

ADMINISTRATIVE-CONFIDENTIAL

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SUPPLEMENTAL REPORT TO THE PRESIDENT
by
THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
ON DISTRIBUTION OF SALK VACCINE

July ____, 1955

INTRODUCTION

On May 16, when I reported to you on the distribution of the Salk poliomyelitis vaccine, I indicated that this supplemental report would be submitted to you on or about July 1. During the time since my earlier report, the Department has been concerned with two basic problems: (1) the safety of the vaccine, and (2) the voluntary control plan for allocating supplies of the vaccine. The primary purpose of this report is to review developments in connection with the voluntary control plan for equitable distribution of the vaccine. This is done in the perspective of safety and supply considerations.

SUMMARY OF MAJOR EVENTS WITH RESPECT TO SALK POLIOMYELITIS VACCINE SINCE MAY 16, 1955

Safety Matters

Although my previous report dealt almost wholly with the problems of equitable distribution, it also emphasized that "safety of the vaccine must be the paramount consideration; and the questions of safety in quantity production must be determined by the best scientific advice, uninfluenced by any other factors".

On June 10, the Public Health Service technical report on Salk poliomyelitis vaccine, primarily dealing with questions of safety, was made public. It included a detailed review of the events that led up to the temporary cessation of the vaccination program and a technical evaluation of the safety standards for testing vaccine. It also described the reasons for amending the Minimum Requirements for testing. These technical studies were completed with the invaluable cooperation of outstanding scientists who were--and are--serving as special consultants to the Public Health Service. The cooperation of the manufacturers themselves was a key factor in bringing these studies to a successful conclusion.

Clearance of the vaccine under the amended Requirements is made on the recommendation of a Technical Committee on Poliomyelitis Vaccine appointed by the Surgeon General on May 26.* Since that date approximately 2,588,000 cc. of vaccine have been released.

Supply Outlook

The events of the past several weeks with respect to safety testing have had the effect of curtailing the supply of poliomyelitis vaccine. It has been necessary for the manufacturers to perform additional tests on partly finished and finished lots of vaccine and to gear the revised tests to new production. The production of a batch of poliomyelitis vaccine under the amended Minimum Requirements takes no longer, or little longer, than the time needed for production under the earlier Requirements once the manufacturer has incorporated the tests in his routine processing.

The delay in the release of new vaccine in June was caused by the need for additional testing under interim clearance procedures which were applied to the vaccine already completed, or in process of production at the time the new standards were established. This additional testing was time-consuming. A given batch required from two to five or more additional weeks for its completion, depending upon the extent of the additional testing needed and the arrangements of individual manufacturers. Slightly more than one million cc. of vaccine has been released since the first of July, and, according to the best available information, by August the rate of supply of new vaccine should begin

*Members of the Committee are: Dr. James Shannon, National Institutes of Health, Chairman; Dr. William Workman, National Institutes of Health, Secretary; Dr. Jonas E. Salk, University of Pittsburgh; Dr. Thomas Francis, Jr., University of Michigan; Dr. David Bodian, Johns Hopkins University; Dr. Richard Shope, Rockefeller Institute for Medical Research; and Dr. Joseph Smadel, Walter Reed Army Medical Center.

to increase considerably.

Distribution Matters

Final details for the interstate distribution plan, to take effect upon completion of the National Foundation for Infantile Paralysis program, also have been worked out since the report of May 16. Representatives of the medical and health professions, of the pharmaceutical and drug industries, and State officials have collaborated with the Department of Health, Education, and Welfare in the development of the plan. A simple but effective interstate distribution pattern has been worked out, and all manufacturers have agreed to conform to it. Details of the plan are set forth in Chart A.

The Governor of each State, Territory, and Possession has appointed a State official (1) to serve as liaison with the National Advisory Committee on Poliomyelitis Vaccine and (2) to develop an intrastate distribution plan. State* advisory committees, generally made up of representatives of the health professions, the public, and the drug trade, have been appointed in 44 of the States to serve as advisors to the State health departments in planning their intrastate programs. As of July 1, meetings with personnel of all State agencies responsible for the program had been held by regional officials of the Department to assist in the development of the intrastate distribution plans.

At the request of a number of State health officials, special attention has been given to the development of a simple record or

*By definition "State" includes also Territories, Possessions and the District of Columbia.

reporting system on distribution and administration of vaccine to maintain current information on its flow at every stage from the manufacturer's plant to the vaccinated child.

The system calls for reporting (1) by the manufacturers to the Public Health Service of vaccine available for shipment; (2) by the manufacturers to the Service and to State health departments of actual shipments; and (3) by druggists to State health departments of retail sales. In addition, the American Medical Association has requested all physicians to keep records of the vaccine they administer.

