

# DPT NEWS

## Dissatisfied Parents Together

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Vol. 3 No. 1

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

Spring 1987

## President Reagan Signs Vaccine Injury Compensation and Safety Bill Into Law

After four and a half years of determined effort by Dissatisfied Parents Together (DPT), the 99th Congress overwhelmingly approved and President Reagan reluctantly signed into law the National Childhood Vaccine Injury Act of 1986. The vaccine injury compensation and safety legislation was part of the Omnibus Health Bill (S. 1744), which contained a number of bills on health-related topics supported by more than 50 major health organizations and drug companies. Although the no-fault compensation system became law when President Reagan signed it on November 14, it will not go into effect until Congress passes a separate bill authorizing funding to pay for the system.

Passage of the bill came only after a long and often frustrating struggle by DPT to persuade Congress and the Reagan Administration to acknowledge the vaccine injury and safety crisis. The issue was the subject of nearly a dozen congressional hearings, most of which included testimony by Dissatisfied Parents Together. Even after the bill passed the House and Senate in the waning hours of the 99th Congress, DPT was involved in a hard-fought battle to prevent key White House officials from convincing President Reagan to exercise a pocket-veto on the grounds the bill was too expensive and did little to limit vaccine injury lawsuits and court awards.

In the end, all of the negotiating, maneuvering, and good old fashioned arm twisting culminated in DPT holding a November 6 vigil in front of the White House. Simultaneous vigils were held in Santa Clara, California; St. Petersburg, Florida; Chicago, Illinois; and Tulsa, Oklahoma. President Reagan signed the bill eight days later.

### History of A Struggle Against Great Odds

Soon after Dissatisfied Parents Together (DPT) was founded in 1982 following the broadcast of "DPT: Vaccine Roulette" in Washington, D.C., it became evident that DPT's commitment to help vaccine injured children and prevent future vaccine damage would succeed only if DPT could win credibility for the vaccine injury issue and for the organization. Like David against Goliath,

DPT represented essentially powerless vaccine injured victims pitted against three of the most powerful and wealthy segments of our society: the pharmaceutical industry, organized medicine, and the federal government.

The early days in 1982 and 1983 were lonely ones for the handful of DPT founders in Washington, D.C. who were trying to convince Congress that there were many more vaccine injured children in America than the drug companies, medical organizations and government health agencies were willing to admit. The first in Congress to respond to DPT's concerns were Congressman Dan Mica (D-FL) and Senator Paula Hawkins (R-FL).



**Vaccine Victim's Plea**—Measles vaccine injured Stacy Scholl (right) of St. Petersburg, Florida, and Senator Orrin Hatch (R-Utah) urge President Reagan to sign the Omnibus Health Bill at an October 28 Capitol Hill press conference.

A member of the Senate Labor and Human Resources Committee, Hawkins was well known for her activism in health issues involving children. During the more than four years it took to pass legislation addressing the vaccine injury issue, she proved to be a steadfast supporter of the many goals DPT had set. This included the creation of a federal no-fault compensation system for children damaged or killed by vaccines that also protected their right to seek justice in the court system.

DPT's four year effort on Capitol Hill was led by DPT President Jeff Schwartz, one of the founders of DPT, whose daughter was injured by a DPT shot and eventually died from her injuries. A lawyer with 15 years of experience as a lobbyist for environmental health issues, he was a principal architect of the first vaccine injury compensation legislation (S. 2117) introduced by Hawkins in November 1984.

S. 2117 was the product of nearly two years of difficult negotiations between DPT and the American Academy of Pediatrics (AAP). Although several "exclusive remedy" (no lawsuits) federal vaccine injury compensation schemes had been proposed for years by the AAP and the American Medical Association (AMA), S. 2117 rejected that approach. The new bill (1) offered parents of vaccine injured children a no-fault compensation system alternative to a lawsuit; (2) preserved a parent's right to sue in court; and (3) instituted safety reforms to reduce vaccine damage. Seven months later, Congressman Henry Waxman (D-CA), chairman of the House Energy and Commerce Subcommittee on Health and the Environment, introduced a companion bill in the House.

### DPT's First Choice Is Scuttled By Strong Opposition

Although DPT persuaded six Democratic and Republican Senators to co-sponsor the bill, opposition to S. 2117 by drug companies, the Department of Health and Human Services, and the AMA was too strong. They maintained the bill unfairly favored vaccine injured children, citing that it did not place

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# Justice Department Moves to Take Jury Award From Child Brain Damaged by DPT Vaccine

The U.S. Justice Department filed a brief asking an Ohio appeals court to overturn the March 1986 jury verdict in *Tyler White v. Wyeth Laboratories*. In that trial, Wyeth Laboratories was ordered to pay \$2.1 million to Tyler White and his parents after the jury considered evidence documenting the unreasonably dangerous formulation of its whole cell pertussis vaccine.

Tyler White was a healthy four month old baby until he went into a massive convulsion

within hours of his second DPT shot in 1983. Now five years old, his uncontrolled seizures are so severe and he is so profoundly retarded that he will require institutionalization for the rest of his life.

During the three week trial in Cleveland, an eight-member jury considered evidence documenting that Wyeth manufactured its whole cell pertussis vaccine in an unreasonably dangerous and inherently unsafe way; that it could have made the product safer; and

that it did not properly inform physicians and the public of the product's dangers. Wyeth holds the rights to produce a purified acellular pertussis vaccine similar to the one effectively used in Japan since 1981.

## Justice Moves to Block Lawsuits and Federal Compensation

The Justice Department does not dispute the fact that the pertussis vaccine caused Tyler White's brain damage, but is "concerned about the effect of the decision in this case on the nation's public health." This is the first time the Justice Department has intervened in a private lawsuit solely involving compensatory damages for medical care of a child injured by a legally mandated vaccine.

In July 1985, Deputy Assistant Attorney General Robert Willmore testified at Senate hearings against no-fault vaccine victim compensation legislation supported by Dissatisfied Parents Together (DPT). Willmore stated that "the tort system will work in these (vaccine damage) cases" and asserted that the Administration did not want to "reduce by one penny the complete compensation to which prevailing plaintiffs are entitled for all their medical and custodial care expenses."

The Justice Department has stated that it will seek to overturn the jury verdict on the grounds that the Food and Drug Administration (FDA) has licensed the 50-year old whole cell pertussis vaccine as safe. Court documents revealed that the vaccine manufacturers and the FDA have known for several decades that the mouse test used by the FDA to screen the vaccine for safety does not predict its ability to cause death and brain damage in children.

## DPT Protests Justice Department's Action

In a national press release issued by Dissatisfied Parents Together, DPT President Jeff Schwartz was quoted as saying, "We are shocked and appalled that the Justice Department would try to rob Tyler White and his family of medical care expenses awarded by a jury. There is no valid public policy purpose for the Justice Department to intervene to protect the negligence of Wyeth."

Tyler's mother, Joanne White, wrote a letter to Mrs. Reagan and asked her for help in stopping the Justice Department from interfering in the case. Although the White House reviewed the case, it did not act to stop Justice from filing the brief on behalf of Wyeth. The case is now in the appeals court, where it will eventually be heard by three Ohio judges.

## Pennsylvania Hearing Produces Heated Debate

On October 7, 1986 the Pennsylvania House Health and Welfare Committee held a hearing as part of an investigation into the safety and effectiveness of the pertussis vaccine. At the hearing, Pennsylvania DPT leader Judy Webb Glomb and State Representative Kathy Durham (R-160) blasted a pediatrician from the Pennsylvania Medical Society who told legislators that 50 pertussis vaccine deaths per year "is the price we have accepted to pay to protect all our children against the ravages of pertussis."

After Dr. Richard Baltz made that statement, Glomb said, "I am very upset that a doctor would sit right in front of me and say that 50 children must die. We don't need to give up any lives. We can protect our children against whooping cough with a better vaccine and better procedures." In even stronger language, Dur-

ham said, "It sickens me to hear you say even one life is the price you have to pay" for a vaccine. Baltz responded, "It is difficult to say any loss of life is worth anything else, but we have to look at what is good and DPT is good."

### Immunization Certificates Recalled

Judy Glomb's infant daughter, Bernadette, died on February 14, 1985 following a DPT shot reaction. A series of articles about Bernadette's vaccine death ran in the *Delaware County Daily Times* later that year. Glomb contacted Durham after learning that Pennsylvania school authorities were telling parents that pertussis vaccine was required for entry to school. Pennsylvania law does not require children to be injected with pertussis vaccine. The state's school immunization certificates, which doctors must sign, also incorrectly stated the vaccine was required for school entry. Durham sent a letter to the Secretary of Health asking that the certificates be recalled and one million new ones be printed, which was done. She then introduced a resolution calling for an investigation into the state's vaccination program.

The Pennsylvania State Chapter of DPT asked the legislature to pass a vaccine safety bill similar to those passed in Maryland, West Virginia, and New Jersey. Other parents testifying at the hearing included Janice Reed of Great Bend, whose DPT injured son has an uncontrollable seizure disorder; Debbie Weldon of Marcus Hook, whose son had severe reactions to pertussis vaccine; Carlene Cioffi of Williamsport, whose pertussis vaccine injured son has an uncontrollable seizure disorder; and John Larkin of Philadelphia, whose son died following a reaction to pertussis vaccine.

## DPT News

The DPT News is published by Dissatisfied Parents Together (DPT), a non-profit, educational, charitable, and research organization. This newsletter is sent free to members of DPT, who pay \$20 annual dues to belong to the organization each calendar year. Members may obtain an additional copy for \$2 (non-members for \$4) by writing to Newsletter Copies, DPT, 128 Branch Rd., Vienna, Va., 22180. Readers contributing articles or letters for inclusion in the newsletter should write to Editor, DPT News, at the above address. All rights reserved. No article contained in this newsletter may be reproduced whole or in part without permission.

Barbara Loe Fisher, Editor

# Parents Demonstrate at CDC in Atlanta

Members of Dissatisfied Parents Together (DPT) carrying posters of children who died or were brain damaged by reactions to DPT vaccine demonstrated in front of the Centers for Disease Control (CDC) in Atlanta on Monday, May 12, 1986. The demonstration was held to protest the lack of a national mandatory vaccine reaction reporting system that will give an accurate count of how many children are killed or injured by vaccines every year in the U.S.

After the demonstration the parents voiced their concerns during a formal presentation and discussion at a meeting of the CDC's Immunization Practices Advisory Committee (ACIP) attended by health officials responsible for surveillance of vaccine reactions. The event was organized by DPT Vice President Barbara Loe Fisher and DPT Director Kathi Williams at DPT National in Washington, D.C., and Georgia DPT state coordinator Leslie Uhl Chapman in Atlanta.

## Children From Eighteen States Represented

About 25 mothers and fathers from Kansas, New York, Illinois, Virginia, Oklahoma, Pennsylvania and Georgia traveled to Atlanta to march. They carried signs bearing the pictures of DPT injured children from 18 states with statements such as "DPT: Know the Risks," "CDC: Investigate Our Babies' DPT Deaths," "We Want A Safe Vaccine," "Give Us The Best DPT," "Kids With Shots Still Get Whooping Cough," and "Help Save Our Babies."

Children on tricycles and babies in strollers were among the marchers, who moved slowly and silently in single file back and forth under grey skies in front of CDC headquarters. Just as the march ended and parents went into the building to appear before the ACIP committee, the threatening skies erupted in a thunderstorm that lasted the rest of the afternoon.

## Parents Report Vaccine Deaths

Nine parents made presentations to members of the ACIP committee during a two hour discussion with the vaccine policymakers. Even though all ACIP meetings are open to the public, ACIP would not allow television cameras to enter the room. However, reporters were allowed to remain and take notes.

In an opening statement, DPT Director Kathi Williams said, "We are here to speak to you on behalf of parents who want to protect their children from vaccine reactions as well as childhood diseases." Officially reporting their children's pertussis vaccine deaths to the CDC were David McCutcheon of Rye, New York, whose 20 month old son, Nicholas, died within eight hours of his fourth DPT

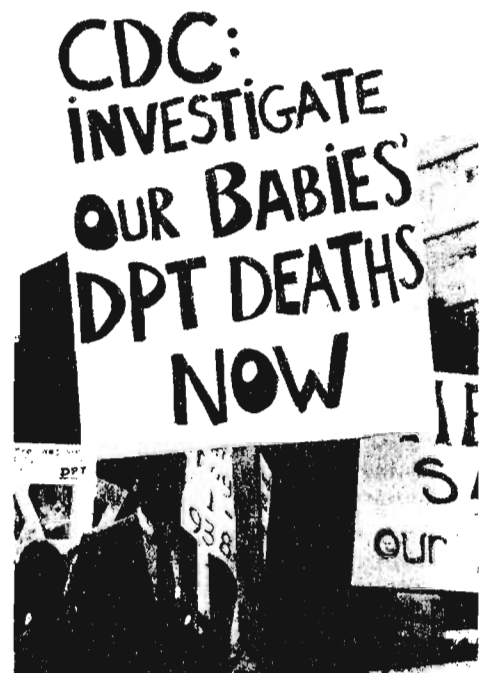
shot; Dianna Anderson of Cambridge, Illinois, whose three month old daughter, Erika, reacted within hours of her first DPT shot and continued to exhibit neurological signs until her death 33 days later; and Michael Rodee of Emporia, Kansas, whose six month old son, Andy, reacted within minutes of receiving his third DPT shot and died 96 hours later.

