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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE COMMUNICABLE DISEASE CENTER

POLIOMYELITIS SURVEILLANCE UNIT 50 7TH STREET, N.E., ATLANTA, GA.

AN ESTIMATE OF

THE EXTENT OF THE NATIONAL PROBLEM
OF POLIOMYELITIS ASSOCIATED WITH CUTTER VACCINE

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SPECIAL NOTE

This report has been prepared primarily as a working document for the Expert Committee on Poliomyelitis of the Public Health Service.

Those assisting in the preparation of this report were Dr. Alexander D. Langmuir, Dr. Neal Nathanson, and Mr. Earl Diamond. Material help was given in the statistical analyses by Dr. R. E. Serfling, Mrs. Ida L. Sherman, Mr. Jack Karush, and Dr. Jack Hall.

The regular PSU Reports from May 1 to May 14, with the weekly summaries, present the current information available on poliomyelitis cases associated with polio vaccine. The PSU Special Report No. 1 (May 14, 1955) summarizes the data on cases occurring among parents and siblings of vaccinated children. In this report an attempt is made to interpret the national picture as fully as possible and to make a forecast of the extent of the problem as it appears from the present epidemiological data.

The cumulated epidemiological information to date reveals a clear and marked association of poliomyelitis cases among persons receiving Cutter vaccine, and nothing but a purely coincidental relation with cases receiving either Wyeth or Lilly vaccine. No cases have been reported following inoculation of Pittman-Moore or Parke-Davis vaccine, although a few coincidental cases can surely be anticipated. The epidemiological data to date are wholly consistent with the pattern of a common source epidemic, with Cutter vaccine as the vehicle of infection.

This report, therefore, will be concerned solely with what is termed the "Cutter Incident." Three phases may be outlined:

The <u>first phase</u> is the occurrence of cases among Cutter vaccinated children.

The <u>second phase</u> is the occurrence of cases among familial associates of Cutter vaccinated children.

The third phase is the possible occurrence of further spread in the community from Cutter vaccinated sources.

The first phase began on April 27 with the report of 6 cases. The extent of this phase is taking clear definition. A total of 59 PSU accepted cases are on record as of May 13. The additional cases to be expected can be estimated, as will be brought out below.

The second phase began on May 7, with the report of the first case in a parent of a Cutter vaccinated child (Tenn-X1). To May 13, a total of 9 Cutter contact cases have been accepted. An attempt will also be made to forecast the extent of this problem.

The third phase has not yet become evident. The data on interfamilial cases indicate that further community spread is inevitable. The extent of spread could result in a marked unseasonable rise in incidence of poliomyelitis, particularly in areas where large numbers of children received Cutter vaccine. Spread beyond these areas can also be anticipated. Potential foci have clearly been seeded throughout the country, as revealed by the occurrence of cases in Tennessee and Georgia, where only a limited amount of Cutter vaccine was used.

The distribution of intervals from inoculation to onset of paralysis in the 59 Cutter vaccinated children are shown in Table 4 of the Third Weekly Summary Report. These intervals compare closely with the distribution of inoculation periods of inoculation poliomyelitis in cynomolgus monkeys.

The comparison becomes even closer if one considers the probability that some cases in Cutter vaccinated children are still to be reported and that these may be expected to show longer intervals from inoculation and first paralysis than those cases reported already.

The expected number of cases still to be reported in Cutter vaccinated children can be estimated by a simple statistical calculation, if Certain assumptions are made. These are:

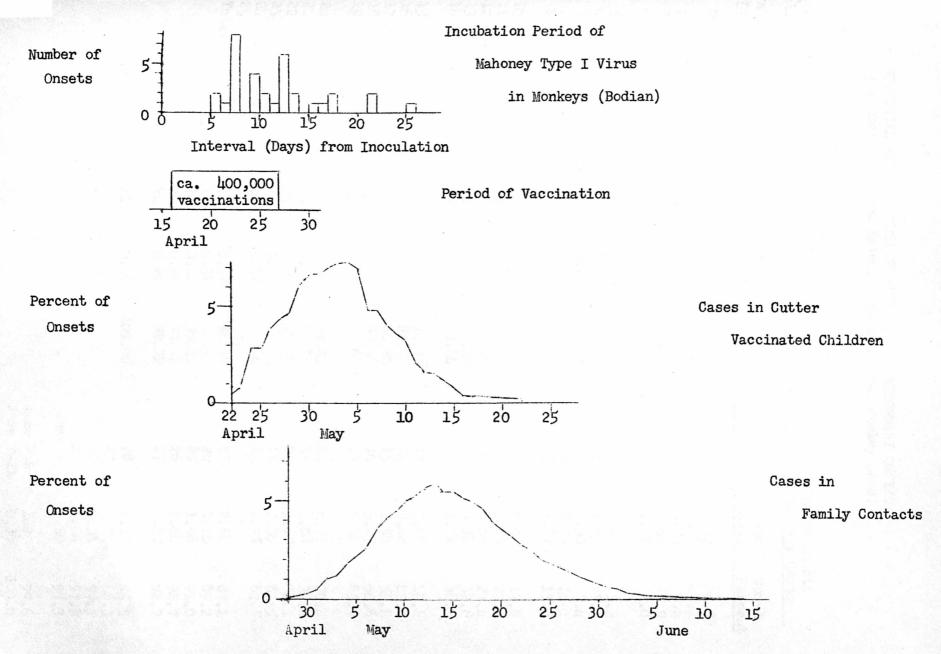
- 1. That the Cutter vaccine was used essentially evenly from April 16 to April 27.
- 2. That the incubation period reported for cynomolgus monkeys applies to humans receiving Cutter vaccine.
- 3. That the involved batches of Cutter vaccine were used evenly throughout the period.

