FOR OFFICIAL USE ONLY NOT FOR FUBLICATION

THE WYETH PROBLEM

An Epidemiological Analysis of The Occurrence of Poliomyelitis In Association with Certain Lots of Wyeth Vaccine

Prepared by

The Poliomyelitis Surveillance Unit
Epidemiology Branch
Communicable Disease Center
Department of Health, Education and Welfare

This report was written by Dr. Alexander D. Langmuir, Dr. Neal Nathanson and Dr. Wm. Jackson Hall. Grateful acknowledgment is made to the following Poliomyelitis Reporting Officers: Dr. F. I. Hudson, Delaware, Dr. William Schrack, and Dr. James Purvis, Pennsulvania, Dr. Edward Davens, Maryland, Dr. Williams Woolridge, District of Columbia and Dr. Malcolm Robbins, Ohio.

Dr. Philip Brachman and Dr. Peter Isacson, Epidemic Intelligence Service Officers, participated in the field investigation of some of the cases included in this report.

Laboratory diagnostic services were performed on specimens from some of the cases and their contacts by Dr. Werner Henle and Dr. Klaus Hummeler, Virus Diagnostic Research Laboratory, Children's Hospital of Philadelphia, and by Dr. Karl Habel and Dr. Alexis Shelokov, Laboratory of Infectious Diseases, Mational Microbiological Institute, NIH, Bethesda, Maryland.

The Poliomyelitis Surveillance Program was established at the direction of the Surgeon General on April 28, 1955 immediately following the recognition of the Cutter Incident. The purpose of the Surveillance Program was to keep in close current touch with the occurrence of poliomyelitis throughout the country in order to detect any further association of cases with certain lots of vaccine, to provide a broad evaluation of the national vaccine program, and to distribute regular reports to State and Federal officials and others having technical or administrative responsibilities in the control of poliomyelitis.

During the middle of May a small number of cases was reported to the Poliomyelitis Surveillance Unit (PSU) which raised the question of a possible association with vaccine manufactured by Wyeth Laboratories. The data were included currently in the regular PSU reports. Considerable discussion regarding the significance of the reports has taken place. Some special field and laboratory studies have been undertaken, but up to the present, the data have not been consolidated into a single document.

Because of the importance of this "Wysth Problem," to the broad issue of the safety of poliomyelitis vaccines, the present report has been prepared. It summarizes in detail the information that has been reported to the PSU in Atlanta. Even now (August 31, 1955) the data are incomplete, but it is possible to give a general description of the epidemiological findings. A full evaluation of the Wyeth Problem would require a detailed investigation of each reported case in the area where Wyeth Vaccine was distributed and also must include consideration of the laboratory studies and results of safety tests and special studies which have not been reported to the PSW.

Narrative Account of Development of the Wyeth Problem

Between May 9th and 17th, 1955, the Pennsylvania State Health
Department reported to the PSU in Atlanta, four cases of poliomyelitis
which had previously received vaccine manufactured by Wyeth Laboratories.
In three of these four cases the paralysis had started in the left arm
which was the site of inoculation. The cases were widely scattered from
Philadelphia to Eric Counties. The three separate lots of vaccine which
were involved were designated by numbers 235, 236 and 237. The possibility
that these cases might have been associated in some way with the administration of the vaccine could not be ignored.

The problem was discussed fully with officials of the Pennsylvania Health Department. It was learned that a number of additional cases of suspected poliomyelitis were then under investigation. These had been reported principally from Harrisburg and surrounding counties in central Pennsylvania, an area where lot 236 had been principally used in NFTP supported clinics. Some of these cases were known to be "vaccine associated." Accordingly, two Epidemic Intelligence Service Officers were assigned to the State to assist in intensive field investigations and specimen collections.

As additional information became available, the situation remained confused. A number of vaccine associated cases were verified, but the intervals between inoculation and onset of symptoms and the location of sites of inoculation and site of first paralysis did not clearly indicate a significant association with the vaccine. A number of the cases were associated with vaccinated children only through community contacts. These were considered to be of limited significance because thorough investigation would probably have elicited some sort of community contact with a first or second grade child for a large proportion of persons in the area. Some

cases were also confirmed in which no association with vaccine was found. Thus, the possibility could not be excluded that poliomyelitis might have been spreading naturally in the area at a somewhat higher prevalence than was usual at this season and that the apparent association of cases with Wyeth Vaccine was coincidental. It was believed that additional time was necessary for further field and laboratory observations before a conclusion could be reached.

