FUNDING OF THE CHILDHOOD VACCINE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON
SELECT REVENUE MEASURES

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDREDTH CONGRESS

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Chairman RANGEL. Thank you. Whom do you represent, Mr. Butler?

Mr. BUTLER. I started working on the cost of a vaccine compensation program for the American Academy of Pediatrics in 1984. In fact, I was introduced to the academy by Mr. Jeff Schwartz, president of Dissatisfied Parents Together. In 1986, I updated the 1984 cost study. The 1986 study was sponsored by the academy and three drug companies; Merck, Lederle, and Connaught. My most recent work which is reflected in today's testimony has been sponsored by the academy and Merck.

Chairman RANGEL. Now we hear from the Dissatisfied Parents Together, Mr. Schwartz.

STATEMENT OF JEFFREY H. SCHWARTZ, PRESIDENT, DISSATISFIED PARENTS TOGETHER

Mr. SCHWARTZ. Thank you, Mr. Chairman.

I am Jeff Schwartz. I am the president of Dissatisfied Parents Together, and I appear here today on behalf of that group.

We, like the academy, joined in support of the initial legislation. We are here today to assist the subcommittee in devising appropriate funding legislation. Our group calls itself Dissatisfied Parents Together because our children have been killed or permanently brain damaged by legally mandated childhood vaccines. The law said we had to give these vaccines to our children supposedly to protect their health, but the law did not see to it that these vaccines were as safe as they possibly could be. And when our children suffered instead of benefitted from these vaccines, the law, at least until recently, turned its back and looked away.

The timing for this hearing is particularly poignant for our family, Mr. Chairman. Last week my wife and I should have celebrated the sixth birthday of our daughter Julie. Instead, later this month, we will be paying our third anniversary visit to her grave. She died as a result of a vaccine-induced seizure disorder that began within hours of her third DPT shot. But it is not just our family that grieves. Families from every State in the United States have joined this mom and pop group when they discovered their children too had been permanently disabled or died from the side effects of mandated vaccines. So for 5 years this group has struggled to care for our children who survive, to hold our families together, to mourn the lost lives and dreams and potential that have been needlessly squandered, and to get the Government and the medical community to acknowledge the existence—and to honestly determine the magnitude—of this dark side of the mandatory vaccination program. We also have been pushing for safer vaccines and greater safety to prevent needless injuries in the future. Please understand, Mr. Chairman, we are not an antivaccine group. Our voice in support of getting safer vaccines and a safer system to prevent these injuries gradually is being heard.

Last year Congress passed Public Law 99-660 which included the vaccine injury compensation program. Now, this subcommittee faces this difficult question:

How should the system be funded?

We want to be as constructive as possible, and we don't want to be dogmatic about exactly how to fund the system. So we prefer to lay out some principles that we would like to see reflected in this legislation.

First, the new legislation needs to reflect facts, not fantasy, facts as to how many children really are permanently disabled and killed by mandated vaccines, not wishful thinking and fatally flawed studies or so called passive data bases that foolishly minimize the size of this problem, facts that spotlight the unjustified profits and unsubstantiated claims of some vaccine makers who have told the Congress that they had to raise DPT prices by almost 10,000 percent because of the so-called liability crisis, but tell their shareholders there is no problem, and then say they are setting aside a liability reserve of $8 per dose, yet that liability reserve apparently does not exist anywhere except in the bottom line as profits, facts as to whether there really is, or ever was, a liability crisis; and facts as to whether these vaccine makers will voluntary roll back their enormous price rises if the compensation system is funded to head off the so-called crisis. Will they really bring down the price if we rely on them voluntarily to do it?

Secondly, funding should be available for all children who have been seriously injured or killed by these vaccines, not only for those injuries and deaths that occur in the future.

I want to highlight a third point, Mr. Chairman, because this is the point that Mr. Waxman and the Treasury spokesman made and we agree strongly. Funding sources have to be reliable and adequate to pay for a lifetime of around the clock care for these multiple handicapped individuals who can't care for themselves. Unless the funding sources are reliable and assure compensation for the lifetime of the child, parents have no practical alternative but to seek compensation through the tort system.

Fourth, the funding mechanism should provide for lump sum settlements. Here I think there is broad consensus forming, or fully funded annuities backed by the U.S. Government, so that parents who are inclined to do so can confidently elect to receive compensation for their children in lieu of pursuing court cases.

Fifth, the funding mechanism needs to be reasonably prompt and result in an up or down decision. Under the law there is no enforceable deadline for compensation decisions to be made and thus the process can drag on for years. The new funding mechanism should not tamper with the law's existing safeguards. Nor should it reopen all the questions the administration wants to reopen. We have been begging the administration for positive proposals for years and we turned to the Congress only out of despair that we could never get anything from them. The tort remedy, the right of the parents to sue in the event of negligence, wrongdoing, unreasonably dangerous vaccines, or inadequate compensation must be preserved. The new funding mechanism should strengthen, not undercut, the incentives for development and use of safer vaccines.

This point, too, has to be stressed. The best way to reduce the economic costs of this program in the future is to stop the occurrence of preventable vaccine-induced deaths and disability. You have been told that a handful of kids get injured inevitably. We ask you to look behind that assertion because we think the facts

show that a number of these cases are preventable. They could have been prevented with stronger safeguards. We want you not to fund this new law in a way that takes away its safeguards.

Time limits preclude listing all our concerns here. We would be pleased to submit our more full statement for the record.

We do want to conclude by expressing our desire to work with the staff and the subcommittee. We do think constructive proposals can be forthcoming and we do want to stand in support of properly crafted legislation, but we will strongly oppose any attempt to further restrict the parents' right to go to court to sue to protect our children's right. We ask this subcommittee to limit the scope of this legislation so it will focus on fair, adequate, reliable and appropriate funding sources and techniques for the compensation part of the law.

We urge you, too, don't assume when there is a compensation system that works that the manufacturers will bring their prices down. They have told the other subcommittees that they can't or won't do that. We ask you to look, as part of the function of this bill, to bringing down the prices. Ask the question: Why are the prices as high as they are? What is the real cost of this product? It looks like the cost of producing pertussis vaccine is 2 percent of the price which means 98 percent is going somewhere else. Where? Where, if there is no real liability reserve?