## A Call For Better Reporting, Diagnosis, and Contraindications

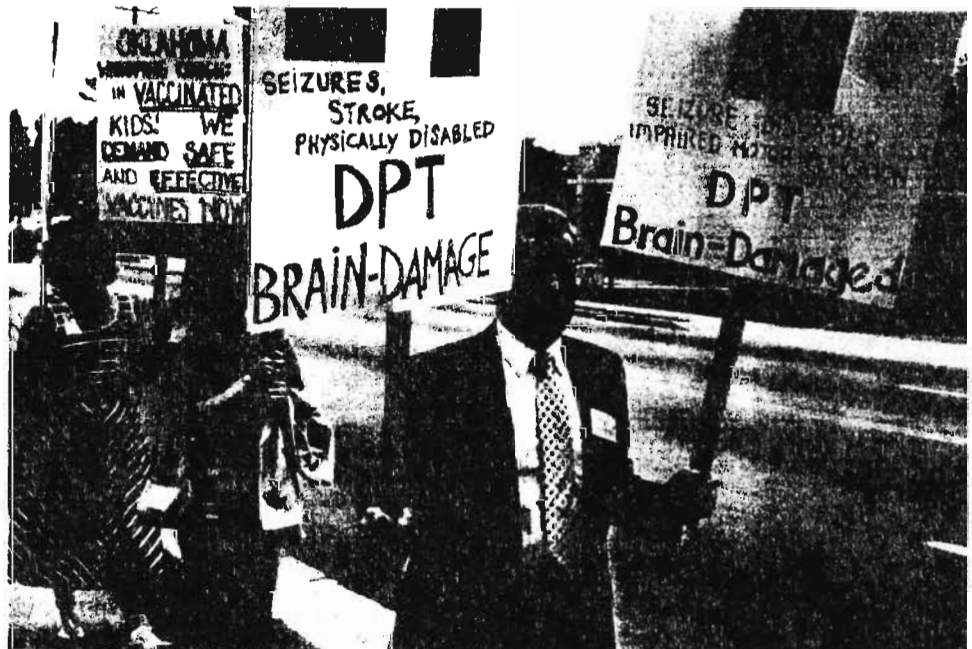
Robb Stuart Chapman, whose infant son, John, died after a DPT reaction in 1984, spoke on "Deaths Following DPT Vaccination." He emphasized that "DPT may not cause true SIDS events, but DPT deaths are being tossed into what is increasingly called 'that wastebasket SIDS category.'" Pennsylvania DPT President Judith Webb Glomb, whose infant daughter, Bernadette, died after a DPT reaction, spoke on "Public Education and Vaccine Reaction Reporting Problems." She reported on a survey she conducted among pediatricians in private practice indicating few give vaccine information to parents or report reactions.

Oklahoma DPT President Karen Booker Cline, whose infant daughter, Sabra, died after a DPT shot reaction, spoke on "Families With Multiple DPT Reactions." Noting that the medical literature points to genetic predisposition to vaccine reactions, she reported

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Investigations Needed—Mike Rodee (left) of Emporia, Kansas and Kathleen Clark of Atlanta, Georgia ask the CDC to investigate DPT vaccine deaths at the May 12 Atlanta march.



National Support—Kansas DPT member Myron Rodee (right), Pennsylvania DPT chapter President Judy Glomb (center) and Oklahoma DPT chapter President Karen Cline (left) carry signs with messages for the CDC during the May 12 demonstration in Atlanta.

# CDC Demonstration in Atlanta...

(Continued from page 3)

on her survey of 45 families—28 of whom had more than one child who reacted severely to DPT. On behalf of DPT she called for “immediate inclusion of a family history of severe reactions to DPT as a contraindication to receipt of pertussis vaccine” and consideration of a personal or family history of severe allergies as a contraindication.

## Whooping Cough Occurs In Many Vaccinated Children

“Obviously whooping cough is occurring in a significant number of fully or partially vaccinated individuals,” said DPT Vice President Barbara Loe Fisher, whose nine year old son has multiple learning disabilities from a reaction to his fourth DPT shot at age two-and-a-half. Fisher’s fully vaccinated sister contracted whooping cough in 1981 and passed it on to a fully vaccinated four year old daughter and unvaccinated three week old daughter.

Fisher reported on her investigation of whooping cough reports in 1985 in eight states reported by the American Academy of Pediatrics (AAP) as having had “near epidemics” during that year. She found that whooping cough increases reported in these



**Getting the Word Out**—DPT Vice President Barbara Loe Fisher (right) explains DPT’s goals to CNN television medical correspondent Dan Rutz as DPT Director Kathi Williams (center) gives an interview to an Atlanta television station during the May 12 demonstration at the CDC.

states in 1985 were not true increases in disease incidence, but primarily reflected an increase in reporting of the disease due to recent publicity about the vaccine. She also found that more than 50 percent of the pertussis cases in all eight states occurred in vaccinated individuals. One state reported that more than 70% of its pertussis cases had received three or more DPT shots, and 45% had received four or more DPT shots.

“We know the vaccine is only protective for 2 to 5 years and that once immunity has worn off, there is a susceptible older child and adult population carrying the disease, often in atypical form and transmitting it to vulnerable newborns,” said Fisher. “Doesn’t this fact necessitate a reevaluation of the benefits and risks of the vaccine? And don’t we need a more effective pertussis vaccine as well as a less reactive one?”

## DPT Charges Conflict of Interest

Fisher also asked how ACIP members can be objective in making decisions about national vaccine policy when ACIP members testify on behalf of vaccine manufacturers in vaccine damage lawsuits. Noting that Alan Hinman, M.D., CDC Director of Immunization, and ACIP member Edward Mortimer, Jr., M.D., have given depositions on behalf of DPT manufacturers in DPT vaccine damage cases, she asked, “As individuals responsible for making vaccine policies and approving the use of new vaccines, you must remain impartial and objective in order to effectively carry out those responsibilities. How can you remain impartial when you are testifying in court against children damaged by the very whole cell vaccine you promote? How can you objectively evaluate the Japanese vaccine

when you are testifying for American vaccine manufacturers whose primary defense in law suits is that there is no safer alternative to the whole cell vaccine?”

## Demonstration’s Purpose Linked To Defects In System

The main purpose of the Atlanta demonstration was to increase public awareness of the fact that (1) the U.S. does not have a vaccine adverse reaction reporting system that properly evaluates vaccine risks; (2) vaccine deaths are often misclassified as sudden infant death syndrome (SIDS); (3) physicians are not properly educated about vaccine reactions and contraindications; (4) high risk children are not properly pre-screened by physicians because CDC vaccination guidelines are too lax; (5) whooping cough is occurring in vaccinated children; (6) and the purified, less reactive DPT vaccine used in Japan since 1981 to control whooping cough has not yet been offered to American parents.

During the ACIP meeting, the demonstration’s co-organizer Leslie Chapman pointed out, “We feel that if this Committee is involved in recommending that the immunizations be mandated throughout the land, we really feel that it has equal responsibility to mandate or encourage the passage of laws to report reactions to find out the risks. It is astounding that the people here assembled do not appear to feel that they need to know how many babies are actually being damaged or killed—the actual body count.”

In a press release issued by DPT National before the May 12 march, Chapman emphasized that DPT’s purpose in demonstrating in Atlanta was to help save the lives of children, Chapman stated, “We want the deaths and brain injuries of these children to be counted in official statistics. When the CDC opens its eyes to the size of this national tragedy, we trust it will take steps to make sure the babies



**On the Line**—Atlanta demonstration co-organizer Leslie Chapman leads a line of marchers along the street bordering CDC headquarters during the May 12 demonstration.



**Sign Painting**—The night before the May 12 march in Atlanta, Oklahoma DPT President Karen Cline uses her sign painting talent to hand-letter posters.

of today and tomorrow do not suffer the way ours have suffered," she stated.

### Media Is Supportive Of DPT's Efforts

The media generally understood and was supportive of DPT's effort to educate the public and appeal to the CDC to take steps to prevent vaccine injuries and deaths. During the Atlanta march, Barbara Fisher was interviewed live on "The Joan Hamburg Show" on WOR-Radio in New York City and on WSB-Radio in Atlanta. She and Kathi Williams were also interviewed by CNN and Ted Turner Cable News, which ran news spots on the march for two days. Atlanta stations WXIA-TV, WAGA-TV, and WSB-TV covered the march live and ran stories on the evening news featuring interviews with Robb and Leslie Chapman, David McCutcheon, Karen Cline, Kathi Williams and Barbara Fisher.

Dianna Anderson worked with WOC-TV in Davenport, Iowa; WHBF-TV in Rock Island, Illinois; WQAD-TV in Moline, Illinois; the *Quad-City Times*, and *The Daily Dispatch* in Moline, which included interviews with her and taped coverage of the march. Karen Cline worked with KWTW-TV in Oklahoma City, which featured the march on the evening

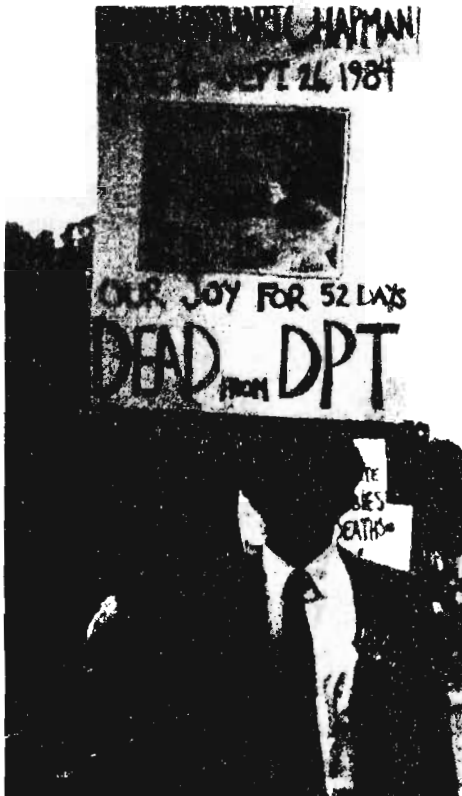
news, and *Tulsa World* and *Muskogee Daily Phoenix* ran photos of Karen and articles about the event.

The May 13 *USA Today* had a story on page 4 entitled "Death tale prompts vow on DPT vaccine" quoting Leslie Chapman. *The Atlanta Constitution* ran a photo and story about the march on May 13 quoting Kathi Williams and David McCutcheon. Denise Judd of American Fork, Utah could not come to Atlanta but sent a poster with a photo of her son, Bronson, who died following a DPT reaction. Denise obtained coverage of the march in *The Daily Herald* in Provo. Both AP and UPI sent stories out over their wire services, generating articles about the march in newspapers around the country.

On May 13, the ABC-TV "News This Morning" showed footage of the march. On May 14, Dr. Bob Arnot, medical reporter for CBS, included footage of the march and gave an excellent summary of DPT's concerns and goals on the CBS "Morning News." The June 9 issue of *Medical World News* featured a detailed summary of DPT's presentation to ACIP. The July 23 *Medical Tribune* also gave an in-depth analysis of DPT's concerns about whooping cough occurring in vaccinated children as did the August issue of the *East West Journal*.



**Vaccine Deaths Reported**—Holding pictures of their children who died following DPT reactions, Dianna Anderson of Cambridge, Illinois (right) and David McCutcheon of Rye, New York take part in the May 12 demonstration in front of the CDC in Atlanta.



**In Memory**—Robb Chapman participates in the May 12 Atlanta march by carrying a sign with a photo of his son, John, who died following a DPT reaction.

## You Make the Difference!

Dissatisfied Parents Together (DPT) made significant progress during 1986 primarily because of you—the members of DPT. At crucial points during the year, you rallied when a call for action went out from DPT National. You made the victories—large and small—possible. Those of you who marched in Atlanta or at the candlelight vigils, those of you who renewed your DPT membership or made an extra donation during the fund raising campaign, or sent a telegram to the White House or wrote a letter to your local newspaper—all of you are responsible for the success DPT achieved in 1986.

