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STATEMENT OF
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BEFORE THE
SELECT REVENUE MEASURES SUBCOMMITTEE
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

Mr. Chairman and Members of the Subcommittee:

I am pleased to have this opportunity to discuss the Treasury Department's views regarding possible methods for financing the compensation program for vaccine-related injuries established by the National Childhood Vaccine Injury Act of 1986, P.L. 99-660 (the "Vaccine Act").

I will begin by discussing the factors that led to the adoption of the Vaccine Act. I will then discuss the compensation program established by the Vaccine Act and the tax provisions that were considered in connection with, but not ultimately included in, the Vaccine Act. Finally, I will describe the Administration's serious concerns regarding both the form of the compensation program and possible methods that have been suggested for financing the program.

Despite the Administration's concerns regarding the provisions of the Vaccine Act, I wish to make it clear that the Administration supports creation of a no-fault compensation program for persons injured by childhood vaccines. Within the next few weeks, we expect to propose a program that will provide equitable, no-fault compensation to injured persons, and predictable (and hence insurable) liabilities for vaccine manufacturers. Although I am not prepared today to discuss the details of this alternative proposal, I wish to emphasize our willingness to work with this Committee and other interested parties in designing a fair and responsible compensation program for persons injured by childhood vaccines.

Background

Perhaps the greatest public health triumph of the United States in the twentieth century has been the virtual elimination of the threat of many once feared communicable childhood diseases. In 1952, more than 20,000 cases of paralytic polio were reported in the United States. By 1986, the number of reported cases had dropped to two. In the 1930s, as many as 250,000 cases of pertussis (whooping cough) were reported annually, resulting in annual deaths of up to 7,500. During the past ten years only 1,000 to 4,000 cases of pertussis have been reported annually, with deaths ranging from five to 20. Similar dramatic declines have been experienced in the incidence of diphtheria, tetanus, measles, mumps, and rubella.

This public health triumph has been achieved principally as a result of the development of effective vaccines providing immunization from these diseases and the adoption of effective vaccination programs for children. All states today have laws requiring one or more of the following vaccinations: diphtheria, tetanus, and pertussis (usually administered as a combination vaccine referred to as DTP), measles, mumps, and rubella (usually administered as a combination vaccine referred to as MMR), and polio.1/ Approximately fifty million doses of these vaccines are administered annually in the United States.

The success of mandatory vaccination programs is due in large part to the Federal government's efforts. Since 1962, through the Centers for Disease Control (CDC), the Department of Health and Human Services has provided direction and leadership to state and local health agencies in implementing these programs. The Federal government also provides substantial financial support for vaccination programs. CDC immunization grants to states currently pay for more than one-fourth of all childhood vaccines used in the United States. Moreover, the Federal government bears a share of the costs of childhood vaccines purchased under Medicaid's Early Periodic Screening, Diagnosis, and Treatment Program.

While universal vaccination programs have been tremendously successful, they have not been without cost. Approximately half of all children receiving the DTP vaccination experience some type of minor local or systemic reaction; up to 9,000 children annually experience more serious reactions, including high fevers, shock-like episodes, persistent or unusual crying, or convulsions.2/ Approximately 50 to 75 children suffer serious long-term or permanent injuries each year as a result of adverse reactions to the DTP vaccine, including prolonged convulsions and severe brain damage that can lead to mental retardation and even death.3/ Serious injuries from other childhood vaccines are more rare. The measles portion of the MMR vaccine is associated with serious central nervous system injuries approximately once per million doses of vaccine, while the polio vaccine is estimated to cause the recipient or the recipient's close nonimmune contacts to develop paralytic polio approximately once per 3 million doses.4/ The other childhood vaccines generally produce only minor side effects.

1/A series of three DTP vaccinations typically is given during the first year of life, with a fourth dose recommended in the second year of life and a booster dose prior to school entry. Two doses of oral polio vaccines typically are given during the first year of life, with a third dose in the second year and a fourth dose prior to school entry. A single MMR vaccination is given, typically at fifteen months of age.

2/Cody, "Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children," 68 PEDIATRICS No. 5, 650, 652 (November 1981). Hinman, "Pertussis and Pertussis Vaccine, Reanalysis of Benefits, Risks and Costs," 251 JAMA No. 23, 3109, 3111 (June 15, 1984).

3/Hinman, supra note 2, at 3111.
The Department of Health and Human Services is funding trials of new forms of pertussis vaccines in an effort to bring a safer pertussis vaccine to the United States market.

4/Immunization Practices Advisory Committee. Poliomyelitis Prevention. Morbidity and Mortality Weekly Report, v. 31, January 29, 1982.

