1999 SENATE HUMAN SERVICES

SB 2126

1999 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB2126

Senate Human Services Committee

❑ Conference Committee

Hearing Date January 6, 1999

Tape Number	Side A	Side B	Meter #
1		x	1,459
1		x	3,910
Committee Clerk Signature	Carol Kolodejchuk		

Minutes:

SENATOR THANE opened the hearing on SB2126 SENATOR THANE commented that he was convinced that the vaccination for Hepatitis B is a must.

MURRAY SAGSVEEN, ND State Health Officer, introduced the bill. He recommends this bill be passed in written testimony attached.

DR. STEPHEN MCDONOUGH supports SB2126 with written testimony attached. The bill will add the vaccine to the Health Immunization Law.

SENATOR DEMERS asked about the cost. It is weight based and very expensive for adults. Is it available through the public health clinics? DR. MCDONOUGH answered that it will continue to be available. It is administered in two different time frames - it is available to hospitals; to infants going home, it is offered to parents. Most of infants are getting the vaccine right when they leave the hospitals. It is provided by our department at no charge to the hospitals

and the clinics and public health departments who follow up with the shots. I see no changes; it is also given at the 7th grade level in schools to catch up on children who have not received it. We started giving it in 1992. SENATOR DEMERS asked if the policy differed for adults, because there have been no free sights for students in higher ed. It's about $100 per injection That is correct. It is less expensive when given to an infant. We only have funding for new born children. Eventually, we will have all the students immune. SENATOR DEMERS thought that was optimistic, but the follow-up is needed to complete the immunization. The advantage to giving it to small children is that they are required to have follow-up shots until school age.

REPRESENTATIVE ROSE, a sponsor of the bill, supports SB2126. It is important to protect our children from deadly diseases. In ND we have the highest number of parents with children under 5 in the work force. These children are in day care centers. Crowded areas increase the risk of exposure to various diseases. She described the effects of HIB and possible death. Vaccination is the best way to prevent this. Hepatitis B is very serious also. It can be spread without knowing you have the disease.

DAVID PESKE, ND Medical Association, supports bill. The Assoc. has been involved in discussions of the bill; no physician, so far, has opposed the bill.

WAYNE SANSTEAD, Dept of Public Instruction, supports bill.

MURRAY SAGSVEEN represents the Children's Service Coordinating Committee and this committee has made an number of grants on catch-up on Hepatitis B so the last one was the llth and 12 graders in Fargo were all immunized under this grant, so there is funding available for those issues.

The hearing on SB2126 was closed.

SENATOR LEE moved a DO PASS on SB2126. SENATOR DEMERS seconded the motion.

The motion carried 6-0. SENATOR THANE will be the carrier.

Date: 1/6/99
Roll Call Vote #: 1

1999 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2126

Senate HUMAN SERVICES COMMITTEE Committee

☐ Subcommittee on _____
or
☐ Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Pass

Motion Made By Senator Lee Seconded By Senator DeMers

Senators	Yes	No	Senators	Yes	No
Senator Thane	✓				
Senator Kilzer	✓				
Senator Fischer	✓				
Senator Lee	✓				
Senator DeMers	✓				
Senator Mutzenberger	✓				

Total 6 (yes) 0 (no)

Absent 0

Floor Assignment Sen Thane

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2126: Human Services Committee (Sen. Thane, Chairman) recommends **DO PASS** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2126 was placed on the Eleventh order on the calendar.

1999 HOUSE HUMAN SERVICES

SB 2126

1999 HOUSE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB2126

House Human Services Committee

❑ Conference Committee

Hearing Date March 10, 1999

Tape Number	Side A	Side B	Meter #
1	x		0.0-end
1		x	0.0-end
2	x		0.0-end
2		x	32.2-end
3	x		0.0-end
Committee Clerk Signature			

Minutes:

Opened hearing on Senate Bill 2126.

Senator RALPH KILZER, District 47 testified in support of the bill. (Testimony attached.)

Senator RUSSELL THANE, District 25, testified as one of the sponsors of the bill. Hepatitis B is preventable. Thinks SB2126 is good legislation that should not be undermined by a national television program looking for ratings.

MURRAY SAGSVEEN, State Health Officer testified in support of SB2126. (Testimony attached.) Rep. TODD PORTER questioned the reason for taking control away from the legislature and giving it to the health council. Mr. SAGSVEEN said the reason for this change was to provide faster implementation of new vaccination programs that come up between legislative sessions. In response to other questions Mr. SAGSVEEN also said that it takes six to

nine months for a new rule to be implemented by the health council. There are eleven members on the Health Council of which 3-4 have health backgrounds. Hearings for public hearings are done through the newspapers. The general response to the hearings is dependent on the controversy surrounding the particular issue. Hearings are generally held in Bismarck although the Health Council currently has plans to conduct meetings around the state in the future. Generally written testimony for a hearing will be accepted for 30-60 days after the hearing date.

Dr. ERIC MAST, Chief, Hepatitis Surveillance Unit, Epidemiology Section, Hepatitis Branch, National Center for Infectious Diseases testified in favor of the bill. (Testimony and Slides attached.) In response to questions Dr. MAST said that since the beginning of the vaccination there has been a reported 70% decline in infection even though the way the disease acts makes it difficult to accurately determine the effectiveness of the vaccine without another study. As regards child-to-child spreading of the infection it can happen through biting, sharing toothbrush and, theoretically, saliva to eye contact, though no evidence of this exists. The duration of the protection provided by the vaccine is not yet known because it has not been in use long enough. As to the safety of the vaccine, the Center of Disease Control has no rating system on which to judge this.

Dr. TODD TWOGOOD, representing the North Dakota American Academy of Pediatrics testified. (Testimony attached.)

Dr. STEVEN HAMAR, of the North Dakota Medical Association testified that every year in the United States nine thousand health care workers are infected with hepatitis B and 200-250 of them will die. There were also problems with the polio vaccine when it came out. It is of concern and the committee should act.

KAREN (NO LAST NAME) of Parents of Kids with Infectious Diseases (PKIDS) testified. (Testimony attached.)

Dr. STEPHEN MCDONOUGH, Chief Medical Officer, State Department of Health testified. (Testimony attached.) In response to questions Dr. MCDONOUGH told the committee that parents can keep their children from receiving the vaccination if there are religious objections or of a physician says there is a health risk for child. They can't refuse the vaccine except on these grounds.

PENNI WESTON representing the North Dakota Nurses Association testified in support of SB2126. (Testimony attached.)

LINDA JOHNSON handed out written testimony for Dr. WAYNE STANSTEAD, State Superintendent, Department of Public Instruction supporting Senate Bill 2126. (Testimony attached.)

OPPOSITION to Senate Bill 2126

Dr. BRIAN BRIGGS, Minot testified in opposition to SB2126. (Testimony attached.)

RON STEWART, Valley City, testified against the bill on the basis of it being against the Bill of Rights. He does not believe in the World Health Organization or the Center for Disease Control. They have been giving out misleading information. He is concerned about doctor who have brought medicine into disrepute. He does not think that any bills prepackaged by the advisory commission on intergovernmental relations should be considered by the legislature.

CAMILLA LEEDAHL from Leonard, ND testified. (Testimony attached.)

MARY SAYLER from Fargo, ND testified. (Testimony attached.)

PAMELA O'KEEFE testified in opposition to SB2126. She does not think the Center for Disease Control hasn't done the long term intensive study to know the affects of the vaccine, particularly in the long term. She also thinks that some of the evidence about the contraction of hepatitis B is anecdotal. It appears that mandatory vaccination is being required for a disease that it is claimed cannot be contracted through casual contact. Finally, she thinks that children are already being vaccinated by doctors with the consent of parents after discussion of the risks and benefits. There is no need for a mandate.

WILLIAM SCHUH testified against SB2126. (Testimony attached.)

SUZIE SUND KLUNDT testified that she has had personal experience in immunizations. Her child had an adverse reaction from a second shot. Pediatrician said the daughter should never have another shot. When pediatrician moved, new one said he would not treat, even in emergency if not immunized. Had to find new doctor. She became more informed about immunizations. The decision on immunizations should not be made by the pediatrician. It should be a parental choice.

STACEY RYAN testified against the bill. (Testimony attached.) She also said that she does not believe there has been enough study on the effects of immunizations on a newborn's undeveloped immune system. She believes they could interfere with the natural development of the system.

GREG BOYER, Executive Director of the North Dakota Family Alliance, testified. This bill will transfer the control of determining future immunization from the legislature to the North Dakota Health Council which is a dangerous step away from citizen input to the legislative

process. It gives a state agency control over the population. It moves immunization decisions from the parents to a state agency. Keeping this power in the hands of the legislature would provide better response to an epidemic outbreak. The legislators are the voice of the people of North Dakota and should not give that up.

Dr. NEIL ESLINGER from Bismarck testified. (Testimony attached.) In response to a question Dr. ESLINGER stated that he was chiropractor.

SUSAN BEEHLER from Mandan testified that the television program made her think that we should wait before making the shots mandatory.

BERNICE THOMAS testified that she wanted to restate the two major objections. Parents should be able to stop the immunization if they wanted. Some consideration should also be given determine how many different immunizations a child can safely receive. Finally, she objected to the Health Council being given legislative authority.

LANA PROCIV testified that her son died one month after receiving the hepatitis B immunization. For her the risks are 100%.

Hearing closed on SB2126.

COMMITTEE DISCUSSION

Rep. TODD PORTER moved an amendment that would retain the authority in the legislature and permit parents to exempt their children from immunizations. The motion was seconded by Rep. ROXANNE JENSEN. After discussion the question was called. The amendment PASSED on roll call vote #2: 13 YES, 2 NO, 0 ABSENT.

Rep. ROBIN WEISZ moved an amendment that would require immunization records to be provided to local school district. Seconded by Rep. ROXANNE JENSEN. Motion PASSED on voice vote: 15 YES, 0 NO, 0 ABSENT.

Rep. ROXANNE JENSEN moved DO PASS AS AMENDED, Seconded by Rep. CAROL NIEMEIER.

Motion PASSED on roll call vote #3: 12 YES, 3 NO, 0 ABSENT.

CARRIER: Rep. AMY KLINISKE

Prepared by the Legislative Council staff for
Representative Porter
March 10, 1999

PROPOSED AMENDMENTS TO SENATE BILL NO. 2126

Page 1, line 1, replace "subsection" with "subsections" and after "1" insert "and 3"

Page 1, line 5, replace "Subsection" with "Subsections" and after "1" insert "and 3"

Page 1, line 14, after the second underscored comma insert "and" and remove ", and any other"

Page 1, remove line 15

Page 1, line 16, remove "prevention and required by the state health council"

Page 1, after line 18, insert:

"3. Any minor child, through the child's parent or guardian, may submit to the institution authorities either a certificate from a licensed physician stating that the physical condition of the child is such that immunization would endanger the life or health of the child or a certificate signed by the child's parent or guardian whose religious, philosophical, or moral beliefs are opposed to such immunization. The minor child is then exempt from the provisions of this section."

Renumber accordingly

Date: 3-10-99
Roll Call Vote #: 2

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2126

House Human Services Committee

☐ Subcommittee on

or

☐ Conference Committee

Legislative Council Amendment Number Amendment #1

Action Taken Pass

Motion Made By Porter Seconded By Jensen

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price - Chairwoman	✓		Bruce A. Eckre		✓
Robin Weisz - Vice Chairman	✓		Ralph Metcalf	✓	
William R. Devlin	✓		Carol A. Niemeier	✓	
Pat Galvin	✓		Wanda Rose		✓
Dale L. Henegar	✓		Sally M. Sandvig	✓	
Roxanne Jensen	✓				
Amy N. Kliniske	✓				
Chet Pollert	✓				
Todd Porter	✓				
Blair Thoreson	✓				

Total Yes 13 No 2
Absent 0

Floor Assignment

If the vote is on an amendment, briefly indicate intent: Immunization authority remains ~~not~~ with the legislature and parents have option to exempt children.

Adopted by the Human Services Committee
March 10, 1999

VR
3/11/99

HOUSE AMENDMENTS TO SENATE BILL NO. 2126 **HUMSER** **3/11/99**

Page 1, line 1, replace "subsection" with "subsections" and after "1" insert "and 3"

Page 1, line 5, replace "Subsection" with "Subsections" and after "1" insert "and 3"

Page 1, line 14, after the second underscored comma insert "and" and remove ", and any other"

Page 1, remove line 15

Page 1, line 16, remove "prevention and required by the state health council"

Page 1, line 18, overstrike "superintendent of public instruction" and insert immediately thereafter "public school district in which the child resides"

Page 1, after line 18, insert:

"3. Any minor child, through the child's parent or guardian, may submit to the institution authorities either a certificate from a licensed physician stating that the physical condition of the child is such that immunization would endanger the life or health of the child or a certificate signed by the child's parent or guardian whose religious, philosophical, or moral beliefs are opposed to such immunization. The minor child is then exempt from the provisions of this section."

Renumber accordingly

Date: 3-10-99
Roll Call Vote #: 3

1999 HOUSE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB2126

House Human Services Committee

☐ Subcommittee on

or

☐ Conference Committee

Legislative Council Amendment Number

Action Taken Do Pass As Amended

Motion Made By Rep Jensen Seconded By Rep Niemeier.

Representatives	Yes	No	Representatives	Yes	No
Clara Sue Price - Chairwoman	✓		Bruce A. Eckre	✓	
Robin Weisz - Vice Chairman	✓		Ralph Metcalf	✓	
William R. Devlin	✓		Carol A. Niemeier	✓	
Pat Galvin		✓	Wanda Rose	✓	
Dale L. Henegar	✓		Sally M. Sandvig		✓
Roxanne Jensen	✓				
Amy N. Kliniske	✓				
Chet Pollert	✓				
Todd Porter	✓				
Blair Thoreson		✓			

Total **Yes** 12 No 3
Absent 0

Floor Assignment Rep Kliniske

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2126: Human Services Committee (Rep. Price, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (12 YEAS, 3 NAYS, 0 ABSENT AND NOT VOTING). SB 2126 was placed on the Sixth order on the calendar.

Page 1, line 1, replace "subsection" with "subsections" and after "1" insert "and 3"

Page 1, line 5, replace "Subsection" with "Subsections" and after "1" insert "and 3"

Page 1, line 14, after the second underscored comma insert "and" and remove ", and any other"

Page 1, remove line 15

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Renumber accordingly

1999 TESTIMONY

SB 2126

Statement of

Murray G. Sagsveen
State Health Officer

Senate Bill No. 2126

Regarding
Required Immunizations for School Children

Before the
Senate Human Services Committee

January 6, 1999

Thank you for the opportunity to outline the Department's testimony in support of SB 2126 which would add hepatitis B, and *Haemophilus influenzae type b* [called "Hib"] to the list of immunizations that school children are required to receive to be admitted to any school in North Dakota.

The bill also gives the State Health Council the power under its rulemaking authority to add additional vaccines to the list of those required for school children, if another vaccine has been recommended by the US Centers for Disease Control and Prevention [CDC] and the Health Council determines the additional immunization would be beneficial to the health of North Dakota school children.

The childhood immunization program is one of the most effective public health programs provided by the State Department of Health in cooperation with local public health units, physicians, and community clinics. There are almost 150 public health and clinic sites at which vaccines are administered in North Dakota. And, because of Federal support for the immunization program the fiscal impact of this bill is very modest -- about $11,400 per biennium.

At this time I would like to call on Dr. Stephen McDonough, the Chief Medical Officer of the Department who will provide a more detailed explanation of this measure and the Department's immunization program.

Statement of

Stephen McDonough, M.D.
Chief Medical Officer
State Department of Health

on
Senate Bill No. 2126

Regarding
Required Immunizations for School Children

Before the
Senate Human Services Committee

January 6, 1999

Good morning, Mr. Chairmen, and members of the Committee. I am Dr. Stephen McDonough, Chief Medical Officer of the North Dakota Department of Health. Our Department supports SB 2126 which adds hepatitis B, and Haemophilus influenzae type b (called "Hib") to the list of immunizations that school children are required to receive before they enter school. The bill also gives the State Health Council the power, under its rulemaking authority, to add additional vaccines to the list of those required for school children.

***Haemophilus influenzae type b* [Hib]**

Let me first address the inclusion of "*haemophilus influenzae type b* [Hib] in this bill. *Hib* has been a required immunization for school children since 1991 when the Health Council added that vaccine to the list of required immunizations. Subsequently, the Attorney General reversed her position and advised the Department that the Health Council does not have the rulemaking authority to add additional vaccines to the immunizations required for school children. Therefore, SB 2126 merely clarifies the legal requirement for the *Hib* vaccine.

The Department of Health Immunization Database indicates that as of December 1997 about 96 percent of the children in North Dakota under the age of three had received the *Hib* vaccine; about 3 percent higher than the national average for young children receiving this vaccine. The *Hib* vaccine program has proven very successful. *Haemophilus influenzae type b* used to be the most common cause of meningitis in children. Cases of Hib disease dropped dramatically from 20 to 25 cases per year prior to infant immunization to 7 cases in 1991, 3 cases in 1992, and 0 cases since then.

Hepatitis B : The Disease

Hepatitis B is a serious disease caused by the hepatitis B virus (HBV) which is present in the blood and body fluids of an infected individual. The virus can be transmitted from mother to baby at birth as well as through unprotected sexual intercourse, and unsterilized needles. HBV infection can cause acute illness that leads to loss of appetite; tiredness; pain in muscles, joints, or stomach; diarrhea or vomiting; and yellow skin or eyes (jaundice). HBV can also cause chronic infection, especially in infants and children, that leads to liver damage (cirrhosis), liver cancer, and death.

Each year in the United States, an estimated 200,000 people have new HBV infections, of whom more 11,000 people are hospitalized and 20,000 remain chronically infected. Overall, an estimated 1.25 million people in the United States have chronic HBV infection, and 4,000 to 5,000 people die each year from hepatitis B related chronic liver disease or liver cancer (Centers for Disease Control and Prevention (CDC).) Persons with chronic hepatitis are 12 to 300 times at higher risk of liver cancer. The lifetime risk of HBV infection for US population is 5 percent. Although HBV is primarily a sexually transmitted disease, health care providers can develop HBV infection from exposure to blood or by needle stick injury.

Hepatitis B Vaccine

Infant immunization with the Hepatitis B vaccine (usually beginning as a newborn upon hospital discharge) started in North Dakota on October 1, 1992. Beginning August 1995, the Department of Heath began providing HBV for routine immunization of 7th grade children. North Dakota has a low rate of HBV infection with 1 to 7 cases reported annually compared to a peak of 25 cases in 1989. Making Hepatitis B a required vaccine should increase the percent of children receiving this preventive treatment from the current level of approximately 87 percent to, hopefully, the 93 to 95 percent range and thereby increase the "herd protection" of all North Dakota residents.

Health Council Rulemaking Authority

Allowing the Health Council to add vaccines to the required list will allow more rapid improvement of children's health. This can be illustrated by the prompt introduction of the *Hib* vaccine, which was approved by the FDA on October 5, 1990. On November 1, 1990, local public health units began administering Hib vaccine to infants. In September 1991, the State Health Council gave final approval to an administrative rule *requiring* Hib vaccine for infants in daycare. And, as I mentioned, cases of Hib disease soon dropped dramatically from 20 to 25 annually prior to infant immunization to 7 cases in 1991, 3 cases in 1992, and 0 cases since then.

Several vaccines have either recently been approved or will likely be approved. Rotavirus vaccine (given orally at 2, 4 and 6 months of age) will be distributed in 1999 and will greatly reduce cases of diarrhea and dehydration among infants and young children. Requiring rotavirus vaccine for infants and young children in daycare and head start may be possible as early as the year 2000, before the next legislative session. Pneumococcal (seven-valent) vaccine may be approved, in the near future, for infants at 2, 4, and 6 months with a booster at 12-15 months.

Pneumococcal infections are responsible for many cases of ear infections, blood infections and pneumonia in young children.

As chickenpox (varicella) vaccine becomes more popular, the time may come to require the vaccine for school entry. Intranasal influenzae vaccine, along with other vaccines, may also become licensed in the future. State Health Council rulemaking authority would also be helpful in case of a national or regional emergency, such as a dangerous influenza outbreak.

Fiscal Impact

The Department has estimated that the state share of the incremental cost of this legislation -- for immunization of children who are not now receiving the hepatitis B vaccine -- will be about $11,400 per biennium.

Conclusion

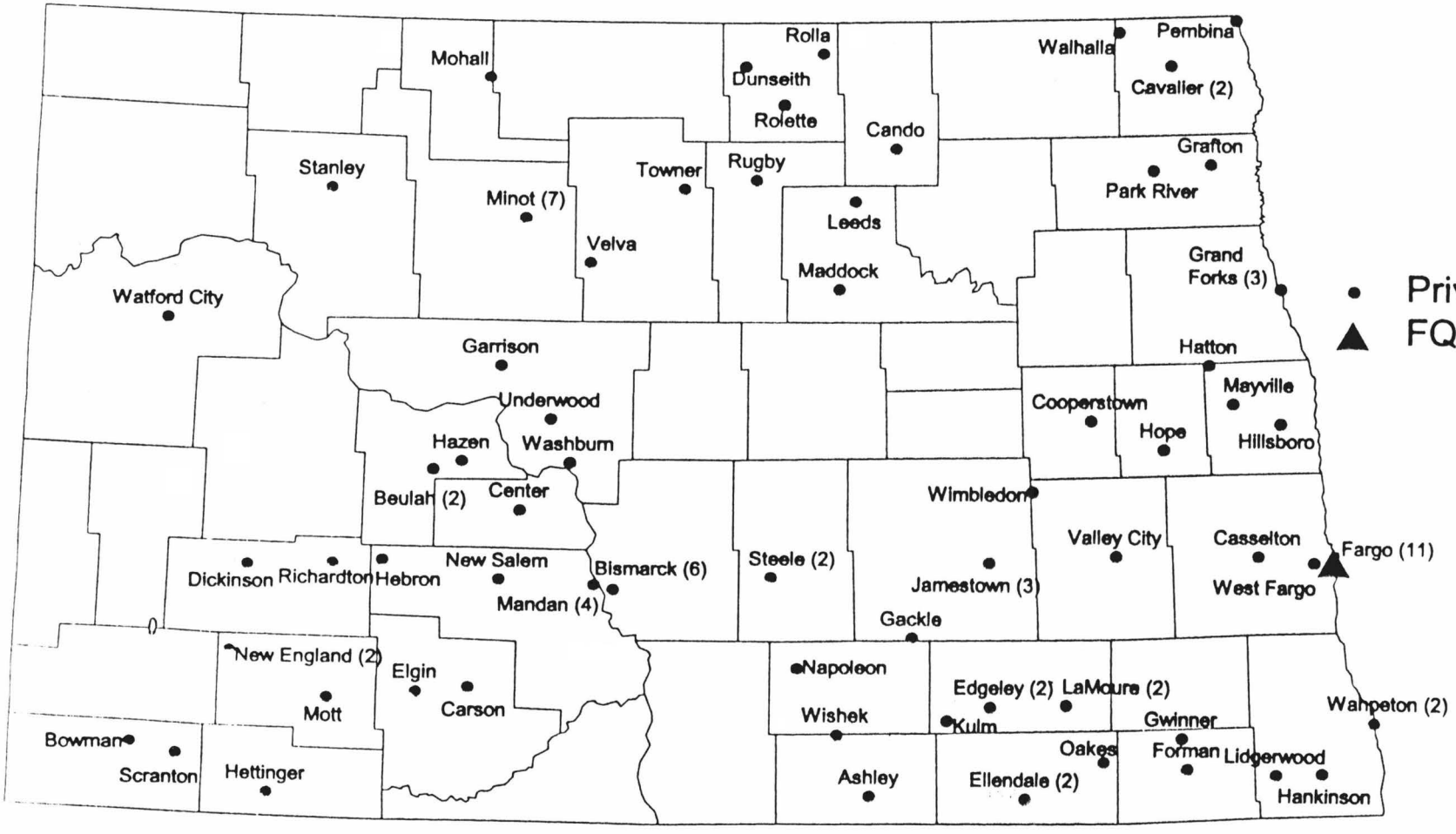
North Dakota has a proud tradition of an excellent childhood immunization program. North Dakota was the only state not to have a measles case during the national measles epidemic of 1988-1992. Smallpox, diphtheria, tetanus, measles, mumps, rubella, polio, and Hib have either disappeared or become extremely rare. Pertussis and hepatitis A remain vaccine preventable diseases that will occasionally produce outbreaks. Hepatitis B remains a problem for young sexually active unnimmunized adults.