We should thank each other and take pride in what, together, we have accomplished on behalf of America's children during the past year. And yet, there is the realization that although we have won a few battles, we haven't yet won the war. Until all parents have accurate information with which to protect their children from vaccine injuries; until the U.S. has a safer and more effective pertussis vaccine; until parents can exercise greater freedom to choose which vaccines they want for their children; until America's mass vaccination system is reformed to better prevent vaccine deaths and injuries; and until parents are able to obtain fair compensation for children injured or killed by vaccines in the court system as well as in a compensation system, DPT's job will not be over.

If we keep our spirit and stay together, we can find ways to keep our organization and our cause alive. We all need to make the financial commitment of donating at least \$20 per year to DPT by renewing our memberships. We need to make an extra donation (no matter how small) to DPT at Christmas or during the month of our child's birthday. We need to donate our time and talents to DPT.

If we don't do it, no one else will. 1987 will either be the year we make the commitment to win the war no matter how long it takes, or we decide it is over. Either way, you will make the difference.

# STATE CHAPTER NEWS

Ten state groups have fulfilled requirements to become official DPT state chapters and have been chartered by DPT National. These include Alaska, California, Illinois, Maine, Minnesota, New Jersey, New York, Oklahoma, Pennsylvania, and West Virginia. More state chapters are in the process of forming.

Following is a round-up of news from several state chapters around the country, both those that have been chartered and those in formation. More news from other state chapters will be included in the next issue of DPT News.

## FLORIDA

Florida DPT chapter coordinators Velvet Carter and Wendy Scholl report that DPT members in their state wrote hundreds of cards, letters, and telegrams and participated in special events such as the St. Petersburg vigil in support of the Omnibus Health Bill. Special acknowledgement goes to Donna and John Gary of Sarasota, whose granddaughter died following a DPT reaction; Sara and Bob Lewis of St. Petersburg, whose daughter, Julia, is DPT injured; Marcie and Jim Meyer of Clearwater, whose daughter, Jennifer, is DPT injured; Linda and Bill Culhane of Clearwater, whose son, Chris, is DPT injured; Rick and Martha Dube of Orlando, whose daughter, Isabelle, is DPT injured; Robbie and Judy Wheeler of Clearwater, whose son, Kent, is DPT injured; and Donna Keith of Pinellas Park, whose son, Greg, is measles vaccine injured. Many Florida parents celebrated the signing of the bill by President Reagan at a picnic at the home of Bill and Linda Culhane.

## MINNESOTA

*Annual Meeting Held:* Minnesota DPT President Karen Trunk of Princeton, reports that the annual meeting of Minnesota DPT was held on May 10, 1986 at Hamlin University in St. Paul. Speakers and distinguished guests included David Bartholomew, district director of U.S. Representative Gerry Sikorski's office; Martin Preiser and Anthony Colantoni of the Chicago law firm of McDowell & Colantoni, Ltd.; Todd Rapp, a St. Paul lawyer from Estes, Parsinen & Levy; Barbara Ashley, a Minneapolis lawyer from Tanick & Heins; and Dr. and Mrs. Michael Gibbs.

Topics discussed included ways of getting legislation passed; how to get your Congressman to notice and appreciate your concerns; and details of being involved in litigation. Families attending had the opportunity to ask questions and offer comments. Dr. Gibbs, a Minnesota chiropractor who has taken a special interest in the DPT vaccine issue, wrote a letter to the editor of the Minnesota Chiropractic Association Journal asking Minnesota

chiropractors to financially support Dissatisfied Parents Together.

*Brain Injuries Discussed at Institute:* Karen Trunk attended a one week course at the Institutes for the Achievement of Human Potential in Philadelphia entitled "What To Do About Your Brain Injured Child." Topics covered were brain and growth development, psychological problems of brain injured children and their families; the brain as a computer; the testing of children; leaving the wounded children behind; and the Institutes' program. Karen reports that the \$500 cost of the course was "the best investment we've made for our son's future. We've seen many improvements in our son—especially better seizure control." Karen, whose son, Barry, is DPT vaccine injured, says that interested parents can write to: The Institutes for the Achievement of Human Potential, 8801 Stenton Ave., Philadelphia, PA, 19118.

## NEW JERSEY

New Jersey DPT chapter President Anne Miller of Cranford, reports that New Jersey Governor Thomas Kean signed the New Jersey vaccine safety bill (S.1696) into law on May 16, 1986. Senator Louis Bessano (R-Union County) was the bill's sponsor. The Senator presented Anne and Gail O'Connor

of Essex County, with the pen used to sign the bill. Anne's three year old son, Frank, is DPT injured as is Gail's 21 year old son, Brian. A photo of the Senator giving Anne the pen appeared in four New Jersey newspapers.

Anne is currently working with the state health department on the information booklet which will be given to parents prior to vaccination. The booklet is being modeled after the Maryland information booklet for parents that DPT helped write. Approximately \$75,000 in state funds have already been allocated to produce and distribute the one million information booklets to New Jersey parents.

## NEW YORK

*Buffalo Branch Forms:* New York Chapter President Janet Ciotoli of Binghamton reports that throughout 1986, New York DPT continued to hold quarterly meetings and generate publicity about the organization and the issue. A very active branch of the state chapter was formed in Buffalo by coordinators Barbara and Greg Chwojdak, whose son, Joey, is DPT vaccine injured. The Buffalo branch has held several public meetings and Barbara and Greg are responsible for generating a remarkable amount of media cover



**Vaccine Safety in New Jersey**—New Jersey DPT President Anne Miller of Cranford (center) accepts the pen that New Jersey Governor Thomas Kean used to sign the state's new vaccine safety bill from State Senator Louis Bessano (left) as Gail O'Connor of Essex County looks on.

age in their area.

Barbara and Greg arranged for Janet Ciotoli and DPT Vice President Barbara Loe Fisher to appear as guests on a popular morning talk show "AM Buffalo" (WKBW-TV) on April 18, 1986. Janet and Barbara's 20-minute appearance prompted so many letters from viewers that "AM Buffalo" scheduled a whole hour show on October 29 that featured Janet; Barbara; Ohio DPT member Joanne White, whose son, Tyler, is DPT vaccine injured; DPT plaintiff's attorney Boyd McDowell of McDowell & Colantoni in Chicago; and two Buffalo area pediatricians.

*Measles Scare Stopped in Rochester:* When one case of measles was reported in Monroe County, the county health department threatened to ban 400 junior high school students from school unless they were revaccinated with MMR (measles-mumps-rubella) vaccine. The 400 students had been vaccinated with MMR between 12 and 15 months of age and, although New York law requires vaccination after 12 months of age, health officials now maintain that immunity is not achieved unless a child is vaccinated after 15 months of age. Protesting that parents had not been given information on MMR vaccine risks and reactions, consumer activist and DPT member Judy Braiman-Lipson of Rochester, filed a complaint with the state's Attorney General's Office. Due to Judy's quick and decisive action, students were not barred from school if they were not revaccinated. . . . Judy, who is President of the Empire State Consumers Organization, was also responsible for convincing Wegman's Supermarkets (one of the largest supermarket chains in New York) to carry *DPT: A Shot in the Dark* on their bookshelves.

*Medical Students Are Told DPT Risks:* For the second time in a year, Janet Ciotoli spoke to medical students at Wilson Memorial Hospital about pertussis vaccine reactions and preventing vaccine injuries. The students were on rotation from Upstate Medical Center in Syracuse. . . . she also attended a conference sponsored by the New York Community Action Network (NYCAN) which is networking with other New York consumer activist organizations to identify common goals.

*Bowl-A-Thon Raises Money:* New York's Second Annual Spring Bowl-A-Thon, which was organized by Janet Ciotoli and New York Vice President Janice Reed, made \$1100. Supporters pledged a "penny a pin" or more for a three-game total for each individual bowler entered. The fundraiser was combined with a Baby Blanket Raffle (the blanket was

donated by New York DPT chapter Treasurer Anita Donovan).

#### WEST VIRGINIA

*Hearings Held on Vaccine Safety Law:* In 1985, West Virginia DPT chapter President Linda Thornton of Pinch, was responsible for convincing the state legislature to pass the second vaccine safety bill in the nation (Maryland was the first in 1984). Linda's five year old son, Ryan, is severely brain damaged from a DPT shot. Linda and twelve other parents attended a December 11, 1986 hearing in Charleston on proposed guidelines for implementing the bill.

Linda presented the state health department with a parent information booklet that was endorsed by William Neal, M.D., chairman, Department of Pediatrics, West Virginia University, and was supported by the West Virginia Advocates for the Developmentally Disabled. The booklet is almost identical to the one developed for Maryland's vaccine safety bill by Dissatisfied Parents Together and the state Department of Health and Mental Hygiene, Maryland Medical and Chirurgical Faculty, and Maryland chapter of the American Academy of Pediatrics. DPT President Jeff Schwartz negotiated for more than two years with Maryland health officials for lan-

guage in the booklet that would truly present both sides of the issue. The West Virginia state health department has not indicated yet whether or not it will approve the booklet for use in West Virginia.

*\$600 Raised For DPT:* Linda reports that she and five DPT members in her state collected more than \$600 for DPT's "Dear Friends" fund raiser including Chris McConiha; Betty Coleman; Ann Lough; and Carl Ruben. . . . The November 27 Times-West Virginian named Ann, Ed, and Mark Lough of Fairmont, "Family of the Year." Ann and Ed's only child, 31 year old Mark, was left brain damaged after a DPT shot reaction.

#### WISCONSIN

*First Chapter Meeting Held:* Wisconsin DPT chapter coordinator Linda Leuzinger of Milwaukee, reports that 30 parents from five cities attended the chapter's first support meeting held on January 15, 1986. Linda and Kathy Cavallo, also of Milwaukee, are working with Kathy's sister, Patty Reynolds, to organize the Wisconsin chapter. Linda's four year old son, Justin, was left with severe brain damage following a DPT reaction and suffers from uncontrolled seizures. Kathy Cavallo's six year old child was also damaged by a reaction to a DPT shot.

## DPT Receives More Than 4,000 Letters After DPT Story Airs on "Today Show"

Television Reporter Lea Thompson, who broke the story about pertussis vaccine damage in the U.S. in 1982, updated her story on the August 21 "Today Show." The five-minute segment alerted parents about high risk factors, showed children who were damaged or died following DPT reactions, and ended with DPT's address being shown. DPT received more than 4,000 letters from parents searching for more information after viewing the update.

Lea produced the update during a week-long appearance as guest host on the "Today Show." Some of the footage shown was taken from her Emmy award winning documentary "DPT: Vaccine Roulette" broadcast on WRC-TV in Washington, D.C. in April, 1982.

In her August 21 update, Lea focused on the vaccine damage lawsuits that have mounted during the past four and a half years, and the concurrent price hike by vaccine manufacturers

lobbying Congress for legislation to relieve them of liability for vaccine injuries. DPT President Jeff Schwartz talked about the need for safety reforms and a fair vaccine injury compensation bill. Because NBC received so many calls from parents about the update, DPT's address was shown again on the "Today Show" on August 22.

Among the children of DPT members seen on the "Today Show" update were Richie, who died after a DPT reaction, and is the son of Janet and Anthony Ciotoli; Traci, who is developmentally delayed from a DPT reaction, and is the daughter of Haviland and Debbie Abbot; Stevie, who died after a DPT reaction, and is the son of Steve and Debbie Pusateri; and Julie, who died at the age of three after suffering with seizures since her third DPT shot. Julie is the daughter of Jeff Schwartz and Donna Middlehurst.

# Most DPT Lawsuit Settlements Kept Secret

During 1986, more DPT vaccine damage lawsuits were settled out of court, most on condition that the amounts be kept confidential. Following is a summary of some of the product liability and medical malpractice cases brought against drug companies and physicians. Names of the plaintiffs in the cases have not been given to protect the privacy of parents and children, but the names of the law firms handling the cases have been included.

**vs. Connaught Laboratories.** Settled for an undisclosed amount in April 1986 in Florida. Grounds: failure to warn and negligent design of product. The child, now seven, reacted to her second DPT shot at eleven months of age. She is moderately retarded with medication resistant seizures. Plaintiff's attorneys: Mike Eriksen and John Romano of Cone, Wagner, Nugent, Johnson, Roth & Romano, P.A. in West Palm Beach, Florida.

**vs. American Cyanamid.** Settled in September 1986 in Tampa, Florida for \$700,000. Grounds: strict liability and negligence. The child, now seven, reacted to her first DPT shot with seizures. She is profoundly retarded and has uncontrolled seizures. Plaintiff's attorney: Anthony Colantoni of McDowell & Colantoni in Chicago, Illinois.

**vs. Lederle Laboratories et al.** Settled in September 1986 in Lowndes County, Mississippi for an undisclosed amount. Grounds: failure to warn and defective design. The DPT vaccine damaged child currently suffers from infantile spasms. Plaintiff's attorneys: Jim Lees and Tom Wilson of Preiser & Wilson in Charleston, West Virginia.