The adjoining states, Delaware, Maryland, the District of Columbia, and Ohio, where Wyeth Vaccine had also been widely distributed, were alerted to the situation. Between May 23rd and 27th, five new cases among family contacts were reported from Maryland. These cases had been carefully investigated. Four were definitely paralytic. All had family association with a child who had been inoculated with Wyeth Vaccine lot number 236. The intervals between date of inoculation in the child and onset of symptoms in the contact ranged from 19 to 26 days. The cases were distributed rather widely over the State. Essentially no other cases of poliomyelitis had been reported in the state except in association with poliomyelitis vaccine. These facts, which tended to point much more directly toward the existence of some definite type of association of the cases with Wyeth Vaccine lot 236, were brought to the attention of the Technical Committee on Poliomyelitis Vaccine of the Public Health Service. This incident is mentioned in the Technical Report on Salk Vaccine. The following footnote appears on page 27 of that report:

"Although the numbers are small and the data inconclusive, the Wyeth Company, acting in part on the advice of the Technical Committee on Poliomyelitis Vaccine, elected to withdraw the unused portion of the lot of vaccine."

Since that time, case investigations by some of the states have been continued and laboratory studies performed. Revisions in the data and additional cases have been reported to the Poliomyelitis Surveillance Unit in Atlanta and published currently in the PSU Reports. Up to August 31st, a total of 82 vaccine-associated cases with onsets on or before June 25th has been reported to PSU from the four states and the District of Columbia. The present report summarizes this information.

Sources of Data and Definitions

The information used in this report was obtained from the following sources:

- 1. Reported Incidence of Poliomyelitis was derived from the morbidity reports published by the National Office of Vital Statistics. Since the data for 1955 are based on the uncorrected weekly reports made currently by the states, the comparable uncorrected reports for previous years were also used. Data for counties or subdivisions of states were derived from the weekly reports by counties issued separately by the respective states. It is common for totals of county reports to differ from the state totals reported to NOVS.
- 2. <u>Individual Case Data</u> were reported to the PSU by the Polio-myelitis Reporting Officers in the respective states. The information was not always complete at the time of the first report and supplementary reports often led to corrections as well as additions. The records are not yet fully complete. Information was reported routinely to PSU only on vaccine-associated cases, although some reports of other cases were also submitted.
- 3. <u>Utilization of Vaccine</u> was obtained from the National Foundation for Infantile Paralysis, from the State Poliomyelitis

Reporting Officers and from the Poliomyelitis Vaccine Activity
Section, Bureau of State Services in Washington. The states
were of course the main source of the information even though
it flowed to PSU by various channels. The figures in this report are believed to represent the best that are available short
of individual visits to counties and local health jurisdictions.
4. Laboratory results were reported to PSU by the two laboratories that expressed willingness to accept surveillance specimens in this area:

- a) Virus Diagnostic Research Laboratory, Children's Hospital of Philadelphia.
- b) Laboratory of Infectious Diseases, NMI, NIH.

 The following definitions used in the PSU Reports are also used in this report:
 - 1. Accepted Cases are cases of poliomyelitis reported by the states to PSU in which the data are sufficiently substantial and complete to warrant a conclusion that a valid diagnosis has been made and that further changes are unlikely. The decision to accept a case is a matter of personal judgment and is often made only after phone conversation or correspondence with the Polio Reporting Officer in the state.
 - 2. <u>Vaccine Associated Cases</u> are those in which there is a history of association with poliomyelitis vaccine administration. Three distinct types of association are recognized:
 - a. <u>Vaccinated cases</u> (VC): Those giving a definite history of receiving poliomyelitis vaccine prior to onset;
 - b. Family Contact Cases (FC): Those occurring among parents or siblings of vaccinated children;

c. Community Contact Cases (CC): Those occurring among friends, neighbors, school associates or other persons having history of definite exposure to a vaccinated child.

It should be recognized that the vaccinated cases and the family contact cases are clearly defined entities that can be readily identified and classified by simple interview. The community contact cases are not so clearly defined. Often the degree or frequency of exposure is difficult to measure. The intensity of the field epidemiological investigation will materially influence the findings.

Findings

The findings are limited to a Study Area consisting of Pennsylvania, Delaware, Maryland, the District of Columbia, and Ohio. In this area Wyeth Vaccine was distributed for NFTP supported clinics. A substantial amount of Lilly Vaccine was also distributed in Ohio. Small amounts of Cutter Vaccine were also distributed through commercial channels. The findings are also limited to a Study Period extending for 12 weeks from April 3 to June 25th. This period extends from a date beginning several weeks before inoculations were given to a date well after vaccine related cases could be expected to occur. The NFTP clinics in this area were held from April 24th to May 7th, at which time use of the vaccine was temporarily suspended throughout the country. Both field and laboratory data regarding cases occurring during this Study Period are still being reported to PSU. In this report the data are limited to information received through August 31st on vaccine associated cases inoculated prior to May 7th.