There are a number of questions that need to be asked.

We come here primarily to say we think constructive funding approaches can be found. There are a variety of funding mechanisms that can be used. We are concerned about a funding mechanism like leaving it to year-to-year appropriations. We don't want to have to fight a political battle each year. and I don't see how in good conscience we can advise our parents to give up their right to go to court and sue in return for a yearly fight to see whether or not they can get their children's health care needs met.

We really appreciate the chairman's leadership on this issue and the subcommittee's interest and we stand ready to work with you constructively on this legislation.

[The prepared statement and attachment follow:]

Dissatisfied Parents Together (DPT) 128 Branch Road, Vienna, VA 22180 (703) 938-DPT3

TESTIMONY BEFORE THE SUBCOMMITTEE
ON SELECT REVENUE MEASURES,
HOUSE COMMITTEE ON WAYS AND MEANS
March 3, 1987

Jeffrey H. Schwartz, President
Dissatisfied Parents Together (DPT)

Mr. Chairman, and Members of the Subcommittee:

My name is Jeffrey H. Schwartz. I am President of Dissatisfied Parents Together (DPT), and I appear here today on behalf of that group.

Mr. Chairman, we welcome this Subcommittee's consideration of alternative means of funding the newly-enacted vaccine injury compensation law. We appreciate the invitation to appear before you today. In our testimony, we will briefly:

- explain who Dissatisfied Parents Together is; and
- set forth the major principles that we believe should guide the development of legislation to fund the vaccine injury compensation system.

I. DISSATISFIED PARENTS TOGETHER

Our group calls itself Dissatisfied Parents Together because our children have been killed or permanently brain-damaged by legally mandated childhood vaccines. The law said we had to give these vaccines to our children, supposedly to protect their health. But the law didn't see to it that these vaccines were as safe as they possibly could be. And when our children suffered, instead of benefited, from these vaccines, the law--until recently--turned its back and looked away.

The timing of this hearing is particularly poignant for our family, Mr. Chairman. Last week, my wife and I should have celebrated the sixth birthday of our daughter, Julia. Instead, later this month we will be paying our third anniversary visit to her grave. Three years have passed since she died as a result of a vaccine-induced seizure disorder that began within hours of her third DPT (diphtheria-pertussis-tetanus) shot.

But it is not just our family that grieves. Families from every state in the United States have joined this "Mom & Pop" group, when they discovered their children, too, had become permanently disabled or had died from the side effects of mandated vaccines.

For nearly five years, we have struggled:

- to care for the children who survive;
- to hold our families together, financially and emotionally;
- to mourn the lost lives, dreams, and potential that have been needlessly squandered, and to comfort each other and our children;
- to get the government and the medical community to acknowledge the existence--and to honestly determine the magnitude--of this dark side of the mandatory vaccination program;
- to push for safer vaccines, and greater safety in the way we produce, test, and administer current vaccines.

We are not an anti-vaccine group. We long for the availability in the U.S. of a less-reactive pertussis (i.e., whooping cough) vaccine, as Japan has used effectively since 1981. And we believe parents should have the right to conscientiously object to mandated vaccines which needlessly jeopardize the lives and health of our children.

Gradually, our voice is being heard. In November 1986, the Congress enacted Public Law 99-660, which included a national childhood vaccine injury compensation and safety program. While that law differed in several significant respects from what our group had sought, it did

represent the first official acknowledgement of these vaccine-injured children.

II. WHERE DO WE GO FROM HERE?

Now this Subcommittee faces the next difficult question: How should the new compensation system be funded? We offer what we believe is a constructive approach. We will refrain from rigid adherence or opposition to any particular funding mechanism. We would like to work with this Subcommittee and staff to develop an appropriate approach.

We do offer, however, the following eight major principles that, in our view, should be reflected in this funding legislation:

1. First, the new legislation should reflect facts, not fantasy...

   - facts as to how many children really are permanently disabled and killed by mandated vaccines, not wishful thinking, fatally flawed studies, or so-called passive "data bases" that foolishly minimize the size of this problem;

   - facts to spotlight the unjustified profits and unsubstantiated claims of some vaccine makers, who told the Congress they had to raise DPT vaccine prices by almost 10,000% because of the so-called "liability crisis," but who told their shareholders, "no problem";

   - facts as to whether there really is (or ever was) a vaccine "liability crisis"; and

   - facts as to whether vaccine makers will voluntarily roll back these enormous price rises if the compensation system is funded to head off this so-called "crisis."

2. Funding should be available for all children who have been seriously injured or killed by these vaccines, not just those whose injuries or deaths occur after enactment of this enabling legislation.

3. Funding sources should be reliable and adequate to pay for a lifetime of round-the-clock care for those multiply handicapped individuals who cannot care for themselves.

4. The funding mechanism should provide for lump sum settlements or fully-funded annuities backed by the U.S. Government, so that parents who are inclined to do so, can confidently elect to receive compensation for their children in lieu of pursuing tort remedies against vaccine manufacturers.

5. The funding mechanism should assure a reasonably prompt up-or-down decision on the compensability of the claim. (Under P.L. 99-660, there is no deadline for compensation decisions to be made and thus the process may drag on for years.)

6. The new funding law should not tamper with existing safeguards of P.L. 99-660 which are critical to the integrity, fairness, and workability of that scheme. These critical safeguards include:

   - preservation of parents' right to sue vaccine makers and doctors in cases involving negligence, unreasonably dangerous vaccines, or compensation results which are inadequate to meet the injured child's needs;

   - assuring that compensation decisions in specific cases will be made by a politically-independent and secure entity specially suited to adjudicate claims; and

assuring that any change to state tort law resulting from P.L. 99-660 only becomes effective with respect to specific claims for which there is adequate and reliable compensation system funding available to meet lifetime care needs of these disabled individuals.

7. The new funding mechanism should strengthen, not undercut, the incentives for development and use of safer vaccines. The best way to reduce the economic costs of this program in the future is to stop the occurrence of preventable vaccine-induced deaths and disabilities.