Each of the six manufacturers, the American Pharmaceutical Association, the National Association of Retail Druggists, and the American Medical Association have pledged to cooperate in carrying out the plan developed by this Department on the recommendation of the National Advisory Committee on Poliomyelitis Vaccine. All of these groups have encouraged their members to keep the records mentioned above.

On May 17 legislation was introduced in both houses of the Congress to provide grants-in-aid to the States for the purchase of vaccine for use in public vaccination programs. The Senate Labor and Public Welfare Committee and the House Interstate and Foreign Commerce Committee have both held hearings on this legislation at which the Surgeon General and I, and other officials of the Department, have testified in support of the measure. On July 12 these Committees reported separate bills dealing with grants to the States for poliomyelitis vaccination programs.

We have sought to keep the public fully informed of developments with respect to poliomyelitis vaccine as they occurred.

On June 22 I addressed a letter to each Governor summarizing recent actions taken by the Department with respect to the distribution of the vaccine. Set forth below is a summary similar to that sent to the Governors and keyed to the eleven recommendations contained in my report to you of May 16.

DEPARTMENTAL ACTIONS SINCE MAY 16 AS TO THE
RECOMMENDATIONS IN THE REPORT OF THAT DATE

Recommendation No. 1: Resources of the Public Health Service

On May 16 there was submitted to the Senate Appropriations Committee a preliminary estimate of the funds required by the Public Health Service for testing, research, and epidemic intelligence related to the poliomyelitis vaccination program. A revised estimate was submitted to the Senate on May 26 in the amount of \$1,600,000, of which \$750,000 was for additional testing and research related to testing. The balance was for epidemiological studies to aid in evaluation of the effect of vaccination upon the occurrence of poliomyelitis; and for the establishment of a Poliomyelitis Vaccine Operations Unit in the Public Health Service to serve the National Advisory Committee on Poliomyelitis Vaccine and to be responsible for the program of interstate vaccine distribution. These funds were included in the Health, Education, and Welfare 1956 Appropriation Bill as it passed the Senate on June 6.

In addition to this estimate of \$1,600,000 a separate supplemental request for funds amounting to \$400,000 to provide for the enlargement of facilities for the housing of monkeys at the National Institutes of Health was submitted to the Congress on June 16. Hearings were held on this latter item by a subcommittee of the House Appropriations Committee on June 27, and the full Committee approved the request on July 12. Development of plans for construction of a building in Bethesda, Maryland, to

house the Division of Biologics Standards, including its expanded testing and research program, are in progress.

Recommendation No. 2: Program of the National Foundation for Infantile Paralysis

All manufacturers have agreed not to distribute vaccine for commercial sale until the current vaccine needs of the National Foundation for Infantile Paralysis program for first and second grade school children have been met.

Inasmuch as several States and cities have postponed completion of vaccination of first and second grade children until schools reopen in the fall, the Foundation program will have to be rescheduled. The Foundation is currently in process of collecting detailed information on the present status and future plans of its vaccination program on a State-by-State basis. This information, when available, will provide a basis for determining when the voluntary control system will go into effect.

As of July 2, on the basis of incomplete reports, 6,293,602 children had received their first injections under the Foundation program, 509,308 of these had second injections. In addition, 18,392 of the children who participated in the 1954 field trials had received "booster" doses. Arrangements will be made by the Department for release of vaccine for distribution in normal channels under the allocation plan as soon as it is clear that the current needs of the Foundation can be met.

Recommendation No. 3: Priorities

The National Advisory Committee for Poliomyelitis Vaccine at its first meeting on May 2 had recommended that the first age group priority be for children 5 through 9, inclusive. Subsequently, the Committee met on June 22 and recommended that, when the available supply of vaccine warrants expansion of the designated age groups, adjustments be made by

expanding the existing priority groups to include both older and younger children so that the priority group will become increasingly broader. For example, the age group might be broadened by including all children aged 4 through 10, or 3 through 11. The Committee will take action on this matter whenever the supply situation makes it feasible.

Recommendation No. 4: Departmental Responsibility

This recommendation called upon the Secretary to "direct on a national level the division among the States of the entire output of Salk vaccine, as pledged by the manufacturers". (Recommendations 5, 6, 8, 9 and 10 also bear specifically on this point and are discussed in greater detail below.)