**vs. Wyeth Laboratories.** Settled in September 1986 in Eugene, Oregon for an undisclosed amount. The court records are sealed. Grounds: negligence, product liability, strict liability, breach of express and implied warranty. The child, now eight, suffered seizures within hours of her first DPT shot at six months. She is not expected to develop mentally beyond the age of 12 to 18 months and has daily seizures with weekly grand mal convulsions. Plaintiff's attorneys: Gary Shockey, of Spence, Moriarity & Schuster in Jackson,

Wyoming; and John Hilts in Medford, Oregon.

**vs. Lederle Laboratories.** Settled in September 1986 in Macon, Georgia for an undisclosed amount. Grounds: failure to warn and defective design. The DPT vaccine damaged child, now eight, has a permanent severe seizure disorder and is profoundly retarded. Plaintiff's attorneys: Jim Lees and Tom Wilson of Preiser & Wilson in Charleston, West Virginia.

**vs. Lederle Laboratories.** Settled in September 1986 in Asheville, North Carolina for an undisclosed amount. Grounds: failure to warn and defective design. The DPT vaccine damaged child is now five and is profoundly retarded, cannot coordinate use of her limbs, and has a chronic seizure disorder. Plaintiff's attorneys: Jim Lees and Tom Wilson of Preiser & Wilson in Charleston, West Virginia.

**vs. Lederle.** Settled in October 1986 in Spokane, Washington for an undisclosed amount. The court records are sealed. Grounds: defective product (hot lot) and defective design. The child, now eight, reacted to his first DPT shot at two months of age. He is severely retarded and has an uncontrolled seizure disorder. Plaintiff's attorneys: J. Gregory Casey and Douglas E. Ecton of Casey & Ecton in Spokane; and Daniel Huntington of Richter, Wimberley, Ericson, Woods & Brown in Spokane.

**vs. Lederle Laboratories.** Settled in November 1986 for \$300,000 in Fort Worth, Texas. Grounds: defective design. The child, now eight, reacted to his second DPT shot at six months of age and is mildly retarded with a left side hemiparesis and seizure disorder. Plaintiff's attorney: Jan Champion of Tyn-dall, Champion & Smoger in San Jose, California.

**vs. Dr. Aaron Newberg, et al.** Settled in December 1986 in Philadelphia, Pennsylvania for \$190,000. Grounds of the medical malpractice lawsuit included the fact that the doctor did not adhere to contraindications.

Now 14 years old, the pertussis vaccine damaged child has a chronic, non-progressive encephalopathy manifested by psychomotor retardation and a chronic seizure disorder. Plaintiff's attorney: Tom Wilson of Preiser & Wilson in Charleston, West Virginia.

**vs. Wyeth Laboratories and Dr. Joan Moffett.** Settled with Wyeth for an undisclosed amount in January 1987 in West Palm Beach, Florida. Grounds: strict liability and negligence. A malpractice case against Dr. Joan Moffett is continuing. The child was hospitalized with a complex seizure of more than 30 minutes duration 25 days after his first DPT shot at two months of age. The child's pediatrician, Dr. Joan Moffett, proceeded to give a second DPT shot and the child went into severe convulsions within hours of the shot. Now seven years old, he is severely retarded and has from one to seven grand mal convulsions every week. The malpractice suit will go to trial in April, 1987. Plaintiff's attorney: Alan McDowell of McDowell & Colantoni in Chicago, Illinois.

**vs. Dr. Overcash.** This medical malpractice case was settled for an undisclosed amount in January 1987 in Raleigh, North Carolina. The child, who is now four, is DPT vaccine damaged and suffers with status epileptic seizures and is moderately retarded. Plaintiff's attorneys: Jim Lees of Preiser & Wilson in Charleston, West Virginia; and Rick Poling of Karney, Poling & Smith in Charlotte, North Carolina.

**and vs. Lederle, Connaught, and Merrill National and Dr. Thomas E. Furlong.** Settled with the drug companies in February 1987 in Cincinnati, Ohio for \$575,000. Grounds: strict liability and negligence. The malpractice case against Dr. Furlong is continuing. Two children, both with the same mother, died from complications arising from DPT shot reactions. The first child died at age eight from seizure complications that began when she reacted to a DPT shot at two months of age. Her sister died at two and a half years old from seizure complications that began when she reacted to a DPT shot at four months of age. Their mother had reacted to DPT shots with seizures when she was a child.

When the children's pediatrician, Thomas Furlong, M.D., suggested that the mother's newborn son receive a DPT shot, she would not permit her son to receive pertussis vaccine. Dr. Furlong reported the mother to state health and child welfare authorities. At this point, the mother sought legal advice which culminated in a lawsuit against the drug companies and a malpractice suit against Dr. Furlong. The malpractice suit is expected to go to trial this summer. Plaintiff's attorneys: Alan McDowell and Bruce Kiselstein of McDowell & Colantoni in Chicago, Illinois.

## France Suspends DPT Vaccination

On March 29, 1986, the Minister of Health of France suspended all DPT vaccinations in that country following the deaths of five babies within 24 hours of a DPT shot. All of the deaths were classified as sudden infant death syndrome (SIDS), even though one of the babies was 19 months old and far beyond the recognized 12 month age limit for SIDS.

France lifted its suspension and resumed DPT vaccinations about a month later, but only after withdrawing two lots of DPT vaccine from the

market. The lots were withdrawn even though France health officials decided that five deaths were a "coincidence."

The events in France closely resemble an incident which occurred in Tennessee in 1979. During that year, a suspected "hot lot" of DPT vaccine was withdrawn from the U.S. market after 11 babies died shortly after receiving a DPT shot. The Centers for Disease Control concluded the deaths were a "coincidence."



# CDC Unclear About DPT Vaccine Death Definition

The following exchange between CDC Director of Immunization Alan Hinman, M.D.; DPT Vice President Barbara Loe Fisher; Georgia DPT coordinator Leslie Chapman; and ACIP Chairman Samuel Katz, M.D. occurred at the May 12 ACIP meeting following DPT's demonstration in front of the CDC. The full 40-page transcript of the meeting between DPT and ACIP can be obtained by sending an \$8.00 donation to DPT, 128 Branch Road, Vienna, Virginia 22180.

**Fisher:** Dr. Hinman, in April (1985) Mrs. Leslie Chapman and I came to this Committee and the question we repeatedly asked was "What criteria does the CDC use to define a pertussis vaccine death?" I still don't understand what criteria you use to distinguish pertussis vaccine deaths from SIDS deaths.

**Hinman:** We accept the definition—to date we have accepted the classification and diag-

nosis that is on the report.

**Fisher:** Without any independent CDC investigation into whether or not that diagnosis is correct?

**Hinman:** We request hospital records, death certificates, and autopsy reports but we accept the death classification given to us.

**Fisher:** Coroners then receive no guidance from the CDC as to how they might try to distinguish a pertussis vaccine death?

**Hinman:** That is correct.

**Fisher:** Does the CDC have plans to so educate coroners?

**Hinman:** Not at the present time.

**Fisher:** Why? Why don't you have any plans?

**Hinman:** At the moment, I don't know how I would differentiate an event which you might consider the cause of pertussis vaccine death,

and one which you might not consider the cause of a pertussis vaccine death.

**Fisher:** In other words, the CDC does not know how to distinguish a pertussis vaccine death from a SIDS death?

**Hinman:** At the present time, we are collecting and categorizing these deaths as they are provided to us. We are not ourselves imposing a definition.

**Fisher:** Dr. Hinman, when a baby dies after exhibiting classic pertussis vaccine reaction symptoms—high pitched screaming, convulsions, shock/collapse—do you feel that should very definitely be classified as SIDS?

**Hinman:** I don't know.

**Chapman:** What is being done to find out?

**Fisher:** You don't know? When the definition of SIDS does not include those physical and mental symptoms? Why would you even have a question that it would be diagnosed as SIDS?

**Hinman:** SIDS is both a clinical and pathological profile. In studies of SIDS a substantial proportion of children who die suddenly are found to have had some symptoms before they die—a respiratory infection or other symptoms. I think it is difficult to draw a precise line as to what might be considered symptoms and what might not.

**Fisher:** Do SIDS deaths normally involve convulsions and collapse/shock episodes and high pitched screaming?

**Hinman:** Not particularly.

**Fisher:** Not particularly? I would think then that it wouldn't be very hard to try and distinguish a pertussis vaccine death from a SIDS death when you are exhibiting clearly pertussis vaccine reaction symptoms that have been in the literature for 50 years. I don't understand what the problem is.

**Katz:** I do think that you are emphasizing a point that I can agree with. . . . but I think the problem in definition doesn't lie here as to what is sudden infant death syndrome. . . . the problem isn't with the Centers for Disease Control or the Division of Immunization, nor regrettably is it their function to educate pathologists or coroners or other people who do autopsies. . . . The cases that you have cited, I would certainly agree with you could not in my opinion qualify as SIDS.

**Fisher:** But Doctor, it is your responsibility to survey vaccine reactions. And if the vaccine reaction reporting system is trying to find out how many deaths occur that are related to the vaccine, somebody has got to make a determination. I mean, if not you, who? . . . The coroner's findings are accepted here for your statistics for pertussis vaccine deaths.

## Congress to Investigate 10,000% Increase in DPT Prices

In response to a 10,000 percent increase in the price of DPT vaccine over the past four years, in August 1986 Ohio Senator Howard Metzenbaum initiated a Government Accounting Office (GAO) investigation into the price hike by drug companies. This action followed a charge by Dissatisfied Parents Together at a July 25 congressional hearing that DPT manufacturers may be making an estimated \$80 million windfall profit from the price increases.

The government pays for half of the 18 million doses of DPT vaccine sold by drug companies annually—as much as \$100 million. Senator Metzenbaum questioned why DPT vaccine cost 11 cents per dose in 1982 and now costs \$11.40. "It is the taxpayer and the individual consumer who is footing this bill. I want to find out the reasons behind this price increase and why this money is not going into research on safer and less expensive vaccines," said Senator Metzenbaum.

### DPT Charges Drug Companies with Making Windfall Profits

When Lederle Laboratories announced its latest price increase in May 1986 from \$4.29 per dose to \$11.40 per dose of DPT vaccine, the drug company claimed that \$8.00 of the total price was being set aside to cover costs of lawsuits brought by parents of children injured or killed by the pertussis vaccine. In July 25 testimony, DPT President Jeff Schwartz asserted that the price hike was un-

justified because only a handful of vaccine damage lawsuits have been settled or lost by drug companies.

"What proof does Lederle offer that it needs upwards of \$50 million per year to pay for DPT-related liability expense or that it could not get liability insurance in the private sector for less than \$50 million per year?" asked Schwartz. "Lederle tells the Congress, doctors, and consumers that it must go out of the vaccine business unless it can raise its prices nearly 10,000 percent, but it tells the Securities and Exchange Commission, Wall Street, and prospective investors that the lawsuits pose no risk of 'material adverse effect' on the company," he said. He added that Lederle and Connaught Laboratories have a monopoly market of the DPT vaccine, which is mandated by law for all children entering school.

### Health Subcommittee Finds Few Court Awards Made

DPT's charges were underscored by a report of the House Health Subcommittee which revealed that only \$16.2 million was paid in settlements by seven U.S. vaccine manufacturers to 52 children injured by all childhood vaccines during the past five years. This works out to an average of \$300,000 per case, and it is not clear how much of the \$16.2 million payout was covered by insurance. Out of the cases that went to trial, vaccine manufacturers won four and lost six. Five are on appeal.

# Reagan Signs Compensation Bill. . .

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caps on court awards or prevent lawsuits. Their anxiety was being fueled by the growing number of pertussis vaccine damage lawsuits being won or settled out of court by plaintiff's attorneys using evidence that (1) the vaccine was improperly tested; (2) parents were given inadequate warnings about vaccine risks; and (3) drug companies knew how to make the vaccine safer.

After a year of hearings, S. 2117 could not get out of the health committees in the Senate. So it was scuttled in favor of a new bill (S. 827) that was introduced by Senator Hawkins in 1985 after further negotiations between DPT and the AAP. S. 827 retained most of the safety provisions of S. 2117 and added some new protections. While it preserved a parent's right to sue, the new bill reduced the kinds of vaccine reactions and conditions which would automatically enable children to receive federal compensation. S. 827 was supported by DPT, but with less enthusiasm.