Passage of SB 2126 will update North Dakota's immunization requirements and provide the State Health Council with flexibility for the future.

* * *

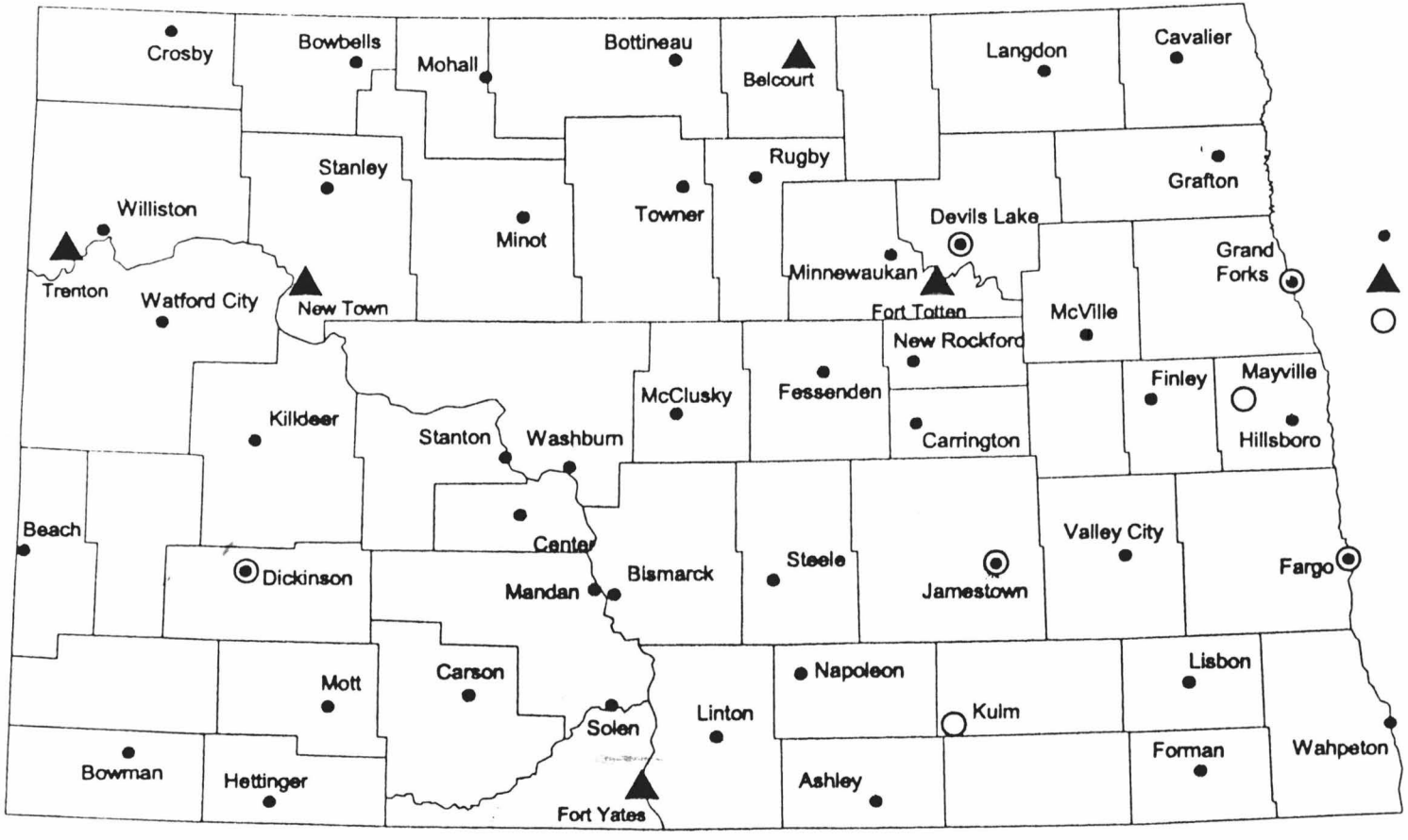
Mr. Chairman, this completes my formal testimony. I would be pleased to answer any questions you or other Committee Members have regarding this Bill or the Department's immunization program.

North Dakota Prevention Partnership Private Providers



** of November 1, 1998

North Dakota Prevention Partnership Public Providers

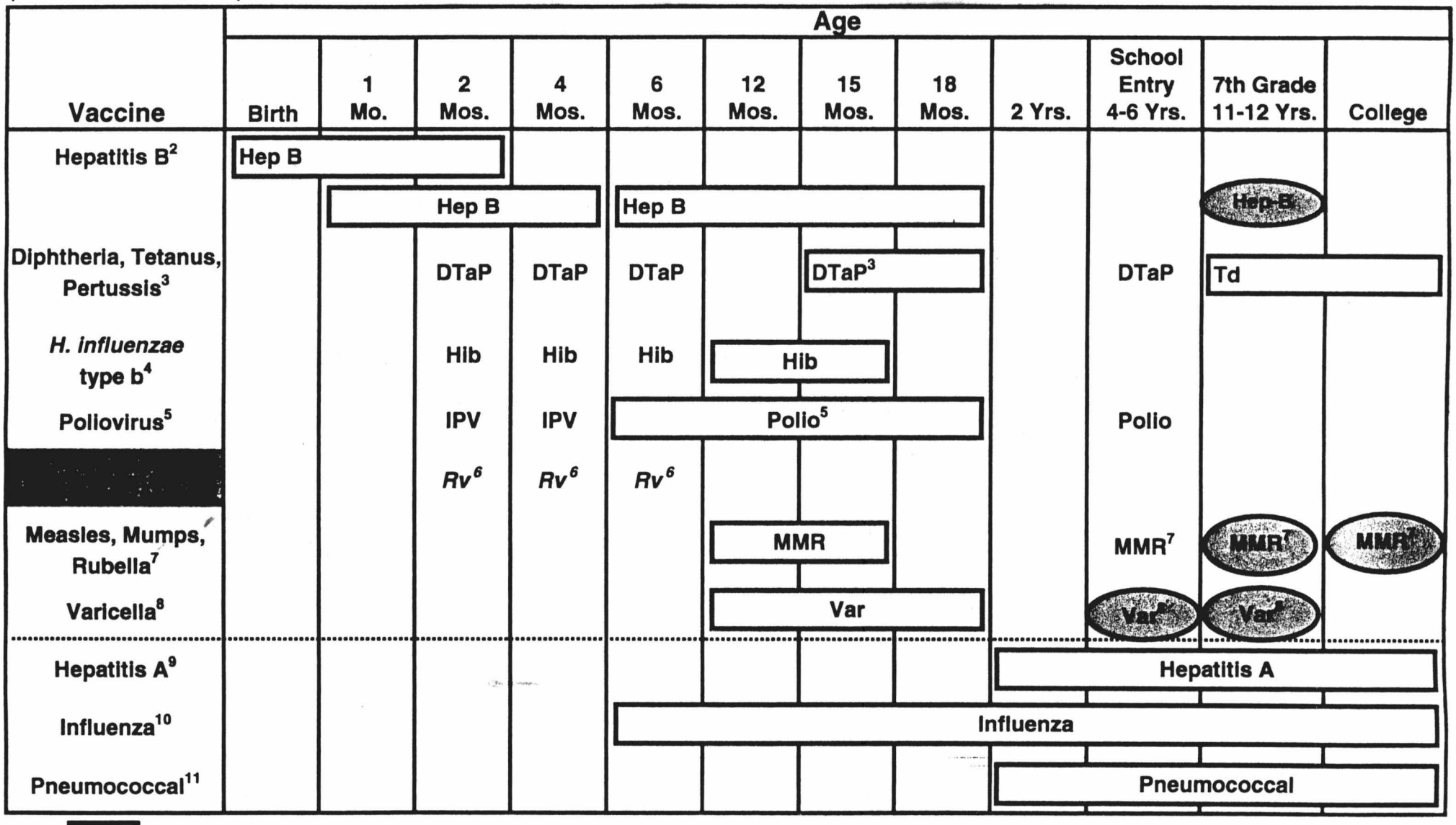


- Local Public Health Department
- Indian Health Services
- Other Public
- ND State Hospital

** ^s of November 1,1998

North Dakota
Recommended Childhood Immunization Schedule
January-December 1999

Vaccines[1] are listed under the routinely recommended ages. Vaccines listed below the dotted line are for selected populations. North Dakota state law (Chapter 33-06-05-01) requires children in daycare and schools be age-appropriately immunized against diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, poliovirus, measles, mumps and rubella.



Range of recommended ages for immunization

cines to be given if previously recommended doses were n given earlier than the recommended minimum age.

January 6, 1999

Chairman Thane and Members of the Senate Human Services Committee.

For the record I am Representative Wanda Rose from District 32, Bismarck. I am speaking in support of SB 2126. It is important that we protect our children, our future, from deadly diseases. In ND we have the highest number of parents of children under the age of 5 who are in the workforce. This means many young children are placed in day cares centers. Crowded areas increases the risk of young children being exposed to Haemphilus influenzae type B.

Haemophilus influenzae type b (Hib) disease is serious. It is most common in children less than 5 years old. Hib can cause meningitis (infection of the brain and spinal cord coverings), lasting brain damage, pneumonia, infections of the blood, joints, bones, soft tissue under the skin, throat, and the covering to the heart. And death. Before 1992, Hib was the most common cause of bacterial menigitis in the US. Before the introduction of infant vaccination, 1 child in 200 was affected before age 5. One out of 20 children who get Hib meningitis will dies and 10-30% of survivors will have permanent brain damage. Vaccination is the best way to protect against Hib disease. By requiring the vaccination the percentage of vaccinated infants would increase thus further decreasing the risk of young children being exposed to Hib..

Hepatitis B is also a serious disease. Hepatits B can destroy the liver. Lead to livercancer. According to CDC each year 200,000 people get hepatitis B. More than 11,000 people have to stay in the hospital for care. 4,000-5,000 people die from hepatitis B. A person can spread Hepatitis B virus without even knowing they have it. Today 33 states and the District of Columbia require Hepatitis B vaccination. Vaccination is the best way to protect against hepatitis B.

The need to include other recommended immunizations is because new vaccines for other diseases are being developed. For example a new vaccines includes one for Rotavirus. Rotavirus is the most common cause of severe diarrhea in children in the US. Virtually all children have one or more rotavirus infections in the first 5 years of life. Each year in the US, rotavirus is responsible for approximately 500,000 physician visits and 50,000 hospitalizations. Needless to say how many lost workdays for parents. Children ages 3-24 months have the highest rates of severe disease and hospitalization. Vaccination is the best way to protect against Rotavirus.

I urge your support of SB2126.

Comments on SB2126 by Wayne Sanstead

Thank you Mr. Chairman, members of the committee, it is a pleasure to be with you at the start of the session on a bill that has as much importance as I think this does to the prevention difficulties for youngsters in the future. We certainly, in the Department of Public Instruction stand in support of the legislation and have been involved in the parties discussion surrounding its preparation for some time. And my help. Linda Johnson is here; maybe she will want to speak to the bill as well, but I would be pleased to say that the department favors it. It's the first time I have signed one of these, we've had a couple of educations during these meetings, but I have not said anything as far as these are concerned. That surprised a lot of people.

TESTIMONY ON (SB #2126)
SENATE EDUCATION COMMITTEE
January 6, 1999
By Dr. Wayne G. Sanstead, State Superintendent
Department of Public Instruction

Mr. Chairman and members of the Senate Committee on Human Services. It is a pleasure to be with you at the start of this legislative session to join with those in support of the enactment of Senate Bill 2126. It is an important piece of legislation because it will clearly serve as a valuable prevention tool in assuring student readiness for school. We in the Department of Public Instruction have been involved and will continue to be involved with our colleagues in the State Health Department in the promotion of immunizations for children as a means of health protection.

Further, we believe that the monitoring of this immunization program is concurrent with the admittance of out-of-home care for the child, be it schools, day-care, head-start program or nursery school. In the case of a child in home-based instruction the current law reads "this certification shall be filed with the superintendent of public instruction." I would like to call your attention to the fact that in SB2143 this certification would be amended to 'filed with the local school district' to be in compliance with the other home-based statute located in N.D.C.C. 15-34.1-06.

TESTIMONY ON SB 2126

PRESENTED BY SENATOR RALPH KILZER

MARCH 10, 1999

Good morning Madame Chairman Price and members of the House Human Services Committee. It is once again my privilege to return home and to appear before the House Human Services Committee.

It is very fortunate in the modern day that we now have a vaccine to prevent the devastating affects of infection of haemophilus influenza type b in youngsters and hepatitis b in patients of all ages. I am very proud to be one of the sponsors in this effort to completely eradicate hepatitis b and to eradicate the terrible morbidity and occasional fatalities that go along with this disease. Others will talk specifically about the epidemeology and the pathogenisus of hepatitis b. I wish to focus on another significant clinical consequence of this disease - the need for transplantation.

Two weeks ago, Dr. Charles Rosen, was here in town for the Thursday noon conference that I frequently attend at the Holiday Inn. Dr. Rosen is the chief liver transplant surgeon at the Mayo Clinic. I am proud to say that he grew up in District 47 and attended Highland Acres School. He does approximately 100 liver transplant at the Mayo Clinic each year. He tells me that more than half of these cases he does each year are the consequence of previous infection with either hepatitis b or hepatitis c. At the present time there are more than 8000 people awaiting liver transplants in this country. The average length of being on the liver receiver list, awaiting a transplant, is 366 days. Many of the patients do die before they are able to receive a liver. The limiting factor in the present situation of receiving liver transplants is the lack of donors. New technology include using a single donor liver to be divided up and given to two recipients. However, this is not as satisfactory as receiving a compatible liver from a donor. Some surgical centers are starting to use living donors although there definitely is a risk to donors. Its not like kidneys where we have two and we can easily spare one. In the liver situation we have a large right lobe and a small left lobe that can be used. However, there is only portal vein and one hepatic artery.

One of the ways to reduce the need for liver transplants would be to immunize the population so that one of the main sources, infection with hepatitis b and hepatitis c, would disappear. If that would occur then we could use donor livers more appropriately for people who have congenital problems such as biliary atresia and auto-immune problems such as primary sclerousing coanginas.

I wish to emphasize that we need to do all we can to eradicate hepatitis b and hepatitis c. Many people are dying while waiting for liver transplants. At the present time because no vaccine was available to prevent hepatitis b & c. We now have a vaccine for hepatitis b and there will be soon a vaccine for hepatitis c. We need to do everything we can to practice good public health and make livers available for people who need them.

I would be happy to stand for any questions. I ask your support of SB 2126.

Testimony on Senate Bill 2126

before the

House Human Services Committee

Murray G. Sagsveen, State Health Officer

March 10, 1999

Good morning, Rep. Price and members of the Human Services Committee. Dr. Steve McDonough and I are appearing today in support of Senate Bill 2126.

The bill would:

- Add hepatitis B and Haemophilus influenzae type b (called Hib) to the list of immunizations that schoolchildren must receive before admission to any school in North Dakota. Several experts, including Dr. Twogood and Dr. Hamar, will be testifying on this issue.
- Give the State Health Council rulemaking authority to add additional vaccines to the list of those required for schoolchildren, if the additional vaccines have been recommended by the U.S. Centers for Disease Contol and Prevention (CDC) and the Health Council determines the additional immunizations would be beneficial to the health of North Dakota schoolchildren.

The childhood immunization program is one of the most effective public health programs provided by the Department of Health in cooperation with local public health units, physicians, and community clinics. Any, because of federal support for the overall national immunization program, the fiscal impact of this bill will be very modest.

It is my understanding that this bill has generated letters and telephone calls to House members, particularly after the 20/20 special about hepatitis B. Accordingly, we invited an expert from the U.S. Centers for Disease Control and Prevention to attend this hearing and provide expert testimony to the committee. Dr. Eric Mast, from the CDC, will be testifying this morning.

It is also my understanding that some opposition to the bill is based on information provided by the National Vaccine Information Center. It is my suggestion that you consider information from the Center with caution – the Michigan attorney general issued a *Notice to Cease and Desist* against the Center in January because of alleged solicitations that were "patently false, misleading and deceptive."

For the reasons that will be explained in detail by the following witnesses, I urge this committee to give a "do pass" recommendation to Senate Bill 2126.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

Statement of
Eric E. Mast, M.D., M.P.H.
Chief, Hepatitis Surveillance Unit
Epidemiology Section, Hepatitis Branch
National Center for Infectious Diseases
Centers for Disease Control and Prevention

Regarding
Prevention of Hepatitis B Virus Infection in the United States

Before the
House Human Services Committee
North Dakota Legislative Assembly

March 10, 1999

My name is Dr. Eric Mast. I am Chief of the Hepatitis Surveillance Unit, Hepatitis Branch, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I will provide testimony on hepatitis B. Specifically, I will address the clinical features of hepatitis B, the disease burden associated with hepatitis B in the United States, how the hepatitis B virus is transmitted, the safety and effectiveness of hepatitis B vaccine, and current recommendations for use of hepatitis B vaccine in the United States.

To supplement my testimony, I have attached copies of my slides and a Question and Answer sheet about hepatitis B vaccine that was developed at CDC. Thank you for the opportunity to discuss this serious infectious disease and how to prevent it with vaccination.

Attachments

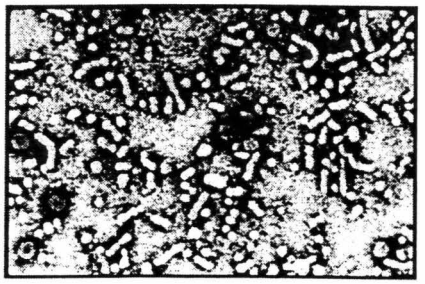
Prevention of Hepatitis B Virus Infection in the United States

Hepatitis Branch
Centers for Disease Control and Prevention
March 10, 1999

Hepatitis B

- What is hepatitis B?
- What is the burden of disease associated with hepatitis B in the United States?
- How is hepatitis B virus transmitted?
- How effective is hepatitis B vaccine?
- How safe is hepatitis B vaccine?
- What are the current recommendations for hepatitis B vaccination in the United States?

Hepatitis B Virus



Hepatitis B - Clinical Features

• Clinical illness after new infection	<5 yrs, <10% ≥ 5 yrs, 30%-50%
• Signs and symptoms:	fatigue, loss of appetite, nausea, vomiting, abdominal pain, fever, joint pain, jaundice
• Death after new infection:	0.5%-1%
• Chronic (lifelong) infection:	<5 yrs, 30%-90% ≥ 5 yrs, 2%-10%
• Death from chronic infection (cirrhosis, liver cancer):	15%-25%

Hepatitis B

- What is hepatitis B?
- What is the burden of disease associated with hepatitis B in the United States?
- How is hepatitis B virus transmitted?
- How effective is hepatitis B vaccine?
- How safe is hepatitis B vaccine?
- What are the current recommendations for hepatitis B vaccination in the United States?

Hepatitis B: Burden of Disease United States

- About 200,000 persons infected each year
- 1 of 20 persons have been infected with HBV during their lifetime (about 12.5 million)
- 1 of 200 persons have chronic (lifelong) infection with HBV (about 1.25 million)
- 4-5000 persons die each year from hepatitis B-related chronic liver disease (cirrhosis, liver cancer)

Hepatitis B

- What is hepatitis B?
- What is the burden of disease associated with hepatitis B in the United States?
- How is hepatitis B virus transmitted?
- How effective is hepatitis B vaccine?
- How safe is hepatitis B vaccine?
- What are the current recommendations for hepatitis B vaccination in the United States?

Concentration of Hepatitis B Virus in Various Body Fluids

High	Moderate	Low/Not Detectable
blood	semen	urine
serum	vaginal fluid	feces
wound exudates	saliva	sweat
		tears
		breastmilk

Hepatitis B Virus Transmission

- Mother to Infant
- Child to Child
- Sexual Contact
- Percutaneous Exposures

Hepatitis B

- What is hepatitis B?
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- How safe is hepatitis B vaccine?
- What are the current recommendations for hepatitis B vaccination in the United States?

Effectiveness of Hepatitis B Vaccine

- Protective antibody levels are present in >90% of adults and >95% of children who receive the 3-dose series of hepatitis B vaccine.
- Protection lasts for at least 15 years and booster doses are not currently recommended in the United States.

Hepatitis B

- What is hepatitis B?
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- How effective is hepatitis B vaccine?
- How safe is hepatitis B vaccine?
- What are the current recommendations for hepatitis B vaccination in the United States?

Safety of Hepatitis B Vaccine - I

- >20 million persons have received hepatitis B vaccine in the United States
- >500 million persons have received hepatitis B vaccine worldwide

Safety of Hepatitis B Vaccine - II

- In clinical trials of hepatitis B vaccination involving >200,000 persons:
  - About 30% of adults and <10% of children had sore arms and/or local swelling
  - 10%-15% had muscle aches, headache, and/or low grade fever (<24 hours)
  - No serious events reported
  - Not designed to find rare serious events

Vaccine Adverse Events Reporting System

- VAERS accepts all reports of adverse health events which follow vaccination, regardless of whether the adverse event is known to be caused by the vaccine.
- VAERS case reports alone cannot be used to determine whether an adverse event is caused by the vaccine.
- Additional studies are needed to determine whether the vaccine causes serious adverse events reported in VAERS.

