Approved: 2-24-94
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by Chair Sandy Praeger at 10:00 a.m. on February 16, 1994 in Room 526-S of the Capitol.

All members were present except:

Committee staff present: Norman Furse, Revisor of Statutes
William Wolff, Legislative Research Department
Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:

Patricia E. Baker, General Counsel, Kansas Association of School Boards
Mrs. Monty R. Bertelli, Berryton
Tom Hitchcock, Kansas State Board of Pharmacy
Terrence Boyle, Drug Enforcement Administration, Overland Park
Carl Schmitthenner, Kansas Dental Association
Dr. Taylor Markle, Kansas City, Kansas

Others attending: See attached list

The Chair briefed the Committee on House Substitute for **SB 397** - a hospice certified to participate in the medicare program may be called a licensed Hospice - that was heard as **SB 397** during the 1993 legislative session. After Committee discussion, the Committee agreed to concur with the House subcommittee report.

Continued hearing on SB 575 - Inoculations of pupils

Pat Baker, KASB, appeared before the Committee and stated that while Kansas school districts support universal immunization for all children in the state, they oppose the provisions of **SB 575** that deal with mandatory exclusion of pupils because of not meeting immunization requirements. She noted that parents who do not ensure immunizations may not always ensure school attendance if that is not required by law, and that the bill excuses all those children from terms of the compulsory attendance law. (Attachment 1)

Mrs. Monty R. Bertelli, Topeka, appeared before the Committee and noted that she was not present to argue the pros and cons of vaccinating children, but her opposition to **SB 575** is that by removing one more of the already limited exemptions recognized by the existing law which is the personal grounds exemption, a parent who comes to the conclusion the dangers of vaccination outweigh the benefits will face almost insurmountable obstacles to enrolling that child in school without the vaccinations. Mrs. Bertelli told the Committee about her son who died within hours of receiving his first set of vaccinations. (Attachment 2)

Hearing on HB 2605 - Civil penalties for violation of pharmacy act on uniform controlled substance act or rules and regs, and grounds for disciplinary action against manufacturers or wholesalers.

Tom Hitchcock, KSBP, appeared before the Committee and submitted written testimony in support of **HB 2605**. He noted that the bill consists of three changes in the pharmacy act: (1) allow the Board to assess an administrative fine against any licensee or registrant, other than a retail dealer, in the amount not to exceed $500 for each violation of the pharmacy act or controlled substances act; (2) place the responsibility on the licensee to show of their rehabilitation to warrant the public trust following a felony conviction; and (3) allow the Board to sanction a manufacturer or wholesale distributor if they are found to be in violation of the pharmacy act or controlled substances act. (Attachment 3) Committee discussion related to provisions of the bill of which three sections were contained in 1993 **SB 84**.

There were no opponents to **HB 2605**.

Hearing on SB 715 - Uniform controlled substances act schedule changes

Tom Hitchcock, KSBP, addressed the Committee in support of **SB 715** which would change the Uniformed Controlled Substances Act and add the drugs aminorex and alpha-ethyltryptamie to Schedule I of the act. The drug levo-alphacetylmethadol is moved from Schedule I to Schedule II. The bill also moves all hydrocodone drugs from Schedule III to Schedule II, (SOMA) and adds the drug carisoprodol to Schedule IV. Such changes in the bill would bring the Kansas controlled substances statutes into compliance with the description and scheduling as found in the federal regulations of controlled substances. (Attachment 4)

Terrence Boyle, supervisory investigator for the Drug Enforcement Administration, appeared before the Committee in support of the bill and noted that since Oklahoma has placed the drug, soma, in Schedule IV, addicts are crossing the border into Kansas to obtain the drug here since it is presently a non-controlled substance in Kansas. (Attachment 5) Committee and staff discussion related to definition and scheduling of drugs as mentioned in the bill.

There were no opponents to **SB 715**.

Action on SB 715

Senator Hardenburger made a motion **SB 715** be recommended favorably for passage and placed on the consent calendar, seconded by Senator Langworthy. The motion carried.

Action on HB 2605

Senator Ramirez made a motion **HB 2605** be recommended favorably for passage, seconded by Senator Lee. The motion carried.

Hearing on SB 722 - Administration of intravenous sedation and general anesthetics by dentists

Carl Schmitthenner, KDA, appeared before the Committee in support of **SB 722** and noted that the bill provides the Kansas Dental Board with the authority to develop appropriate qualifications for dentists who administer intravenous sedation and general anesthesia in their offices as to assure the continued safety of the public. (Attachment 6)

Dr. Taylor Markle, certified oral and maxillofacial surgeon from Shawnee, Kansas, addressed the Committee and submitted written testimony in favor of **SB 722**. He noted that Kansas Society of Oral and Maxillofacial Surgeons has drafted proposed rules and regulations that the Kansas Dental Board may use and noted there are two levels - (1) conscious sedation and (2) deep sedation or general anesthesia. Each category would have different education and training requirements. Dr. Markle stated that within each category there is a grandfathering clause for those people who have used these anesthetics in the last three years and would like the Kansas Dental Board to determine the competency and regularity of the anesthetics given by these particular practitioners for proper licensure. (Attachment 7)

During Committee discussion it was pointed out that Kansas is one of three states that do not have any regulations in regard to conscious sedation and general anesthesia, and that an opinion from the Attorney General noted a grandfather exception cannot be added to the provisions of a statute by promulgating such clause through rules and regulations. Staff commented that specific language would be needed to cover this situation by statute, and the grandfather clause would be a blanket exception to the general rule as being created by the statute.

Also speaking in support of **SB 722** was an oral surgeon from Wichita.

The meeting was adjourned at 11:00 a.m.

The next meeting is scheduled for February 17, 1994.

GUEST LIST

COMMITTEE: SENATE PUBLIC HEALTH & WELFARE DATE: 2-16-94

NAME	ADDRESS	COMPANY/ORGANIZATION
Pat Baker	Topeka	KASB
Joseph Conroy	Emporia	KS Assoc Nurse Anesthetists
Donna Bales	Wichita	AKH
Carolyn Carter	Hutchinson	AKH.
Adrienne Bertelli	Topeka	
Taylor L. Marker	Shawnee	self
John Brammer	Wichita	Self
Carl Schmitt Hennen	Topeka	Kansas Dental Assn.
Kay Clark	Wichita	nurse anesthetist
Courtney Clark, M.D	"	Anesthesiologists
Jan Rose	Topeka	Social Work
KEITH R LANDIS	TOPEKA	CHRISTIAN SCIENCE COMM ON PUBLICATION FOR KS
Pat Johnson	Topeka	Ks State Board of Nursing
David Hanzlick	Topeka	KS Dental Assn
Stephen Zoller	Topeka	KDA
Robert Wood	Topeka	KDA
Carol Macdonald	Topeka	Kans. Dental Board
Marjorie Jantz	Prairie Village	Jo. Co. Comm. on Aging
Cathy Holdren	Seneca	self
Terri Roberts	KSNA Topeka	KSNA

KANSAS ASSOCIATION OF SCHOOL BOARDS

1420 S.W. Arrowhead Rd, Topeka, Kansas 66604
913-273-3600

575

Testimony on SB 525
before the
Senate Committee on Public Health & Welfare
by
Patricia E. Baker
Associate Executive Director/General Counsel
Kansas Association of School Boards

February 10, 1994

Madam chairman, committee members, thank you for the opportunity to appear on behalf of Boards of Education of Kansas school districts.

While Kansas school districts ardently support universal immunization for all children in this state, we oppose the provisions of SB 575.

Kansas schools may, currently, exclude students who are not immunized and many, by policy, do so. Schools have a long history of working with parents, health care providers and health departments to ensure protection through immunization.

The current law allows each school district to deal with unique circumstances which may occur. Transfer students, foster children, and unique family situations all call for flexibility. The local school officials are in the best position to respond.

We are particularly concerned about the mandatory exclusion of pupils at a time when schools are trying desperately to get kids into school and keep them there. School improvement efforts and especially

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attention to at-risk student needs mitigate against punishment of students for the failure of their parents or guardians to seek appropriate health care. We are concerned that parents who do not ensure immunizations may not always ensure school attendance if that is not required by law. SB 575 excuses all these children from terms of the compulsory attendance law. That is not good public policy.

We reiterate our willingness to work with local and state health officials to improve immunization rates. We urge the committee to consider alternatives to mandatory exclusion from school. Perhaps requiring health officials to do follow-up investigations where the immunization requirements are not met would more closely fit the problem. Making a health concern only an educational problem--does the children no favor and may do them harm.

We urge you to reject the provisions of SB 575 and not to punish children by depriving them of educational opportunities. Thank you.

STATEMENT IN OPPOSITION TO SENATE BILL 575

Monty R. Bertelli
5135 S.E. Tecumseh Rd.
Berryton, Kansas 66409

I wish to thank the Chairperson and the committee for providing me the opportunity to speak in opposition to Senate Bill 575.

I am not here today representing a state agency seeking to expand its power and control over the citizens of Kansas. Nor am I here as a lobbyist for a special interest group seeking to benefit by this legislation. Rather, I am here representing Zachary, a 4 year old boy who only wants to grow up in Kansas and receive the best education available. The passage of Senate Bill 575 will deprive him of that opportunity. For you see, Zachary is a twin whose brother died within hours of receiving his first set of vaccinations, and Zachary has not received, nor will he receive, any future inoculations.

This decision has not been made by uninformed, uneducated or uncaring parents. I am a a certified court reporter, and my husband is a college graduate with a law degree. As a result of our tragic experience, my husband and I have read more medical journal articles

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and studies on the subject of childhood vaccinations, especially DPT, than most pediatricians.

I am not here to argue the pros and cons of vaccinating children. I truly believe that if, after reviewing the literature, a parent makes an informed decision that the benefits of vaccination outweighs the dangers of the vaccine, that decision should be honored. My opposition to Senate Bill 575 is that, by removing one more of the already limited exemptions recognized by the existing law - the personal grounds exemption, a parent, who comes to conclusion the dangers outweigh the benefits, will face almost insurmountable obstacles to enrolling that child in school without the vaccinations. I find it objectionable that the state finds it necessary to hold a child's education hostage in order to coerce parents into vaccinating their children against their will. [I find it ironic that at the same time this committee is considering legislation that will prevent a child who wants an education from going to school, the House is discussing a bill that would pay children to keep them in school.]

There are legitimate "personal grounds" for a parent not wanting a child vaccinated. From the testimony on this bill, and the promotion of

the Kansas vaccination program, one is left with the impression that childhood vaccinations are safe. Such is not the case. As noted, my wife and I lost a son to the DPT vaccine. That is not an opinion or speculation, but the conclusion of a special master of the federal court in a lawsuit we commenced. That decision and the resulting monetary award were not appealed. This is not an isolated case. [See attachment #1].

Of the DPT vaccine, of which I am familiar, the Center for Disease Control, in its literature, states that one out of every 1750 shots administered will result in the child having seizures or shock collapse. Permanent brain damage or death has been estimated, by some authorities, to occur to 1 out of every 100,000 children, but that estimate has been placed as low as 1 out or every 15,000 children for brain damage and 1 out of every 35,000 children for death. (See attachments #4 & #5).

Since passage of the National Childhood Vaccine Injury Act (Public Law 99-660) in 1986, 1080 families have been compensated in the sum of $450 million dollars. There are presently 4056 cases pending.

By removing the "personal grounds" language from the law, only two exemptions remain; religious and medical reasons. The religious grounds are limited to a few denominations. And, as anyone who has dealt with a physician concerning obtaining the required medical statement will attest, the attitudes of the medical community provide a major obstacle.

This attitude is demonstrated by looking at the reporting of adverse reactions by doctors. Under the National Childhood Vaccine Injury Act, a vaccine adverse affects reporting system was established. Doctors are required by law to report any adverse affects to their patients which occur within 30 days of a vaccination. According to the FDA, for the 20 month period between March 1, 1990 and July 31, 1992, 17,221 such reports were filed; 2,500 were labeled serious by the FDA, including 300 deaths. Fifty-three (53) reports have been received from Kansas; forty-six relating to the DPT vaccine resulting in 34 injuries and 12 deaths.

A study conducted by the National Vaccine Information Center revealed that for the period January, 1989 through June, 1991 only approximately 13% of adverse reactions to the DPT vaccine were actually

reported. [See attachment #3]. Generally, when contacted, the doctors justified their lack of reporting the vaccination reactions by claiming the DPT shot had nothing to do with the child's death or injury. The doctors often cited information given out by the American Academy of Pediatrics and the Center for Disease Control that vaccines do not cause death or brain damage; so they feel justified in refusing to report.

With doctors holding this attitude, it is not hard to understand why it is difficult, if not impossible, to find a doctor who will provide the necessary medical statement exempting a child from vaccinations. Our case provides an excellent example. The doctor told us our son died from SIDS. Even after reviewing the coroner's report, hearing the expert medical testimony, and reading the material we gave him, the doctor refused to change his position. He insisted that we bring Zachary back for his vaccinations, and when we would not, he refused to continue as Zachary's doctor. This is not an uncommon reaction. [See attachment #2].

It has been argued that since Zachary suffered no ill effects from the first shot he should have nothing to fear by continuing the

vaccination series. Unfortunately, that argument fails to understand the nature of the DPT vaccine. As a Fresno, California newspaper reported, following a three month investigation, the DPT vaccine varies widely from batch to batch, even when produced by the same manufacturer, but the law allows all bottles of vaccine to be labeled with standardized information. In reality, the toxicity of the vaccine may vary as much as 450% between manufacturers and even between different batches by the same manufacturer. [See attachment #4]. This was corroborated in a 1990 article appearing in the Neuropediatrics medical journal, advising doctors of these facts. [See attachment #5].

From the prior testimony, it would appear that approximately 15% of Kansas children are not now vaccinated. I have not heard what portion of that 15% is composed of parents with personal grounds for not vaccinating their children, as opposed to a lack of financial resources, or concern for the child's welfare, or just procrastination. I believe a vast majority of that 15% fall within those latter three categories. Only a small percentage will avail themselves to the "personal grounds" exemption. There ought to be another, better way to

reach the children in those three categories without removing the "personal grounds" exemption from truly committed parents, or eliminating the discretion of local boards of education over enrollment.

I would like to conclude with what our doctor said during one of our conversations over whether the DPT shot killed our son. While not admitting that there was any connection, he stated that if there was, the fact that some children die or are permanently injured is the price society pays to protect the majority of its people. Well, I submit to you, that Adrienne and I have paid our share of that price, and we do not intend to make another payment with the life of our son Zachary. If this legislation passes, the State of Kansas may attain it sought after goal of 99% child vaccination, but it will do so not by coercing compliance but because his family has moved to one of the 20 states that still provide for philosophical objections. [See attachment #6].

Attachment #1

LIFESTYLES

Mary Winter, Lifestyles Editor ■ 892-5361

When vaccinations backfire

Injured kids' fund ignored, parents charge

By John Accola
Rocky Mountain News Staff Writer

Hundreds, possibly thousands of children stricken with vaccine-related disabilities may never receive money available to them because of government foot-dragging, lawyers and parent groups charge.

Since 1988, the federal government has awarded more than $50 million to 77 families of children who died or were brain injured after being vaccinated for diphtheria, whooping cough, polio and other childhood diseases.

But critics say the government has failed to get word of the program to other parents, and that many of those who now qualify for compensation will soon be ineligible to apply.

Brett and Julie Wilson of Colorado Springs, whose 8-year-old daughter Jade suffered seizures and permanent brain damage after two vaccinations, learned of the program by chance from an attorney friend in Wyoming. In April, the U.S. Claims Court awarded the Wilsons $4.5 million, the program's largest compensation award.

"It's a wonderful, compassionate system that will ensure Jade receives the special education and 24-hour care she needs for the rest of her life," says Wilson, a vocational rehabilitation counselor. "But it was an act of God that we ever found out about it."

Anthony M. Colantoni, a Chicago attorney who specializes in vaccine-related litigation, suspects there are hundreds of other vaccine-injury cases similar to the Wilsons'. Yet he says the agency in charge of publicizing the compensation fund, the U.S. Department of Health and Human Services (HHS), "has done precious little."

Of major concern is the Sept. 30 filing deadline for claims involving children who

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Frank Kummer/Rocky Mountain News

Julie and Brett Wilson and daughter Jade outside their Colorado Springs home.

Doctors stress most shots safe for infants, tots

How safe are childhood vaccinations?