## The Threat Of A Worse Bill

One of the reasons DPT decided to support S. 827 even though it was a somewhat weaker bill from a vaccine victim's standpoint, is that heavy lobbying by the Administration, drug companies, and the AMA for a far worse bill was becoming a very real threat. For example, in 1985 a bill (H.R. 1780) essentially written by Lederle Laboratories was introduced into the House by influential Congressmen Edward Madigan (R-IL) and James Broyhill (R-NC). The bill proposed to drastically curtail parents' right to sue and provided no safety provisions. Later, the Administration would propose a bill that offered parents no federal compensation at all while placing severe caps on court awards.

## Publicity About Reactions & Lawsuits, Shortages & Epidemics

DPT's concern that opposing forces might muster enough clout to push through a bad bill was bolstered by increasing attention being given the vaccine injury issue in the media. By mid-1985, the publication of *DPT: A Shot in the Dark*, co-authored by DPT Vice President Barbara Loe Fisher and Harris L. Coulter, and media coverage of the controversy was having an impact on public opinion and putting pressure on Congress "to do something." But pressure on Congress was also mounting because of publicity about vaccine price increases, the "lawsuit crisis," "vaccine shortages," and alleged "whooping cough epidemics" created by those seeking to discredit vaccine critics and restrict parents' right to access the court system.

All three DPT manufacturers—Wyeth, Connaught, and Lederle—continued to manufacture DPT vaccine at full speed and to profit from vaccine price hikes despite the fact that Wyeth announced it had "ceased production and distribution" of the vaccine in 1984 because of the high cost of lawsuits. At one point Connaught began stockpiling the vaccine while refusing to distribute it, saying it could not get liability insurance and asking Congress for immunity from lawsuits.

A panic about vaccine shortages and imminent whooping cough epidemics seemed to be gathering force. It was later revealed in congressional testimony that Wyeth had not stopped making pertussis vaccine at all. It had quietly resumed production of even greater amounts of pertussis vaccine and was selling it to Lederle for distribution under Lederle's label.

By late 1985, more DPT lawsuits had been settled out of court but most of the court records were sealed or kept secret as a condition of the settlement. The manufacturers continued to complain that they were being unfairly victimized and should be held blameless for vaccine injuries because they produced the vaccine in accordance with Food and Drug Administration (FDA) standards.

## AAP Breaks With DPT

DPT members wrote and called Congressmen and Senators in their states and eventually S. 827 was co-sponsored by 15 Democratic and Republican Senators, as well as endorsed by some ten national health organizations such as the American College of Physicians, American Nurses Association, and Epilepsy Foundation of America.

But despite this support, it was becoming apparent that S. 827 was stalemated in House and Senate health committees just as S. 2117 had been. To make matters worse, the AAP took action that resulted in the collapse of the fragile coalition between DPT and the AAP.

In November 1985 the AAP issued a press release that blamed parents delaying vaccination because of "recent publicity about the vaccine's safety" as the cause for "near epidemics" of whooping cough in eight states. An investigation by DPT Vice President Barbara Loe Fisher revealed that more than half of the pertussis cases reported in the eight states during 1985 occurred in vaccinated individuals, and that reported increases were mainly a result of stepped up disease surveillance due to recent publicity about vaccine reactions.



**A Call for Action**—DPT President Jeff Schwartz calls for a congressional investigation of the DPT vaccine and congressional support of vaccine safety and compensation legislation at a 1985 Capitol Hill press conference.

In March 1986, DPT issued a national press release assailing the AAP for issuing false and misleading information to the public. DPT also criticized erroneous information contained in a new AAP poster used in pediatrician's waiting rooms that ominously predicted that if children weren't given pertussis vaccine "almost 500,000 could fall victim to pertussis. Over 14,000 cases would end in death." The AAP eventually admitted that the estimate was a gross overestimation and recalled the poster.

## The Bill That Almost Was

In early 1986, the AAP joined with the drug companies in creating a bill that put caps on court awards, allowed drug companies to use compliance with FDA standards as a defense to prevent lawsuits, and limited the amount of compensation that could be awarded in the federal system. At the same time, DPT President Jeff Schwartz began to put a new bill together with the legislative staff of Christopher Dodd (D-CT).

A novel departure from the concept of a federally funded compensation system, Dodd's

proposed bill would have handled vaccine injury claims entirely in the tort system with both fault and no-fault options. Drug companies would have been entirely responsible for paying claims. Incentives were created for manufacturers to settle with parents for past and future medical expenses, loss of future earned income, and \$100,000 for pain and suffering. If parents rejected the settlement offer, they could still bring a lawsuit with a \$350,000 cap placed only on pain and suffering.

Of course, DPT opposed the AAP/drug company bill. The drug companies and AAP opposed the Dodd bill. Neither one was ever introduced into Congress, and the legislative stalemate continued.

#### **Waxman Introduces His Bill After Vaccine Prices Skyrocket**

In the summer of 1986, Lederle hiked the price of a dose of DPT vaccine from \$4.29 to \$11.40, reflecting a 10,000 percent increase over the 11 cents per dose price charged in 1982. Lederle claimed that \$8 of the new price increase was necessary to cover costs of lawsuits. Because the federal government pays for half of the 18 million doses of DPT vaccine sold each year, the enormous price hike placed added pressure on Congress to come up with a compensation bill that would get out of health committees and onto the floor for a vote.

This prompted Congressman Waxman to introduce a new bill (H.R. 5184). In a startling reversal from his earlier support of DPT's position, Waxman's new bill would have: (1) eliminated children more than four years of age from the federal compensation system; (2) allowed drug companies to use compliance with FDA standards as a defense in certain kinds of lawsuits; (3) restricted lawsuits under strict liability (defective product) theory; (4) provided no home care payments to parents who kept their vaccine injured child at home if keeping the child at home was more expensive than placing the child in an institution; and (5) contained few safety provisions to reduce vaccine injuries.

#### **DPT Opposes Waxman Bill and Blasts Drug Companies at House Hearing**

In testimony before a July 25, 1986 congressional hearing on Waxman's new bill, Jeff Schwartz told the health subcommittee that DPT strongly opposed the bill and said that "enactment of H.R. 5184 would in our view do more to protect the profits of drug companies than the health of America's children." He maintained that the drug companies are "crying Liability crisis all the way to the bank."

Calling Lederle's recent vaccine price hike an apparent "80 million dollar rip-off of American consumers," Schwartz said the drug companies pay out far less in lawsuit settlements than the price increases will generate in huge windfall profits for them.

During the hearing, a Lederle spokesperson admitted that Lederle might not lower its prices even if the new Waxman bill were passed, then appeared to reverse himself under questioning from Committee members. Lederle expressed disapproval of Waxman's new bill because it did not eliminate all liability from vaccines that adhered to FDA standards, and because caps were not placed on court awards. The AAP testified in support of the bill.

On the basis of DPT's testimony, several weeks later Senator Howard Metzenbaum (D-OH) initiated a congressional investigation into the price hike by drug companies.

#### **Time Runs Out**

By the beginning of September 1986, it became clear that time was running out. If the 99th Congress adjourned and a compensation bill was not enacted, efforts would have to start from scratch in the 100th Congress. In an effort to get legislation passed that would address the vaccine injury issue, Congressman Waxman and his staff began several weeks of intense negotiations with DPT, the AAP, and drug companies. A great deal of pressure was exerted to reach an acceptable compromise between all the parties.

Bi-partisan support on the House health subcommittee began to materialize as Congressman Madigan, the ranking Republican, helped Waxman, the subcommittee's Democratic chairman, achieve a consensus. During the negotiations, DPT was able to convince the subcommittee to (1) eliminate the provisions which protected vaccine manufacturers from lawsuits if they complied with FDA standards; (2) permit lawsuits to be brought on the grounds of strict liability; (3) provide home care payments for parents who elect to keep their vaccine damaged child at home even if that care is more expensive than placing the child in an institution; (4) reinstate the important safety provisions to cut down on vaccine injuries; and (5) avoid any caps on court awards of actual damages.

One remaining sticking point for DPT, however, was the provision of the emerging Waxman-Madigan bill that children more than four years of age would not be able to enter the no-fault compensation system. DPT argued for opening up the system to all vaccine damaged children, no matter how old they

were. However, the bill was voted out of the subcommittee with an eight year cut-off and sent to the full House Committee on Energy and Commerce.

#### **The Fight For Older Children**

After a polling of DPT state chapter leaders, it became clear that the DPT membership could not support the bill unless all vaccine damaged children regardless of age were eligible to apply for federal compensation. House Committee members, however, were very concerned about the potential costs of the bill. In order to persuade the full Committee to open the system up to all children, DPT had to agree to modify the compensation system so that children injured prior to date of enactment of the bill (November 14, 1986) could only be awarded future unreimbursed medical expenses. These children injured in the past, unlike the children injured in the future after date of enactment, would not be awarded money for pain and suffering, loss of future earned income, or past medical expenses in the compensation system. However, they would be allowed to pursue a lawsuit without any restrictions or caps placed on court awards.

Even with this concession, however, it remained questionable whether an amendment would be approved to open up the system to all older children. With the leadership of Reps. Tom Tauke (R-IA) and Gerry Sikorski (D-MN) and a flurry of phone calls by DPT members in various states to their congress-

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**Key Supporter**—Congressman Henry Waxman (D-CA) has been a key supporter of vaccine safety and compensation legislation.

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men on the Committee, the crucial amendment DPT wanted allowing the older children to be considered for compensation was added to the bill. (However, only 3,500 children injured or killed prior to the bill being enacted could be awarded federal compensation. Awards would be made on a first come, first serve basis.)

The bill now had overall support from DPT, the AAP, and Merck & Co. (manufacturer of the MMR vaccine), although the DPT manufacturers Lederle and Connaught continued to vigorously oppose the bill. The AMA did not take a position. Jeff Schwartz summed it up when he said the final result "left nobody delighted but most major players willing to support the bill."

## The Bill Escapes From the House and Goes to the Senate

With only a two or three weeks remaining in the 99th Congress, the bill was sent to the House Ways and Means Committee for approval of the funding mechanism, which proposed to finance the compensation system by placing a surcharge on vaccine sales. The bill languished in Ways and Means until Dan Rostenkowski (D-IL), the Committee's chairman, made it clear that there wasn't enough time for the Committee to consider the controversial new funding provisions.

Knowing the bill would die unless he reworded it to eliminate the funding provisions, Waxman did just that. The bill was then scheduled for an up-or-down vote (no amendments allowed) by the entire House of Representatives. In the meantime, the Reagan Administration stepped up its lobbying against the bill, protesting that it was an expensive "new entitlement program," and the Departments of Justice and Health and Human Services sent Congress strongly worded letters opposing its passage.

The bill finally made it to the floor of the Democrat controlled U.S. House of Representatives. Almost unbelievably, it passed unanimously.

Now the bill faced an uphill fight to get past the Senate Labor and Human Resources Committee and onto the floor of the Senate for a vote before the 99th Congress adjourned. Facing opposition from the Administration and DPT manufacturers, it seemed destined to die in the Republican controlled Senate. And if it didn't die in the Senate, a presidential veto seemed almost certain.

## Waxman and Hatch Put Together "The Great Compromise"

In the last week of the 99th Congress, the bill found itself again languishing without momentum. Knowing the Administration did not like the bill, Republican Senator Orrin Hatch from Utah, Chairman of the Labor and Human Resources Committee, was holding it up in hopes of making changes that were more acceptable to the Administration. Hatch had been a co-sponsor with Hawkins of S. 2117 and S. 827 but he also was concerned about going against White House policy. At this late stage, if even one powerful Senator insistently opposed consideration of the bill, it meant the bill would not come to the Senate floor for a vote and would die.

DPT members in Hatch's home state contacted the media and urged him to support the new bill passed in the House. Only 72 hours before Congress adjourned, Hatch dropped his opposition. But taking his place was the Senate Majority Leader Robert Dole (R-KS). DPT members in Dole's state contacted the media and urged him to support the bill. Dole dropped his opposition 24 hours later, but was replaced by Senator Strom Thurmond (R-SC), the powerful head of the Judiciary Committee. Thurmond proved to be a nearly intractable opponent of the bill, following the lead of Attorney General Ed Meese. Meese and lawyers in the Justice Department made no secret of their disapproval of the bill on grounds that it was too expensive and did not cut off lawsuits or place caps on court awards.

But in the final 48 hours of the 99th Congress, the staunch Democrat Waxman and the staunch Republican Hatch conferred and formed a rare alliance. With the help of Senators Edward Kennedy (D-MA), Paula Hawkins, Robert Stafford (R-VT), Christopher Dodd (D-CT), Dan Quayle (R-IL), and Congressmen Edward Madigan, James Scheuer (D-NY), Howard Nielsen (R-UT), Ron Wyden (D-OR), Fred Eckert (R-NY), Thomas Tauke (R-IA), Thomas Bliley (R-VA), and William Dannemeyer (R-CA), Waxman and Hatch created an Omnibus Health Bill (S. 1744) that contained a number of diverse health bills that each side wanted badly to become law. It was a highly unusual move, but the only way for each to achieve key legislative victories on issues that had been unresolved for years.