With the close cooperation of the Executive Committee of the Association of State and Territorial Health Officers and of the manufacturers, and with guidance from the National Advisory Committee on Poliomyelitis Vaccine, a detailed plan has been worked out for the interstate distribution of poliomyelitis vaccine. The elements of the plan provide for:

- (a) allotment of available vaccine to each of the States on a formula basis (see Recommendation 5 below);
- (b) determination by each State of the proportions of its allotment destined for (i) purchase by public agencies, and (ii) normal drug distribution channels; and
- (c) shipment of vaccine by manufacturers in accordance with State plans, including a regular reporting system from the manufacturers to both the Federal and State governments.

Recommendation No. 5: Plan of Allocation Among the States

Each manufacturer has agreed to a plan under which, after the current vaccine requirements of the National Foundation for Infantile Paralysis program have been met, that manufacturer will ship into the various States a portion of every lot of his vaccine cleared by the Public Health Service. The plan provides for each State to receive an amount equivalent to the percentage of that State's population in the priority age group to the total population of the United States in that age group. The right hand column of the attached table (B) shows each State's percentage of the total U.S. population aged 5-9 inclusive not eligible for vaccine under the Foundation program. For example, California has 8.121%, Maryland has 1.581%, and Vermont has 0.247% of this population group. In accordance with the percentages in the table, out of every 100,000 cc. of vaccine cleared and ready for shipment, California would receive 8,121 cc., Maryland 1,581 cc., and Vermont 247 cc.

The manufacturers have agreed to adhere to instructions from the Public Health Service, based on State plans, as to the amounts to be shipped to each State. They will also provide State health officers with copies of invoices of shipments into their States, and furnish full reports to the Public Health Service on total output and shipments.

Recommendation No. 6: State Responsibility

Suggested plans for intrastate distribution have been considered in detail with the Executive Committee of the Association of State and Territorial Health Officers. The secretary of that Committee on June 9 forwarded suggested procedures to all State health officers.

Beginning on June 14 a series of regional meetings were held between representatives of this Department and State authorities concerned with the poliomyelitis vaccination program. In addition, regional representatives of the Department met in Washington June 20-23, inclusive, to help prepare regional personnel to assist State authorities in working out the State plans for vaccine distribution.

On June 16 a request was submitted to the Congress for \$4.5 million for grants to aid the States in administering (a) intrastate poliomyelitis vaccine distribution programs and (b) poliomyelitis vaccination programs. House hearings were held on this request on June 27, and the item was approved by the Appropriations Committee on July 12.

Recommendation No. 7: Enforcement of Food, Drug, and Cosmetic Act and State Laws

Responsibility rests with the Food and Drug Administration for enforcing laws prohibiting unauthorized sales of Salk vaccine outside normal drug distribution channels. A request for additional funds in the amount of \$300,000 for this purpose was submitted to Congress on June 16, hearings were held in the House on June 27, and the House Appropriations Committee favorably reported the request on July 12.

Recommendation No. 8: Adherence to Priority Plan by Physicians; Record Keeping

The American Medical Association has endorsed the Department's proposal that physicians vaccinate only children within the priority age group 5-9 until further notice and has asked all the physicians of the nation to adhere to this recommendation. The Association has also asked physicians to keep records of the name and age of each child vaccinated, the date of vaccination, its site, the name of the manufacturer and the lot number of the vaccine used. This recommendation to its membership was

announced by the Association on May 30 and carried on radio and television that evening and in the morning papers of May 31.

Recommendation No. 9: Record Keeping by Distributors

Each manufacturer will keep essential records and advise the Department of the availability, and of actual shipments of vaccine, and also will supply the responsible State agency with copies of invoices of all shipments into the State. The American Pharmaceutical Association and the National Association of Retail Druggists have urged druggists to keep appropriate records, including the name of the manufacturer, the lot number, and the customer receiving the vaccine handled by the druggist. On request of the Executive Committee of the Association of State and Territorial Health Officers, the Public Health Service has developed report forms for use by druggists in reporting to State officials concerning the sale of vaccine.

Recommendation No. 10: Federal Funds for Grants to States

On May 17 the Administration's proposal for Federal grants to the States for the purchase of vaccine was introduced in identical Senate and House bills: S.1984, S. 1989, H.R.6286, and H.R.6287. Departmental witnesses testified in favor of these bills before the House Interstate and Foreign Commerce Committee on May 25 and 27, and the Senate Labor and Public Welfare Committee on June 14.

