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

TESTIMONY ON H.R. 5184
BEFORE THE HOUSE SUBCOMMITTEE
ON HEALTH AND THE ENVIRONMENT
JULY 25, 1986

Mr. Chairman and Members of the Subcommittee:

My name is Jeffrey H. Schwartz. I am President of Dissatisfied Parents Together. We are a nationwide group of parents concerned with the safety and effectiveness of the pertussis part of the DPT vaccine. Our group is composed largely of parents of children who have suffered brain damage or death because of the pertussis (whooping cough) vaccine.

We appreciate the Subcommittee's invitation to appear here today and present our views on H.R. 5184. For more than four years now our group has worked for passage of a strong vaccine safety and victim compensation law. We continue to support enactment of S. 827, which we, together with the American Academy of Pediatrics, helped to develop. We note with pride and appreciation your sponsorship of similar legislation in the last Congress, Mr. Chairman. We applaud your leadership in keeping this important issue in the congressional and public spotlight. Dissatisfied Parents Together stands ready to work with this Subcommittee to help enact legislation which, above all, will protect the health and lives of all children.

It is thus with deep regret that Dissatisfied Parents Together strongly opposes enactment of H.R. 5184. While there are a number of positive features in the bill, 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.

We know that is not your intent, Mr. Chairman. But we believe this would be the inevitable effect, if H.R. 5184 were to pass in its current form. The vaccine manufacturer's own documents filed with the SEC tell the real story: they are crying "liability crisis" all the way to the bank.

Lederle tells the Congress, the doctors, and consumers that they must go out of the vaccine business unless they can raise their prices 9500% in four years to cover "liability-related" expenses. But they tell the SEC, Wall Street, and prospective investors that the lawsuits pose no risk of "material adverse effect" on the company. (See Appendix A--Lederle's DPT Profits: An $80 Million Dollar Rip Off of American Consumers?)

Mr. Chairman, Dissatisfied Parents Together heartily endorses your closing words in the December 1984 oversight hearing which exposed the trumped-up nature of the alleged "vaccine shortage":

> The Government should not be in the business of guaranteeing profits to the drug industry or protecting physicians from gross negligence. What we are in the business of doing is guaranteeing that children will be protected from those dreaded diseases that can be prevented. That is our obligation.

> Before we pass any legislation. . .we will have to shed light on those very questions you raised. We will have to receive all the information we need in order to make the proper decisions. And we will get it even if we have to go get a subpoena in order to get that information. . . .
>
> We are not going to be in the game of chicken and let down the public interest in order to be stampeded into any action that is not the wisest and most thoughtful possible.

Unfortunately, H.R. 5184 in its present form falls far short of that standard. The bill suffers from five fundamental flaws:

1. H.R. 5184 would destroy important incentives now provided by tort law to produce the safest possible vaccines and to administer more safely the vaccines we now have. (Appendix C)

2. H.R. 5184 would override state tort protections and procedures, and do so in a selective and unfair way: vaccine-damaged children's rights would be overridden in states which provide greater levels of protection; states which decide to restrict or abolish State protections for vaccine-damaged children would remain free to do so. (Appendix D)

3. H.R. 5184 would not fairly or adequately compensate children who are severely damaged by mandated childhood vaccines. (Appendix E)

4. H.R. 5184 would not safeguard the existing vaccine supply or keep vaccine prices and profits at reasonably low levels. (Appendix F)

5. H.R. 5184 would further undercut parents' confidence in the vaccine system, not build that confidence. (Appendix G)

Because the time for oral statement is so limited, we have prepared these Appendices which summarize the bill's major defects and identify provisions of the bill which, in our view, particularly need to be deleted or changed.

To highlight these concerns, however, we would like to pose the following questions about the bill:

Q1: <u>If one of the principal goals of the bill is to protect the existing vaccine supply</u>, why does the bill apply the defenses and limitations on the tort system even to companies which no longer supply vaccines or stop producing vaccines in the future? Why does the bill fail to include provisions to require prior notice to the government before an existing vaccine maker may withdraw from the market, to require government stockpiling of vaccines, or to authorize government reinsurance or co-insurance if private market insurance is unavailable at reasonable rates?

Q2: If one of the principal goals of the bill is to keep vaccine prices reasonably low, why does the bill fail to put any cap on the prices or profits which vaccine makers can exact for their mandated products? Why does the bill fail to assure that any cost savings that may occur are returned to the public? And why does the bill fail even to establish any mechanism to inquire into the legitimacy of price rises which the vaccine makers claim, but do not prove, to be the result of "liability costs"?