For example, Hatch and the Administration had long supported the Drug Export Act allowing drug companies to export drugs to foreign countries which have not yet been ap-

proved by the FDA. The pharmaceutical industry desperately wanted this bill to pass but Waxman had long opposed it. Now Waxman reluctantly agreed to make it part of the Omnibus Health Bill in exchange for Hatch's support of the House vaccine injury legislation. With these kinds of trade-offs, the Omnibus Health Bill contained something for everyone including a provision that protects doctors who professionally review their peers from lawsuits; funds for research into Alzheimer's disease; a federal grant program to coordinate services for the chronically mentally ill; the training of health care professionals in geriatric medicine; and, of course, the National Childhood Vaccine Injury Act of 1986.

## The House Passes It Unanimously

By Friday, October 17, Congress was already ten days late in adjourning. Tired and anxious to go home to either campaign or rest, legislators in both houses of Congress were continuing sessions well into the night in order to wrap it up. That evening at about 8:30 p.m., Waxman stood up and introduced the Omnibus Health Bill. Praising the bill, Congressman Scheuer said, "I do congratulate again the gentleman from California, Mr. Waxman, and the gentleman from Illinois, Mr. Madigan, for their truly expert abilities in crafting a very finely etched compromise that harmonizes all of the various sensitive issues involved and produces a result very much in the public interest."

The bill passed quickly and unanimously.

## In The Senate: Hatch Is Bloodied But Victorious

The next day was a Saturday, and weary legislators were rushing to adjourn by that evening. Now in the Republican controlled Senate, the fate of the bill was in Orrin Hatch's hands. Up against stiff opposition from his own Administration, Hatch had the unenviable job of persuading key members of Reagan's staff in the White House not to prevent the bill from passing the Senate.

The Administration's refusal to permit the Omnibus Health Bill to come to the Senate floor for a vote continued to be solely focused on intense dislike of the vaccine injury compensation portion. Strom Thurmond would not budge from his threat to kill the bill, even though DPT members in his home state and many of his fellow Senators were pressing him to change his mind.

Hatch spent the entire day making calls to the White House to urge Attorney General Ed Meese and other advisors to let the bill go.

Remembering that long day, Hatch is quoted by one source as saying, "Even with its imperfections and limitations, I knew how historic and important this bill was. I knew how much good it would do. At one point, I was so frustrated and disappointed at the prospect of it failing that I turned toward the window and wept."

At 7:45 p.m. on that Saturday night, Majority Leader Dole suggested a brief recess after informing those remaining in the nearly empty Senate chambers that "the distinguished Senator from Utah is still working on a vaccine bill. He is now talking with the Attorney General."

After the recess, Hatch appeared looking exhausted but relieved. He introduced the bill, explaining that the White House was "very upset" with the vaccine injury portion of it because they feared it would be too expensive. Albert Gore, Jr. (D-TN) congratulated Hatch and said, "Over the last few days and particularly the last 10 hours, I have seen a real tiger fighting to preserve some remarkable achievements on behalf of the American people." Hatch acknowledged that Dole had been "very anguished over this bill." Dole responded that Hatch had been "literally climbing the wall today to get this done. A few of us are bruised and battered. But he succeeded and I think that is an indication of his determination . . . I do know [he] had a number of conversations today with the Attorney General, with the Chief of Staff at the White House, and I don't know how many other people. It is a tribute to his doggedness and determination."

Then, in a matter of seconds, the long day was over as the bill passed unanimously in the Senate. The reality of children injured and killed by vaccines had been officially acknowledged by the U.S. Congress for the first time in history. Now all that was needed was the signature of the President.

#### An Unlikely Coalition Forms

After the Omnibus Health Bill passed the House and Senate, DPT found itself in the strange position of joining forces with traditional adversaries including the pharmaceutical industry, medical organizations, and government health agencies in a campaign to persuade President Reagan to sign the bill. It was evident that only a united campaign to prevent a presidential veto would save the bill.

While everyone waited for the bill to be enrolled (sent from Congress to the White House for the President's signature), DPT participated in a strategy planning meeting

held on Capitol Hill. Racing against a potential ten day deadline before a presidential pocket-veto could go into effect, DPT National moved to mobilize the organization's resources in an all-out effort to save the compensation legislation.

Because the vaccine injury legislation was the portion of the bill that the Reagan Administration did not want, there was a feeling on the part of the pharmaceutical industry, medical organizations and some congressional staffers that the less said about vaccine injured children, the better the chances of the bill passing. DPT disagreed, maintaining that the best way to counter the opposition was to address the vaccine injury issue straightforwardly.

#### The Justice Department Remains A Mighty Adversary

The biggest hurdle that had to be overcome was the strong opposition of Justice Department officials, who had testified at congressional hearings against federal compensation for vaccine injured children. The Justice Department was also on record as being opposed to vaccine injury lawsuits and had, in fact, filed a brief on behalf of a drug company which had lost a DPT damage case in Ohio.

Although HHS Secretary Otis Bowen, M.D.

as well as Treasury, Commerce, and Office of Management and Budget (OMB) officials had opposed the bill before Congress passed it, during the intense public campaign to get President Reagan to sign the bill they dropped their opposition one by one. Only Attorney General Ed Meese and Justice Department officials remained unmoved.

#### DPT Mobilizes To Save The Bill

DPT National mobilized DPT members and supporters to call, write, and send telegrams to the White House, and to write letters to their local newspapers. A national press release was issued, calling on President Reagan to "do what he knows in his heart is right," and editors of major national newspapers and television networks were contacted. DPT state chapter leaders were asked to try to obtain editorials endorsing the bill in state newspapers and on television stations and to encourage everyone to send a message to the White House.

The *New York Times* wrote an editorial strongly endorsing the compensation bill, as did the *Los Angeles Times* and *Chicago Tribune*. The *Wall Street Journal* wrote an error-filled, stinging indictment of the compensation legislation because it did not cut off lawsuits, and called on Congress to give the

(Continued on page 14)



**A Safer Future**—New York DPT President Janel Ciotoli (right) asks President Reagan to sign the Omnibus Health Bill (S. 1744) at the November 6 White House vigil.

# Reagan Signs Compensation Bill. . . .

(Continued from page 13)

President a line-item veto so the compensation portion of the Omnibus Health Bill could be stricken. An editorial in *USA Today* opposed the idea of federal no-fault compensation because it gave too much protection to drug companies. Television stations in most states where DPT members actively sought coverage, featured the vaccine injury issue and the bill.

So many reporters, DPT members and supporters, and national organizations responded to the call for action that, after the bill was signed, one White House source said, "The White House received more public inquiry and comment on the vaccine injury bill than on any other bill in the 99th Congress."

## Stacy Speaks For Vaccine Injured "Kids" At Capitol Hill Press Conference

In an effort to focus national attention on the bill, the coalition put together a Capitol Hill press conference that was publicized by both DPT and Hill and Knowlton, Inc. The bill's strongest congressional supporters, Senator Orrin Hatch (R-UT) and Congressman Henry Waxman (D-CA), were to be featured speakers, and all of the groups who supported the bill were to attend. Although there was disagreement among the groups as to whether a vaccine injured child should appear at the October 28 press conference, eventually approval was given for Florida DPT chapter founder Wendy Scholl and her daughter, Stacy, to attend.

Ten year old Stacy, who suffered a severe reaction to a measles shot that left her left arm and leg permanently affected, had already publicly pleaded with President Reagan to sign the bill on a Florida television news show. Now she and her mother got on a plane in Tampa, and made the journey to Washington, D.C. to make the same plea in a national forum. Wendy Scholl used her savings to pay for the plane tickets because, she said, "If Stacy could make a difference, it will be worth it."

Like so much during the four year legislative effort that was "touch and go," Stacy's appearance was almost canceled when last minute objections by some supporters of the Omnibus Health Bill surfaced. DPT started making plans to have Stacy give her statement in the hall after the press conference. Then, just minutes before the press conference began, everyone agreed Stacy could speak.

When it came time for her to make her statement, Senator Hatch lifted her up onto a chair

so she could see over the mass of microphones attached to the podium before her. With remarkable poise and self confidence, Stacy read her statement in a clear voice to a silent, standing room-only crowd of reporters. "My name is Stacy. I am a vaccine injured kid," she said. "But I can talk and walk. Some of my friends can't. So I am here for them. . . . I am here for all children who want to stay healthy. Please sign this bill. We need you to care about us. If you won't help us, who will?"

After she finished, she turned to Senator Hatch and hugged him tightly. And in the end, a photo of Senator Hatch and Stacy appealing to the President to sign a bill helping vaccine injured children appeared the next day in major newspapers across the country.

After Hatch and Waxman spoke, the various groups supporting the bill were ready to answer questions. But reporters only had one question and it was for Dissatisfied Parents Together: what would happen if the President did not sign the bill? DPT Vice President Barbara Loe Fisher replied, "All of us had to give up a lot in order to get here. If the President doesn't sign the bill, then the fragile compromises that have been made will be shattered. It may be a long time before we ever get another bill."

## DPT Candlelight Vigil At The White House Simultaneous Vigils Held In Four States

After the press conference, DPT received

word that the bill had not yet been sent to the President, so the ten day deadline for a pocket-veto was extended. There was only one more action that DPT could take to try to convince President Reagan to sign the bill: hold a November 6 candlelight vigil at the White House with parents carrying posters of children killed or injured by vaccines. Margie Bloom-Roza, Santa Clara, California DPT chapter President; Karen Cline, Oklahoma DPT chapter President; Mary Jean Kremer, Illinois DPT chapter President; and Wendy Scholl and Velvet Carter, Florida DPT chapter coordinators, agreed to organize simultaneous vigils in their states.

Illinois: In Chicago, about 40 parents and children braved the strong winds swirling around the Dirksen Federal Building from 4 to 6 p.m. and marched with their handmade posters urging the President to sign S. 1744. Because the wind was so strong (the Dirksen Building is thought to be the windiest spot in the "Windy City"), the candles kept blowing out. But the signs held up, including one carried by Sean Kremer that said, "I am a vaccine injured kid." Illinois DPT President Mary Jean Kremer said, "We were blowing all our good wishes to Washington that evening."

Mary Jean, her husband, Tom, her sons Patrick and Brian, and her mother, Jean Beagley, all marched along with vaccine injured Sean.



**On the Job**—DPT Director Kathi Williams shows DPT's demonstration permit to a White House guard after he challenges the right of parents to demonstrate directly in front of the White House during the November 6 candlelight vigil.

Sharon Long and her husband, Terry, marched in memory of their son, Michael, who died after a DPT reaction. Dianna Anderson, of Cambridge, and members of her family marched in memory of Dianna's infant daughter, Erika, who died following a DPT reaction. Jerry Clark, whose daughter is DPT injured, was there as was a representative from the Illinois chapter of the Alzheimer's Disease and Related Disorders Association, which had legislation for Alzheimer's research included in the Omnibus Health Bill.

Dr. Barry Kaufman, of WMAQ-TV, interviewed Mary Jean and her family and covered the vigil on the evening news. He also did a follow-up story the day the President signed the bill.

**Oklahoma:** The cold winds were blowing in Tulsa, too, as 15 hardy supporters of S. 1744 stood firm against 35 mph gusts to hold their vigil in front of the Federal Building from 5 to 6:30 p.m. Oklahoma DPT President Karen Cline and her husband, Tim, marched in memory of their infant daughter, Sabra, who died following a DPT reaction. Their son, Christopher, was also there. Gwendolyn Dennis marched in memory of her daughter, Vanessa, who died at six months following a DPT shot reaction. And Oklahoma DPT Secretary Jeannie Burge, whose infant daughter caught whooping cough from fully vaccinated adults and whose nephew is DPT vaccine injured, was among the marchers.

All three Tulsa television stations covered the vigil on the evening news, as did the *Tulsa World* and *Muskogee Phoenix* newspapers. Karen also gave several live interviews on Tulsa and Oklahoma City radio programs.

**Florida:** Like marchers in Chicago and Tulsa, parents participating in the vigil in St. Petersburg demonstrated with handmade posters from 5 to 7 p.m. in front of the Federal Building but couldn't light their candles because of strong winds. Among the marchers were Florida DPT chapter coordinator Wendy Scholl and her measles vaccine injured daughter, Stacy; Florida DPT chapter coordinator Velvet Carter, her husband, Dick, and their DPT injured son, Chris; Martha and Rick Dube and their DPT injured daughter, Isabelle, who made a two hour drive from Orlando; and Donna Keith and her measles vaccine injured son, Greg. David Jackson, who helped organize the vigil, was also among those who marched.