Medical experts at the University of Colorado Health Sciences Center and The Children's Hospital stress that only in a very small fraction of cases does a vaccination result in a serious reaction.

Of seven vaccines given in various combinations — diphtheria, pertussis (whooping cough), tetanus, polio, measles, mumps and rubella — pertussis is the most debated.

Dr. Donald W. Schiff, a professor of pediatrics and past president of the Academy of Pediatrics, says children most at risk are those with neurological disorders, such as tuberous sclerosis, or infants susceptible to allergies or who have an ongoing illness, such as strep throat.

Dr. Mary Glode, a pediatric disease specialist at Children's, says as many as 70% to 80% of small children who receive a DPT vaccination will develop a mild fever and experience possible soreness and swelling at the shot site within 24 hours.

About one in 800 may experience seizure or seem tired and unresponsive. Doctors should be notified immediately in these cases, but even these symptoms rarely cause permanent damage, Glode says.

Other symptoms to watch for: extended crankiness, unusual sleeping patterns and a high fever.

The National Vaccine Information Center — operated by Dissatisfied Parents Together, a group that was instrumental in pushing through the National Vaccine Injury Compensation Program — has several brochures on vaccination risks. The group can be contacted at 128 Branch St., Vienna, Va. 22180. Telephone: 1-(703)-938-3783.

The federal government has also set up a toll-free information hotline for parents requesting information on the National Vaccine Injury Compensation Program. That number is 1-(800)-338-2382.

Colorado Springs girl won $4.5 million for vaccination injury

COLORADO SPRINGS — The spiral-bound diary Brett and Julie Wilson started in 1981 for their newborn daughter Jade is filled with memorable firsts.

But among the handwritten entries documenting baby Jade's first smile, tiny steps and spoken words are two events the parents will forever regret.

On a pink, flower-bordered page following "Routine Visits to the Doctor," Jade's diary notes that at ages 4 months and 6 months, she received two vaccinations for diphtheria, whooping cough (pertussis) and tetanus.

Today, she is mentally retarded and plagued by epilepticlike seizures — a victim of a rare inherited neurological disorder that medical experts say was aggravated by her two DPT vaccinations.

"What happened to us is every parent's worst nightmare," says Brett Wilson, 35, a vocational rehabilitation counselor for the handicapped. "Jade was a beautiful, healthy baby — a developmentally above-average child. Now she's lost her chance to lead a normal life ... and it was the vaccine that did it."

In the scientific community, the debate on whether childhood vaccinations actually cause permanent injury has yet to be settled. But in April, the U.S. Claims Court in Washington, D.C., found the evidence of vaccine injury convincing enough to award Jade $4.5 million.

The record award — four times the average judgment for a vaccine-related disability — will be paid out of a little-known, federal compensation fund set up in 1988 for children who died or showed injuries after being vaccinated for whooping cough and other diseases.

The National Vaccine Injury Compensation Program has been a godsend for Jade and her parents, who worry about the lifetime of special care Jade will need for her medical and physical disabilities.

For years the Wilsons had assumed their daughter's disease — a disorder called tuberous sclerosis (TS) that has a 50% chance of causing retardation — was unavoidable.

Jade received her vaccinations before and after her TS diagnosis in late 1981. And although she suffered spasms and abnormal sleep patterns within hours after both shots, doctors had played down any TS-vaccine link.

But on a visit to Wyoming six years later, Brett Wilson ran into Robert Moxley, a Cheyenne attorney he knew from his high school and college days. Moxley noted the parallels between a client's suspected vaccine-injury problems and Wilson's daughter.

From there, Wilson and Moxley tracked down Dr. Manual Gomez, a Mayo Clinic researcher who had recently completed a study concluding that children with TS should not receive immunizations, particularly the pertussis portion of the DPT vaccine.

Another medical expert at The Children's Hospital independently concluded Jade's TS seizures — as many as 120 a day — were aggravated by the vaccine, thereby increasing her chances of mental retardation.

Now 8, Jade is attending second grade at High Plains Elementary School with normal kids her own age. Although she requires tutors in the summer and an additional special education teacher in the classroom, her parents are strong believers in the mainstreaming concept.

Even with lots of professional attention, experts doubt Jade will ever be able to hold a normal job, live on her own or drive a car.

Nevertheless, Jade seems gifted with an indomitable spirit. "I hate it when the other kids call me dumb," she says. "And sometimes at night I pray for my seizures to go away. They're yucko."

Says her dad, "She's an amazing little specimen of human energy. We feel really blessed."

2-8 John Accola

Government program helps vaccine victims

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were killed or injured by vaccinations before Oct. 1, 1988.

"It's really tragic," says Colantoni. "This program is running on its second anniversary, and the vast majority of the people who could most benefit don't even know it exists."

The U.S. Claims Court reports a caseload of 297 vaccine-injury compensation claims — far fewer than the 3,000-plus claims health officials anticipated when the program was launched two years ago.

Still, HHS officials say their primary means of publicizing the program — notifying professional medical organizations, state and national bar associations — is effective.

Created by the National Childhood Vaccine Injury Act of 1986, the program compensates families of children killed or injured by seven vaccines that most states require for enrollment in school.

The no-fault program does not require parents to prove that the company that produced the vaccine or the doctor who administered it were negligent. Nor is proof required that a vaccination was the actual cause of death or injury.

Generally, as long as it is established that the victim suffered seizures, respiratory or cardiac failure, shock or a brain injury, or lost consciousness between three and 15 days after a vaccination, claims will be awarded.

Death cases qualify for a $250,000 lump sum. But there is no limit in non-fatal disability cases, in which awards are calculated by determining the cost of past and future medical and nursing care, education, and lost wages.

Attorney fees are restricted; to date, only about 4% of the roughly $50 million in awards has gone to lawyers.

Tullio F. Albertini, the federal official in charge of overseeing the National Vaccine Injury Compensation Program, denies the government has been negligent in notifying parents of the program or the upcoming filing deadline.

"The law says ... Health and Human Services shall undertake a reasonable effort to inform the public of the availability of the program. We believe we have done that," he says.

Albertini said he and other officials have been interviewed repeatedly by the media and that the department's nationally distributed newsletter has publicized the program. Most recently, the government set up a toll-free hotline number to provide information.

But Boston attorney Michael Hugo and Dissatisfied Parents Together, a group whose children have suffered severe reactions from vaccinations, feel so strongly about the information issue that they have sued HHS in federal court.

The May 17 lawsuit asks the U.S. District Court to order HHS publicize the program in public service announcements on television, newspaper ads and by distributing posters and fliers at public health clinics throughout the country.

Hugo, who represents a half-dozen Colorado clients with claims for vaccine-injury compensation, estimates that up to 40,000 children have serious but not necessarily permanent reactions to vaccinations.

But in the established medical community, there is still considerable debate as to whether vaccinations represent a potential danger to even a small fraction of the 57,000 American children who receive them every week.

Leaders of the American Academy of Pediatrics say there is no proof that childhood vaccinations cause brain damage or death. In a paper last January to the Institute of Medicine, academy spokesman Dr. Edward A. Mortimer said some medical researchers' studies linking the vaccine DPT (diphtheria, tetanus and pertussis) to brain damage and death has created an anti-vaccine atmosphere among personal injury lawyers and journalists "reminiscent of a Salem witch hunt."

However, Barbara Loe Fisher of the National Vaccine Information Center — operated by Dissatisfied Parents Together — cites a decade-old University of Southern California study that shows one in 875 DPT shots results in either a seizure or a shock-like reaction.

"There has been so little information in the past on the downside of vaccines that most parents don't know what the adverse reactions are," she said. "There are parents out there who don't even realize their children are vaccine-injured."

If the Sept. 30 filing deadline is missed, claims for injuries that occurred before Oct. 1, 1988, can still be pursued through traditional litigation — an often slow and expensive process that rarely results in judgment against vaccine manufacturers.

Hugo thinks it's likely HHS has been overwhelmed by the newness of the program.

Fisher, however, suspects a conspiracy. She notes that HHS officials opposed the compensation program when it was debated in Congress and that its own medical researchers refuse to recognize vaccine-injury cases.

"The government does not want to acknowledge the existence of these children," Fisher says.

"That's nonsense," replies David Benor, legal counsel for HHS. "Whether we believe (vaccinations cause injury) is not even an issue. We are administering a statute, and we're carrying out that responsibility the best way we can."

Gary Golkiewicz, one of seven court-appointed officials overseeing the claims hearings for the U.S. Claims Court, says the program appears to be doing what it was designed to do: Most compen-

This is the other baby who is buried close to my daughter just 2 years later.

e program

ston High School student, joins Michael Sullivan 'ayers in a skit about drug abuse. A program for :gh School was presented by The Improbable oholics and addicts emphasizing the problems in- using drugs. PHOTO BY BIZ PAYNTER

sion slated on arten planning

Weston ssociation School of or a panel indergar-

ther have sperience nd advis- ducational ren. The the publ- ibrary at Alphabet at 7:30

Country School, along with one of the Country School kindergarten teachers, will review the curriculum for the kindergarten year. They will highlight the success of the program in preparing children for elementary school.

Ready for kindergarten

Hildred Simons has been the director of the John Winthrop School for Young Children in Boston for 20 years. She will discuss what characteristics she looks for to determine whether a

Family discusses its DPT tragedy

BY MYRNA CHANDLER GOLDSTEIN
TOWN CRIER CORRESPONDENT

WAYLAND — Michael Vincent, the first-born child of Wayland native and town Park and Recreation Department employee Michael Lindeman, was born on Jan. 16, 1985. He died almost three months later only hours after receiving his first routine DPT (diphtheria-pertussis-tetanus) vaccination.

It was because of this tragedy that Lindeman and his wife, Kim, who is also a native of Wayland, were selected on March 15 to be one of seven families interviewed for a Channel 7 investigative report. The feature, which was taped on March 16 and is expected to air this week, will examine the controversy surrounding the DPT shot.

"My wife and I saw a Feb. 5, 1985, Barbara Walter's report on the vaccine," Lindeman explained. "As new parents we were very worried, and we questioned our pediatrician several weeks before Michael was scheduled to be vaccinated. She maintained that the shot was both necessary and safe."

"Michael received the shot at noon," Lindeman continued. "He became very pale and fussy. He developed a fever, refused to eat, and cried intensely. Eventually, by 8 p.m. he drifted off to sleep in his swing. Then I picked him up and placed him next to me on the couch. He was so listless. At 11 p.m. I put him into bed. I awakened at 5 a.m. and went to check him. At first I thought he was sound asleep. And then I knew he was dead. I tried CPR and called 911. They (emergency personnel) responded quickly but there was nothing they could do."

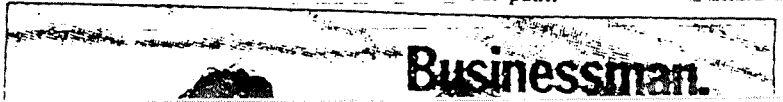
"We knew immediately," Lindeman, "that it was the shot. It was too much of a coincidence. He had a shot and less than 14 hours later he was dead. We had put our trust in the doctor. We do not believe that physicians know the whole story."

Received support

Lindeman and his wife received a great deal of support from friends, family, and community members, and they have tried to be of assistance to others whose children have experienced severe DPT reactions. "There is nothing we can do to bring back Michael, but we can help other families and help to educate the public about the problems with this vaccine."

As a result of The National Childhood Vaccine Act of 1986, which was described in the March 15, 1990, issue of the Town Crier, Lindeman and his wife have been "compensated" for Michael's death. The remuneration is meaningless to Lindeman. "Take the money and give me Michael. How can anyone put a monetary value on a child's life? We have participated in the compensation program because it was very important to us that they count him as a DPT death."

"We will live with the loss for the rest of our lives. We watch our other children so carefully — we know how precious each life is. I remember the day as if it were yesterday," Lindeman concluded. "Unless you have experienced the loss of a child you can not understand our pain."



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Parents Compensated for Vaccine Death

Inquiry by Wayland couple unveils disturbing data about DPT related problems

By Maureen O'Grady

Lee Ann Manley would have turned seven years old next month. But she died when she was eight weeks old from a reaction to a DPT vaccination, which is administered to children to protect them from diphtheria, pertussis — whooping cough — and tetanus.

The federal government recently compensated Lee Ann's parents, Wayland residents Martin and Janet Manley, for their daughter's death.

The Manley's are one of the first families to be compensated for a DPT-related death under the National Childhood Vaccine Injury Compensation Act, which allows parents of children who have been injured or killed by vaccines prior to October 1988 to submit claims for compensation.

Janet Manley says the $240,000 from the government, which will be paid to the family over a four-year period, does not matter as much as the fact that now it will be easier to get a count of damages and deaths which have resulted from the DPT shot.

There is a time and financial limit to the compensation program for victims who reacted before October 1988. The program will end after four years and a total of $320 million has been awarded for up to 3,500 children injured or killed by vaccines before October 1, 1988.

"I kept saying..."

"That's why the push is on to get people to file and to get an accurate count," says Manley.

When she remembers the day Lee Ann died, Janet Manley says she told the rescue crew that came to the house after Lee Ann's seizure that her daughter must be reacting to the shot she had received three hours earlier.

"I kept saying, 'She just had a DPT shot, she's having a reaction.'"

But doctors attributed Lee Ann's death to Sudden Infant Death Syndrome, or SIDS.

"They said it had nothing to do with the shot. And I was willing to accept it was SIDS, that it was nobody's fault. But the shot still haunted me."

After doing research and talking to other parents who had similar experiences, Manley says she learned several things and saw "too many coincidences" between SIDS cases and DPT shot reactions.

Wayland's Janet Manley holds a picture of her daughter Lee Ann, who died seven years ago after her first DPT vaccine.

PHOTO BY OTA RICHTER

For example, two years after Lee Ann's death, an infant named Michael Lindeman was buried next to her in the Wayland cemetery, an official victim of SIDS, but one who died just hours after his first DPT shot.

Benefits & risks

"That's at least two victims right here in this small town," she says. "Who knows how many more there are?"

Other things Manley says she has learned:

- For years, doctors have known that the vaccination can cause severe reactions such as permanent brain damage, seizures and even death. But the vaccine is still used because of the philosophy that "the benefits outweigh the risks" and doctors often do not tell parents about the risks.
- Japan uses an acellular pertussis vaccine, which does not contain the actual cells of pertussis bacteria and which has caused fewer reactions than the American whole cell vaccine. But no real comparison between the two vaccines has been completed yet.

U.S. researchers say no one can make decisions about a new American vaccine until the effectiveness of the Japanese vaccine is determined.

Doctors may be in the dark

In addition, lack of funding has slowed down research.

- DPT shots cost at least 25 times more today than they did in 1982, with manufacturers citing rising liability costs and critics saying manufacturers are using the liability factor to make a profit.
- Federal government regulations allow manufacturers to have a 450 percent toxicity variation from batch to batch of the vaccine.

"Sometimes even the doctors don't know how toxic a batch they're using," Manley says. "Even the hot lots, the very bad batches that cause the most reactions, pass regulations. ... We're still living in the dark and it's up to the government to say to the manufacturer that they have to come up with a safer vaccine."

- The largest percentage of children with whooping cough have had the pertussis vaccine which is supposed to prevent the illness.

Manley says she has met many people who have had whooping cough who are "alive and well today" because of antibiotics.

"I don't doubt that if Lee Ann had had whooping cough, she'd be alive and well today. I can't tell anybody to get the P part of the DPT shot."

Manley had three children after Lee Ann's death and none of them have had the the P part of the shot.

She says Lee Ann's death has made her "more leery" of the medical field.

"I respect doctors, but I don't feel as if they're God and I look into things more. Children make you stronger because you stand up for them.

To get a parent information packet about the DPT shot and possible reactions, parents can send $5 to DPT — Dissatisfied Parents Together — 128 Branch St., Vienna, Va, 22180. It is not an anti-vaccine booklet and has been approved by the Centers for Disease Control.

2-11

In memory of Lee Ann

Wayland's Janet Manley has been fighting to prove her infant's death happened because of a reaction to vaccine

By Sean Smith

PHOTO BY JOHN MOTTERN

Janet Manley poses with her children, Julie (left) and Kelly, next to a photo of her daughter, Lee Ann, who died three years ago. The photo was taken the day before Lee Ann's death, which Manley believes could have been caused by an inoculation.

Three years later, Janet Manley still remembers the scream.