Reported Incidence: The numbers of cases of poliomyelitis reported from the Study Area for the 12-week Study Period and for comparable

periods in the previous five years are shown in Table 1. These three months include the period of seasonal low incidence for poliomyelitis in this Middle Atlantic area. During this particular year, 1955, the reported incidence was greater than in any of the previous five years in each of the four states. Only in the District of Columbia was the incidence similar to that of previous years.

The 12-week attack rates for reported cases for 1955 are shown in Table 2. The rate for Delaware, 4.9 for 100,000, is five times higher than that for any other state in the group. The rates for Maryland and Ohio were similar, being 1.0 and 0.9 respectively. The rate for Pennsylvania was relatively low but, as will be brought out later, the incidence varied in different parts of the state.

The reported cases for 1955 are shown by week of report in Table 3. The weekly totals for the whole area show a low incidence, from 3 to 6 cases during April, a progressively increasing incidence from 8 to 23 cases through May and a variable number from 17 to 35 cases during June. Among individual states there are certain points that may deserve attention. In Pennsylvania, a small concentration of 20 cases was reported during the middle two weeks of May. The weekly incidence continued at about this level through June. In Delaware, the state with by far the highest rate, the incidence rose from three cases in April to nine cases in May and then it fell to six cases in June. In Maryland, all but two of the 25 cases were reported after the middle of May. Similarly, in the District of Columbia, the four cases there were reported in the last half of the 12-week period. In Ohio, cases were reported throughout the period but more than half were reported in June.

While these figures of reported incidence are the only readily available data to indicate the distribution of poliomyelitis cases over a broad area, they must be interpreted with extreme caution. Many factors of error enter into such data and unless carefully evaluated they may lead to incorrect conclusions. For example, reporting practices vary from state to state. While it is usual to accept a practicing physician's report, states vary in the intensity and quality of their follow-up investigations. It is not uncommon during such periods of low incidence to find that the diagnosis of poliomyelitis can be verifified on only 50 percent or less of the cases reported. Also, it is quite common for occasional missed cases of poliomyelitis from the previous year to be discovered in orthopedic clinics and then be reported for the first time in the spring of the year. When studying weekly reported cases it must be remembered that a lag of one week and often more may exist between onset of the case and date of report to NOVS. Thus the total reported incidence of poliomyelitis cases is only a starting point. Careful follow-up investigations of the cases are necessary before accurate interpretations can be made. Care must be taken in comparing the PSU accepted cases with the uncorrected reported figures.

<u>Vaccine Associated Cases</u>: A total of 82 vaccine associated cases with onset of disease within the Study Period was reported to PSU from the Study Area. They are summarized in Table 4 and Appendices A and B. Of these, 57 were "Accepted by PSU" as poliomyelitis; 40 were paralytic and 17 were nonparalytic cases. A preponderance of paralytic cases over nonparalytic cases is present in all states but Ohio, where the ratio is slightly less than 1 to 1.

There were 25 cases reported to PSU that were not accepted. Of

these the diagnosis was subsequently revoked in seven cases and in 18 the data remain as yet incomplete. Most of these reported were from Pennsylvania. All but one were either nonparalytic or paralytic status was unknown. For some, crucial data were missing. Mention is made of this group of 25 "non-accepted cases" because at one time they were counted as cases of poliomyelitis by the states. Almost certainly they were reported to NOVS and are included in the data shown in Tables 1, 2, and 3. They will not be included, however, in the subsequent tables.

A distribution of 57 PSU accepted vaccine associated cases is presented in Table 5 according to state, vaccine manufacturer and type of association. Wyeth Vaccine was associated with 43 cases which occurred in all five areas; Lilly Vaccine was associated with six cases, all in Ohio; and Cutter Vaccine was associated with eight cases, six in Maryland and two in Ohio.

The six Cutter associated cases in Maryland constitute an unusual concentration of cases that was studied in detail by Dr. Shelokov of the MTH. All resided in a small two block suburban area in Towson in Baltimore County. On April 16th, one child received Cutter Vaccine from a private physician. The child had no noticeable symptoms following inoculation. On May 8, the child's mother developed severe paralytic poliomyelitis. Between May 19th and June 3rd, five additional cases of poliomyelitis, four of them paralytic, occurred among community contacts within this two block area. Stool specimens yielded Type I poliomyelitis virus from the inoculated child, from five of the six cases, and from many household and community contacts in the small area. While this little outbreak of Cutter associated cases may not directly be related to the analysis of the Wyeth problem, mention of it is made in this report

to aid in the interpretation of the general morbidity figures for Maryland. It is believed that these six cases should be classified as a separate group and not considered part of the normal incidence of policmyelitis in the State.

