheriae*. While the incidence of diphtheria has decreased from about 20 cases per 100,000 population before the general use of diphtheria toxoid[1-3] to about 55 cases reported between 1976 and 1981, the ratio of fatalities to attack rate has remained constant at about 5%-10%. The highest case fatality rates are in the very young and the elderly. Diphtheria toxoid induces antitoxin. Following adequate immunization with diphtheria toxoid is thought to protect for at least 10 years.[1]

It significantly reduces both the risk of developing diphtheria and the severity of clinical illness. It does not, however, eliminate carriage of *C. diphtheriae* in the pharynx or on the skin.[1] A serum level $\geq$0.01 toxin neutralization units/ml is generally considered protective.[4]

Tetanus is an intoxication manifested primarily by neuromuscular dysfunction, caused by a potent exotoxin elaborated by *Clostridium tetani*. The incidence of tetanus has dropped dramatically with the routine use of tetanus toxoid, remaining relatively constant over the last decade at about 100 cases reported annually. Spores of *C. tetani* are ubiquitous, and there is essentially no natural immunity to tetanus toxin. Thus, universal primary immunization with tetanus toxoid with subsequent maintenance of adequate antitoxin levels by means of timed boosters is necessary to protect all age groups.[1] Tetanus toxoid is highly effective, with a failure rate in fully immunized persons of less than 4 per 100 million.[5] Protective levels of serum antitoxin ($\geq$0.01 toxin neutralization units/ml)[4] are achieved which persist for at least 10 years after full immunization.[1]

Pertussis is a disease of the respiratory tract caused by *Bordetella pertussis*. This gram negative coccobacillus produces an array of biologically active components that escape from the site of infection and produce systemic effects, including an endotoxin-related febrile response, attenuation of the host's febrile and inflammatory responses, lymphocytosis, leukocytosis, effects on glucose homeostasis, and possible neurotoxicity. The role of each of the different components in the pathogenesis of and immunity to pertussis is not well understood.

Pertussis is a highly communicable disease, which, unique for a bacterial-disease, has an attack rate in unimmunized populations of over 90%.[1] As a result of immunization with pertussis vaccine, the number of reported cases and associated mortality has de-

clined from about 120,000 cases and 1,100 deaths in 1950[6] to an annual average of about 2,300 cases and 10 fatalities over the last 10 years.[7] Accurate data do not exist, as bacteriological confirmation of pertussis can be obtained in less than half of the cases. [illegible] pertussis occur in infants and young children; two-thirds of reported deaths occur in children less than one year old. Older children and adults, in whom classic signs are often absent, may go undiagnosed and serve as reservoirs of disease.[1]

Evidence of the efficacy of pertussis vaccine can be provided by the recent British experience, where a reduction in the number of immunized individuals from 79% in 1973, to 31% in 1978 resulted in an epidemic of 102,500 pertussis cases and 36 deaths between late 1977 and 1980, and 1,440 cases per week reported during the winter of 1981-82. A similar situation occurred in Japan.[8]

Because the incidence and severity of pertussis decrease with age, routine pertussis immunization is not recommended for persons 7 years of age or older.[1]

INDICATION AND USAGE

Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed is indicated for active immunization of infants and children through 6 years of age against diphtheria, tetanus, and pertussis.[1-9]

CONTRAINDICATIONS

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

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

The Committee on Infectious Diseases of the American Academy of Pediatrics recommends that pertussis vaccine should be withheld when a previous dose has been followed by convulsion, encephalitis, local neurological signs or collapse. Nor should infants who experience excessive somnolence, excessive screaming (persistent crying or screaming for three or more hours duration) or temperature more than 105° F (40.5° C) receive additional doses of the vaccine.[4]

The Immunization Practices Advisory Committee (ACIP) of the U.S. Public Health Service[1] recommends that hypersensitivity to vaccine components, presence of an evolving neurologic disorder, or a history of a severe reaction (usually within 48 hours) following a previous dose all remain definitive contraindications to the receipt of pertussis vaccine. Severe reactions include collapse or shock, persistent screaming episode, temperature 40.5° C (105° F) or greater, convulsion(s) with or without accompanying fever, severe alterations of consciousness, generalized and/or local neurologic signs, or systemic allergic reactions.[1]

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

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

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

WARNING

THIS PRODUCT IS NOT RECOMMENDED FOR IMMUNIZING PERSONS AFTER THEIR SEVENTH BIRTHDAY. DO NOT ATTEMPT ROUTINE IMMUNIZATION IF THE CHILD HAS A PERSONAL OR FAMILY HISTORY OF CENTRAL NERVOUS SYSTEM DISORDERS. SHOULD ANY SYMPTOMATOLOGY RELATED TO NEUROLOGICAL DISORDERS DEVELOP FOLLOWING ADMINISTRATION, DO NOT ATTEMPT FURTHER ADMINISTRATION OF PERTUSSIS VACCINE. CONVULSION, ENCEPHALITIS, FOCAL NEUROLOGIC SIGNS, COLLAPSE, SHOCK, EXCESSIVE SCREAMING (PERSISTENT CRYING OR SCREAMING FOR THREE OR MORE HOURS DURATION), EXCESSIVE SOMNOLENCE, SEVERE ALTERATION OF CONSCIOUSNESS, SYSTEMIC ALLERGIC REACTIONS OR TEMPERATURE MORE THAN 105° F (40.5° C) ARE CONTRAINDICATIONS FOR ANY FURTHER USE OF PERTUSSIS VACCINE.

If such disorders are found, the infants or children should be given diphtheria and tetanus toxoids (DT) instead of DTP. If DT is used, three doses at least 4 weeks apart, followed by a fourth dose 6-12 months later, are recommended for infants. For children 1 year of age or older, two doses of DT at least 4 weeks apart followed by a third dose 6-12 months later, are recommended.[9]

The occurrence of sudden-infant-death syndrome (SIDS) has been reported following administration of DTP.[illegible] A causal relationship between DTP immunization and the syndrome has not been established.[13,14]

Prior to administration of this vaccine, health care personnel should inform the parent, guardian, or other responsible adult of the benefits and risks to the child of DTP vaccine. For recent information about the estimated range of risks of severe reactions following DTP administration, consult references 1, 15, 16, 17, 18, and 21.

DTP should not be given to infants or children with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection unless the potential benefit clearly outweighs the risk of administration.

If the vaccine is used in persons receiving immunosuppressive therapy, the expected antigenic response may not be obtained.

Special care should be taken so the injection is not made into a blood vessel.

PRECAUTIONS

A. *General*

1. This product should be used for the age group between 2 months and the 7th birthday.
2. A separate sterile syringe and needle or a sterile disposable unit should be used for each individual patient to prevent transmission of hepatitis or other infectious agents from one person to another.
3. *Since this product contains both a bacterial suspension and an adjuvant, shake vigorously before withdrawing each dose from multiple dose vials.*
4. Before the injection of any biological, the physician should take all precautions known for prevention of allergic or any other side reactions. This should include: A review of the patient's history regarding possible sensitivity, the ready availability of epinephrine 1:1000 and other appropriate agents used for control of immediate allergic reactions; and a knowledge of the recent literature pertaining to use of the biological concerned, including the nature of side effects and adverse reactions that may follow its use.

B. *Information for Patient*

1. Prior to administration of any dose of DTP, the parent or guardian should be asked about the recent health status of the infant or child to be injected.
2. WHEN AN INFANT OR CHILD IS RETURNED FOR THE NEXT DOSE IN THE SERIES, THE PARENT SHOULD BE QUESTIONED CONCERNING OCCURRENCE OF ANY SYMPTOM AND/OR SIGNS OF AN ADVERSE REACTION AFTER THE PREVIOUS DOSE (SEE CONTRAINDICATIONS; ADVERSE REACTIONS)

ADVERSE REACTIONS

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

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

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

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

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

DOSAGE AND ADMINISTRATION

Shake vigorously before withdrawing each dose from the multiple dose vials.

Before injection, the skin over the site to be injected should be cleansed and prepared with a suitable germicide. After insertion of the needle, aspirate to help avoid inadvertent injection into a blood vessel. Expel the dose slowly and terminate the dose with a small bubble of air (0.1 to 0.2 ml).

The basic immunizing course for infants and children through 6 years of age consists of three doses of 0.5 ml each at 4- to 8-week intervals, followed by a fourth dose of 0.5 ml approximately one year after the third dose.

It is recommended that active immunization against diphtheria, tetanus, and pertussis be started at 2 months of age.[1-9] All doses should be injected intramuscularly, preferably into the midlateral muscles of the thigh or deltoid, with care to avoid major peripheral nerve trunks.

Interruption of the recommended schedule with a delay between doses does not interfere with the final immunity achieved; nor does it necessitate starting the series over again, regardless of the length of time elapsed between doses.[1]

A recall (booster) dose of 0.5 ml is indicated at age 4-6 years, preferably prior to entrance into kindergarten or elementary school. However, if the fourth dose of the basic immunizing series was administered after the fourth birthday, a recall (booster) of DTP prior to school entry is not considered necessary.[1]

For either basic or recall (booster) immunization against tetanus and diphtheria of individuals 7 years of age and older, the use of Tetanus and Diphtheria Toxoids Adsorbed

CONNAUGHT

DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE ADSORBED USP

FOR PEDIATRIC USE

SPECIAL NOTICE: *EXPOSURE OF THIS VACCINE TO TEMPERATURES BELOW 2°C (35°F) OR ABOVE 25°C (77°F) FOR AS LITTLE AS 24 HOURS RESULTS IN CONDITIONS WHICH MAKE RESUSPENSION OF THE VACCINE DIFFICULT.*

CARE SHOULD BE TAKEN NOT TO STORE THIS PRODUCT NEAR FREEZING SURFACES. ALWAYS RETURN UNUSED PORTION TO REFRIGERATION, 2°C TO 8°C (35°F to 46°F), IMMEDIATELY AFTER USE.

DO NOT USE IF RESUSPENSION CANNOT BE ACHIEVED BY VIGOROUS SHAKING.

DESCRIPTION

This product combines diphtheria and tetanus toxoids, adsorbed with pertussis vaccine in a sterile isotonic sodium chloride solution containing sodium phosphate to control pH; each 0.5 ml injection contains not more than 0.25 mg of aluminum added in the form of aluminum potassium sulfate. Thimerosal (mercury derivative) 1:10,000 is added as a preservative. The mixture provides an immunizing dose of each component in the total dosage prescribed below. Each single dose contains 4 protective units of Pertussis Vaccine based on the U.S. Standard Pertussis Vaccine.

INDICATIONS

For active immunization of infants and young children against diphtheria, tetanus and pertussis simultaneously. Injections should be started at 2 to 3 months of age and be completed no later than the age of 6 years. Immunization should always be started at once if whooping cough or diphtheria is present in the community.

CONTRAINDICATIONS

Persons 7 years of age and older should not be immunized with Pertussis Vaccine. Immunization should be deferred during the course of any acute illness, however, a minor illness not associated with fever such as a mild upper respiratory infection need not preclude vaccination. The benefit/risk ratio of routine immunization with this product should be carefully considered by the responsible physician if the child has a personal or family history of central nervous system disease or convulsions.[2] The occurrence of a severe reaction following administration of this product, consisting of high fever (39°C or above), somnolence, screaming, shock, convulsions, encephalopathy or thrombocytopenia, is a contraindication to further use of this vaccine. Anaphylactoid and/or allergic reactions, immunosuppressive therapy, recent gammaglobulin, plasma, or blood transfusions, immunodeficiency disorders, leukemia, lymphoma, or generalized malignancy are also contraindications.[2] Simultaneous administration of DTP with another vaccine should be avoided unless they have been shown to be effective when used together. The clinical judgment of the responsible physician should prevail at all times.

The occurrence of any type of neurological symptoms or signs following administration of this product is an absolute contraindication to further use.

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

WARNING

This product is not recommended for immunizing persons 7 years of age and older.

The benefit/risk ratio of routine immunization with this product should be carefully considered by the responsible physician if the child has a personal or family history of central nervous system disorders or convulsions.[2] Should any symptomatology related to neurological disorders develop following administration, do not attempt further administration of pertussis antigen. The development of "excessive screaming syndrome" is an absolute contraindication for any further use of pertussis vaccine.

If the vaccine is used in persons receiving immunosuppressive therapy, a recent injection of immune globulin or having an immunodeficiency disorder, the expected antibody response may not be obtained.[2]

Special care should be taken so the injection is not made into a blood vessel.

ADVERSE REACTIONS

Adverse reactions may be local and include pain, erythema, tenderness, heat, edema and induration at the site of injection. Significant reactions attributed to the pertussis vaccine component have been high fever (greater than 39°C), a transient shocklike episode, excessive screaming, somnolence, convulsions, encephalopathy, thrombocytopenia, and hemolytic anemia.[3,4] Such reactions almost always appear within 24 to 48 hours after injection but have been thought to occur after an interval as long as seven days. A small nodule may develop at the site of injection and remain for a few weeks before being completely absorbed. Sterile abscesses have been reported. Systemic reactions include mild to moderate transient fever, chills, malaise, and irritability.

Neurological disorders such as encephalopathy, possibly due to the pertussis component, have been reported to occur rarely following the injection of this product and they may be fatal or result in permanent damage to the central nervous system.

There have been rare reports of Sudden Infant Death Syndrome (crib death) after the administration of DTP Vaccine. However, available data indicate no association between DTP vaccination, in general, and sudden infant death, in particular.[5]

Neurological complications have been reported. These include cochlear lesion,[6] brachial plexus neuropathies,[7,8] paralysis of the radial nerve,[9] paralysis of the recurrent nerve,[10] accommodation paresis, EEG disturbances, and one reported case of swallowing difficulty.[11] In the differential diagnosis of polyradiculoneuropathies following administration of tetanus toxoid, tetanus toxoid should be considered as a possible etiology.[12]

STORAGE

To maintain potency it is necessary to store this vaccine at a temperature which will maintain ice continuously in a solid state. This vaccine may remain fluid at temperatures above -14° C (+7° F) because of its sorbitol content. If frozen, the vaccine must be completely thawed prior to use. An *unopened* container of vaccine that has been frozen and then is thawed may be carried through a maximum of 10 freeze-thaw cycles, provided the temperature does not exceed 8° C (46° F) during the periods of thaw, and provided the total cumulative duration of thaw does not exceed 24 hours. If the 24-hour period is exceeded, the vaccine then must be used within 30 days, during which time it must be stored at a temperature between 2-8° C (36-46° F).

DISCLAIMER OF REPRESENTATIONS AND WARRANTIES

This vaccine has been produced and tested in accordance with the regulations of the United States Food and Drug Administration for the production of Poliovirus Vaccine, Live, Oral Trivalent. The manufacturer makes no representation or warranty, expressed or implied, with respect to the merchantability or fitness for use of this vaccine other than that the vaccine has been produced in accordance with the standards for its production prescribed by the United States Food and Drug Administration and applicable thereto at the time of its release by the manufacturer. While the use of this preparation and other measures described herein are consistent with accepted standards of medical practice, their use as described cannot be expected necessarily to assure a specific result.

HOW SUPPLIED

2084-08 - 10 (0.5 ml) DISPETTES® Disposable Pipettes
2084-12 - 50 (0.5 ml) DISPETTES®

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LEDERLE LABORATORIES DIVISION
American Cyanamid Company, Pearl River, N.Y. 10965

REV. 12/83

80:12

POLIOVIRUS VACCINE, LIVE, ORAL TRIVALENT ORIMUNE®

0.5 ml Dose

Contains Sorbitol

SABIN STRAINS TYPES 1, 2 and 3

FOR ORAL ADMINISTRATION - NOT FOR INJECTION

DESCRIPTION

Manufacture and Composition: ORIMUNE® TRIVALENT VACCINE is a mixture of three types of attenuated polioviruses which have been propagated in cercopithecus monkey kidney cell culture. The cells are grown in the presence of Eagle's Basal Medium consisting of Earle's Balanced Salt Solution containing amino acids, antibiotics and calf serum. After cell growth, the medium is removed and replaced with fresh medium containing the inoculating virus but no calf serum. The final vaccine is diluted with a modified cell culture maintenance medium containing sorbitol. Each dose (0.5 ml) contains less than 25 micrograms of each of the antibiotics, streptomycin and neomycin.