The scream was louder than loud, she recalls, and it seemed to pierce the very walls of the doctor's office. The scream came from the mouth of her eight-week old daughter Lee Ann, as she received her DPT (diptheria-pertussis-tetanus) vaccine shot, the same kind of shot that millions of American children are inoculated with each year. Although Manley expected Lee Ann to cry from the pain and surprise of the needle prick, Manley grew alarmed at the intensity of her daughter's crying.

"Almost as she received the shot, her back arched and her eyes rolled up," says the 32-year-old Wayland mother of two, recounting the event in a quiet, straightforward voice. But it was the scream which was even more horrifying to Manley. "It was like a nightmare, the kind where you scream and no sound comes out? That's what it seemed like."

Within hours, Lee Ann Manley was dead of what was then diagnosed as Sudden Infant Death Syndrome (SIDS), and her mother's quest for answers — and for accountability — began. The impetus behind her search was a growing conviction that the DPT vaccination could have caused Lee Ann's death, laced with frustration at what she felt was the inability or even unwillingness on the part of the medical profession to consider that possibility.

That belief has lent a special poignancy to the efforts of Manley and Martin, her husband of five years, to overcome one of the greatest traumas known to adults: the loss of a child, especially one so young. But over the past three years the Manleys — particularly Janet — have channeled their emotions into action, by taking part in a national alliance of parents who share their concern about the safety and effectiveness of the DPT vaccine's pertussis (whooping cough) portion.

Activism born of bereavement can be an outlet, a catharsis, but it also has the potential to create more pain and frustration; as Janet Manley has found, the world doesn't always change, no matter how fervent the plea. But if her quest is not yet fully realized, she feels no regrets for having begun it, she says, because it has set her priorities straight and opened up her world.

"I did learn what it's like to lose someone you love," Manley says. "I never knew how to react to someone who had had a family member or a loved one die. I didn't know what to say to them or how to act. Now, there's a common understanding, especially among parents whose children have died. There's a special closeness to all of them, and I do feel the pain with them, and I know they feel it with me. It's kind of a relief knowing there's someone else who understands without having to put it into words. *No one* can understand it unless they've been through it."

Janet Manley has always considered herself a strong-willed person, and believes "we were

Continued on page 10

Lee Ann

Continued from page 1

all put here for a purpose."

But she hadn't foreseen becoming an advocate for safer vaccination, she admits — she and Martin were trying to accept that their little girl, their first child, was gone.

The loss had devastated them, Manley recalls. The night Lee Ann had died, she says, "we decided we might go jump off a bridge together. . . it might sound sick, but at the time we both laughed: you know,'Oh, we'll all be together.' I've heard of other cases like that, and I can understand it, because that's the easy way out — the hard way is to go on living without them."

Life after Lee Ann *was* hard, Manley says. She had to attend the funeral wearing a maternity dress, because she wasn't able to fit into her regular clothes yet. She and Martin had to clear out the room they had prepared for Lee Ann only a few months before, store away the crib and the kiddie toys, and Janet notes that they would still wake up out of habit during the night at what had been Lee Ann's feeding times.

Meanwhile, something continued to nag at Janet Manley. It was the inescapable feeling that the shot Lee Ann received that day had been at least partly responsible for her death. On the face of it, the idea seemed implausible: the DPT vaccine has been in use since the early 1950s, and is a customary part of childhood inoculations; what's more, it has been credited with the sharp drop-off of pertussis cases, which were responsible for an estimated 7,000 infant deaths a year in the U.S. before the vaccine came into use, according to Lynn Mofenson, director of communicable disease control for the state Department of Public Health. In 1985 there were 50 reported cases in the commonwealth, says Hofenson.

Manley says she was rebuffed when she brought up the fact of Lee Ann's reaction to the shot, first by the rescue squad who came to take Lee Ann to the hospital, then the doctor who tried to save her, and finally the coroner who performed the autopsy on Lee Ann. The pertussis vaccine

Continued on next page

PHOTO BY JOHN MOTTERN

"The hardest part about losing a child," says Janet Manley, "is to go on without them as if they never existed."

From previous page

has been cited as causing a certain amount of discomfort to children, including swelling and fever, but more extreme reactions — like convulsions or brain damage — have been very rare, according to most available medical research.

What grated on Manley was that no one seemed willing to even look into the possibility that Lee Ann might have died from the DPT shot. Instead, she says, the doctors simply diagnosed it as a case of SIDS, and that was that. But Manley couldn't shake the feeling that there was more to it.

Several months later, Manley says, her mother told her she had heard something about DPT, and urged Janet to do some research. She read through newspaper articles and some medical studies, she says, and "there it was: this shot has been *known* to kill some babies. It's very high in toxicity, the batches vary drastically, yet they're all labeled the same. . ."

Reading on, Manley says, she discovered that reliable data on vaccine injuries is hard to come by, because gaps occur in relaying important information: parents, uninformed about the possible side-effects of an inoculation, don't report reactions to their doctors; doctors may not recognize a severe reaction, or may not believe that one is taking place and make a different diagnosis, and do not report incidents to health authorities and so on.

As a result, Manley says, she learned there is a disparity of opinion as to the extent of DPT-related trauma and death. Government studies put the frequency of brain damage from the vaccine at one in 310,000 shots; another study estimated it at one in 110,000 and others used figures like one in 15,000 or one in 875. But the variance in numbers didn't matter so much to Manley as what they were saying: that a DPT shot could very well have caused her daughter's death.

"I knew in my gut that the shot had had something to do with it," she says. "But I was willing to accept that it was

Continued on next page

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Lee Ann

From previous page

SIDS and go on from there. But when I realized that a shot, which has been known to kill, was given my baby and she died, and no one even wanted to acknowledge the *possibility* of a connection. And the fact that it could have been prevented, it could have been avoided, and I could have my little girl here today, is sick. If it's happened to me, it could happen to somebody else."

Manley found most of this information through a Virginia-based group called Dissatisfied Parents Together (the acronym is the same as the vaccine's). The group does not condemn vaccinations wholesale, Manley says, and is not out to antagonize the medical profession. Instead, she says, they feel more information about vaccines should be available to parents and doctors, so they may make informed decisions about how and when a child should receive an inoculation.

"Lee Ann had been getting over a cold," Manley says. "Maybe, if the shot was delayed, she would have been stronger — it wouldn't have hurt any to delay. All I know is, if the doctor had said to me 'Listen, I should tell you that this shot has been known, in rare cases, to cause brain damage or death,' I would have said 'Whoa, hold on, let's look at this.'"

Along with public education, the DPT group also advocates the manufacture of safer vaccines, adds Manley, who is no longer as active with the group as she used to be — having two small children to take care of limits her time, she says. And recently, she notes, the President signed into law a bill the DPT group had pushed for, which among other things mandates a more formalized system for reporting suspected vaccine reactions, and establishes some federal compensation for children injured by vaccines.

"The DPT organization is not anti-vaccine," Manley says. "They are pro-safer vaccine and a less reactive vaccine. We all want to believe that vaccines are for the good of all and for the safety of our children."

Lynn Mofenson, director of communicable disease control for the state Department of Public Health, says the state is not unaware of the concerns voiced by Manley and the DPT group (Mofenson says she cannot comment on specific cases, like the Manleys, especially if she is unfamiliar with them). In Massachusetts, she says, the vaccine is manufactured under strict supervision of the Department of Public Health. Furthermore, she adds, the laboratories which process the vaccine have sent out advisories stating which children should receive DPT shots and which should defer theirs. All the while, new vaccines are constantly being considered and evaluated, Mofenson says.

In the end, though, Mofenson says the questions surrounding the DPT vaccine come down to a matter of risks versus benefits. "By the very fact that immunization is introducing a foreign substance into your body, there *is* a chance for a rare reaction," she says. "We're talking about very infectious diseases: if someone with pertussis coughs in a room full of unimmunized persons, 90 percent can get it. But I very much support educating consumers, and I support people asking questions. . . I have a four-year-old daughter, so I've had to go through the same process."

Manley believes in God, she says, believes in Heaven, and feels Lee Ann is in "the safest place" of all. "Yet, I feel I can make good of her death by, in some way, helping someone else," she says. "So I do feel like her life had a purpose, and maybe her one little life is going to mean many other lives — even if it's just one other life, I'll feel happy."

Pursuing answers in the aftermath of tragedy

By SUSAN LA TOUR

WAYLAND — The death of her granddaughter following what was to have been a routine visit to a pediatrician last year shook Donna Gary and set her on a path that has taken her beyond Wayland and private grief.

She has become a crusader in a public debate involving the medical community, vaccine manufacturers, lawyers, damaged children and aggrieved parents.

Gary believes that pertussis (whooping cough) vaccine caused the death of her eight-week-old grandchild, Lee Ann Manley.

In June she appeared on the television show "People Are Talking" and on Sept. 10 she was in Washington, D.C., to testify for a second time before a congressional hearing.

At these hearings, she talked about what happened when her granddaughter received her first diptheria-pertussis-tetanus (DPT) shot as part of a five-dose immunization series that is required by law of all children before they enter kindergarten.

The baby, said Gary, reacted immediately with arched back and high-pitched screaming. Afterwards, she was inconsolable, said Gary, and within four hours she was dead.

Autopsy questioned

An autopsy was performed and the cause of death was listed as Sudden Infant Death syndrome, also known as crib death, but Gary wondered if the shot were responsible. She began talking with people and reading everything she could find on the subject.

"It didn't take long," she said, "to realize that a problem exists that not only affects us but innumerable others as well."

The problem she saw was adverse reactions to mandatory shots, particularly the pertussis vaccine, which can produce serious responses ranging from high temperatures to death. In cases of what Gary calls a "living-death," some children end up with severe, permanent neurological disorders. They may be mentally retarded, have ongoing seizure problems and be handicapped in other ways.

Adverse reactions to the vaccine occur more often than many realize, said Gary, because physicians are not required to report adverse reactions. Also, there is no national agency that is compiling the data.

"As a parent, as a grandparent," she said, "I suddenly wanted to warn everybody."

Through her readings she discovered Dissatisfied Parents Together, a national citizens' organization headquartered in Washington, D.C., that was formed about two and a half years ago. It seeks to educate people, particularly parents, about risks relating to the disease of pertussis and to its vaccine so parents working with a physician can decide if a DPT shot should be postponed or waived.

Other goals

It is also lobbying for a safer vaccine, for better recordkeeping of adverse reactions and for compensation to those who are suffering as a result of the vaccine.

When Gary found out about the group and learned that it was doing just what she wanted to do, she knew right away, she said, that it was important for her to start a New England chapter. She took that step this summer and now coordinates the New England chapter of Dissatisfied Parents Together, which has a mailing address of P.O. Box 3403, Framingham, Mass. 01701.

Gary emphasizes that she and the organization are not anti-vaccine. "We're pro a safer vaccine," she said.

Commenting on the safety of the pertussis vaccine, state epidemiologist Dr. George Grady said, "We have to realize that we live in a society that has risks. There's no such thing as a vaccine that's 100 percent safe and there never will be." There are risks whenever the body is injected even if the substance is sterile water, he said.

Grady said he sees the issue from three points of view, as a father, a practicing physician and a public health official. As a father he did not hesitate to have his three children receive their DPT shots. As a physician, he's aware, he said, that pertussis can cause agony in small children and death when prolonged coughing "quite literally causes a child to cough its lungs out," gasping for breath through inflamed airways.

Protecting society

In his role as a public health officer he is concerned about what will happen if parents in increasing numbers refuse to have their children immunized against the contagious disease.

The vaccine was introduced to the United States in the late 1940s. According to Dr. Martin Smith, pedicatrician and president of the American Academy of Pediatrics, 265,269 children caught whooping cough in 1934 and 7,518 died, whereas today fewer than 5,000 cases, involving 45-50 pertussis-related deaths, are reported annually.

Smith testified on behalf of the academy at the Sept. 10 congressional hearing for a bill that would give financial compensation to vaccine victims. Proposed jointly by the academy and Dissatisfied Parents Together, the bill also focuses on vaccine research and a national system for recording adverse reactions.

Smith told the hearing that as the pertussis vaccine was used and the incidence of the disease was severely reduced, public concern about whooping cough tended to wane and worries about rare reactions to the vaccine mounted.

In the 1970s, he said, concerns and publicity regarding a few vaccine reactions in Britain and Japan eroded their immunization programs. Both suffer annual epidemics of pertussis, said Smith. Each country has reported thousands of cases and 35-40 deaths per year, he said.

High risk children

However, Smith feels the vaccine should be deferred under certain circumstances, for example, if a child has a personal history of convulsions or conditions that would predispose the child to seizures. The series of shots should be discontinued, he said, if there is a severe neurological reaction, persistent, unconsolable screaming for three hours or more, a shock-like state, an allergic reaction or a temperature of 105 or more within 24 hours of the shot) that is unexplained by other causes.

Smith said that statistics show that there will be approximately 50 serious, permanent neurological disorders a year resulting from the pertussis vaccine.

That toll, he said, "is inevitable if we are to maintain an immunized population."

Dissatisfied Parents Together is comprised mainly of parents or relatives of children who are part of that toll and it recommends that the vaccine be postponed if a child is not well at the time the shot is to be given. It also feels that the list of high risk children should include those with family (not just personal) histories of neurological diseases and those who have severe allergies, particularly milk allergies.

Both Smith and Grady believe that there should be a national system for compensating the children who have been injured by participating in mandated immmunization programs.

"These children are soldiers injured in the defense of their country," said Smith.

The legal avenue

As it now stands, he said, vaccine victims receive compensation only if legal steps are taken which are based on proving fault on the part of the producer or the administrator of the vaccine. "In fact, there is most often no fault on the part of either party." Litigation is slow and costly and a large part of it goes to the legal process, he said.

Litigation has made several pharmaceutical companies decide to stop producing pertussis vaccine and now the only private United States-based manufacturer is Lederle, which reports that it is facing spiraling and unpredictable costs because of lawsuits.

Many within the medical community feel this threatens the supply of vaccine. Others, including Gary, hope the lawsuits will pressure manufacturers to produce a safer vaccine.

In Massachusetts several lawsuits are either filed or in the wings.

Much of the pertussis vaccine that is used in Massachusetts is produced by the state. Massachusetts and Michigan are the two states in the country that produce their own vaccine.

Lee Ann Manley's parents, who live in Wayland, have taken steps which could lead to a lawsuit that would charge the state with negligence in the manufacture and distribution of the pertussis vaccine, said their lawyer Michael Hugo, who's with Jenner and Benjoya in Boston.

According to Hugo, there are about 100 of these suits pending or being filed across the nation and Jenner and Benjoya is handling five of them.

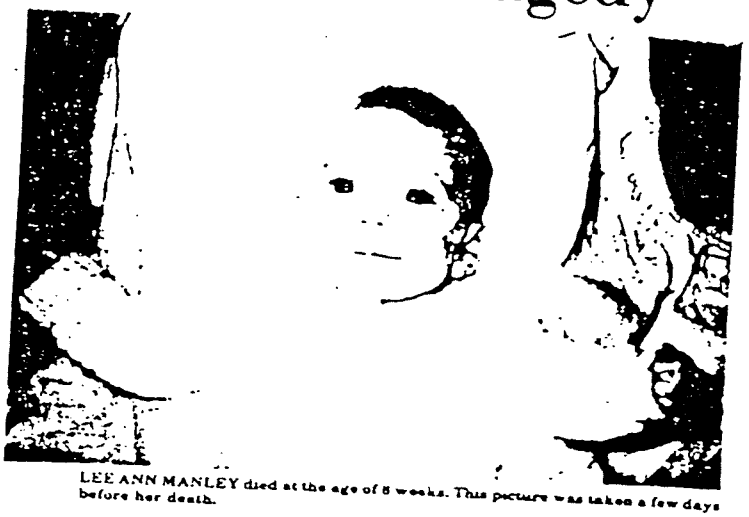
Heightening awareness

For Gary, the legal arena per se is not the center of her focus. She is committed to making both physicians and parents more aware of the pertussis problem.

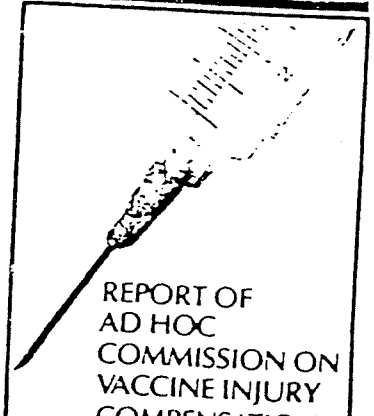
The information sheet which the New England Chapter of Dissatisfied Parents Together sends out for $3 concludes:

"It is important for us, as parents, to be equally concerned and knowledgeable about the risks of pertussis disease as we are about the risks of the current pertussis vaccine. Pertussis disease has the potential to cause seizures, brain damage and even death, just as the pertussis vaccine can. Most of America's medical community believes that the risk of serious illness or death from the highly infectious pertussis disease is far greater than the possible effects which can be caused by the vaccine."

