Testimony Concerning Funding
Of the National Childhood Vaccine Injury
Compensation Program
By Robert B. Johnson
President
Lederle Laboratories Division, American Cyanamid Company

before the

HOUSE WAYS AND MEANS COMMITTEE
Subcommittee on Select Revenue Measures
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Mr. Chairman and members of the Subcommittee:

The passage of the National Childhood Vaccine Injury Act of 1986, as recommended by the House Energy and Commerce Committee, has left this Subcommittee with an exceedingly difficult task. In our view, the 1986 Act represents a well-intentioned, but seriously flawed, effort to deal with a very complex problem. I hope today to offer a few observations from the vantage point of my company, Lederle Laboratories, a major manufacturer of two of the three vaccines covered by the new law.

The Energy and Commerce Committee indicated that the 1986 Act was designed to serve two purposes. First, it was intended to offer compensation for those unfortunate few who, through no fault of anyone, incur injuries in the course of the nation's childhood vaccination programs.

Second, it was intended to help control the cost of the nation's vaccine programs by providing predictability to vaccine manufacturers faced with an unprecedented onslaught of product liability litigation. This unpredictability has led to dramatic increases in vaccine prices and has threatened the continuity of supply. It also discourages research and development of new and improved vaccines.

We believe that the 1986 Act fails to achieve its objective of containing costs. In fact, it will probably significantly increase the cost of vaccines. The reasons for this failure are identifiable and should be corrected before any effort is made to provide funding.

Let me first explain how we conclude that the Act will increase vaccine costs, a very large proportion of which fall directly on the federal government. I will then identify three of the items most in need of revision.

The 1986 Act creates a new entitlement program which is likely to be far more expensive than anything predicted last year. It will therefore result in heavy new taxes on users of vaccines. Under the law:

1. The criteria for awarding compensation are so vague and open-ended that large numbers of unmeritorious cases may actually receive compensation.

2. Minor injuries are eligible for compensation (if medical bills exceed $1,000). Such a system is likely to attract a large number of "nuisance" claims which will be expensive to process.

3. Substantial attorneys fees can be awarded whether or not a claimant is successful. This will attract more claims and raise the cost of the program.

4. Virtually unlimited retroactivity opens the system to a vast number of old claims that, because of their age, will be difficult or impossible to refute.

5. The long-term liabilities imposed on the fund cannot be predicted because any award can be reopened at any time.

In this context, a kind of adverse selection might well occur: cases that would never result in compensation awards

under prior law would collect large sums from the federal fund, while the significant cases that expose manufacturers to large potential liabilities would remain in the tort system. There also may be additional costs for separate suits brought against physicians, who may not be protected by the new law. For these reasons, this Subcommittee cannot assume that every dollar of tax it imposes on users of vaccines would be offset by a dollar reduction in vaccine prices. Because the Act places no significant limitations on tort suits, my company's liability costs would not change appreciably.

At present we include $8.00 per dose in our price for DTP vaccine -- the vaccine for diptheria, tetanus, and pertussis -- to provide for future product liability costs. Those costs might go down if the new law provided any reasonable limitations on a claimant's recovery. But the law makes no significant changes in the rules of tort law that led me to establish the $8.00 charge.

First, although the law reduces the possibility of unjustified punitive damage awards, this change will probably have little impact on vaccine prices. The likelihood of punitive damages was so unpredictable and unquantifiable that it was not a signficant factor in the $8.00 per dose liability charge. In any event, juries inclined to award huge amounts to sympathetic plaintiffs can base their awards on other categories of damages, such as lost wages or pain and suffering.

The Act also states that a warning is presumed to be adequate if it complies with certain governmental standards. But even this obviously sensible provision is of limited help since it is made inapplicable in all cases where the plaintiff can convince a jury that the manufacturer was negligent in failing to add something else to his warning. With this limitation, the new provision does not significantly change existing law.

With regard to claims alleging that a vaccine's "design" is defective, presumably because of the claim that a "safer" vaccine was possible, the law provides no new defense at all. In fact, one federal judge in Utah has recently read the new law in a way that confirms plaintiffs' right to maintain tort suits based on design defect claims. While we disagree with this judge's interpretation of the Act, it is rapidly becoming clear that the new law will not be of any significant help to manufacturers in coping with the litigation they face. For those cases going into the tort system, we would expect no significant reduction in liability exposure if the new law were to go into effect.

We believe those cases in which claimants accept compensation from the government fund are likely to be the weaker ones. Lawyers will advise plaintiffs with good cases to go to court to escape the award limitations in the administrative system. The manufacturer will still be faced with the cases in which sympathetic juries will award large sums.