The two Cutter Vaccine associated cases reported from Ohio followed administration of commercially distributed vaccine of the same lot. These cases were similar to the other Cutter Vaccine associated cases in the country.

The 43 Wyeth and the six Lilly Vaccine associated cases will be considered further after presenting the data on the distribution of vaccine throughout the Study Area.

Distribution of Vaccine: Five lots of Wyeth Vaccine and two lots of Lilly Vaccine were distributed for NFIP supported clinics in the Study Area. Particular lots were used exclusively in certain areas, but in other areas two or more lots were used in large amounts, and in many counties of Pennsylvania small amounts of several Wyeth lots were used for make-up clinics and for supplementing short supplies. Map 1 shows the areas where one lot was predominantly used and areas where two or more lots were used in large amounts.

Wyeth lot 234 was used almost entirely in the southwestern counties of Pennsylvania centered around Pittsburgh; about 400 first inoculations were also made with this lot in Maryland. Wyeth lot 235 was used in Philadelphia, northeastern and northwestern Pennsylvania, and in northwestern Ohio; it was also used together with lot 236 in counties surrounding Philadelphia—Bucks, Montgomery, Delaware and Chester. Wyeth lot 236 was used in Delaware, Maryland, the District of Columbia and a large region in south central Pennsylvania surrounding Harrisburg;

it was also used together with lot 235 in the counties surrounding Philadelphia as already mentioned. Wyeth lot 237 was used primarily in a large irregular area in Pennsylvania including northern, central and some eastern and southern counties, and in northeastern and southwestern Ohio. Wyeth lot 238 was used in unknown but small amounts in widely scattered areas of Pennsylvania.

Two lots of Lilly Vaccine were used in Ohio, approximately 17,500 cc's of lot number 8124-649336 and approximately 120,500 cc's of lot number 8125-649337. These lots were used throughout most of the state except for the northwestern counties.

Table 6 shows the approximate numbers of first inoculations in NFTP supported clinics by states, lot numbers and manufacturers. The number of inoculations of Cutter Vaccine (all commercial supply) in this area is not known. The approximate number of eligibles, 1st and 2nd grade children in each state is also given with the percent inoculated. These percentages range from 78 in Maryland to 93 in the District of Columbia, with a figure of 82% for the Study Area as a whole.

Distribution of Vaccine Associated Cases: The distribution of the vaccine associated cases by State, type of association and manufacturer was shown previously in Table 5. The vaccinated and family contact cases were equally frequent, 22 cases falling in each category. Only 13 community contact cases were accepted, and if the cluster of Cutter associated cases be deleted as a separate isolated problem, then the community contact cases would become even less numerous, only 8 remaining.

The distribution of the Wyeth vaccine associated cases by lot number is shown in Table 7. No cases were associated with lot 234; eight cases with lot 235; 26 cases with lot 236; three cases with lot 237; and

none with lot 238. In six cases data on the exact lot used were incomplete, bringing the total of Wyeth Vaccine associated cases to 43.

The occurrence of Wyeth and Lilly Vaccine associated cases according to the areas where the specific lots were used (Map 1) and in relation to the total reported cases of poliomyelitis in these areas is shown in Table 8. Attack rates for total reported cases during the 12-week Study Period reveal relatively high incidence rates of 1.4 per 100,000 or higher in Delaware, in the counties of southeastern Pennsylvania surrounding Philadelphia and Harrisburg and in northwestern Ohio. The rates for Maryland and the "mixed" areas in Ohio were 1.0 and 0.9 respectively and the rates for the other areas of Pennsylvania and Ohio and for the District of Columbia were low.

The vaccine associated cases in general tended to occur with greater frequency in the areas where the attack rates for total reported cases were high, with one notable exception. The largest concentration of vaccine associated cases, a total of 15, occurred in Maryland where the attack rate for total reported cases was only moderate.

In fact, the total of the reported cases in Maryland for the 12-week period was only 25. Taking the 15 Wyeth associated cases, together with the cluster of six Cutter associated cases mentioned previously, gives a total of 21 vaccine associated cases and leaves only four other cases for the full 12-week period not known to be related to the vaccine. These findings will be discussed more fully below.

A consolidation of the figures in Table 8 according to specific lot numbers is shown in Table 9. The composite attack rates for total reported cases still reveal marked differences although the high rates for Delaware and southwestern Pennsylvania are lowered by including Maryland and the District of Columbia in lot 236 composite area.