8. The new funding mechanism should reflect the fact that both the government and the vaccine makers have been responsible for these preventable injuries. For nearly 25 years, both government and the industry have known that the only existing "safety test" for pertussis (whooping cough) vaccine is basically irrelevant to the vaccine's potential to cause brain damage or death. During this same period, FDA standards have allowed the marketing of pertussis vaccines with as much as 2700% variation in potency. Neither industry nor the government has done much to develop a new safety screening test or tighter quality control measures.

Time limits preclude listing all our concerns here. We would be pleased to submit supplementary comments in writing. We would also be pleased to meet with Subcommittee members and staff to help define a mechanism or mechanisms that can meet these concerns and the legitimate concerns of others being voiced today.

III. CONCLUSION

Mr. Chairman, Dissatisfied Parents Together stands ready to support and help enact properly-crafted legislation to fund the vaccine compensation part of P.L. 99-660. But we will strongly oppose any attempt to further restrict parents' rights to go to court to sue to protect our childrens' rights. So long as a lawsuit is an option, we can keep the pressure on for development and use of the safest possible vaccines for future children. So long as a lawsuit is an option, we can hold accountable those whose negligence or callous indifference have led to our children's deaths and disabilities. So long as a lawsuit is an option, we can assure that any compensation system is a real alternative to the fault-based system, not another way of denying the problem or attempting to sweep it cheaply under the rug and out of sight.

So we implore this Subcommittee to limit the scope of this implementing legislation. We hope it will focus on fair, appropriate, reliable, and adequate funding sources and techniques for the compensation part of the law. We hope you will also question the legitimacy of the exorbitant price rises which a few companies have imposed on the taxpayer and powerless consumers who are mandated by law to buy this product, no matter what the cost. We urge you to confer subpoena power on GAO to get all pertinent information from all manufacturers and suppliers of mandated childhood vaccines.

Neither the government, nor "private industry" should be able to hide behind a veil of secrecy when the issues relate to the safety and fair pricing of these mandatory "public health" products. We urge this Subcommittee to mandate a full independent investigation of the real basis for the drastic increase in vaccine prices (when only 1% of the price reflects production costs).

ORIGINAL ARTICLES

Neurologic complications in oral polio vaccine recipients

Between April 1982 and June 1983 four children 3 to 24 months of age were referred for evaluation of neurologic abnormalities found to be compatible with vaccine-related poliovirus infection, which had not been suspected by referring physicians. Patients were epidemiologically unrelated residents of Indiana, and none had prior symptoms suggestive of immunodeficiency. All had received poliovirus vaccine orally (first dose in three, fourth dose in one) and a diphtheria-tetanus-pertussis injection in the left anterior thigh within 30 days of symptoms. A vaccine-like strain of poliovirus was isolated from each patient, and each had symptoms (left leg paralysis in three; developmental regression, spasticity, and progressive fatal cerebral atrophy in one) persisting for at least 6 months. Immune function was normal in two with poliovirus type 3 infection, and abnormal (hypogammaglobulinemia, combined immunodeficiency) in two with type 1 and type 2 infection, respectively. The incidence of observed vaccine-related poliovirus infection in Indiana recipients of orally administered poliovirus vaccine was 0.058 per 100,000 per year, significantly greater ($P < 0.001$) than predicted. (J Pediatr 1986;108:878-881)

John W. Gaebler, M.D., Martin B. Kleiman, M.D., Morris L. V. French, Ph.D., Gordon Chastain, B.S., Charles Barrett, M.D., and Charles Griffin, B. S.

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Current knowledge of the risk of poliomyelitis and the rates of vaccine-associated complications is required to determine whether the live or the inactivated poliovirus vaccine is optimal for control of poliomyelitis.[1] In the United States, calculation of the risk of vaccine-associated complications has relied on practicing physicians recognizing and reporting cases to state and local health departments, and ultimately to the Centers for Disease Control. From 1969 to 1981, the "best available paralytic poliomyelitis case count" compiled by the CDC averaged four cases per year among recipients of orally administered poliovirus vaccine.[1] Although the risk to adult OPV recipients and adult contacts of vaccinees is recognized by most physicians, the risk to presumably healthy infant vaccine recipients is not generally appreciated. We have recently recognized four cases of vaccine-related neurologic compli-

See related article, p. 1031.

BAPPCC	Best available paralytic polio case count
CT	Computed tomography
DTP	Diphtheria-tetanus toxoid-pertussis vaccine
IPV	Inactivated poliovirus vaccine
OPV	Orally administered poliovirus vaccine

cations in infant vaccine recipients. All four occurred between April 1982 and July 1983 in Indiana, a state with a population of 5.5 million. In each instance the referring physician failed to associate the neurologic abnormality

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with administration of OPV; referring diagnoses included trauma in two, spinal cord tumor, and failure to thrive.

CASE REPORTS

Patient 1. In March 1983, this previously healthy 1-year-old boy had fever, irritability, and left leg weakness 22 days after the initial dose of DTP (left anterior thigh) and OPV. The onset of symptoms was associated with minor trauma. In the ensuing 4 days, fever resolved and he became unable to walk, crawl, or sit. On admission the only abnormality was flaccid left leg paralysis; sensation was normal. The cerebrospinal fluid contained 23 WBC/mm³; glucose concentration was 54 mg/dl, and protein 131 mg/dl. Serum IgA was 89 mg/dl (normal 19 to 55 mg/dl), IgM 124 mg/dl (31 to 77 mg/dl), and IgG 798 mg/dl (442 to 890 mg/dl). Serum complement, T and B cell quantitation, T cell subsets, phytohemagglutinin lymphocyte stimulation, somatosensory evoked responses, and computed tomography of the head all yielded normal results. Poliovirus type 3 was isolated from stool and throat, and was characterized by the van Wezel and Hagendoek[2] method (performed at the CDC) as similar to Sabin strains. Serum obtained 3 to 10 weeks after paralysis had neutralizing activity of ≥1:640 against poliovirus type 3. A complement fixation antibody titer against *Mycoplasma pneumoniae* was 1:64, 1 week after admission, and had fallen to 1:8 within 21 days. Cold agglutinin titers were ≤1:4 in both serum specimens. Cultures for *M. pneumoniae* were not done. Two years later the leg flaccidity and muscle atrophy persisted; development and growth were otherwise normal. A complete series of IPV was given, after which neutralization titers to poliovirus types 1 and 3 were ≥1:40. Serum neutralizing antibody activity failed to develop during and after completion of the IPV series.