Wendy and Stacy Scholl, Velvet and Chris Carter, and Martha and Isabelle Dube were interviewed by two television stations (WTSP

and WTVT) and the interviews were aired on the evening news with live coverage of the vigil. The *St. Petersburg Times* also ran an article.

**California:** There was no wind in Santa Clara, as 65 supporters of S. 1744 carried signs and marched from 5 to 7 p.m. Dr. Margine Bloom-Roza, whose son, Sam, is DPT vaccine injured, said, "We brought in people from a 120-mile radius." Pediatric immunologist and allergist Kevin Geraghty, M.D., and his wife, Connie, of El Cerrito, made the drive to be there, as did Rochelle McNary, of San Jose, and her DPT injured son, Chris. Eddie Souza, the Mayor of Santa Clara, spoke to the group about the importance of the vaccine safety and compensation bill. He and his wife, Lavelle, accompanied their DPT injured son, Jerry.

The California vigil was covered by several television stations in San Francisco and San Jose.

**Washington, D.C.:** Despite fears that nearly a week of freezing rain would continue into the day of the vigil, it turned out to be cold, clear, and sunny on November 6. With only seven days notice, some 75 members and their relatives and friends from east coast states made arrangements to journey to Washington, D.C. They brought candles, walking shoes, and hand-made posters with pictures of children injured or killed by vaccines bearing slogans such as "Justice for our Children—Sign S.



**Safer Vaccine Wanted—DPT Secretary Jacqui Middaugh (right) and Carol Hall (left) of Virginia march in front of the White House at the November 6 vigil.**

1744" and "Mr. Reagan, Show Us You Care About Children." Everyone who came held onto the hope that their presence would change President Reagan's mind.

Most participants met in the Virginia suburbs and climbed aboard the bus that DPT National had arranged to take them to the White House. After White House guards challenged DPT's permit to demonstrate directly in front of the White House instead of across the street in Lafayette Park, the vigil finally began about 5:30 p.m. With orders from White House guards to "keep moving," parents lit candles, held posters, and pushed children in strollers as they circled back and forth in front of the brightly lit White House.

State leaders who orchestrated attendance at the vigil include West Virginia President Linda Thornton, who drove up with her husband, Phil, her son, Brett, and her five year old vaccine injured son, Ryan. West Virginia Vice President Betty Coleman drove up with her four year old vaccine injured daughter, Sadaria. New York DPT President Janet Ciotoli and her husband, Anthony, marched in memory of their son, Richie, who died following a DPT reaction. New York DPT Vice President Janice Reed marched with a sign with a photo of her DPT vaccine injured son, Joshua, as did Janice's mother, Marilyn Swavola. Buffalo DPT chapter coordinator Greg Chowjidak held a sign with a photo of his DPT vaccine injured son, Joey. New Jersey DPT President Anne Miller was there on behalf of her vaccine injured son, Frank. Pennsylvania DPT chapter President Judy Glomb and her husband, Tim, marched in memory of their daughter, Bernadette, who died following a DPT reaction. Janet, Janice, Greg, Anne and Judy brought 25 marchers from New York, Pennsylvania and New Jersey with them including Marilyn Bowker of Walton, whose four-month old son died following a DPT reaction 23 years ago; Don Austin and son, Dave, of South New Berlin, who marched for DPT vaccine damaged John Austin, now 23 years old; Matty Laferrara of Bethpage, whose grandson, Louis, is DPT vaccine injured; and New York DPT Treasurer Anita Donovan whose nephew, Richie, died after a DPT reaction.

Georgia DPT coordinator Leslie Chapman flew in with her 10 month old daughter the afternoon of the vigil and flew back to Atlanta three hours later after it was all over. "I just had to be there in memory of John," said Leslie, whose infant son died after a DPT reaction. Carol Hall of Virginia, came with her whole family including her five year old

*(Continued on page 16)*

# Reagan Signs Compensation Bill...

(Continued from page 15)

DPT vaccine injured daughter, Nikki. And Gerrie Cohn of Maryland, marched and participated in television interviews with her 17 year old daughter, Traci, who was left severely damaged by a DPT shot. Claudia Bias of Washington, D.C., marched for her vaccine injured son and Laura Shaw of Maryland marched for her vaccine injured daughter. A representative from the National Alliance for the Mentally Ill came to march in support of legislation in the Omnibus Health Bill that provided improved care for the mentally ill.

Two Washington D.C. television stations (featuring Lea Thompson of WRC-TV and Wes Sarginson of WMAL-TV) broadcast live interviews from the White House vigil. Several cable stations, AP, and UPI were also there.

## Merck & Co. Plays Major Role

In the final days before President Reagan finally agreed to sign the Omnibus Health Bill, the pharmaceutical industry lobbied very heavily in hopes of winning the provision that would allow U.S. drug companies to export drugs not yet approved by the FDA to foreign countries. Although the three DPT vaccine manufacturers remained either opposed or uncommitted, Merck & Co., the manufacturer of MMR vaccine, played an instrumental role in changing the Administration's mind about exercising a pocket veto. Finally, a few days before the pocket veto deadline ran out, word came from the White House that Attorney General Ed Meese and other key White House officials had decided to withdraw their opposition.

## President Signs The Bill With "Serious Reservations"

Without fanfare, with only a few witnesses and no reporters present, President Reagan signed the Omnibus Health Bill on November 14. Immediately afterwards, there were reports in the media that DPT vaccine manufacturers and White House officials who wished to "remain anonymous" were vowing to try to amend the bill to further restrict lawsuits and curtail federal compensation when the 100th Congress deliberated funding of it.

## DPT Has Won A Battle, But Not The War

As those responsible for finding ways to fund the system begin to realize that "50 to 75" children injured and killed by all vaccines every year is not a realistic figure, others are trying to find ways to weaken the law under the guise of "cutting costs" and "protecting the mass vaccination system." In February Capitol Hill meetings, DPT learned that

HHS, the AAP, and the vaccine manufacturers are going to attempt to pass an amendment to the law that would destroy its integrity. Their goal is a familiar one: to minimize acknowledgement of and responsibility to the many children who have been killed or injured by vaccines.

They may try to: (1) make the compensation system an "exclusive remedy" by barring lawsuits; (2) place severe caps on lawsuit awards; (3) administratively set up the federal compensation system in such a way that very few children will be awarded compensation. The unhappy reality is that DPT may have to be prepared to fight the battle to retain the law's integrity all over again. On the other hand, DPT has also learned that allies in both the

Senate and the House are committed to limit the new legislation to funding without permitting the basic provisions of the law to be changed.

Until another battle begins anew, one fact remains: the National Childhood Vaccine Injury Act of 1986 is law. In just four and a half years, Dissatisfied Parents Together was able to gain enough credibility and generate enough public concern to realize two of its major goals: official recognition that the vaccine safety issue is a real one; and acknowledgement that vaccine manufacturers, negligent physicians and the government should be responsible for compensating children for their vaccine injuries.

## Federal Judge Uses Preemption Ruling to Dismiss DPT Lawsuit

On February 9, 1987 a Virginia federal judge ruled that the federal government has preempted the field of vaccine regulation and dismissed a DPT vaccine damage lawsuit brought against American Cyanamid (Lederle Laboratories' parent company) on the grounds of negligent design defect. The judge agreed with American Cyanamid, whose defense was that state product liability laws are not valid in the cases of deaths or injuries resulting from vaccines approved by the Food and Drug Administration (FDA). The federal preemption defense is also currently being supported by the U.S. Justice Department.

The decision was rendered by federal Judge Claude Hilton, who was appointed by President Reagan, in the U.S. District Court for the Eastern District of Virginia, Alexandria Division. It involves a child, now four, who reacted to her third DPT shot with infantile spasms and is moderately retarded. Judge Hilton ruled that Congress, through the Public Health Services Act and the Food and Drug Cosmetic Act, has preempted the field of vaccine regulation and has thereby precluded a litigant from bringing an action for vaccine injury based upon state common law tort theories of negligent design or failure to warn.

## Case May Go to U.S. Supreme Court

The decision is being appealed to the Fourth Circuit Court of Appeals by the plaintiff's attorney's, Anthony Colantoni, Martin Preiser, and Mike Inman of McDowell & Colantoni in Chicago; and Robert Zelnick of Nagoette, Borinski & Zelnick in Woodbridge, Virginia. The appeal will be heard by a panel of three judges selected randomly by the Fourth Cir-

cuit Court. It is expected that if the appeal is upheld, the plaintiff's attorneys will file a petition with the U.S. Supreme Court. If the appeal is overturned, then American Cyanamid is expected to file a petition with the U.S. Supreme Court.

Vaccine manufacturers have tried unsuccessfully for some time to use the federal preemption defense. The Virginia case is only the second time that DPT vaccine manufacturers have successfully argued they should be held blameless in vaccine injury lawsuits if they can prove their vaccine adhered to FDA standards. In December, a Texas judge ruled that strict liability could not be used as grounds for suing a DPT manufacturer on the basis of federal preemption. Because all vaccine released for use to the public adheres to FDA standards, if federal preemption is upheld by the U.S. Supreme Court, vaccine injury lawsuits based on negligent design will be virtually eliminated in the U.S.

## Congress Protects Vaccine Injury Lawsuits

Plaintiff's attorneys believe that the federal preemption ruling will not prevail because there is clear evidence that Congress fully intended to permit and even protect state product liability lawsuits against drug companies manufacturing vaccines according to FDA standards. One good example is Public Law 99-660 containing the new vaccine injury compensation bill passed by Congress and signed by President Reagan in 1986. That bill expressly protects the right of parents of vaccine damaged children to go to court to sue drug companies for their children's vaccine injuries.



**CORRECTIONS:**Pg. 11, col. 3: strike "enactment"-  
insert "funding." Strike "November  
14, 1986."Pg. 17, col. 2: strike "\$25,000"-  
insert "\$250,000."

# Provisions of the National Childhood Vaccine Injury Act

**D**PT National has received many questions about provisions in the National Childhood Vaccine Injury Act (Public Law 99-660). The new law makes a distinction between children injured or killed prior to the date Congress passes a law funding the compensation system (Congress has not yet passed funding for the system) and those injured or killed after that date. Children who are injured or killed after the date of funding will receive more compensation in the no-fault system, but will be more restricted in bringing a lawsuit. Children injured before the date of funding will not be able to get as much compensation in the no-fault system, but will have unrestricted access to the courts to pursue a lawsuit. Following is a brief explanation of several areas of concern that parents of children who have been injured or killed by vaccines in the past have about the law.

However, parents should keep in mind that recent developments on Capitol Hill suggest there are efforts underway by the Administration, American Academy of Pediatrics, and vaccine manufacturers to pass an amendment to the law which would seriously undermine key provisions protecting vaccine victims' rights. Therefore, the following information is subject to revision if an amendment is passed changing these provisions.

## When Can Parents Apply for Compensation?

The no-fault compensation system mechanism will not take effect until the 100th Congress passes a new law funding it. Congress has indicated it wants to explore other ways of funding the system than applying a surcharge tax to vaccines, and the debate could continue through the spring and summer. Currently, there is not way to predict when the system will be funded, when it will be operational, or how long it will take for applications to be processed. Therefore, the receipt of actual awards may be several years away.

Parents cannot apply for compensation until the system is funded. The two-year deadline to apply for federal compensation for children injured or killed in the past will not begin running until the day the system is funded. That means that parents will have at least two years from the date the funding law passes to apply for federal compensation. As currently written, the compensation system will only provide compensation for past deaths and injuries to the first 3,500 children injured or killed prior to the date of funding who apply and are granted compensation. After 3,500 children receive awards, there will be no more money in the federal compensation system

for children injured or killed before that date.

## How will parents Know When the System Is Funded?

As soon as a funding law passes, DPT National will issue a bulletin to all DPT members who have up-to-date memberships notifying them of the date that the system has been funded and any changes that have been made. Keep your membership up-to-date if you want to be notified.

## What Will the System Give to Children Injured or Killed In The Past?

As currently written, children injured or killed prior to the date of funding will only be able to receive federal compensation for future unreimbursed medical care expenses, including custodial care or home care. There will be no awards for pain and suffering, loss of future earned income, or past medical expenses. Parents of children who have been killed by vaccines will be awarded \$25,000.

## Is Compensation Automatic?

Federal compensation is not automatic. Awards in the compensation system will depend on proving that one of the covered vaccines (DPT, OPV, MMR) caused the child's injuries or death. In the compensation system, causation by a vaccine will be presumed whenever a child's injury fits within the table of compensable events (including the time frame for certain reactions) stated in the law. If your child's injuries did not occur within the time frames set in the table, compensation may still be awarded upon proof that the vaccine in the most likely explanation for the resulting injuries or death.