"However, recognition of and concern about the dangers of pertussis disease do not diminish our need and responsibility to recognize and be concerned about the dangers of the pertussis vaccine. The challenge today is for parents, physicians, scientists, manufacturers and health officials to recognize the risks of both the disease and the vaccine and work together to assure production of a safer, effective pertussis vaccine for America's children."



LEE ANN MANLEY died at the age of 8 weeks. This picture was taken a few days before her death.



DPT SHOTS, which immunize children against diptheria, pertussis (whooping cough) and tetanus, are required by law. The pertussis component of the shot can cause severe reactions and is the center of a debate that involves public health officers, doctors, lawyers, vaccine manufacturers, damaged children and aggrieved parents.

scene from beacon hill

Will a new image for the MDC help matters?

By REP. ROYALL H. SWITZLER

Have you noticed that the Dukakis administration has recently undertaken a new campaign to spruce up the image of whits, instead of the familiar dirty vehicles of green and black. The name has also been changed from MDC Police to Metropolitan Police or Metro for short.

The projections of cost are in the range of $500 million in the first year.

The second proposal is for the Metropolitan Water Resources Authority, a semi- metropolitan or "wholesale" portion - will be recovered. Costs associated with the running and the upgrading of the local de-

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AN OPEN LETTER TO PARENTS

1705

[Donna Middlehurst is the treasurer and corresponding secretary for DPT, the wife of DPT president Jeff Schwartz, and the mother of Julie Middlehurst-Schwartz. Julie was three years old when she died in status epilepticus in the spring of 1984. She went into her first grand mal convulsion within hours of her third DPT shot and, until her death, suffered uncontrollable convulsions. Following is an open letter to parents from Donna.]

Dear Parents,

For the past two years in my capacity with DPT, I have read letters from hundreds of families describing their child's death or serious reaction to a DPT shot. During that time, I also coped with my daughter's problems. Then the unthinkable happened to my husband and me. Five months ago, I held my daughter in my arms for the last time. She was wrapped in a green hospital sheet in the shock-trauma room at Phoenix Childrens Hospital. As I looked at her sweet face, the face of a little three year old girl who only hours before had been her lively, mischeivous, funny, happy, alive self, all I could do was hold her cold body close and say, "Julie, I am so, so sorry."

A few months ago on Memorial Day, I was filled with anger and bitterness as I watched the cermonies honoring the unknown Vietnam soldier. When our nation engages in a military war we count the dead and wounded. We set aside one day a year to remember them and their sacrifice. We build monuments, however belatedly, where people can come and see the names etched in black granite and think about the costs of our wars.

But in the war against this particular disease, my child is a casualty and no one cares. The medical professionals, the drug companies, the government health officials don't care that this vaccine is killing and injuring our children. They don't want to know about it and they don't want to do anything to stop it. It is hard enough to go to hearings and read medical articles and see children treated as numbers, statistics. It is even harder not to have them counted at all.

There is a war going on. It is true that we are winning the war against disease but no one is counting the bodies of the dead and wounded or honoring them in any way. No one is asking, does the cost in this war have to be this great? Is there some other way we could fight it?

As a parent, I never thought that I would have to read my child's autopsy report or make burial arrangements for her or attend her funeral. It is just not right, just as it is not right for a parent to have to contemplate institutionalizing a child that can never take care of himself or herself.

I want to thank all the parents who have helped draw attention to this issue. I hope parents who have not done so will educate themselves so that they can reduce the chances of this happening to their child, their grandchild, their neighbor's child and the child in front of them in the line at the supermarket. But after you have met your own needs, I hope that you will join with us to change the situation. Don't leave the fight to those of us who are already weakened by this tragedy in our own lives. Join us. We need you.

- Donna Middlehurst

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WAYLAND WESTON
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National Vaccine Act important to Manley

BY MYRNA CHANDLER GOLDSTEIN
TOWN CRIER CORRESPONDENT

WAYLAND — The passage of the National Childhood Vaccine Act of 1986 and its implementation on Oct. 1, 1988, has a special significance to Wayland resident Janet Manley. This act, which is concerned with monitoring the administration of vaccines and "compensating" victims, will now provide the family with some remuneration. "Of greater significance," Manley explained, "is that it will ensure that there are more reliable statistics on deaths and serious disabilities caused by vaccines." It can, however, do nothing to bring back Manley's infant daughter, Lee Ann.

In May 1983, when Lee Ann was only 8 weeks old, she had a routine well baby physical. Although Lee Ann had a small cold, she was generally a cheerful and contented baby who was in good health. As part of her medical examination, Lee Ann was given a DPT (diphtheria-pertussis-tetanus) vaccination. Manley is still haunted by Lee Ann's response to the shot — a sharp, piercing, bone-chilling scream. "She arched her back and her eyes rolled up," Manley remembers. "At home, it was almost impossible to console her. Finally she cried herself to sleep. A few hours later she was dead."

Although Lee Ann's death was officially classified as SIDS (Sudden Infant Death Syndrome), Manley is convinced that the pertussis (whooping cough) portion of the DPT vaccination was responsible for the loss of her first-born child. With the assistance of her mother, Manley has become actively involved with Dissatisfied Parents Together, a national citizens organization that attempts to educate people about potential vaccine risks and complications. It is this group that has been instrumental in the passage of the National Childhood Vaccine Injury Act of 1986.

The DPT vaccination has been part of routine pediatric medicine since the 1950s, and it has been credited with dramatically reducing the incidence of pertussis cases in the United States. Statistics indicate that before the development of the DPT vaccination approximately 7,000 children died each year of pertussis.

Differences in toxicity

Dissatisfied Parents Together, according to Manley, is not against the DPT vaccine. It is opposed to the huge disparity of toxicity that is permitted between different batches, and the lack of reliable medical research and statistical evaluation that this vaccine has received.

Some government statistics, Manley continued, report that one in every 310,000 DPT shots will result in a brain damage. Other studies estimate that the frequency

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$816,663 override

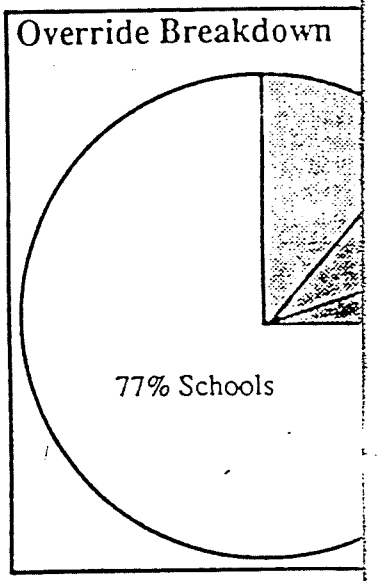
Selectmen vote 4-1 to 'bundle' the question

BY ANNE HARDING
TOWN CRIER STAFF

WAYLAND — Voters will be faced with a single $816,663 override question this April 24, along with a $10,000 debt exclusion to fund stopgap repairs to Sherman's Bridge.

Monday night, selectmen pared down $848,868 worth of override requests from 14 departments approved by the Finance Committee last week. Voting on each request one by one, the board said no to $3,000 for selectmen, $12,720 for the highway surveyor (to pay for a new van), $1,485 for the Conservation Commission and $25,000 for the Joint Communications Center (to replace the department's ailing tape recording machine).

From five override requests not approved by the Finance Committee, selectmen chose to add



$10,000 for hazardous waste collection to the override. Currently, the Highway Department has $10,000 in its budget for hazardous waste collection, enough for one hazardous waste collection day. The override would pay for one more day. The department had requested an additional $30,000.

If the question passes, it will add 65 cents to Wayland's current ta

Schwoegler inaugurate

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BY ANNE HARDING
TOWN CRIER STAFF

WAYLAND — Lake Cochituate's gotten dirtier since Bruce Schwoegler moved to its shores 16 years ago.

The pea soup green of the lake in August is a local manifestation of how the world's mushrooming population is making itself felt in the environment; the increase of global temperatures by one degree during

Manley

CONTINUED FROM WAYLAND'S PAGE 1

is actually one in 110,000 shots. Still other research indicates that the incidence is really one in 15,000 shots or one in 875 shots.

"We are not against the medical profession," Manley stressed. "We simply do not believe that physicians know the complete story about the DPT vaccination. We believe that many parents do not report DPT reactions to their physicians, and that doctors may not always correlate a child's illness with the shot."

Manley hopes that The National Childhood Vaccine Injury Act will help to improve the quality of the vaccine and provide more accurate statistics of its effects.

According to material provided by Dissatisfied Parents Together, the act provides for the creation of "safety provisions for the administration of vaccines to help prevent future vaccine injuries, and a mandate for federal health agencies to promote the improvement of existing vaccines and develop safer vaccines." It also establishes "a no-fault federal compensation system alternative to suing vaccine manufacturers or physicians on behalf of individuals who died or suffered brain damage from reactions to mandated vaccines (diphtheria, pertussis, tetanus, mumps, measles, rubella, polio)."

Five elements

The safety reform section of the law consists of the following five elements:

- All doctors who administer vaccinations are required to report certain vaccine reactions to federal health authorities. (In the past, the reporting of vaccines reactions was

subtracted from the compensation award to an individual or his legal representative but is paid directly to the attorney by the court."

Persons who wish to file a claim for vaccine injury or death should contact the U.S. Claims Court, 717 Madison Place, N.W., Washington, D.C. 20005 or telephone 202-633-7257.

Between Oct. 1, 1988 and Nov. 1, 1989, 184 claims for injuries and deaths from vaccines were filed in the U.S. Claims Court. Of these, 107 were reviewed and 27 were recommended for compensation. As of Nov. 1, 1989, 15 cases had been paid compensation ranging from $156,456 to $1,052,171. In most of the pending cases the court was awaiting further relevant material.

Additional information on the DPT shot may be obtained from the nonprofit National Vaccine Information Center, 128 Branch Rd., Vienna, Va. 22180. Of particular interest to parents is the "Parent Information Booklet" ($5). It is a 27 page publication which "details facts about your family history and your baby's own situation to determine whether the DPT shot should be postponed or perhaps not given at all." It also lists the "types of serious adverse reactions and what to do if one occurs." Finally, the booklet describes "your rights regarding reporting a serious reaction and medical exemptions from further DPT shots."

Looking for a safer vaccine

BY MYRNA CHANDLER GOLDSTEIN
TOWN CRIER CORRESPONDENT

WAYLAND — The story of the Manley tragedy is very painful to hear. Lee Ann arrived at the physician's office in May 1983, with a small cold. She received a physical examination and a DPT vaccination. Within four hours, Lee Ann was dead.

What then should parents do? What will happen if large numbers of parents fail to immunize their children for pertussis? Is there a safer alternative vaccine?

Representatives of the Massachusetts Department of Public Health are very concerned that if the public fails to immunize its young population then "large numbers of children will become sick with pertussis and die."

In a telephone interview, Mary Ann Hart, spokeswoman for the Massachusetts Department of Public Health, commented that in 1984 there were 20 cases of pertussis in Massachusetts. "Because some parents are not immunizing for this disease, there were 317 cases of pertussis in 1989. That is a very dramatic and disturbing rise."

Hart reported that during the past two years (1988, 1989) there have been no deaths in Massachusetts from pertussis. "But between 1985 — 1987 there were three deaths."

The vaccine, Hart said, is most effective in early childhood. "As children get older the effects of the vaccine wane. By the time people have reached adulthood, they may catch pertussis. In adults pertussis is more like bronchitis; many cases of pertussis may then pass the disease on to children who will get very sick."

Hart said that 99.05 percent of all Massachusetts children are immunized for pertussis.

Susan Lett, the medical director of the Massachusetts Immunization Program, reported that there is very little deviation in the toxicity levels of the different batches of pertussis vaccine. "We test the vaccine here and then we send samples of each batch to the FDA (Food and Drug Administration). They check the vaccine again and then return it to us. The Massachusetts pertussis vaccine has a very low toxicity level and is better than those made commercially."

Serious reactions

Nevertheless, there are some very serious reactions to the vaccine. As a result researchers in Japan and Sweden have developed new types of pertussis vaccine which are known as "acellular vaccines." Unfortunately, Lett said, there are several problems with the acellular vaccines. "Studies indicated that many of the people who were vaccinated with these came down with the disease. The efficacy rate of the acellular vaccines was only 45 to 60 percent. The people immunized with this vaccine also tend to catch serious bacterial diseases. We are concerned that these acellular vaccines may compromise an individual's immune system."

There is also a need, Lett continued, for an adult pertussis vaccine. "Adults represent 70 percent of the people who catch pertussis."

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accine reactions in an individual's ermanent medical record.

- All doctors are required to e e pa ecord of the date that each vaccination was given; the manufacturer's ame and lot number; the signature of the person administering the vaccines; the address where the vaccine was administered; and the professional title (M.D., R.N.) of the person administering the vaccine.
- Doctors must provide parents with information about childhood diseases and vaccines prior to vaccination.
- The act mandates that the federal government promote the improvement of existing vaccines and develop safer vaccines.

The National Childhood Vaccine Injury Act of 1986 includes a provision for compensation. "All individuals or legal representatives of children who have died or been permanently injured by diphtheria, pertussis, tetanus, measles, mumps, rubella, and polio vaccines are eligible to apply for federal compensation. Injuries must have lasted for at least six months in order to be eligible."

It is important to note that the "compensation portion of the bill is divided into two parts: those individuals who died or were injured by mandated vaccines in the past before the date of enactment of the law (Oct. 1, 1988) and those who died or were injured after that date. Depending upon which group the individual is in, different guidelines, amounts of compensation, and restrictions apply to both filing a compensation claim or filing a lawsuit."

Attorney fees

The law provides for the payment of a maximum of $30,000 in attorney fees. "This fee is not

Attachment
H 2

DPT Director Thrown Out of Doctor's Office

Dear DPT Members:

I want to share with you the news about the birth of my daughter, Kaitlyn Rose, on July 29, and the unfortunate experience I had with a pediatrician who gave her a check-up at two weeks of age. The experience taught me that while Dissatisfied Parents Together (DPT) has accomplished much since we began in 1982, we have so much more to do before parents can truly exercise their right to make appropriate vaccination decisions for their children.

Having recently moved to Woodbridge, a Virginia suburb of Washington, D.C., shortly before my daughter was born, I had to find a new pediatrician to care for her. The pediatrician who was recommended to me is well known and has one of the largest pediatric practices in the area.

When I took Kaitlyn to see him for a two-week check-up, we got into a discussion about vaccinations. I told him I planned to give her the DT (diphtheria-tetanus) shot because we have a family history of seizures and DPT reactions. Despite the fact that I have had a seizure disorder since I was a child and despite the fact that my son suffered 8 hours of high-pitched screaming and episodes of deep sleep following his fourth DPT shot, the doctor insisted that Kaitlyn return at two months of age and receive the DPT shot. He said the American Academy of Pediatrics (AAP) and Centers for Disease Control (CDC) do not consider Kaitlyn a high-risk child. I told him that I could not allow her to receive the pertussis vaccine, and began to list the recognized authorities who acknowledge she is at risk. He then told me he would not treat Kaitlyn in his practice and told me never to come back.

I left the office, angry that I had been discriminated against by a physician who knew less than I did about the pertussis vaccine. I was shocked and hurt that my child could be denied medical care because I was trying to protect her from vaccine damage or death. I have since learned that the public health department in my county refuses to administer the DT shot to parents who request it unless they can obtain a medical excuse from a private pediatrician exempting their child from the pertussis vaccine. What chance do parents in my county have of doing that if all the pediatricians follow the example of this doctor? And is it ethical to deny these children protection against the diseases of diphtheria and tetanus?

When I left the doctor's, I looked down at Kaitlyn and made a pledge to her that I would never, never be bullied or intimidated by anyone into giving her a DPT shot that I know could kill or injure her. I know the truth about this vaccine — it is all there in DPT's parent information packet and *DPT: A Shot in the Dark,* and it is there every day when I talk to parents whose children have suffered uncontrollable convulsions or died after their DPT shots. I know that I may have many battles to face in the future with the school system or health authorities over my decision, but I will never back down. I am Kaitlyn's mother and I will do whatever I have to do to protect her from harm.