The potency is expressed in terms of the amount of virus contained in the recommended dose as tissue culture infective doses ($TCID_{50}$). The human dose of vaccine containing all three virus types shall be constituted to have infectivity titers in the final container material of $10^{5.4}$ to $10^{9.4}$ for Type 1, $10^{4.5}$ to $10^{8.5}$ for Type 2 and $10^{5.2}$ to $10^{9.2}$ for Type 3.[1]

Color Change: This vaccine contains phenol red as a pH indicator. The usual color of the vaccine is pink, although some containers of vaccine, shipped or stored in dry ice, may exhibit a yellow coloration due to the very low temperature or possible absorption of carbon dioxide. The color of the vaccine prior to use (red -pink - yellow) has no effect on the virus or efficacy of the vaccine.

INDICATIONS AND USAGE

The purpose of administering any attenuated, live, virus vaccine is to stimulate the body mechanism to produce an active immunity by simulating the natural infection without producing untoward symptoms of the disease. To accomplish this with live poliovirus vaccine, it is necessary for the virus to multiply in the intestinal tract. A primary series of this vaccine is designed to produce an antibody response to poliovirus Types 1, 2 and 3. This response is comparable to the immunity induced by the natural disease. The antibodies thus formed help protect the individual against clinical poliomyelitis infection by any of the three types of poliovirus. When used in the prescribed manner for primary immunization, type specific neutralizing antibodies will be induced in 90% or more of susceptibles.

This vaccine is indicated for use in the prevention of poliomyelitis caused by poliovirus Types 1, 2 and 3.

Infants starting at six to twelve weeks of age, *all unimmunized children* and *adolescents* through age 18 are the usual candidates for routine prophylaxis.

The Immunization Practices Advisory Committee (IPAC) of the Public Health Service states that trivalent oral poliovirus vaccine (TOPV) and inactivated poliovirus vaccine (IPV) are both effective in preventing poliomyelitis. TOPV is the vaccine of choice for primary immunization of children in the United States when the benefits and risks for the entire population are considered. TOPV is preferred because it induces intestinal immunity, is simple to administer, is well accepted by patients, results in immunization of some contacts of vaccinated persons, and has a record of having essentially eliminated disease associated with wild poliovirus in this country.[2] The choice of TOPV as the preferred poliovirus vaccine in the United States has also been made by the Committee on Infectious Diseases of the American Academy of Pediatrics and a special expert committee of the Institute of Medicine, National Academy of Science.[3,4] TOPV is also recommended for control of epidemic poliomyelitis.[2,3]

Past history of clinical poliomyelitis or prior vaccination with IPV in otherwise healthy individuals does not preclude the administration of TOPV when otherwise indicated.

Serologic evidence indicates that measles and rubella vaccines or combinations (measles-mumps-rubella vaccine) given simultaneously with trivalent oral poliovirus vaccine can be expected to give adequate antibody response.[5]

Routine poliomyelitis immunization for adults residing in the continental United States is not necessary because of extreme unlikelihood of exposure. However, primary immunization with IPV is recommended whenever feasible for those unimmunized adults subject to *increased risk* of exposure, as by travel to or contact

with epidemic or endemic areas and for those employed in hospitals, medical laboratories, clinics or sanitation facilities. If less than 4 weeks are available before protection is needed, a single dose of TOPV is recommended, with IPV given later if the person remains at increased risk. Immunization with IPV may be indicated for unimmunized parents and those in other special situations where, in the judgement of the attending physician, protection may be needed.[2] (see CONTRAINDICATIONS and ADVERSE REACTIONS.)

CONTRAINDICATIONS

Under no circumstances should this vaccine be administered parenterally.

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

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

PRECAUTIONS

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

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

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

Use in Pregnancy:

Although there is no convincing evidence documenting adverse effects of either TOPV or IPV on the developing fetus or pregnant woman, it is prudent on theoretical grounds to avoid vaccinating pregnant women. However, if immediate protection against poliomyelitis is needed, TOPV is recommended.[2] (See CONTRAINDICATIONS and ADVERSE REACTIONS.)

ADVERSE REACTIONS

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

The risk of vaccine-associated paralysis is extremely small for vaccinees, susceptible family members and other close personal contacts.[2] However, prior to administration of the vaccine, the attending physician should warn or specifically direct personnel acting under his authority to convey the warnings to the vaccinee, parent, guardian or other responsible person of the possibility of vaccine-associated paralysis. The Centers for Disease Control report that during the years 1969 through 1980 approximately 290 million doses of TOPV were distributed in the United States. In the same 12 years, 25 "vaccine-associated" and 55 "contact vaccine-associated" paralytic cases were reported. Twelve other "vaccine-associated" cases have been reported in persons (recipients or contacts) with immune deficiency conditions.[2] These statistics do not provide a satisfactory basis for estimating these risks on a per person basis.[14]

When the attenuated vaccine strains are to be introduced into a household with adults who have not been adequately vaccinated or whose immune status cannot be determined, the risk of vaccine-associated paralysis can be minimized by giving these adults three doses of IPV a month apart before the children receive ORIMUNE.[2] The CDC reports that no paralytic reactions to IPV are known to have occurred since the 1955 cluster of poliomyelitis cases caused by vaccine that contained live polioviruses that had escaped inactivation.[2]

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

"Because of the overriding importance of ensuring prompt and complete immunization of the child and the extreme rarity of OPV-associated disease in contacts, the Committee recommends the administration of OPV to a child regardless of the poliovirus-vaccine status of adult household contacts. This is the usual practice in the United States. The responsible adult should be informed of the small risk involved. An acceptable alternative, if there is strong assurance that ultimate, full immunization of the child will not be jeopardized or unduly delayed, is to immunize adults according to the schedule outlined above before giving OPV to the child."[2]

The Immunization Practices Advisory Committee has concluded that "Oral polio vaccine remains the vaccine of choice for primary immunization of Children."[2]

ADMINISTRATION

ORIMUNE is to be administered *orally, under the supervision of a physician. Under no circumstances should this vaccine by administered parenterally.* For convenience, the vaccine is supplied in a disposable pipette containing a single dose of 0.5 ml. The vaccine can be administered directly or mixed with distilled water, tap water free of chlorine, simple syrup USP or milk. Alternatively, it may be adsorbed on any one of a number of foods such as bread, cake or cube sugar.

Community Programs:

Poliovirus Vaccine, Live, Oral Trivalent has been recommended for epidemic control. Within an epidemic area, TOPV should be provided for all persons over 6 weeks of age who have not been completely immunized or whose immunization status is unknown, with the exceptions noted under immunodeficiency.[2,3]

DOSAGE

Dose: Each single dose consists of 0.5 ml of Poliovirus Vaccine, Live, Oral Trivalent ORIMUNE.

Initial Administration (Primary Series)

Infants: The primary series is three doses. The Immunization Practices Advisory Committee (Public Health Service) recommends that the three dose immunization series be started at 6 to 12 weeks of age, commonly with the first DTP inoculation. The second dose should be given not less than 6 and preferably 8 weeks later. The third dose is an integral part of the primary immunization and should be administered 8 to 12 months after the second dose.[2]

The American Academy of Pediatrics recommends that the vaccine be administered at 2 months, 4 months, and at approximately 18 months of age. An optional dose of TOPV may be given at 6 months in areas where poliomyelitis is endemic.[3]

Administration to the newborn (under 6 weeks) is not generally recommended because of the varying persistence of maternal antibodies. However, in certain tropical endemic areas, where poliomyelitis has been increasing in recent years, the physician may wish to administer TOPV to the infant at birth, and complete the basic course during the first six months of life.[3] If the physician chooses to immunize the infant at birth, it may be wise to wait until the child is three days old, and it may be prudent to recommend abstention from breast-feeding for two to three hours before and after oral vaccination to permit establishment of the vaccine viruses in the gut.[14]

Older Children and Adolescents (through age 18): Two doses, given not less than 6 and preferably 8 weeks apart and the third dose 6 to 12 months after the second dose.[2,3]

Adults: See INDICATIONS and ADVERSE REACTIONS. Where ORIMUNE is given to unimmunized adults, the dosage is as indicated for children and adolescents.

Booster Doses - School Entrance: On entering elementary school, all children who have completed the primary series should be given a single follow-up dose of trivalent oral poliovirus vaccine.[2,3] All others should complete the primary series.

The Public Health Service Advisory Committee does not recommend routine booster doses of vaccine on the basis of current information, beyond that given at the time of entering school.[2] Recent data indicates that over 95% of children studied five years after full immunization with oral poliovirus vaccine had protective antibodies to all three types of polinvirus.[17]

Increased risk: If an individual who has completed a primary series is subjected to a substantially increased risk by virtue of contact, travel or occupation, a single dose of TOPV has been suggested.[2]

syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilized vaccine, and agitate to mix thoroughly. Withdraw the entire contents into a syringe and inject the total volume of restored vaccine subcutaneously.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

10 Dose Vial (available only to government agencies/institutions)

Withdraw the entire contents (7 mL) of the diluent vial into the sterile syringe to be used for reconstitution, and introduce into the 10 dose vial of lyophilized vaccine. Agitate to ensure thorough mixing. The outer labeling suggests "For Jet Injector or Syringe Use". Use with separate sterile syringes is permitted for containers of 10 doses or less. The vaccine and diluent do not contain preservatives; therefore, the user must recognize the potential contamination hazards and exercise special precautions to protect the sterility and potency of the product. The use of aseptic techniques and proper storage prior to and after restoration of the vaccine and subsequent withdrawal of the individual doses is essential. Use 0.5 mL of the reconstituted vaccine for subcutaneous injection.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

Each dose contains not less than the equivalent of 1,000 $TCID_{50}$ of the U.S. Reference Measles Virus, 5,000 $TCID_{50}$ of the U.S. Reference Mumps Virus and 1,000 $TCID_{50}$ of the U.S. Reference Rubella Virus.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. M-M-R II, when reconstituted, is clear yellow.

HOW SUPPLIED

No. 4749 — M-M-R II is supplied as a single-dose vial of lyophilized vaccine, NDC 0006-4749-00, and a vial of diluent.

No. 4681/4309 — M-M-R II is supplied as follows: (1) a box of 10 single-dose vials of lyophilized vaccine (package A), NDC 0006-4681-00; and (2) a box of 10 vials of diluent (package B). To conserve refrigerator space, the diluent may be stored separately at room temperature.

Available only to government agencies/institutions:

No. 4682X — M-M-R II is supplied as one 10 dose vial of lyophilized vaccine.

NDC 0006-4682-00, and one 7 mL vial of diluent.

Storage

It is recommended that the vaccine be used as soon as possible after reconstitution. Protect vaccine from light at all times, since such exposure may inactivate the virus. Store reconstituted vaccine in the vaccine vial in a dark place at 2 - 8°C (35.6 - 46.4°F) and discard if not used within 8 hours.

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MSD | M-M-R® II (MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE, MSD)

M-M-R® II
(Measles, Mumps, and Rubella Virus Vaccine Live, MSD)

DESCRIPTION

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live, MSD) is a live virus vaccine for immunization against measles (rubeola), mumps and rubella (German measles).

M-M-R II is a sterile lyophilized preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live, MSD), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and grown in cell cultures of chick embryo; (2) MUMPSVAX® (Mumps Virus Vaccine Live, MSD), the Jeryl Lynn (B level) strain of mumps virus grown in cell cultures of chick embryo; and (3) MERUVAX® II (Rubella Virus Vaccine Live, MSD), the Wistar RA 27/3 strain of live attenuated rubella virus grown in human diploid cell (WI-38) culture.[1,2] The vaccine viruses are the same as those used in the manufacture of ATTENUVAX (Measles Virus Vaccine Live, MSD), MUMPSVAX (Mumps Virus Vaccine Live, MSD) and MERUVAX II (Rubella Virus Vaccine Live, MSD). The three viruses are mixed before being lyophilized. The product contains no preservative.

The reconstituted vaccine is for subcutaneous administration. When reconstituted as directed, the dose for injection is 0.5 mL and contains not less than the equivalent of 1,000 $TCID_{50}$ (tissue culture infectious doses) of the U.S. Reference Measles Virus; 5,000 $TCID_{50}$ of the U.S. Reference Mumps Virus; and 1,000 $TCID_{50}$ of the U.S. Reference Rubella Virus. Each dose contains approximately 25 mcg of neomycin. The product contains no preservative. Sorbitol and hydrolized gelatin are added as stabilizers.

CLINICAL PHARMACOLOGY

Clinical studies of 279 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies, a single injection of the vaccine induced measles hemagglutination inhibition (HI) antibodies in 95 percent, mumps neutralizing antibodies in 96 percent, and rubella HI antibodies in 99 percent of susceptible persons.

The RA 27/3 rubella strain in M-M-R II elicits higher immediate post-vaccination HI, complement-fixing and neutralizing antibody levels than other strains of rubella vaccine[3-9] and has been shown to induce a broader profile of circulating antibodies including anti-theta and anti-iota precipitating antibodies.[10,11] The RA 27/3 rubella strain immunologically simulates natural infection more closely than other rubella vaccine viruses.[11-13] The increased levels and broader profile of antibodies produced by RA 27/3 strain rubella virus vaccine appear to correlate with greater resistance to subclinical reinfection with the wild virus,[11,13-15] and provide greater confidence for lasting immunity.

Vaccine induced antibody levels following administration of M-M-R II have been shown to persist for at least two years without substantial decline.[16] Antibody levels after immunization with M-M-R (Measles, Mumps, and Rubella Virus Vaccine Live, MSD), containing the HPV-77 strain of rubella, have persisted for 10.5 years without substantial decline.[17] If the present pattern continues, it will provide a basis for the expectation that immunity following vaccination will be permanent. However, continued surveillance will be required to demonstrate this point.

INDICATIONS AND USAGE

M-M-R II is indicated for simultaneous immunization against measles, mumps, and rubella in persons 15 months of age or older. A booster is not needed.

Infants who are less than 15 months of age may fail to respond to the measles component of the vaccine due to presence in the circulation of residual measles antibody of maternal origin, the younger the infant, the lower the likelihood of seroconversion. In geographically isolated or other relatively inaccessible populations for whom immunization programs are logistically difficult, and in population groups in which natural measles infection may occur in a significant proportion of infants before 15 months of age, it may be desirable to give the vaccine to infants at an earlier age. Infants vaccinated under these conditions at less than 12 months of age should be revaccinated after reaching 15 months of age. There is some evidence to suggest that infants immunized at less than one year of age may not develop sustained antibody levels when later reimmunized. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunization.[18]

CORRECTION

THIS DOCUMENT
HAS BEEN REPHOTOGRAPHED
TO ASSURE LEGIBILITY

syringe to be used for reconstitution. Inject all the diluent in the syringe into the vial of lyophilized vaccine, and agitate to mix thoroughly. Withdraw the entire contents into a syringe and inject the total volume of restored vaccine subcutaneously.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

10 Dose Vial (available only to government agencies/institutions)

Withdraw the entire contents (7 mL) of the diluent vial into the sterile syringe to be used for reconstitution, and introduce into the 10 dose vial of lyophilized vaccine. Agitate to ensure thorough mixing. The outer labeling suggests "For Jet Injector or Syringe Use". Use with separate sterile syringes is permitted for containers of 10 doses or less. The vaccine and diluent do not contain preservatives; therefore, the user must recognize the potential contamination hazards and exercise special precautions to protect the sterility and potency of the product. The use of aseptic techniques and proper storage prior to and after restoration of the vaccine and subsequent withdrawal of the individual doses is essential. Use 0.5 mL of the reconstituted vaccine for subcutaneous injection.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis B and other infectious agents from one person to another.

Each dose contains not less than the equivalent of 1,000 $TCID_{50}$ of the U.S. Reference Measles Virus, 5,000 $TCID_{50}$ of the U.S. Reference Mumps Virus and 1,000 $TCID_{50}$ of the U.S. Reference Rubella Virus.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. M-M-R II, when reconstituted, is clear yellow.

HOW SUPPLIED

No. 4749 — M-M-R II is supplied as a single-dose vial of lyophilized vaccine, NDC 0006-4749-00, and a vial of diluent.

No. 4681/4309 — M-M-R II is supplied as follows: (1) a box of 10 single-dose vials of lyophilized vaccine (package A), NDC 0006-4681-00; and (2) a box of 10 vials of diluent (package B). To conserve refrigerator space, the diluent may be stored separately at room temperature.

Available only to government agencies/institutions:

No. 4682X — M-M-R II is supplied as one 10 dose vial of lyophilized vaccine.

NDC 0006-4682-00, and one 7 mL vial of diluent.