Patient 2. In April 1982, 2 weeks after receiving a fourth dose of DTP (left anterior thigh) and OPV, this 2-year-old boy had fever and left arm and leg weakness. Until this illness, the patient had been completely healthy and had never had any illness or infection suggestive of an immunodeficiency disorder. On admission 6 days later he had left hemiparesis, with greatest weakness in the leg. No other significant abnormalities were found on physical examination; normal lymphoid tissue was present. The cerebrospinal fluid contained 19 WBC/mm³; protein concentration was 40 mg/dl, and glucose 71 mg/dl. CT of the head yielded normal findings. The ECG demonstrated a focus of slow activity in the right central and temporal regions. Poliovirus type 1 was isolated from the nasopharynx, and was characterized by the CDC as Sabin-like by the van Wezel technique. Sera obtained 1 and 2 weeks after the onset of paralysis had poliovirus type 1 neutralization titers of 1:10. Neutralization titers to types 2 and 3 were <1:10. Serum IgA was 2 mg/dl (normal 26 to 74 mg/dl), IgG 50 mg/dl (553 to 971 mg/dl), and IgM 12 mg/dl (27 to 73 mg/dl). Mumps and *Candida* skin tests produced reactions. Peripheral blood lymphocytes included 3% B cells; T cells, T cell subsets, and helper/suppressor ratio were normal. Two months later the left arm weakness had resolved and the ECG was normal. Flaccid paralysis and muscle atrophy of the left leg persisted. Intravenously administered gammaglobulin therapy was begun. The patient has remained in good health, with infrequent, mild respiratory tract infections, and the paralysis has persisted. He continues to require gammaglobulin supplements for humoral immunodeficiency.

Patient 3. This 9-month-old boy was referred for evaluation of failure to thrive and developmental regression in June 1982. At 8 months he sat alone, attempted to crawl, and babbled. He received doses of DTP and OPV at 4 months, and again at 6 months of age. At 7½ months he became listless, verbal activity decreased, and spontaneous use of the left arm and leg decreased slightly. Complete evaluation for failure to thrive and slow development at 8 months of age concluded with a diagnosis of cerebral palsy of undetermined origin. At admission he was alert, did not verbalize, and had spastic quadriparesis with decreased use of the left side. Cerebrospinal fluid, CT of the head, and nerve conduction velocities were all normal. An ECG showed mild generalized cerebral hemispheric dysfunction. Serum IgA concentration was <0.3 mg/dl (normal 19 to 55 mg/dl), IgG 7 mg/dl (442 to 890 mg/dl), and IgM 2.4 mg/dl (31 to 77 mg/dl). Blood lymphocytes were 16% T cells and 38% B cells; T cell subsets were 15% T4 and 28% T8. T cell response to phytohemagglutinin was markedly depressed. Poliovirus type 2, characterized by the CDC as Sabin-like, was recovered from stool and throat within 24 hours of tissue inoculation; high titers (10^5/ml) of poliovirus were recovered from both sites until death. Virus was not isolated from cerebrospinal fluid. The serum IgG was maintained at 400 to 600 mg/dl with intravenously administered gammaglobulin supplements. At 10 months, CT showed profound bilateral cerebral atrophy, most marked in the frontal and temporal regions. Neurologic and respiratory function progressively worsened, and the patient died at 21 months. Permission for postmortem examination was refused.

Patient 4. This previously healthy 3-month-old boy demonstrated left leg weakness in July 1983. He was referred to a community hospital for evaluation of a possible spinal cord tumor. Four weeks earlier he had received initial DTP (left anterior thigh) and OPV. The only abnormality at examination was flaccid left leg paralysis; sensation was intact. Lumbar puncture was not done. Poliovirus type 3 (CDC) was isolated from stool. Serum IgG concentration was 275 mg/dl (normal 311 to 549 mg/dl); IgA 49 mg/dl (8 to 34 mg/dl), and IgM 52 mg/dl (19 to 41 mg/dl). T cell numbers and function were normal. Neutralization titers against type 3 poliovirus were ≥1:32, 2 and 4 weeks after the onset of paralysis. Paralysis and left leg atrophy persisted at 18 months; growth and development have otherwise been normal.

DISCUSSION

The criteria used for including cases in the BAPPCC are illness clinically and epidemiologically compatible with poliomyelitis, paralysis, and persistent neurologic deficit after 60 days.[1] Patients 1, 2 and 4 fulfilled these criteria. Clinical and laboratory findings in our patients were comparable to those of the BAPPCC. The CDC reported a male/female ratio of 2.7:1 in vaccine recipients. Eleven of

the 37 vaccine recipients in the BAPPCC were immunodeficient, as were two (patients 2 and 3) of our four patients. Paralysis occurred in the leg in which the DTP was administered in our patients with paralysis; such localization of paralysis by wild polio infection after intramuscular injection has been reported.[3] No such data exist for vaccine strains. Paralysis was in a lower limb in 93% of the patients in the BAPPCC. Evidence for vaccine polio infection as the cause of illness in patient 3 is not definitive. This patient would not have fulfilled the criteria for inclusion in the BAPPCC. His findings were strikingly similar to those in a published report[4] of a child with combined immunodeficiency in whom progressive hypertonia and regression of social and motor development resulted from persistent poliovirus infection; poliovirus was isolated from throat and stool but not from CSF, which was normal. At autopsy, a strain of poliovirus type 2 with some dissociation of antigen and neurovirulence markers was recovered from brain tissue. Because permission for autopsy could not be obtained in our patient, and thus we were unable to examine or culture neural tissue, the diagnosis could not be firmly established.