Institute of Medicine Report

- Vaccine Safety Committee of the Institute of Medicine conducted a comprehensive scientific review of possible adverse consequences of hepatitis B vaccine
- Findings published in: "Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality" - 1994

Institute of Medicine Report

Rare Adverse Events Reviewed

- Evidence establishes a causal relation
  - Anaphylaxis (~1/600,000 doses)
- Evidence inadequate to accept or reject causal relation
  - Arthritis
  - Demyelinating diseases of the CNS (multiple sclerosis, optic neuritis, transverse myelitis, guillain-barre syndrome)
  - Death from Sudden Infant Death Syndrome (SIDS)

Hepatitis B Vaccine and Multiple Sclerosis

World Health Organization Experts Meeting
Geneva, September 28-30, 1998

"The data available to date, although limited, does not demonstrate a causal association between hepatitis B immunization and CNS demyelinating diseases, including multiple sclerosis."

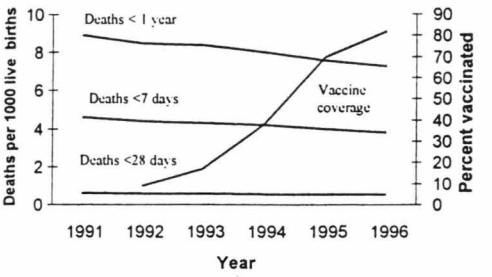
"No evidence presented at the meeting indicates a need to change public health policies with respect to hepatitis B immunization."

Hepatitis B Vaccine and Multiple Sclerosis

National Multiple Sclerosis Society
Medical Advisory Board Statement
August 14,1998; reissued January 22,1999

"In the view of the Medical Advisory Board of the National Multiple Sclerosis Society, there is no evidence of a link between hepatitis B vaccination and MS."

Hepatitis B Vaccine Coverage and Infant Deaths, United States,1991-96



Hepatitis B

- What is hepatitis B?
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- How is hepatitis B virus transmitted?
- How effective is hepatitis B vaccine?
- How safe is hepatitis B vaccine?
- What are the current recommendations for hepatitis B vaccination in the United States?

Elimination of Hepatitis B Virus Transmission United States

Objectives

- Prevent chronic HBV infection
- Prevent HBV-related chronic liver disease
  - cirrhosis
  - liver cancer
- Prevent acute symptomatic HBV infections

Elimination of Hepatitis B Virus Transmission United States

Strategy

- Prevent perinatal HBV transmission
- Routine vaccination of all infants
- Catch-up vaccination of all adolescents
- Vaccination of persons in "high-risk" groups

Routine Childhood Hepatitis B Vaccination

Rationale I

- Hepatitis B is a pediatric disease
  - ~30,000 children infected each year before routine infant hepatitis B immunization began.
  - 30%-90% of HBV infections in childhood lead to chronic (lifelong) infection.
  - More than 1/3 of the 1.25 million persons with chronic (lifelong) HBV infections were infected during childhood.

Routine Childhood Hepatitis B Vaccination

Rationale II

- Programs to screen pregnant women would prevent less than 1/2 of infections in children because only 20%-50% of children with HBV infection have an infected mother.
- Thus, routine infant vaccination is needed to ensure that all children at risk for infection are protected.

Estimated Lifetime Morbidity and Mortality of Vaccine Preventable Diseases Before Availability of Vaccine, United States

Disease	Clinical Cases (per million)	Long-term Sequelae (per million)	Deaths (per million)
Hepatitis B	25,000	7000	1000-1500
H. influenza B invasive disease	5,000	1500	300-600
Measles	900,000	300	200-400
Mumps	75,000	5	3-5
Polio	14,000	4500	100-400
Pertussis	600,000	40	200-300
Rubella	300,000	750	10-15

Routine Childhood Hepatitis B Vaccination

Rationale III

- Routine infant vaccination will protect against infection acquired later in life.
  - Vaccination of persons in high risk groups has not been a successful public health strategy.
  - About 1/3 of adolescents and adults do not know how they became infected.
  - Thus, routine vaccination is needed to ensure that all persons are protected.

Questions and Answers about Hepatitis B and the Vaccine that Protects You

Table of Contents

Questions and Answers about hepatitis B and and The Vaccine That Protects You

Q. **What is hepatitis B?**

A. Hepatitis B is a serious disease caused by the hepatitis B virus (HBV) which is present in the blood and body fluids of an infected individual. The virus can be transmitted from mother to baby at birth as well as through unprotected sexual intercourse, and unsterilized needles. Transmission is also possible with household contacts and from child to child. HBV infection can cause acute illness that leads to loss of appetite; tiredness; pain in muscles, joints, or stomach; diarrhea or vomiting; and yellow skin or eyes (jaundice). HBV can also cause chronic infection, especially in infants and children, that leads to liver damage (cirrhosis), liver cancer, and death. Each year in the United States, an estimated 200,000 people have new HBV infections, of whom more than 11,000 people are hospitalized and 20,000 remain chronically infected. Overall, an estimated 1.25 million people in the United States have chronic HBV infection, and 4,000 to 5,000 people die each year from hepatitis B related chronic liver disease or liver cancer *(Centers for Disease Control and Prevention (CDC), 1990; Margolis, 1991; West, 1992).*

Q. **How is hepatitis B vaccine used to prevent hepatitis B and its related complications?**

A. Hepatitis B vaccine prevents both HBV infection and those diseases related to HBV infection. It has been available since 1982. Hepatitis B vaccines currently available in the United States are made using recombinant DNA technology, and contain only a portion of the outer protein of HBV or hepatitis B surface antigen [HBsAg] *(Emini, 1986; Stephenne, 1990)*. The vaccine does not contain any live components. The vaccine is given as a series of three intramuscular doses. More than 95 percent of children and adolescents, and more than 90 percent of young, healthy adults develop adequate antibody to the recommended series of three doses *(Szmuness, 1980; Zajac, 1986; Andre, 1989)*. Persons who respond to hepatitis B vaccine are protected against acute hepatitis B as well as the chronic consequences of HBV infection, including cirrhosis and liver cancer *(CDC, 1991 a; Hadler, 1992)*.

Q. **For whom is hepatitis B vaccine recommended?**

A. The Advisory Committee on Immunization Practices (ACIP) recommends hepatitis B vaccine for everyone 18 years of age and younger, and for adults over 18 years of age who are at risk for HBV infection *(CDC, 1991 a,b; CDC, 1996; CDC, 1997; ACIP, 1998; Humiston, 1998)*. Hepatitis B vaccine has been recommended as a routine infant vaccination since 1991, and as a routine adolescent vaccination since 1995 *(CDC, 1991,CDC 1996)*. Adults who are at increased risk of HBV infection and who should receive the vaccine include: sexually active heterosexual adults with more than one sex partner in the prior 6 months or a history of a sexually transmitted disease; homosexual and bisexual men; illicit injection drug users, persons at occupational risk of infection; hemodialysis patients; and household and sex contacts of persons with chronic HBV infection; clients and staff of institutions for the developmentally disabled *(CDC, 1991 b)*.

Q. **Why is vaccination for hepatitis B required by many states for school entry?**

Without state and local immunization laws many more people would become sick or die from hepatitis B. Immunization requirements also help protect persons who are too sick to receive the vaccine. This is done by ensuring that a large number of persons are protected with vaccine which prevents transmission of hepatitis B on to others who are not protected. The enforcement of mandatory school immunization laws has significantly increased vaccine coverage (Robbins, 1981). Before hepatitis B vaccine was recommended for all children there were approximately 30,000 infants and children each year who would become infected with hepatitis B (*Margolis, 1991*). Vaccination requirements for enrollment/attendance at day care and programs like Head Start and public and private schools and colleges in the United States, are established at the State and local levels. Laws or regulations are typically enacted by State legislatures with authority granted to State and/or local health departments for rule making, monitoring and enforcement. There are no Federal laws requiring vaccinations for day care, Head Start, school or college attendance.

Rule making is usually based on immunization schedule recommendations established by nationally recognized authorities, including the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatric's (AAP) Red Book Committee. Vaccination requirements between states vary slightly but all states have requirements in some combination against diphtheria, tetanus, pertussis, measles, mumps, rubella and polio. Vaccination against *haemophilus influenzae* type b is required for attendance at day care centers and Head Start programs in most states. More states are adding requirements for vaccination against hepatitis B and varicella (chickenpox) disease to day care and/or school attendance requirements.

In every instance, such requirements have significantly reduced illnesses and death from diseases that vaccines prevent. Vaccine coverage levels are higher in school-age children and those enrolled in licensed day care centers and Head Start programs then among any other comparable group of infants, children or adolescents. These levels have been well documented at or above 95 percent in all states for many years.

Vaccination requirements for day care and school attendance are also successful in other ways. For

example, children with leukemia or who suffer from problems with their immune system may not receive some vaccines. The effect of compulsory and mass vaccination programs is to better reduce the likelihood of exposure of these children to diseases that could be life-threatening. The greater the number of children who refuse vaccination, the greater the risk of disease is to persons who can not be immunized because of health reasons. Likewise, the community benefits by having a large number of persons vaccinated and protected from disease. High coverage levels limit the introduction or spread of disease, benefiting everyone.

The 1996 ACIP recommendations on adolescent immunization is jointly endorsed by the AAP, the American Academy of Family Physicians, and the American Medical Association. The statement reads in part: "In the United States, state vaccination laws and regulations for kindergarten through grade 12 are effective in ensuring high coverage levels among school attendees and have led to a marked decline of overall morbidity and mortality from vaccine-preventable diseases. Additional state laws and regulations requiring documentation of up-to-date immunization of adolescents, or a reliable history of disease-related immunity, at entry into sixth grade would ensure implementation of these recommendations and would lead to further reduction in transmission of vaccine-preventable diseases."

Q. **Why not vaccinate children in those families where there is the highest risk of HBV infection, rather than vaccinating all infants/children?**

A. Routine immunization of infants and adolescents is recommended for several reasons. One is that there is a large disease burden attributable to HBV infections that occur among children. Approximately 30,000 infants and children were infected each year before routine infant hepatitis B immunization began and CDC estimates that one-third of the chronic HBV infections in the United States come from infected infants and young children. The majority of these infections occur among children of mothers who are not infected with HBV and thus would not be prevented by perinatal hepatitis B prevention programs. Other than for infants born to HBV infected pregnant women, there is no way to identify and selectively vaccinate those children at risk of infection (*Margolis, 1991)*.

Another reason we vaccinate infants and older children is that it will provide them protection against exposure to HBV infection when they are older adolescents and adults. While most HBV infections occur among older adolescents and young adults, vaccination of persons in high risk groups has generally not been a successful public health strategy. In addition, about 30 percent of persons do not know where they acquired their acute HBV infection *(Alter, 1990)*.

Q. **Is hepatitis B vaccine safe?**

A. Hepatitis B vaccines have been shown to be very safe when given to infants, children or adults *(CDC, 1991 a; Greenberg, 1993)*. More than 20 million persons have received hepatitis B vaccine in the United States and more than 500 million persons have received the vaccine worldwide. The most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever *(Szmuness, 1980; Francis, 1982; Zajac, 1986; Stevens, 1985; Andre, 1989; Greenberg, 1993)*. Studies show that these side effects are reported no more frequently among those vaccinated than among persons not receiving vaccine *(Szmuness, 1980; Francis, 1982)*. Among children receiving both hepatitis B vaccine and diphtheria-tetanus-pertussis (DTP) vaccine, these mild side effects have been observed no more frequently than among children receiving DTP vaccine alone *(CDC, 1991 a; Greenberg, 1993)*.

Whenever large numbers of individuals are vaccinated, rare reports of subsequent adverse events occur. In order to determine whether they are caused by or are just coincidental events following vaccination requires further study. Such reports do not mean that the vaccine is unsafe, since millions of persons have received the vaccine without any problem.

Q. **Is there an association between hepatitis B vaccine and serious side effects?**

A. Serious side effects reported after receiving hepatitis B vaccine are very uncommon *(Andre, 1989; CDC, 1991 a; Greenberg, 1993; Niu, 1996)*. While reported, there is no confirmed scientific evidence that hepatitis B vaccine causes chronic illness, including multiple sclerosis, chronic fatigue syndrome,

rheumatoid arthritis, or autoimmune disorders. There is no risk of HBV infection from the vaccine.

Large-scale hepatitis B immunization programs in Taiwan, Alaska, and New Zealand have observed no association between vaccination and the occurrence of serious adverse events. Furthermore, surveillance of adverse events in the United States after hepatitis B vaccination have not shown a clear association between hepatitis B vaccine and the occurrence of serious adverse events including Guillain-Barre' syndrome, transverse myelitis, optic neuritis, and seizures *(Shaw, 1988; CDC, 1991 a; Niu, 1996; Niu 1998 CDC, unpublished data)*. Additional evaluations are ongoing. A recent study suggested persons developing rheumatoid arthritis after hepatitis b vaccination were genetically at-risk for rheumatoid arthritis (*Pope, 1998*).

A low rate of anaphylaxis (hives, difficulty breathing, shock) has been observed in vaccine recipients based on reports to the Vaccine Adverse Event Reporting System (VAERS), with an estimated incidence of 1 in 600,000 vaccine doses distributed. One case has been reported in 100,763 children (10-11 years old) vaccinated with recombinant vaccine in British Columbia and no cases were observed in 166,757 children vaccinated in New Zealand. Although none of the persons who developed anaphylaxis died, anaphylactic reactions can be life-threatening, and therefore further vaccination with hepatitis B vaccine is contraindicated in persons with a history of anaphylaxis after a previous dose of vaccine. There have been rare reports of hair loss after hepatitis B vaccination, with the majority of individuals regrowing their hair (*Wise, 1997*). Studies are in progress to better quantify the possible slight risk of hair loss.

Any presumed risk of adverse events associated with hepatitis B vaccination must be balanced with the expected 4,000 to 5,000 HBV-related liver disease deaths that would occur without immunization, assuming a 5 percent lifetime risk of HBV infection.

Q. **Does hepatitis B vaccination cause demyelinating diseases such as multiple sclerosis (MS)?**

A. The scientific evidence to date does not support hepatitis B vaccination causing MS or other demyelinating diseases.

Multiple sclerosis is a disease of the central nervous system characterized by the destruction of the myelin sheath surrounding neurons, resulting in the formation of "plaques." MS is a progressive and usually fluctuating disease with exacerbations (patients feeling worse) and remissions (patients feeling better) over many decades. Eventually, in most patients, remissions do not reach baseline levels and permanent disability and sometimes death occurs. The cause of MS is unknown. The most widely held hypothesis is that MS occurs in patients with a genetic susceptibility and that some environmental factors "trigger" exacerbations. MS is 3 times more common in women than men, with diagnosis usually made as young adults.

The concern that hepatitis B vaccination may cause MS or exacerbate it derives from case reports and media attention in France and, more recently, televised news reports in the United States. However, it is possible that these MS case reports are purely coincidental to hepatitis B vaccination. Carefully controlled studies (currently underway) are needed to determine the nature of these reports.

Other than these case reports, what then is the current scientific evidence that hepatitis B vaccination causes MS or other demyelinating diseases? First, extensive pre-licensure clinical trials did not document such an effect. Second, hundreds of millions of persons worldwide have been immunized without developing MS (or any other autoimmune disease). This finding provides important negative evidence as well as an appropriate framework for assessing this possible association-namely, that if vaccination causes MS, it does so extremely rarely.

Third, prospective studies of MS patients have shown that exacerbations appeared to be more frequent after nonspecific viral illnesses *(Sibley, 1985)*. This is presumably due to generalized stimulation of the immune system that occurs with such infections *(Owen, 1980)*. There have been reports of exacerbations of MS following immunization of persons who already had MS but no evidence that vaccination increases the rate of MS in otherwise healthy persons. Given the large number of vaccinations administered worldwide, it is not surprising that surveillance systems in the U.S., France, and elsewhere

(Quast, 1991), have received some reports of MS temporally (coincidentally) associated with vaccinations. As with all such case reports, however, they only constitute signals of possible causal associations. Further controlled studies are necessary to establish causation.

A recent (and largest to date) multi-center randomized double-blind placebo controlled trial of influenza immunization in 104 MS patients failed to show any difference in attack rate or disease progression over 6 months between vaccines and placebo recipients *(Miller, 1997)*. This study suggests that even if a vaccine can exacerbate MS, it must do so only among a small minority of MS patients.

Fourth, whether vaccinations actually cause an overall excess of MS in the population (vs. being just one of multiple possible triggers for MS in genetically susceptible individuals, without causing an excess of MS) can only be evaluated in a population-based study.

Finally, MS is an autoimmune disorder in which a person's antibodies attack the body's own myelin (a sheath that covers the nerves). According to the "molecular mimicry" hypothesis, the hepatitis b vaccine must somehow be similar to the myelin in three dimensional structure thus provoking anti-myelin antibodies to form. However, recent research (as yet unpublished) using genetic sequencing has not shown a similarity between hepatitis B vaccine and myelin basic protein. This research raises doubts about the validity of the "molecular mimicry" hypothesis.

Although scientific evidence to date does not support hepatitis B vaccination causing multiple sclerosis (MS) or other demyelinating diseases, studies are currently being organized in the Vaccine Safety Datalink project at CDC and elsewhere because of public concern about this issue in France and other places and because there is little available research on this specific topic *(Chen, 1997)*. Computerized medical records on approximately 5 million or 2 percent of the U.S. population are available in this study. It will probably be at least one year, however, before any results are available

In the meantime, the concern regarding a suggested association between vaccination and MS or any other chronic illness must be weighed against the very strong evidence that vaccines have in protecting against disease and death.

Q. **Are there any studies being conducted to examine what relationship, if any, exists between the hepatitis B vaccine and multiple sclerosis (MS)?**

A. YES, there are at least six research projects underway. In recent years, several unproven theories have caused concern in the general public by suggesting there is an association between the hepatitis B vaccine and demyelinating disorders, including MS. As a result, the research studies described below were developed to investigate these hypotheses further.

The first two research projects were sponsored by the French Medications Agency, an organization similar to the United States Food and Drug Administration (FDA). One was a case-control study based on clinical reports of demyelinating disorders that were seen in 11 neurology centers across France. The second was also a case-control study. This research project was based on approximately 4 million patients receiving care through general practices in the United Kingdom. A third project was done by one of the vaccine manufacturers. Preliminary results from all three studies were shared with the French Medications Agency and the Viral Hepatitis Prevention Board in September 1998. These results are not yet available to others. If determined to be scientifically sound, these papers will be published in peer-reviewed medical journals in the near future.

The CDC's National Immunization Program (NIP) is using the Vaccine Safety Datalink (VSD) Project to examine whether there is an increased risk of MS following hepatitis B vaccination. The VSD contains data on more than 6 million people which is collected from four health maintenance organizations on the west coast. All vaccines administered within the study population are recorded. Available data include vaccine type, date of vaccination, concurrent vaccinations, the manufacturer, lot number and injection site. After vaccine administration, the medical records are monitored for potential health effects occur around the time of immunization. In this project, a case-control research design is being used to study patients 18 to 49 years of age without a prior diagnosis of MS or optic neuritis. NIP

anticipates that within the study population, about 500 patients will be diagnosed with MS by a physician using specific criteria. This study is being funded and organized by CDC in collaboration with Kaiser Permanente HMO's in Portland, Oregon, Northern California, and Southern California, and Group Health Cooperative of Puget Sound in Seattle, Washington. Research results will be available within the next few years.

Data from the Harvard Nurses Health Study (NHS) are being used to examine whether a possible relationship between hepatitis B vaccine and MS exists. NHS data collection began in 1976 and longitudinal follow-up is on-going. The study population includes a randomly selected cohort of nurses age 25-55. Researchers are using a nested case-control design with approximately 200 MS cases having been identified. Cases are being verified by follow-up questionnaires to the patient's physician as well as classification by a blinded panel of neurologists. Two control groups are being used. Every MS patient will be matched with five healthy controls and one control with a diagnosis of breast cancer (to control for recall bias). This study is being supported by Merck and results are expected during the fall of 1999.

Researchers at the University of Lyon in France are examining whether immunization (with any vaccine) increases the short-term risk of relapse in patients already diagnosed with MS. This project, known as the VACCIMUS study, employs a case-crossover design (where cases also serve as controls). The study includes 600 MS patients identified from neurology departments belonging to a network specializing in MS. Researchers will compare vaccination history in the three months prior to a relapse with a control period. This project is funded, in part, by Pasteur Merieux Connaught and results are expected in the fall of 1999.

Q. **Does the scientific evidence support a causal link between hepatitis B vaccine and infant deaths?**

No. The National Center for Health Statistics, the primary Federal organization responsible for the collection, analysis, and report of health statistics, shows a consistent decline in new born deaths (infants from birth to 30 days of age) since 1935. Much of this decline is due to great improvements in sanitation, health care, and infectious disease control that have taken place during this time. Since 1991, infants have been receiving hepatitis B vaccine on a routine basis starting as early as the first day of life. Examination of newborn deaths during this time does not reveal any increase in reports, but continues to show a steady decrease in numbers of newborn deaths (*Kiely, 1998*). In a review of the 1991-1994 reports to VAERS, there were no unusual reports believed to be causally related to hepatitis b vaccine that occurred in infants given the vaccine (*Niu et al., 1996*).

Some persons have questioned whether Sudden Infant Death Syndrome (SIDS) deaths could be related to vaccines. Several studies have looked at an association between SIDS and vaccines. The Institute of Medicine reviewed these studies and concluded that there was no evidence to prove a relationship existed between DTP and SIDS (*IOM,1991*). Almost all infants are vaccinated during the first year of life. Therefore, any infant with a medical illness or who dies is likely to have been vaccinated earlier in life. Since vaccinations are usually administered at ages 2 months, 4 months and 6 months, a statistically measurable chance of any event, death or otherwise, can occur within 24 hours of vaccinations by coincidence alone (*AAP, 1995*). Medical scientists have no convincing evidence or proof that there is a connection between SIDS and vaccines. In fact, deaths from SIDS have been decreasing in the past few years (*Willinger et al., 1998*). If SIDS were some how related to hepatitis B vaccines we would expect to see an increase in SIDS deaths since 1991 after hepatitis B vaccine was recommended for all infants. A few years ago some people had questioned whether the Diphtheria, Pertussis, Tetanus (DPT) vaccine was somehow related to SIDS deaths. In one study, scientists examined data from the National Institute of Child Health and Human Development's, Sudden Infant Death Syndrome Cooperative Epidemiological Study. The results confirmed earlier preliminary findings that DTP immunization was not a key factor in the occurrence of SIDS (*Hoffman et a., 1987*). In another analysis of the question looking at VAERS data scientists determined how many cases of SIDS would be expected to occur around the time a DPT vaccine is given based on chance alone. Based on birth and immunization rates, and the incidence of SIDS, scientists expected approximately 34 cases of SIDS to occur within 24 hours of receipt of DPT vaccine based purely on chance. Therefore 34 cases of SIDS would be expected to be reported to the Vaccine Adverse Event Reporting System unrelated to the vaccine but occurring around

the time DPT vaccine was given. The average number of observed reports of all deaths, not just SIDS, within 24 hours of DTP reported to the Vaccine Adverse Event Reporting System was 22 reports for the year the analysis took place (*AAP, 1992*). Today more is understood about the cause of SIDS. Recent evidence shows that babies who are positioned on their stomach have a greater risk of SIDS. Scientists believe that this sleeping position may interfere with the babies ability to breathe properly resulting in the increased risk of SIDS death (*AAP, 1992*).