Storage

It is recommended that the vaccine be used as soon as possible after reconstitution. Protect vaccine from light at all times, since such exposure may inactivate the virus. Store reconstituted vaccine in the vaccine vial in a dark place at 2 - 8°C (35.6 - 46.4°F) and discard if not used within 8 hours.

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31. Unpublished data from the files of Merck Sharp and Dohme Research Laboratories.

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MSD | M-M-R® II (MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE, MSD)

M-M-R® II
(Measles, Mumps, and Rubella Virus Vaccine Live, MSD)

DESCRIPTION

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live, MSD) is a live virus vaccine for immunization against measles (rubeola), mumps and rubella (German measles).

M-M-R II is a sterile lyophilized preparation of (1) ATTENUVAX® (Measles Virus Vaccine Live, MSD), a more attenuated line of measles virus, derived from Enders' attenuated Edmonston strain and grown in cell cultures of chick embryo; (2) MUMPSVAX® (Mumps Virus Vaccine Live, MSD), the Jeryl Lynn (B level) strain of mumps virus grown in cell cultures of chick embryo; and (3) MERUVAX® II (Rubella Virus Vaccine Live, MSD), the Wistar RA 27/3 strain of live attenuated rubella virus grown in human diploid cell (WI-38) culture.[1,2] The vaccine viruses are the same as those used in the manufacture of ATTENUVAX (Measles Virus Vaccine Live, MSD), MUMPSVAX (Mumps Virus Vaccine Live, MSD) and MERUVAX II (Rubella Virus Vaccine Live, MSD). The three viruses are mixed before being lyophilized. The product contains no preservative.

The reconstituted vaccine is for subcutaneous administration. When reconstituted as directed, the dose for injection is 0.5 mL and contains not less than the equivalent of 1,000 $TCID_{50}$ (tissue culture infectious doses) of the U.S. Reference Measles Virus; 5,000 $TCID_{50}$ of the U.S. Reference Mumps Virus; and 1,000 $TCID_{50}$ of the U.S. Reference Rubella Virus. Each dose contains approximately 25 mcg of neomycin. The product contains no preservative. Sorbitol and hydrolized gelatin are added as stabilizers.

CLINICAL PHARMACOLOGY

Clinical studies of 279 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies, a single injection of the vaccine induced measles hemagglutination inhibition (HI) antibodies in 95 percent, mumps neutralizing antibodies in 96 percent, and rubella HI antibodies in 99 percent of susceptible persons.

The RA 27/3 rubella strain in M-M-R II elicits higher immediate post-vaccination HI, complement-fixing and neutralizing antibody levels than other strains of rubella vaccine[3-9] and has been shown to induce a broader profile of circulating antibodies including anti-theta and anti-iota precipitating antibodies.[10,11] The RA 27/3 rubella strain immunologically simulates natural infection more closely than other rubella vaccine viruses.[11-13] The increased levels and broader profile of antibodies produced by RA 27/3 strain rubella virus vaccine appear to correlate with greater resistance to subclinical reinfection with the wild virus,[11,12,13] and provide greater confidence for lasting immunity.

Vaccine induced antibody levels following administration of M-M-R II have been shown to persist for at least two years without substantial decline.[15] Antibody levels after immunization with M-M-R (Measles, Mumps, and Rubella Virus Vaccine Live, MSD), containing the HPV-77 strain of rubella, have persisted for 10.5 years without substantial decline.[17] If the present pattern continues, it will provide a basis for the expectation that immunity following vaccination will be permanent. However, continued surveillance will be required to demonstrate this point.

INDICATIONS AND USAGE

M-M-R II is indicated for simultaneous immunization against measles, mumps, and rubella in persons 15 months of age or older. A booster is not needed.

Infants who are less than 15 months of age may fail to respond to the measles component of the vaccine due to presence in the circulation of residual measles antibody of maternal origin, the younger the infant, the lower the likelihood of seroconversion. In geographically isolated or other relatively inaccessible populations for whom immunization programs are logistically difficult, and in population groups in which natural measles infection may occur in a significant proportion of infants before 15 months of age, it may be desirable to give the vaccine to infants at an earlier age. Infants vaccinated under these conditions at less than 12 months of age should be revaccinated after reaching 15 months of age. There is some evidence to suggest that infants immunized at less than one year of age may not develop sustained antibody levels when later reimmunized. The advantage of early protection must be weighed against the chance for failure to respond adequately on reimmunization.[18]

Previously unimmunized children of susceptible pregnant women should receive live attenuated rubella vaccine, because an immunized child will be less likely to acquire natural rubella and introduce the virus into the household.

Non Pregnant Adolescent and Adult Females

Immunization of susceptible non pregnant adolescent and adult females of childbearing age with live attenuated rubella virus vaccine is indicated if certain precautions are observed (see below and PRECAUTIONS). Vaccinating susceptible postpubertal females confers individual protection against subsequently acquiring rubella infection during pregnancy, which in turn prevents infection of the fetus and consequent congenital rubella injury.[19]

Women of childbearing age should be advised not to become pregnant for three months after vaccination and should be informed of the reasons for this precaution.*

It is recommended that rubella susceptibility be determined by serologic testing prior to immunization.** If immune, as evidenced by a specific rubella antibody titer of 1:8 or greater (hemagglutination-inhibition test), vaccination is unnecessary. Congenital malformations do occur in up to seven percent of all live births.[20] Their chance appearance after vaccination could lead to misinterpretation of the cause, particularly if the prior rubella-immune status of vaccinees is unknown.

Postpubertal females should be informed of the frequent occurrence of self limited arthralgia and possible arthritis beginning 2 to 4 weeks after vaccination (see ADVERSE REACTIONS).

Postpartum Women

It has been found convenient in many instances to vaccinate rubella-susceptible women in the immediate postpartum period (See *Nursing Mothers*.)

Revaccination: Children vaccinated when younger than 12 months of age should be revaccinated. Based on available evidence, there is no reason to routinely revaccinate persons who were vaccinated originally when 12 months of age or older. However, persons should be revaccinated if there is evidence to suggest that initial immunization was ineffective.

Use with other Vaccines

Routine administration of DTP (diphtheria, tetanus, pertussis) and/or OPV (oral poliovirus vaccine) concomitantly with measles, mumps and rubella vaccines is not recommended because there are insufficient data relating to the simultaneous administration of these antigens. However, the American Academy of Pediatrics has noted that in some circumstances, particularly when the patient may not return, some practitioners prefer to administer all these antigens on a single day. If done, separate sites and syringes should be used for DTP and M-M-R II.[21]

M-M-R II should not be given less than one month before or after administration of other virus vaccines.

CONTRAINDICATIONS

Do not give M-M-R II to pregnant females; the possible effects of the vaccine on fetal development are unknown at this time. If vaccination of postpubertal females is undertaken, pregnancy should be avoided for three months following vaccination. (See PRECAUTIONS, *Pregnancy*.)

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

History of anaphylactoid reaction to eggs (see HYPERSENSITIVITY TO EGGS below).

Any febrile respiratory illness or other active febrile infection.

Active untreated tuberculosis.

Patients receiving immunosuppressive therapy. This contraindication does not apply to patients who are receiving corticosteroids as replacement therapy, e.g., for Addison's disease.

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

Primary immunodeficiency states, including cellular immune deficiencies, hypogammaglobulinemic and dysgammaglobulinemic states.

Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.[22]

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*NOTE: The Immunization Practices Advisory Committee (ACIP) has recommended "In view of the importance of protecting this age group against rubella, reasonable precautions in a rubella immunization program include asking females if they are pregnant, excluding those who say they are, and explaining the theoretical risks to the others."[13]

**NOTE: The Immunization Practices Advisory Committee (ACIP) has stated "When practical, and when reliable laboratory services are available, potential vaccinees of childbearing age can have serologic tests to determine susceptibility to rubella.... However, routinely performing serologic tests for all females of childbearing age to determine susceptibility so that vaccine is given only to proven susceptibles is expensive and has been ineffective in some areas. Accordingly, the ACIP believes that rubella vaccination of a woman who is not known to be pregnant and has no history of vaccination is justifiable without serologic testing."[19]

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HYPERSENSITIVITY TO EGGS

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic or other immediate reactions (e.g., hives, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion should not be vaccinated. Evidence indicates that persons are not at increased risk if they have egg allergies that are not anaphylactic in nature. Such persons may be vaccinated in the usual manner. There is no evidence to indicate that persons with allergies to chickens or feathers are at increased risk of reaction to the vaccine.[18]

PRECAUTIONS

General

Adequate treatment provisions including epinephrine, should be available for immediate use should an anaphylactoid reaction occur.

Due caution should be employed in administration of M-M-R II to persons with a history of febrile convulsions, cerebral injury or any other condition in which stress due to fever should be avoided. The physician should be alert to the temperature elevation which may occur following vaccination. (See ADVERSE REACTIONS.)

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

Excretion of small amounts of the live attenuated rubella virus from the nose or throat has occurred in the majority of susceptible individuals 7-28 days after vaccination. There is no confirmed evidence to indicate that such virus is transmitted to susceptible persons who are in contact with the vaccinated individuals. Consequently, transmission through close personal contact, while accepted as a theoretical possibility, is not regarded as a significant risk.[13] However, transmission of the rubella vaccine virus to infants via breast milk has been documented (see *Nursing Mothers*).

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

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

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

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with M-M-R II. It is also not known whether M-M-R II can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, the vaccine should not be administered to pregnant females; furthermore, pregnancy should be avoided for three months following vaccination (see CONTRAINDICATIONS).

In counseling women who are inadvertently vaccinated when pregnant or who become pregnant within 3 months of vaccination, the physician should be aware of the following: (1) In a 10 year survey involving over 700 pregnant women who received rubella vaccine within 3 months before or after conception (of whom 189 received the Wistar RA 27/3 strain), none of the newborns had abnormalities compatible with congenital rubella syndrome;[23] (2) Although mumps virus is capable of infecting the placenta and fetus, there is no good evidence that it causes congenital malformations in humans. Mumps vaccine virus also has been shown to infect the placenta, but the virus has not been isolated from the fetal tissues from susceptible women who were vaccinated and underwent elective abortions;[24] and (3) Reports have indicated that contracting of natural measles during pregnancy enhances fetal risk. Increased rates of spontaneous abortion, stillbirth, congenital defects and prematurity have been observed subsequent to natural measles during pregnancy. There are no adequate studies of the attenuated (vaccine) strain of measles virus in pregnancy. However, it would be prudent to assume that the vaccine strain of virus is also capable of inducing adverse fetal effects.

Nursing Mothers

It is not known whether measles or mumps vaccine virus is secreted in human milk. Recent studies have shown that lactating postpartum women immunized with live attenuated rubella vaccine may secrete the virus in breast milk and transmit it to breast-fed infants.[25] In the infants with serological evidence of rubella infection, none exhibited severe disease; however, one exhibited mild clinical illness typical of acquired rubella.[26,27] Caution should be exercised when M-M-R II is administered to a nursing woman.

ADVERSE REACTIONS

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

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

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Moderate fever [101-102.9°F (38.3-39.4°C)] occurs occasionally, and high fever [above 103°F (39.4°C)] occurs less commonly. On rare occasions, children developing fever may exhibit febrile convulsions. Rash occurs infrequently and is usually minimal, but rarely may be generalized.

Forms of optic neuritis, including retrobulbar neuritis, papillitis, and retinitis may infrequently follow viral infections, and have been reported to occur 1 to 3 weeks following inoculation with some live virus vaccines.

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

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

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

There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 6-22 cases of SSPE per million cases of measles. The results of a retrospective case-controlled study conducted by the Center for Disease Control suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent higher risk of SSPE.[28]

Local reactions characterized by marked swelling, redness and vesiculation at the injection site of attenuated live measles virus vaccines, and systemic reactions including atypical measles, have occurred in persons who received killed measles vaccine previously. M-M-R II was not given under this condition in clinical trials. Rarely, more severe reactions that require hospitalization, including prolonged high fevers and extensive local reactions, have been reported.[29] Panniculitis has been reported rarely following administration of measles vaccine.[30]

Transient arthritis, arthralgia and polyneuritis are features of natural rubella and vary in frequency and severity with age and sex, being greatest in adult females and least in prepubertal children. This type of involvement as well as myalgia have also been reported following administration of MERUVAX II (Rubella Virus Vaccine Live, MSD). In children, joint reactions are rare and of brief duration if they do occur. In women, incidence rates for arthritis and arthralgia are generally higher than those seen in children (children: 0-3%; women: 12-20%),[31] and the reactions tend to be more marked and of longer duration. Symptoms may persist for a matter of months or on rare occasions for years. In adolescent girls, the reactions appear to be intermediate in incidence between those seen in children and in adult women. Even in older women (35-45 years), these reactions are generally well tolerated and rarely interfere with normal activities.

DOSAGE AND ADMINISTRATION

FOR SUBCUTANEOUS ADMINISTRATION

Do not inject intravenously

The dosage of vaccine is the same for all persons. Inject the total volume of the single dose vial (about 0.5 mL) or 0.5 mL of the 10 dose vial of reconstituted vaccine subcutaneously, preferably into the outer aspect of upper arm. *Do not give immune globulin (IG) concurrently with* M-M-R II.

During shipment, to insure that there is no loss of potency, the vaccine must be maintained at a temperature of 10°C (50°F) or less.

Before reconstitution, store M-M-R II at 2 - 8°C (35.6 - 46.4°F). *Protect from light.*

CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of the vaccine because these substances may inactivate the live virus vaccine. A 25 gauge, 5/8" needle is recommended.

To reconstitute, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine.

Single Dose Vial — First withdraw the entire volume of diluent into the

Letters to the editor

DPT parent responds to report on interview of health official

To the editor:

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

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

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

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

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

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

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

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

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

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

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

Shannon Kohler
Soldotna

People

Klatt urges parents to immunize children

By JANET HEVLY
Staff Writer

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

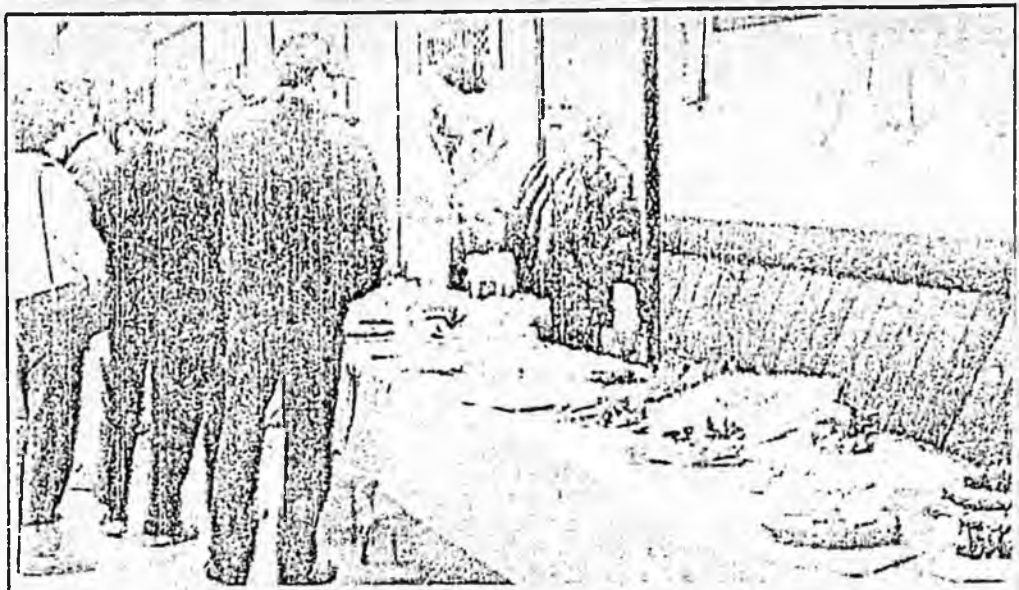
Parents who delay having their children immunized until after six months of age are actually missing their prime opportunity to immunize against pertussis when it is most effective, Klatt said. Whooping cough is most fatal to children under six months of age.

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

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

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

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



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

BRIEFING PAPER

H.B. 277: A Bill relating to the immunization of minors
proposed by Alaska DPT and sponsored by Rep. Mike Navarre

The following is an outline of the main components of H.B. 277, evidence that supports the need for each of these goals, and sources of this supporting information. Any item referred to can be obtained from Rep. Mike Navarre's office or by contacting Alaska DPT office at the address listed at the end of this paper.