The relative advantages and disadvantages of IPV and OPV have been extensively reviewed.[5] The major disadvantage of OPV is the potential risk of neurologic complications in vaccine recipients and susceptible contacts. The dramatic reduction of the number of cases of endemic and epidemic poliomyelitis in the United States has served to increase the proportion of cases that are vaccine associated. From 1971 to 1981, the BAPPCC included 153 cases of poliomyelitis.[1] Of these, 37 occurred in vaccine recipients, 36 in susceptible contacts of vaccine recipients, and 60 were either sporadic, imported, or epidemic cases that could not be associated with vaccine usage. The 37 neurologic complications among vaccine U.S. recipients yielded an annual incidence of 0.002 per 100,000 population. In Indiana, we observed an annual incidence of 0.058 per 100,000 ($P = 0.006$), remarkably higher than expected for the 15-month interval. The 1980 census estimated the Indiana birth rate to be 85,000 live births per year. A survey by the Indiana State Board of Health in 1980 reported that 88% of children younger than 2 years of age had received three or more doses of OPV. Based on a similar birth rate and immunization practices, the risk of neurologic complications among vaccine recipients younger than 2 years of age was approximately one in 37,500 for the interval during which our patients were observed. This differed with the estimate of two or three per million vaccinees reported by others.[6]

Physicians currently in practice in the United States may not recognize the symptoms of poliomyelitis or of vaccine-induced neurologic complications. The annual number of reported cases of poliomyelitis fell to fewer than 0.1 per 100,000 after 1965.[1] Inasmuch as more than 50% of physicians in practice in the United States completed training after 1965, many have not seen a patient with poliomyelitis.[4] If the diagnosis is considered, laboratory confirmation may be difficult for many practicing physicians. At the time of paralysis, antibody titers have often already peaked and a significant change in titer is no longer demonstrable. One or more strains of vaccine poliovirus may be excreted in the stool for several months after immunization. Because infection with other enteroviruses, and perhaps *M. pneumoniae*, may cause paralytic disease, culture and serologic tests for these pathogens should be performed to exclude these causes. Grist and Bell[7] reported that serologic confirmation of poliovirus infection in Scotland was most often requested by orthopedic surgeons or neurologists attending to late complications. Moreover, the facilities for viral cultures are not easily available to physicians in small community hospitals. Vaccine-related poliovirus infection may not have been considered in patient 3 if viral cultures had not been done. Although the association of complications with vaccine administration can usually be made with reasonable certainty by temporal association, physicians may be reluctant to do so without laboratory confirmation.

The current method of surveillance in the United States, that is, passive reporting of cases, may underestimate the frequency of vaccine-related complications. In other countries, active surveillance has been shown to discover cases more efficiently.[8] Finally, physicians may be hesitant to associate paralysis with the vaccine or to report vaccine-associated complications for fear of potential liability. Because major sequelae appear to affect the legs in most instances, surveillance directed at patients attending rehabilitation centers, brace shops, crippled children services, and specialists in neurology and orthopedic surgery might yield a higher incidence of vaccine-associated paralytic poliomyelitis. Perhaps the advisability of concomitant administration of DTP with OPV should be examined, or alternative vaccine regimens explored.

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CHILDHOOD IMMUNIZATIONS

A REPORT

PREPARED BY THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 1986

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IV. SURVEY OF VACCINE MANUFACTURERS

A. Introduction and Methods

The shortage in the supply of DTP vaccine in early 1985 raised questions regarding the dependability of the supply of vaccines in the United States. Testimony by commercial vaccine manufacturers at the time the shortage became apparent in December 1984 suggested that certain characteristics of the vaccine market, particularly the potential for costly liability suits against vaccine manufacturers and the limited size of the market for vaccines, are threatening the reliability of vaccine supply. There are currently only a few institutions involved in the production and distribution of vaccines. There is only a single supplier of some products. Some believe that the potential of large awards in suits alleging vaccine related injuries has increased the cost of manufacturers' liability insurance. In at least one instance, a manufacturer was forced temporarily to withdraw its products from the market when liability insurance become unavailable.

In light of this situation, the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce decided to survey producers of childhood vaccine products to obtain more detailed information. During the spring of 1985, the staff of the Subcommittee developed a questionnaire for this survey. The questionnaire focused on five major issues related to the production and distribution of childhood vaccines: 1) vaccine compensation litigation and claims; 2) the cost of product liability insurance for vaccine manufacturers; 3) research and development activities; 4) vaccine pricing and sales information; and 5) stockpiles and inventories of vaccines. Information in these areas was requested for the time period from January 1980 through March 1985. The questionnaire was mailed to the five commercial manufacturers and distributors of vaccines used in childhood immunization programs (MMR, DTP, polio and Haemophilus influenzae vaccines) and to the two State organizations involved in the production and distribution of vaccines. These seven organizations completed the questionnaires and returned them to the Subcommittee.

B. Summary of Findings

1. Litigation

During the study period (January 1980 through March 1985), there were 299 suits filed against the producers of childhood vaccines seeking compensation for injuries alleged to be due to vaccines.

Nearly 60 percent of these cases were for injuries related to DTP vaccines. Most of the 299 suits (84 percent) were for injuries related to childhood vaccines. Over the same 63-month interval, 83 claims were filed with the vaccine producers that did not result in litigation. Table 9 shows the number of suits filed by year. The rate at which these suits have been filed has increased every year since 1980.

Table 9. Number of Vaccine Injury Lawsuits Filed by Year, 1980-1985

Year	Number of suits
1980	24
1981	29
1982	39
1983	70
1984	101
1st Qtr. 1985	36
1985 (est.)	144
63-Month total	299

Damages claimed in the vaccine injury suits fall into two categories, compensatory and punitive damages. For the 299 suits filed during the study period, requests for damages amounted to $3.5 billion, $2.52 billion for compensatory damages and $960 million for punitive damages. However, many of these suits (about 40 percent) did not specify an exact amount of damages but only requested damages in excess of nominal or jurisdictional amounts (minimum damages required for filing suit; this amount may vary from jurisdiction to jurisdiction). Given that many of these suits have not requested a specific level of damages suggests that the claims against vaccine manufacturers are more than the $3.5 billion in damages already specified.

Some of the survey respondents provided case by case information on requests for damages. Assuming similar patterns of requests for damages for all respondents, the data suggest that nearly half of the currently specified damages are requested by a relatively small proportion of the suits. There are an estimated 30 suits (10 percent) requesting damages in excess of $25 million each. These cases account for an estimated $1.7 billion (48 percent) of the total specified prayers for damages. Seven suits ask for damages in excess of $100 million each.