Evaluation of the number of injuries caused by childhood vaccinations is difficult, since initial doses generally are administered during the first year of life -- a time when many disabilities first become evident. Thus, in many cases, the onset or manifestation of disabilities such as mental retardation, cerebral palsy, and epilepsy may be temporally related to a vaccination, although not actually caused by it.

The injuries caused to a few individuals as a result of participation in mandatory vaccination programs that are beneficial to most raises the important social policy issue of whether the injured individuals are to be compensated for their injuries and, if so, who is to bear the cost of compensation. This is by no means a unique issue; it has become a matter of public debate in connection with injuries resulting from exposure to or use of goods and services ranging from asbestos to football helmets to medical care.

In general, compensation for vaccination-related injuries, like most other product liability and medical malpractice injuries, has been accomplished through the tort system, with those injured filing lawsuits against the persons who are alleged to be responsible for causing the injuries. Although state tort laws differ, the producer of a product generally is liable for injuries caused by the product if it is shown that the injuries were caused by the product and the producer was negligent. In most states, negligence need not be shown if it can be shown that a defect existed in the design, manufacture, or instructions for use of the product. In recent years, there has been an increasing tendency of the courts to find the producers of goods and services responsible for injuries caused by those goods and services. Moreover, there has been a growth in the number of very large awards for noneconomic compensatory damages, such as pain and suffering, and for punitive damages. These developments have resulted in large losses for the providers of many goods and services and for their insurers, and have led many to call for major reforms to the tort system or for the development of alternative means to compensate injured persons.

The experience of vaccine manufacturers illustrates the broader tort and liability insurance "crisis." In 1985, 100 lawsuits claiming damages for DTP vaccine-related injuries were filed against Lederle Laboratories. This number exceeded the number of claims filed against Lederle in the three previous years combined. Merck Sharp & Dohme reports a similar, although less sharp, rise in the number of claims filed against it for MMR vaccine-related injuries. A recent judgment against American Cyanamid Co. awarded $2 million in compensatory damages and $8 million in punitive damages for injuries resulting from polio vaccination.5/ Although this award was subsequently reversed, vaccine manufacturers and their insurers anticipate increasing numbers of claims and awards of this magnitude.

Primarily as a result of increasing and unpredictable tort litigation and a related inability to obtain adequate insurance coverage at an acceptable cost, several drug companies, including Wyeth Laboratories and Parke, Davis & Co., have recently ceased producing childhood vaccines. Their departure has left only three producers of the standard childhood vaccines for the entire United States market. DTP vaccines are produced by Lederle Laboratories and Connaught Laboratories, the MMR vaccine is produced by Merck Sharp & Dohme, and the oral polio vaccine is produced by Lederle. Producers of the DTP vaccine are exposed to the greatest tort liability risk. Because of its inability to

5/Johnson v. American Cyanamid Co., District Court No. 81 C 2470 (Sedgwick County), rev'd 718 P. 2d 1318 (Kan. 1986).

obtain insurance, Connaught ceased producing DTP vaccine for a nine month period in 1984 and 1985. Currently, Connaught and Lederle set aside approximately $8 per DTP vaccine dose as a self-insurance reserve for tort claims. This reserve represents more than 70 percent of the price of the vaccine.

Description of the Vaccine Act

The Vaccine Act establishes a compensation program that is intended to serve as the primary source of compensation for injuries caused by DTP, MMR, and polio vaccinations.6/ In addition, the Vaccine Act modifies state tort laws by imposing several limitations on the remedies that may be sought for such injuries from manufacturers of the vaccines. The Vaccine Act did not, however, include a funding mechanism for its compensation program, and neither that program nor the modifications of state tort laws will go into effect until a funding mechanism is enacted.

Claims Procedure. Under the Vaccine Act's compensation program, claims for compensation would be filed in Federal district court (with a copy served on the Secretary of Health and Human Services). Each claim would be assigned to a judicially appointed special master, who would examine and make a proposed finding on the merits of the claim and the amount of compensation. The underlying facts of the claim and the proposed findings of the special master would be subject to review by the district court.

Basis of Compensation. In general, compensation would be awarded under the program for specified injuries (or significant aggravations of such injuries) that occur within stated time periods after vaccination, and for any other injuries that a claimant proves were caused by a covered vaccine. Compensation would not be awarded if a preponderance of the evidence indicates that the injury was caused by factors unrelated to the administration of the vaccine.