I. Parental Choice: To allow philosophical objection (parental discretion) on administration of immunizations without threat of exclusion from a school, preschool, or day care in this state.

A. Twenty-two states in the United States allow this exemption. See attachment #1.

B. No studies have been conducted by the Center of Disease control to correlate use of this exception and greater rates of disease. Due to the small numbers that invoke this exemption, they state it would be difficult to make meaningful comparisons. (from AK State Legislature House of Representatives Research Agency request: Laws concerning Mandatory Immunization, #87.065)

C. Questionable effectiveness of vaccines*

1. Approximately half of the cases of whooping cough (pertussis) in 1984/1985 epidemic had received pertussis vaccine at some point in their life. (from correspondence of May 1, 1986 , Ak. Public Health Dept.)
2. Nationally, of the 1,051 affected with measles who were between 16 months and 28 years of age, 842 (80.1%) had been vaccinated on or after their first birthday which is the currently recommended timetable for measles vaccination. (from Morbidity and Mortality Weekly Report, Jan. 10, 1986 Vol. 35, #1)

D. Questionable safety of vaccines*

1. All short term and long term possible adverse reactions recognized by National Center of Disease Control that may result from vaccinations (see official MSAEFI report form, attachment #2)
2. All of the above and more also listed in manufacturers inserts from vaccines

*See bibliography for additional information regarding safety and effectiveness

II. Parent Immunization Information: To mandate

that each parent receive extensive written information as to the risks as well as the benefits of each vaccine before vaccination and with immunization information provided by Public Health at birth. This information would include:

A. Manufacturer's product insert from each vaccine which includes ingredients of product, adverse reactions that may occur from use of product, and contraindications to warrant discontinuing use of product
   1. DPT vaccine: Lederle Lab Division, American Cyanamid Co., Pearl River N.Y., 10965, or from Public Health Dept.
   2. Polio; Live Oral: same as DPT. Please note that this insert contains a "Disclaimer of Representations and Warranties".
   3. MMR: (measles, mumps, rubella): Merck, Sharp & Dohme, Div. of Merck & Co., Inc., Westpoint PA., 19486 or from Public Health Dept.

III. Adverse Reaction Reports: To mandate that all

health care providers (physicians, nurses, etc.) report to the Public Health Dept., all occurences of serious adverse reactions resulting from immunizations, and that long-term follow-up investigations be included

A. From correspondence with Public Health Dept: "The State does not have any specific regulations regarding the reporting of adverse reactions following immunizations. Health care providers who administer vaccines are encouraged to report possible adverse reactions to this office. This is a passive surveillance system which relies on the integrity of the health care providers to comply." (from letter dated November 14, 1986)

B. Paragraph excerpt from newspaper interview with Michael Klatt, manager Ak. Immunization program: "He acknowledges that the reaction reporting system hasn't been effective in the past and that many parents may not have associated illnesses occurring after a vaccine as related to the vaccine. 'I have no doubt that the adverse reactions were under-reported.'" (from Peninsula Clarion, Feb. 18, 1987)

C. Interviews with Alaska parents and adverse reaction report forms on file with AK. DPT--all fit the criteria of severe adverse reactions, several contacted doctors, hospitals or health centers about reaction; none were reported until contact with AK. DPT, few still reported. Includes: one child partially paralyzed, 2 cases of 105 degree fever with development of cerebral palsy, one child with nerve damage deafness, one case of SIDS, developmental delay, convulsions, etc.

D. Alaska DPT stresses the importance of mandatory adverse reaction reporting with follow-up so that parents may be able to accurately ascertain the benefit/risk ratio when determining whether to immunize.

IV. Immunization Records:

to insure that the vaccination manufacturer and lot # be kept on file for at least three years and to insure that reaction be recorded in minors permanent medical record so that no further doses of questionable vaccine be administered to minor, even if location of administration varies.

This briefing paper was prepared by:
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(907) 262-3825

Founded in 1982, Dissatisfied Parents Together is a National non-profit educational organization concerned with protecting children from death and injury from whooping cough (pertussis) and the pertussis vaccine, the "P" component of the DPT shot.

The Alaskan Chapter of DPT has expanded their concerns to all diseases and all State mandated vaccines. We are not anti-vaccine, but stress that parents have the right to be educated about all the aspects of any vaccine to be administered to our children. We also stress that Alaskan parents should have the right to decide which if any vaccines are to be administered to our children without threat of exclusion from State schooling or liscensed day care.

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 (7821)	☐	☐	☐
4. Adenopathy:			
Local (Injection Site Area) (7856)	☐	☐	☐
Generalized (7856)	☐	☐	☐
5. Allergic Event: (9995)	☐	☐	☐
Hives (7080)	☐	☐	☐
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	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:

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: If recovered, send to State Office — ☐☐ Mo. ☐☐ Day ☐☐ Yr. — Duration of Illness ☐ Days

30 DAY FOLLOWUP: If not recovered at 7 days, carry out 30 Day Followup and send to State Office — ☐☐ Mo. ☐☐ Day ☐☐ Yr. — ☐☐ Days

	Recovered	Partially Recovered*	Not Recovered*	Not Located	Dead
SEVEN DAY FOLLOWUP	☐	☐	☐	☐	☐
30 DAY FOLLOWUP	☐	☐	☐	☐	☐

* Comments _____

Reviewed By Immunization Project 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 [illegible] questions to vaccination and is voluntary except when required as a condition of immunization grant awards.

Exemptions from Immunization Requirements (K-12)

▨ Allowed ☐ Not Allowed

State	Medical	Religious	Philosophical
Alabama	▨	▨	
Alaska	▨	▨	
Arizona	▨	▨	▨
Arkansas	▨	▨	
California	▨	▨	▨
Colorado	▨	▨	▨
Connecticut	▨	▨	
Delaware	▨	▨	▨
Dist. of Col.	▨	▨	
Florida	▨	▨	
Georgia	▨	▨	
Hawaii	▨	▨	
Idaho	▨	▨	▨
Illinois	▨	▨	
Indiana	▨	▨	▨
Iowa	▨	▨	
Kansas	▨	▨	
Kentucky	▨	▨	
Louisiana	▨	▨	▨
Maine	▨	▨	▨
Maryland	▨	▨	
Massachusetts	▨	▨	
Michigan	▨	▨	▨
Minnesota	▨	▨	▨
Mississippi	▨		
Missouri	▨	▨	▨
Montana	▨	▨	▨
Nebraska	▨	▨	▨
Nevada	▨	▨	
New Hampshire	▨	▨	
New Jersey	▨	▨	
New Mexico	▨	▨	
New York	▨	▨	
North Carolina	▨	▨	
North Dakota	▨	▨	▨
Ohio	▨	▨	▨
Oklahoma	▨	▨	▨
Oregon	▨	▨	
Pennsylvania	▨	▨	▨
Puerto Rico	▨	▨	
Rhode Island	▨	▨	▨
South Carolina	▨	▨	
South Dakota	▨	▨	
Tennessee	▨	▨	
Texas	▨	▨	
Utah	▨	▨	▨
Vermont	▨	▨	▨
Virginia	▨	▨	
Washington	▨	▨	▨
West Virginia	▨		
Wisconsin	▨	▨	▨
Wyoming	▨	▨	

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

Representative Niilo Koponen
Box V (MS 3100)
Juneau, Alaska 99811

November 12, 1987

Dear Representative Koponen,

Enclosed is the video, "Vaccine Roulette", that I mentioned I would send to you in earlier correspondence. It was taped from the original television broadcast that was aired on April 19, 1982 by WKC-TV, Washington D.C. I hope that you can take the time to view it and also arrange to have the other H.E.S.S. committee members view it.

Given your concern as to the high death rate of Alaska's infants, I've enclosed some sudden infant death/DPT vaccine information compiled by our national DPT group. When I received these booklets last winter, I then wrote to our health dept. to ascertain their statistic gathering in regards to SIDS and vaccinations. To quote David A. Spence, M.D., Medical Officer with Alaska Public Health in charge of SIDS statistics and information gathering: "Regarding your question about the time of vaccination and SIDS occurance, our office does not collect those statistics."

I feel confident that you will be able to see the need to gather vaccine information in regards to sudden infant deaths. I hope that you will be able to set the machinery in motion to begin collecting those statistics and remedy this information gap.

Also enclosed is a chart of data received by AK-DPT from 10 states that allow a philosophical objection to immunizations in their statutes. We sent questionnaires to all 22 in early October, but to date only 10 have responded. We shall add to the chart as more states respond. This data consistently shows that even with the allowance of parental choice, the vast majority of parents choose to immunize and cases of disease are rare.

Representative Navarre recently told me that he will try to arrange with the H.E.S.S. committee to hear HB 277 in early January. AK-DPT and I are eagerly awaiting the chance to present our bill and supporting material to your committee. I look forward to meeting you at that time.

Sincerely,

Shannon Kohler

Shannon Kohler

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

VOL. 8 NO. 12

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IN THIS ISSUE:

More Anti-Vaccine Arguments

Dr. Robert Mendelsohn

Older folks sometimes question why I devote so much space to immunizations (this is the seventh People's Doctor Newsletter on the subject in the past eight years). There are at least four reasons:

1) Those who are grandparents and great-grandparents share some responsibility for the health of their grandchildren.

2) Older folks who have certain diseases which usually are attributed by doctors to the aging process may be interested in such other possible causes for their conditions as immunizations given to them decades earlier.

3) The scientific, political, and economic insights gained from the controversies surrounding immunizations may further one's understanding of other controversial issues in medicine.

4) Some of you may be participating directly--as judges, lawyers, and jurors--in present and future legal battles on behalf of parents who are fighting to keep their children from being immunized, as well as legal battles to compensate children (and some adults) who were damaged by immunizations.

Q

Ever since my daughter was born almost three years ago, I have been compiling an extensive file on the pros and cons of vaccinations. So far, she remains unimmunized, but one serious worry remains in my mind. Should she be immunized against tetanus? Most anti-vaccination people seem to feel that the tetanus shot is the lesser of two evils--I am told that tetanus germs are everywhere.

I realize you have changed your advice from pro-tetanus for everyone to only for farm dwellers, and we do not live on a farm. If I choose not to vaccinate my child, what if she winds up in a hospital emergency room badly cut or with a puncture wound?--M.H.

A

Are tetanus shots necessary?

You have every right to closely question me on the tetanus vaccine, since that was the last vaccine I abandoned. It wasn't hard for me to give up vaccines for whooping cough, measles, and rubella because of their disabling and sometimes deadly side effects. The mumps vaccine, a high-risk, low-benefit product, struck me and plenty of other doctors as silly from the moment it was introduced. Arguments for the diphtheria vaccine were vitiated by epidemics during the past 15 years which showed the same death rate and the same severity of illness in those who were vaccinated vs. those who were not vaccinated. As for smallpox, even the government finally gave up that vaccine in 1970, and I gave up on the polio vaccine when Jonas Salk showed that the best way to catch polio in the United States was to be near a child who recently had taken the Sabin vaccine. But the tetanus vaccine exercised a hold on me for a much longer time.

As you point out, I gave up belief in this vaccine in stages. For a while, I still held onto the notion that farm families and people who work around stables should continue to take tetanus shots. But in spite of my early indoctrination with fear of "rusty nails," in recent years, I have developed a greater fear of the hypodermic needle. My reasons are:

1) Scientific evidence shows that too-frequent tetanus boosters actually may interfere with the immune reaction.

2) There has been a gradual retreat of even the most conservative authorities from giving tetanus boosters every one year to every two years to every five years to every 10 years (as now recommended by the American Academy of Pediatrics), and according to some, every 20 years. All these numbers are based on guesses rather than on hard scientific evidence.

3) There has been a growing recognition that no controlled scientific study (in which half the patients were given the vaccine and the other half were given injections of sterile water) has ever been carried out to prove the safety and effectiveness of the tetanus vaccine. Evidence for the vaccine comes from epidemiologic studies which are by nature controversial and which do not satisfy the criteria for scientific proof.

4) The tetanus vaccine over the decades has been progressively weakened in order to reduce the considerable reaction (fever and swelling) it used to cause. Accompanying this reduction in reactivity has been a concomitant reduction in antigenicity (the ability to confer protection). Therefore, there is a good chance that today's tetanus vaccine is about as effective as tap water.

5) Until the last few years, government statistics admitted that 40 percent of the child population of the U.S. was not immunized. For all those decades, where were the tetanus cases from all those rusty nails?

6) There now exists a growing theoretical concern which links immunizations to the huge increase in recent decades of auto-immune diseases, e.g., rheumatoid arthritis, multiple sclerosis, lupus erythematosus, lymphoma, and leukemia. In one case, Guillain-Barre paralysis from swine flu vaccine, the relationship turned out to be more than just theoretical.

Risks of tetanus vaccine

In preparing my courtroom testimony on behalf of a child who allegedly was brain-damaged as a result of the DPT (diphtheria, pertussis, tetanus) vaccine, I reviewed the prescribing information (package insert) for the Connaught Laboratories product which was administered to this child. The 1975 and 1977 package insert information which measured seven-and-a-half inches long listed three scientific references in support of the indications, contraindications, warnings, cautions, and adverse reactions to this vaccine. By 1978, the length of the insert had grown to 13 1/2 inches, and the number of scientific references had increased to 11. By 1980, the package insert was 18 inches long, and the references numbered 14. Of those newly-added references, seven (three from U.S. medical journals and four from foreign medical journals) dealt specifically with reactions to the tetanus DPT portion of the (toxoid) vaccine.

An article in the Archives of Neurology (1972) described brachial plexus neuropathy (which can lead to paralysis of the arm) from tetanus toxoid Four patients who received only tetanus toxoid noticed the onset of limb weakness from six to 21 days after the inoculation. A 1966 article published in the Journal of the American Medical Association reports the first case of "Peripheral Neuropathy following Tetanus Toxoid Administration." A 23-year-old white medical student received an injection of tetanus toxoid into his right upper arm after an abrasion of the right knee while playing tennis. Several hours later, he developed a wrist drop of his right hand. He later suffered from complete motor and sensory paralysis over the distribution of the right radial nerve (one of the major nerves innervating the arm and hand). One month later, no residual motor or sensory deficit could be found.

Reference is made to an article in the Journal of Neurology, 1977, entitled "Unusual Neurological Complication following Tetanus Toxoid Administration." The author reports a 36-year-old female who received tetanus toxoid in her left upper arm following a wound to her finger. Five days later, she noticed a weakness first of the right, and then of the left arm and later of both legs. She complained of dizziness, instability, lethargy. chest discomfort, difficulty in swallowing, and inarticulate speech. She staggered when she walked, and she could take only a few steps. Her EEG showed some abnormalities. After a month, she was discharged without neurologic disturbance, but she continued to feel weak and anxious. Examinations during the next 11 months showed continued emotional instability and some paresthesias (numbness and tingling) in the extremities. The medical diagnosis was "a rapidly progressing neuropathy with involvement of cranial nerves, myelopathy, and encephalopathy."

The Journal of Allergy and Clinical Immunology, 1973, carried an article entitled "Hypersensitivity to Tetanus Toxoid," and in a volume entitled "Proceedings of the II International Conference on Tetanus" (published by Hans Huber, Bern, Switzerland, 1967), an article appeared entitled "Clinical Reactions to Tetanus Toxoid."

A 44-year-old article in the Journal of the American Medical Association (1940) was entitled "Allergy Induced by Immunization with Tetanus Toxoid." That same year, an article in the British Medical Journal reported on "Anaphylaxis (a form of shock) following Administration of Tetanus Toxoid." In 1969, a German medical journal reported a case of paralysis of the recurrent laryngeal nerve (the nerve to the voicebox) after a booster injection of tetanus toxoid. The patient developed hoarseness and was unable to speak loudly, but the nerve paralysis subsided completely after approximately two months.

Should your doctor reassure you that tetanus vaccine is completely safe, or that "the benefits outweigh the risks," or that you should have a shot "just in case," why not share these citations with him?

DPT and SIDS

A study from UCLA's School of Medicine linking DPT vaccine to sudden infant death appeared in the journal Pediatric Infectious Disease (January 1983). Conducted by Larry Baraff, M.D., and co-workers, this is the third major research project which links childhood immunizations, and more specifically, the whooping cough (pertussis) component, to crib deaths.

As far as the other two studies are concerned, in 1979 I reported to you the work of Robert Hutcheson, Director of Epidemiology of Tennessee's State Department of Public Health. Dr. Hutcheson statistically associated Wyeth's DPT vaccine with sudden infant death. In June 1982, I reported to you the work of Nevada's William Torch, M.D., which established the same relationship.