The questionnaire asked for information on the resolution of vaccine injury cases. However, it should be noted that product liability cases typically require several years before they are either settled or tried in court. Thus, the following information on the resolution

of vaccine injury cases filed between January 1980 and March 1985 must be considered incomplete, although it is the best information available at this time.

Of the 299 cases filed between January 1980 and March 1985, 52 cases have been settled (17 percent), 27 cases have been dismissed on motion (9 percent), and three cases have been tried in court (about 1 percent). The remaining 216 cases (72 percent) were still pending as of March 1985.

The survey respondents paid out a total of $16.2 million in settlement payments for the 52 cases that had been settled. As noted by some of the respondents, this figure does not include settlements paid during the 63-month study period on cases filed prior to January 1980.

Three of the 299 cases had been tried by March 1985. In addition, the respondents indicated that six additional cases, filed before the study period, had been tried between January 1980 and March 1985, and one of the 285 cases was tried after the close of the study period in May 1985. Of the ten total cases tried, four resulted in verdicts for the defense (three affirmed on appeal, one appeal is still pending) and six found for the plaintiffs (one subsequently settled for a lesser amount, five appeals are still pending). If the five pending verdicts are upheld on appeal, the vaccine manufacturers will have to pay a total of $17.7 million in damages to plaintiffs. It should be noted, however, that more than half of this amount ($10 million) results from a single verdict. Only this last verdict (recently overturned) detailed the award by type of damages: $2 million in compensatory and $8 million in punitive damages.

The questionnaire requested data on the annual defense costs of vaccine injury litigation that was not reimbursed by insurance. The respondents spent $4.7 million on litigation in 1983 and $9.8 million in 1984.

2. Liability Insurance

The survey included several questions related to the liability insurance coverage of the vaccine producers. Because the liability coverage arrangements of the two State owned producers differ from the arrangements of the five commercial producers, the responses to these questions are presented separately for the State producers.

The liability of two State organizations producing and distributing vaccines is insured by the respective State governments. Both States are self-insured and must pay any awards themselves. In one State, the State's liability for damages is limited by statute to $100,000 per claim.

All five commercial producers had insurance coverage of their liability for vaccine injury lawsuits under umbrella policies that

also covered the liability of their parent corporations for all other products manufactured and distributed. Therefore, it is difficult to separate the cost and coverage of insurance for liability related to vaccine injuries from the cost and coverage of liability insurance for other products. Also, changes in a parent corporation's premium or coverage may be related to liability for products other than vaccines.

The five commercial producers were covered by umbrella policies held by their parent corporations with total annual aggregate and per occurance liability limits of about $1.3 billion dollars in 1985. Between 1984 and 1985, two firms increased their liability limits, one firm's limits stayed the same, and one firm's limits were reduced. The fifth firm lost its liability for DTP vaccines except for contracts existing as of June 1984 and was not able to renegotiate a new insurance contract until April 1985. The policy limits of all the policies in effect in 1984 applied to both defense and indemnity costs. This changed somewhat in 1985 when one firm's policy limits excluded defense costs for DTP vaccine injury cases.

All five commercial firms are self-insured to some extent and retain funds each year to cover any self-insured expenses. In 1985, the total self-insurance retentions of these five firms was $41 million. This amount represents an increase of 39 percent over the $29.5 million in self-insurance retentions in 1984. It should be noted that this level of retention is intended to cover the self-insured liability for all products of the parent corporations, not just for vaccine related liability expenses.

The liability insurance policies for all of the commercial respondents contained special provisions relating to coverage of vaccine products. Coverage for swine flu vaccine was excluded from all policies. However, it should be noted that under the Swine Flu Act (P.L. 94-380), manufacturers were generally relieved of their liability for injuries resulting from the administration of the swine flu vaccine, with the liability for such claims being transferred to the Federal Government. Beginning in 1985, two manufacturers' insurance policies impose a $250,000 deductible for claims related to certain vaccines, subject to specified annual limits. One manufacturer's policy excludes from coverage the cost of legal defense for cases related to certain vaccines. Under this policy, the manufacturer will have to pay any costs of defending itself. The liability insurance policies are generally cancellable with 90 days notice.

In 1984, the parent companies of the five commercial vaccine manufacturers surveyed paid $10.2 million in liability insurance premiums. This amount is slightly less than the $10.7 million in premiums that was paid in 1980. However, it should be noted that premium data for 1985 submitted by two respondents suggests that their liability insurance premiums would be somewhat higher in 1985 than they were in 1980, representing a large one year increase between 1984 and 1985. All five respondents indicated that they expected their liability premiums to increase substantially in the near future (estimates ranging from 50 to 300 percent) for coverage with liability

limits that are 50 or more percent lower than current limits. None of the companies obtain their insurance policies through competitive bidding. According to one respondent, "the issue is availability at any price." One of the State producers once sought competitive bids for liability coverage of vaccines distributed outside its borders, but did not accept any of the bids after it realized that the revenues from out-of-state sales would not even cover the bid premiums.

In 1980, the total product liability insurance premiums of the parent companies of the five commercial respondents were approximately 0.086 percent of annual gross sales, premiums of $10.7 million on sales of $12.5 billion. By 1984, these premiums had declined to 0.063 percent of gross sales. During this period, gross sales increased faster than liability insurance premiums for four of the five respondents.

Finally, the questionnaire asked for information regarding losses and payments that were paid by these firms' liability insurers for vaccine related claims and suits. For four of five respondents, the annual losses and expenses from 1980 through 1984 were less than their self-insurance retention amounts. That is, the insurers for these four companies did not pay out any losses. For the fifth firm, the insurer paid out approximately $700,000 in settlement costs.

3. Research

All seven survey respondents (including the two State organizations) conduct programs of research and development for new and safer vaccines. Some of these research efforts are now in the clinical trials stage of development. The descriptions of these research and development efforts were generally vague due to the confidential nature of these activities in a commercial environment. However, it appears that some efforts are being made to develop new vaccines. Also, some of the current research efforts are being directed toward the improvement of existing products, including improved childhood vaccines.