Amount of Compensation. If compensation is awarded under the program, the claimant ordinarily would be entitled to receive reimbursement of medical, rehabilitative, and special education expenses (with future expenses paid as incurred), damages for lost earnings, damages for pain and suffering and emotional distress in an amount not to exceed $250,000, and death benefits in the amount of $250,000. No punitive damages could be awarded under the program. Reasonable attorneys' fees of all successful claimants and all unsuccessful claimants who filed in good faith with a reasonable basis for their claims also would be paid under the program.

6/Several bills addressing the issue of childhood vaccine-related injuries were introduced in the 99th Congress. H.R. 4777, supported by the Administration, proposed to rely on the tort system, as modified by the bill, to provide compensation for such injuries. The bill would have limited tort awards for noneconomic damages to $100,000 and eliminated punitive damage awards for such injuries. H.R. 5546, H.R. 5184, H.R. 1780, S. 1744, and S. 827, none of which was supported by the Administration, proposed Federally-administered and funded compensation programs. H.R. 5546 and S. 1744, without their financing provisions, were enacted as the Vaccine Act.

Tort System as Alternative Remedy. The Vaccine Act's compensation program is intended to provide the primary source of compensation for vaccination injuries. Thus, injured persons would be barred from filing a state tort claim against a vaccine manufacturer for more than $1,000 unless compensation is first sought under the program. The program would not, however, be the exclusive source of compensation. Tort liabilities of persons other than vaccine manufacturers, e.g., physicians, hospitals, and clinics, would not be affected by the Vaccine Act. Moreover, the Vaccine Act would permit an injured person to file a tort claim against a vaccine manufacturer if a claim under the compensation program were first pursued and the injured person elected not to accept the judgment of the district court under the program. Thus, individuals could pursue a tort suit if they believed that they would obtain a larger recovery from the tort system than from the compensation program. A lack of certainty that the compensation program will have adequate funds to pay for future medical expenses, discussed below, also could encourage claimants to pursue tort claims.

Modifications to Tort System. In those cases where injured persons elect to seek damages from vaccine manufacturers through the tort system, the Vaccine Act would modify state tort laws in several respects. The most significant modifications would make it more difficult, although perhaps only marginally so, for injured persons to recover punitive damages from manufacturers and would provide specific defenses for manufacturers against other damage claims.7/

Compensation for Retroactive Claims. The compensation program generally would apply to injuries resulting from vaccines administered after the effective date of the Vaccine Act. Compensation also would be provided, however, for certain claims relating to prior vaccinations.8/

7/The Vaccine Act would preclude any punitive damage award if a manufacturer shows that it had complied, in all material respects, with applicable provisions of Federal regulatory statutes, unless the plaintiff shows that there had been fraud or wrongful or illegal actions relating to the safety and effectiveness of the vaccine on the part of the manufacturer. The Vaccine Act also would modify state tort laws to permit warnings of dangers associated with the use of a vaccine to be given to the doctor administering the vaccine, rather than directly to the family of the child being vaccinated, and to preclude tort liability for "unavoidable" side effects in the absence of a finding that the vaccine was not properly prepared or was not accompanied by proper warnings. A showing by the manufacturer that it had complied with all material Federal regulatory requirements would give rise to a rebuttable presumption that the vaccine was accompanied by proper warnings (but would not give rise to a presumption that the vaccine was not defective in design).

8/Section 2111(b)(1)(B) of the Vaccine Act provides that "no person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of [the Vaccine Act] if compensation has been paid under [the Vaccine Act] for 3500 petitions for such injuries or deaths." Although we understand that the intent of this provision is to permit compensation for up to 3,500 claims relating to prior vaccinations, the literal terms of the provision permit consideration of all claims filed before compensation has been awarded for 3,500 claims. The number of back claims to receive compensation could therefore greatly exceed 3,500.

Funding Provisions

Trust Fund and Excise Tax. As noted earlier, the Vaccine Act did not include a funding mechanism for its compensation program. Under H.R. 5546, an earlier version of the Vaccine Act, the costs of the compensation program would have been borne by a newly-created National Vaccine Injury Compensation Trust Fund (the "Vaccine Trust Fund"). The assets of the Vaccine Trust Fund would have consisted of (a) revenues generated by a manufacturers' excise tax on each dose of vaccine, (b) amounts recovered by the Vaccine Trust Fund as a result of subrogated claims against manufacturers, and (c) appropriations from the General Fund, repayable with interest (an initial repayable appropriation of $40 million would have been provided by H.R. 5546). The excise tax rates would have been based on estimates of the proportionate share of compensation costs attributable to each particular vaccine. The proposed tax rates were $1.56 per dose for DTP vaccines, $1.52 per dose for MMR vaccines, and $0.10 per dose for live polio vaccines. For calendar years after 1987, the rates would have been indexed for inflation.