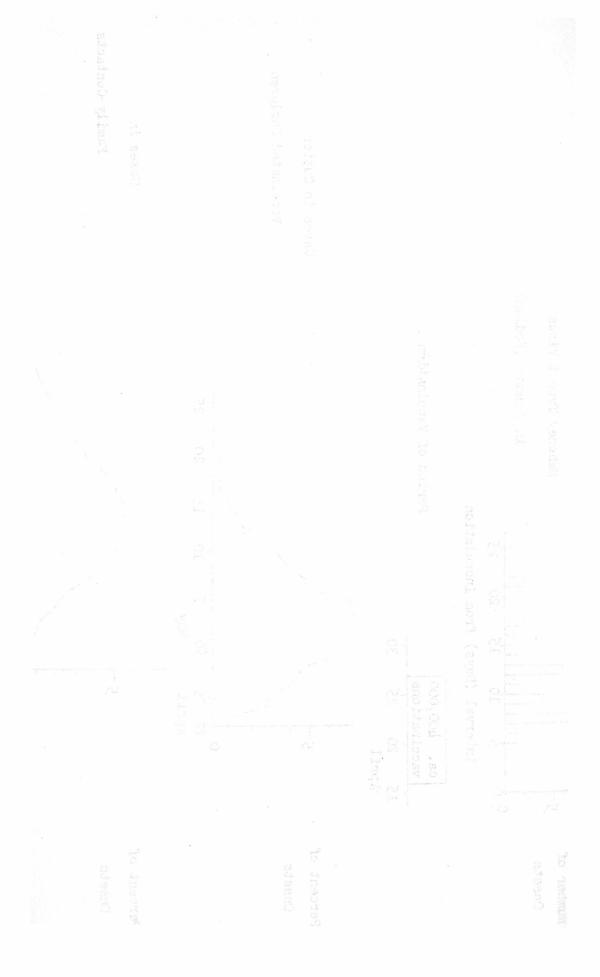
The first assumption is reasonably supported by detailed data provided to PSU by NFIP. The second assumption is supported by Table 4 in the Third Weekly Report. The third assumption cannot be supported until all the data are in, but it would appear to be reasonable.

The results of the calculation are shown in the table and figure
attached. While the total number of cases cannot be predicted, the pro-
Portion of the total that should be expected to have occurred can be
forecast. On May 13 percent should have developed first paralysis.
At this time a total of 59 Cutter associated cases were accepted. Allowing
a lag of from 4 to 6 days for diagnosis and reporting, it may be estimated
that from to percent are still to come to recognition.
inerefore, a total of to Cutter associated cases can be
Expected.

A similar prediction may be developed regarding the epidemic curve among parents and siblings of vaccinated children, by applying the monkey incubation period data to the distribution of Cutter vaccinated cases. This is shown again in the table and figure. The peak of this epidemic curve comes approximately 10 days later than that for the Cutter vaccinated cases, and logically it is more spread out, particularly at the tail.

No quantitative method has yet been conceived to predict the extent or character of the spread in the general community.





ESTIMATED DISTRIBUTION OF PRIMARY AND SECONDARY ONSETS (Incubation Period Based on Experimental Monkey Data)

Incubation Period (Mahoney Type I) in Monkeys Ref: Bodian		Estimated Onsets in Vaccinated Persons			Estimated Onsets of Secondary Cases		
Days from inoc.	No. of Onsets	Date	Percent of Onsets	Cumul. Percent	Date	Percent of Onsets	Cumul. Percent
0 1 2 3 4		Apr 22 23 24 25 26	0.52 0.78 2.86 2.86 3.91	0.52 1.30 4.17 7.03 10.94	Apr 28 29 30 May 1 2	0.03 0.06 0.33 0.46 1.12	0.03 0.1 0.4 0.9 2.0
5 6 7 8 9	2 1 8 0	27 28 29 30 May 1	4.43 4.69 6.25 6.77 6.77	15.36 20.05 26.30 33.07 39.84	3 4 5 6 7	1.24 1.83 2.30 2.73 3.67	3.3 5.1 7.4 10.1 13.8
10 11 12 13 14	4 2 1 6 2	2 3 4 5 6	7.03 7.29 7.29 7.03 4.95	46.88 54.17 61.46 68.49 73.44	8 9 10 11 12	4.06 4.53 5.05 5.34 5.72	17.8 22.4 27.4 32.8 38.5
15 16 17 18 19	0 1 1 2	7 8 9 10	4.95 4.17 3.65 3.38 2.08	78.39 82.56 86.20 89.58 91.67	13 14 15 16 17	5.88 5.48 5.54 5.25 5.04	44.4 49.8 55.4 60.6 65.7
20 21 22 23 24 25	1	12 13 14 15 16	1.56 1.56 1.30 1.04 0.52	93.23 94.79 96.09 97.14 97.66	18 19 20 21 22	4.77 4.00 3.67 3.39 2.95	70.4 74.4 78.1 81.5 84.5
Total	32	17 18 19 20 21	0.52 0.52 0.52 0.26 0.26	98.18 98.70 99.22 99.48 99.74	23 24 25 26 27	2.64 2.10 1.86 1.64 1.47	87.1 89.2 91.0 92.7 94.2
		22	0.26	100.00	28 29 30 31 June 1	1.19 0.96 0.81 0.64 0.58	95.3 96.3 97.1 97.8 98.3
					June 2-6 June 7-1	1.29 1 0.36	99.6 100.0