Q. **How is vaccine safety monitored after it is licensed for use?**

A. The Vaccine Adverse Event Reporting System (VAERS) ensures the safety of vaccines distributed in the United States. VAERS reports are usually submitted by health care professionals or vaccine manufacturers, however anyone can submit a report to VAERS. VAERS is administered, monitored and analyzed jointly by the CDC and FDA. Persons who wish to report a possible health effect related to a vaccine should notify their health care provider and can also call the VAERS program at 1-800-822-7967.

Q. **Can the Vaccine Adverse Event Reporting System (VAERS) be used to determine the number of side effects that occur after people receive hepatitis B vaccine?**

A: No. There are several reasons why numbers of cases from VAERS can not be used to determine numbers of side effects that occur after people receive vaccines. First, VAERS accepts all reports of adverse health events which follow vaccination regardless of the cause. Therefore VAERS contains a mix of vaccine-caused side effects and health effects not related to vaccines. Second, the same case may be reported to VAERS more than once. This can happen when different people file the same report. For instance, a health care provider, a parent and a manufacturer may all send VAERS the same report resulting in several entries of the same case into the data base. Other reports are filed more than once because vaccines are typically given in combination with other vaccines so the same report may be filed separately under each vaccine. Reports are also filed separately from the same case under each adverse effect listed. For instance, one report that listed fever and headache and persistent crying would be filed separately into the system under each health effect reported. In addition the details and diagnosis of a given report may be incomplete or inaccurate depending on a person's access to complete clinical information. Without fully understanding these and other limitations, VAERS data can easily be misinterpreted or analyzed incorrectly leading to false conclusions about reports of health effects occurring after vaccine administration. (*Chen et al., 1994; Ellenberg et al., 1997*).

Serious health events reported to VAERS, such as reports of death, are followed up by VAERS staff. Autopsy and death certificate records are requested and reviewed for each death report. Follow up for other serious reports is done to collect additional clinical information including recovery status. The vast majority of death reports to VAERS are later determined not to be related to vaccines.

Scientists use VAERS data to look at overall trends or unusual occurrences. In a review of the 1991-1994 reports to VAERS, no unusual reports felt causally related to hepatitis b vaccine occurred in infants given the vaccine were found. (*Niu et al., 1996*). Of the 12 million doses of hepatitis B vaccine given in these age groups, the vast majority reported no side effects. Another study reviewed preliminary VAERS data which at first suggested that more severe adverse events may occur in children receiving one brand of hepatitis B vaccine, however further analysis found that this was false and not a true difference. This study showed some of the problems involved with interpreting VAERS data (*Niu et al., 1998*).

In addition, data from the National Center for Health Statistics, the primary Federal organization responsible for the collection, analysis, and reports of health statistics, show a consistent decline in new born deaths (infants from birth to 30 days of age) since 1935. Much of this decline is due to great improvements in sanitation, health care, and infectious disease control that have taken place during this time. Since 1991, infants have been receiving hepatitis B vaccine on a routine basis starting as early as the first day of life. Since 1991, infants have been receiving hepatitis B vaccine on a routine basis starting as early as birth. Examination of newborn deaths during this time does not reveal any increase in reports, but continues to show a steady decrease in numbers of newborn deaths (*Kiely, 1998*).

Q. **Where can I find more information about hepatitis B and hepatitis B vaccine?**

Further information regarding hepatitis B and hepatitis B vaccine can be obtained by contacting the Hepatitis Hotline of the Hepatitis Branch, CDC at 1-888-4HEP-CDC (or 1-888-443-7232) and by contacting your local or State health department. For information about vaccines contact the National Immunization Program, CDC Information Hotline at 1-800-232-2522 (English) or 1-800-232-0233 (Spanish);or visit the CDC National Immunization Program website at http:/www.cdc.gov/nip, or the CDC Hepatitis Branch web site at http://www.cdc.gov/ncidod/diseases/hepatitis/hepatitis.htm

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Vaccine Safety and Development Activity

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SB2126

NORTH DAKOTA AMERICAN ACADEMY OF PEDIATRICS STATEMENT ON THE HEPATITIS B IMMUNIZATION

Mrs chairman and committee members, my name is Todd Twogood, and I am a pediatrician practicing full time in Bismarck, at Medcenter one. Today I am representing the North Dakota American Academy of Pediatrics and support the policy statements of the National American Academy of Pediatrics (AAP). As pediatricians and health care providers, we are now approaching the end of the second decade of the battle to control hepatitis B through vaccination programs. Initial vaccine strategies targeted high risk populations, however, this has failed to impede the spread of the hepatitis B virus. Hepatitis B vaccine has been recommended as a routine infant vaccination since 1991, and in adolescents since 1995. Now, lets move forward in making universal vaccination the way to implement these recommendations.

In regards to hepatitis B vaccination, is it necessary for our children? The answer is YES! The risk of infection, and it leading to chronic disease is very real. The Center for Disease Control (CDC), estimates that approximately one-third of chronic disease from hepatitis B comes from infants and children. Hepatitis B vaccine is a safe way to provide protection against this serious and life threatening disease.

Whenever universally recommended prevention programs are considered, allegations of adverse effects and implications of them seem newsworthy. Often, these stories are not scientifically based and are only anecdotal. The research shows that there is no evidence of a causal relationship between hepatitis B and the development of several different disorders (including multiple sclerosis). The AAP states " Parents should not be mislead by the occasional inflammatory reports in the press. Hepatitis B vaccines are very safe and effective and should continue to be given to all children as part of their routine vaccine schedule".

Karen (PKIDS)

March 10, 1999 Bismarck, ND

Testimony from Hepatitis B Mom

I'm here to talk about my family. I'm not here to add to the list of statistics related to immunization issues. I'm here to personalize them, to bring them to a level that you can relate to from the heart rather than from a business, political or clinical standpoint. My husband and I have three young children. One of the twins is a hepatitis B carrier. I'd like to put a face on the virus for you (picture). Although he is asymptomatic, a biopsy at age 3 confirmed that he already had cirrhosis. He did not respond to a 7 month course of interferon, a form of chemotherapy, and no other treatment has been available for him. He has had cirrhosis long enough that he must be monitored frequently for liver failure and cancer.

Fear

There is a four-letter "F" word which we try to shield our children from. It's something they shouldn't know anything about at such a young age. The word is Fear. Fear of social repercussions, Fear of financial ruin, Fear of sickness, death and loss.

Social Issues

You may have noticed that I have not provided our family name. I can't. The first thing hep B families learn, usually after rejection by friends or family, is to go to extreme lengths to protect their child's privacy. We can not risk exposing our children's plight on programs like 20/20 to help inform others of the dangers of this disease. We desperately want to reach out for comfort when we learn our child has an incurable illness, but we can't. Local hospitals offer support groups for parents of children with cancer, but not for hepatitis.

We therefore formed a non-profit corporation, **PKIDs**, or Parent of Kids with Infectious Diseases. **PKIDs** is determined to not only help families with infected children, but also to educate the public about chronic viruses including hepatitis. My role as a member of the **PKIDs** Advisory Board enables me to accomplish my personal goal of making sure that other families are better prepared to deal with social and emotional issues related to infectious viruses than my family was.

Emotional Issues

Parents feel an overwhelming need to warn day care workers, teachers, Sunday school caretakers, babysitters, playmates and their parents that extra care needs to be taken if our child scrapes his knee, bites or is bitten or has a bloody nose. We want to tell everyone to ***get the shots***. Yet we agonize over the negative consequences of "telling"....will our child be treated fairly, will he be ostracized on the playground, will we ever find a babysitter? Will he have any friends or will our children be singled out as the kids to avoid? Will information given to the school nurse in confidence wind up as the topic of conversation at a PTA meeting? There are discrimination and disability laws that guarantee my child a public education, but there are no laws to protect my child's heart....

My husband and I attended a school training meeting with a group of parents. During casual conversation, a mom mentioned that she'd heard that there was a child with hep B in our school

district. She went on to tell the other concerned parents that she had visited the school superintendent in an effort to identify the child so that she could better protect her son by isolating the children. We sat paralyzed in silence, waiting for glances to turn in our direction (they didn't!), and all I could think was, ***get your kid the shots if you want to protect him***. We supervise our child's play, we coach his soccer games, we are there as much as possible in order to protect other people's children. But it's obviously impossible to continue this vigilance as the children grow older. When a neighbor tried to put a bandage on our child's bleeding cut I pushed her away. She thinks I'm overprotective. She has no idea I was protecting *her*. ***No one else should have to live with this virus. It's preventable.***

Financial Issues

We worry about our ability to provide the best care for our child. His interferon treatment cost well over $20,000 and only a portion was covered by insurance. We are self-employed and watched our health insurance premiums triple. Those premiums now exceed our mortgage payment. We can't change carriers because we fear he could become sick or need a transplant during the "pre-existing condition exemption period" with a new policy. If no cure or control is found in the very near future, he will most likely need a liver transplant. We have been warned that transplant and post-transplant care could ruin us financially, and it is only a temporary solution for him. The virus would eventually attack the new liver as well. We wonder whether we will be able to afford to put our children through college, whether we will ever be able to afford retirement.

Emotional Issues

I call this virus IT. Capital I, capital T. Stephen King fans will understand why. IT invades our lives, our thoughts, our spiritual beliefs, no matter what defenses we erect. I watch my happy children playing and IT reminds me that we will soon have to tell my son that he has a serious illness. Whenever he doesn't feel well, I wonder, "Is this IT"? How long will he be able to play the sports he loves? How will IT affect his school performance? The quality and length of my son's life are huge unknowns, but statistics make it difficult to be optimistic. You can all look at your young children and fantasize about their senior proms and weddings. I cannot.

My son is a leader. He is clever, creative, charming. He is very protective of our other children and they look up to him. I fear the effect IT will have on his brothers, worry about how they will deal with his illness, or worse. I fear that I will watch my child die, the worst possible thing that can happen to a parent. ***No other family should ever have to experience this pain***. ***Three shots can prevent IT.***

Closing

Hepatitis B is transmitted primarily through blood and sexual contact with infected persons. There are young, asymptomatic carriers who have not yet been diagnosed. Infected children and young adults will be socializing with and dating *your* children. It is clear to me that those of you who oppose immunizing our state's children are well informed about things such as vaccine composition and side effects. I beg you to educate yourselves about the hepatitis virus and disease progression as well. Only then will you be able to make a truly informed decision regarding school immunizations and how to best protect your children.

Thank you for listening.

Karen
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Statement of

Stephen McDonough MD
Chief Medical Officer
State Department of Health

on
Senate Bill No. 2126

Regarding
Childhood Immunizations

Before the
House Human Services Committee

March 10, 1999

Good morning, Madame Chairman, and members of the Committee. I am Dr. Stephen McDonough, Chief Medical Officer of the North Dakota Department of Health. Our Department supports SB 2126 which adds hepatitis B, and *Haemophilus influenzae* type b (called "Hib") to the list of immunizations that schoolchildren are required to receive before they enter school. The bill also gives the State Health Council the power, under its rulemaking authority, to add additional vaccines to the list of those required for school children.

***Haemophilus influenzae* type b [Hib]**

Let me first address the inclusion of '*haemophilus influenzae* type b [Hib] in this bill. *Hib* had been a required immunization for school children since 1991 when the Health Council added that vaccine to the list of required immunizations. Subsequently, the Attorney General reversed her position and advised the Department that the Health Council does not have the rulemaking authority to add additional vaccines to immunizations required for school children. Therefore, SB 2126 merely clarifies the legal requirement for the *Hib* vaccine.

The Department of Health Immunization Database indicates that as of December 1997 about 96 percent of the children in North Dakota under the age of three had received the Hib vaccine about 3 percent higher than the national average for young children receiving this vaccine. The Hib vaccine program had proven very successful. *Haemophilus influenzae* Type b used to be the most common cause of meningitis in children. Cases of Hib disease dropped dramatically from 20 to 25 cases per year prior to infant immunization to 7 cases in 1991, 3 cases in 1992, and 0 cases since then.

Hepatitis B: The Disease

Hepatitis B is a serious disease caused by the hepatitis B virus (HBV) which is present in the blood and body fluids of an infected individual. The virus can be transmitted from mother to baby at birth

as well as through unprotected sexual intercourse, and unsterilized needles. HBV infection can cause acute illness that leads to loss of appetite; tiredness; pain in muscles, joints, or stomach; diarrhea or vomiting; and yellow skin or eyes (jaundice). HBV can also cause chronic infection, especially in infants and children, that leads to liver damage (cirrhosis), liver cancer, and death.

Each year in the United States, an estimated 200,000 people have new HBV infections, of whom more than 11,000 people are hospitalized and 20,000 remain chronically infected. Overall, an estimated 1.25 million people in the United States have chronic HBV infection, and 4,000 to 5,000 people die each year from hepatitis B related chronic hepatitis or liver cancer. Persons with chronic hepatitis are 12 to 3000 times at higher risk of liver cancer. The lifetime risk of HBV infection for US population is 5 percent. Although HBV is primarily a sexually transmitted disease, health care providers can develop HBV infection from exposure to blood or by needle stick injury.

Hepatitis B vaccine

Infant immunization with HBV vaccine became available on October 1, 1992 in North Dakota. Beginning August 1995, the NDDH began providing HBV for routine immunization of 7th grade children. Immunization has achieved some success in North Dakota with 1 to 7 cases reported annually compared to a peak of 25 cases in 1989. Adding HBV vaccine for kindergarten or 1st grade children should increase the immunization level from approximately 87 percent to, hopefully, 93 to 98 percent. HBV infection should gradually disappear in North Dakota. Thirty-five states have hepatitis B immunization laws, including Wyoming and Minnesota.

The 20/20 program incorrectly stated that children are forced to be immunized. Informed consent is obtained from parents who receive a vaccine information statement of benefits and risks. Religious exemption is allowed under North Dakota law. Our Department does not use a heavy-handed approach when dealing with parents who object to immunizations. In fact, we respect a parent's religious belief to not immunize their children, even though we do not agree with that belief.

The 20/20 program may seem like 'new' news, but in fact, sensationalized and inaccurate news coverage of immunization side effects has occurred in the past. The old DTP vaccine was alleged to have caused SIDS. Studies eventually showed that immunized children were less likely to develop SIDS. The Vaccine Compensation Program exists to help children and families when an extremely rare complication occurs. Large surpluses have occurred in the program due to the small number of vaccine complications. The 20/20 program would have been more objective, but no less emotional, if a parent of a child who died of hepatitis B disease were interviewed. I am not aware of any child in North Dakota who has had a serious reaction to HBV but I know of an infant who died in early 1992 of liver failure from hepatitis B disease.

Why should the Health Council be given authority to add vaccines?

Allowing the Health Council to add vaccines to the required list will allow more rapid improvement of children's health. This can be illustrated by the prompt introduction of the Hib vaccine, which was approved by the FDA on October 5, 1990. On November 1,1990, North Dakota public health departments began administering Hib vaccine to infants. In September 1991, the State Health Council gave final approval to an administrative rule requiring Hib vaccine for infants in daycare. Although Hib was not specifically mentioned in the school immunization law, the Attorney General approved the rule on July 16, 1991. Cases of Hib disease dropped dramatically from 20 to 25 annual cases prior to infant immunization to 7 cases in 1991, 3 cases in 1992, and 0 cases since then. **North Dakota was the first state in the country to eliminate Hib infection.**

Several vaccines have either recently been approved or will likely be approved. Rotavirus vaccine (given orally at 2, 4 and 6 months of age) will be distributed in 1999 and will greatly reduce cases of diarrhea and dehydration among infants and young children. Requiring rotavirus vaccine for infants and young children in daycare and Head Start may be possible as early as the year 2000, before the next legislative session. Pneumococcal (seven-valent) vaccine may be approved, in the near future, for infants at 2, 4, and 6 months with a booster at 12-15 months. Pneumococcal infections are responsible for many cases of ear infections, blood infections and pneumonia in young children. As chickenpox (varicella) vaccine becomes more accepted, the time may come to require the vaccine for school entry. Intranasal influenza vaccine, along with other vaccines, may also become licensed in the future. State Health Council authority would also be helpful in case of a national or regional emergency, such as a dangerous influenza outbreak.

The Centers for Disease Control has recently recommended that certain states or counties with high rates of hepatitis A infection have all of their children immunized against this disease. North Dakota has experienced five outbreaks of hepatitis A in the past 25 years with recent outbreaks in 1992 and 1996. Hundreds of residents in Traill County received immune globulin injections in 1996 as a result of exposure to hepatitis A in a restaurant. During 1987 to 1997, Benson, Sioux, Rolette, and Mountrail Counties had hepatitis A infection rates greatly exceeding national and state averages. Either the Health Council (if 2126 is passed) or the 2001 Legislative Assembly should address daycare and Head Start hepatitis A immunization. Health Council authority would be timelier and avoid writing certain counties into the North Dakota Century Code.

Vaccine manufacturers are working on an improved meningococcal vaccine, one that would protect infants against disease. Last month a two-year-old child died in Williston of an overwhelming meningococcal blood infection while another child developed meningitis. When the improved meningococcal vaccine becomes available and is recommended by the Centers for Disease Control and

Prevention, when our Department can provide the vaccine to physicians and health departments, when the vaccine is accepted by physicians and parents, then it would be a benefit to children's health to require the vaccine for preschool children attending day care, as soon as possible.

Health Council members are responsible citizens representing consumer, health care professions, and industry. The Governor appoints them. Meetings are open to the public. A public hearing is required for any proposed rule. The Health Department does not recommend vaccines to be added to the list of required vaccines unless the vaccine is widely available at no, or low, cost. The vaccine must have wide acceptance by physicians and parents.

Conclusion

North Dakota has a proud tradition of an excellent childhood immunization program. Smallpox, diphtheria, tetanus, measles, mumps, rubella, polio, and Hib have either disappeared or become extremely rare. However, pertussis and hepatitis A remain vaccine preventable diseases that will occasionally produce outbreaks. Hepatitis B remains a problem for young sexually active unimmunized adults. Our higher than average immunization levels have had a noticeable benefit among our children. North Dakota was the only state not to have a measles case during the national measles epidemic of 1988-1992 and the first state to eliminate Hib.

Passage of SB 2126 will update North Dakota Century Code and provide the State Health Council with flexibility for the future.

Madame Chairman, this completes my formal testimony. I would be pleased to answer any questions you or other Committee members have regarding this Bill or the Department's immunization program.

NDNA
NORTH DAKOTA NURSES ASSOCIATION

549 Airport Rd. • Bismarck, ND 58504 • Phone: (701) 223-1385 • Fax: (701) 223-0575

TESTIMONY ON SB 2126

Chairperson Price and members of the House Human Services Committee. My name is Penni Weston and I represent the North Dakota Nurses Association and am testifying in support of SB 2126.

This piece of legislation will allow us to give the children of our state a most precious gift. The gift of protection from deadly diseases.

As adults and parents, we will go to any extreme to protect our children. During this session thus far, we have looked favorably on legislation that protects our children from rabies, vicious dogs, inhalant chemicals and sexual predators. These dangers are lurking out there and we do not want to expose our children to any of these risks. The chances of your child or mine personally experiencing one of these dangers may be small, however, we have taken a stand that any chance at all is not acceptable. We should be proud of the actions we have taken to protect our kids.

Protecting our children from deadly diseases is no different. We have the vaccines available to us that can protect our children from these dangers as well. How can we justify telling our children we had the vaccine available to prevent them from contracting a deadly disease but we decided not to? It seems absurd to me that we may enact legislation to protect our children from the bite of a rabid animal, and yet we are questioning whether we should protect them from deadly diseases.

You will hear testimony later about the "horror stories" that could happen as an adverse reaction to a vaccination. Let me remind you that there is no conclusive evidence that these effects, many of which occur several years after vaccination, are a direct result of the vaccine.

I will pass around pictures of the diseases that we have successfully prevented by immunizing our children. As you can see, these diseases can cause pain, suffering, scarring and permanent disabilities. I have also attached a summary of the laws in all 50 states regarding hepatitis B. As you can see, North Dakota is only one of 12 states that does not mandate Hepatitis B vaccination of our children.

The bottom line here is what will happen if we don't pass this legislation? As my young, healthy children would say, "Don't even go there." Please vote **DO PASS ON SB 2126.**

What's your state doing?

An empty box in this table indicates that the state answered this question with a "NO."