On July 12, the Senate Labor and Public Welfare Committee voted to report a bill (S.2501) authorizing appropriation of an unspecified amount for allotment to the States to carry out poliomyelitis vaccination programs (including, but not limited to, the purchase of vaccine) for children and expectant mothers. Allotments would be based on a formula taking into

account the population, the financial needs, and the extent of the problem in the States. On the same day the House Interstate and Foreign Commerce Committee reported a different bill (H.R.7126) which, in addition to authorizing limited outright grants, would permit open-end Federal matching of State and local funds used to purchase vaccine, and would, also, authorize specific grants to the States for administration of the vaccine through mass inoculation programs. As of this date, neither of these bills has had floor action.

On June 15 a request for \$30 million was submitted to the Congress to be made available on enactment of the above-mentioned proposal. As of this date, no hearings have been scheduled on this request.

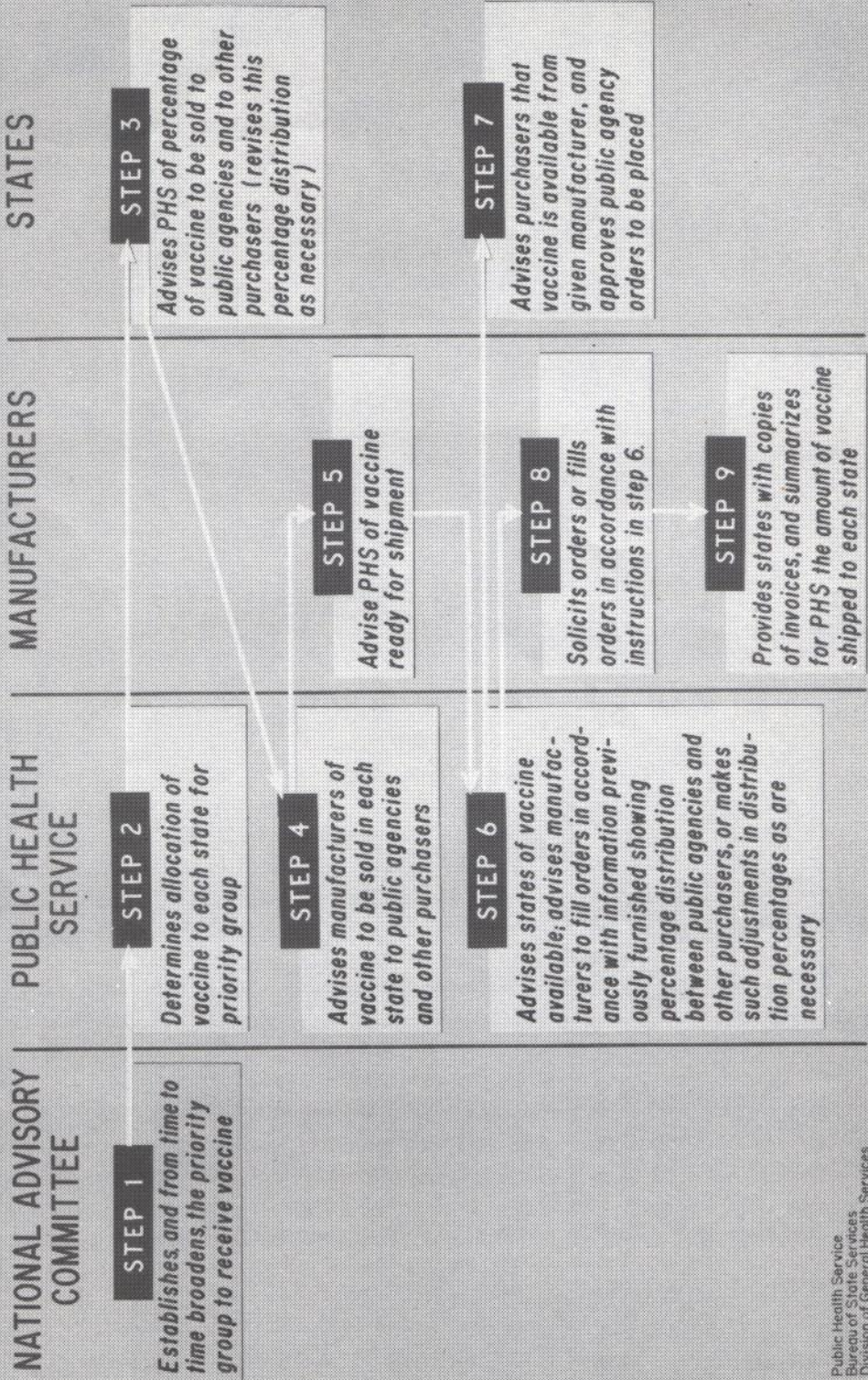
Recommendation No. 11: International Supply

This matter is under study in the Executive Branch of the Government in anticipation of the time when the vaccine supply will be adequate to make international distribution possible.