The latest study of Dr. Baraff, carried out together with the Los Angeles County Health Department, found that 53 of 145 SIDS (Sudden Infant Death Syndrome) victims whose families were interviewed, had received a DPT immunization. Of these 53, 27 had received this immunization within 28 days of death. Six of these 27 deaths occurred within 24 hours of DPT immunization, and 17 occurred within one week of immunization. The most striking finding of this study was that no deaths occurred in the fourth week following immunization. The authors conclude that "The excess of deaths in the 24 hours and first week following immunization and the absence of deaths in the fourth week following immunizations were all statistically significant." They call for more studies to substantiate their findings, despite the fact that this is already the third investigation, and all three have pointed in the same direction.

Since sudden infant death is one of the major causes of mortality in the pediatric age group (approximately one in 600 live births), every parent must take immediate action to protect his own child from becoming a DPT/SIDS statistic. Therefore, when your doctor tells you it's time for your baby to get a DPT shot, ask him if he has carefully read the studies of Hutcheson, Torch, and Baraff. Ask him what he thinks of the last sentence in the Baraff study which suggests that "If further studies substantiate our findings, it seems prudent to consider rescheduling DPT immunization until after the period of highest risk of SIDS, i.e., the latter half of the first year of life." Ask your doctor if he might even go as far as Dr. Mendelsohn and junk DPT altogether. Or more significantly, ask him if he's giving DPT shots to members of his own family. Finally, if you have friends or relatives who have lost a baby to SIDS and who were told by their doctors that the cause of SIDS is "unknown," encourage them to get a copy of their doctor's records in order to determine the exact time relationship between DPT immunization and death.

Pennsylvania doesn't require pertussis vaccine

The laws requiring mandatory immunization for school entry are becoming curiouser and curiouser. When I recently appeared on a Pittsburgh TV station to discuss the hazards of immunizations, a list was displayed which gave the vaccines required before a child can enter school in the State of Pennsylvania. Surprisingly, whooping cough (pertussis) was not on the list.

On my return to Chicago, my editor, Vera Chatz, telephoned the State of Pennsylvania Department of Public Health in Harrisburg to check out this information. She confirmed that, while the whooping cough vaccine is "recommended" for children at earlier ages, it is not required for school entry.

Mrs. Chatz then called out own Illinois State Department of Public Health and discovered that the pertussis vaccine is required for school entry, but is not required after the age of six because everyone agrees that this vaccine is too dangerous to use after age six. She therefore logically asked, "If my child has never received the whooping cough vaccine, why not wait until his sixth birthday to start him in school?" The man at the other end laughed and replied, "I guess you're right."

What do we learn from this? First, we learn there is apparently quite a significant variation from one state to the next, even in those 28 states which have no shots/no school laws. Therefore, if a dispute should arise about vaccinations between you and the school your child attends, you must immediately contact your own state department of public health and ask (in writing, if necessary) for their exact rules.

Second, if your doctor insists that your little infant must receive the DPT vaccine or he will be unable to enter school later in life, ask him (if you live in Pennsylvania, or other states with similar regulations) whether he is aware that the pertussis component of DPT vaccine is not, repeat not, required for school entry.

Your doctor then may retreat to a fallback position on DPT (since there is general agreement among doctors that the whooping cough component is certainly the vaccine most likely to cause severe neurological damage such as epilepsy, cerebral palsy, and mental retardation), telling you that he will give your child only DT vaccine. At that point, instead of quietly acquiescing, take this opportunity to ask your doctor for the readily available information (e.g., included in the package insert of Connaught Laboratories vaccine) which documents the short- and long-term risks of the tetanus component.

Q When our seven-month-old daughter received her first DPT shot three months ago, she ran a fever that peaked at 100.8. She became very fussy and cried off and on, sleeping between her cries. She would wake and cry and jump at the slightest touch or movement. Occasionally, she jumped and cried without any known cause. On the next day, she was her usual self.

After hearing about her reaction, the doctor wants to divide the next DPT shot, giving half the dosage one week and the other half two weeks later. What do you think is best for our baby?--Mr. & Mrs. J.C.

Dividing DPT dosage

A Your doctor was wise to withhold the next full DPT shot after you reported your child's reaction to the first shot. Although quite a few doctors recommend divided doses of DPT vaccine, there never has been a scientific study which proves that divided doses are less likely to result in catastrophic neurological reactions (cerebral palsy, mental retardation, convulsions, sudden infant death, etc.) than are full doses. So return to your doctor, and ask him to provide the evidence which supports his advice.

$10 million polio vaccine judgement

Those of you who still are enthusiastic about the polio vaccine should know that a Wichita, Kansas, jury awarded $10 million to a father who contracted polio after his infant daughter was vaccinated against the disease with Orimune, the live oral polio vaccine manufactured by Lederle Laboratories. This verdict, reported in the National Law Journal, June 18, 1984, is the largest verdict thus far in the product liability suits involving Orimune.

The father, Emil Johnson, first showed symptoms of polio 10 to 12 days after his child was immunized. Since then, he has suffered from irreversible bulbar poliomyelitis paralyzing his lungs. He can barely walk across a room before he keels over.

The jury found that Orimune was marketed without adequate warnings of its risks and found Lederle negligent in failing to warn that non-immunized people (Johnson had never been immunized) faced an increased risk of contracting polio by coming into contact with anyone who had received the oral vaccine.

Johnson's lawyers based their case on an interoffice memo written by a Lederle doctor that discussed "the possibility of reduced Orimune sales if the company took steps to inform doctors of the risks associated with administering the drug."

The son of polio vaccine developer Jonas Salk, Dr. Darrell Salk of the University of Washington Medical School, testified on behalf of Johnson. The younger Salk advocated a return to his father's vaccine, a killed virus vaccine given by injection. Dr. Salk said he is aware of 16 pending lawsuits involving Orimune, but Lederle declined to reveal how many cases have been brought against them.

We now have the opportunity to watch the Doctors Salk attack the Sabin vaccine. In previous years, Doctor Sabin attacked the Salk vaccine. I think they're both right.

Pediatricians attack DPT

More pediatricians have joined in attacking DPT vaccine. First, pediatrician-immunologist Kevin Geraghty, M.D., of El Cerrito, California, conducted a major study which linked that immunization to Sudden Infant Death Syndrome.

Now pediatrician Mark Thoman, M.D., head of the American Academy of Clinical Toxicology reports (Veterinary and Human Toxicology, August, 1984) that we are seeing more reactions from DPT today than a few years ago. He states: "The reason for this is that until almost 15 years ago, there was a

pharmaceutical manufacturer that had approximately 50 percent of the market with fewer reactions." The preparation of this manufacturer yielded a purer vaccine (known as a split-cell vaccine) with fewer reactions, both mild and serious.

This company wanted to get out of the vaccine business, and its rights and patents were picked up by another manufacturer who had been using the older "whole-cell" method of preparation. According to information obtained by Dr. Thoman (1426 Woodland, Des Moines, IA 50309), "The newer, safer vaccine was never used! Instead, the older reactogenic form was continued."

Dr. Thoman gives a very careful checklist of contraindications to DPT including neurological history, previous reactions (yes, even mild ones), strong history of convulsions or SIDS in the family, etc. He points out that the split-cell vaccine is being used in different parts of the world but is not available in the United States. He asks: "Isn't is ironic that we require or recommend immunizations in order to start school only to, in some cases, compromise some of the children by the very method we are using to supposedly protect them?"

Speaking to his fellow doctors, he concludes, "Perhaps we could be reminded of the concept that many of us learned during our training... primum non nocere...Above all, let's do no harm!"

Add this safer whooping cough vaccine to the growing list of medications (Laetrile included) that can only be obtained by crossing a border or an ocean.

Another M.D.'s opinion

As the immunization controversy heats up, many pediatricians have lined up in support of vaccines. On the other hand, critics of immunizations now have been joined by one of the giants in American medicine, the Cleveland Clinic's eminent surgeon, George Crile, Jr., M.D.

In a letter he wrote me after he participated with me and eight other medical authorities in a conference on "Dissent in Medicine," Dr. Crile commented: "I was very much interested in your Newsletter [Vol. 2, No. 4]. In the first paragraph, you state that some of these viruses could be molecules in search of diseases, and I absolutely agree. I think that the live vaccines in all are very dangerous. I remember Dr. Owen Wangensteen [the Mayo Clinic's renowned surgeon], who was an old man when he had his, nearly died as the result of neurological complications from that immunization. I would never have one. I think you are completely right about the whooping cough vaccine. The symptoms it produces seem to be more serious than the disease, and I am very much interested in whether the current epidemic of hyperactivity in children could have its origin in the measles vaccine. Certainly that should be looked into. I think that vaccinating with living viruses is almost by definition dangerous... Do you remember when the polio vaccine first came out? They had been using the live vaccine abroad for two or three years, but it was held up and was not allowed to be imported here until Salk could perfect his killed vaccine, and then we went right back and used the live one. Well, I think that the Salk vaccine, being a killed vaccine is safe, and now that the incidence of disease is way down, we could go back to that."

It will be interesting to see how other medical authorities, in fields other than pediatrics, now line up on the immunization issue.

Wyeth halts DPT manufacture

In June, 1984, Wyeth Laboratories, one of the most distinguished pharmaceutical companies in the country, gave up the manufacture and distribution of DPT vaccine. This then left only two commercial producers

(of the original 17) of this injection designed to prevent diphtheria, whooping cough and tetanus--Lederle Laboratories here in the U.S., and Connaught Laboratories from Canada.

My first reaction to the Wyeth decision was delight that the American system of free enterprise was working. Faced with the loss of millions of dollars as a result of legal action by parents of vaccine-damaged children, the drug manufacturers had increased the price of the vaccine tenfold. As judges and juries throughout the country have had the opportunity to carefully listen to and deliberate on the vaccine controversy, increasing numbers of children who suffer from convulsions, epilepsy, mental retardation, cerebral palsy, and other forms of neurologic damage are receiving the financial compensation to which they are justly entitled. Now, the true cost of vaccines is becoming known not only to the manufacturers, but to the American public at large.

I could hardly wait for Connaught and Lederle to follow Wyeth's example so that the DPT controversy would be clearly settled by the law of supply and demand: No vaccine available because no one wants it.

However, on second--and more sober--thought, another, more sinister scenario seems possible. What if Connaught and Lederle do indeed throw in the towel, leaving the U.S. without a supply of DPT? (Connaught Laboratories has withdrawn from manufacturing DPT vaccine--and then there was one.) Won't the top vaccine cheerleaders--the Centers for Disease Control and the American Academy of Pediatrics--immediately predict the return of those diseases?

Indeed, an epidemic of whooping cough in this country had already been invented. But, thanks to former top government virologist J. Anthony Morris, Ph.D. (and the honest editors of the Maryland State Journal who in 1983 published his analysis), the so-called "epidemic" turned out to consist almost exclusively of three categories:

1) bacteriologically unproven cases

2) children under two months of age and thus not even eligible for DPT and

3) cases in children who were completely immunized.

This kind of careful analysis conceivably should scotch such episodes of "creative diagnosis' in the future.

But if this strategy of vaccine-pushers were to go into operation, the American public might well panic and put enough pressure on Congress to rush through legislation which immunizes the manufacturers, just as they did with the ill-fated swine flu vaccine program of the mid-70's. For those of you who don't remember, the vaccine manufacturers refused to produce that material unless the government assumed liability for damage. The doctors, especially those at the Centers for Disease Control, whipped the public into a frenzy of fear, and the government caved in. Of the 80 million people (led by President Gerald Ford) who rolled up their sleeves to receive shots for an epidemic which never occurred, thousands now are paralyzed by Guillain-Barre syndrome. It is you and I, as taxpayers, and not the vaccine manufacturers, who are paying the cost.

I recommend that every reader of this Newsletter:

1) Learn about whooping cough, a very difficult disease to definitely diagnose and one which is easy to confuse with other diseases. Pertussis may look like little more than the common cold, or it may show the full-blown picture of whooping, vomiting and respiratory distress.

2) Learn about the contraindications and adverse reactions to the vaccine.

3) If your doctor claims that you or your child has whooping cough, make sure that he carries out the proper laboratory tests, including special culturing techniques and blood tests.

American physicians, as well as drug manufacturers, have been enraged at the failure of a bill proposed by Florida Senator Paula Hawkins which is piously described as "compensation for vaccine-damaged children." If that were indeed the case, why haven't doctors pushed such legislation during the past 40 years? Why did it take media disclosures

educating members of the public (who legitimately responded by going to the courts) to spur doctors to belatedly run to government? No, the real motivating force behind the Hawkins bill is to protect the doctors and the manufacturers. Indeed, that bill may well limit the compensation to damaged children.

If your local newspapers are not carrying details of this latest attempt to shift to the taxpayers a responsibility which traditionally has been assumed by business, you may contact former top government virologist J. Anthony Morris, Ph.D. (P.O. Box 40, College Park, MD 20740), who together with attorney Robert Kaufman of Gaylord, Michigan, is spearheading the effort to keep the liability for this vaccine, whose dangers are increasingly being recognized, right where it belongs--with the companies who make the vaccine and the doctors who administer it.

Until 1983, pediatricians did not inform parents of the risks of immunization. Then, as a result of media exposure, they admitted that one in a million children might be damaged by the vaccines. And what are their latest statistics? United Press quotes James Strain, M.D., president of the American Academy of Pediatrics: "Our main concern is with the pertussis (whooping cough) vaccine. One in 3,000 doses causes permanent injury to a child." Quite a precipitous drop from one in a million!

Also, until recently, the Academy showed little concern about vaccine-damaged children, regarding such cases as the inevitable price that must be paid (by the damaged child and his parents) for the protection of the entire population. Now, the Academy is showing some concern, and it wants tax dollars rather than vaccine manufacturers' insurance or profits to be used to compensate parents for death, loss of income, and medical care of the child. The benevolent pediatricians even are somewhat concerned with the child's pain and suffering, recommending that compensation for this item be granted "to a limited extent."

In the same UPI article, another Academy priority was noted--their fight against the "Baby Doe" rules that forbid hospitals and doctors to withhold food or medical care from handicapped infants. Dr. Strain said the Academy proposed a "bioethical committee representing society, disabled people, perhaps clergy." (Emphasis mine.)

He continues, "The government should not involve itself in the ethical dilemma..."

I can understand the traditional resentment pediatricians feel towards government, but one wonders why pediatricians hesitate to involve clergy in a committee that deals with ethical questions.

Rubella update

The latest recommendations from the Centers for Disease Control (Journal of the American Medical Association, July 12, 1984) contain a few interesting lines. First let me tell you the bad news and then the good news about rubella vaccine-induced arthritis. The bad news is that up to 40 percent of those vaccinated in the large-scale field trials suffered joint pain (arthralgia). The good news is that less than two percent developed frank arthritis.

Second, in its zeal to completely eliminate rubella, the CDC now recommends that "proof of rubella immunity for attendance at day care centers should be required and enforced. Licensure should depend on such requirements...Vaccination should be extended to include all post-abortion settings...Should become routine before discharge from a hospital for any reason...Vaccines should be offered to adults any time contact is made with the medical system...Consideration should be given for making rubella immunity a condition of employment...Immunity should be required for

attendance for both male and female (college) students."

The CDC explains its drive for enforcement by saying, "Less rigorous approaches, such as voluntary appeals for vaccination, have not been effective..."

Tough guys, those government docs. Perhaps they should be transferred to the State Department to conduct diplomatic relations with the Russians.

Q What is your opinion of the increasing number of vaccines being required for dogs and cats? Our 30-year-old son has never had a shot, and he is healthy. I want the same for my pets, yet the powers that be make that very difficult.--E.W.

A *Vaccine for animals*

My good friend Tom Brewer, M.D., author of "What Every Pregnant Woman Should Know" (Random House, $8.95), is fond of pointing out that animals often get better medical care than do human beings. For example, a dairy farmer never would restrict the salt intake or arbitrarily limit the weight gain of a pregnant cow the way obstetricians have been carrying out such practices in pregnant humans.

While I believe that modern doctors have a lot to learn from veterinarians, perhaps when it comes to immunizations, veterinarians can learn something from such doctors as Richard Moskowitz, M.D. In recent years, Dr. Moskowitz, who specializes in homeopathic medicine, has publicly raised the possibility that the increasing number of vaccines (particularly live virus vaccines) decades later may be responsible for the production of such auto-immune diseases as rheumatoid arthritis, multiple sclerosis, Guillain-Barre paralysis and certain tumors.