Here is some current U.S. immunization information

State	% of 65 y/o who report receiving influenza vaccine in the past year. (BRFSS* '97)	% of 65 y/o who report ever having received pneumo-coccal vaccine. (BRFSS* '97)	Do you have a hepatitis B prenatal screening law?	Do you have any hepatitis B childhood vaccination mandate?	Is there a hepatitis B daycare law? Who is covered &/or what is date of implementation?	Is there a hep B kindergarten &/or 1st grade law? Date of implementation?	Is there a hepatitis B middle school law? Date of implementation?	Are pharmacists authorized to vaccinate?
AL	62.6	47.5						yes
AK	58.3	39.2						yes
AZ	72.9	59.4		yes	yes 97	yes 9/97		
AR	61.1	39.1	yes	yes	yes/born 12/91	yes 9/98	yes 9/98	yes
CA	65.5	49.8	yes	yes	yes 97	yes 97	yes 9/99	yes
CO	74.4	53.3		yes	yes 97	yes 97	yes 97	
CT	67.2	43.0		yes	yes/born 1/94	yes 9/96		
DE	68.6	52.6		yes		yes 9/99	yes 9/99	yes
DC	54.3	32.3		yes	yes 97	yes 97	yes 97	
FL	62.3	45.5	yes	yes		yes 9/98	yes 97	
GA	58.5	48.5		yes	yes/born 1/92	yes 9/97		yes
HI	71.1	51.7	yes	yes	yes 1/98	yes 1/98		
ID	66.4	50.2		yes	yes/born 12/91	yes 97		yes
L	67.8	44.7	yes	yes	yes 10/98		yes 10/98	yes
IN	62.5	38.0		yes		yes 7/99		yes
IA	69.7	51.5		yes		yes 1/99		yes
KS	61.5	43.7	yes	yes		yes 9/99		yes
KY	61.2	38.6	yes	yes	yes/born 10/92	yes 8/98		yes
LA	58.4	32.2	yes	yes	yes 98	yes 98		
ME	72.1	50.0						
MD	63.4	41.0		yes	yes 01	yes 01	yes 9/06	
MA	66.0	52.7	yes	yes	yes 96	yes 96	yes 9/99	
MI	63.6	45.6	yes	yes	yes 97	yes 9/00	yes 00	yes
MN	69.0	48.3		yes		yes 9/00	yes 9/01	
MS	61.1	45.9						yes
MO	70.3	44.3	yes	yes	yes/born 1/90	yes 9/97	yes 9/99	yes
MT	68.4	50.8						
NE	65.8	49.8						yes
NV	56.5	53.5	yes					
NH	64.6	49.6		yes	yes/born 1/93	yes 10/96		
NJ	60.7	33.9						
NM	72.8	50.1		yes	yes 9/00	yes 9/02	yes 9/99	yes
NY	64.5	38.9	yes	yes	yes/born 1/95	yes 9/98		
NC	64.6	50.6	yes	yes	yes/born 7/94	yes 9/98		

ND	64.8	40.8						
OH	65.4	38.5		yes	yes 8/99	yes 8/99		yes
OK	69.3	40.4		yes		yes 9/97	yes 9/97	yes
OR	69.8	55.9		yes	yes 9/98	yes 9/98	yes 9/00	
PA	65.8	47.1		yes		yes 9/97		
RI	67.7	43.0						
SC	74.3	41.6		yes	yes/born 1/92	yes 9/98	yes 9/98	yes
SD	65.6	40.6						yes
TN	69.1	45.0	yes	yes	yes/born 9/97	yes 7/99		yes
TX	68.0	44.4		yes	yes/born 9/92	yes 9/98		yes
UT	66.1	48.5		yes	yes 7/99	yes 7/99		
VT	69.5	51.6		yes			yes 9/99	
VA	67.7	53.6		yes	yes/born 1/94	yes 9/99		yes
WA	70.3	51.6		yes	yes 9/97	yes 9/97		yes
WV	58.2	41.3						
WI	66.1	42.6		yes	yes 97	yes 97	yes 97	yes
WY	72.4	50.9		yes	yes/born 1/96	yes 9/99	yes 9/98	

* BRFSS = Behavioral Risk Factor Surveillance System which uses random-digit-dialed telephone survey of U.S. adults to gather data. *(MMWR 10/2/98)*

NOTE: If you find an error or have an update, please contact *NEEDLE TIPS & the Hepatitis B Coalition News* at 651/647-9009.

Return to NEEDLE TIPS index
Home Page

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This page was updated on January 19, 1999

TESTIMONY ON (SB #2126)
HOUSE HUMAN SERVICES COMMITTEE
March 10, 1999
By Dr. Wayne G. Sanstead, State Superintendent
Department of Public Instruction

Ms. Chairperson and members of the House Committee on Human Services. I was pleased to be present at the Senate Human Services Committee on January 6, 1999 in support of the enactment of Senate Bill 2126. I believe it is an important piece of legislation because it will clearly serve as a valuable prevention tool in assuring student readiness for school. We in the Department of Public Instruction have been involved and will continue to be involved with our colleagues in the State Health Department in the promotion of immunizations for children as a means of health protection.

As of this date approximately 40 states now have a middle school or first grade requirement for Hepatitis B. The states that have had this requirement in place for a number of years have seen a decrease in the number of Hepatitis B cases reported. This disease kills 5,000-6,000 Americans per year and is totally preventable by use of the vaccine.

The virus is 100 times more potent than the AIDS virus. You've heard about this already from the medical experts and will probably hear more.

Further, we believe that the monitoring of this immunization program is concurrent with the admittance of out-of-home care for the child, be it schools, day-care, head-start program or nursery school. In the case of a child in home-based instruction the current law reads "this certification shall be filed with the superintendent of public instruction." I would like to call your attention to the fact that in SB2143 this certification would be amended to 'filed with the local school district' to be in compliance with the other home-based statute located in N.D.C.C. 15-34.1-06. This bill has passed and will be filed with the local school district.

Eclectic - Clinical Medicine
Homeopathy - Naturopathy

PHONE 838 6011

BRIAN E. BRIGGS, M.D.
NUTRITIONAL THERAPY
718 SIXTH STREET S W
MINOT, NORTH DAKOTA 58701

February 24, 1999

SENATE BILL 2126

My name is Brian E. Briggs, MD. of Minot, ND where I have been a practicing physician since 1960. I am here to oppose passage of Senate Bill 2126 which has to do with mandating immunizations for all children in this State before they can be entered into any education program. I have provided each of the committee members a copy of three different women's objections to a mandatory program of this nature. All three spoke accurately about the hazards of Hepatitis B vaccinations which are to be given shortly after birth during a time when the child has minimal ability to make antibodies to any antigens. In 1996 Center for Disease Control recorded 10,637 cases of Hepatitis B including only 279 in children under 14 years. Since 1990 there have been 24,000 hospitalizations following Hepatitis B vaccinations including 400 deaths.

In ND 87 percent of all 2 year olds and 80 percent of 7th graders already have been voluntarily vaccinated. In the United States in recent years small epidemics of the usual childhood diseases have been recorded with up to 30% of those infected having been previously vaccinated for that disease. This certainly demonstrates that 100% compliance would not change that percentage and also that no vaccine is 100% safe or effective.

My personal concern with the bill is that no exemption to the mandate is provided for any reason including:

1. sensitivity to the vaccine
2. status of the child
3. choice of the parent, who has responsibility for the child's welfare
4. questionable choices by the CDC such as the Swine-flu vaccine of years ago. Physicians have a responsibility to work for the well

being of their patients rather than the good of society.

Several years ago an effort was made by the medical community to control breast cancer. The proposal was to do mammograms on 20 million women under fifty. This, they believed, would enable them to identify very early malignancy and thereby save 700 lives. The negative side of such a large test group was that in one out of every 25,000 subjects the radiation would cause cancer.* There are 800 25,000's in 20 million.

In this mandated effort to protect 27,000 children who may be at risk for getting infected with Hepatitis B, the government has already vaccinated 20,000,000 infants, children, and adults at an estimated cost of $800,000,000. If, as the Physicians' Desk Reference says, the adverse reaction rate (including arthritis, neurological disorders, and death) is 1% or less, then the number of victims would be 200,000 at 1% and 100,000 at .5%. The cost of the mammogram program could be estimated at almost 2 1/2 billion dollars. These are not medical solutions, they are financial solutions.

In addition I am in agreement with Ms. Schlafly's statement that since 1993, "The Clinton administration has been steadily working toward federal control of the entire health care industry" which in turn would ultimately give the federal government a data base on and control over every American citizen. Since the French Health Ministry has suspended the use of Hepatitis B vaccinations in their country because of suspected neurological adverse reactions, we certainly do not need to move in the opposite direction and give up more freedom of choice in medicine for both doctors and patients.

Sincerely,

Brian E. Briggs, MD

BEB:crb

* The Politics of Cancer Revisited, Samuel Epstein, MD 1998

Camilla Leedahl
15470 County Road 2
Leonard, ND 58052
701-645-2578

Testimony before the House Human Services Committee on SB 2126 March 10, 1999

Madame Chairperson, members of the committee,

I am Cam Leedahl from Leonard, North Dakota. I am a mother of three children and a registered nurse. I am opposed to SB 2126 for two main reasons:

1) It takes from me the right to make informed health care decisions about my child.
2) It transfers power from the legislature to make decisions about mandatory immunizations and gives it to the state health council.

Personally, I am not opposed to all immunizations. My children have received various vaccinations. I have a child with asthma that receives a flu shot, with my approval, each year. However, I do not want my children to receive the Hepatitis B vaccine. As a trained health worker, I do understand that Hepatitis B is a serious disease. I understand its various methods of transfer, and who is at risk for this disease. I also have been researching the studies of this vaccine. While my research has not been exhaustive, I have seen enough to warrant caution. The Hepatitis B vaccine is still in the experimental stage. The studies on long term benefits and risks are inconclusive. Some who receive the vaccine suffer long term complications, including death. New Zealand reported an increase of juvenile diabetes mellitus following their initial Hepatitis B vaccine program. I do not want this substance injected into my child to protect him from a disease that he is not at risk to get. This disease is not spread by casual contact. My child does not engage in the activities that are associated with this disease. His health would be more at risk from *receiving* the *vaccine*!

At the present, the legislature retains control over what immunizations are to be mandatory for children. The legislature is designed to be responsive to the citizens of North Dakota. It is to hear evidence and weigh implications of suggested laws -- just as you are doing now. However, the state health council, comprised of unelected officials, does not need to be responsive to the people of North Dakota. When it comes to making decisions that affect the health and autonomy of families, there needs to be caution. There needs to be a check. This bill creates too much unchecked authority for a state office. One argument that has been given to support this transfer of authority is that there would be a quicker response to a dangerous

epidemic. That is not a strong enough justification. You cannot tell me that if there was a deadly threat to the people of North Dakota, that the governor and the legislators would not be able to activate adequate, informed emergency measures in response to such a threat.

Stopping this bill does not mean you do not care about the health of children. Stopping this bill does not prevent anyone from getting the vaccine, if they wish. The state health council has data showing that voluntary immunization is occurring in large numbers. The chief medical officer of the state health council stated the Hib program is very successful, with 96% of children under 3 vaccinated against Hib. He stated there have been zero cases of the illness in this state since 1992! Hepatitis B is not highly contagious. There is a low rate of infections in our state, with only 1 to 7 cases reported annually. The state health council reports 87% of students have been vaccinated against Hepatitis B under various programs. Voluntary immunization is working. Why fix what is not broken?

This is not a good bill. It needs a do not pass recommendation from your committee. Thank you for considering my comments.

Madame Chairman and members of the House Human Services Committee: I am Mary Sayler and my husband Roger and our four children live in Fargo. I am here to testify in opposition to SB 2126 because this legislation directly affects my children.

The current program of information and voluntary parental consent in the state of North Dakota has been highly successful. Health department records show that there has not been one recorded case of Haemophilus influenza type B in the state since 1993. In light of this, I can find no justification to mandate what is already being done through information and voluntary parental consent.

I am opposed to mandating Hepatitis B immunizations for every child who is enrolled in any day care or school, including home educated students. According to the State Health Department, Hepatitis B is contracted primarily through use of contaminated intravenous needles or through sexual contact with an infected person. In North Dakota, parents are offered information on Hepatitis B and the vaccine at their child's birth in the hospital, at every well child check up through out pre-school, before entering Kindergarten, at the 7th grade level and again in high school. With this program of information and parental consent, 87% of all 2 year olds in the state have been immunized against Hepatitis B and 80% to 90% of all 7th graders. In the past 5 years there were only 19 cases of Hepatitis B in our state. Only two were in the age bracket below 20. According to the vaccine's manufacturer, up to 50% of the people who complete the series of shots will NOT have discernible antibodies within 7 years. This means that up to 50% of the kindergarten students who would be required to receive this immunization will have no protection by the time they are 12. I would also like to point out that immunizations carry with them risks and potentially serious side effects. These risks and side effects are acknowledged by the manufacturers and the federal government. The government created the National Childhood Vaccine Injury Act of 1986, which has paid out nearly $1 billion dollars for vaccine injuries and deaths.

I feel a significant problem with this bill is that it treats all minor children in the state as though their risk of disease is the same. For instance, federal health agencies are currently working on more then 200 new vaccines. They cover a very broad spectrum from diarrhea, ear infections and pneumonia to herpes and gonorrhea. Not all children are at the same level of risk for these diseases. Aren't parents, with their family physician, the ones who should make medical decisions that affect their children? Additionally, many of these vaccines are a departure from the traditional public health practice which mandated immunizations only for diseases contracted in a casual manner and that the general public was a risk for. Hepatitis B and some of the new vaccines are for sexually transmitted diseases and I have serious objections to requiring my minor children to be immunized against sexually transmitted diseases. The health department has the latitude to do a good job and has done a good job by focusing care where it is needed. That job must respect the rights of parents and include voluntary parental consent.

Of equal concern is the transfer of authority to mandate " any other immunization against disease recommended by the Center for Disease Control and Protection and required by the state health council." This language results in a transfer of power from an elected Legislature to an appointed board. The State Health Council is a group of 11 members who are appointed to three year terms by the governor. Their duties include monitoring overall health care costs and quality of health care in North Dakota. Four of the members come from the health care field, five represent consumer interests, one is from the energy industry and one is from the manufacturing and processing industry. I mean absolutely no disrespect to any of the members of the board but I simply do not feel that the make up of this board qualifies them, or was ever intended to qualify them, to make the kind of medical decision that would affect the bodily integrity of my children. Yet passage of this bill would enable this board to MANDATE any vaccine the Center for Disease Control recommends.

You are elected representatives - accountable to the people of North Dakota. Elected because you convinced a majority of voters in your district that you were capable of representing them and their concerns. Every law you pass affects people - individuals and families. This is a tremendous responsibility and one I am sure you take seriously. You are accountable to me in a manner the state health council will never be. However, this bill would allow the health council to mandate any immunization recommended by the CDC to literally every person in this state

under the age of 18. No federal agency should be able to come into North Dakota and with an 11 member appointed board be able to mandate programs that are paid for by tax dollars. Likewise, no agency that is funded by tax dollars should have the ability to so personally affect the lives of such a large segment of our state's population without legislative oversight.

North Dakotans have never been as educated, as informed or have access to as much information as they do now. This is not the time in our state's history to deprive parents of their rights or to transfer power from the elected legislature to an appointed board. Defeat of this bill will not deny anyone the opportunity to receive these immunizations. It will respect the rights of parents and keep intact the authority of the Legislature. Our legislative system is one of checks and balances and accountability to the citizens. I ask for a NO vote on SB 2126.

Thank you very much. I would be happy to answer any questions.

TESTIMONY PRESENTED TO THE HOUSE HUMAN SERVICES COMMITTEE CONCERNING SENATE BILL 2126

By William M. Schuh
Private Citizen
on March 10, 1999

Chairman Price and honorable members of the House Human Services Committee. **Please Vote Do Not Pass on Senate Bill 2126**

Content.

SB 2126 amends state laws concerning immunization for children entering schools to require additional immunization against Hepatitis B, and haemophilus influenza type b (Hib). In addition SB 2126 mandates that every child receive any other immunization against disease recommended by the centers for disease control and prevention and required by the state health council.

This bill removes all parental discretion and control over the inoculation of their children, and hands it to federal and state agencies. It also removes all further oversight of the legislature and gives the legislative power to the same federal and state agencies. SB 2126 essentially says that anything these agencies say must be shot into our childrens' bodies, and we have nothing to say about it. This is a large and inappropriate transfer of power.

Analysis.

The routine right to control the medical treatment and care of children belongs to parents. They, with the advice of their family physicians and other health professionals, are most qualified to make decisions concerning the needs and risks incurred by their children, and they are responsible for their childrens' welfare. Parents are also the only parties fully oriented toward protecting the individual child, and who will have little tendency to view that child as a statistic. While there are some circumstances in which the rights and obligations of parents concerning these matters might need to be mitigated for the public good, they should be serious circumstances, involving large potential for contagion to others. The rights and obligations of parents regarding their children should never be subverted or given to another party on a routine, or wholesale basis.

It can be argued that when a child enters a school, within close quarters of others, and where he or she may serve as a source of contagion, there may be a justifiable reason for parents to submit, in some cases, to inoculations for the public good. However, the justification for laws mandating routine inoculations of children should always be based on potential for spreading disease to others, and very substantial need. It should not be based on the welfare of the individual child, except in the most exceptional of cases. The parent, not the state, is the routine guarantor of the welfare of the individual child. It is not up to the state, the city, the school, or the Center for Disease Control to decide what medication my child receives. Matters of medication are far too dangerous to be left indiscriminately to any government body.

In rare cases where public contagion warrants overriding the routine parental right, it should not be routinely passed to a board or civil service entity. Rather, it should be retained under the oversight of elected officials, our legislature, to make a determination on whether the facts of the case warrant overriding a very important right.

There are many, and some here today, who do not believe that the risks of contagion in North Dakota for hepatitis B, justify the mitigation of that parental right. My own children have received the shots by my choice as a parent. I am not opposed to the inoculation in itself. But I believe that unless there are very serious and common risks of contagion that cannot be met with voluntary compliance, the choice should remain with parents.

Most importantly, I believe that this legislature will be abdicating its responsibility in protecting the people of this state, if it hands the routine power to mandate any medical procedure, including new inoculations, to any non parental party. I believe that the welfare of our children and our families depend on the careful deliberation of a legislative body, elected by the people themselves, and accessible to the people themselves, whenever the rights of parents to protect their childrens are to be compromised for any special case or need, or for the public good.

Please Vote Do Not Pass on SB 2126

Madam Chairwoman and committee:

My name is Stacey Ryan. I am here because my husband and I strongly oppose SB 2126. As parents we feel we have the right to choose what we feel is right for our child. My husband and I feel we have made an educated and informed choice when we decided not to vaccinate our daughter. We decided that there were too many risks associated with the vaccinations. Controversial issues about vaccinations are being reported more frequently than ever before. We understand that these issues are not theories and only hypothesis but we feel that there is too much research yet to be done before we can decide to vaccinate our child. When all of the research is in and they can dispel our fears and doubts and prove to us there is no possible adverse health risks or death, we would reconsider our decision but not until then.

Sincerely,

Lotte Ryan
Stacey Ryan

Dr. Neil Eslinger

SB2126

As I write this letter, my mind races with the multitude of issues of this bill. I write this at the request of [redacted]rned parents, for the un-informed and mis-informed parents and public, and most of all for the rights and health of [redacted]ture children.

I am opposed to taking the legislative power away from citizens. I am opposed to violations and restrictions of personal rights and freedoms. I am opposed to mandatory vaccinations. I am opposed to vaccinations. Therefore I am opposed to SB2126.

The Declaration of Independence begins: "When in the course of human events,... and to assume among the powers of the earth, the separate and equal station to which the Laws of Nature and of Nature's God entitles them,...

"We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the Pursuit of Happiness. That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed..."

God, not governments and medicine, gave men and women children. God, not governments, gave men and women the responsibilities of caring for and raising those children. And, God, not governments, is who parents need to answer to when making decisions for their children. This fact should be clear to all. The parent, by the grace of God, has been empowered to bring into this physical existence a child to love, care for, raise and release into the world. There is no governmental law of mankind that gives one person authority over another in caring for one's own family.

The physician from the CDC tried to discredit any information received that was referenced to the National Vaccine Information Center (State of Michigan). Barbara Loe Fisher and Kathi Williams are the co-founders of this organization, who I happen to know personally. They are both mothers whose children were damaged by vaccination. They came together in approx. 1982-83 and formed the NVIC to inform other parents and the public of the dangers of v[redacted]cinations, so that the damage and deaths caused to their children were not in vain. They helped enact the National [redacted]ne Injury Compensation Program in Congress in1986. They are a non-profit organization surviving only through donations from the public, and their desire for their children to be more than mere statistics. It is the CDC and vaccine manufacturers who have everything to gain by misleading and misinforming the public - Not the National Vaccine Information Center.

Barbara Loe Fisher, President of the National Vaccine Information Center, writes:

"Today, a massive nationwide public misinformation campaign led by the federal government is underway to convince the American public that vaccines are totally safe and effective, do not cause death or injury, and must be used by everyone in order to protect the public health. Led by the federal government with the enthusiastic cooperation of the drug companies and physician organizations, there is a concerted effort to hide the Truth about vaccine risks and convince state legislators to pass oppressive mandatory vaccination laws to force all children to be vaccinated with each new vaccine the drug companies produce, even in cases when informed parents have come to the conclusion that their children are being placed at unreasonable risk for vaccine injury and death.

In the face of this oppression and coercion, most Americans still don't realize that the government has no idea how many children are being killed or injured by vaccines and has no plan to find out if the injections of so many viral and bacterial antigens into newborns is resulting in negative changes to their immune and neurological systems, or even changing the genetic blueprint of whole generations. The people do not realize that the government is not bothering to analyze the extent to which mass vaccination may be affecting the epidemiology of disease around the globe, leaving populations vulnerable to new, more virulent forms of disease and immune system disorders.

While there is increasingly zealous enforcement of mandatory vaccination laws, at the same time, physicians are refusing to report deaths and injuries following vaccination to the federal government and, when reports are made, there is inadequate follow-up to find out if the recently administered vaccine caused the reported death or injury. Federal physician vaccine policymakers have also convinced Congress that too much information about vaccines just scares the public needlessly, so they are busy working to cut down on the amount of information given to the public on vaccine risks.

The people have had the Truth kept from them and so they are very vulnerable to the big lie."

The physician from the CDC presented information that led people at the hearing to believe that Hep B vaccine [redacted]ides immunity for 15 years. Where is he attaining this information from? The studies noted in the literature state c[redacted]vise.

1
NE

In one study of 773 individuals vaccinated with the hep B vaccine, after 5 years antibody levels (presumed to correlate with immunity) in 42% of the recipients declined sharply or no longer existed. In addition, 4.4% became infected with the virus!! *New England Journal of Medicine,* July 24,1986

[redacted]ns, C.E., et al. "Prospects for control of hep B virus infection: implications of childhood vaccination and long-term protection." *Pediatrics* 1992; 90: pp.170-173

In another study of the hep B vaccine, 48% of the vaccine recipients had inadequate antibody levels after four years. Pasko, M.T., Beam, T.R. "Persistence of anti-HBs among health care personnel immunized with hep B vaccine." *American Journal of Public Health* 1990; 80: pp.590-593

In a separate study, fewer than 40% of vaccine recipients had protective antibody levels after five years. Street, A.C., et al. "Persistence of antibody in healthcare workers vaccinated against hep B." *Infection Control and Hospital Epidemiology* 1990; 11: pp 525-530

The medical literature contains other case studies documenting vaccine failures: Ballinger, A.B., Clark, M.L. "Severe acute hep B infection after vaccination." *Lancet* 1994; 344: pp 1292-1293.

Goffin, E., et al. "Acute hepatitis B infection after vaccination." *Lancet* 1995; 345: p.263

Despite immunization programs targeting high-risk groups, the incidence of hep B has risen 37% since the introduction of the vaccine. Freed, G.L., et al. "Reactions of pediatricians to a new Centers for Disease Control recommendation for universal immunizations of infants with hep B vaccine." *Pediatrics* 1993; 91: pp 699-702.