Limited Federal Liability. Under H.R. 5546, any claim filed against the Vaccine Trust Fund could have been paid only out of the assets of the Vaccine Trust Fund. If the Vaccine Trust Fund had insufficient assets available to pay claims for a period of 180 days, the compensation program and modification of state tort laws would cease to be effective until sufficient funds to pay all of the claims payable under such Vaccine Trust Fund became available.

Discussion

In General. In signing the legislation that contained the Vaccine Act, President Reagan indicated his support for the goal of compensating persons who suffer injuries as a result of childhood vaccinations. The President, however, also expressed serious reservations concerning the compensation program contained in the Vaccine Act and the financing program that was contemplated but not enacted. The Administration's concerns regarding the compensation program contained in the Vaccine Act are threefold.

First, the compensation program would not serve as the exclusive source of compensation for vaccination injuries, but merely as an alternative, preliminary forum to the tort system. Despite the modifications to the tort system discussed above, it can be expected that many injured persons with potentially large claims, particularly claims for pain and suffering, will continue to resort to the tort system. This would undermine the basic goal of the Vaccine Act to provide equitable compensation to injured persons while enabling manufacturers to produce beneficial vaccines without threat of financial ruin. Inequitable differences in compensation awards would occur depending upon whether a recovery was made through the compensation program or through the tort system. More importantly, the continued exposure of vaccine manufacturers to unpredictable and potentially massive tort liabilities would threaten the ability of manufacturers to continue vaccine production. In this regard, the public health costs of a national shortage of childhood vaccines (as occurred in November 1984 in the case of the DTP vaccine) must be recognized.

Second, the Vaccine Act's compensation program would entail unnecessarily high administrative costs. The payment of attorneys' fees of all successful, and many unsuccessful, claimants would encourage claims of questionable merit or

seriousness. In addition, for the larger claims that would ultimately be pursued through tort litigation, the compensation program would simply represent an additional layer of administrative cost.

Finally, we are concerned by the Vaccine Act's delegation to the Judicial branch of responsibility for administering the compensation program. The judiciary is not well equipped to assume oversight responsibility for the scope or functioning of the program. In addition, delegation of such administrative responsibility to members of the Judicial branch would raise possible constitutional issues regarding the separation of powers.

Source of Funding. Many of the Administration's specific concerns regarding possible methods for financing the Vaccine Act's compensation program reflect broader concerns regarding the basic form of the program as well as the assumption that the program should be financed with Federal tax revenues (either from new excise taxes or existing taxes). As indicated earlier, in several weeks the Administration will propose an alternative no-fault compensation program that should permit vaccine manufacturers to obtain workable insurance arrangements. We believe this approach is consistent with the goal of providing equitable compensation, but will result in a more efficient allocation of costs and benefits. Accordingly, we strongly urge that the issue of how to fund the Vaccine Act be considered in the context of reconsideration of the basic structure of the compensation program itself.

Public Funding Mechanisms. As discussed earlier, the problem of compensating injured persons and properly allocating the costs of such compensation is not limited to childhood vaccines, but exists for a wide range of goods and services. Thus, among our concerns with respect to any public funding mechanism for the Vaccine Act is that it could encourage the creation of similar Federal programs for persons injured by other goods and services.

In addition, a public funding mechanism would supplant market pricing and private insurance as means for providing compensation and allocating the costs of such compensation to the appropriate producers. We do not believe that this is either necessary or appropriate. Among the most serious consequences of this approach would be the loss of appropriate incentives for manufacturers to produce safer vaccines.

Excise Tax. Although the Administration has general objections to any public funding mechanism for the Vaccine Act, funding the compensation program through an excise tax, as contemplated in an earlier version of the legislation, is perhaps the least attractive alternative. First, the creation of a new excise tax would entail substantial administrative costs. The Internal Revenue Service would have to develop new forms, regulations and procedures, while also collecting the tax and auditing vaccine manufacturers. Establishment and operation of the related trust fund would also generate new costs. For example, three separate organizations within the Treasury Department -- the Office of Tax Analysis, Financial Management Service, and the Internal Revenue Service -- share responsibility for making excise tax transfers to a trust fund.

In addition, we are concerned that funding the Vaccine Act's compensation program through an excise tax would create a substantial risk that the program would either operate at a deficit or be unable to compensate many injured persons. Since excise tax rates could be adjusted (other than for inflation) only by Congress, maintenance of an adequate funding level would depend on reasonably accurate predictions of the number and

amount of claims. For a variety of reasons, however, accurate predictions of future claims are highly unlikely.