The ratio of vaccine associated cases per 100,000 inoculations has been employed as an index for comparing the relative frequency of associated cases with individual lots of vaccine. This is a ratio and not an attack rate because the total persons exposed to family contact and community contact with vaccinated children is not known. The highest ratio, 11.3 per 100,000 inoculations, was observed for Wyeth lot 236. A ratio of 4.0 was found for lot 235, 1.3 for lot 237, and 0 for lot 234. The ratio for the Lilly Vaccine was 4.3. Thus considerable differences were observed both in attack rates for total reported cases and in the ratios of vaccine associated cases per 100,000 inoculated persons, in relation to the specific lots of vaccine employed and the areas where they were used.

The distribution of the cases associated with Wyeth Vaccine lot 236 are shown by counties in Map 2. The cases were widely scattered throughout the area roughly in proportion to the concentrations of population.

The intervals between date of inoculation and the date of onset of symptoms in the vaccinated cases and in the family and community contact cases are shown in Table 10 according to specific lots of vaccine. The cases associated with lot 236 were scattered throughout the 56-day period with seven of the nine vaccinated cases occurring within 21 days, and with nine of the 12 family contact cases occurring within the interval from 15 to 42 days. The cases associated with the other lots were also scattered but showed some tendency to concentrate in the range of eight to 35 days.

The correlation of site of inoculation with the site of first paralysis in the 21 vaccinated cases associated with Wyeth and Lilly Vaccines is shown in Table 11. First paralysis at the site of inoculation was observed in three cases, one following lot 235 and two following lot

236. In three other cases, bulbar involvement was first recognized, and in the remaining cases first paralysis developed either distant from the site of inoculation or data are incomplete.

Paralysis was observed in eight of the nine vaccinated cases associated with lot 236, but in only two of the five cases associated with lot 235, in neither of the two cases associated with lot 237 and in one of the three Lilly vaccinated cases. Moreover, a similarly high proportion of paralytic cases was observed among the family and community contact cases (Appendix A).

Discussion

The basic question for which this epidemiological analysis has been prepared is whether Wyeth Vaccine lot 236 was related in a causative manner with cases of poliomyelitis or whether the occurrence of the vaccine associated cases was coincidental. Two general approaches were followed. The first was a study of the frequency of occurrence of vaccine associated cases in relation to the incidence of total reported cases in states and subdivisions of states where specific lots of vaccine were used. The second approach was a study of the intervals between inoculation and onset of symptoms in the vaccine associated cases and a study of the correlation between site of inoculation and the site of first paralysis in the vaccinated cases according to lot number of vaccine.

The study of total reported incidence of poliomyelitis was undertaken on the premise that if poliomyelitis infection were low or absent from an area where an infective lot of vaccine was employed, then most of the cases occurring subsequently should be vaccine associated. The occurrence of Cutter vaccine associated cases in Idaho in April and May, 1955 is an example of such a situation. If, on the other hand, poliomyelitis

infection were naturally spreading in an area where vaccine was extensively employed, then a certain number of vaccine associated cases would occur even if the vaccine were free of infectiveness. The frequency of occurrence of such coincidental cases should be directly proportional to the amount of vaccine used and the incidence of naturally occurring disease in the area. If given accurate data, it should be possible to estimate the number of coincidental vaccinated cases and family contact cases that would be expected to occur. Any estimate of coincidental community contact cases would be much more difficult.

Unfortunately the available information regarding the general occurrence of poliomyelitis within the Study Area is quite variable from state to state. The weekly figures for total reported cases are uncorrected for the inclusion of delayed cases and of cases in which the diagnosis was subsequently revoked or in which the data are quite incomplete. Therefore valid estimates cannot be made of the number of coincidental vaccine associated cases that might have been expected. Instead only broad comparisons will be made area by area.

In Delaware, a total of 18 cases were reported to NOVS during the 12-week Study Period, giving the highest attack rate in the Study Area. Two cases, both associated with Wyeth Vaccine lot 236 were accepted by PSU. Both of these occurred in vaccinated children; no cases among family or community contacts were reported. The lack of such contact cases is somewhat unexpected because as outlined above, in an area of highest incidence one might expect the greatest frequency of coincidental cases. A more thorough investigation of the 18 cases reported from Delaware both for history of some association with vaccine and for validity of diagnosis might reveal important information. The present

data as they now stand do not warrant a conclusion that infective vaccine had been distributed.

In Pennsylvania, the incidence of reported cases during the Study Period varied from moderately high rates, 1.4 to 1.6, in the southeastern counties surrounding Philadelphia and Harrisburg, to low rates of 0.3 to 0.5 in the rest of the State. In the counties surrounding Harrisburg a total of 18 cases were reported to NOVS, and eight vaccine associated cases were accepted by PSU. In five of these eight cases, Wyeth Vaccine lot 236 was associated and in the remaining three, the association was with either lot 236 or 238. Five of these eight vaccine associated cases were among community contacts. In addition, 6 other vaccine associated cases from this area were reported to PSU but were not accepted or were revoked. These are listed in Appendix B.