Specifically, we want to know how Congress, by its inaction and silence, can condone what appears to be an $80 million "rip off" of the American public?

Q3: If one of the principal goals of this legislation is to assure adequate and just compensation of vaccine-damaged children, how can payments for home care be denied and "institutionalization" of these children effectively be required because it may be cheaper to put these children in a State hospital? Why does the bill only authorize, not require, loans from the Treasury to the Compensation Fund when the tax revenues prove to be inadequate to pay the medical care expenses of vaccine-damaged children who elect to receive compensation in lieu of a lawsuit?

Q4: If one of the goals of this bill is to preserve incentives for the safest possible vaccines, why does the bill preempt state laws which would allow recoveries for injuries resulting from faulty vaccines which are unreasonably dangerous, defective, and otherwise avoidably dangerous? Why does the bill require parents to endure the added delay, expense, and stress of going through the compensation system, even for injuries which clearly result from manufacturer negligence? Why should the public, rather than the negligent drug companies, have to pay for these injuries? Why should compliance with government standards be an absolute defense to exemplary damages, when drug companies have known for more than 20 years that the only so-called "safety" test required by the FDA for pertussis vaccine is basically unsound, and in those two decades have done nothing to warn physicians or the public about the irrelevance of the mouse toxicity ("safety") test or to develop an effective safety test? (See the Koehler memorandum, Appendix B.)

There are many more questions about this bill that need to be answered. We would like permission to provide supplemental comments on the bill for the record.

We offer our critique of H.R. 5184 in a constructive spirit, and hope it will be received accordingly. We continue to support passage of S. 827. We are working with Senators Dodd, Simon, Hawkins, and Hatch on a possible substitute as well. We will be pleased to work with this Subcommittee to define and pass a bill which is "the wisest and most thoughtful possible."

APPENDIX A:

LEDERLE'S DPT PROFITS:
AN $80 MILLION DOLLAR RIP-OFF OF AMERICAN CONSUMERS?

1. Summary

In the three-year period from May 1984-May 1987, it is estimated that Lederle Laboratories will reap more than $100 million in profit from the DPT vaccine alone. This raises real questions as to the validity of Lederle's claim that, "We deeply regret having to raise the price of DTP vaccine. Unfortunately, the current litigation and insurance crisis has left us no other alternative in order to remain in the DTP market."[1]

2. Where does the $80 million Lederle profit estimate come from?

This estimate is derived as follows:

- Estimated profit on Lederle's sale of Wyeth's 1984-85 production	$19.1	mil.
- Estimated profit on Lederle's own production (1985)	12.3	mil.
Subtotal	$31.4	mil.
- Estimated annual profit with price at $11.40/dose and estimated costs at $8.20/dose (assuming $8.00/dose were necessary for liability-related expenses)	$20	mil.
- Difference between Lederle's estimated May 1986-May 1987 revenues for "liability" reserve and estimated pay-out during the same period	40	mil.
- Estimated earnings on investment of reserve	4	mil.
- Estimated insurance coverage (reimbursement) for claims paid plus tax benefits	6	mil.
Subtotal	$70	mil.
TOTAL	$101.4	mil.

Even allowing $20 million as "reasonable profit," this still would leave $80 million plus as windfall profit to Lederle.

3. What is the support for this estimate?

A. Lederle's sale of Wyeth's production (1984-85):

In 1984-85, Lederle purchased DPT vaccine from Wyeth Laboratories at $.20/dose and sold the same vaccine at $2.80/dose--a 1400% mark-up. An estimated 11.3 million doses was to have been purchased by Lederle in

return for assuming Wyeth's liability. Lederle's President testified, however, that of the $2.60/dose price increase imposed by Lederle, only "30-40 percent" was due to liability related expenses.[2] (Lederle's President had earlier told Congress, "You can have profitability as low as 10 cents a dose, depending on the number of doses that are sold."[3])

Thus, Lederle presumably paid Wyeth approximately $2.26 million and then resold the same vaccine for $31.64 million (11.3 mil. doses x $2.80/dose). Allocating 35 percent of the difference to cover "liability-related" expenses, Lederle would have made a profit of $19.1 million on Wyeth's vaccine. This is an almost 850% return on investment.