Many parents all over this country are being discriminated against by ignorant physicians and overzealous health authorities. Until the AAP and CDC revise their recommendations to screen out all high-risk children, physicians will continue to follow the party line — no matter how wrong it is — and more children will be hurt and killed by this vaccine. Dissatisfied Parents Together (DPT) has got to be there for parents, ready to provide the information and support they need to help them stand by their convictions no matter what pressure they face.

One of the goals DPT has not been able to successfully reach is to compile a list of physicians around the country who are sensitive to the issue of children at high risk of reacting to the pertussis vaccine. If you know of physicians in your state who are sensitive to this issue, please forward their names and addresses to us so we may refer other parents of high-risk children to them.

Yours truly,
Kathi Williams, Director
Dissatisfied Parents Together (DPT)

2-20

Doctors Refuse to Report Vaccine Reactions, NVIC/DPT Assists Families in Reporting

Between January 1989 and June 1991, the NVIC/DPT collected information on more than 61 vaccine reactions, injuries and deaths from families. Because only 8 of the 61 reactions were reported to the Centers for Disease Control (CDC) by the physicians who gave the vaccinations, the NVIC/DPT helped the families report the reactions.

Ann Millan, NVIC/DPT Director, who has been assisting parents with reporting reactions for the past two years, reports that "Most of the physicians who gave these vaccinations told the parents that their child's sudden death or brain injury had nothing to do with the vaccination. Most of these parents contacted us because they are searching for information and are not aware that what happened to their child should be reported to the CDC or that there is a federal compensation program for vaccine injuries and deaths."

Ann, who is assisting an additional 25 families in reporting their childrens' reactions, has become a vocal critic of the government's adverse reaction reporting system. "It is a joke," she said, "because doctors do not take it seriously. Even though they are required by law to report serious adverse events which occur within 30 days of vaccination, they refuse to do it. Doctors are being told in medical journals, by the American Academy of Pediatrics (AAP) and by the CDC that vaccines do not cause death or brain damage. So they feel justified in refusing to report."

In September 1990, and again in June 1991, Barbara Loe Fisher, who is a member of the National Vaccine Advisory Committee (NVAC), asked the committee to examine the problem of nationwide underreporting of vaccine reactions by physicians and make recommendations to maximize reporting. "Serious consideration should be given to recommending legislation and applying penalties to those physicians who refuse to obey the law," she said. Barbara has requested this subject be on the agenda for the November meeting of the NVAC.

(Anyone having a reaction to report, call NVIC/DPT for assistance in reporting and we will put you in contact with other parents for support.)

Attachment
3

2-21

NVIC FINDS DOCTORS ARE REFUSING TO REPORT VACCINE REACTIONS

After following up on 21 of the many severe vaccine reactions reported to the National Vaccine Information Center (NVIC) in 1990, the NVIC found that doctors are refusing to report reactions to state and federal health authorities as is required by Public Law 99-660 (*The National Childhood Vaccine Injury Act of 1986*). The Center discovered that pediatricians are refusing to report reactions because they are being told by vaccine policymakers in the Centers for Disease Control (CDC) and American Academy of Pediatrics (AAP) that the pertussis vaccine does not cause permanent brain damage and death.

Responding to an increasing number of reports of reactions leading to death and permanent injury following DPT vaccinations, Ann Millan, NVIC Director of Administration, contacted 21 parents who had written NVIC telling of their child's suspected DPT reactions and asking if there was any kind of federal reporting system. She learned that 18 out of the 21 doctors who gave the vaccines, refused to report reactions and the majority refused to give parents the manufacturer's name and lot number when requested by the Center, despite the legal requirement to do both.

In most cases, the doctors often justified their lack of reporting the vaccine reactions, and subsequent deaths and injuries, by claiming the DPT shot had nothing to do with the child's death or injury. The doctors often cited information given out by the CDC and AAP that the vaccine is completely safe as proof. All but a few of the 21 reactions were eventually reported by the parents themselves to the Food and Drug Administration (FDA) or CDC, but only after five months of assistance from the NVIC.

"The behavior of these doctors toward parents, who were only trying to have their child's reactions reported to health authorities, is not only professionally irresponsible but is also inexcusable," said Mrs. Millan. "These mothers and fathers were trying to cope with what had happened to their children and, at the same time, had to make repeated phone calls to their doctors and beg them to provide the vaccine manufacturer's name and lot number. Some of the doctors told parents they 'forgot' to record the information, others gave parents false manufacturer's names and lot numbers, and one parent had to retain a lawyer to obtain the information. After five months, all but a few of the 21 reactions were reported by the parents themselves to the proper government agencies."

After finally obtaining identifying information about the DPT vaccine associated with the 21 reactions, the NVIC discovered that two seizures and two deaths were reported to have followed receipt of DPT vaccine from Lederle Lots 256-957/959/960/965; one death and two seizures involved DPT vaccine from Connaught Lot 0B11061; and two seizures and one reaction involved vaccine from Connaught Lot number 8F01010.

Formal Protest Lodged

In a September 16 report to the National Vaccine Advisory Committee (NVAC), a federal vaccine policy advisory committee established under Public Law 99-660 and administered in the Department of Health and Human Services, NVAC committee member Barbara Loe Fisher, Executive Vice President of the National Vaccine Information Center, asked, "How many more deaths and injuries following vaccination occur each day and are never acknowled[illegible] or reported by physicians?" S[illegible] asserted that the government's new adverse reaction reporting system is "a cruel joke" and will remain useless if doctors continue to refuse to report reactions. "There will be no way to draw scientifically valid conclusions about the relationship between vaccine reactions and long term consequences unless physicians abandon their biased attitude that there is no "cause and effect" and obey the law by reporting vaccine reactions without having to be coerced by parents and the National Vaccine Information Center," said Ms. Fisher.

Blaiming the lack of reaction reporting on the CDC and AAP for sending out a "no cause and effect" message to public and private pediatricians, she suggested the solution to physicians refusing to obey the law is to urge Congress to pass legislation applying legal sanctions against doctors who fail to report vaccine reactions or keep vaccination records.

Ms. Fisher asked the FDA to answer questions about whether the FDA has (1) looked at the production records of the lots associated with the 21 vaccine reactions the Center documented to determine whether there are any especially toxic pertussis batches that are causing the DPT lots to be highly reactive; (2) follow up to determine how many reactions, injuries and deaths have been associated nationwide with these lots; or (3) recalled one or more of the lots.

The FDA has still not made a formal reply to these questions.

(A copy of the 16-page report submited to the Committee can be obtained for $3 from the NVIC.)

2-22

Vaccine hurts 1 child in 15,000, or 100,000, or 300,000, or . . .

How many children are hurt by pertussis vaccine? The figure most often ed, at public health clinics all over the untry, is one permanent case of brain damage in 310,000.

Sometimes the word *doses* or *injections* is noted. Often, it isn't, creating an impression that the number refers to children.

Since three doses are given to infants in the first six months, the odds seem to be that one child in roughly 100,000 will suffer permanent brain damage.

Not everyone agrees with those figures.

Dr. Kevin Geraghty, Bay Area Physicians for the Study of Pertussis Vaccines: "I'm convinced in my heart of hearts that 100 American infants a year are dying and another 250 are brain-damaged from DPT. I would be prepared to clinically defend that to scientists."

Geraghty believes as many as one in 15,000 children suffer brain damage and as many as one in 35,000 die following DPT vaccination.

Other experts read the statistics in other ways.

Dr. Alan Hinman, director, national Centers for Disease Control, Atlanta: "If one considers brain damage as being the most severe adverse reaction, the maximum number of children a year is about 50."

Dr. James Cherry, professor of pediatrics and chief of the Division of Infectious Diseases at the Center for the Health Sciences, University of California at Los Angeles: "The risk may be one in 100,000 children. I actually used one in 62,000 children when I calculated risks and benefits."

Dr. John Robbins, until last year director of the Bureau of Biologics at the Food and Drug Administration, now a researcher at the National Institute of Child Health and Human Development: "About everyone agrees that the incidence of major complications is almost infinite. You have to go to the hundreds of thousands before you see a permanent complication, one in a half a million, maybe one in a quarter million."

Dr. Edmund Burke, professor and pediatric consultant, Mayo Clinic, Rochester, Minn.: "We have some and they are very, very rare. Vaccine reaction [brain damage] is about one in 300,000."

Figures worldwide vary according to which study is examined. For example, in Great Britain two studies were completed on the whooping cough vaccine in the mid-1970s.

The Committee on Safety of Medicines concluded that one in 53,000 children vaccinated was severely brain-damaged. The National Childhood Encephalopathy study determined that one in 100,000 children was left permanently brain-damaged by the DPT shot. (For comparison, polio vaccine causes severe damage in one in about 5 million children.)

In West Germany, the government stopped recommending the shot after a study showed one in 39,000 children was affected.

In Sweden, two studies done by Dr. Justus Strom surveyed more than 200,000 children and looked at 10 years of whooping cough in the country. Strom found three times more brain damage and disorder caused by the vaccine than caused by the disease, a rate of one in 46,000 children.

Robbins calls the Swedish study "100 percent bull." He charged that Strom "put cases in there that had nothing to do with the vaccine. He's a doctor who studied this in 1973-74 and wrote an article. Just because it's in the scientific literature doesn't mean it's correct."

The figures accepted and used by the federal government and the American Academy of Pediatrics come from the British National Childhood Encephalopathy study: One in 100,000 children are permanently brain-damaged.

"What they don't tell you," Geraghty said, "is that the vaccines vary. For example, they [British] don't immunize until 6 months of age; we start at 2 months. They give it three times; the U.S. gives it five times. They do not give it to kids we routinely give it to, plus our vaccine is at least 50 percent stronger than theirs."

Cherry, considered one of the country's DPT experts, agreed that the U.S. and British vaccines are different, "but they probably aren't very different. One of the problems is that the American density standard is different than the international standard.

"I must admit, I've reread and reread those and I'm not sure I know about the strength of the vaccines."

As for the age variation, Cherry said, "At one point, the British were giving it fairly late . . . Now they give it at 3 months, 5 months and 10 months. But that's all they do.

And that, he said, "is probably wrong." Because school-age children don't get booster shots, they can carry the infection home to babies who are too young for immunization.

Robbins said, "There's no difference in the vaccines, and their [British] reaction rates are the same as ours."

Attachment #1

DPT

THE FRESNO BEE

Workshop on Neurologic Complications of Pertussis and Pertussis Vaccination

By J. H. Menkes[1] and M. Kinsbourne[2]

[1]Professor Emeritus of Neurology and Pediatrics University of California, Los Angeles, and [2]Lecturer and Clinical Associate in Neurology Harvard University, Director, Department of Behavioral Neurology, Shriver Center, Waltham, Massachusetts, U.S.A.

Abstract

A multidisciplinary workshop held from September 29 to October 1, 1989, at Airlie House, Warrenton, Virginia, considered the neurologic complications of whooping cough and pertussis vaccine.

Pertussis mortality in the U.S. in 2–3/1000 cases. Seizures occur in 1.9% of cases, and encephalopathy in 0.3%. Reviewing all data, it appears likely that a combination of one or more bacterial toxins, asphyxia, CO_2 retention and loss of cerebral vascular autoregulation is responsible for neurologic symptoms. The timing of the encephalopathy suggests that it results from increased lysis of bacteria, and release of endotoxin. The encephalopathy is not confined to the paroxysmal phase.

In evaluating side-reactions to the vaccine, the following must be kept in mind:

1. Vaccines are not standardized between manufacturers.
2. For a given manufacturer, vaccines are not standard from one batch to the next.
3. Unless the vaccine is properly prepared and refrigerated, its potency and reactivity varies with shelf life.

In fact, the whole question of vaccine detoxification has never been systematically investigated.

Listed in order of increasing severity, observed adverse reactions include irritability, persistent, unusually high pitched crying, somnolence, seizures, a shock-like "hypotensive, hyporesponsive" state, and an encephalopathy. Since the neurologic picture is not specific for pertussis vaccination, its temporal relationship to the vaccination is the critical variable for determining causation.

Although the majority of seizures following pertussis vaccination are associated with fever, it was the consensus of the neurologists attending the workshop, that these do not represent febrile convulsions, but are non-benign convulsions.

The incidence of post-vaccine encephalopathy is difficult to ascertain. The most carefully conducted retrospective case-control study reported that the relative risk of a previously normal infant for the onset of an illness leading to encephalopathy with permanent subsequent disability was 4.2 times greater during the first 72 hours following DPT vaccination than in controls. From this study, the risk for permanent brain damage following DPT has been calculated as 1:310,000 doses.

It was the consensus of the workshop, and in particular of the participating neurologists, that although the vaccine may possibly accelerate neurologic signs or symptoms in some children, and a small proportion of apparent complications may be coincidental, there was no inherent difficulty in assigning cause and effect to the vaccine and subsequent permanent neurologic residua.

It was also the consensus that there was no demonstrated association between DPT vaccination and SIDS, because sudden death after pertussis vaccination is too rare to be detectable in the context of presently available series. Sudden death may occur in infants in the course of whooping cough, and following pertussis vaccination.

As was pointed out by several pediatric neurologists, the inherent problem in linking pertussis vaccination to infantile spasms is the extreme difficulty in determining the exact timing of their onset.

In implicating pertussis vaccination in the evolution of subsequent neurologic residua, a careful consideration of the mechanism for vaccine-induced brain damage plays an important supporting role. Pertussis toxin has been shown to alter cellular signalling. It also affects the catecholaminergic and GABAergic systems in brain. Although normally a protein of the size of PT would not be able to cross the blood-brain barrier, factors known to disrupt the blood-brain barrier include brief hypertensive episodes such as might occur during a coughing paroxysm, hypoxia, and prolonged seizures, whether or not they are accompanied by hypoxia. In addition, a direct, endotoxin-mediated attack on the endothelial cells could create a local defect of the blood-brain barrier.

In summary, it was the consensus that there is sufficient experimental data to implicate both endotoxin and PT in adverse neurologic reactions to pertussis vaccine.

Key words

Pertussis vaccination – Post-vaccination encephalopathy – Pertussis

Received March, 28, 1990; accepted April 28, 1990

Neuropediatrics 21 (1990) 171–176

Attachment # 5

2-24

A multidisciplinary workshop held from September 29 to October 1, 1989, at Airlie House, Warrenton, Virginia, considered the neurologic complications of whooping cough and pertussis vaccine. The workshop enabled interaction between outstanding neuroscientists and some of the most prominent workers in the area of pertussis infection and vaccination.

Pertussis

As described by *James W. Bass* (Tripler Army Medical Center, Honolulu, Hawaii), whooping cough evolves in three phases (2). Patients are most contagious during the initial *catarrhal* stage; the *paroxysmal* stage which lasts from a few days to several weeks, is marked by the characteristic paroxysmal cough accompanied by vomiting and lymphocytosis. In newborns and young infants pertussis may however present with apnea and cyanotic spells, and a history of cough may be elicited only if specifically sought for. The erythrocyte sedimentation rate remains normal in uncomplicated pertussis. The convalescent phase occurs when paroxysms subside but chronic cough persists.

Bordetella pertussis organisms are not invasive. They remain attached to the cilia of the respiratory epithelium.

Patients are usually afebrile; fever indicates a secondary bacterial infection. B. pertussis produces 30 to 50 antigens and several toxins. The exotoxin, pertussis toxin (PT), has been most studied. Heat-stable toxins, including a lipopolysaccharide endotoxin, are also produced, as well as a tracheal cytotoxin factor (15, 25).

Pertussis mortality in the U.S. is currently 2–3/1000 reported cases, although there is significant underreporting of cases. In Third World countries, mortality can be as high as 50%. Complications include bacterial pneumonia, seen in 16% of hospitalized children, sinusitis and otitis. Seizures are encountered in 1.9% of cases, and encephalopathy in 0.3%. Subdural or subarachnoid hemorrhage are rare complications.

When pertussis encephalopathy develops, it occurs during the first week of the paroxysmal state in most cases. It is usually associated with fever, seizures, alterations of consciousness, and focal neurologic signs, notably acute visual loss in the presence of normal optic discs. It may be secondary to retinal changes induced by cough paroxysms. CT scans have been normal, but no MR imaging studies have been reported.