While 14 of 18 total reported cases from this area of Pennsylvania were reported to PSU as vaccine associated, the evidence for a possible causal relationship between the vaccine and the disease remains confused. Most of the vaccine associated cases were community contacts, in several cases the exact lot number of vaccine was not ascertained and the clinical information necessary for a firm diagnosis is missing in several more. Thus no conclusion can be reached one way of the other.

In the four populous counties surrounding Philadelphia, where lots 235 and 236 were used in approximately equal amounts, three cases associated with lot 236 and one case with lot number data incomplete were accepted. It is interesting that in this area which had approximately the same population and the same incidence of poliomyelitis as the counties surrounding Harrisburg, no community contact cases were identified. The number of vaccine associated cases in this area is too small to warrant any conclusion.

In the remainder of Pennsylvania, comprising a population of more than 8,000,000, where Wyeth Vaccine lots 234, 235 and 237 were used, the attack rates were low. Only three vaccine associated cases were identified, two with lot number 235 and one with data incomplete. Obviously such few cases could have occurred by coincidence.

In Maryland, on the other hand, a situation existed that strongly suggested a causative relation of poliomyelitis cases with the Wyeth Vaccine lot 236. Here the circumstances are somewhat analogous to those in Idaho. As mentioned above, 21 of the 25 total cases reported during the 12-week Study Period were PSU accepted vaccine associated cases. Of these, six were in the isolated cluster of Cutter associated cases in Towson and 15 were associated with Wyeth Vaccine lot 236. It is difficult to account for these findings by any other hypothesis than that infective amounts of live virus were present in the vaccine.

In the District of Columbia, one vaccine associated case in a family contact was accepted and one other vaccine associated case was reported to PSU but not accepted. Only four total cases were reported to NOVS during the Study Period. Such small numbers do not permit conclusions.

In Ohio, the attack rates for total reported cases varied in different subdivisions of the State in a manner quite similar to that in Pennsylvania. Vaccine associated cases were identified with both of the Wyeth Vaccine lots 235 and 237 and the Lilly Vaccine used in the State. The frequency of vaccine associated cases occurred roughly in relation to the attack rates for total reported cases. There is little evidence to suggest that these vaccine associated cases were other than coincidental.

The consolidation of the incidence data for the whole Study Area by lot number of vaccine used (Table 9) reveals a ratio of vaccine associated cases per 100,000 inoculations of 11.3 for Wyeth lot 236. This ratio is more than two and one-half times higher than the ratio for Wyeth lot 235, 4.0, and for Lilly Vaccine, 4.3. While no simple test for statistical significance can be applied to these ratios, the numbers of cases and total inoculations are sufficiently substantial to suggest the conclusion that lot 236 was related in a causative way with at least some of the vaccine associated cases.

The study of the intervals between dates of inoculation and onset, and the comparison of the site of inoculation and the site of first paralysis failed to contribute definitive evidence for or against this conclusion. Most of the intervals between onset and inoculation fell within the single or double incubation periods that would be expected if infective amounts of virus were present in the vaccine. The picture is clouded, however, by the occurrence of a few very early and very late cases. Presumably a number of these cases were coincidental.

Only two of the eight paralytic cases among children vaccinated with lot 236 were first paralyzed at the site of inoculation. The lack of a sharper correlation stands in striking contrast to the findings in the Cutter incident where a correlation was found in 76 percent of the paralytic cases for which complete information was available.

Conclusion

The epidemiological analysis of total reported cases of poliomyelitis and of vaccine associated cases in Pennsylvania, Delaware, Maryland, the District of Columbia, and Ohio leads to the conclusion that many of the vaccine associated cases occurred coincidentally, but some of the cases can only be accounted for on the basis that infective amounts of live virus were present in the vaccine.

Coincidence is a reasonably adequate explanation for the cases associated with Wyeth lots 235, 237, and 238 and with the Lilly Vaccine used in Ohio. Some of the cases associated with Wyeth lot 236 in Delaware and southeastern Pennsylvania may also have occurred coincidentally. The presently available data both on the natural occurrence of poliomyelitis and on the vaccine associated cases in this area are not sufficiently accurate and detailed to permit definite conclusions.

In Maryland, however, 15 cases associated with Wyeth lot 236 occurred under circumstances which can only be accounted for on the basis of infective amounts of live virus being present in the vaccine.