Plunket, J. "Hepatitis B becoming more prevalent." *Medical Economics Publishing* April 8, 1992

[redacted]**ys indicate that a majority of pediatricians and family practitioners (87%) do not believe the hep B vaccine is needed by their newborn patients.** Freed, G.L., et al. "Reactions of pediatricians to a new Centers for Disease Control recommendation for universal immunizations of infants with hep B vaccine." *Pediatrics* 1993; 91: pp 699-702.
Freed, G.L., et al. "Family physician acceptance of universal hep B immunization of infants." *Journal of Family Practice* 1993; 36: pp. 153-157.

There was also a surgeon from Bismarck who testified about "health"-care workers having high incidence of hepatitis. Are not most people in this environment forced to have the vaccine? If the vaccine is an "immunization" shouldn't it be protecting these people already? The vaccine has failed in the high risk group (IV drug users, prostitutes and hospital workers), so now it should be forced into children?

Health workers who are frequently exposed to infected individuals may become naturally immunized rather than infected. Dienstag, J.L., and Ryan, D.M. "Occupational exposure to hep B virus in hospital personnel: infection or immunization?" *American Journal of Epidemiology* 1982; 115(1): pp. 26-29

There are very controversial issues concerning the use of vaccinations. If that statement alone surprises anyone, I would question whether they have actually looked into this issue. You will find most members of the medical community will dismiss any negativism involved in the vaccination issue and become furious at such a suggestion. For those of you who find yourself reacting in such a way, I suggest you ask yourself "What do I really know about vaccinations?", "Where did I attain this information?", "What is the vested interest of my source?", "Can it be traced to the producer of the vaccine or drug company, or was it independent research?", "Did it come from a professor who simply repeated what someone told them or are did they actually research for themselves?", "What bias is there and how [redacted]s that affect the outcome of the information involved?", etc... Just because you want something to be true doesn't [redacted]t is. If you are able to open your mind enough, you may find you have no ground to stand on - the fear of this alone can cause one to grasp and hold onto anything.

2
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The four cornerstones for those who support vaccinations are the assumptions: **1)** Vaccines are relatively harmless **2)** Vaccines are effective **3)** Vaccines were primarily responsible for the decline in infectious diseases **4)** [redacted]cines are the only practical and dependable way to prevent both epidemics and potentially dangerous diseases.

[redacted]**TS** - Issue 1 To develop a vaccine, one must first acquire a toxic bacterium or a live virus. To make a "live" vaccine, the live virus must be attenuated, or weakened for human use. This is accomplished by serial passage -- passing the virus through animal tissue several times to reduce its potency. For example, a measles virus is passed through chick embryos, polio virus through monkey kidneys, and the rubella virus through human diploid cells -- the dissected organs of surgically aborted fetuses!!(1-3) "Killed" vaccines are "inactivated" through heat, radiation, or chemicals. (4) The weakened germ must then be stregthened with adjuvants (antibody boosters) and stabilizers. This is done by adding drugs, antibiotics, and toxic disinfectants to the concoction: neomycin, streptomycin, sodium chloride, sodium hydroxide, **aluminum** hydroxide, **aluminum** hydrochloride, sorbitol, hydrolized gelatin, **formaldehyde**, and thimerosal (a **mercury** derivative) (5,6) Aluminum, formaldehyde, and mercury are extremely toxic substances with a long history of documented hazardous effects. Studies confirm again and again that microscopic doses of these substances lead to cancer, neurological damage, and death. (7-10) Yet, each of them may be found in childhood vaccines. In addition to the deliberately planned additives, unanticipated matter may contaminate the shots. For example, during the serial passage of the virus through animal cells, animal RNA and DNA -- foreign genetic material -- is transferred from one host to another. Because this biological matter is injected directly into the body, researchers say it can change our genetic makeup. (11-13) Undetected animal viruses may jump the species barrier as well. This is exactly what happened during the 1950s and 1960s when millions of people were infected with polio vaccines that were contaminated with the SV-40 virus undetected in the monkey organs used to prepare the vaccines (14-15) SV-40 (Simian Virus #40 -- the 40th virus detected since researchers began looking), (16) is considered a powerful immunosuppressor and trigger for HIV, the name given to the AIDS virus. It is said to cause a clinical condition similar to AIDS, and has been found in [redacted]n tumors, leukemia, and other human cancers as well. Researchers consider it to be a cancer-causing virus. (17,18) [redacted]witch's brew in then forced into a healthy child under mandation of the federal government, under the mis-informed and mis-led parents' perception that this miracle potion has the ability to defeat disease - as was told to them by the way medicine has written their history book.

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6. *Physicians' Desk Reference*, (Montvale, NJ: Medical Economics Data Production, 1995). Also see *Physicians' GenRx*, (New York: Data Pharmaceutica, 1993).
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16. Eva Lee Snead, MD, *Some Call it AIDS: I Call it Murder*, (San Antonio, Texas: AUM Publications, 1992), p. 36.
17. Caroline K.Y. Fong, PhD., "Cell Culture Contamination With Adventitious Viral Agents," *VA Practitioner*, (Feb. 1994), p.60.
18. See Note 12, p.101.

Jamie Murphy, Medical Researcher, puts it most eloquently in his book, *What Every Parent Should Know About Childhood Immunization:* "What sane person would consider using a hazardous waste, carcinogenic in rats, used in the manufacture of inks, dyes, explosives, wrinkle-proof fabrics, home insulation, and a major constituent of embalming fluid, and inject it into the delicate body of an infant? What could formaldehyde, aluminum, phenol, mercury, or any [redacted]mber of other deadly chemical substances used in vaccines possibly have to do with preventing disease in children? ***[redacted]fact that they <u>are needed at all</u> in the vaccine formula argues that the product is toxic, unstable and unreliable [redacted]r <u>without</u> their presence."***

The National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) set up a federal vaccine injury compensation program which included safety provisions such as mandatory reporting and recording of vaccine - [redacted]ciated adverse events. Currently, approximately 1 BILLION dollars has been distributed to families with children [redacted]vere damaged or killed by vaccines. Between 12,000 and 14,000 hospitalizations, injuries and deaths following [redacted]nation are reported every year to the federal Vaccine Adverse Event Reporting System. The physician from the CDC downplayed reactions, but failed to mention the FDA estimates that doctors report less than **10 percent** of all adverse events that occur after drugs or vaccines are given to patients.

It is common knowledge that the medical profession does not have the ability to determine what doesn't seem to harm one person will not harm another. The *Journal of the American Medical Association* (*JAMA*) reported that serious adverse prescribed drug reactions kill 106,000 people annually, making it the 4th leading cause of death in America (heart disease 743,460; cancer 529,904; stroke 150,108). This does not include the 2,216,000 patients that are permanently disabled, require hospitalization, or prolonged hospitalization. The *Public Citizen* magazine reported that malpractice is responsible for the deaths of 80,000 people annually, one every seven minutes. This figure does not include iatrogenic injury. In *JAMA*, LL. Leape reports an additional 180,000 people die each year partly as a result of iatrogenic(physician induced) injury - which is equivalent to 3 jumbo jet crashes every 2 days. If we add all of these statistics, medicine is responsible for 336,000 deaths annually, thus making the practice of medicine the 3rd leading cause of death in America. This is more than the next three leading causes of death combined (stroke 150,108; pulmonary disease 101,077 and accidents 90,523).

Author Gerard Anderson, Ph.D., professor, Health Policy and Management, John Hopkins School of Public Health said, "This country spends more resources than any other industrialized nation by a wide margin. Yet, between 1990 and 1995 the United States fell to position **23** out of 29 leading industrialized nations in terms of **infant mortality**. This country ranked twentieth out of 29 in 1995 in terms of life expectancy for women, and twenty-first in terms of life expectancy for men." Does it sound like we are heading in the right direction?

[redacted] You can not determine how safe it is for a person to take one drug (all drugs have side effect) let alone combine [redacted]ferent drugs. How can anybody rationalize combining 11 + different vaccines into a healthy newborn? No studies h[redacted]e been done to investigate the long term effects of vaccines **(except finding out that contaminated polio vaccine is responsible for a form of cancer 40+ years later - the NVIC estimates that 10% of the world's population is affected by this due to genetic carry-over).** Dr. Stephen Marini, a former Immunohematologist, states, "There is no credible scientific data to demonstrate that the injection of multiple antigens simultaneously into a baby, particularly a baby under the age of one year, is safe and effective. There is no credible scientific evidence to negate the hypothesis that vaccines cause immediate or delayed damage to the immune system and neurological disorders including asthma, learning disabilities, hyperactivity, autism, chronic fatigue syndrome, lupus, diabetes, epilepsy, multiple sclerosis, Guillain-Barre syndrome, and other diseases. There is no assurance that the agency charged with detailing and reporting adverse events following vaccinations is not ethically constrained by its conflicting responsibility of promoting a vaccine..." **It is called a Human Population Study - wait and see.** The results are showing up in medical journals. It is just a matter of who is willing to admit fault, and who is willing to disregard and blindly pursue the myth of vaccination providing immunity.

There are articles in medical journals that show direct and indirect relationships to initial and long term vaccine damage including: cancer, leukemia, diabetes, arthritis, asthma, allergies, autism, hyperactivity, epilepsy, autoimmune disorders (AIDS), neurological disorders, mental retardation, intestinal disorders, Gulf War Syndrome, Sudden Infant Death Syndrome (children don't die from SIDS - that is their classification), and most recently Shaken Baby Syndrome (cases where there were subdural hematomas with X-rays showing no broken bones, bruises or any sign of physical damage).

In 1997, the first International Public Conference on Vaccinations was held in Washington D.C. with parents, doctors, scientists, health officials, lawyers, ethicists, journalists and consumer activists from 34 states and five countries [redacted]nding. **Distinguished medical doctors and vaccine researchers from the US, Canada and Great Britain [redacted]sed the biological mechanisms of vaccine injury and death and why chronic illness in the form of immune a[redacted]eurological dysfunction can be caused by vaccination. Topics included vaccines and infant death;**

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biological mechanisms of vaccine injury and vaccine reaction blood tests; vaccines and learning disabilities; measles virus and measles vaccine; hepatitis B vaccine injuries; viral vaccines and chromosome damage; vaccine administration combined with other hazardous exposures; and vaccine regulation and polio vaccine contamination. The consensus among the research scientists was that vaccination programs are causing injuries and deaths because of inadequate vaccine safety research, testing, manufacturing and monitoring for long term effects.

What if a majority of the money donated and raised for cancer research and other organizations was given to independent researchers (non governmental and no ties to vaccine manufacturers) for scientific investigation into vaccination?

FACTS - Issues 2,3,4

Despite all the material above, many feel the threat of diseases and outbreaks may possibly outweigh any risks. That would be under the assumption that vaccinations actually reduce or prevent diseases and epidemics. In cases where the whole story is presented, I have not come across any scientific study that showed epidemics or diseases have declined due to vaccination. According to the World Health Organization in Geneva, Switzerland there has been a steady decline of infectious diseases in most 'developing' countries. The WHO states that it appears that generally improved conditions of sanitation are largely responsible for preventing 'infectious' diseases.

Viera Scheibner Ph.D., who was studying "Sudden Infant Death Syndrome" by monitoring respiration of infants, found a correlation between SIDS and the DPT vaccine. She then went on to investigate vaccinations and authored a book titled **Vaccination: The Medical Assault on the Immune System** - *100 years of Orthodox Research shows that Vaccines Represent a Medical Assault on the Immune System.* Scheibner comments that the proponets of vaccination seem to totally ignore the well-documented fact that all infectious diseases, including those against which they vaccinate, have been on the decline for decades, before any vaccine was even developed. Better living conditions, better nutrition, uncrowded living, and above all, better sanitation and clean water are the only factors that should be credited with in incidence, mortality and especially severity of infectious disease. The best evidence for the validity of this is that many diseases, like bubonic plague, scarlet fever and tuberculosis which used to cause many deaths, have basically disappeared without mass vaccination programs. Even smallpox receded substantially, although not entirely, despite the low percentage of people vaccinated.

"The greatest threat of childhood diseases lies in the dangerous and ineffectual efforts made to prevent them through mass immunization...Much of what you have been led to believe about immunizations simply isn't true. I not only have grave misgivings about them; if I were to follow my deep convictions...I would urge you to reject all inoculations for your child," Pediatrician Robert Mendelsohn, M.D. He goes on to say "it is commonly believed that the Salk vaccine was responsible for halting the polio epidemics that plagued American children in the 1940s and 1950s. If so, why did the epidemics also end in Europe, where polio vaccine was not extensively used?" Polio, like many other diseases were naturally declining prior to vaccination. Polio cases actually increased after mass vaccination in1952. When this occurred, the live vaccine was taken off the market. Then a reclassification of polio occurred prior to reintroducing the vaccine, in which instead of only having to exhibit paralytic symptoms for 24 hours, the new definition required the paralysis to exist for at least 60 days. Meaning those previously considered to have polio were statistically eliminated.

Researcher C. Kent remarks that statistics are often "cooked" to "prove" that the mass inoculation campaign was working. Cases formerly reported as polio were now reported as meningitis. So while polio statistics dropped, statistics for viral or asceptic meningitis soared.

Medical journals have also acknowledged the practice of diagnosing according to vaccination record. Example - If a **vaccinated** child has a "whooping" cough, there is an assumption that because the child is vaccinated it can not be whooping cough, it must be bronchitis. Whereas, if an **unvaccinated** child has a "whooping" cough, because they were unvaccinated it is whooping cough. The mere indication that medical journals acknowledge this type of diagnosing [illegible] that children that are often **FULLY vaccinated** still develop the diseases.

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When various out breaks occur, it is often blamed on the unvaccinated. In almost all cases, the fully vaccinated population makes up the highest percentage of the out-break.

In the Cincinnati whooping cough (pertusis) outbreak in the summer of 1993, <u>more than 80 percent</u> of the children under five who got whooping cough had been <u>fully vaccinated</u> . D.C. Christie,et al., "The 1993 Epidemic of Pertussis in Cincinnati: Resurgence of Disease in a highly Immunized Population of Children," New England Journal of Medicine (July 7,1994), pp.16-20.

Numerous other studies indicate that children vaccinated against pertussis are still susceptible to the disease. S.A. Halperin, et al., "Persistence of Pertussis in an Immunized Population: Results of the Nova Scotia Enhanced Pertussis Surveillance Program," *Journal of Pediatrics* (Nov, 1989), pp.686-693.

20th Immunization Conference Proceedings, Dallas, Texas, May 6-9, 1985 (U.S. Department of Health and Human Services, Oct.1985), pp.83-84

Cynthia Cournoyer in her book, **What About Immunizations**? *Exposing the Vaccine Philosophy*, states that on pure statistics, your child has a much greater chance of dying in a car accident (50,000 annually) than catching or dying from any of the childhood diseases combined. Simply taking the child in the car to the doctor is riskier than the chance of catching or dying of these childhood diseases.(p.5)

Immunologists have shown that when diseases occur, the body naturally develops life long immunity to the strain and that many natural childhood diseases are necessary for properly developing the immune system. That doesn't mean we should by-pass natural barriers and inject biological toxins directly into the blood stream! Sanitation, clean water, proper nutrition (including breast-milk), exercise, rest, a nervous system functioning free of interference and LOVE are the only things capable of developing the immune system to Immunize.

Legally, everyone must be informed of the potential risks of the use of vaccines. According to the Law, you must be <u>informed</u>(of all potential risks), but you don't have the <u>choice</u>. Is that constitutional? What if Adolf Hilter <u>informed</u> the Jews that they could be murdered five different ways, yet either way, they were going to be murdered? Would he be considered a humanitarian and a just dictator because he informed them, yet took away their human rights and choices. The Post-Holocaust Standards of Research: **The Nuremberg Code** is a 10-point declaration governing human experimentation which was developed in response to the inhumane experiments conducted by Nazi scientists and physicians. The Code states that voluntary and informed consent is absolutely essential at all times.

If you are informed and you do not want to take the risks for yourself or for your child, you are labeled as negligent, ignorant, a child abuser, and a criminal. I believe the opposite could be considered true. Paavo Airola, Ph.D. comments about this position in her statement "Is it any wonder that some doctors have called vaccination 'legalized child abuse'?"

If you choose to have your children vaccinated that is your choice. My choice not to vaccinate is exercising my personal freedom and liberties and it is not infringing upon the rights of others. **<u>If vaccines work, the vaccinated should have no fear of the unvaccinated child or person!!!!!!!!!!!!</u>** Recently, I heard this response to the previous statement that shows common sense is not so common - "Well yes that is true, but we do not want the unvaccinated child to bring a disease to the vaccinated children that they are not vaccinated against." If that unvaccinated child was vaccinated they would not have been protected from that disease either!?!? It seems the only thing ever eradicated by vaccines is Common Sense.

I personally don't feel that medical personal should have the ability to manipulate what God has designed, and contribute to the development of hybrid autoimmune diseases (AIDS) which endangers all people, vaccinated or unvaccinated. So now they can struggle to "defeat" that which they have created in their "war against diseases"!

The physicians who testified in favor of this bill, went so far as to criticize the media (20/20) for sensationalism and trying to sell a newspaper. A media which basically gives them free advertising of their "miracle products". The

media, is for the most part, funded by drug companies with continual drug advertisements and propaganda distributed directly to the national stations, which is then reported as "News" and always under the name of science - until [redacted]ething goes wrong. How dare they criticize the media for finally reporting the truth and informing the public. The [redacted]ns put themselves in a dangerous position for funding when they go against the medical establishment.

Let's put it this way - If I was only interested in being financially wealthy, I would be a vaccine manufacturer. I would have the media report my vaccine as a 'scientific breakthrough'; I would have the government mandate it and force it on everyone; and I would have the government protect me from lawsuits from the damage it creates; and I would continually brainwash officials and the public to believe that my magical product was necessary for them to exist as humans. People would depend on me, and live in FEAR without my product.

Barbara Loe Fisher from the National Vaccine Information Center commented "...if the state can tag, track down and force citizens against their will to be injected with biologicals of unknown toxicity today, there will be no limit on what individual freedoms the state can take away in the name of the greater good tomorrow."

She also goes on to say, "The right to have control over what is put into our bodies and be free to refuse to be injected with foreign substances that can harm or kill us or our children is a human right so fundamental, it shouldn't have to be debated or fought for in a democracy like ours. But, unfortunately, those who profit from the violation of this basic right, have become very wealthy and politically powerful. And because we've been complacent, rather than vigilant, about protecting the liberties our founding fathers fought so hard for us to have, we're now in a public health crisis that is threatening our lives and the lives of our children."

The one who is victorious, the one with the power, and the one with the money writes history. This is evident within recent history as people question the way in which whites(usually male) have portrayed slavery, the acquisition of land from the native Americans, and so forth. Only recently has the slantedness in the writing of history become [redacted]arent. For example, if the Nazi's were the victors, our perception of the Holocaust would most likely be that it was a [redacted]us event within the development of a superior race and a needed action to perpetuate those ideals. At least that is [redacted]the Nazi's would write the story.

An individual's reality only goes as far as they can perceive - that is how they view the world. If an individual does not investigate, they hold the view given to them by their predecessors and are limited by history's slant. Prior to Christopher Columbus, people accepted that the earth was flat and would perpetuate this thinking to their children. Due to Columbus's investigation, a whole new world became part of his reality and therefore ours.

The medical establishment, the drug and vaccine manufacturers, along with certain governmental establishments have the money and the power to write history with their perception, and to convince others to not think beyond it.

It is my vision and prediction, that one day, the proponents of vaccines will also be re-newing their membership in The Flat Earth Society.

Dr. Neal N. Eslinger

Dr. Neal N. Eslinger - North Dakota Resident, Citizen of the United States of America, Child of GOD

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March 9, 1999

Dear Representatives of the House:

Please consider the attached literature regarding the potential side effects of the Hepatitis B Vaccine before voting on Bill SB2126.

It is evident that the overall benefit of the vaccine needs to be carefully considered against the possible side effects. I strongly feel the negative effects on the autoimmune system are valid. Due to the potentially permanent life changing reaction to the vaccine further studies need to continue before any consideration is given to requiring the vaccine to be mandatory.

I fear this bill that leaves no room for discernment. The vaccine needs to remain optional and parental discretion allowed.

Thank you.

Respectfully,

Cindy Doll

Cindy Doll

NATIONAL VACCINE INFORMATION CENTER

Contact: 703-938-0342

For immediate release

January 27,1999

HEPATITIS B VACCINE REACTION REPORTS OUTNUMBER REPORTED DISEASE CASES IN CHILDREN ACCORDING TO VACCINE SAFETY GROUP

National Poll Reveals Majority of Americans Want Informed Consent Rights

Washington, D.C. – The National Vaccine Information Center (NVIC) released figures this week which show that the number of hepatitis B vaccine-associated serious adverse event and death reports in American children under the age of 14 outnumber the reported cases of hepatitis B disease in that age group. NVIC is calling the government-mandated hepatitis B vaccination of all children a "dangerous and scientifically unsubstantiated policy." At the same time, a national poll reveals that two thirds of all Americans want the right to make informed, voluntary decisions about vaccination.

Independent analysis of raw computer data generated by the government-operated Vaccine Adverse Event Reporting System (VAERS) confirms that in 1996, there were 872 serious adverse events reported to VAERS in children under 14 years of age who had been injected with hepatitis B vaccine. The children were either taken to a hospital emergency room, had life threatening health problems, were hospitalized or were left disabled following vaccination. 214 of the children had received hepatitis B vaccine alone and the rest had received hepatitis B vaccine in combination with other vaccines. 48 children were reported to have died after they were injected with hepatitis B vaccine in 1996 and 13 of them had received hepatitis B vaccine only before their deaths. By contrast, in 1996 only 279 cases of hepatitis B disease were reported in children under age 14. (Click here to see graph)

1997 hepatitis B disease statistics from eight states reinforce the lack of hepatitis B disease in young children, particularly in children under 5 years old. For children under 5 years old, New Hampshire reported 1 case of hepatitis B; Washington state reported 2 cases; Michigan reported 9 cases; and Texas reported 13 cases. Pennsylvania, Massachusetts, New Jersey and Illinois reported no hepatitis B cases in children under 5 years old.(Click here to see graph) By contrast, in 1997 there were a total of 106 VAERS reports of hepatitis B vaccine-related serious adverse events and 10 deaths in children under age 5 living in the eight states with 13 of the reported serious adverse events and 2 deaths occurring in children receiving only hepatitis B vaccine. (Click here to see graph)

There were 24,775 hepatitis B vaccine-related adverse events reported to VAERS in all age groups, including 9,673 serious adverse events and 439 deaths between July 1, 1990 and October 31, 1998. Out of this total, 17,497 reports were in individuals who received only hepatitis B vaccine without any other vaccines. 5,983 of the reports were for serious events

and there were 146 deaths, which means that 35 percent of reports in all age groups after receipt of hepatitis B vaccine only are for serious events. (Click here to see graph)

During the same time period, there was a total of 2,424 adverse event reports, with 1,209 serious events and 73 deaths in children under age 14 who got hepatitis B vaccine alone without any other vaccines. This means that 52 percent or 1 out of 2 reports for children under age 14, who only receive hepatitis B vaccine, are for serious events.