First, the Vaccine Act's compensation program would provide compensation for relatively minor injuries, since it would require a claimant to show only $1,000 of unreimbursed expenses, standards of proof would be relaxed, and the attorneys' fees of all successful, and many unsuccessful, claimants would be reimbursed. Thus, the compensation program would encourage the filing of many claims that are not filed under the present tort system because of the lack of evidence as to the cause of the injury and the costs of pursuing a tort claim. Second, it is difficult to predict the number of cases in which claimants would resort to the tort system after initially proceeding under the vaccine compensation program. Third, the Vaccine Act covers at least the first 3,500 retroactive cases to file a claim. The actual number of back cases that exist and the amount of claims that might be made are unknown. In addition, as discussed earlier, we are concerned that the costs of administering the program will be higher than expected. Without knowing the number of individuals who would actually receive compensation from the program, the amount of their compensation, or the costs of administering the program, it is impossible to set appropriate excise tax rates.

The danger that the compensation program would be inadequately funded is compounded by the fact that the program would be operated on a pay-as-incurred basis. Under a pay-as-incurred approach, no payment would be made to injured persons for long-term medical care and similar future costs until those costs are incurred. It would thus be difficult to recognize and correct funding deficiencies before they become unmanageable.

The tendency of compensation programs to expand in scope and cost and the difficulty of funding a compensation program with excise tax revenues when outlays are unknown are illustrated by the experience of the Black Lung Disability Trust Fund, the structure of which is similar to that contemplated for the Vaccine Trust Fund.9/ The Black Lung Disability Trust Fund has been operating at a deficit since its initial creation in 1977. As of the end of fiscal year 1986, the Black Lung Disability Trust Fund had paid out $4.979 billion in cash benefits and medical expenses and incurred $328 million in administrative costs. It had also accumulated $1.033 billion in interest costs on repayable advances from the General Fund. During this period, however, the excise tax on coal that was intended to fund this spending produced revenues of only $3.454 billion (other interest receipts totaled $5 million). Consequently, the Black Lung Disability Trust Fund is now $2.88 billion in debt. Under P.L. 99-272, interest accruing on this debt during fiscal years 1986 through 1990 was forgiven.

9/The Black Lung Disability Trust Fund, established under section 9501 of the Internal Revenue Code, provides benefits to individuals and their survivors disabled by pneumoconiosis, known as black lung disease. The fund is partially funded by an excise tax on the sale of coal (except lignite). The current rate of tax is $1.10 per ton for coal from underground mines and $.55 per ton for coal from surface mines, with a cap of 4.4 percent of the sales price for each ton of coal produced. Individuals and their survivors generally receive payments on a monthly basis.

Lump Sum Trust Fund. The heightened risk of funding deficiencies resulting from operating the Vaccine Act's compensation program on a pay-as-incurred basis could be avoided if all benefits were paid on a lump sum basis. Under this approach, each claimant would receive an annuity contract representing the net present value of all current and projected future costs. Similarly, payments for lost wages and medical benefits to individuals injured before the effective date of the Vaccine Act would be in the form of a lump sum benefit.

Funding a compensation program on this basis would reduce the possibility that claims would greatly exceed revenues in the long-term and ensure injured parties that future benefits would in fact be paid. Moreover, administrative costs would be lower than under a pay-as-incurred approach because the compensation program would deal with each successful claimant on a single occasion, rather than periodically. Despite these relative advantages, if a lump sum trust fund were funded through an excise tax, initial tax rates would be significantly higher than under a pay-as-incurred trust fund.

General Appropriation. An alternative method of providing revenue for the Vaccine Act's compensation program would be through appropriations from the General Fund. The Administration does not support funding a compensation program in this manner. Under the current constraint on government spending, any new program funded from general revenues would divert resources from existing activities. Moreover, appropriations generally can be reduced or eliminated as part of the annual budget process. If the proper funding amount is not fixed or guaranteed on a long-term basis, many injured persons will have little incentive to accept awards under the compensation program, and will be encouraged to pursue claims through the tort system. This would undermine the basic purpose of the compensation program.

In summary, the Administration has serious reservations about the compensation program envisioned in the Vaccine Act as well as any public funding mechanism that might be adopted to finance it. We continue to support the basic objective of the Vaccine Act, however, and will work to produce a fair and responsible program for compensation of persons injured by childhood vaccines.

This concludes my prepared remarks. I would be glad to respond to any questions.

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