Table 1

Reported Cases of Poliomyelitis for Four States and the District of Columbia for the 12 Week Period April 3 to June 25, 1955 and for Comparable Periods in 1950 to 1954

States	Report 1950	ed Case	s* for 1952	the 12 1953	Week Pe	riod in: 1955
Pennsylvania	18	11	9	38	21	64
Delaware	1	1	2	1	1	18
Maryland	3	2	2	11	14	25
District of Columbia	7†	1	1	5	3	4
Ohio	23	11	42	72	60	7 5
Total	49	26	56	127	89	186

Table 2

Poliomyelitis Attack Rates for Four States and the District of Columbia for the 12 Week Period April 3 to June 25, 1955

States	Reported Cases*	Population**	Attack Rate per 100,000
Pennsylvania	64	10,779,000	0.6
Delaware	18	367,000	4.9
Maryland	25	2,602,000	1.0
District of Columbia	4	861,000	0.5
Ohio	75	8,554,000	0.9
Total	186	23,163,000	0.8

^{*} Data from Weekly Morbidity and Mortality Reports of the National Office of Vital Statistics.

^{**} Population estimates for July 1, 1954 from the Bureau of Census.

Reported Cases* of Poliomyelitis
for Four States and the District of Columbia
for the Weeks Ending April 9 through June 25, 1955

		APR	IL			MA	ΥY			JU	NE		
States	9	16	23	30	7	14	21	28	4	11	18	25	Total
Pennsylvania	0	1	2	2	2	10	10	3	9	7	8.	10	64
Delaware	0	1	1	1	. 0	2	2	5	3	2	1	0	18
Maryland	0	0	0	2	0	0	2	7	3	5	1,	2	25
District of Columbia	0	0	0	0	0	0	0	2	0	1	0	1	4
Ohio	3	4	3	0	7	2	5	6	9	20	4	12	75
Total	3	6	6	5	9	14	19	23	214	35	17	25	186

^{*}Data from Weekly Morbidity and Mortality Reports of the National Office of Vital Statistics

Table 4

Vaccine Associated Cases of Poliomyelitis
for Four States and the District of Columbia
for the Period April 3 to June 25, 1955

Vaccine Associated Cases Reported to PSU Cases Not Accepted PSU Accepted Cases TOTAL P* NP* Revoked States Incomplete Pennsylvania Delaware Maryland District of Columbia Ohio Total

^{*} P - paralytic; NP - Non-paralytic

Table 5

Vaccine Associated Cases of Poliomyelitis Accepted by PSU for Four States and the District of Columbia for the Period April 3 to June 25, 1955 by Vaccine Manufacturer and Type of Association*

State		V C	Wyeth FC	CC	ΛC	Lill FC	•	T/O	Cutte			Sub-To		m - 1 - 1
Duave		VC	ru		70	r C	CC	VC	FC	CC	ΛC	FC	CC	Total
Pennsylvania	a	7	3	5		•					7	3,	. 5	15
Delaware		2	0	0							2	0	0	2
Maryland		3	9	3				(0 1	5	3	10	8	21
District of	Columbia	0	1	0	,						0	1	0	1
Ohio		6	4	0	3	3	0		1. 1	0	10	8	0	18
	Sub-Total	18	17	8	<u>3</u>	3	0		1. 2	5	22	22	13	<u>57</u>
	Total		43			6			8			57		

^{*}VC - Vaccinated cases; FC - family contact cases; CC - community contact cases.

Distribution of Vaccine and Number of
Eligibles in NFIP Clinics April 24 to May 7, 1955 in Four
States and the District of Columbia by Vaccine Manufacturer and Lot Number

Table 6

		imate Numbe Vaccine Lot		Inoculation	ns* (in 1000 Lilly	<u>'s)</u>	No. of Eligibles 1st & 2nd Graders	% of Eligibles
State	234	235	236	237	Vaccine	Total	(in 1000's)	Inoculated
Pennsylvania	106	101	75	96		378	479	79
Delaware			20		•	20	214	83
Maryland			109			109	1140	78
District of Columbia			26			26	28	93
Ohio		100		140	138	378	441	86
Total	106	201	230	236	138	911	1112	82

^{*}Does not include 400 first inoculations with Wyeth Vaccine Lot Number 234 in Maryland, nor an unknown, but small number of first inoculations with Wyeth Vaccine Lot Number 238 in Pennsylvania.