VAERS depends primarily upon physicians reporting and causation cannot be conclusively determined without in-depth follow-up of each serious event and death report. NVIC maintains that reports made by doctors to VAERS represent only a small fraction of the vaccine-related injuries and deaths which occur in the U.S. every year. A former FDA Commissioner wrote in *JAMA* in 1993 that one study showed "only about 1 percent of serious events" attributable to drug reactions are reported to the FDA.

A 1994 NVIC survey of 159 doctors' offices in 7 states revealed that only 28 out of 159 doctors (18%) said they make a report to the government when a child suffers a serious health problem following vaccination. In New York, only one doctor out of 40 surveyed reported vaccine adverse events to the government.

In a related development, NVIC also released the results of a national poll of 1,000 registered voters, taken by The Polling Company on December 8-11, 1998, which showed that 2 out of 3 (68%) Americans support a parent's right to be informed of the risks of diseases and risks of vaccines and be able to choose whether or not their children receive certain vaccines which could potentially hurt them. A plurality (45%) of

Americans oppose state laws requiring all five-year olds to get the hepatitis B vaccine before being allowed to attend kindergarten and, when given information about risks of hepatitis B vaccination, 59 percent of respondents were less likely to support such mandatory vaccination laws.

Only 25 percent of Americans believe that people, after getting information about risks and benefits of medical procedures such as the administration of prescription drugs and vaccines, should then be *required to follow the orders* of their doctors or public health officials. The poll's margin of error is +/-3.1% at the 95% confidence level (i.e. the same survey could be administered to a similar population and yield comparable results in roughly 19 of 20 cases).

Hepatitis B is primarily an adult disease most often transmitted through infected blood. Highest risk populations are IV drug users and people with multiple sex partners. In 1991 the CDC recommended that all infants be injected with the first dose of hepatitis B vaccine at birth before being discharged from the hospital newborn nursery, even though the only newborns at risk for contracting hepatitis B are those born to hepatitis B infected mothers. By 1998, only 15 states required mandatory screening of pregnant women for hepatitis B infection so babies born to infected mothers could be effectively targeted for hepatitis B vaccination, and yet 35 states required all children to get 3 doses of hepatitis B vaccine or be denied entry to daycare, kindergarten, high school or college.

The U.S. has historically had one of the lowest rates of hepatitis B disease in the world even before a hepatitis B vaccine was in use. In 1990, a year before the CDC issued the order for

all children to get the vaccine, there were 21,102 cases of hepatitis B reported in the U.S. out of a total US population of 248 million. In 1996, there were 10,637 hepatitis B cases reported. According to the October 31, 1997 *Morbidity and Mortality Weekly Report* published by the Centers for Disease Control, "Hepatitis B continues to decline in most states, primarily because of a decrease in the number of cases among injecting drug users and, to a lesser extent, among both homosexuals and heterosexuals of both sexes."

In October 1998, France became the first country to end hepatitis B vaccination requirements for schoolchildren after reports of chronic arthritis, symptoms resembling multiple sclerosis and other serious health problems following hepatitis B vaccination became so numerous that the Health Minister of France suspended the school requirement.

"As more states mandate hepatitis B vaccination, NVIC is getting more reports of children dying or suffering rashes, fevers, seizures, arthritis, diabetes, chronic fatigue and other autoimmune and brain dysfunction following their hepatitis B shots," said NVIC co-founder and president Barbara Loe Fisher. "Newborn babies are dying shortly after their shots and their deaths are being written off as sudden infant death syndrome. Parents should have the right to give their informed consent to vaccination and Congress should give emergency, priority funding to independent scientists, who can take an unbiased look at this vaccine, instead of leaving the search for the truth in the hands of government officials who have already decided to force every child to get the vaccine," she said.

Drug companies marketing the genetically engineered recombinant DNA hepatitis B vaccine in the U.S. used studies to demonstrate safety which only monitored children for 4 or 5 days after vaccination. Professor Bonnie Dunbar, Ph.D., a Texas cell biologist and pioneering vaccine researcher, said "It takes weeks and sometimes months for autoimmune disorders, such as rheumatoid arthritis, to develop following vaccination. No basic science research or controlled, long term studies into the side effects of this vaccine have been conducted in American babies, children or adults." Dr. Dunbar has joined consumers in calling for informed consent to hepatitis B vaccination as well as NIH funding for independent research to determine the biological mechanism for hepatitis B vaccine reactions, to identify high risk factors and to develop therapies to repair vaccine damage.

Founded in 1982, the National Vaccine Information Center is the oldest and largest vaccine safety and informed consent rights advocacy organization representing health care consumers and the vaccine injured. NVIC was instrumental in the creation of the National Childhood Vaccine Injury Act of 1986, which has paid out nearly $1 billion dollars for vaccine injuries and deaths. For more information or to report a vaccine reaction, call 1-800-909-SHOT or access http://www.909shot.com.

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THE VACCINE REACTION

"When it happens to you or your child, the risks are 100%"

Published by the National Vaccine Information Center

Barbara Loe Fisher, Editor

Excerpts from "HEPATITIS B VACCINE: THE UNTOLD STORY"

Hepatitis B Not Highly Contagious - Unlike other infectious diseases for which vaccines have been developed and mandated in the U.S., hepatitis B is not common in childhood and is not highly contagious. Hepatitis B is primarily an adult disease transmitted through infected body fluids, most frequently infected blood, and is prevalent in high risk populations such as needle using drug addicts; sexually promiscuous heterosexual and homosexual adults; residents and staff of custodial institutions such as prisons; health care workers exposed to blood; persons who require repeated blood transfusions and babies born to infected mothers.

According to *CDC Prevention Guidelines: A Guide to Action* (1997), a book written by federal public health officials at the U.S. government Centers for Disease Control (CDC), "the sources of [hepatitis B] infection for most cases include intravenous drug use (28%), heterosexual contact with infected persons or multiple partners (22%) and homosexual activity (9%)." According to *Harrison's Principles of Internal Medicine* (1994), mother to child transmission of hepatitis B "is uncommon in North America and western Europe."

Although CDC officials have made statements that hepatitis B is easy to catch through sharing toothbrushes or razors, Eric Mast, M.D., Chief of the Surveillance Section, Hepatitis Branch of the CDC, stated in a 1997 public hearing that: " although [the hepatitis B virus] is present in moderate concentrations in saliva, it's not transmitted commonly by casual contact."

Hepatitis B Not A Killer Disease For Most - Symptoms of hepatitis B disease include nausea, vomiting, fatigue, low grade fever, pain and swelling in joints, headache and cough that may occur one to two weeks before the onset of jaundice (yellowing of the skin) and enlargement and tenderness of the liver, which can last for three to four weeks. Fatigue can last up to a year. According to *Harrison's,* in cases of acute hepatitis B "most patients do not require hospital care" and "95 percent of patients have a favorable course and recover completely" with the case-fatality ratio being "very low (approximately 0.1 percent)."

Those who recover completely from hepatitis B infection acquire life-long immunity. Of those who do not recover completely, fewer than 5 percent become chronic carriers of the virus with just one quarter of these in danger of developing life threatening liver disease later in life, according to *Robbins Pathologic Basis of Disease* (1994), a medical college textbook.

The *Guide to Clinical Preventive Services* (1996), written under the supervision of the U.S. Department of Health and Human Services (DHHS), states that the risk of developing a chronic hepatitis B infection is higher in infected infants than in infected older children and adults: "Infections during infancy, while estimated to represent only 1-3% of cases, account for 20-30% of chronic infections." Because infants born to infected mothers are at highest risk for developing chronic hepatitis B infections, routine screening of pregnant women for hepatitis B infection is one of the most important public health measures that can be taken to prevent chronic hepatitis B carriers. *The Merck Manual* (1992), a major medical reference used by physicians, notes that "postexposure vaccination is recommended for newborn infants of hepatitis B positive mothers."

Hepatitis B Low In U.S. - The U.S. and western Europe have always had among the lowest rates of hepatitis B disease in the world (0.1% to 0.5% of the general population) compared to countries in the Far East and Africa, where the disease affects 5-20% or more of the population. According to *Guide to Clinical Preventive Services*, in the U.S. "the greatest reported incidence [of hepatitis B] occurs in adults aged 20-39" and "the number of cases peaked in 1985 and has shown a continuous gradual decline since that time."

Even though hepatitis B disease is uncommon in the general population in the U.S., it continues to be high among those engaged in high-risk behaviors, especially IV drug use. *Guide to Clinical Preventive Services* states that "In recent years, a growing number of injection drug users have become infected; currently, between 60% and 80% of persons who use illicit drugs parenterally (through the skin such as with a needle stick) have serologic evidence of [hepatitis B] infection."

In 1991, there were 18,003 cases of hepatitis B reported in the U.S. out of a total U.S. population of 248 million. According to the October 31, 1997 *Morbidity and Mortality Weekly Report* published by the CDC, in 1996 there were 10,637 cases of hepatitis B reported in the U.S. with 279 cases reported in children under the age of 14 and the CDC stated that "Hepatitis B continues to decline in most states, primarily because of a decrease in the number of cases among injecting drug users and, to a lesser extent, among both homosexuals and heterosexuals of both sexes."

CDC Recommends All Infants Get Hep B Vaccine - Even though hepatitis B is an adult disease, is not highly contagious, is not deadly for most who contract it, and is not in epidemic form in the U.S. (except among high risk groups such as IV drug addicts), in 1991 the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) recommended that all infants be injected with the first dose of hepatitis B vaccine at birth before being discharged from the hospital newborn nursery. A similar recommendation was also made by the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP). This, despite the fact almost nothing is known about the health and integrity of an individual baby's immune and neurological systems at birth.

In 1991, media reports generated by the CDC used hepatitis B disease statistics that were

not anchored in documented fact but are still used today to promote mass hepatitis B vaccination. Most of the inflated disease statistics originate with statements generated by the Centers for Disease Control. In the 1991 ACIP Recommendations calling for mass vaccination with hepatitis B vaccine published in the *Morbidity and Mortality Weekly Report,* the CDC states that there are an "estimated 1 million-1.25 million persons with chronic hepatitis B infection in the United States" and that "each year approximately 4,000-5,000 of these persons die from chronic liver disease" and that "an estimated 200,000-300,000 new [hepatitis B] infections occurred annually during the period 1980-1991." The CDC gives no scientific reference for this data other than the CDC.

Just one year before the government's call for mass vaccination, hepatitis B vaccine maker SmithKline Beecham in their 1990 hepatitis B vaccine product insert stated, "The CDC estimates that there are approximately 0.5 to 1.0 million chronic carriers of hepatitis B virus in the U.S. and that this pool of carriers grows by 2% to 3% (12,000 to 20,000 individuals) annually."

Hep B Vaccine Licensed By FDA Without Adequate Proof of Long Term Safety - In 1986, the FDA gave Merck & Co. a license to market the first recombinant DNA hepatitis B vaccine, which replaced the old hepatitis B vaccines made from blood taken from human chronic hepatitis B virus carriers. In awarding Merck & Co. and, later, SmithKline Beecham Pharmaceuticals, licenses to market their genetically engineered hepatitis B vaccines in the U.S., the FDA allowed both drug companies to use "safety" studies which only included a few thousand children monitored for only four or five days after vaccination to check for reactions. As "proof" their hepatitis B vaccine is safe to be used in children, Merck & Co. stated in their 1993 product insert that "In a group of studies, 1636 doses of RECOMBIVAX HB were administered to 653 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose."

Merck & Co. found that injection site and systemic complaints, such as fatigue and weakness, fever, headache and arthralgia (joint pain), were reported following up to 17 percent of all hepatitis B injections. Because the FDA did not require drug companies to provide scientific evidence that hepatitis B vaccine does not compromise the immune and neurological systems of children and adults over weeks, months or years post-vaccination, Merck & Co. warns in the 1996 product insert that "As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials" and SmithKline Beecham (1993) has a similar warning that "it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions.

Another warning in the Merck 1996 product insert is "it is also not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity" and "it is not known whether the vaccine is excreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when the vaccine is administered to a nursing woman."

And, although doctors routinely inject hepatitis B vaccine into children along with many other vaccines such as DPT, HIB, MMR and chicken pox vaccine, Merck & Co. state in the 1996 product insert: "Specific data are not yet available for the simultaneous administration of RECOMBIVAX HB with other vaccines."

Hep B Vaccine Efficacy Also Questioned - All vaccines stimulate only an artificial,

temporary immunity, and the length of immunity conferred by the hepatitis B vaccine and the future need for more "booster" doses later in life is still not clear. Merck & Co state in their 1996 hepatitis B vaccine product insert that "the duration of the protective effect of RECOMBIVAX HB in healthy vaccinees is unknown at present and the need for booster doses is not yet defined."

In the *CDC Prevention Guidelines: A Guide to Action* (1997), the CDC states "The duration of protection [of hepatitis B vaccine] and need for booster doses are not yet fully defined. Between 30% and 50% of persons who develop adequate antibody after three doses of vaccine will lose detectable antibody within 7 years but protection against viremic infection and clinical disease appears to persist." If immunity only lasts 7 years, babies vaccinated with hepatitis B vaccine may be candidates for more shots at age seven.

IOM Report Reveals Lack Of Adequate Scientific Studies - In *Adverse Events Associated with Childhood Vaccines* published in 1994 by the Institute of Medicine, National Academy of Sciences, observations about the limitations of hepatitis B vaccine studies included the statements that "it is important to note that individual trials usually involved a few hundred subjects for study...when larger vaccination programs were monitored, observations of adverse events were necessarily less detailed and less accurately reported" and "the studies were not designed to assess serious, rare adverse events; the total number of recipients is too small and the follow-up generally too short to detect rare or delayed serious adverse reactions."

The IOM report also noted that no controlled observational studies or controlled clinical trials have ever been held to evaluate repeated reports that hepatitis B vaccine can cause Guillain-Barre syndrome; arthritis; transverse myelitis, optic neuritis, multiple sclerosis and other central demyelinating diseases of the nervous system (degeneration of the myelin sheath of the brain that helps transmit nerve impulses); or sudden infant death syndrome (SIDS).

A major conclusion of the Institute of Medicine report was that almost no basic science research has been undertaken to define at the cellular and molecular level the biological mechanism of vaccine-induced injury and death. The report concluded that "The lack of adequate data regarding many of the adverse events under study was of major concern to the committee...the committee encountered many gaps and limitations in knowledge bearing directly or indirectly on the safety of vaccines. These include inadequate understanding of the biologic mechanisms underlying adverse events following natural infection or immunization, insufficient or inconsistent information from case reports and case series...and inadequate size or length of follow-up of many population-based epidemiologic studies...."

Medical Literature Cites Immune System/Brain Damage - During the past decade, there have been many reports in the medical literature (primarily in international medical journals rather than U.S. medical journals) that hepatitis B vaccination is causing chronic immune and neurological disease in children and adults, including *lupus:* Tudela & Bonal (1992); Mamoux & Dumont (1994); Guiserix (1996); *arthritis, including polyarthritis and rheumatoid arthritis:* Christan & Helin (1987); Hachulla et al (1990); Rogerson & Nye (1990); Biasi et al (1993),(1994); Vautier & Carty (1994); Hassan & Oldham (1994); Rheumatic Review (1994); Gross et al (1995); Pope et al (1995); Cathebras et al (1996); Soubrier et al (1997); *Guillain Barre Syndrome GBS)*: Shaw et al (1988), Tuohy (1989);

demyelinating disorders such as optic neuritis, Bell's Palsy, demyelinating neuropathy, transverse myelitis and multiple sclerosis: Shaw et al (1988); WHO (1990); Reutens et al (1990); Herroelen et al (1991); Nadler (1993); Brezin et al (1993); Mahassin et al (1993); Kaplanski et al (1995); Baglivo et al (1996); Marsaudon & Barrault (1996); Berkman et al (1996); Waisbren (1997); *diabetes mellitus*: Poutasi (1996); Classen (1996); *chronic fatigue*: Salit (1993); Delage et al (1993); *vascular disorders:* Fried et al (1987); Goolsby (1989); Cockwell et al (1990); Poullin & Gabriel (1994); Mathieu et al (1996); Graniel et al (1997); and others.

In 1996, Burton A. Waisbren, M.D., a cell biologist and infectious disease specialist, who is a founding member of the Infectious Disease Society of America and past President of the Infectious Disease Society of Milwaukee, pointed out in the *Wisconsin Medical Journal* that "there is an increasing number of reports in the refereed medical literature about demyelinizing

diseases occurring after an individual has received the hepatitis B vaccination...since the hepatitis B virus itself has been reported to cause autoimmune problems, should we not be wary of giving antigens that seem to have triggered these problems?" Waisbren, in a presentation before a 1996 Institute of Medicine Vaccine Safety Forum, warned that genetically engineered hepatitis B vaccines contain polypeptide sequences that are present in human neurologic tissues such as myelin and that, by a mechanism called molecular mimicry, these polypeptides can act as autoantigens which can induce autoimmune demyelinating diseases of the brain such as multiple sclerosis.

In that same year, Montinari et al published a study in Italy evaluating 30 children and adults, the majority aged 3 to 9 months, who suffered central nervous system disorders, such as seizures and autism, following hepatitis B vaccination. The purpose of the study was to investigate whether there is an immunogenetic basis (autoimmune type) responsible for the demyelination process in the brain that can occur following recombinant hepatitis B vaccination. The authors concluded "autoimmune diseases are more frequent in nations where vaccines are widely used, the so called "clear" communities" and they identified several potential genetic markers that "may visualize risk patients for autoimmune diseases following hepatitis B vaccination.

Montinari's work to identify genetic factors for predisposition to hepatitis B vaccine reactions is important in light of the study in 1989 by Alper et al to identify genetic factors for those who do not respond to hepatitis B vaccination. In that study, the authors concluded that there was genetic predisposition to failure to respond to the vaccine. They stated: "These results support our hypothesis that the production of anti-HBsAg [vaccine-induced antibodies] is a dominant trait and that the inability to produce high titers of anti-HBsAG after adequate immunization is a recessive trait..." The authors concluded that the genetic markers they identified are most prevalent in caucasians of European descent "and is associated with a wide variety of diseases with autoimmune features in this population, including Type 1 diabetes mellitus..."

In 1996, Barthelow Classen, M.D., CEO of Classen Immunotherapies Inc., published an epidemiologic study in the *New Zealand Medical Journal* and reported that there was a 60 percent increase in Type 1 diabetes (juvenile diabetes) following a massive campaign in New Zealand from 1988 to 1991 to vaccinate babies six weeks of age or older with hepatitis B vaccine. His analysis of a group of 100,000 New Zealand children prospectively followed

since 1982 showed that the incidence of diabetes before the hepatitis B vaccination program began in 1988 was 11.2 cases per 100,000 children per year while the incidence of diabetes following the hepatitis B vaccination campaign was 18.2 cases per 100,000 children per year.

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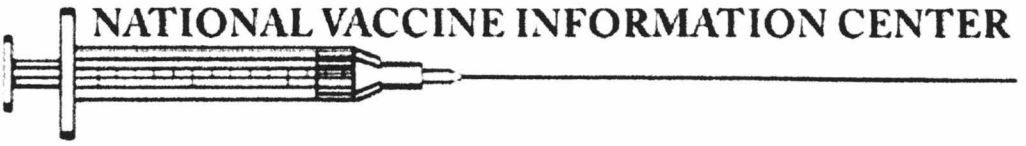

HEP B VACCINE VICTIMS IN FRANCE SUE;

FRANCE SUSPENDS HEP B VACCINE MANDATE

In October 1998, the Minister of Health in France suspended the hepatitis B vaccine requirement for school children after repeated reports of the development of autoimmune and neurological disorders after hepatitis B vaccination. The action came following reports in the medical literature as well as lawsuits against vaccine manufacturers and the French government.

According to a July 31, 1998 issue of *Science*, an American scientific journal, French attorneys representing 15,000 French citizens have filed a lawsuit against the French government "accusing it of understating the vaccine's risks and exaggerating the benefits for the average person." One French physician has reportedly collected data on more than 600 people suffering from serious immune and neurological dysfunction following hepatitis B vaccination, many with symptoms resembling multiple sclerosis.

Litigation by hepatitis B vaccine victims and citizens seeking informed consent to vaccination is being reinforced by data from France released at the 62nd Annual Meeting of the American College of Rheumatology, held November 8-12, 1998 in San Diego, California linking hepatitis B vaccine to the development of autoimmune rheumatoid disease such as lupus and rheumatoid arthritis. The French data confirms a 1998 Canadian study published in *The Journal of Rheumatology (*1998: 25:1687-93) by Pope et al discussing evidence that recombinant hepatitis B vaccine may trigger the development of rheumatoid arthritis in genetically susceptible individuals.

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The Vaccination Debate
Vaccination Information

"Official data have shown that the large-scale vaccinations undertaken in the US have failed to obtain any significant improvement of the diseases against which they were supposed to provide protection."- **Dr. A. Sabin-Developer of the Polio Vaccine**

"Many here voice a silent view that the Salk and Sabin Polio Vaccine, being made of **monkey kidney tissue** has been directly responsible for the major increase in Leukemia in this country." **Dr. Frederick Klenner, Polio Researcher, USA**

"The greatest threat of childhood disease lies in the dangerous and ineffectual efforts made to prevent them through mass immunization." –**Dr. R. Mendelsohn, Author and Pediatrician**

Did You Know...

- In 1977, Dr. Jonas Salk (inventor of the Salk polio vaccine) testified along with Other scientists that most (87%) of the polio cases which have occurred in the U.S. since the early 1970's probably were the by-product of the polio vaccine itself.

- That up to 90% of the decline in death rates from infectious disease occurred BEFORE vaccination commenced.

- That in the UK, since 1970, more than 200,000 cases of Whooping Cough have occurred in fully vaccinated children.

- That in the US, despite compulsory vaccination, measles is on the increase and many outbreaks are occurring amongst vaccinated children.

- That a tuberculosis vaccine trial in India involving over 260,000 indians resulted in more TB cases in the vaccinated than the un-vaccinated.

- That almost every Polio case in the US in the last 30 years has been associated with the vaccine itself.