The cause of seizures in whooping cough is uncertain. In most instances, they are afebrile, and unrelated to the hypoxia which attends a coughing paroxysm. Hypoglycemia, which often attends whooping cough, is not known to be sufficiently severe to produce seizures, although CSF glucose has not been examined systematically. It is likely that seizures attending whooping cough represent a mild form of encephalopathy. There is no evidence that PT in isolation can induce encephalopathy. If this were the case, this complication should be seen during the catarrhal stage of the disease, when the highest concentration of B. pertussis organisms occurs in the respiratory passages. Rather, the timing of the encephalopathy suggests that it results from increased lysis of bacteria, and release of endotoxin. It has, however, not been demonstrated that the endotoxin enters the blood stream. A heat-stable neurotoxin, distinct from PT, and related to endotoxin, has been demonstrated to induce convulsions in mice.

Pertussis encephalopathy is thought to be fatal in one-third of patients, leave neurologic residua, including learning disabilities, in one-third, the remainder of survivors being normal.

The neuropathology of whooping cough was reviewed by *William Bell* (University of Iowa, Iowa City, Iowa). Almost all published studies are old. The brain shows nonspecific alterations, notably swelling, anoxic-ischemic changes, venous congestion, and petechial hemorrhages (10). To an uncertain extent, these result from airway obstruction and metabolic derangements, in particular, the dehydration and metabolic alkalosis that result from vomiting which usually attends the coughing 9 paroxysms. The role the various toxins of B. pertussis play in the evolution of these neuropathologic alterations is unknown. Some encephalopathies develop in the absence of significant paroxysms.

Reviewing all data, it appears likely that a combination of one or more bacterial toxins, asphyxia, CO_2 retention and loss of cerebral vascular autoregulation is responsible. In particular, hypoxia may result in a breakdown of the blood-brain barrier, allowing the bacterial toxins to enter the central nervous system.

Pertussis vaccine

The whole-cell vaccine and its preparation were reviewed by *John Cameron* (Institute Armand Trappier, Laval, Quebec). All vaccines in current use in the U.S.A. and the U.K. are whole-cell vaccines. Production methods differ between manufacturers. Thus the US vaccine contains 1.7 times as many bacteria as vaccines recommended by the WHO. In essence, whole-cell vaccine is produced from several bacterial strains that differ in serologic composition. Various factors, notably the number of subcultures used and the medium on which bacteria are grown affect the concentration of the various bacterial antigens. Organisms are killed by heat, methiolate or formalin. There is therefore considerable variation from manufacturer to manufacturer with respect to toxicity, potency, and histamine content of the vaccine. In addition, the significance of the various antigens relative to vaccine effectiveness and toxicity is unknown.

Various in-process tests have been used. These include a test for the general safety of the vaccine, the mouse toxicity test. This nonspecific test is related in the number of organisms and the lipolysaccharide (LPS) content of the vaccine. An opacity test, a potency test, and determination of serologic components and stability are also employed. After its preparation, the pertussis vaccine is added to tetanus and diphtheria toxoids and is adsorbed on aluminum phosphate.

In evaluating side-reactions to the vaccine, the following must be kept in mind:

1. Vaccines are not standardized between manufacturers.
2. Even with the same manufacturer, vaccines are not standard from one batch to the next.
3. Unless it is properly prepared and refrigerated, the vaccine's potency and reactivity varies with shelf life.

It is therefore evident that at least some of the differences between various studies on the incidence of adverse reactions to vaccines reflect differences in the vaccines used.

Neurological vaccine injuries

The neurologic complications of pertussis vaccination were reviewed by *Edward Mortimer* (Case Western Reserve University, Cleveland, Ohio) and by *Jean Aicardi* (Hôpital des Enfants Malades, Paris). In ascending order of severity, these are fever, irritability, persistent unusually high pitched crying, excessive somnolence, seizures, a shock-like "hypotensive, hyporesponsive" state, and encephalopathy. These complications have been described in numerous publications, commencing with those of *Madsen* (5, 7, 9, 20).

In *Aicardi*'s personal series of 20 cases of seizures or encephalopathy, the onset was within 72 hours, and usually within 24 hours of pertussis vaccination. Seventy-five per cent of his cases developed within 12 hours of the vaccination and 80% within 24 hours, a pattern often reflected in the literature and not compatible with the notion of a chance association (22). Neurologic complications most often followed the first vaccination. There was frequently a change in consciousness, most characteristically coma of several days' duration, followed by an abrupt arrest in development. Seizures tended to assume the form of convulsive status epilepticus or of severe myoclonic epilepsy. This entity, which is usually seen unrelated to DPT vaccination, has its onset with uni- or bilateral clonic seizures in a setting of fever, which often is low grade. Initial attacks are followed by myoclonic seizures, atypical absence attacks, or complex partial seizures, and are accompanied by progressive mental deterioration. The EEG is initially normal in some 75% of cases, but tends to deteriorate. The CSF is usually normal.

Since this neurological picture is not specific to pertussis vaccination, its temporal relationship to vaccination is critically important for determining its cause. Inasmuch as subsequences are not necessarily consequences, several epidemiologic studies have been attempted in order to relate the incidence of apparent vaccine reactions to the background rate of infantile encephalopathy, and to ascertain whether pertussis vaccine renders prematurely overt the inevitable manifestations of a pre-existing disorder.

Analytical epidemiologic studies may be divided into prospective cohort studies, and retrospective case-control studies.

The best designed prospective cohort study is that of *Cody* et al (7) which compared adverse reactions of DPT and DT vaccination. Persistent crying was common with DPT. Seizures followed 0.06% and the hypotensive-hyporesponsive state followed 0.06% of DPT vaccinations. Neither of these complications followed DT vaccinations. As was subsequently noted in the workshop, these complications did not follow immunization with the Swedish acellular pertussis vaccine. Not surprisingly, the prospective incidence of seizures in this study is greater than in retrospective studies such as those of *Ehrengut* (12) (1:2200), or *Ström* (14, 29) (1:6500). Of the other prospective case-control studies (14, 26) some indicate similar incidences, whereas others did not show an excess of seizures during the first 72 hours following vaccination (31).

Although the majority of seizures following pertussis vaccination are associated with fever, it was the consensus of the neurologists, that they could not be described as febrile convulsions, because they are not necessarily benign. Follow-up studies of children in the *Cody* series who experienced seizures or the hypotensive/hyporesponsive state following DPT did not disclose any sequelae (1), but the sample size was far too small for conclusions to be drawn. The absence of permanent complications or seizures in their sample contrasts with a 10% incidence of permanent residua, but a lower incidence of seizures in retrospective studies such as those of *Ehrengut* or *Strom*. Clearly, seizures without sequelae tend to be forgotten.

Because vaccine-induced encephalopathy is so rare, a case-control study is appropriate. Diseased individuals are identified, case controls are selected, and the timing of exposure to the vaccine is ascertained retrospectively.

The only retrospective case-control study is that conducted in the U.K. (23). This study reported that the relative risk of a previously normal infant for the onset of an illness leading to permanent encephalopathy was 4.2 times greater during the first 72 hours following DPT vaccination than in controls. From this study, the risk for permanent brain damage following DPT has been calculated as 1:310,000 doses, with the 95% confidence interval being 1:50,000 to 1:18,000,000.

Mortimer listed the following doubts about the NCES results (6):

1. A possible selective referral of DPT recipients.
2. Similar effect following DT administration.
3. An admittedly non-significant decreased risk for encephalopathy 8–28 days after DPT administration.
4. Of the 11 cases with irreversible encephalopathy, 7 were said to have had other diseases.

In view of these reservations, *Mortimer* felt that it was not possible to prove an absolute negative, namely that there was not such an entity as post-pertussis vaccine encephalopathy, and even if this entity did exist, its incidence was too low to be measurable.

With respect to the suggestion that pertussis vaccine might accelerate the clinical onset of a latent disease, *Kinsbourne* (Shriver Center, Waltham, Mass.) pointed out that no mechanism exists which would do so without also rendering such a disease more severe.

It was the consensus of the workshop, in particular of the participating neurologists, that regardless whether on rare occasions, the vaccine may accelerate the appearance of neurologic signs or symptoms of an underlying disease, and some apparent complications may be coincidental, there was no problem with assigning a cause and effect relationship between the vaccination and subsequent permanent neurologic residua.

Pertussis vaccination and SIDS

The relation between pertussis vaccine and SIDS was examined by *Donald Peterson* (University of Washington, Seattle, Washington). He defined SIDS as the sudden death of any infant, unexpected by history, in which a thorough postmortem examination fails to demonstrate an adequate cause of death. The diagnosis of SIDS is far from precise, and

several entities, including infantile botulism, homicide, idiopathic infantile apnea, and malignant hyperthermia are responsible for a significant proportion of SIDS cases. The bulk of cases probably have some as yet undefined etiology. The incidence, 2/1000, has been relatively constant over the last twenty years. Sudden death occurs in whooping cough. In some instances, it accompanies a paroxysm; in others it results from apnea unassociated with a characteristic paroxysm.

No increased risk for SIDS during the first 24 hours following DPT immunization could be found in the Tennessee study (17) and in the retrospective study of *Hoffman* et al (18). To the contrary, the incidence of DPT vaccination was lower in SIDS infants than in control infants. This is apparently because children in chronic ill health, which is a risk factor for SIDS, often remain unvaccinated. In contrast, *Walker* and coworkers (30) found the SIDS morbidity rate from 0 to 3 days following immunization to be 7.3 times that during the period beginning 30 days after immunization. *Peterson* pointed out that this study suffered from the deficiencies of retrospective cohort studies. Additionally, *Walker* failed to control for a shift in the time of the first DPT vaccination to a later age at which the incidence of SIDS is at its height.

David Lane (School of Statistics, Univ. of Minnesota, Minneapolis, MN) reviewed the problems inherent in attempts to examine the association of relatively common events, such as SIDS, and a superimposed rare event such as DPT vaccine encephalopathy. For statistically reliable validation or disproof of pertussis vaccine-induced SIDS, a population of five million children would have to be studied. Since such a project is manifestly unworkable, other strategies have to be used. He favored pooling data from several studies. Thus if each individual study showed a slight inclination to an excess risk, pooled data might disclose an effect which could not be demonstrated otherwise. *Kinsbourne* commented that this logic extends to pooling published case reports, which over more than five decades have documented encephalopathic reactions to pertussis vaccine, but rarely to other vaccines.

It was the consensus of participants that an association between DPT vaccination and SIDS has not been demonstrated. When sudden death occurs in infants in the course of whooping cough and following pertussis vaccination it is preceded by encephalopathic symptoms and therefore does not meet the criteria of SIDS. If indeed sudden death occurred from a vaccine-induced hypotensive/hyporesponsive state, or from anaphylactic shock, and if a small proportion (some 1 %) of sudden deaths in infants were due to DPT vaccination, this association is too rare to be detectable from presently available data which lumps these infants together with those properly diagnosed as SIDS.

Martin Bellman (Child Development Center, London) reviewed the relationship between DPT vaccination and infantile spasms (4). The NCES study, in which he participated, found no positive evidence to link these two events. The relative risk of 2.46 for the onset of infantile spasms within one week of DPT immunization was not significant, and had to be compared with a relative risk of 2.0 in DT immunized infants. For both series there was an excess of cases during the first six days following vaccination followed by a non-significant deficit over the ensuing three weeks. This could reflect a tendency for parents to use immunization as a retrospective marker for the onset of infantile spasms. Studies by *Melchior* (21) and *Fukuyama* et al (16) have supported the thesis that the onset of infantile spasms is unrelated to DPT vaccines.

Kinsbourne pointed out that negative results attributable to lack of statistical power cannot be used to make negative inferences. In the *Fukuyama* study, two cases of infantile spasms out of 110 in which there was detailed information as to past vaccination history had the onset of seizures within two days of vaccination. In these two cases no injurious factors other than vaccination served as etiology. Inasmuch as the etiology for infantile spasms was known or suspected in all but 12 of the 110 cases, one might conclude that DPT vaccination is a likely, albeit unproven, cause for some 16% of cases of idiopathic (cryptogenic) infantile spasm. The incidence of chance occurrence within two days of vaccination was 2%. Whereas these numbers are too small to permit statistical analysis, they cannot be used to conclude that there is no relationship.

The *Melchior* study intended to examine the effect on the onset of infantile spasms of a change in the time of initiating DPT vaccine in Denmark from 5 months to 5 weeks. *Kinsbourne* pointed out that prior to the acceleration of the vaccination schedule, 12% of cases of infantile spasms had their onset before two months of age as compared with 23% after the change in schedule. These figures are also consistent with the supposition that a minority (11%) of infantile spasm cases is vaccine-induced.

Relative to these and several other studies including the recent one of *Shields* and coworkers (27) examining the linkage between infantile spasms and DPT vaccination, *Aicardi* and other pediatric neurologists attending the workshop, pointed out the extreme difficulty in determining the exact timing of the onset of infantile spasms. Further to the issue of cause and effect, *Kinsbourne* remarked that with respect to the more usual, encephalopathic, consequences of pertussis vaccination, given that seizures, often prolonged are an undisputed acute consequence, it would be unprecedented if they never led to epilepsy, and that as a shock-like state is an equally undisputed adverse reaction, it would be surprising if it never led to brain damage or death. A continuum of severity is the rule in symptoms of neurological disease.

In implicating pertussis vaccination in the evolution of subsequent neurologic residua, evidence as to possible mechanisms for vaccine-induced brain damage plays an important supporting role.

Pathogenesis of vaccine injury

Peter Behan (Southern General Hospital, Glasgow) incriminates several pathogenetic mechanisms in post-pertussis vaccine encephalopathy. The major one develops within the first 24 hours of immunization, but another mechanism remains active up to one week following immunization. He stressed that before two years of age the immature brain cannot react to an autoimmune challenge. As a consequence, neuropathological examination of infants succumbing to pertussis vaccination cannot be expected to confirm this mechanism of brain damage.

Behan reported on 49 autopsied cases of acute hemorrhagic leukoencephalopathy (3). Whooping cough was responsible for four of these, and DPT vaccine for one. The pathological picture was compatible with an endotoxin-induced

generalized *Schwartzman* reaction, which activates complement and produces endothelial damage. *Bell* pointed out that endothelial damage had not been observed in brains of other patients succumbing to whooping cough. Most of these were infants, however, and these changes would not be expected. *Behan* found that in the majority of cases the LPS component is responsible for the endothelial cell damage. This is supported by several experimental studies cited by *Kinsbourne*. The endothelial cells of the blood-brain barrier may be particularly susceptible to complement mediated antigenic attack.

William Oldendorf (Brentwood V. A. Hospital) found that brain endothelial cells have a higher density of mitochondria than other types of endothelial cells, and that they are antigenically unique.

Although the *Schwartzman* reaction is responsible for the majority of vaccine-related neurological complications, particularly those that evolve within 24 hours of vaccination, others may be caused by an anaphylactic reaction. In yet others, a concurrent benign infection may act in conjunction with the vaccine to produce the *Schwartzman* reaction.

The effects of pertussis toxin on cellular signalling were reviewed by *Toshiaki Katada* (Tokyo Institute of Technology, Yokohama). His group has shown that the G proteins are the target of pertussis toxin (19). G proteins are guanine nucleotide-binding cells surface receptors for a number of hormones and neurotransmitters. They act by controlling adenyl cyclase activity. Pertussis toxin causes several of the G proteins to be ADP-ribosylated (11). This reduces their affinity for GTP, and reduces the release of GDP from GTP. Although PT has no direct effect on GTPase activity, it prevents activation of GTPase. Since PT is covalently bound, binding is irreversible.

Pertussis toxin-induced ADP ribosylation impairs the ability of a cell to react with receptors. Thus PT abolishes the opiate-induced hyperpolarization of locus ceruleus neurons and reduces or abolishes the late inhibitory postsynaptic potential of hippocampal neurons. It also reverses adenosine inhibition of neuronal glutamate release.

Solomon Moshe (Albert Einstein School of Medicine, Bronx, NY) reviewed the epileptogenesis in the immature brain (24). The immature brain is more susceptible to seizures than the adult brain. There are many factors that can influence seizure susceptibility as a function of age, including differences in catecholamine content, and response to GABAergic drugs. Pertussis toxin can affect both catecholaminergic and GABAergic systems, but the interactions are complex and depend on the site to which pertussis toxin is applied. Both facilitatory and inhibitory effects have been reported. To date there are no experimental studies on the epileptogenicity of pertussis toxin in the immature brain.

Oldendorf reviewed the physiology of the blood-brain barrier. Being a protein, PT would not be expected to cross the blood-brain barrier under physiological conditions even in the immature and fetal brain. Factors known to disrupt the blood-brain barrier include brief hypertensive episodes such as might occur in a coughing paroxysm, hypoxia, osmotic agents such as mannitol, and prolonged seizures, with or without hypoxia (8). In particular, a direct, endotoxin-mediated attack on the endothelial cells would create a local defect of the blood-brain barriers (13).