B. Lederle's sale of its own (1985) production:

During a similar period, Lederle produced 7.3 million doses of its own vaccine.[4] Sales prices increased from $2.80/dose to $4.29/dose in July 1985.[5] Assuming $.20/dose production cost, a conservative $2.80 price, and 35 percent liability related expense, Lederle would have made a profit of $12.3 million on these doses of vaccine.

C. Lederle's May 1986-May 1987 production:

- In 1986, Lederle is distributing "more than one-third" of the approximately 18 million doses of DPT vaccine sold annually--or about 6.3 million doses.[6] A recent article estimated Lederle's annual DPT sales at 10 million doses/year.[7] At $11.40/dose, Lederle's current annual gross revenues would range from $71.8 million to $114 million (depending on the number of doses sold--6.3-10 million). Assuming conservatively that the lower production figure were correct, total production expenses at $.20/dose would be $1.3 million. This would leave $70.5 million for liability-related expenses and profit.

- If $8/dose were set aside for "liability-related expenses" ($50.4 million @ 6.3 million doses), that would mean $3.40/dose would be available for production related expenses and profit. With $.20/dose production costs, Lederle would be making a minimum $20 million/year profit.

- This minimum figure assumes the entire remaining $50.4 million were really needed annually to cover Lederle's DPT "liability-related" expenses. What proof does Lederle offer that it could not get liability insurance in the private sector for less than $50 million/year? We have only Lederle's assertion for this.

- What proof does Lederle offer that it needs upwards of $50 million/year to pay for DPT-related liability expenses? No such proof is offered. If the American Academy of Pediatrics estimates that only 1 in 310,000 shots results in permanent brain damage, then presumably Lederle would be liable only for payments for 19 children a year. Is Lederle claiming that liability-related

expenses amount to $2.6 million lump sum per child? What is the support for any such claim?

- In its letter to physicians, Lederle claimed that it had been named as defendant in 100 new DPT lawsuits in 1985. It also stated that "many of these claims are based on cases where the vaccine was administered in the 1960's and 1970's."[8] Is Lederle implying that it had no occurrence-based insurance coverage in the 1960's and 1970's to help pay for these claims? (For the purpose of this analysis, we assume conservatively that $6 million would be reimbursed or paid by Lederle's previous insurers.) Is Lederle implying that even with this coverage, it will need an additional $50 million to cover these claims? Is Lederle suggesting that all of these claims will be settled or result in verdicts for the plaintiffs? Where is the proof that Lederle needs $50 million annually to pay for these expenses?

- In fact, it appears that Lederle now settles no more than 10 DPT cases per year. Even assuming average settlements of $700,000/case and defense attorneys' fees and costs of $300,000/case, this would still mean maximum out-of-pocket expenses for liability in 1986 of $10 million. Another $40 million would be pocketed as profit by Lederle under the guise of its insurance reserve.

- Even this analysis does not account for several other sources of revenue for Lederle from the so-called "liability"-driven price rise. First, it fails to account for the interest earned by Lederle when it gets use of this money instead of American consumers getting use of the funds (e.g., $40 million liability reserve). Second, it fails to account for the tax benefits which captive insurance carriers get. Third, it assumes that Lederle pays all verdicts and settlements by lump sum payments rather than by structured settlements financed by annuities. This is probably not the case. What is the proof that Lederle pays all verdicts and settlements in full at the time of their entry?

- Lederle's own documents filed with the Securities and Exchange Commission support the above analysis: the company is not only not seriously threatened by the pending lawsuits,[9] vaccine sales at these inflated prices constitute a major source of profit for the company.[10]

4. Conclusion

Lederle and Connaught together now have a monopoly market and a product mandated by law. Under these circumstances, doesn't the American public deserve a fair review of State or federal governments of the prices and profits which the vaccine makers are collecting? Don't the foregoing questions need to be answered publicly in order for the American public to retain any confidence in this program?

NOTES FOR APPENDIX A

1. Letter to Physicians from R.B. Johnson, President, Lederle Laboratories, May 20, 1986, p. 2.

2. In 1982, typical prices of DPT vaccine in the public sector were $/10-.12/dose, with private sector prices slightly higher. Hearings before the House Health and Environment Subcommittee, Dec. 1984, p. 266. Presently, Lederle charges $11.40/dose of the same vaccine.