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We shall continue to review the progress of the total national program for distribution of the vaccine and to report to you as the situation requires.

PLAN FOR INTERSTATE DISTRIBUTION OF POLIOMYELITIS VACCINE



ESTIMATE OF THE AMOUNT OF POLIOMYELITIS VACCINE NEEDED TO VACCINATE CHILDREN AGES 5 THROUGH 9

State	Estimated number of children ages 5 through 9 June 30, 1955	Estimated number of children eligible to receive vaccine in NFIP program ^{1/}	Children eligible to receive vaccine otherwise	Number of cc's and percentage distribution of vaccine allocated to each State	
				Number of cc's allocated for 1st and 2nd inoculations	Percent distribution
Totals	15,903,370	9,221,997	6,681,373	13,362,746	100.000
Alabama	349,994	206,394	143,600	287,200	2.149
Arizona	106,175	65,000	41,175	82,350	0.616
Arkansas	210,230	126,014	84,216	168,432	1.261
California	1,105,940	563,337	542,603	1,085,206	8.121
Colorado	140,172	110,550	29,622	59,244	0.443
Connecticut	195,493	139,349	56,144	112,288	0.840
Delaware	34,447	26,565	7,882	15,764	0.118
Dist. of Columbia	66,933	28,308	38,625	77,250	0.578
Florida	318,955	189,928	129,027	258,054	1.931
Georgia	394,152	249,641	144,511	289,022	2.163
Idaho	68,447	43,570	24,877	49,754	0.372
Illinois	804,732	436,098	368,634	737,268	5.517
Indiana	404,141	311,638	92,503	185,006	1.385
Iowa	248,649	153,471	95,178	190,356	1.425
Kansas	187,063	121,204	65,859	131,718	0.986
Kentucky	309,945	189,286	120,659	241,318	1.806
Louisiana	324,288	179,437	144,851	289,702	2.168
Maine	87,960	49,385	38,575	77,150	0.577
Maryland	245,659	140,000	105,659	211,318	1.581
Massachusetts	419,187	237,653	181,534	363,068	2.717
Michigan	697,837	456,111	241,726	483,452	3.618
Minnesota	306,870	145,374	161,496	322,992	2.417
Mississippi	255,630	162,652	92,978	185,956	1.392
Missouri	367,767	223,147	144,620	289,240	2.165
Montana	65,352	34,612	30,740	61,480	0.460
Nebraska	124,546	72,701	51,845	103,690	0.776
Nevada	19,332	14,513	4,819	9,638	0.072
New Hampshire	47,353	28,761	18,592	37,184	0.278
New Jersey	441,987	267,722	174,265	348,530	2.608
New Mexico	93,844	63,432	30,412	60,824	0.455
New York	1,269,034	835,614	433,420	866,840	6.487
North Carolina	458,738	253,862	204,876	409,752	3.066
North Dakota	68,131	34,448	33,683	67,366	0.504
Ohio	794,485	448,461	346,024	692,048	5.179
Oklahoma	221,129	128,361	92,768	185,536	1.389
Oregon	158,414	88,799	69,615	139,230	1.042
Pennsylvania	954,282	483,282	471,000	942,000	7.050
Rhode Island	67,600	40,138	27,462	54,924	0.411
South Carolina	263,657	156,093	107,564	215,128	1.610
South Dakota	68,287	35,894	32,393	64,786	0.485
Tennessee	344,589	216,283	128,306	256,612	1.920
Texas	868,472	589,711	278,761	557,522	4.172
Utah	89,314	63,672	25,642	51,284	0.384
Vermont	37,171	20,693	16,478	32,956	0.247
Virginia	356,167	225,337	130,830	261,660	1.958
Washington	240,011	132,138	107,873	215,746	1.615
West Virginia	211,409	131,730	79,679	159,358	1.193
Wisconsin	342,160	192,221	149,939	299,878	2.244
Wyoming	31,884	19,261	12,623	25,246	0.189
Alaska	13,863	10,000	3,863	7,726	0.058
Hawaii	50,294	27,356	22,938	45,876	0.343
Puerto Rico	320,158	50,000	270,158	540,316	4.043
Virgin Islands	3,099	--	3,099	6,198	0.046
Canal Zone	4,073	2,790	1,283	2,566	0.019
Guam	4,453	--	4,453	8,906	0.067
American Samoa	3,416	--	3,416	6,832	0.051
DEPARTMENT OF DEFENSE:					
Continental U. S.	141,000	--	141,000	282,000	2.110
Abroad	75,000	--	75,000	150,000	1.123

^{1/} Includes 1st and 2nd grades and 1954 controls and those vaccinated in 1954.