

CABINET PAPER—PRIVILEGED

Property of the White House—For Authorized Persons Only

CI - 24

April 29, 1955

The White House
Washington

THE CABINET

The Salk Vaccine

For information of Cabinet Members, attached is a statement by the Secretary of Health, Education, and Welfare touching upon some of the problems involved in the production and distribution of the new Salk anti-polio vaccine.

The attached statement is circulated for reference in connection with the discussion of this subject by the Cabinet at its April 29 meeting.



Maxwell M. Rabb
Secretary to the Cabinet

CABINET PAPER—PRIVILEGED

Property of the White House—For Authorized Persons Only

REPORT OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON STATUS AND BACKGROUND OF SALK POLIOMYELITIS VACCINE

Chronology

On April 12, Dr. Thomas Francis of the University of Michigan reported that field trials of the Salk poliomyelitis vaccine conducted last year indicated that the vaccine was 60 to 90 percent effective as a preventive for polio. Simultaneously, the National Foundation for Infantile Paralysis announced that it would provide vaccine for all first and second grade children in the United States. On the same day the Department of Health, Education, and Welfare announced that under the National Biologics Control Act, six firms had been granted licenses to manufacture the vaccine. They were: Cutter Laboratories, Berkeley, California; Eli Lilly Co., Indianapolis, Indiana; Parke-Davis & Co., Detroit, Michigan; Pittman-Moore Co., Zionville, Indiana; Sharp and Dohme, Philadelphia, Pennsylvania; and Wyeth Laboratories, Inc., Marietta, Pennsylvania.

It was apparent, however, that even though some of these companies were already producing the vaccine, the supply situation would be critical for the next several months.



On April 14, the President directed the Secretary of Health, Education and Welfare to survey and report to him on the best means of assuring equitable distribution of the vaccine.

On April 22, a scientific and technical meeting was attended by 25 groups and organizations representing the health and medical professions, the pharmaceutical and drug industries, and other professional groups. Among the recommendations of that group was the establishment of a National Advisory Committee on Poliomyelitis Vaccine to serve over the next few months. The Secretary, on the same day, recommended and received approval for the appointment of such a committee. The other recommendations of the conference, detailed below, were made public at the same time.

On April 27, a meeting was held of some 50 national organizations broadly representative of the public interest. The purpose was to provide them with current information about the availability of the vaccine and to give them full opportunity to express their views on the difficult questions of supply and distribution. They were advised that their viewpoints would be made immediately available to the National Advisory Committee. At the meeting, an announcement was made of the membership and chairman of that committee--Dr. Chester Keefer, Special Assistant to the Secretary for Health and Medical Affairs and Advisor to the President.

Cutter Vaccine Suspension

The Public Health Service late on April 26 and during the early morning of April 27 received reports of six cases of polio contracted by children vaccinated with materials from the Cutter Laboratories of Berkeley, California.* Shortly before noon the Surgeon General instructed Cutter temporarily to withdraw all of its vaccine. All State Health Departments were immediately notified and the suspension was reported to Mr. Hagerty's office, to the Chairmen of the Congressional Committees concerned with HEW legislation, to the California members of the House and Senate, and to the press. Wire service and Washington reporters met with Drs. Keefer and Scheele within ten minutes after the announcement and the reasons for suspension were fully and carefully explained.

* As of noon April 27: 11 cases

CABINET PAPER—PRIVILEGED

Property of the White House—For Authorized Persons Only

- 2 -

In this as in later TV interviews and a press announcement, the Surgeon General stressed that the action was taken in the public interest, that no necessary indictment of Cutter products should be made, and that the immunization program should continue. It was pointed out that the report on the Salk vaccine indicated from 60 to 90 percent effectiveness and that some cases of polio had to be expected. Public Health Service personnel left immediately for Berkeley to check the vaccine produced in the Cutter Laboratories.

Extent of Polio Problem

Poliomyelitis is a Nationwide problem that has risen steadily from year to year.

A total of 38,741 new cases and 1,620 deaths were reported to the Public Health Service in 1954. This was the third highest year of polio incidence in U.S. history, being exceeded only in 1949 and 1952.

The peak incidence for the country as a whole occurs in the 5 to 9 year age group, but many attacks of the disease occur among both younger and older children and adults. In 1954, polio struck hardest among children 5 and 6 years of age.

Polio is typically a summer disease, usually beginning in April and lasting through October. It reaches a peak in August and September. In general, the West South Central and the Pacific States show a rising incidence well ahead of the rest of the country.

Development of the Vaccine

Poliomyelitis had been recognized in the eighteenth century. Until quite recently, however, scientists were not sure where the disease came from, how it entered the body, or how to control it.

Conquest of polio became possible in 1949, when Dr. John Enders, of Harvard University, succeeded in cultivating the polio virus in human tissue cultures. This paved the way for the production of the large quantities of virus prerequisite to production of vaccine.

This achievement, together with discoveries that there are three distinct types of polio virus and that the virus travels through the blood stream before reaching the nervous system, was basic to the development of a vaccine.

In developing the vaccine, Dr. Jonas E. Salk, with funds provided by the National Foundation for Infantile Paralysis, ably applied all the basic developments of the many scientists who contributed to the conquest of polio.



CABINET PAPER—PRIVILEGED

Property of the White House—For Authorized Persons Only

- 3 -

Supply

Present and Estimated Future Poliomyelitis Vaccine Supply

The present and estimated future poliomyelitis vaccine supply is summarized in Table I. The data were obtained from the 6 manufacturers and pooled by our Department.