Since animals have immune systems that are not too different from those of humans, ask your verterinarian if any research has been done on the danger of vaccines to pets, comparable to the research showing the dangers of vaccines to humans.

Another View

by Marian Tompson
Executive Director,
Alternative Birth Crisis Coalition

Richard Moskowitz, M.D., graduated Phi Beta Kappa from Harvard University, received his M.D. from New York University's medical school, and teaches homeopathic medicine at the National Center for Homeopathy in Washington, D.C. Although the lecture he recently gave on immunizations will be published in its entirety in the "Dissent in Medicine" volume (Spring, 1985, Contemporary Books), let me now share with you Dr. Moskowitz's lucid explanations between the difference in naturally acquired immunities and what he (and others) suspects happens when we try to provide that immunity with a vaccine.

"For the last 10 years or so," began Dr. Moskowitz, "I have really felt a deep and growing compunction against giving routine immunizations to children. At first, I basically believed, and still believe, that people have the right to choose for themselves. But soon I discovered I just was not able to give the shots, even when the parents wished me to

"We all know that measles is a disease of the respiratory tract, primarily. It is inhaled primarily by the susceptible person on contact with the infected droplets produced by coughing and sneezing of the person with the disease. Once inhaled, it undergoes a long period of silent multiplication inside the tonsils, the adenoids, the accessory lymphoid tissues, the pharynx. Then it goes to the regional lymph nodes of the head and neck and eventually, several days later, into the blood, entering the spleen, liver, the thymus and the bone marrow--what you might call the visceral organs of the immune system. This incubation period lasts 10 to 14 days, and by the time the first symptoms of the measles appear, you begin to see circulating antibodies in the blood. At the height of the illness, when the child is sneezing and coughing

and his eyes are running, we have the peak of the antibody response. In other words the 'illness' that we see is precisely the definitive effort of the immune system to clear the virus from the blood, which it does by sending it out exactly the same way that it came in. When a child recovers from the measles, you have true immunity. That child will never, never again get the measles no matter how many epidemics he is exposed to. [Earlier in the speech, Dr. Moskowitz cited repeated findings that booster shots have no effect on someone who has been vaccinated against measles and is no longer immune. Such a booster shot, he says, does not restimulate the immunity.] Furthermore you have the sense that that person will respond vigorously and dramatically to whatever infectious agents he is exposed to. The side benefit of that disease is a nonspecific immunity that charges or primes his immune system so that it can better respond to the subsequent challenges that it is going to meet in the future.

"Now by contrast, when you take an artificially attenuated measles vaccine and introduce it directly into the blood and bypass the portal of entry, there is no period of sensitization of the portal of entry tissues. There is no silent period of incubation in the lymph nodes. Furthermore the virus itself has been artificially weakened in such a way that there is no generalized inflammatory response. By tricking the body in this way, it seems to me that we have done what the entire evolution of the immune system seems to be designed to prevent. We have placed the virus directly and immediately into the blood and given it free and immediate access to the major immune organs and tissues without any obvious way of getting rid of it. The result of this, of course, is the production of circulating antibodies which can be measured in the blood. But that antibody response occurs purely as an isolated technical feat, without any generalized inflammatory response or any noticeable improvement in the general health of the organism. Quite the contrary, in fact. I believe that the price we pay for those antibodies is the persistence of virus elements in the blood for long periods of time, perhaps permanently, which in turn presupposes a systematic weakening of our ability to mount an effective response not only to measles but also to other infections. So, far from producing a genuine immunity, if what I am saying is correct, the vaccine may act by actually interfering with or suppressing the immune response as a whole in much the same way as radiation and chemotherapy, corticosteroids and other anti-inflammatory drugs do.

"We already have adequate models from our study of experimental virology to show us what sorts of chronic disease are likely to result from chronic long-term persistence of viruses and other proteins within cells of the immune system. We know that live viruses are capable of surviving or remaining latent within host cells for years without continually provoking acute disease. They do this by attaching their own genetic material to the cell, an extra piece of genetic material. They replicate along with the cell. That allows the host cell to continue its normal functioning but continuing to synthesize the viral protein. Latent viruses produce various kinds of diseases. Because the virus is now permanently incorporated within the genetic material of the cell, the only appropriate immunological response is to make antibodies against the cell, no longer against the virus.

"So it is my feeling," concludes Dr. Moskowitz, "that immunizations promote certain types of chronic diseases. And far from providing a genuine immunity, the vaccines are actually a form of immunosuppression."

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Another View

by Marian Tompson
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Did you know that the so-called "herd immunity" theory, which assumes that if enough members of the population are vaccinated everyone will be protected, has been proved false in epidemiological studies? In 1971 in Casper, Wyoming, a rubella epidemic occurred one year after 83 percent of the city's schoolchildren had been vaccinated against rubella. (Ninety-one of the 125 cases occurred in vaccinated children.) Several years after the smallpox vaccine was introduced into the Philippines (it was first given in 1910) and after 95 percent of the population--8 million people--had been given 24,500,000 doses of vaccine, the Philippines experienced its worst smallpox epidemic in history.

Did you know that the incidence of measles actually has been declining steadily for the past 100 years? This certainly leads one to question the drug industry's claim that this drop is due to vaccinations. From 1958 to 1966, the number of measles cases reported each year dropped from 800,000 to 200,000. But it wasn't until 1967 that the live vaccine which is presently used was introduced, this after the killed virus vaccine which came out in 1963 was found to be ineffective and potentially harmful. Besides this cyclical decline, we must question the reliability of the numbers of cases now being reported. A survey of pediatricians in New York City revealed that only 3.2 percent of pediatricians actually were reporting measles cases to the health department. In 1974, the Centers for Disease Control determined that there were 36 cases of measles in Georgia, but the Georgia state surveillance system reported 660 cases that same year.

Did you know that, while there was a reported sharp decline in the incidence of polio after the introduction of the oral polio vaccine, the definition of polio was changed at the same time? The definition no longer included aseptic meningitis cases, thus hardly leaving a basis for comparison.

Did you know that when immunity to a disease is acquired naturally, the possibility of reinfection is only 3.2 percent? If the immunity comes from a vaccination, the chance of reinfection is 80 percent. Studies from the Faroe Islands have shown that adults who had acquired measles immunity naturally still were protected 65 years later.

Did you know that the article "Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children" (Pediatrics, Nov. 1981, Vol. 68, No. 5) reported only 18 serious reactions in children who had been given 15,752 shots? But if you read the article closely, you found that each child in the study received 5 shots adding up to 3,150 series. Thus, more than one out of every 175 children who received the full DPT series suffered severe reactions.

This information was given to me by Keith Block, M.D., a family physician from Evanston, Illinois, who has spent years collecting data in the medical literature on immunizations. He is alarmed at the potential hazards of vaccinations which artificially introduce a foreign protein as well as a "slow virus" into the human body which doesn't belong there and which can create serious health hazards such as the Guillain-Barre Syndrome which was linked to the swine flu vaccine. Vaccinations, Dr. Block explains, plant a seed which may be triggered months or years later by a variety of situations such as life stresses, medication, refined sugar, etc. "Living as we do, in a well-fed, hygienic society," Dr. Block points out, we end up trading off what would usually be a relatively minor illness for a potentially serious disease. Instead of taking personal responsibility for our body's immunological system, we try to handle everything with a vaccine, insulting our bodies and creating a sicker more endangered species. We are, literally, walking time bombs!" Those are strong words, I'll admit, but they're certainly worth pondering.

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IN THIS ISSUE:

Recent Immunization Research

Dr. Robert Mendelsohn

When I first went public with my syndicated column and The People's Doctor Newsletter, it was almost taboo to mention the risks of immunizations, except, of course, if that mention were safely tucked away within the pages of medical journals. But as the years went by, the information began to trickle out to the public.

This year, as a result of Lea Thompson's NBC-TV documentary, "Vaccine Roulette," immunization has become one of the most hotly-discussed subjects in the country. Requests for the documentation of the hazards of immunizations presented in my Newsletters pour in from M.D.'s, chiropractors, nurses, journalists and just plain people.

This is my fourth Newsletter on this subject. Something tells me it won't be the last.

Other criticisms of compulsory immunization

Just so that you know I am not alone in my criticism of compulsory immunization laws, Dr. F. M. White, Director of Communicable Disease Control and Epidemiology with the Alberta, Canada, Health Department and more recently with the British Columbia Ministry of Health, also is concerned about the ethical considerations of immunizing in view of "the present lack of precise knowledge of the field." Connaught Laboratories' "Biolines" quotes Dr. White as saying, "There is an important ethical distinction between treatment and preventive programs...Are all immunizations of proven value and do we really know what we are doing?"

Fifteen years before Dr. White voiced his concerns, Sir Graham Wilson in his book "The Hazards of Immunizations" showed a good grasp of the ethical problems which accompany immunization. "Once a vaccine has been introduced, with apparently good results, it becomes extremely difficult ever to find out its real value," wrote Wilson. "Moral objections may be too strong to permit a properly-controlled trial."

Ask your own doctor whether the vaccine he wants to inject into your child ever has been scientifically proven by controlled studies. Or does he just "believe" in the vaccine?

Government admits vaccine dangers

While I was preparing to give testimony as an expert witness in some upcoming law cases which deal with children who are alleged to have been damaged by immunizations, I reviewed some government documents which never before had come to my attention.

The November 20-21, 1975 minutes of the 15th meeting of the Panel on Review of Bacterial Vaccines and Toxoids with Standards of Potency, presented by the Bureau of Biologics and the Food and Drug Administration, contain a remarkably complete analysis of vaccines which are currently in use. While the overall conclusion is that vaccines are worthwhile and good, I thought you might like to read part of the darker side of immunizations described by the eminent scientists on this committee, a side which rarely reaches the public eye.

The section on diphtheria immunization contains the sentence: "For several reasons, diphtheria toxoid, fluid or absorbed, is not as effective an immunizing agent as might be anticipated. Clinical (symptomatic) diphtheria may occur occasionally in immunized individuals--even those whose immunization is reported as complete by recommended regimens." The panel claims that when diphtheria does occur in such an individual, "It appears to be milder." The report continues with "...the permanence of immunity induced by toxoid...is open to question."

Regarding the combination diphtheria/tetanus vaccine used in adults, the panel stated that this substance has never been shown conclusively to be an adequate primary immunizing agent. Furthermore, the intervals between booster doses of TD (diphtheria/tetanus) in adults sufficient to maintain diphtheria immunity have not been established. Efforts by producers to reduce the reactions of the toxoid by increasing purification "may have resulted in diminished immunogenicity."

In other words, as the diphtheria/tetanus vaccine is made safer in order to cut the severity of reactions to it, it gives less protection against the disease. Since no controlled studies have recently been carried out on this vaccine, maybe now it's just plain old water.

While giving tetanus toxoid generally high marks, the scientists from the Bureau of Biologics and the Food and Drug Administration point out, "The antigenicity [degree of potency] of tetanus toxoid can vary considerably from preparation to preparation." Furthermore, "Recent changes in manufacturing procedures may have resulted in lowering of the immunizing potency of tetanus toxoid in some products; hence there is a need for re-evaluating the primary antigenicity of current preparations."

The panel continued: "Most of the local and febrile [fever] reactions that are seen appear to be related to more frequent inoculations than are necessary."

Now, on to whooping cough. While noting the reduction in this disease over several decades, the panel concedes that "Not all of this remarkable decline can be attributed to widespread use of the vaccine for the reason that some decline in morbidity [illness] and mortality from pertussis was observed in the United States and other Western countries prior to the institution of vaccination."

On one hand, the scientists claim the incidence of whooping cough is low, yet they qualify this statement: "The exact rates, however, are unknown for several reasons. Cases are frequently unreported or not recognized." Since many laboratories are not equipped to routinely test for whooping cough germs, "The infection may go undiagnosed...Infection in immunized persons may cause bronchitis but without typical whooping."

In one of the most important admissions in the entire document, the panel concluded: "Therefore, reports of pertussis obtained by the Center for Disease Control probably represent only a fraction of all pertussis infections occurring throughout the country."

How pure is the whooping cough vaccine? The panel stated, "In contrast to some other immunizing agents, such as diphtheria and tetanus toxoids, pertussis vaccine is a relatively crude preparation that con-

tains the majority of the bacterial constituents, most of which are probably not relevant to the induction of immunity to the disease."

Has your doctor told you the kind of reactions which are due to the whooping cough vaccine? The panel described them as follows: "Significant reactions that have been attributed to pertussis vaccine have included high fever...a transient shock-like episode, excessive screaming, somnolence, convulsions, encephalopathy, and extremely rarely, thrombocytopenia [deficiency of clotting elements in the blood]. Such reactions almost always appear within 24 to 48 hours after injection, but have been thought to occur after an interval as long as seven days."

How common are these complications? The panel first used the word "rare," but immediately thereafter confessed that the rates (of complications) are "difficult to define precisely at least in part because they are often not reported." The report further points out that vaccine of higher potency may produce more reactions.

Panel members admitted that the whooping cough vaccines pose a special problem since they "do not exhibit the effe tiveness and safety which have been achieved with certain other immunizing agents." The report conceded that "Without adequate surveillance of disease rates, the effectiveness of current vaccines and immunization programs cannot be monitored."

How long does immunity last? According to the panel, "Experience with modern pertussis immunization is not of sufficient duration to predict whether childhood immunization may in some instances postpone natural infection until a later age."

Should your child receive whooping cough vaccine before starting school? The panel reported: "The usefulness of the currently recommended booster dose at school entrance has never been fully documented." The panel admitted that the ultimate significance, if any, in terms of permanent results of vaccine-induced somnolence, excessive screaming, and high fever is unknown. Without such knowledge, satisfactory recommendations for further immunizations when any of these reactions occurs cannot be made.

How often do complications occur? In the understatement of the decade, the panel states, "Physicians are expected to report complications of immunization to manufacturers, in the United States, but compliance with this expectation is less than optimum." The panel further points out, "Many physicians are not cognizant of their clinical features. Further, both physicians and manufacturers have been held liable for damage suits by patients who may suffer adverse effects from established vaccines. All these factors undoubtedly discourage reporting; without maximum reporting or some other form of surveillance, definition of the rates and significance of untoward reactions to current and future vaccines cannot be ascertained."

The panel criticized the laboratory procedures used in the production and testing of pertussis vaccine and, not surprisingly, recommended increased public support for more research studies. "Without such basic studies, a more effective and safer pertussis vaccine cannot be developed." I agree, and I further suggest that all pertussis immunization be suspended while such research is being conducted on this obviously low-quality vaccine.

The panel actually recommends that "The vaccine label should warn that if shock, encephalopathic [brain damage] symptoms, convulsions, or thrombocytopenia [a clotting disorder] follow a vaccine injection, no additional injections with pertussis antigens should be given....The label should also include a cautionary statement about fever, excessive screaming, and somnolence." (Wouldn't it be wise to ask your doctor for a peek at the label the next time he tries to immunize your child?)

The panel's final recommendation is for legislation providing federal compensation for "the few individuals" injured and disabled by participating "in a meritorious" public health program. The panel members frankly admit, "Such legislation would protect manufacturers and physicians against liability...." (Does everyone remember the swine flu vaccine? Its manufacturers did succeed in passing the buck of liability to the federal government so that you and I now are paying for the many cases of paralysis and other damage which resulted from that immunization--for a disease that never materialized.)

The panel's criticism of other vaccines--typhoid (TAB vaccine which is the now-discontinued typhoid-paratyphoid vaccine received by all who served in the armed forces during World War II), cholera, plague--is required reading for anyone whose travel agent tells him he needs these shots in order to travel abroad.

On the very last page of the minutes, the government panel mentions its "careful note" of a report on the potential for oncogenic (tumor-producing) action of aluminum and oil adjuvants, substances which were added to increase the action of many vaccines: "There is little doubt that some of the material containing aluminum as adjuvant appears to be carcinogenic [cancer-producing] in a strain of Swiss mice."

The panel also is investigating the possibility of retrospectively examining the human experience with the incidence of fibrosarcomas [malignant tumors of connective tissue] at the usual sites of injections of vaccines."

Immunizations as seeds of long-term damage

Six months ago, NBC-TV did an expose on the risks of whooping cough vaccine (a component of the DPT triple immunization recommended for all U.S. infants), and Channel 5 in Chicago ran a feature on its nightly news entitled "DPT: Vaccine Roulette." Channel 5 heralded this feature in Chicago newspapers with full-page ads headlined: "Will this child be a victim of vaccine roulette?"