In summary, it was the consensus that there is sufficient experimental data to implicate both endotoxin and PT in adverse neurologic reactions to pertussis vaccine.

Alternative vaccines

In view of the severity of adverse reactions to the currently used vaccines, considerable effort has recently been directed to the development of alternative vaccines. The Swedish trial of acellular vaccines was reviewed by *Jann Storsaeter* (Karolinska Institute, Stockholm) (28).

Two vaccines, one containing pertussis toxin (JNIH #7), the other pertussis toxin and filamentous hemagglutinin (JNIH #6), were compared with a placebo which contained the carrier solution of the vaccines (formalin, thiomersal and aluminum phosphate) JNIH #6 has been used in Japan since 1981 to immunize children over two years of age. Vaccine and placebos were administered subcutaneously. (According to *Cameron* this route of administration would be expected to induce a higher incidence of local reactions than intramuscular injection.) Except for persistent crying there were no significant side reactions. No seizures or hypotensive/hyporesponsive states were seen in 2847 infants. The vaccines were considered to be 74% and 86% efficacious, respectively. Vaccine JNIH #6 protected better against mild cases of pertussis; both vaccines were equally effective against severe cases. However, the development of invasive bacterial disease over the course of subsequent months in 1.5/1000 infants vaccinated with JNIH #6 resulted in discontinuation of the vaccine trials, although no relationship between these miscellaneous infections and the vaccine has been suggested (28). *Reno Rappuioli* (SCLAVO, Siena, Italy) pointed out that the acellular vaccines also include active toxins, and that formalin does not fully denature PT. According to *Cameron*, vaccine detoxification has never been fully investigated.

Rappuoli reviewed the preparation of a new genetically recombinant vaccine.

Of the several candidate molecules for the vaccine, pertussis toxin (PT) was selected. Adenylate cyclase, although important in virulence, was difficult to purify. The 69 KDalton protein was a good antigen, but it too has not been purified in sufficient quantities. Although it was protective against the aerosol challenge, immunization with the 69 KD protein did not protect against the intracerebral challenge.

PT consists of five subunits, arranged into two domains. Domain A, consisting of the S1 subunit, is the active molecule in terms of toxicity and antigenicity, whereas domain B is necessary for binding of the protein to the cell surface. The S 1 subunit, being devoid of lysine, is not readily detoxified with formalin, and either domain alone provides no protection. The gene for pertussis toxin has now been cloned, and a change in the amino acid sequence of S1 results in loss of conformation structure of the subunit and as a consequence, a loss of ADP ribosylation of the G proteins. As a result of this modification, toxicity was reduced by 10^6 but antigenicity was preserved.

This new recombinant vaccine is to enter Phase I clinical trials in the near future. Not only should this vaccine give rise to fewer toxic reactions, but anaphylactic reactions should be fewer as well, since the unmodified PT

potentiates anaphylaxis. Workshop participants foresaw that once the recombinant vaccine receives widespread use, its reduced toxicity will result in increased acceptance by the public of vaccinations against pertussis, and with it a resumed decline in the incidence of the disease.

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2-29

Attachment # 6

NVIC/DPT mini NEW

NATIONAL VACCINE INFORMATION CENTER
Dissatisfied Parents Together (NVIC/DPT)
204-F Mill Street, Vienna, VA 22180
(703) 938-DPT3

IMMUNIZATION EXEMPTION BULLETIN

FREEDOM OF CHOICE NOT TO VACCINATE YOU OR YOUR CHILD

The National Vaccine Information Center, Dissatisfied Parents Together (NVIC/DPT) supports an educated parent's right to choose when to vaccinate or not to have a child vaccinated with a vaccine the parent considers to be a danger to the child's health.

The accompanying NVIC/DPT miniNews Bulletin, *Mandated Childhood Vaccines* and reading *A Shot in the Dark* by Harris Coulter and Barbara Loe Fisher, helps to show the seriousness of your vaccination decision. The Center encourages every parent to become educated on each vaccine and their individual state laws if they want the right to choose. It is important this decision be based on each individual's research and education, rather than the attitude of what your friends are doing or the fact that you do not want "to make your child cry."

If you have made an informed decision not to vaccinate with one or all vaccines, there are twenty states that allow a philosophical objection to vaccinations; in other words, freedom of choice. Forty eight of the fifty states allow a religious exemption. Certain states have a very loose definition of religion, beliefs. This means that one need not be a member of a religion which specifically prohibits vaccination in order to obtain the exemption.

In addition to the religious and philosophical exemptions, there is a medical exemption which is currently accepted in all states. This exemption often requires the signature of your attending physician. Sadly the American Academy of Pediatrics (AAP) and the Centers for Disease Control (CDC), in their vaccine recommendations for health care professionals, have very limited reasons for a medical exemption. There are more specifics in the manufacturer's package insert for each vaccine and the Physician's Desk Reference (PDR); however, these too are very limited.

Each state has their own special way of dealing with exemptions. You will be able to find a copy of your public health law on immunizations from the state statute book in the reference section of your local library. Be sure you have all of the up-dates. Not only will this give you your exemption information but also which vaccines are mandated in your state. Any agency receiving state or federal funds must abide by the state law.

After you have explored the type of exemption you want to pursue, you should then be able to move forward with more confidence. It is important you do no more than the law requires. Lengthy explanations and attempts to educate the establishment will only target you as a irrational parent.

States which do not require vaccination against pertussis for pre-requisite to school entry include AZ, NY, OR, PA, RI, WA, TX and ID. All fifty states require diphtheria, measles, rubella, and polio vaccination. All states except AZ and NY require tetanus vaccination, and all states except AK, AZ, AR, IA, KY, MD, NM, SC, VT, and WV require mumps vaccination. All states except MS and WV allow a religious exemption to vaccination. Philosophical objection to vaccination is allowed in AZ, CA, CO, ID, IN, LA, ME, MI, MN, NE, ND, OH, OK, PA, RI, UT, VT, WA, and WI.

Every state law is very fragile. Immunization campaigns are in process all over the United States and part of that campaign is to make vaccinations 100% mandatory. In some states private doctors are reporting their patients to state health officials if a parent refuses vaccinations. In other states, if a child is diagnosed with a vaccine related disease, they are reported to the health department and many parents are threatened with child abuse. Please report anything you hear regarding state law changes to NVIC/DPT. Hopefully, the Center can try and alleviate any proposed legislation.

The National Vaccine Information Center, Dissatisfied Parents Together (NVIC/DPT) has members in each state who are parent representatives on the vaccine issues. Many are familiar with their immunization laws and are willing to help others. These names will be provided to members, upon request.

In addition, there are two other resources we have for our members. (See the NVIC/DPT Resource List for more materials on the vaccine issue.)

Neil Miller, author of *Vaccines: Are they Really Safe and Effective?* has individual packets on each states' laws and is making them available to our members for a $3 fee. Write New Atlantean Press, PO Box 9638-83, Santa Fe, NM 87504, telephone: 505/983-1856.

Grace Girdwain has expanded her pamphlet (which is no longer available), *Your Personal Guide to Immunization Exemptions* and the book is available from Dorrance Publishing Co., Inc., 643 Smithfield St., Pittsburgh, PA 15222-2505, telephone 412/288-4543, for $9.95.

Health and school authorities are quick to tell parents that vaccines are mandatory. That is a true statement! However, there are also waivers and exemptions to those mandatory vaccinations.

Kansas State Board of Pharmacy

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STATE OF KANSAS

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HOUSE BILL 2605

SENATE PUBLIC HEALTH & WELFARE COMMITTEE
February 15, 1994

MADAM CHAIRPERSON, MEMBERS OF THE COMMITTEE, MY NAME IS TOM HITCHCOCK AND I SERVE AS THE EXECUTIVE SECRETARY FOR THE BOARD OF PHARMACY. I APPEAR BEFORE YOU TODAY ON BEHALF OF THE BOARD IN SUPPORT OF HB 2605.

THE BILL CONSISTS OF THREE (3) CHANGES IN THE PHARMACY ACT. THE FIRST CHANGE APPEARS ON PAGE 1, LINES 13 THROUGH 27, IN THE FORM OF A NEW SECTION. THIS SECTION WILL ALLOW THE BOARD TO ASSESS AN ADMINISTRATIVE FINE AGAINST ANY LICENSEE OR REGISTRANT, OTHER THAN A RETAIL DEALER, IN THE AMOUNT NOT TO EXCEED $500 FOR EACH VIOLATION OF THE PHARMACY ACT OR CONTROLLED SUBSTANCES ACT. AS A COMPARISON THE BOARD OF NURSING, BOARD OF HEALING ARTS, AND BOARD OF VETERINARY EXAMINERS ALL HAVE THE AUTHORITY TO IMPOSE CIVIL FINES AS WELL AS BOARDS OF PHARMACY IN 33 OTHER STATES. SUCH ADMINISTRATIVE FINES, AS NOTED ON LINES 26 & 27, WOULD BE DEPOSITED INTO THE STATE GENERAL FUND.

THE SECOND CHANGE IN ALSO ON PAGE 1, LINES 33 THROUGH 35, SPECIFICALLY PLACES THE RESPONSIBILITY ON THE LICENSEE TO SHOW OF THEIR REHABILITATION TO WARRANT THE PUBLIC TRUST FOLLOWING A FELONY CONVICTION. PREVIOUSLY THE BOARD HAD TO DETERMINE WITH INVESTIGATION IF THE LICENSEE WAS OR WAS NOT REHABILITATED.

THE THIRD CHANGE IS ON PAGE 3, LINES 19 THROUGH 24, WOULD ALLOW THE BOARD TO SANCTION A MANUFACTURER OR WHOLESALE DISTRIBUTOR IF THEY ARE FOUND TO BE IN VIOLATION OF THE PHARMACY ACT OR CONTROLLED SUBSTANCES ACT.

THE BOARD OF PHARMACY RESPECTFULLY REQUESTS THE FAVORABLE PASSAGE OUT OF COMMITTEE HOUSE BILL 2605. THANK YOU.

Senate PHFW
Attachment # 3
2-16-94

Kansas State Board of Pharmacy

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STATE OF KANSAS

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TOM C. HITCHCOCK
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SENATE BILL 715

SENATE PUBLIC HEALTH & WELFARE COMMITTEE
February 16, 1994

MADAM CHAIRPERSON, MEMBERS OF THE COMMITTEE, MY NAME IS TOM HITCHCOCK AND I SERVE AS THE EXECUTIVE SECRETARY FOR THE BOARD OF PHARMACY. I APPEAR BEFORE YOU TODAY ON BEHALF OF THE BOARD IN SUPPORT OF SB 715.

THERE ARE FOUR (4) CHANGES IN THE BILL THAT BRING THE KANSAS CONTROLLED SUBSTANCES STATUTES INTO COMPLIANCE WITH THE DESCRIPTION AND SCHEDULING AS FOUND IN THE FEDERAL REGULATIONS OF CONTROLLED SUBSTANCES. THE FIRST IS THAT WHICH MAKES AN EXCEPTION OF A SPECIFIC CHEMICAL AS STATED ON PAGE 1, LINES 27 & 28. THE SECOND AND THIRD CHANGES ARE THE ADDITION OF TWO CHEMICALS WHICH APPEAR ON PAGE 6, LINES 19 THROUGH 21 AND LINES 22 THROUGH 25 AND ARE NAMED, DESCRIBED AND GIVEN A 4 DIGIT DEA CODE NUMBER FOR IDENTIFICATION. THE FOURTH CHANGE IS ON PAGE 8, LINES 18 THROUGH 20 AND LISTS THAT CHEMICAL WHICH WAS EXCEPTED ON PAGE 1. IT IS ALSO NAMED, DESCRIBED AND GIVEN A 4 DIGIT DEA CODE NUMBER. THIS DRUG WAS EXCEPTED FROM SCHEDULE C-I AND ADDED AS A C-II DRUG.

THE REMAINING THREE (3) CHANGES ARE THOSE AS REQUESTED BY THE BOARD OF PHARMACY. IT ELIMINATES TWO EXCEPTIONS WHICH DEAL WITH COMBINATIONS CONTAINING HYDROCODONE. THIS IS FOUND ON PAGE 10, LINES 34 THROUGH 38 AND LINES 39 THROUGH 43. THIS WOULD SCHEDULE ALL HYDROCODONE CONTAINING DRUGS INTO SCHEDULE C-II IN KANSAS AS COMPARED TO FEDERAL SCHEDULING AS A C-III BY DEA. IF RESCHEDULED BY THE PASSAGE OF THIS BILL, THE C-II SCHEDULE WOULD TAKE PRECEDENCE IN KANSAS. THE THIRD AND LAST CHANGE IS THE ADDITION ON PAGE 14. LINE 18, OF THE DRUG CARISOPRODOL (BRAND NAME SOMA) WHICH DISPLAYS NO DEA IDENTIFICATION NUMBER BECAUSE IT IS NOT SCHEDULED IN FEDERAL REGULATIONS. AGAIN, THE C-IV SCHEDULE WOULD TAKE PRECEDENCE IN KANSAS.

THE RATIONAL FOR MOVING ALL HYDROCODONE CONTAINING DRUGS FROM C-III TO C-II IS BECAUSE THESE DRUGS ARE THE MOST HIGHLY ABUSED LEGAL DRUGS IN KANSAS AND THE ENTIRE COUNTRY. ALSO, THE SCHEDULING OF CARISOPRODOL IS AN ATTEMPT TO SLOW DOWN THE AVAILABILITY OF THIS HIGHLY ABUSED LEGAL DRUG. THE ATTACHED ARTICLE RELATES TO THE PROBLEMS OF FRAUD, FORGERY AND AVAILABILITY FOR ABUSIVE USE OF THESE DRUGS IN TEXAS.

THE BOARD RESPECTFULLY REQUESTS FAVORABLE PASSAGE OUT OF COMMITTEE SB 715.
THANK YOU.

Senate PH&W
Attachment # 4
2-16-94

TEXAS STATE BOARD OF PHARMACY

Newsletter

VOLUME XVIII, NUMBER 1 FALL/WINTER 1993-94

PRESIDENT'S COLUMN

The New Pharmacy Act and Improved Health Care

by Ann H. Peden, R.Ph.

I am honored to be the new president of the Board and very pleased that I can bring some GOOD NEWS to you through this column. The new Texas Pharmacy Practice Act, which became effective on September 1, 1993, is a tribute to the positive outcomes that can be accomplished when all of the facets of pharmacy work together. The one goal that everyone shared was allowing the pharmacist to be more patient oriented and changing the law to allow pharmacists to provide better patient care.

Pharmaceutical Care has now been recognized and legally defined as not only the provision of drug therapy but includes all of the other cognitive services we provide to assist in the cure or prevention of disease, the elimination or reduction of symptoms, or the slowing of a disease process. Our identity as pharmacists is no longer tied specifically to dispensing a product but encompasses our knowledge and communication skills.

This should be GOOD NEWS to those of you who have felt disenfranchised from the profession because you practice in clinical settings, in drug abuse clinics, for drug information services, home health care agencies, hospice, for insurance, managed care or IV therapy companies, for universities, etc. The NEWS IS EVEN BETTER for those who still practice in traditional settings. Your input during the legislative process resulted in the following changes that will dramatically improve our ability to provide better and more timely pharmaceutical care to our patients.

- Pharmacists may now partially fill (for up to 30 days) Schedule II prescriptions for patients who are terminally ill or in a nursing home. This prevents the time and cost consuming task of having to inventory and destroy large amounts of these drugs or having them unaccounted for altogether. More importantly, it allows patients to get the medication when they need it and without delay even if the pharmacy does not have the whole quantity ordered.
- Pharmacists may now, when exercising

see President's Column on page 4

IT'S EVERYWHERE, IT'S EVERYWHERE!
A View From the Field

by Sam T. Searcy, Police Officer
Narcotics Division, Diversion Squad
Houston Police Department

Here in Houston, it is **everywhere,** hydrocodone products, that is. Vicodin®, Vicodin® ES, Lortab®, and Lorcet®, the drugs of choice, account for 98% of the forged prescription cases that my partner and I file with the District Attorney's Office. All of these cases are a felony of the third degree. It is so common, we actually have a fill in the blank charge for the hydrocodone products that go to the District Attorney's Office.