- The cost of the whooping cough vaccine has risen from 11 cents in 1982 to $15.00 in 1992. The vaccine company is putting away $12.00 per shot to cover legal costs and damages being paid out to patients of brain damaged children who die after vaccination.

- Did you know about the contaminated vaccines given to millions of children in the early 1960's ? These vaccines contained the SV40 virus which causes cancer in animals, as well as changes in human cell tissue cultures.

- In the US, from July 1990 to November 1993, the FDA counted a total of 54,072 adverse reactions following vaccination. It also admitted that this number represented only 10% of the real total, because doctors were refusing to report vaccine injuries. In other words, adverse reactions for this period exceeded half a million.

- More than 500 persons who received swine flu shots between October 1 and December 16, 1976, subsequently contracted Guillian-Barre Syndrome. **Twenty-three of them died.**

- The rubella (German Measles) vaccine has been followed in some cases by transient and not-so-transient arthritis.

- Miss America 1995, Heather Whitestone's loss of hearing followed a childhood DPT shot.

These facts were extracted from the book Vaccination The "Hidden" Facts
By Ian Sinclair

North Dakota Department of Health
Immunization Program
Response to 20/20 Segment on Safety of Hepatitis B Vaccine

Concern: Does hepatitis B cause chronic illnesses?
Response:

- The scientific evidence to date does not support a conclusion that hepatitis B vaccination causes arthritis, multiple sclerosis (MS) or other demyelinating [nerve destroying] diseases.
- Concern that hepatitis B vaccination may cause MS comes primarily from case reports resulting in media attention in France and more recently in the U.S. It is possible that many, if not all, of the MS case reports alleging a possible link to the hepatitis B vaccine are purely coincidental; the vaccination is recommended for most health care workers, many of whom are women in middle age, the time when the symptoms of MS most commonly expresses themselves.
- The concern regarding a suggested association between vaccination and MS or any other chronic illness must be weighed against the very strong evidence of that vaccines directly and effectively protect against disease and death.

Concern: Is the hepatitis B vaccine as safe as other vaccinations?
Response:

- The hepatitis B vaccine has been shown to be very safe. Large-scale hepatitis B immunization programs in the United States, Taiwan, and New Zealand have shown no association between the vaccine and any serious adverse events (including chronic fatigue syndrome, rheumatoid arthritis, or autoimmune disorders, such as lupus, which destroys skin tissue).
- More than 20 million persons have received hepatitis B vaccine in the United States and over 1 billion doses of hepatitis B have been used around the world since 1981 with an outstanding record of safety and efficacy.
- 100 countries have added hepatitis B vaccine into their national immunization program.

Concern: Why does the package insert state that numerous serious adverse reactions have occurred after vaccination with hepatitis B vaccine, including Guillain-Barre syndrome, multiple sclerosis, arthritis, and Lupus-like syndrome?
Response:

The package insert (e.g., Merck) states that there were some adverse reactions reported with use of the marketed vaccine. However, it also states that "In many instances, the relationship to the vaccine was unclear."

Concern: Why are babies being immunized if they are not at risk?
Response:

- It is important to immunize children against hepatitis B, because the consequences for children who become infected are much more severe than for adults. Those who are infected as children have a 30% risk of developing chronic hepatitis B infection and chronic liver disease, compared to a risk of roughly 10% for those who are infected later in life.

- One-third of those who develop hepatitis B have no known risk factors. Universal infant immunization ensures that those who become exposed without their knowledge are protected against the disease.
- While most HBV infections occur among older adolescents and young adults, vaccination of persons in high risk groups has generally not been a successful public health strategy.

Concern: Does the hepatitis B vaccine cause SIDS?
Response:

- An analysis of data from the National Center for Health Statistics show no increase in reports of infant deaths since 1991, the year routine hepatitis B immunization began.

Concern: Does the vaccine cause more harm than the good it prevents?
Response:

- Hepatitis B vaccine is the most effective means of preventing hepatitis B infection and its consequences.
- An estimated 1 million to 1.25 million people in the U.S. have chronic hepatitis B infection and are potentially infectious to others. Hepatitis B is the most common cause of liver cancer worldwide. Each year in the U.S., 150,000 people get hepatitis B and 4,000 to 5,000 die from it.
- Any presumed risk of adverse events associated with hepatitis B vaccination must be balanced with the expected 2,000 to 5,000 hepatitis B related deaths that would occur without immunization.
- Consequences of hepatitis B disease are serious. Long-lasting infection with hepatitis B virus may destroy the liver through cirrhosis, lead to liver cancer, and cause death. Earlier stages include pains in muscles, joints or stomach, diarrhea or vomiting, fatigue, and jaundice.
- A published review of Vaccine Adverse Events Following Vaccination Reporting System (VAERS) data from 1991-94 show no unexpected events in infants, who received approximately 12 million doses of the hepatitis B vaccine during that period. The VAERS database is used to examine overall trends and unusual occurrences for further study, not to determine exact numbers of case reports. VAERS accepts all reports of health effects that follow vaccination, *regardless of the cause*. In some cases, these adverse effects have merely a coincidental rather than a causal relationship to the administration of a vaccine. Other cases may be reported more than once. It is not possible to determine the number of adverse effects from a given vaccine simply by looking at the number of VAERS reports.

Concern: Why is vaccination for hepatitis B required by many states for school entry?
Response:

- Without state and local immunization laws many more people would become sick or die from hepatitis B.
- Immunization requirements help protect persons who are too sick to receive the vaccine. This is done by ensuring that a large number of persons are protected with vaccine that prevents transmission of hepatitis B to others who are not protected. The greater the number of children who refuse vaccination, the greater the risk of disease is to persons who cannot be immunized because of health reasons.

- Likewise, the community benefits by having a large number of persons vaccinated and protected from disease. High coverage levels limit the introduction or spread of disease, benefiting everyone.
- The enforcement of mandatory school immunization laws has significantly increased vaccine coverage. In every instance, such requirements have significantly reduced illnesses and death from diseases that vaccines prevent. Vaccine coverage levels are higher in school-age children and those enrolled in licensed day care centers and Head Start programs than among any other comparable group of infants, children or adolescents.
- Rulemaking is usually based on immunization schedule recommendations established by nationally recognized authorities, including the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatric's (AAP) Red Book Committee.

Prepared: March 5, 1999
Sources: Centers for Disease Control and Prevention, Infectious Diseases Society of America

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Whatever Happened to Informed Medical Choice?

Why are American infants and schoolchildren being forced to submit to hepatitis B vaccinations even though the French Health Ministry has suspended them in schools because of evidence they can cause neurological disorders or multiple sclerosis? (*New York Times*, Oct. 3, 1998) Has America become a nation where the government can force controversial medical procedures on children without allowing their parents informed choice? If you think such things only happen in Communist China, think again. Compulsory health treatment is on the march in the United States.

"Force" is not too strong a word. Across the country, born babies are being injected with hepatitis B ccine only hours after birth (even when their mothers test negative for hepatitis B), and children are told they must present proof of having received three hepatitis B shots before they can be admitted to daycare, kindergarten, fifth grade or high school.

I first became interested in the hepatitis B vaccine when, in connection with the birth of two new grandchildren, I learned that hospitals are routinely injecting newborns with the vaccine during their first 24 hours of life. A series of inquiries produced no convincing medical reason or scientific evidence for this procedure. My new grandchildren were not at risk for hepatitis B, which is primarily an adult disease transmitted through bodily fluids. Those most at risk are the highly promiscuous (heterosexual or homosexual), needle-sharing drug addicts, health care and custodial workers exposed to blood, and babies born to already-infected mothers.

According to a Centers for Disease Control (CDC) report, there were only 10,637 cases of hepatitis B in the United States in 1996, including only 279 cases in children under the age of 14. Hepatitis B is not fatal for most who contract it, and it is not epidemic except among high-risk groups.

For the problem of 279 children who have hepatitis millions of U.S. children are being forced to submit to vaccination consisting of three hepatitis B shots (at about $40 each)! The government isn't just trying to vaccinate the people who are *at risk* for Hepatitis B — that might "stigmatize" them. Instead, the CDC recommends that *all* babies be vaccinated at birth to be ready for risky activities a dozen years later. "Infants are considered the easiest to immunize," says Dr. Walter Orenstein, Director of CDC's Immunization Program. (*New York Times*, July 30, 1997)

To win parental support for hepatitis B vaccinations, the vaccine police de-emphasize sex and drugs as risk factors, instead citing alleged dangers from ear piercing and contact sports. A hepatitis B coordinator said, "We didn't want to have to battle people's moral philosophy over children's vaccinations and having parents tell us, 'My sixth-grader doesn't have sex.'" ("Lining Up for Hepatitis Shots," *New York Times*, July 30, 1997, p.B10)

More than 24,000 reports of hospitalizations and injuries, including about 400 deaths, following hepatitis B vaccinations have been reported since 1990 to the U.S. government's Vaccine Adverse Event Reporting System. There have been no controlled studies to evaluate these reports, there is no adequate proof of the vaccine's long-term safety, and little is known about the effect of vaccines on a newborn baby's immune system. One nationally respected vaccine developer has been repeatedly turned down by the National Institutes of Health for a research grant to study hepatitis B vaccine-related injuries. (*Science* magazine, "A Shadow Falls on Hepatitis B Vaccination Effort," July 31, 1998, p.630)

Vaccines: the Key to Federal Control

It's been clear since 1993 that the Clinton Administration is steadily working toward federal control of the entire health care industry, and a major feature of this control is to compile the health records of all Americans on a government database. The 1996 Kennedy-Kassebaum Act gave the Department of Health and Human Services the authority to establish "unique health care identifiers" so the government can identify and track our medical records. Thanks to Eagle Forum and other alert citizens, last year's Congress postponed this authority until Congress takes further action.

The Clinton Administration is using vaccines as the

reason to build a massive database of the health records of individual Americans. The bureaucrats expect vaccines to be non-controversial because of the remarkable success of the smallpox vaccine in completely eradicating that disease. Here is how the Clinton administration's plan works.

The 1993 Comprehensive Childhood Immunization Act, signed by President Clinton, gave the Department of Health and Human Services (HHS) $400 million to assist states to computerize state vaccine databases, or registries, to tag and track children's vaccinations.

The CDC uses carrot and stick to force the states to obey federal "recommendations." The CDC has the power to withhold money grants if state health officials don't show proof of designated vaccination rates, and the CDC has doled out hundreds of millions of taxpayer dollars to reward state health departments for promoting mass vaccinations. States receive either $50, $75 or $100 per child who is fully vaccinated with all federally recommended vaccines, including hepatitis B.

In 1995, HHS Secretary Donna Shalala gave the states the power to get access to newborn babies' Social Security numbers in order to put them on vaccine tracking databases. Now, the CDC is trying to *link* the state vaccine databases, or registries, into a de facto centralized database containing every child's medical records. Once in place, the national vaccine database can serve two important goals:

First, the database will enable the government to enforce mandatory vaccination of all children, thereby conditioning Americans to accept compulsory control of their individual health care. Although American children entering kindergarten have a 97% to 98% immunization rate for most prescribed vaccines (Statement of Dr. Alan R. Hinman, Director of CDC's Center for Prevention Services, to the U.S. House Subcommittee on Health and the Environment, Mar. 7, 1990), government officials are determined to let no child escape.

The federally monitored vaccine database, which will have all children tagged from birth with an I.D. number, will serve as a gatekeeper to deny the child admission to daycare, kindergarten, school or college, or even access to medical care, without showing proof of all required vaccinations.

Second, once the vaccine database is in place, it will be easy to add *all* medical records. This will accomplish one of the major goals of the Clinton Administration's nationalized health care plan, and will be the key to government's ability to dictate the giving and rationing of health care.

Before any of this happens, it is vital to pass state privacy protections to forbid state officials from sharing personal health data with other states or the federal government. It's also important to keep the feds from preempting existing state privacy laws, which Congress tried to do last year in the so-called Patient Protection bill that fortunately did not pass.

How Are Vaccines Made Compulsory?

Medicine used to have a grand tradition of according patients the right of informed choice before being given drugs or submitting to medical treatment, including the right to refuse unwanted medical procedures. The only vaccination required when I entered public school was for smallpox, and that's the only immunization I ever had.

A national campaign to enforce mandatory vaccination laws started with the Jimmy Carter Administration, and then was aggressively accelerated during the 1990s. Most states have now passed laws requiring children to be injected with about 33 doses of 9 or 10 different viral and bacterial vaccines, including three doses of hepatitis B vaccine, in order to enter public school. A New Jersey court recently upheld the right of a private school to deny admission to a student who objected to taking a vaccine.

When it comes to vaccines, instead of "choice," some states tolerate limited and hard-to-get "exemptions." Most states permit a *medical* exemption, but that must be signed by a doctor. All but two states permit a *religious* exemption, but that can be interpreted narrowly or broadly. Some 16 states permit a *philosophical* exemption, but that can be arbitrarily interpreted by state bureaucrats. There's a big difference between exercising free choice or having to plead with some government functionary to tolerate your exemption.

Where do these intrusive and expensive vaccine mandates originate, and how can they be enforced nationally since immunizations are a state, not a federal matter? The vaccine police have figured out how to override state authority (and even overrule pediatricians who might otherwise act in the interest of their patients). They have developed an intricate system of control outside the spotlight of public scrutiny and without accountability.

U.S. vaccine policy is set by a quasi-governmental group of mandatory-vaccination promoters called the Advisory Committee on Immunization Practices (ACIP), whose members are appointed by the Centers for Disease Control (CDC). ACIP members can have financial ties to the drug corporations, which is a gross conflict of interest since the vaccine manufacturers' profits depend on laws that force vaccines on all children instead of just those at risk. One would think that ACIP's objective would be to promote the health of Americans or to provide information to aid informed choices by patients, but it's not. ACIP's stated purpose is "to increase the safe usage of vaccines."

After ACIP and CDC endorse a given vaccine, then state health officials move to make it mandatory for all children. Sometimes the state law designates a specific vaccine, and sometimes the state law delegates to the state bureaucracy the authority to add a new vaccine to the mandatory list. The unaccountable bureaucrats make regulations that follow CDC instructions and have the impact of law. The drug corporations are involved every

step of the way in securing CDC endorsement of a vaccine and in lobbying legislators and bureaucrats to make its use compulsory.

The *New York Times* recently published a front-page report on how the pharmaceutical corporations spent $5.3 billion last year sending their representatives into doctors' offices and hospitals, with gifts and meals, to sweet-talk physicians into using their brand-name products. The *Times* headlined the news story: "Fever Pitch: Getting Doctors to Prescribe is Big Business." (Jan. 11, 1999) The *Times* explained that "business is a big part of medicine now." Indeed it is. But, of course, doctors have complete freedom to accept or reject the drug corporations' sales pitches.

It's time to hear the rest of the story about how politics is an even bigger part of medicine. With a $5.3 billion marketing budget, the drug corporations can easily afford to lobby thousands of state legislators and federal and state bureaucrats to pass laws that force us to buy their products, particularly vaccines. It is the mandatory feature of vaccines that makes them so profitable for the industry. (How the Hepatitis B mandate was lobbied through the Ohio legislature, bypassing the proper committee, with no notice, study or debate, is described in "Hepatitis B vaccine for Ohio's kindergartners unnecessary," *Cincinnati Enquirer*, Jan. 15, 1999.)

Vaccines are designed to give us immunity from certain diseases, but the most interesting immunity is the drug corporations' immunity from any liability related to vaccine side effects, which Congress gave them by law in 1986. That, combined with coercive state laws, has made vaccines extremely profitable for the drug corporations.

Physicians who respect the traditional Hippocratic Oath have a duty to work for the well-being of their patients (rather than the good of society or any other social goal). This presents a conflict with CDC vaccine policy, which is to promote public health.

The American Academy of Pediatrics (AAP) issues vaccination guidelines for pediatricians. In 1995, however, the AAP and other physician organizations agreed to endorse schedules determined by federal authorities. Some HMOs are requiring pediatricians to achieve a near-perfect vaccination rate of their patients as a condition of their HMO contract, and even be subject to on-site inspection of records to verify compliance.

It's time to have a free and open debate on the pros and cons of the policy considerations that go into laws that make the use of drugs compulsory. Better yet, it's time to give all parents the right of informed choice about medical treatment for their healthy children.

Vaccines a Miracle of Modern Medicine?

Smallpox has been virtually eliminated from the face of the earth, and polio is well on its way to the same fate. We don't hear much about diphtheria, whooping cough, or scarlet fever any more, and the cases of once-common childhood diseases such as measles and mumps have dramatically decreased. Conventional wisdom credits vaccines for these remarkable changes. But there are many variables and unknowns in matters of disease and health. No vaccine was responsible for the dramatic decline of scarlet fever.

Vaccines are supposed to fool the body's immune system into producing antibodies to overcome viral and bacterial diseases in the same way that actually having the disease usually produces future immunity. Natural recovery from infectious diseases usually stimulates the immune system to produce a type of immunity that lasts a lifetime. Once a child has had chickenpox, for example, he will never get it again. However, vaccines provide only an artificial, temporary immunity. That's why booster doses of vaccines are often needed.

Vaccines contain either inactivated (killed) bacteria or viruses **or** they contain live viruses that have been attenuated (weakened). Sometimes, live-virus vaccines can cause the disease they are designed to prevent. The live-virus polio, measles and chickenpox vaccines can cause vaccine-strain infections of these diseases. Drug corporations grow the viruses and bacteria used to make vaccines in either chicken or pig embryonic cell cultures, monkey kidney cells, human embryonic lung cells, yeast cells, or other mediums. Chemicals such as formaldehyde are used to inactivate the viruses or bacteria. Vaccines also contain such additives as aluminum, thimerosal (mercury), gelatin and antibiotics.

It is not clear that the increased use of vaccines always promotes the health of individuals. No vaccine is 100% safe or effective. We hear persistent reports that some children, following vaccination, develop chronic health problems such as seizure disorders, asthma, persistent ear infections, learning disabilities, hyperactivity, autism, diabetes, arthritis, or other autoimmune or neurological disorders. Virginia's Lieutenant Governor John Hager is in a wheelchair because he acquired polio from the vaccine given to his infant son.

Between 12,000 and 14,000 reports of hospitalizations, injuries and even deaths following vaccination are reported to the Vaccine Adverse Event Reporting System every year. The National Vaccine Injury Compensation Program has already paid out $925 million in claims for vaccine-caused injuries and deaths. Nobody knows the real total of adverse reactions following vaccinations because very few doctors report vaccine-associated health problems.

When we ask questions of the scientists who created the vaccines, the drug corporations that make and sell them, the public health officials who issue regulations, and the legislators who pass laws forcing every child to be vaccinated, the answers are unsatisfactory and disturbing. The more we ask questions, the more we find that the subject of vaccines is not all based on science — some of it is politics.

Many vaccines are required without publication of

the risks and benefits. The vaccine establishment's attitude is that such information unduly alarms parents and, anyway, the government knows what's best for children.

New Vaccines Are Coming Fast

A new live virus varicella zoster (chickenpox) vaccine has recently come on the market. Chickenpox is highly contagious but is a mild disease for most children. More than 95% of all American children get chicken pox between the ages of 1 and 9, recover without complications, and have lifelong immunity. The movement to make the chickenpox vaccine compulsory for all children is moving rapidly. Maryland, Oregon, Washington, D.C., and Massachusetts have already used rulemaking authority to mandate use of the chicken pox vaccine, and legislation is pending in several other states. Radio and newspaper advertising for the chicken pox vaccine is designed to frighten parents about the disease.

In 1998, the Food and Drug Administration licensed a live rotavirus vaccine to block one cause of infant diarrhea, even though the vaccine has been shown to be only 50% effective.

The principal selling point used by public health officials in mandating the new chickenpox and diarrhea vaccines is not the health of the child, but that it will save working mothers money from wages lost if they have to stay home with a sick child. ("Cost-effectiveness Analysis of a Rotavirus Immunization Program," *JAMA*, May 6, 1998 p.1371, concludes that this factor accounts for 3/4ths of the alleged savings from the vaccine.)

More than 200 vaccines for a variety of diseases are now under development by drug corporations and government scientists, and there is much talk among government officials about more mandates. A prominent vaccine policymaker has said that all 12-year-olds will be targeted for injection with an AIDS vaccine when it is put on the market.

Can Vaccines Be Worse than the Disease?

The Economist, in an article entitled "Plagued by Cures" (Nov. 22, 1997, p.95), stated: "There is growing evidence that preventing diseases in infancy may be a mixed blessing. Can intervening in an illness sometimes be worse than doing nothing at all? . . . The first possible effect is the replacement of one disease by another. As the incidence of childhood infections has fallen, a number of chronic ailments, such as diabetes and asthma, have become more frequent. In parts of the world where childhood diseases are still common, these chronic ailments are rare. . . . Childhood infections do indeed seem to reduce the probability of chronic disease in an idea known as the 'hygiene hypothesis.' . . . The second possible effect of intervening in a disease is that the intervention makes the disease worse in the long term, not better. A number of viral infections are more dangerous to an adult than an infant."

Science News, in an article entitled "The Dark Side of Immunizations" (Nov. 22, 1997), reviewed several studies by New Zealand and by British researchers showing that vaccinated children have a higher incidence of asthma and diabetes than do unvaccinated children. The article notes that animal studies indicate that an absence of contact with naturally occurring viruses increases the risk of diabetes, and that research in humans suggests that some childhood infections may be advantageous in priming the child's immune system to fight off asthma.

A 1994 study suggested that the pertussis vaccination of infants may increase the risk of asthma five-fold during childhood. (Odent MR, Culpin EE, Kimel T., "Pertussis vaccination and asthma: is there a link?" *JAMA*, 1994; 272:591-592.)

None of this provides conclusive proof, so we need basic science research and large clinical studies, conducted by independent, non-government, non-industry-financed scientists, on the side effects and long-term effects of vaccines and of multiple vaccinations. But neither the government nor the drug corporations appears willing even to talk about this.

Who Should Decide a Child's Care?

When it comes to balancing risks versus benefits, it's not always obvious how to weigh the risks. Parents, not government politicians or bureaucrats, should be balancing the risks and benefits of vaccines for their own children based on complete information.

State legislators and state and federal bureaucrats are seldom physicians or scientists. They get their information from other unaccountable bureaucracies such as the CDC and from the lobbyists for the drug corporations. Scientists and physicians aren't infallible. When I was growing up, tonsillectomies were routinely performed on children. I now am glad my family couldn't afford that unnecessary surgery.

Freedom in America should include allowing parents to make their own informed choice about injecting their babies with potentially dangerous vaccines. Parents should do their own research. Helpful information about vaccines is available from a non-government educational organization: National Vaccine Information Center (NVIC), 512 W. Maple Ave., Suite 206, Vienna VA 22180; 1-800-909-SHOT; fax: 703-938-5768; www.909shot.com

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