3. Hearings before the House Health and Environment Subcommittee, Sept. 1984, p. 248.

4. House Hearings, Dec. 1984, p. 283.

5. Philadelphia Inquirer, May 22, 1986, p. 1-E.

6. Id., p. 6-E.

7. Toronto Globe and Mail, "Pharmaceutical Firms Put Pressure on Governments," July 1986.

8. See nt. 1.

9. "In the opinion of the management, the ultimate liability resulting from all pending suits and claims (after taking into account insurance coverage applicable to the events giving rise to such pending suits) will not have a material adverse effect upon the consolidated position of [American Cynamid, Lederle's parent corporation] and its subsidiaries." American Cyanamid 1985 Annual Report (March 1986), p. 32.

10. "MEDICAL GROUP sales and operating earnings hit record levels in 1984 despite heavy expenditure for new product introductions and the strength of the dollar. The increases were attributable to the continued growth in sales of antibiotics. . .and gains in U.S. sales of biologicals [including DPT vaccine]." American Cyanamid 1984 Annual Report (March 1985), p. 49. [emphasis added]

PERTUSSIS VACCINE
(Pharmaceutical Manufacturers Association)

Drake Hotel, Chicago, Illinois

March 5, 1964

PRESENT

Dr. J. T. Anderson -- Pitman-Moore -- Physician
Dr. E. Bandera -- Parke, Davis -- Physician
Dr. M. Z. Bierly, Jr. -- Wyeth -- Physician
Dr. A. F. Bolyn -- Nat'l Drug Co.
Dr. A. H. Brueckner -- Pitman-Moore
Dr. H. A. Dettwiler -- Lilly
Dr. H. B. Devlin -- Parke, Davis
Dr. J. Ichter -- Merck, Sharp & Dohme -- Physician
Dr. P. B. Koehler -- Nat'l Drug Co. -- Physician
Dr. C. Newman -- Merck, Sharp & Dohme
Dr. F. D. Peck, Jr. -- Lilly -- Physician
Dr. H. D. Piersma -- Lederle
Dr. R. E. Rowand -- Lederle -- Physician

(Cutter and Sherman Laboratories did not respond to the invitation to attend.)

SUMMARY OF MEETING

It has been long felt by those companies preparing pertussis vaccines that the mouse toxicity test bears no relationship to the clinical reactivity of a particular lot of vaccine. At the Pertussis Symposium held at the N.I.H. on October 21, 22, and 23, 1963, it was concluded that the toxicity testing should be re-evaluated and that possibly a cooperative effort in this behalf could be instituted between clinicians and laboratory personnel, as well as between the regulatory agency (D.B.S.) and pharmaceutical industry.

As a result of this meeting last week, the attending members agreed to draw up a protocol for studying the pyrogenicity of various lots of pertussis vaccine after I.V. (and I.M.?) injection in rabbits. This protocol would be presented to Dr. Margaret Pittman and her group at the N.I.H. for discussion and comments. Serving on the group to formulate the protocol are Dr. Dettwiler, Dr. Peck, Dr. Devlin, Dr. Piersma, and Dr. Ichter.

It seemed clear to me that the Lilly group is the prime moving force behind this maneuver to "attack" the mouse toxicity test. Apparently, in spite of the relative low clinical reactogenicity of 'Tri-Solgen', the mouse toxicity test often intervenes with many lots of prepared vaccine and thwarts their commercial distribution and sales.

APPENDIX C:

SELECT PROVISIONS OF H.R. 5184 WHICH UNDERMINE INCENTIVES FOR SAFER VACCINES

1. Abolition of manufacturer liability for injuries or death due to unreasonably dangerous or defective vaccines (sec. 2122(c)).

2. Allowing vaccine manufacturers to raise the "unavoidably dangerous" defense in any vaccine-injury lawsuit, even though it traditionally has been allowed only when the "unreasonably dangerous or defective" basis for recovery (strict liability) was alleged (sec. 2122(b)).

3. Prohibition on punitive damages when vaccine manufacturer complies with FDA standards, even if those standards are widely known to be grossly deficient or ineffective (sec. 2123(d)).

4. An unprecedented requirement for a three-stage trial in vaccine-damage cases (sec. 2123).

5. Mandating as the goal of the National Vaccine Program "to achieve optimal prevention of human infectious diseases through immunization" without any qualifying language as to "prevention of serious adverse reactions to vaccines" (sec. 2101).

6. Requiring parents to seek compensation from the consumer-financed no-fault Fund before they may sue a vaccine manufacturer, even when manufacturer negligence is clearly involved (sec. 2110(b)).