In general, it appears that the research and development of vaccines conducted by the commercial manufacturers is financed by the individual corporations. Only one firm is currently receiving Federal funds for support of a clinical trial of a new vaccine. A second company stated that it had received $400,000 in Federal support for vaccine research and development between 1981 and 1985. A third stated only that it had received some Federal support "at one time." Two firms stated that they had never received any Federal support for vaccine research and development.

Both State producers are also engaged in vaccine research and development with combined expenditures of $535,000 per year. Of this amount, 56 percent comes from State funds, 30 percent comes from Federal funds, and the remaining 14 percent from private philanthropic organizations.

The seven respondents currently hold 27 patents and product licenses for vaccines and vaccine production. Some of these are exclusively held.

4. Vaccine Prices and Sales

Vaccines are commercially sold in three "markets:" sales to the Federal Government (including sales through the CDC's consolidated contract purchases made on behalf of State and local governments); bulk sales to State and local governments and other large purchasers; and retail sales to physicians, clinics and hospitals. The prices charged for vaccines in each of these "markets" vary, due in part to the stronger negotiating positions of large purchasers. The ratios of prices paid in these markets vary both by vaccine and by vaccine manufacturer. Based on responses to the survey, the data suggest that vaccine prices in the bulk sales market are 0 to 50 percent higher than prices paid by the Federal Government. Retail vaccine prices range from 50 to 300 percent higher than the prices paid in the Federal market.

The two State producers do not participate in any of the commercial markets for their products. Both organizations distribute greater than 95 percent of their products within their respective State borders at no cost. One of these entities has sold some vaccine to neighboring States in response to emergency requests. In these cases, the vaccine was sold at market prices and the receiving State was required to assume all liability associated with the vaccines.

Based on the commercial manufacturers' pricing data collected by the survey, the prices of vaccines used in childhood immunization programs increased by between 50 and 900 percent between 1980 and 1984, depending on the vaccine, the manufacturer, and the market. The retail price of DTP vaccine increased by the greatest percentage, with most of that increase occuring since 1983. Prices of other vaccines increased between 50 and 200 percent, with the increases occurring relatively steadily over the 5-year interval.

There were only two instances cited in the survey of sales of vaccines between vaccine manufacturers. The first occurred in 1979 and 1980 when one firm purchased a small amount of DTP vaccine from another. This vaccine was purchased for $1.70 per 15 dose vial and then resold in the retail market to private practitioners at $4.44 per vial. The second sale occurred during the DTP crisis of 1984 and 1985. Based on public testimony by Robert Johnson of Lederle Laboratories, Lederle purchased more than 10 million doses of DTP from Wyeth Laboratories at 20 cents per dose and redistributed it at a price of about $2.80 per dose.

Total sales of vaccines are reported in two ways: gross sales and net sales, where net sales are equal to gross sales less unused

product returned to the manufacturer. Table 10 shows aggregate gross and net sales volume of the survey respondents by type of vaccine for years 1981 through 1984.

Table 10. Gross and Net Sales of Vaccines by Survey Respondents, 1981 - 1984.

Gross sales (in millions)

Year	Childhood vaccines (DTP, MMR and polio)	Other vaccines	Total
1981	$ 68.7	$47.2	$115.8
1982	79.7	61.2	140.9
1983	105.1	68.3	173.4
1984	132.3	73.2	205.5

Net sales (in millions)

Year	Childhood vaccines (DTP, MMR and polio)	Other vaccines	Total
1981	$ 64.0	$39.9	$103.9
1982	73.9	52.8	126.7
1983	99.1	57.8	156.9
1984	126.0	64.5	190.5

In 1984, the gross sales of vaccine products by the survey respondents was $205 million. Net sales in 1984 were 93 percent of gross sales, or $190 million. Between 1981 and 1984, gross sales of vaccine products increased by 77.5 percent (from $115 million to $205 million). Net sales increased by 83.3 percent.

In 1984, childhood vaccines (DTP, MMR and polio) accounted for 64.4 percent of gross vaccine sales ($132.3 million) and 66.1 percent of net sales ($126.0 million). Gross sales of childhood vaccines increased by 92.6 percent between 1981 to 1984, accounting for an increase of $63.6 million in sales revenues. This increase in revenues is largely due to increases in the prices of these products since demand for childhood vaccines has remained relatively constant over this period.

In response to a question about the relative profitability of vaccine products as compared to other products, the five commercial

respondants noted that their vaccine product lines were about as profitable as the other products sold by these corporations, but somewhat less profitable than other pharmaceutical products. One respondent qualified its response by noting that "our pediatric vaccines have become more profitable in recent years . . . ." Other respondents noted that the true profitability of their vaccine product lines could not be determined given the potential liability in lawsuits related to these products.

5. Stockpiles and Inventories of Vaccines

Six of seven survey respondents maintain inventories of finished products. In some cases, vaccine inventories are large enough to supply national demand for several months. In addition, three of the respondents maintained stockpiles of vaccine under contract to the CDC, at the time the survey was conducted. Since March 1985, a fourth company has also entered into a contract with CDC to stockpile vaccine.

Chairman RANGEL. Thank you very much.

Mr. Dorgan.

Mr. DORGAN. Mr. Chairman, I would just like to ask Jeff if he might recount for us your apparently personal experience in seeking redress for the injury done to a family member.

Mr. SCHWARTZ. It is a little bit touchy and personal and I would prefer not to go into great detail about my situation other than to say we filed an initial suit at the time and eventually withdrew the suit even though we thought we had a good claim, because of a variety of personal stressful family circumstances. I would be willing to explain our personal situation in private. The more important point is about what the group's experience is. The group's experience is that our parents have had no alternative but to go to court. So parents who are faced with lifetime care for their children, long after the parents are gone, how are they going to pay for that? They have no choice but to sue and in many instances those suits have been brought.

Now, I think Mr. Waxman did inadvertantly leave one misleading impression. There is a good report done by his staff that says there are a few cases that have been won, a few cases that have been lost; there are a large number of cases that have been settled, et cetera, but the point is so far the awards and settlements are not that big, not as big as the administration and vaccine makers would lead you to believe. We urge you to look at the Health Subcommittee's staff report.[1] The point is some parents have said if they had a choice they would go to a no-fault compensation system. If parents knew it was going to be fair, if they knew it was going to be quick and if they knew it could take care of their children, many parents would be willing to sacrifice the potential for a big score to get their children taken care of.