Now, let us consider how many claims will be filed in the administrative system. No one knows how many, but our experience under the tort system suggests that the number of claims will mushroom. Emotional publicity about injuries attributed to DTP vaccine, coupled with the emergence of a network of plaintiffs' lawyers advertising for clients, has led to a sharp increase in the number of suits filed against us -- from one in 1981, to 29 in 1984, to 110 in 1986. Since the Act provides for virtually unlimited retroactivity, and since the lawyers will be paid out of the government fund, we would expect a flood of claims, both old and new.

The government will need to impose a substantial tax to cover liability stemming from the large number of claims it will

face. We believe that a charge per dose much larger than the level contemplated by the Energy and Commerce Committee will be needed to handle the flood of DTP claims against the fund. On the other hand, we will have to continue most, if not all, of the $8.00 liability charge built into our price.

For this reason, whatever the tax on DTP vaccine turns out to be -- whether $4.00, $8.00, $12.00 or even more -- that amount will simply be added to the price that parents and the government must pay for this essential vaccine. The impact will fall heavily on public health programs which purchase 45% of the doses of childhood vaccines sold in this country. The impact on the Treasury might even be worse if higher prices drive more children into public vaccination programs.

A number of major revisions need to be made in the Act to correct these problems and permit meaningful reductions in liability costs, and hence, in the total cost of the compensation and tort systems. Let me stress three changes in particular:

First, the liability provisions of the 1986 Act should be amended to assure that manufacturers will not be found liable in the tort system if they have fully complied with applicable government regulations. In particular, manufacturers should not face liability under a "design defect" theory in cases where plaintiffs challenge the decisions of public health authorities and federal regulators that the licensed vaccines are the best available way to protect children from deadly diseases. The Act, although not yet implemented, has already been cited by one court as evidence that Congress intended to authorize tort suits against manufacturers to second-guess the licensing of vaccines by the Food and Drug Administration. We firmly believe that this is exactly the opposite of what Congress intended.

Second, the rules which permit claimants to reject administrative compensation and file tort suits need to be tightened. One possibility would be to make the compensation program the exclusive remedy for all true "no-fault" cases. The law could require a federal official to find that a manufacturer had violated applicable government standards or engaged in fraud or the intentional and wrongful withholding of information before a claimant could proceed from the compensation system into the tort system.

Third, provisions should be deleted which may have the effect of preempting innovative state vaccine compensation programs like those recently enacted in North Carolina. Such programs offer real promise for reducing costs far beyond anything possible under the federal law.

With regard to the compensation system, in addition to the items previously mentioned, we think the Subcommittee should carefully consider:

-- Taking the compensation system out of the federal courts and putting it into a less costly administrative forum where there would be a greater potential for obtaining consistent findings on difficult questions of causation, and where there is at least some possibility that award levels could be kept under control.

-- Benefit levels, the extent of retroactivity, and criteria establishing eligibility for the compensation system should all be carefully reviewed to minimize the risk of a "runaway" compensation system.

-- The Subcommittee should look closely at possible amendments that would require potential liabilities to be fully funded when awards are made, rather than looking to uncertain sources of revenue in future years when unknown levels of required periodic payments might actually become due.

A number of other changes should also be considered, including revision of the "insolvency" and subrogation provisions contained in the Act. The current language in these areas increases, rather than decreases, the uncertainty which is the major cause of high vaccine prices.

Finally, any tax should be at a uniform, pre-determined level for each type of vaccine. One type of vaccine should not be asked to subsidize the liability costs of another type. On the other hand, attempts to apportion compensation costs among manufacturers and establish a different tax for each company are doomed to failure. There is no sensible and rational way to allocate the costs of a compensation system other than by a flat tax on each unit sold. Allocation is particularly difficult because the system covers claims on products of manufacturers who are no longer in the business or who cannot be identified and because it covers claims on products of new entrants who have not previously contributed to the fund.

As this discussion indicates, we believe that Congress clearly could have done better last year. We have long supported legislation that would provide timely and fair compensation to the few children who are injured in the immunization program, while limiting liability sufficiently to restore predictability to the vaccine marketplace. Legislation that would have accomplished both purposes without any federal compensation fund or tax was before the Energy and Commerce Committee. Unfortunately, a different approach was selected. That Committee's proposal was endorsed at the end of the last Congress as part of an omnibus health bill without anything approaching a full debate.

I fully understand that this Subcommittee must focus its attention on the fiscal aspects of the vaccine program and that jurisdiction over health policy issues rests in other subcommittees or elsewhere in Congress. But you should not be forced to approach your task while wearing blinders.

The government has a strong fiscal interest in keeping control over spiraling liability costs in the vaccine area. This interest extends beyond the government financed compensation system. If the Subcommittee feels that it cannot deal with certain features of the law that govern tort actions against manufacturers, it should refer the matter to the appropriate subcommittees before taking action on a tax bill.

I thank you for the opportunity to share my company's views with you. We stand ready to work with the Subcommittee and Committee staff to help develop substantive proposals dealing with all of the issues I have discussed.