Once the addiction takes over, this cross-section of our population will do anything to obtain the drug. The most common methods are the forged, altered, or telephoned prescription. As a police officer, I have a "sixth sense." You, as a pharmacist, have this same "sixth sense." You have to make the decision to fill or not to fill each prescription presented.

Several years ago, when a forged prescription was filled, we could count on it being used for self abuse....Not Now! Recently, reports of sales of diverted Vicodin® have surfaced and the going rate on the street is $2.00 per tablet. You must realize that prescription drugs, both controlled and non-controlled, are very hot street items. Why, you ask? Two reasons: they are cheaper and the purchaser knows exactly what they are buying. A tablet of Lorcet® 10 for example, hasn't been cut or mixed with anything.

> "...carisoprodol or Soma® 350 ...HOT! HOT! HOT!"

Not one person I have ever arrested told me that they intended to abuse hydrocodone products. For many people who are given the medication for a legitimate medical purpose, it quickly becomes their drug of choice, and nothing else will do. Once the prescriptions from their doctor stop, the theft of prescription blanks, copies of blanks, and fictitious telephone prescriptions begin. During this time, the tolerance level increases. With a wide range of people, this drug takes over. It is not uncommon to see a person who ingests 30 or more tablets a day.

Not to be outdone, on the other side of the coin is carisoprodol or Soma® 350....HOT! HOT! HOT! And pharmacists fill forged, stolen, or altered prescriptions for 100 tablets and think nothing about it. All I can ask is to PLEASE think about it! My standard line

see It's Everywhere on page 3

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verywhere

continued from page 1

to a pharmacist is to treat Soma® 350 as a controlled substance BUT, also to go one step further and verify the prescription with the prescriber. Because doctors and/or pharmacists are sometimes lax, vast amounts of Soma® 350 are being sold on the street. Again, we see people that we arrest that have become addicted to Soma® 350. Some of these people take up to 100 tablets per day! Soma® 350 is another cross-section drug affecting a wide range of people. From interviewing our suspects, none intended to become addicted to Soma®....it just happened, and they took it from there. It seems such a minor non-controlled substance, but the attention it gets after it leaves your pharmacy is certainly startling. I would have to award it five stars for diversion!

Another popular non-controlled substance that is abused is Stadol®. First we had problems with diversion of the injectable Stadol®. It seemed they all had the same story....once they started abusing it, they could not stop. For convenience, Stadol® nasal spray is quickly rising to the top in popularity. Recently, two nurses were arrested and both were addicted to Stadol® nasal spray. Please make this a "verify" drug.

In the Houston area, various other drugs are popular but seem to come and go, such as Talwin® and PBZ®, and Tylenol® with Codeine #3 and 4. Valium® and Xanax® seem to be making a comeback with a much younger group that before. This time around, the 16, 17, and 18 year old is the user, soon to become, the addicted.

In closing, to curtail diversion of both controlled and non-controlled drugs, you the pharmacist, have to become a stop sign. This means that if the patient tricks the doctor for the prescription, you can stop it, if you form an opinion that the medication is being used for a non-medical purpose. There of course, is no state or federal law that says you must fill a prescription. You can stop it simply by not filling it. You do have that right. Please remember that the 20, 30, or 60 tablets that you filled for a patient is 20, 30, or 60 more than they had when they walked into your store. ☺

CALENDAR

* Indicates Continuing Education Programs presented by American Council on Pharmaceutical Education (ACPE) approved providers with continuing education credit available.

January 1994

1		New Years Day (National Holiday, TSBP Office Closed)
6	*	**Lubbock** "Intermittent vs. Continuous Infusion of H2 Antagonists" Contact: Theresa West, 806/796-6765
11	*	**Austin** "Pathophysiology & Treatment of Vasodepressor Syncope" Contact: Chris Paap, 512/471-4048
17		Martin Luther King, Jr. Day (National Holiday, TSBP Office Closed)
20	*	**Houston** "Reflections of a Profession" Contact: Larry Egle, 713/791-3109
21-22	*	**Houston** "Latest Trends in Contemporary Compounding" Contact: Cyndi Hicks, 800/331-2498
22-23	*	**Austin** "8th Annual Young Pharmacist Leadership Conference" Contact: Jennifer Myhra, 512/471-1737
23	*	**Austin** "Texas Pharmacy Law Review" Contact: Wayne Beisel, 214/618-9652 or Bennett Brooke, 512/346-5850
23	*	**Irving** "Pharmacy Law Issues" Contact: Joy Kovar, 512/836-8382
24-25		NABPLEX and Texas Pharmacy Jurisprudence Examinations - Austin

February 1994

13	*	**Houston** "AIDS Symposium" Contact: Joy Kovar, 512/836-8382
15-16		TSBP Board Meeting
19-20	*	**Houston** "Aseptic Techniques for Home Health Care and Community Pharmacists" Contact: Sandra Webb, 713/795-8337
21		Presidents Day (National Holiday, TSBP Office Closed)
21-22	*	**Houston** "Aseptic Compounding Program" Contact: Cyndi Hicks, 800/331-2498
21-24	*	**Austin** "33rd Annual International Industrial Pharmacy Conference" Contact: Jennifer Myhra, 512/471-1737

March 1994

5	*	**Austin** "Infectious Disease" Contact: Chris Paap, 512/471-4048
9-16	*	**Aboard Ship from Ft. Lauderdale, FL** "CE at Sea" Contact: Joy Kovar, 512/836-8382
12-13	*	**Houston** "Aseptic Techniques for Home Health Care and Community Pharmacists" Contact: Sandra Webb, 713/795-8337
19-23	*	**Seattle, Washington** "APhA 141st Annual Meeting and Exposition" Contact: APhA, 202/429-7580
21-22	*	**Houston** "Aseptic Compounding Program" Contact: Cyndi Hicks, 800/331-2498
26	*	**Houston** "Topics in Home Care Pharmacy" Contact: Sandra Webb, 713/795-8337

April 1994

4	*	**Austin** "Texas Pharmacy Law Review" Contact: Wayne Beisel, 214/618-9652 or Bennett Brooke, 512/346-5850
5		Texas Pharmacy Jurisprudence Examination - Austin
7-10	*	**Abilene** "WTPA 1994 Annual Convention" Contact: Lonnie Hollingsworth, 806/799-5908
16-17	*	**Houston** "Aseptic Techniques for Home Health Care and Community Pharmacists" Contact: Sandra Webb, 713/795-8337
18-19	*	**Houston** "Aseptic Compounding Program" Contact: Cyndi Hicks, 800/331-2498
24-27	*	**San Antonio** "TSHP 46th Annual Seminar & Exhibits" Contact: Mike Knapp, 800/242-8747
29-May 1	*	**South Padre Island** "TPA Region D Meeting" Contact: Chuck Perkes, 512/686-1609

P L A N (Pharmacists Learning Assistance Network) **800/533-3606**

A national, computerized data base of continuing education programs. Continuing education programs are compiled and cross-referenced 3 ways: **by topic** - such as pharmacy administration, drug therapy, or disease state; **by location** - broken down by city and state; and **by calendar** - sorted by date. Take advantage of this free information service by calling the toll free number listed above.

SENATE BILL 715

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

February 16, 1994

MADAM CHAIRPERSON, MEMBERS OF THE COMMITTEE, MY NAME IS TERRENCE BOYLE, SUPERVISORY INVESTIGATOR FOR THE DRUG ENFORCEMENT ADMINISTRATION (DEA). I APPEAR BEFORE YOU TODAY ON BEHALF OF THE KANSAS BOARD OF PHARMACY IN SUPPORT OF SB 715.

SIXTEEN OF THE NINETEEN DEA FIELD DIVISIONS HAVE REPORTED HYDROCOCONE, A SCHEDULE III SEMI-SYNTHETIC NARCOTIC, AS BEING ONE OF THE MORE POPULAR (AND IN SOME AREAS THE MOST POPULAR) DRUG OF ABUSE. HYDROCODONE IS MARKETED IN THE UNITED STATES AS AN ANALGESIC (TRADE NAMES INCLUDE ANEXSIA, LORTAB, LORCET, AND VICODIN) AND AS A COUGH SUPPRESSANT (E.G. HYCODAN AND TUSSIONEX). HYDROCODONE IS BEING ABUSED BY ITSELF AS WELL AS IN COMBINATION WITH OTHER DRUGS. ONE OF THE COMBINATIONS THAT HAS BEEN NOTED IS HYDROCODONE AND SOMA (CARISPRODAL, A NON-CONTROLLED MUSCLE RELAXANT).

THE DIVERSION AND ABUSE OF SOME (CARISPRODAL), MENTIONED EARLIER, IS BECOMING INCREASINGLY WIDESPREAD IN SEVERAL PARTS OF THE UNITED STATES. IT IS USED BY DRUG ABUSERS TO ENHANCE THE EFFECTS OF HYDROCODONE PRODUCTS, AND IT IS USED WITH CODEINE COMBINATION PRODUCTS AND ALCOHOL.

TEXAS AND NEVADA ARE TWO STATES THAT ARE EXPERIENCING PROBLEMS WITH HYDROCODONE. IN HOUSTON, 98% OF THE FORGED PRESCRIPTION CASES FILED WITH THE DISTRICT ATTORNEY'S OFFICE BY THE NARCOTIC DIVISION, DIVERSION SQUAD, ARE FOR HYDROCODONE PRODUCTS.

SOMA IS ANOTHER PRODUCT THAT IS CAUSING CONCERN AMONG LAW ENFORCEMENT OFFICIALS IN HOUSTON. SOMA AS A NON-CONTROLLED SUBSTANCE RECEIVED ATTENTION THAT IS STARTLING. THE DIVERSION SQUAD IN HOUSTON AWARDS SOMA FIVE STARS FOR DIVERSION. THE POLICE ARE SEEING VAST AMOUNTS OF SOMA BEING SOLD ON THE STREET WITH ADDICTS COMPRISING A CROSS SECTION OF THE POPULATION OF HOUSTON.

IN LAS VEGAS, ON THE AVERAGE OF ONCE A DAY, A PHARMACIST WILL ACTIVATE A TELEPHONE NETWORK. SEVENTY-FIVE (75%) OF THE CALLS ARE WARNING OTHER PHARMACISTS OF ATTEMPTS TO PASS A PHONY HYDROCODONE PRESCRIPTION. LAS VEGAS PHARMACISTS POST A FOUR-PAGE, SINGLE-SPACED LIST OF PATIENTS WHO HAVE TRIED TO PASS BOGUS SCRIPTS IN A TWO-MONTH PERIOD. NPHA PRESIDENT TOM SNOW ESTIMATED NINE OUT OF TEN FORGED PRESCRIPTIONS ARE FOR HYDROCODONE.

Senate P H & W
Attachment #5
2-16-94

IN KANSAS, THE PROBLEM THAT EXISTS WITH SOMA IS AS A NON-CONTROLLED SUBSTANCE IT IS APPEALING TO ADDICTS IN OKLAHOMA. OKLAHOMA HAS PLACED SOMA IN SCHEDULE IV. AS A RESULT, SOUTHEASTERN KANSAS HAS EXPERIENCED AN INFLUX OF ADDICTS FROM OKLAHOMA COMING ACROSS THE BORDER TO OBTAIN THEIR SOMA.

HYDROCODONE ABUSE HAS BEEN BROUGHT TO THE ATTENTION OF THE KANSAS CITY OFFICE OF THE DEA DURING THE LAST YEAR. HYDROCODONE IS THE MOST POPULAR CONTROLLED DRUG OF ABUSE AMONG MEDICAL PROFESSIONS IN KANSAS. AT THE PRESENT TIME, THREE SEPARATE INVESTIGATIONS ARE UNDERWAY DEALING WITH PRACTITIONERS ABUSING HYDROCODONE. THE QUALITIES ARE LARGE AND THE ABUSE IS OFTEN UNDETECTED DUE TO THE STATUS OF THE INDIVIDUALS IN THE COMMUNITY.

I RESPECTFULLY REQUEST FAVORABLE PASSAGE OF SB 715 OUT OF COMMITTEE.

THANK YOU.

KDA
KANSAS DENTAL ASSOCIATION

Statement by Carl C. Schmitthenner, Jr.
Senate Bill 722
February 16, 1994

Madam Chairman, Members of the Committee,

I am Carl Schmitthenner. I am the Executive Director of the Kansas Dental Association. The Kansas Dental Association represents 1,171 dentists, or about 80 percent of the dentists in the state of Kansas.

The mission of this professional association is to promote the public health, advance the art and science of dentistry, and to foster an awareness of the obligation and responsibilities of the dental profession to society.

That mission is executed through the policies adopted by the governing body of the Kansas Dental Association known as the Executive Council. Members of the Executive Council are elected by their peers in the eleven local district dental societies.

In fulfilling its mission to promote the public health and discharge the profession's duties to society, the KDA Executive Council voted to accept the changes in the dental practice act that are here before you in the form of Senate Bill 722.

This legislation represents more than seven years of study within the profession, numerous meetings by practitioners who would be affected by these provisions, and consultation with other professional groups, including the Kansas Society of Oral and Maxillofacial Surgeons.

Briefly stated, S.B. 722 provides the Kansas Dental Board with the authority to develop appropriate qualifications for dentists who administer intravenous sedation and general anesthesia in their offices. We believe this legislation represents a positive step to assure the continued safety of the public.

Two members of the Kansas Dental Association are with me today to speak in support of S.B. 722. I would first like to introduce Dr. Taylor Markle, a Kansas City oral surgeon. Following Dr. Markle will be Dr. Stephen Zeller, an oral surgeon from Topeka.

5200 Huntoon
Topeka, Kansas 66604
913-272-7360

Senate P H & W
Attachment #6
2-16-94

Statement by Taylor Markle, D.D.S.
Senate Bill 722
February 16, 1994

I am Dr. Taylor Markle. I am a practicing, Board-certified oral and maxillofacial surgeon in Shawnee, Kansas. I am President of the Kansas Society of Oral and Maxillofacial Surgeons. I graduated from UMKC School of Dentistry in 1981 and graduated from the four-year OMS residency program in 1986 at UMKC. During my residency, I administered hospital-based general anesthesia for six months at Truman Medical Center for general surgery, gynecology, plastic and orthopedic surgery cases. The residency also consisted of 2 1/2 years of out-patient anesthesia training.

The Kansas Society of Oral and Maxillofacial Surgeons are very much in favor of Senate Bill 722.

There are several reasons for supporting this bill. The first and foremost is to protect the citizens of Kansas that receive medications in a dental office that renders them semi-conscious or unconscious.

The bill would authorize the Kansas Dental Board to adopt rules and regs to establish qualifications for dentists who administer in-office intravenous sedation and general anesthesia. At this time, any licensed dentist can administer any anesthetic under the current scope of licensure.

This restriction is similar to what is already in place at hospitals in our state. Hospitals assure patients that their health providers are educated, trained, have correct monitors, emergency equipment and drugs for patient's safety.

We are attempting to provide the same assurance to the dental patients of this state. Currently, there are 47 states that regulate conscious sedation and 48 states that regulate general anesthesia.

Section 1 (b) is current law. Members of the Kansas Society of Oral and Maxillofacial Surgeons have registered nurses under their direct supervision that they employ. These medications would be given under the direct supervision of a licensed practitioner who is authorized to administer that particular anesthetic.

Section 1 (c) provides a dentist the ability to have a registered nurse anesthetist to provide an anesthetic in their office.

Section 2, K.S.A. 65-1444, was amended to allow the Kansas Dental Board in their wisdom to write rules and regulations concerning qualifications like education, training, monitoring devices, emergency equipment and drugs. These rules and regs would authorize a dentist to administer an anesthetic which renders a patient semi-conscious or unconscious.

The Kansas Society of Oral and Maxillofacial Surgeons has drafted proposed rules and regulations that the Kansas Dental Board may use. Our proposal would have two levels -- 1) conscious sedation and 2) deep sedation or general anesthesia.

Each category would have different education and training requirements. Within each category there is a grandfathering clause for those people who have used these anesthetics in the last three years. We would like the Kansas Dental Board to determine the competency and regularity of the anesthetics given by these practitioners for proper licensure.

All patients regardless of anesthetic given would follow a similar pre-operative evaluation. All practitioners using these anesthetic procedures would have the proper monitoring devices, emergency equipment and drugs available which might be designated by these rules and regs.

In conclusion, the Kansas Society of Oral and Maxillofacial Surgeons support Senate Bill 722. We are dedicated to enhance the safety of anesthetics administered to the citizens of the state of Kansas in a dental office.

Senate PH#1
attachment #7
2-16-94