Mr. DORGAN. I didn't mean to leave the impression I wanted to walk you through a personal discussion about your circumstance. I was trying to understand the typical circumstances some find themselves in when they have this sort of injury. My guess is that each family is left pretty much to fend for itself. Do you get a lawyer? How did you go through the time-consuming task of litigation and face an uncertain outcome at the end?

I guess I wanted you to discuss that just generally from your experience.

Mr. SCHWARTZ. I appreciate the question because it is important to understand who these families are prototypically. They involve children who in the long-term problem cases, involve children who have seizure disorders, who are multiple handicapped, who require round-the-clock care, and who have extraordinary expenses of all sorts. In order to sort out all these kinds of problems, parents have to see a number of doctors, therapists, educational specialists, and then lawyers to try to figure out what can be done for these kids. Some of them get good lawyers; some of them get not so good lawyers. Some of them win. Some of them have cases that they have taken to a lawyer but the lawyer has not filed for years. Some of

[1] See report by Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, "Childhood Immunizations," Committee Print 99-LL, 99th Cong., 2d Sess. (Sept. 1986), pp. 85-92.

them have been tried promptly. There is a range of experience and it is frustrating to not be able to be sure that you can provide adequately for your child.

Mr. DORGAN. We talk about kids and children. This is not exclusively kids and children, is it? I know of a case of someone in their 50's who took polio vaccine.

Mr. SCHWARTZ. Contact polio is the situation in which childhood vaccines can transmit impacts to the people who are surrounding them. The law covers those cases, by the way.

The law covers those cases and they well should be covered. But I urge the committee not to assume that we are talking about a one in a million shot. The commonly cited statistics here just really don't bear scrutiny. We can go into greater detail with you and your staff to show you why not, but there is a recent medical journal article that says we have not been looking for the side effects of these vaccines. Once doctors started looking for the side effects of the polio vaccines, they found one in 37,500 cases of severe neurological impact. That is a whole big different magnitude of order than one in 1 million.[2] We think the same is true with respect to these other vaccines. We understand that makes the problem worse from your standpoint but we are trying to be honest with you here and we are trying to get honest recognition of the size of this problem. It is not a minuscule problem.

Mr. DORGAN. It makes it worse especially with respect to the retroactive cap that was placed on the legislation that we passed.

Mr. SCHWARTZ. The retroactive cap works two ways. I honestly believe there are many more kids out there that have been injured or killed by childhood vaccines than that retroactive cap allows for. On the other hand, the ability to document that those injuries vaccine related when they occurred 20 years ago is very difficult because there was not sensitivity then to the dangerous side effects of these vaccines. Doctors weren't recording these reactions. Parents were not sensitized to them years ago. As a practical matter, I think relatively fewer claims for the old cases will be filed than are really justified, because causation will be very difficult to prove with inadequate records.

Mr. DORGAN. Thank you very much.

Mrs. KENNELLY. Your excellent testimony gives us broad latitude. You are more or less saying to us find an answer and we will help you find an answer. I wonder if you would address the present piece of legislation that has been signed, was passed by us and signed. Are there any particular parts that you could say right now, leave those in and go on from there. Are there any parts more important than other parts? We are really thrashing around on this thing.

Mr. SCHWARTZ. Our general message to you is unless you enjoy pain and suffering yourself don't try to revisit the fight that has been going on for 5 years. In terms of our interest we feel most strongly that any restriction on the parents' right to sue to protect their children is a mistake. It is a mistake because that is a right that is necessary to assure adequate care by the manufacturers and

[2] See Gaeblar, et al., "Neurological Complications in Oral Polio Vaccine Recipients," Journal of Pediatrics (June 1986), pp. 878-881.

doctors. That is a right that is necessary to assure that the compensation system really provides adequately for the children's needs. So we think preservation of that right is important.

There are a few minor things we would like to see changed. We don't understand a compensation system that does not have an effective deadline for decisionmaking. There needs to be an up or down decision within a reasonable time so a parent can say, okay, let's take the award or let's go to court. The compensation process must not drag on for years while the children are left uncared for.

We also feel strongly that the decisionmaking about an individual case, whether that case fits within the table or otherwise deserves compensation, should be made by a politically independent entity. That is why we supported the special master/magistrate concept in the Federal courts. We are very concerned that given HHS's historic hostility and denial of this problem, we are very concerned HHS will find a way not to see any of the cases that are really there if the compensation system is put under their charge.

We want the Federal judiciary that has political independence, using a special master or magistrate system, to expedite compensation decisions.

We try not to be dogmatic. There are a lot of things that could be changed in the context of an acceptable total program, but we strongly urge this subcommittee to focus on the funding questions and leave the other questions that we fought through so difficultly for the last 4 years to the resolution that has already been made by Congress. We did not support all parts of the law. We didn't like all parts of it. But we supported the package as a whole because we knew practically this was the best that could be done.

Mrs. KENNELLY. So the bottom line is you want to leave the avenue of litigation open, at the same time provide a revenue source that is permanent and therefore the individual who has had the very serious problem has a choice?

Mr. SCHWARTZ. An incentive we think under the system to take compensation where compensation is adequate and reliable, but allow the parent to sue when there is a clear demonstration of wrongdoing, or otherwise when the parent is determined to go to court.

When a doctor gives the shot four times even though there has been a serious reaction after the second shot, and the third and fourth shots leave the child permanently brain damaged, we ought not take away the right of the parent to sue that doctor, because that lawsuit not only provides for the child's needs but it sends a message to the rest of the doctors to administer this vaccine properly. The same goes for the drug companies. They should take care to manufacture their product properly and to make it as safe as possible.

Mrs. KENNELLY. Thank you.

Chairman RANGEL. Thank you very much. The committee welcomes the opportunity to work with you as we try to reach a conclusion to this bill. Thank you for the great work you have done.

The next panel is Lederle Laboratories, Bob Johnson, president, from New Jersey, Merck & Co., Mr. MacMaster, president, and Connaught Labs, Mr. Williams, executive vice president.