7. Retroactive application of these limits on the tort system, even for injuries and death occurring before date of enactment if the lawsuit has not yet been filed (sec. 2110(a)(2)).

8. Delegation of authority to HHS to add other vaccines to the Vaccine Injury Table and thereby administratively broaden restrictions on tort law protections for vaccine-damaged children (sec. 2115(c)(3)).

APPENDIX D:

PROVISIONS OF H.R. 5184 WHICH SELECTIVELY AND UNFAIRLY OVERRIDE STATE TORT LAWS, PROTECTIONS AND PROCEDURES

1. See Appendix C, items 1-4 and 6-8.

2. Retention of state authority to roll-back, or even eliminate entirely, vaccine-damaged children's right to sue negligent vaccine manufacturers or doctors, as North Carolina has recently done (sec. 2122(a)).

APPENDIX E:

SELECT PROVISIONS OF H.R. 5184 WHICH DENY FAIR AND ADEQUATE COMPENSATION TO CHILDREN WHO ARE SEVERELY DAMAGED BY MANDATED VACCINES

1. Denial of home care compensation to vaccine-damaged children if "institutionalization" of the injured child were substantially cheaper (sec. 2115(b)). [Compare with S. 827 which would have assured eligible children right to home care compensation.]

2. Denial of compensation of medical expenses occurring more than 8 years before enactment, even thought the tort remedy restrictions of the bill could apply to injuries which occurred more than 8 years ago (sec. 2116(a)(2) and (b); sec. 2111(a)(2); sec. 2122).

3. Withholding of reasonably necessary medical care payments to children who are awarded and elect to take compensation in lieu of a lawsuit if the tax levels are inadequate to raise necessary funds and if the Treasury Secretary refuses to use the borrowing authority (sec. 9505(d) and (e)). [Compare with S. 827 which would have made payment to eligible children mandatory.]

4. Limits on the vaccine injury table which are more restrictive than S. 827, coupled with more restrictive alternative causation language (sec. 2114; sec. 2111(c)(1)(C)(ii)).

5. Amount of medical care-therapy-education compensation to be based on "reasonably necessary" standard, rather than "realization of maximum feasible potential," as in S. 827 (sec. 2115(a)(1)(A)).

6. Failure to provide any minimum level of compensation for pain and suffering, even for permanent brain damage, severe disability, or disfiguring injuries (sec. 2115(a)(4)).

7. Limitation of death benefit payment to $250,000 (sec. 2115(a)(2)). [Compare with S. 827, which would provide $300,000-$700,000, and with the Dodd substitute which would provide $500,000 as death payment.]

APPENDIX F:

FAILURE OF H.R. 5184 TO SAFEGUARD EXISTING VACCINE SUPPLY AND TO KEEP PRICES AND PROFITS AT REASONABLE LEVELS

1. The bill seeks to achieve these results primarily by reducing tort protections for vaccine-damaged children.

2. The bill allows these tort protections even for manufacturers who have stopped, or in the future stop, making vaccines.

3. The bill contains no authority, mechanisms, or mandate for reviewing the reasonableness of price increases in mandated vaccines or for limiting prices or profits to reasonable and necessary levels.

4. The bill does not contain any provision--

   (a) authorizing government re-insurance or co-insurance, even in emergency situations when private insurance may be genuinely available;
   (b) requiring government stockpiling of mandated vaccines; and
   (c) requiring any notice to the government by vaccine manufacturers before significantly reducing production or raising price.

APPENDIX G

PROVISIONS OF H.R. 5184 WHICH UNDERMINE PARENTS' CONFIDENCE IN THE VACCINE SYSTEM

1. Mandating a National Vaccine Program whose overriding and unqualified goal is to optimize immunizations, not balanced by the duty to push for safer vaccines, minimization of severe adverse reactions, and more careful adherence to vaccine contraindications (sec. 2101).

2. Putting the HHS vaccine establishment in charge of the new Program and appointment of the Advisory Committees in the bill.

3. Giving HHS authority to add other vaccines to the Vaccine Injury Table and thus administratively broaden the tort law restrictions in the bill.

4. Deletion of the mandate for vaccine reaction reporting and the mandatory reporting table from S. 827 and delegation to HHS of authority to require, or not to require, vaccine reaction reports by private physicians (sec. 2125).

5. See also Appendices C-F.