In the compensation system parents will not

have to prove which manufacturer made the vaccine or that the manufacturer was negligent. Most parents who apply for federal compensation should be represented by a lawyer. Although retaining a lawyer is not mandatory, it would be very difficult for a parent who had no legal assistance to make the necessary proof of causation and the amount of compensation to which the child is entitled.

## Can Parents Still Bring Lawsuits?

As currently written, children injured or killed prior to the date of funding will have a choice of either pursuing a lawsuit or applying for federal compensation. They will have unrestricted access to the court system to pursue a lawsuit. Even if they lose their lawsuit, they may apply for federal compensation, providing they do so within two years of the date of funding and providing 3,500 children have not already been awarded federal compensation.

Parents of children who apply directly for federal compensation and are not satisfied with the award, may refuse the award and pursue a lawsuit. If parents have accepted any money from a lawsuit settlement or jury verdict—no matter how small the amount—they may not apply for federal compensation.

## Where Can Parents Get a Copy of the Law?

Parents can send for a copy of the law from the Government Printing Office by writing to Senate Document Room, B04, Senate Hart Building, Washington, D.C. 20510. Ask for Public Law 99-660 (Title 3). At a library, parents can get a copy of the House Congressional Record for October 17, 1986 which contains the law (see pages H 11597—H 11614).

# Holistic Conference Held in Chicago

**T**he Second Annual Quality Care With Kindness conference will be held at the Embassy Suites Hotel near Chicago's O'Hare Airport from June 26-28, 1987. Sponsored by the (tongue-in-cheek) American Quack Association headed by Roy Kupsinel, M.D. and Jonathan Wright, M.D., it will feature panel discussions with audience participation on vaccinations, SIDS, AIDS, cancer, vivisection, nutrition, V.D.T. emissions, dental amalgam dangers, and the "medical-pharmaceutical cartel."

The subject of vaccination will be covered on Friday, June 26 beginning at 9:30 a.m. Among the panelists who will be discussing vaccinations are Robert Mendelsohn, M.D., author of *Con-*

*essions of a Medical Heretic* and *Medical Malepractice*, Harold Buttram, M.D., an authority on vaccination; Glen Dettman, Ph.D., an Australian scientist who conducts vaccination research; Archie Kalokerinos, M.D., also of Australia, who authored the book *Every Second Child* after finding a link between vitamin C deficiency and infant death shortly after vaccination; and Barbara Loe Fisher, DPT Vice President and co-author of *DPT: A Shot in the Dark*.

For more information about the three-day conference and the schedule of other panel discussions, contact Roy Kupsinel, M.D., P.O. Box 550, Oviedo, Florida 32765.

# DPT Members Raise More Than \$20,000; More Funds Needed to Keep DPT Alive

More than \$20,000 was raised by DPT members during the "Dear Friends" Fund Raising Campaign held during the summer and fall of 1986. Although the goal of the campaign was to raise \$80,000 to help DPT National expand services and continue to operate the organization, the amount raised at least made it possible to continue current operations through June of 1987.

"DPT continues to experience serious financial difficulties. But even though we are still not out of the woods, the money that was raised in the Dear Friends Campaign made it possible for us to continue operating into 1987. We are deeply grateful to all of the parents who made the commitment to participate in this fund raiser," said DPT Director Kathi Williams.

The exact amount raised by DPT parent members was \$23,350. Several couples raised more than \$1,000 for the organization including Sharon and Al Henel of South Cheektowaga, New York, whose 12 year old son, Adam, is DPT injured; Leslie and Robb Chapman of Atlanta, whose infant son, John, died following a DPT reaction; and Dr. and Mrs. William Kulik of Allentown, Pa. Other DPT members who made significant contributions were Judy and Tim Glomb of Aston, Pennsylvania, whose infant daughter, Bernadette, died following a DPT reaction; David McCutcheon of New York City, whose two year old son, Nicholas, died following a DPT reaction; and Donna Middlehurst of Chevy Chase, Maryland, whose daughter, Julie, suffered a severe reaction to a DPT shot at four months and died at age three.

## One Couple's Letter To Friends

Many DPT members who were the most successful in raising funds sent their friends and relatives personal letters asking for donations. In a letter to her friends, Pennsylvania DPT chapter President Judy Glomb said, "On the 23rd of this month, our precious Bernadette would be celebrating her second birthday. As this time grows near, Tim and I can't help but envision what would have taken place: she would have squealed delightfully with every present she opened . . . her eyes would have shined like the stars and her smile would have been as bright as the sun . . . as you know Bernadette's life was tragically cut short as a result of the DPT vaccine . . . and sadly, she was not the first victim, nor will she be the last unless something is done to prevent it . . . As a birthday tribute to our little Bernadette, won't you please send a donation in her name or become a member of DPT and become part of the effort to insure that all little children will have that birthday party that we will forever dream of."

## Membership Drive Coming In April

For the past four years, DPT has existed primarily on \$20 membership donations and \$3 parent information packet donations from parents and other individuals. Because membership is so important to DPT's survival, DPT National will launch the First Annual DPT Membership Drive in April with the goal of raising enough funds to operate the organization through the end of 1987. All DPT members who have not renewed their memberships since July 1986 are being asked to renew. In addition, if each DPT member would find one more individual to join DPT, the organization could double its membership.

## Grants Are Sought

DPT is searching for private corporations or organizations which are interested in lending financial support to DPT's important public education efforts. Unless DPT receives yearly grants from large donors, it will be difficult if not impossible for the organization to continue functioning on a yearly basis. DPT members are encouraged to identify possible grant donors or corporate or small business contributors. Call DPT Director Kathi Williams at 703-938-DPT3 with suggestions.

"We know there are groups or individuals in

the U.S. who have funds available to donate to charitable, non-profit organizations such as ours which do the kind of work that we do. It is just a matter of identifying them and making the necessary contact and application," said Williams.

DPT National is also looking for an individual who has professional experience in writing grants and would like to take on the obtaining of grants or large donations for DPT as a project.

## Donated Services/Office Equipment Needed

DPT National is always looking for members who can donate (or provide "at cost") typesetting, printing, or copying services. DPT National is also in need of a donation of a new IBM "Leading Edge" computer (\$1500) and a new Mita, Panasonic, or Cannon tabletop copier (\$1500) capable of producing at least 4,000 copies per month—or a cash donation enabling DPT to rent-lease a computer or copier for a year. In addition, DPT National will soon have to move out of the free office space (and free use of a copy machine) that has been provided by Vienna Glass Co. for the past four years. Free or reduced rental office space in the South Alexandria-Woodbridge, Virginia area (or a \$6,000 donation to enable DPT to rent a small apartment as an office) is desperately needed.

# CDC Moves to Obtain Better SIDS-Vaccine Death Data

Responding to DPT's call for an end to the misclassification of pertussis vaccine deaths as Sudden Death Syndrome (SIDS), the Centers for Disease Control (CDC) has taken an important first step toward better investigation of deaths reported as SIDS. In an October 28, 1986 letter to DPT National from Alan Hinman, M.D., CDC Director of Immunization, Dr. Hinman stated:

"On the request for clarification from medical examiners regarding sudden infant death syndrome (SIDS), the ACIP was informed that the Division of Maternal and Child Health, Health Resources and Services Administration, intends to review and update its recommended guidelines for the definition and investigation of SIDS cases during 1987. This revision will probably suggest obtaining more clinical information such

as acute and chronic medical symptoms as well as infant immunization history. These updated guidelines will then be presented to the National Association of Medical Examiners for their endorsement and subsequently distributed to active medical examiners and coroners in the United States.

"In addition, the California program in Birth Defects Monitoring has been requested by the Division of Immunization to include specific objective questions as part of its routine interviews of families of infants reported with SIDS to provide grief counseling. These questions would include detailed clinical symptoms manifested in the 2-week period preceding death and the previous history of all vaccinations received by the infant."

# New York DPT Leader Challenges Mandating of Hib Vaccine

New York DPT President Janet Ciotoli is challenging a recently enacted requirement that forces all children between the ages of two and five years of age in day care centers in New York City to be vaccinated with Haemophilus Influenza B (Hib) vaccine. The requirement, which is being enforced by the Bureau of Day Care of the New York City Department of Health, is based upon recommendations by the Centers for Disease Control (CDC) and Ameri-

can Academy of Pediatrics (AAP).

In 1986, the AAP and CDC issued recommendations that all children between the ages of 2 and 5 years old and children in day care centers over 18 months old should be vaccinated with Hib. The Hib vaccine was licensed by the FDA in 1985 and is still undergoing post-marketing surveillance to evaluate its safety and effectiveness.

## Few Cases Of Hib Disease in NYC Day Care Centers

When Ciotoli obtained information on New York City disease statistics for 1981 through 1985, she found that 68% of the cases of Hib disease were reported in children under two years of age (the vaccine is not effective in children under 18 months old). Out of 422 cases, only 39 cases involved children in day care centers. There were a total of 17 deaths from Hib disease during the five year period, with 8 deaths occurring in children under age two.

In a letter to Dr. Steven Martin, pediatric consultant to the New York City Bureau of Day Care, Ciotoli wrote, "For a family totally dependent on day care for economic reasons, the refusal of admittance to day care is an unfair "pressure mechanism" that totally disregards a parent's right to freely explore and fully partake in the decision of their child's health and well-being. Since the Hib vaccine is currently undergoing post-marketing surveillance and development, to mandate Hib for admittance to day care is a premature decision and could result in tragic vaccine injury." Ciotoli also points out that there is no mandatory adverse reaction reporting system in New York City to gather reaction data on Hib vaccine.

## Questions About Effectiveness and Safety

The current Hib vaccine protects against only one strain of bacterial meningitis (there are other kinds of viral and bacterial meningitis) and is not effective in children under 18 months of age. Praxis Laboratories in Rochester, New York developed the Hib vaccine. Only three years old, Praxis has grown into a \$10-million-a-year business as the creator and producer of the first vaccine to be recommended for universal use by the AAP and CDC since the measles vaccine was developed in the 1960's.

There have been questions raised about the vaccine's effectiveness with estimates ranging from about 40% to 90%. One recent study showed the vaccine is only 44% effective. This same study, which was recently presented at a meeting of the Immunization Practices Advisory Committee (ACIP), suggested that children are three times more likely to come down with Hib disease within one week of vaccination than are those who remain unvaccinated. Cases of shock, convulsions, respiratory problems and other reactions have been reported following Hib vaccination but, because the U.S. does not have a mandatory reporting system for vaccine reactions, the reaction rate remains unknown.

## NIH Predicts New Pertussis Vaccine at Least Three to Five Years Away

In a January 20, 1987 article in *The Washington Post*, NIH pertussis vaccine researcher Ron Sekura predicts a purified pertussis vaccine he is developing will be available for use in the U.S. "within three to five years."

In the article Dr. Sekura spoke about how he tested the vaccine, which is made of deactivated pertussis toxin, by injecting it into himself and other adults. He was quoted in the article as saying "If I am going to stick something into a little kid, I have to have enough confidence to stick it into myself." A pilot study involving 100 to 150 children aged 18 months is reported about to begin in Massachusetts using Sekura's vaccine.

### Whooping Cough Outbreak in NIH Labs

The *Post* article also reported that there was a whooping cough outbreak within NIH research laboratories in July of 1985 when airborne pertussis bacteria apparently "floated through the air within the laboratory complex." Seven researchers came down with the disease but other researchers evidently were not given Sekura's vaccine or booster shots of whole cell pertussis vaccine. The article said, "The investigation led to changes in the techniques for handling the large quantities of pertussis bacteria used in making the vaccine. NIH officials decided it was not necessary to give booster vaccines to the researchers during the outbreak."

### DPT Replies to Article

In a letter published in the February 10 *Wash-*

*ington Post*, DPT Vice President Barbara Loe Fisher stated, "... (the) article quoted the vaccine's NIH developer, Ron Sekura, as predicting his vaccine will be 'available within three to five years.' That is what scientists and vaccine regulators at NIH and the FDA told parents in 1982—that a safer vaccine would be available in 'three to five years.' Five years later, we are being told to wait five more years.

"Dr. Sekura is competing with other American pertussis vaccine researchers in the FDA, private universities, and pharmaceutical companies who are in a race for the distinction of being the developer of America's new pertussis vaccine. In the meantime, they alternately ignore or minimize the success of the Japanese acellular pertussis vaccine which has been proven to be much safer and has controlled whooping cough in Japan since 1981.

"This foot dragging would be almost comical except for the wasted lives it represents. We owe it to our children to immediately bring in Japan's purified vaccine to cut down on vaccine damage now, while Dr. Sekura and other American researchers come up with their versions of a safer and more effective pertussis vaccine. Five more years of American children dying and becoming brain damaged by the current 45-year old vaccine is not only an unnecessary human tragedy, it could well bankrupt the federal vaccine injury compensation system recently approved by Congress."