Of course, for the past six years, my readers have been exposed to information about the dangers of immunization. Now, I bring to your attention further revelations by eminent scientist Robert W. Simpson, Ph.D., Professor of Virology, Waksman Institute of Microbiology, Rutgers University.

The Simpson saga began in March, 1976 when, at a Science Writers Seminar sponsored by the American Cancer Society, Dr. Simpson presented a paper which was widely quoted in the press. Press reports stated that Simpson's paper pointed out that "immunization programs against flu, measles, mumps, polio, etc. actually may be seeding humans with RNA to form proviruses which will then become latent cells throughout the body. Some of these latent proviruses could be molecules in search of diseases which under proper conditions become activated and cause a variety of diseases including rheumatoid arthritis, multiple sclerosis, lupus erythematosus, Parkinson's disease and perhaps cancer."

In Chapter II of the Simpson saga, Mrs. Sue Schieler of Milford, Indiana wrote Dr. Simpson, inquiring about links between immunization procedures and multiple sclerosis. Mrs. Schieler sent me Dr. Simpson's response of September 25, 1981 in which he wrote "...I regret to inform you that our earlier studies (1976) at Rutgers University on related work were totally misquoted by the media. We have never obtained any evidence that would implicate vaccination as a cause or contributing factor for such human diseases [as multiple sclerosis]."

In February 1982, I asked Dr. Simpson for his complete paper. I wrote: "Since your (misquoted) statement was so widely publicized, your

complete statement should enable me to correct any misconceptions by the readers of my books, subscription newsletter and syndicated column."

I promptly received a copy of Dr. Simpson's five-page paper entitled "RNA-Containing Viruses of Humans Can Be Transcribed Into DNA Proviruses." While I am sure Dr. Simpson will be happy to supply full copies of this paper to those of you who are interested, let me now share with you some quotes from it which are admittedly out of context.

Discussing the result of studies conducted in his laboratory, Dr. Simpson states: "This finding holds important implications regarding the potential of common RNA viruses (e.g., influenza, measles, mumps, etc.) to persist in human populations in a latent or masked form following either natural acute infection or active immunization with live virus vaccines." (Emphasis mine.)

Dr. Simpson continues, "...the disease potential of such DNA proviruses and their possible existence in human populations needs to be determined in light of ongoing, large scale vaccination programs with live viruses and also with a view to understanding the underlying etiology of human cancer as well as various types of chronic degenerative disease such as multiple sclerosis, Parkinson's disease and rheumatoid arthritis."

Referring to these proviruses (known as molecular intermediates), Dr. Simpson speculates: "Are these molecular intermediates a natural product of acute virus infection or live virus vaccination with common riboviruses?" (Emphasis mine.) He continues, "Regarding the latter point, animal studies now in progress in our laboratory suggest that RS virus can persist in a latent form in lung tissue many months after initial infection...This preliminary finding presents the intriguing possibility that persistence of such riboviruses at the molecular level may not only be a common feature of viral infections but a necessary event for the maintenance of long-lasting immunity...conceivably, some of these latent agents could represent potential 'molecules in search of disease' which under appropriate conditions of environmental stress might infrequently be reactivated as complete or defective viruses capable of evoking a pathological response to their resident host."

Dr. Simpson's scientific paper concludes with this statement: "Finally, the question of the risks associated with the use of live virus vaccines of human RNA viruses that may possibly be transcribed into DNA proviruses must be considered...it is still necessary that public health scientists intensify and improve their surveillance efforts for detecting infrequent complications associated with the large-scale use of such live virus vaccines for immunizing human populations. Such complications might gradually manifest themselves over a very long time course measured in years and might assume a disease course that one would not ordinarily relate to the original vaccine virus."

You now are in a good position to judge whether Dr. Simpson was originally misquoted! But the Simpson saga does not end here. The most bizarre aspect of the entire affair is Dr. Simpson's red-penned note to me on the top of his paper: "This work could not be repeated in our laboratories after the investigator who originally made these observations left."

While I leave it to each of your fertile imaginations to figure out the implications of that cryptic statement, I can assure you that the deeper I delve into research on immunizations, the curiouser and curiouser it gets.

Where to get information on DPT vaccine

The issue of whether or not to immunize is heating up all over the world. In Australia, Drs. Archie Kalokerinos and Glen Dettman, Ph.D., have published their findings on the dangers of DPT vaccine in an excellent booklet entitled "The Dangers of Immunization" (The Humanitarian Society, Box 77, Quakertown, Pennsylvania 18951).

Attorney Robert Kaufman of Gaylord, Michigan has brought legal action against Merck Sharp & Dohme on behalf of a child who is suffering from severe neurologic damage which began after a measles shot. And Chicago attorney Allen McDowell, in his case involving a child who developed mental retardation after a DPT shot, has gathered testimony from medical experts in England (Dr. Gordon Stewart and Dr. John Wilson) and in Germany (Dr. Wolfgang Ehrengut).

Dr. Ehrengut, Director of the Hamburg (Germany) Vaccination Institute, stated in deposition (further information may be obtained from Allen McDowell, Suite 1313, 127 N. Dearborn, Chicago, Illinois 60602) that in Germany, the state pays for vaccine-damaged children "even if the doctor is responsible from some stupidity which they have done, if they have made a mistake, in every case to protect the individual, our state pays. This is paragraph 51 of our so-called Infectious Disease Law. By this law, this individual gets for his whole life some compensation. In this way, this is the best law in the world."

Referring to the United States, Ehrengut said, "To be very frank, your doctors hide complications. They don't tell the truth if they have done something incorrect."

Both these lawsuits and the above-mentioned publication are required reading for anyone whose child may have been damaged by routine immunization as well as for all parents who are concerned about the negative effect of immunizations.

In addition, if you would like to read the testimony J. Anthony Morris, Ph.D., one of the leading vaccine experts in the United States, gave before the Senate Investigating Committee (June 30, 1982), write Dr. Morris at P.O.B. 40, College Park, Maryland 20740 for a copy of his 11-page statement. In this statement, Dr. Morris concludes that "The thrust of the testimony given by Drs. Foege, Fulginiti, Parrott, and Fannin [the chief proponents of mandatory immunization] before the Subcommittee at this hearing on immunization and preventive medicine was either misleading, self-serving, or both, and careful efforts by the public to understand the thrust of their statements will only erode further the public's confidence in vaccines."

Monitoring adverse reactions

Your doctor should know about the September 1979 statement of the Office of Technology Assessment reporting to the U.S. Congress on vaccine and immunization policies. Referring to the Center for Disease Control's system for monitoring adverse reactions to vaccines, the report begins, "The system will not generate data that will permit calculation of incidence rates of adverse reactions among defined populations." In other words, U.S. government doctors, in contrast to those in foreign countries, never have worked out a method for finding out what percent of children suffer damage from vaccines.

The report points out, "Vaccinations are recommended and administered to millions of children and other individuals each year on the presumption [emphasis mine] that the benefits far outweigh the risks. The benefit side of the equation is straightforward: Vaccinations can prevent serious disease. The risk side is not so straightforward since it includes factors that are known that may exist but have not yet been discovered."

Arthritis from rubella vaccine

Now that you are aware, through recent extensive media coverage, that whooping cough (pertussis) vaccine can cause brain damage, I wouldn't want you to fear giving your children whooping cough vaccine while believing that all other vaccines are perfectly safe. That is why I am bringing to your attention the latest research on the German measles (rubella) vaccine.

Six years ago, Dr. Aubrey Tingle, a pediatric immunologist at Children's Hospital in Vancouver, British Columbia, and his co-workers discovered that 30 percent of adults who had been exposed to rubella vaccine suffered arthritis two to four weeks after vaccination, ranging from mildly aching joints to severe crippling. Recently (as reported in Maclean's Magazine, February 8, 1982), these same researchers found live rubella virus in one-third of patients--both children and adults--with rheumatoid arthritis. (Rheumatoid arthritis, of course, is a much more severe degenerative and crippling disease than is rubella arthritis.) In one patient, rubella arthritis developed into rheumatoid arthritis. Ten percent of adults who have the symptoms of arthritis resulting from rubella immunization will suffer extreme pain.

Dr. Tingle pointed out that when the rubella vaccine was first introduced, its promoters said that "all the symptoms disappear in three months." Dr. Tingle soberly reflected, "But that's not correct. We've had patients that we followed for 10 years who are still having recurrent episodes.

"One such victim is Anita Willson, a 32-year-old teacher. In 1975, when she applied for a marriage license in Calgary, she was required to undergo a rubella vaccination. She complied. About two weeks later, she began to experience swelling of her big toe, and the pain soon spread to her fingers and wrists. The diagnosis: arthritis. 'I was so disabled that I couldn't shift gears on my car or open a jar,' Willson recalls. 'Here I was, newly married and with a new job. My whole world came crashing down. It was terrifying.' Willson's arthritis, which now appears to be in abeyance, lasted for five years."

For children who receive rubella immunizations, Dr. Tingle wisely warns, "The longterm effects are the major unresolved issue that we have to face."

Medical News

On sexual freedom

From the British medical journal Lancet comes the following excellent analysis in an article entitled "Biological Effects of Sexual Freedom": "There are something on the order of 250 million new cases of gonorrhea and 50 million new cases of syphilis annually. Other sexually communicable conditions may be even more common... The adverse biological effects of sexual freedom on women and their babies are a disappointing development in the second half of the 20th century."

"MalePractice: How Doctors Manipulate Women," Dr. Mendelsohn's latest book, is now available in paperback from Contemporary Books ($6.95).

"Confessions of a Medical Heretic" is available from WarnerBooks ($3.25).

From the time we began publication seven years ago, the annual subscription price of The People's Doctor Newsletter has remained at $18.00. Since rising costs make it impossible for us to continue publishing at that price, the new annual subscription rate will be $24.00. Individual back issues will now be priced at $2.50.

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IN THIS ISSUE: IMMUNIZATION CONTROVERSIES CONTINUE: Vaccines Implicated in AIDS . . . DPT Seizure Hazards . . . Futility and Risks of Measles, Flu and Pneumonia Shots

This is my eleventh Newsletter on immunizations, and the revelations about the damage they cause continue to appear in the public press.

Dr. Robert Mendelsohn

A hard-hitting salvo against infant vaccines appeared this year in a five-part 16-page newspaper series in the Rochester (New York) Democrat and Chronicle. Entitled "Children at Risk--DPT Dilemma," this special report by reporter Jennifer Hyman represents five months of research, complete with photos of brain-damaged children, graphic depictions of reaction estimates and interviews with doctors on both sides of the vaccine issue.

Hyman discovered what I have been reporting to you for the last several years--doctors who won't give the vaccine to their own children. For example, Dr. Kevin Geraghty, a specialist in pediatric immunology, told Hyman, "You could put a gun to my head, and I wouldn't use the American [DPT] vaccine. No power on earth could make me do it."

According to Hyman, many pediatric neurologists--some say a majority--will not allow their own children to have the vaccination. Hyman learned that doctors still are not informing parents about the vaccine's side effects. Nor were most parents and doctors aware that nine states, including New York, do not require the DPT shot. Of greatest importance are Hyman's revelations that DPT is not the only childhood vaccine with side effects. She tells about adults who develop polio after they have contact with children who recently have been immunized with that vaccine; more fevers have been reported to the Centers for Disease Control after the MMR (measles, mumps, rubella) than after the DPT shot.

Rochester, New York, is not exactly a hotbed of radicalism. And the appearance of this important series indicates that word about vaccine dangers is entering the consciousness of middle America. The Democrat and Chronicle, after receiving thousands of requests from around the country for copies of this series, has made special reprints available.

Q I am enclosing an article from the Denver paper advocating immunizations. I am against immunizations, and so is my daughter, but my son-in-law disagrees with us. In my opinion, the newspaper's statement about increases in some childhood diseases simply is not true. The article seems intended to panic people into getting unnecessary shots for their children. I'd love to know where those statistics came from!--Mrs. E.J.

Vaccine proponents defend themselves

A Thanks for sending me that clipping from your Denver newspaper which blames the increase on the cost of vaccines, as well as the public disputes over vaccine safety and liability and the alleged shortages of some vaccines.

All the above is true. Because of jury awards to children who have been brain-damaged by vaccine, vaccine costs have skyrocketed. As more and more parents begin to recognize the link between vaccines and their child's condition (epilepsy, convulsions, mental retardation, cerebral palsy, Sudden Infant Death, etc.), lawsuits have become commonplace. As drug companies exit the vaccine field, public health authorities worry about vaccine shortages.

Therefore, whenever you read one of the ever-increasing number of articles which try to panic people into vaccinating their children, you also must read about the other side of this most controversial issue. Read about doctors who are concerned about the damage that may appear decades later as a result of immunizations intended to protect children against relatively innocuous diseases. Read about doctors who are concerned about damage to the immune system from immunizations. Read about the sorry record of public health authorities in other preventive matters--the swine flu vaccine included. Read about the many fully-immunized children who nevertheless are getting measles and mumps and whooping cough.

While I share your misgivings about the kind of scare tactic exemplified by this article, at the same time I admit a certain sense of satisfaction. The fact that our public health authorities feel compelled to thus defend themselves indicates that they are being hard hit by vaccine opponents, myself included.

Before 1982 (when the vaccine controversy became a public issue), public health authorities never had to resort to this kind of scare strategy. But now, the public health people know that lots of parents don't believe them anymore. Lots of parents are asking lots of questions of their own doctors before they let their children receive those shots.

By bringing you documented information on the darker side of immunizations, this Newsletter will continue its tradition of opposing the blind acceptance of routine immunizations. But you have to do your part too. Denver is your home town. The Denver newspaper is your newspaper. While I am flattered that you chose to write to me, I urge you to also write to the editor of that newspaper. Tell him how you feel about immunizations and why you feel that way. In case you want to send the editor some medical references which oppose immunizations, send him a copy of this Newsletter.

Can immunizations trigger AIDS?

With increased public awareness of the dangers of immunizations, I repeatedly have been asked about future vaccines, particularly the new genetically-engineered recombinant vaccines. People ask, "Will such vaccines be safer than the present pertussis vaccine? Will such vaccines, because they are not derived from human blood, obviate the danger of catching AIDS from the shot?"

Until now, I have had to answer such questions by invoking some of Mendelsohn's Laws. For example, "Look for quick use of the new vaccines because doctors try to use a new remedy as rapidly as possible before its side effects become known." Or, I reply with another of Mendelsohn's Laws, "Doctors never give up one dangerous remedy until they have an even more dangerous one waiting in the wings."

But now, concerns about genetically-engineered vaccines are surfacing in the highest circles of medicine. Buried deep within the New England Journal of Medicine (December 3, 1986) are three important sentences: "Extensive research is being conducted on recombinant live-virus vaccines in which vaccinia [the smallpox organism] is used as a biologic carrier. Recently, several groups have developed candidate recombinant HIV vaccines. Our case report raises provocative questions concerning the ultimate safety of such vaccines."

Now for the background of those admittedly technically complex, but obviously frightening, sentences. The NEJM article entitled, "Disseminated Vaccinia in a Military Recruit with Human Immunodeficiency Virus (HIV) Disease," was sent to me by Simon Delarue, head of the Paris-based French League Against Vaccinations. The article describes a healthy 19-year-old U.S. Army recruit who began basic training in April, 1984. Within the first three days of basic training, he received multiple immunizations (adenoviruses 4 and 7, measles, rubella, bivalent influenza, trivalent poliomyelitis, tetravalent meningococcus, tetanus, and diphtheria, followed

by a smallpox vaccination at the end of the first week of basic training). Two-and-a-half weeks later, he developed fever, headache and a stiff neck. A spinal tap showed him to be suffering from cryptococcal meningitis. HIV (the AIDS virus) was isolated from his blood.

Interviews conducted by trained investigators with the patient and family members failed to reveal evidence of homosexual activity or intravenous drug use. Four weeks after vaccination, during his hospitalization for the treatment of the meningitis, the patient developed an ulcer at the site of the smallpox vaccination. Within the next few days, 80 to 100 pustular lesions appeared on the buttocks and legs, rapidly progressing to ulcerations. When these lesions were cultured, vaccinia was found. The young soldier died in December, 1985.