Table I

| DATE | N.F.I.P. CONTRACT | CUMULATIVE COMMERCIAL SALE | TOTAL NO. OF IMMUNIZATIONS | Percent of U.S. Population | |
|----------|----------------------|----------------------------------|----------------------------------|---------------------------------|-------------------|
| | | | | MOST SUSCEPTIBLE AGES 1-9 | AGE GROUP 1-19 |
| April 20 | 6.9 | 0.5 | 3,700,000 | 11.9 | 6.7 |
| May 1 | 10.7 | 1.2 | 5,950,000 | 19.2 | 10.8 |
| June 1 | 16.1 | 7.7 | 11,900,000 | 38.3 | 21.6 |
| July 1 | 17.6 | 26.3 | 21,950,000 | 70.7 | 39.9 |
| Aug. 1 | 18.0 | 43.9 | 30,950,000 | 99.7 | 56.3 |

The first priority for production is to fill the National Foundation for Infantile Paralysis contracts. They will be completed by July 15, 1955 when nine million children in age groups 6 to-9 will have been vaccinated under the present projected program.

Beginning May 1 there will be increasing supplies of vaccine for commercial distribution.

By August 1 there should be enough vaccine to immunize all children between 1-9--the most susceptible age groups.

Allocation Problems

The problem of allocation of polio vaccine while it is in short supply centers on equitable distribution of available supplies so that each State receives its fair share of vaccine regardless of ability of the consumer to pay.

The following must be considered:

a) Allocations to States

- 1) For purchase by tax-supported agencies.
- 2) For private practitioners.

b) Allocations for export

c) Allocations for Armed Forces and Federal employees abroad

CABINET PAPER—PRIVILEGED

Property of the White House—For Authorized Persons Only

- 4 -

It has been recommended by producers, distributors, medical societies and some consumer groups that the vaccine be distributed on a voluntary basis. Distribution would be made following recommendations of the National Advisory Committee to producers, and after consultation with State committees set up by Governors.

Shipments after allocation would flow to State health departments, and to ~~private~~ physicians for their respective use. The flow of vaccine would be through normal trade channels.

Tasks of Advisory Committee

The National Advisory Committee, staff for which has been appointed and is already at work, will hold its first meeting on Monday, May 2.

One of its first--and most urgent tasks--will be the development and release of a statement of priorities with respect to age groups.

The Committee will also:

- collect information concerning the production of each company.
- match total production figures against the numbers of persons in the most susceptible age groups for each State, and advise each company of the monthly amount it should distribute to each State until vaccine is no longer in short supply.
- on the basis of reports from the States, advise each company on the amount to be allocated to tax-supported institutions and to private practitioners through the normal channels of trade.

The Governors of the States and Territories have been requested to appoint an official point of contact within the State to keep the National Committee informed as to local needs and conditions.

Economic Problems

The vaccine purchased by the National Foundation for Infantile Paralysis for the 9 million first and second graders, for those who received "dummy shots" last year, and for those who cooperated in the field tests without receiving "control" or "dummy" shots is being provided by the Foundation without cost to the parents. The costs of administering the program in each State are being carried by State health departments, or departments of education. Physicians have volunteered their services without charge.

The Foundation has not agreed to purchase the recommended "booster" injection of one cc. to be given seven months after immunization. This problem is one that will have to be resolved by the States or local communities.

After the Foundation's contract has been filled, there will be two principal groups seeking vaccine:

- 1) State Health Departments -- for the purchase of vaccine for indigent children and persons in public, tax-supported institutions and those for whom the State has agreed to pay the costs.



CABINET PAPER—PRIVILEGED

Property of the White House—For Authorized Persons Only

- 5 -

- 2) Private Practitioners of Medicine -- for the purchase of vaccine for private patients.

During the period of short supply, it is likely that the National Advisory Committee will recommend that each manufacturer allocate not less than X percent of his supply to each State, fair proportions going to State health departments and to private practitioners. These proportions would be worked out after consultation with each State committee.

Five States have already appropriated funds for purchase of the vaccine and thirteen other State legislatures are considering appropriations for this purpose.

Persons who are unable to purchase the vaccine and the services of a private physician will need help. In addition to the aid being provided by the States, it is possible that some form of financial aid will be necessary from the Federal Government. The meeting on April 27 of 50 private groups revealed widespread opinion that some financial assistance from the Federal Government is needed for low income families.

Authority for appropriations for grants to States already exists, but a special additional appropriation would be required.

Technical Committee on Dosage

In the field trials last year three doses of polio vaccine of one cc. each were given at intervals of 2-4 weeks.

Prior to April 12, 1955, it was anticipated by the National Foundation for Infantile Paralysis that this schedule would be recommended for immunization. On this basis, the National Foundation contracted for 25.0 million cc. for delivery June 30, 1955. This amount was to supplement 2.0 million cc. contracted for in connection with the field trials last year.

On April 12, Dr. Salk announced that from his recent experiments a dosage schedule of one cc. should be given twice, two or three weeks apart, with a "booster" dose seven months later. This schedule was adopted by the Foundation.

Like all new biological products, the time-dose relationship requires experimentation in order to arrive at the optimum dosage schedule. It is possible that the amount of vaccine used can be reduced to less than one cc. per dose. In order to keep abreast of the results of experiments, the Public Health Service has set up a Technical Committee on Dosage to recommend the best dosage schedules.

Action for Advisory Committee

To sum up, there are two immediate and urgent problems to be considered at the Monday, May 2, meeting of the National Advisory Committee on Poliomyelitis Vaccine. They are:

1. The establishment and announcement of priorities for age groups throughout the Nation.
2. The development of a formula for equitable distribution of the vaccine during the short supply period on a State-by-State basis to be voluntarily undertaken by the manufacturers.