Live-virus vaccines (such as smallpox, polio, mumps, rubella and measles) have been well-recognized as a cause of severe complications when they are given to patients who have impaired functioning of their immunologic systems. In an attempt to minimize the occurrence of this complication, the U.S. Armed Forces now require screening for HIV antibodies before immunizations are given. And the U.S. Public Health Service has stated that live vaccines are not recommended for use in patients with "clinically apparent HIV-associated immunodeficiency."

The U.S. Army is not waiting for "clinically apparent" AIDS. Instead, on the basis of pre-vaccination AIDS screening, they are excluding recruits with evidence of HIV infection from receiving live virus vaccines.

This article raises a series of important questions:

1) Should your child receive a blood test to see whether he has HIV (AIDS) infection before you allow your doctor to give the live-virus vaccine

2) What about killed viruses?

3) Did you know that Army recruits receive so many vaccines, all within such a short period of time? While the general population no longer is vaccinated against smallpox, military populations are immunized against smallpox "because of strategic defensive military and anti-terrorist considerations."

4) Since we now know that the production of gentically-engineered recombinant vaccines involves the use of smallpox (vaccinia), how safe are any of these new vaccines?

And why are these admittedly provocative questions buried so deeply within the pages of medical journals instead of being headlined on the front pages of your newspapers?

My Newsletter, "AIDS: Linkage to Smallpox Vaccine" (Vol. 11, No. 8), brought you information gleaned from foreign newspapers which linked the AIDS epidemic in Africa to previous smallpox vaccination campaigns.

A perfect correlation exists between the number of AIDS cases, mostly heterosexual, in various Central African countries and the number of people vaccinated in that country. The method of vaccination had the vaccinators using the same needle on 40 to 60 people, passing the needle through a flame as the only means of sterilization.

The only South American country that has a significant number of AIDS cases is Brazil, which happens to be the only South American country that had a recent smallpox vaccination campaign. The relationship between smallpox eradication efforts and AIDS cases could explain the equal distribution of the disease between the two sexes in Africa, in contrast to the United States, where the disease seems to be primarily spread by homosexual sex and intravenous drug use.

I just learned that Harold E. Buttram, M.D., wrote about the relationship between smallpox vaccine and AIDS in the December 1986 issue of Health Report (Clymer Health Clinic, Quakertown, Pa.). The lead article was entitled, "A Theory on the Origin of AIDS: Cross-cultural Immunizations and Immune Malfunction."

Dr. Buttram and researcher John Chriss Hoffmann wrote: "There are grounds for believing that Western vaccines, introduced since World War II into native populations, may have catalyzed the change of the AIDS virus from latent to active states." They quote Dr. Robert Gallo, chief AIDS researcher at the National Cancer Institute, who told the Washington Post on February 2, 1986 that vaccines "trick the immune system into manufacturing antibodies and can be a risk for infected persons."

In other words, Buttram and Hoffmann explain that immunizations may mimic the effects of multiple infections in the healthy carrier of the AIDS virus, possibly activating infection from its latent state. If the present AIDS epidemic did begin in Africa (as is thought), according to Buttram and Hoffman it probably is due to the weakening of the immune system of native Africans from multiple causes, of which immunization is one. They conclude, "There is a great need to study the possible immunosuppressive effects of vaccine."

Another doctor has spoken out on the possible relationship between the AIDS epidemic and vaccinations. Thanks to Santa Monica, California subscriber Johanna Amschl, I have before me the August 7, 1987 issue of the Los Angeles Reader which details Pasadena internist Robert Strecker's belief that AIDS is transmitted through vaccines.

In addition, Jeremy Rifkin, a medical activist in Washington, D.C., has asked the National Institutes of Health to examine world-wide stocks of human vaccines to see if they might be contaminated with animal viruses which could be central in causing AIDS.

How might animal viruses get into vaccines? The Reader describes how smallpox vaccine is manufactured: "A young calf has his belly shaved. Many slashes are made in the skin. A prior batch of smallpox vaccine is dropped into the slashes and allowed to fester over a period of days. During this time, the calf stands in a headstock so that he can't lick his belly. The calf then is led out of the stock to a table where he is strapped down. His belly scabs and pus are scraped off and ground into a power. That powder is the next batch of smallpox vaccine."

Reader reporter Jon Rappaport asked the veterinarian who gave the above description whether incidental viruses which the calf was carrying might be contained in these scabs and, hence, appear in the vaccine. "Reluctantly, he [the vet] said yes."

And don't think that smallpox vaccine, which largely has been abandoned in the United States, is the only vaccine under suspicion. Ten years ago, William Bennett, medical editor of the Harvard University Press, wrote in The Atlantic Monthly (February, 1976) that the SV40 virus (which comes from monkeys--SV stands for Simian Virus) was used, along with its host monkey kidney, during the 1950s and 1960s in the manufacture of polio vaccines and "cold shots."

In 1985, Dr. Jacob Rachlin, head of a group of University of Chicago researchers, reported a study to the American Association of Neurologic Surgeons which turned up SV40 in human cancers. In Rachlin's study, three children with brain tumors were born of mothers who had received polio shots during their pregnancies.

One of Mendelsohn's laws is, "When it comes to medicine, whenever you think things are bad, they usually are worse." These new revelations are powerful evidence that vaccines are more horrible than even I would have imagined.

The last time you took your child (or grandchild) to the doctor for an infant vaccine, did he ask you whether any member of your family ever had a

convulsion? If not, he is in violation of government standards.

As reported by the Centers for Disease Control in its MMWR report (May 15, 1987), the Immunization Practices Advisory Committee (ACIP) recommends that parents of infants and children who have family histories of convulsions should be informed of their children's increased risk of seizure after DPT vaccinations.

"In particular, they should be told, before the child is vaccinated, to seek immediate medical evaluation in the unlikely event of a seizure," says the ACIP.

Doctors like to use words such as "event" or "incident" when something they do leads to trouble. For example, if a mistake is made in prescribing medication in a hospital, an "incident" report is filled out. Similarly, the CDC refers to the risk of neurologic "events" after DPT vaccination. Do these words "incident" and "event" serve to obscure responsibility and make the patient's damage appear to be an act of God Himself?

According to the CDC, studies now show that infants and children with a history of convulsions whose parents, brothers and sisters have a history of convulsions have a "3.2-fold increased risk for neurologic events compared to those without such histories."

So, parents and grandparents, see whether your doctor asks you if anybody in the family has had convulsions before he injects your child. (Approximately five to seven percent of all children have a family history of convulsions.) If there is a family history, see whether he warns you of the increased chance that your child will convulse following the shot. Then see whether he tells you, before he gives the shot, to seek medical care if your child has a convulsive "event." See whether he follows the CDC recommendations to document in your child's medical record that "the small risk of postvaccination seizure and the benefits of pertussis vaccination have been discussed." (That documentation is just in case you later decide to sue for any damage your child may have incurred because the shot was given without affording you the opportunity for informed consent.)

Finally, see whether the doctor talks to you about using acetaminophen, Tylenol included, after the DPT shot to decrease the risk of febrile convulsions. If so, tell him that the CDC confesses that "there are no data on whether the prophylactic use of antipyretics [which may be able to reduce the incidence of postvaccination fever] following the DPT vaccine can decrease the risk of febrile convulsions."

Now watch the language of this next sentence. "Thus, it is reasonable to consider administering antipyretics (such as acetaminophen) at age-appropriate doses at the time of vaccination and every 4 to 6 hours for 48 to 72 hours to children at higher risk for seizures then the general population." Note how carefully the CDC pussyfoots around the issue of acetaminophen. They don't say it is reasonable to give this antipyretic. Instead, they say it is reasonable to consider giving this drug, which they know can be toxic to both the kidneys and liver.

This latest revelation doesn't add very much to our store of knowledge about DPT's safety and efficacy. But it certainly gives us some insights into the byzantine thought processes of government doctors who are supported by your tax dollars and mine.

Japanese pertussis vaccine no panacea

If your doctor says the Japanese whooping cough vaccine (not available in the U.S.) is a more effective vaccine and is a safe substitute for the dangerous U.S. vaccine, ask if he has read the November 1986 issue of the American Academy of Pediatrics Newsletter.

Since the development of this new acellular pertussis vaccine in Japan late in 1981, there has been a continuing decrease of the incidence

of pertussis from the epidemic peak in 1979. But surprisingly, in spite of higher vaccination coverage, the incidence of whooping cough in 1984 was above the levels of the early 1970s.

While you legitimately may be amazed that the incidence of whooping cough in Japan actually was higher after this new vaccine was introduced than it had been a decade previously, this news will not surprise epidemiologists and others who specialize in tracing disease patterns. A long time ago, when smallpox vaccine first was introduced, medical journals carried quite a few reports of an increased incidence of the disease in the years after introduction of the vaccine; the same thing happened initially with the polio vaccine. And, as I inform you below, some communities in the U.S. are reporting an increase in measles cases following introduction of the measles vaccine.

What does it all mean? Does the vaccine paradoxically cause the disease it is intended to prevent, or do the doctors change their criteria for reporting a disease after the vaccine is introduced? While experts continue to ponder these and other hypotheses, you have to be informed about this strange pattern which perplexes scientists.

If your pediatrician tells you that the serious neurological reactions (convulsions, epilepsy, mental retardation, cerebral palsy, sudden infant death, etc.) associated with the original pertussis vaccine have decreased with use of the Japanese vaccine, please remind him that the Japanese do not start routine pertussis vaccination until two years of age. In contrast, the U.S. vaccine is started at two months, and it is given during the high-risk months for Sudden Infant Death Syndrome. In addition, serious neurologic reactions following pertussis vaccination in Japan had already fallen significantly after 1975 when the age of administration of the vaccine was raised to two years. But the rate of whooping cough in children ages two and below is higher than it was before 1975.

All these variables make it impossible to say the Japanese vaccine is any more safe or effective. The lesson to parents is clear. They must ask the same questions about the Japanese vaccine which they have been asking about the U.S. vaccine.

Measles updates

If your doctor has been singing the praises of the measles vaccine, you may want to get a second opinion.

The federal government reports (Morbidity and Mortality Weekly Report, June 6, 1986) that during 1985, out of 1,984 non-preventable cases of measles, 20 percent (395) occurred in children under 16 months of age who were too young for routine vaccination and 3.6 percent (71 persons) were born before the vaccine became available. Of the 1,518 who were between 16 months and 28 years of age, 80 percent (1,207) had been vaccinated on or after their first birthday; one percent (14) had previously had a physician diagnose them as having measles; three percent (48) were non-U.S. citizens, and 16 percent (248) had medical contraindications or exemptions under state law. Please note that 80 percent of these so-called "non-preventable cases" occurred in people who had been properly vaccinated.

So if your doctor tries to remind you of all those cases of measles that would have occurred if no one had been vaccinated (a guess on his part), you might remind him of all those for-sure cases of measles that occurred in spite of the shot.

After there had been no reported cases of measles in the state of Iowa since 1979, 125 cases occurred last year (Waterloo Courier, July 10, 1986).

Most of the cases occurred in children who had received the measles

vaccine. Iowa health officials consulted with the Centers for Disease Control which reported that a number of other communities in the United States had experienced similar problems.

As reported in Science News September 13, 1986, "The war against measles isn't going according to plan." In the first half of 1986, more than twice as many cases were reported as in the first half of 1985 and nearly four times as many as were reported in the first six months of 1986 according to the Centers for Disease Control's Bulletin of August 22, 1986. Half the measles patients had been vaccinated.

Great stuff, that measles vaccine!

Q Should I get a flu shot this year? I'm 66 years old and in good health. My doctor has told me about the pneumonia vaccine and I wonder if I should get that as well.--C.C.

Risks of flu shots and pneumonia shots

A Even though it is almost now winter and these shots are to be given before the flu season begins, plenty of people still are under pressure to be vaccinated against influenza and against pneumonia. That pressure to immunize emanates from at least three sources--one's own doctor, public health doctors, vaccine manufacturers and their public relations firms.

This triad (triumvirate? troika?) will, of course, try its best to frighten people about the dangers of the diseases. Just take a look at the very name of last year's flu--Taiwan flu. Haven't you ever wondered why doctors name flu strains after Asiatic countries? Do you remember the Hong Kong flu? The Singapore flu? The Bangkok flu? The Asian flu? The Russian flu, etc.?

Did you note that, when a strain finally originated in the U.S., doctors didn't call it the New Jersey flu? Instead, they named it after an animal that has a thick, bristly skin and a long, mobile snout--swine flu.

When the scare campaign heads in your direction, don't panic. Instead, keep in mind the fact that the doctor's treatment may be even more dangerous than the disease. Before your doctor fills the syringe, ask him to hand you the prescribing information for the vaccine. When you carefully read the four columns describing Merck Sharp & Dohme's pneumococcal vaccine, Pneumovax, you will learn that, while this vaccine is particularly recommended for older folks who are more likely to be ill, the manufacturer warns that caution should be exercised in giving Pneumovax to individuals "with severely compromised cardiac and/or pulmonary function in whom a systemic reaction would pose a significant risk." Thus, the very people for whom the vaccine is recommended may be the same ones for whom it is the most dangerous!

You also will learn that, in addition to the more common reactions--soreness, redness, fever--neurologic disorders including Guillain-Barre paralysis have been associated with the penumococcal vaccine.

After you have read the small print on the pneumococcal vaccine, read the small print on Fluzone, Squibb-Connaught's influenza virus vaccine. Under the section on warnings, you will learn that this vaccine interacts with anticoagulants, theophylline and anti-convulsants. You will learn that if jet injection is used, special precautions must be taken during sterilization to prevent the transmission of hepatitis or other infectious agents. You will learn that neurologic disorders such as encephalopathy (brain damage) have been linked to this vaccine. These reactions can begin as soon as a few hours and as late as two weeks after vaccination. You also will learn that, when the doctor or his nurse brings in the tray

for your injection, the tray should be carrying two syringes--the second containing adrenalin, in case you go into shock from the vaccine.

Writing for Scripps-Howard News Service, Dr. William Froschauer reports (November 5, 1986) that healthy people under age 65 should not take the flu vaccine because "the risk of suffering serious complications from the vaccine is far greater than that of having serious effects from the flu."

Maybe after you read all this information, you will lean toward rejecting the vaccine. If you still need a clinching argument to help you make up your mind, ask your doctor if he himself has taken those shots.

Q I am a physician who is interested in side effects and risks of vaccinations. In the November 21, 1986, issue of the Journal of the American Medical Association, I read that the most common cause of death in Air Force recruits during basic training is myocarditis. This appears to be caused in some cases by vaccinations given to the recruits. The article refers also to the Annals of Clinical Research (1978) which showed that post-vaccination EKG changes of myocarditis were seen in three percent of asymptomatic recruits in Finland.

Keep up the good work.--Van Alan Valenta, M.D.

Vaccine dangers to recruits

A Thank you for sending me that important and authoritative article which gives a 20-year review of sudden cardiac deaths in Air Force recruits (from the Department of Cardiology, Wilford Hall Medical Center, Lackland Air Force Base, San Antonio, Texas, and the Department of Cardiovascular Pathology, Armed Forces Institute of Pathology, Washington, D.C.).

All the airmen had received meningococcus, influenza and tetanus-diphtheria inoculations on the fourth day of training. On the eighth day, adenovirus, rubella and rubecla inoculations were administered. Vaccinia (smallpox) vaccinations were administered on the third day of the training during the period from 1965 through 1968, but were discontinued thereafter. On the 30th day of the training, oral polio and tetanus-diphtheria boosters were given.

In the Finnish study you refer to in your letter, smallpox and diphtheria immunizations were identified as the most common agents of EKG changes of myocarditis (inflammation of the heart muscle). In another reference from the New England Journal of Medicine, a fatal case of myocarditis occurred after a smallpox vaccination. In the JAMA study, a recruit who died of vaccinia myocarditis was immunized two weeks before.

This study proves one thing: For Air Force recruits, a shot from the doctor may be more tragic than a shot from the enemy.

Potpourri

What's in a name?

Arcadia. Have you noticed that Arcadia is the name of both towns (one in Florida and one in Indiana) in which controversy surrounds AIDS-affected schoolchildren? In Florida, the three hemophiliac Ray children and their parents fled from Arcadia after a mysterious fire destroyed their home. In Indiana, AIDS patient Ryan White and his family found sanctuary in Arcadia after encountering turmoil when he attempted to enter Kokomo's public schools.

Webster defines Arcadia as "a region or scene of simple pleasure and quiet," from the region of ancient Greece which frequently was chosen as a background for pastoral poetry.

There are Arcadias, and then there are Arcadias.

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