Table 7
PSU Accepted Cases of Poliomyelitis Associated with
Wyeth Vaccine in Four States and the District of Columbia for the Period
April 3 to June 25, 1955 by Vaccine Lot Number and Type of Association*

							cine	Lot Num									
	234		235			236			37		238			ete**		otal	
State		VC	FC	CC	VC	FC	CC	<u>VC</u>	FC	CC		VC	FC	CC	VC	FC	CC
Penns ylvania		2	0	0	4	2	2					1	1	3	7	3	5
Delaware					2	. 0	0								2	0	0
Maryland				•	3	9	3								3	9	3
District of Columbia	Ŀ				0	1	0								0	1	0
Ohio		3	3	0				2	1	0		1	0	0	6	4	0
Sub-Total	. 0	<u>5</u>	3	0	9	12	5	2	1	0	0	2	1	3	18	17	8
Total	0		8			26	5		3				6			43	

*VC - Vaccinated cases; FC - family contact cases; CC - community contact cases.

**The possible lot numbers for the cases associated with Wyeth vaccine for which data are incomplete are:

Cases	Lot Numbers	Number of Cases
Pennsylvania VC	237 or 238	1
FC	235,236, or 238	1
CC	236 or 238	3
Ohio VC	235 or 237	ì
		· gasantahunapppappa
Total		6

Distribution of Total Reported Cases and PSU Accepted Cases Associated with Wyeth and Lilly Vaccines in Four States and the District of Columbia for the Period April 3 to June 25, 1955 by State and Vaccine Lot Number Distribution Area

Table 8

Cases Associated Ratio of Total Vaccine Total Attack No. of 1st with Wyeth and Associated Cases Distribution Population Reported Rate per Inoculations Lilly Vaccines per 100,000 State (in 1000's) Area** 100,000 (in 1000's) Cases VC FC CC Total Inoculations Pennsylvania 234 2,687 8 106 0.3 0 3,385 235 76 11 0.3 2.6 236 1,103 18 1.6 47 5* 10.6 237 2,421 96 25 28 0.5 11 * 17 Mixed 1.4 10.7 Delaware 236 18 367 4.9 20 2 10.0 Maryland 236 2,602 25 1.0 109 3 9 3 15 13.8 District of Columbia 236 861 0.5 26 1 1 3.8 Ohio 235 1,461 1.6 9.2 237 655 0.5 29 0 Lilly 1,727 0.3 1.3 43 Mixed 4,711 0.9 2.7 62 8.1 TOTAL 23,163 186 0.8 19 19 5 Д3 911 4.7

*Not including one or more cases in this area for which the lot number data are incomplete; see footnote to Table 7.
**See Map 1.

Table 9

Attack Rates for Total Reported Cases per 100,000 Population and Ratios of Vaccine Associated Cases per 100,000 Inoculations in Four States and the District of Columbia for the Period April 3 to June 25, 1955 by Vaccine Manufacturer and Lot Number

Vaccine Lot No.	States Involved	Population (in 1000's)	Total Reported Cases	Attack Rate per 100,000	No. of lst Inoculations (in 1000's)	Cases Ass with Wyet Lilly Vac VC FC CC	h and cines	Ratio of Total Associated Cases per 100,000 Inoculations
234	Pa.	2,687	8	0.3	106		0	0
235	Pa.,Ohio	4,846	34	0.7	201	5 3	8	ħ*0
Mixed(235 & 236)	Pa.	1,183	17	1.4				
236	Pa.,Del., Md.,D.C.	4,933	65	1.3	230	9 12 5	3 26	11.3
237	Pa.,Ohio	3,076	14	0.5	236	2 1	3	1.3
Mixed (235, 237, & Lilly)	Ohio	4,711	43	0.9				
Lilly	Ohio	1,727	5	0.3	138	3 3	6	4.3
TOTAL		23,163	186	0.8	911	19 19 5	43*	4.7

^{*}Six cases associated with Wyeth Vaccine in which lot number data are incomplete are omitted. (See footnote to Table 7)

PSU Accepted Cases of Poliomyelitis Associated with Wyeth and Lilly Vaccines in Four States and the District of Columbia for the Period April 3 to June 25, 1955 by Interval between Date of Inoculation and Onset of First Symptoms

				th Vacc	ine Lot										lly	
Interval	234		235			236			237			mplete		Va	ccine	
in Days		VC	FC	CC	VC	FC	CC	VC	FC	CC	VC	FC	CC	VC	FC	CC
0-3					1											
4-7	·				1	1							1	1		
8-14		2			. 1		1					1	1	2	. 1	
15-21		1	1		14	3	1	1	1				1		1	
22–28						2									1	
29-35			1		1	2	1				1		•			
36-42					1	2										
43-49						1		1								
59-56		2				1					1					
Indefinite*			1		•		2									
TOTAL	0	5	3	0	9	12	5	2	1	0	2	1	3	3	3	0

^{*}Includes one family contact case associated with Wyeth vaccine lot number 235 having an interval between 23 and 35 days and two community contact cases associated with Wyeth vaccine lot number 236 having intervals between 17 and 46 days.

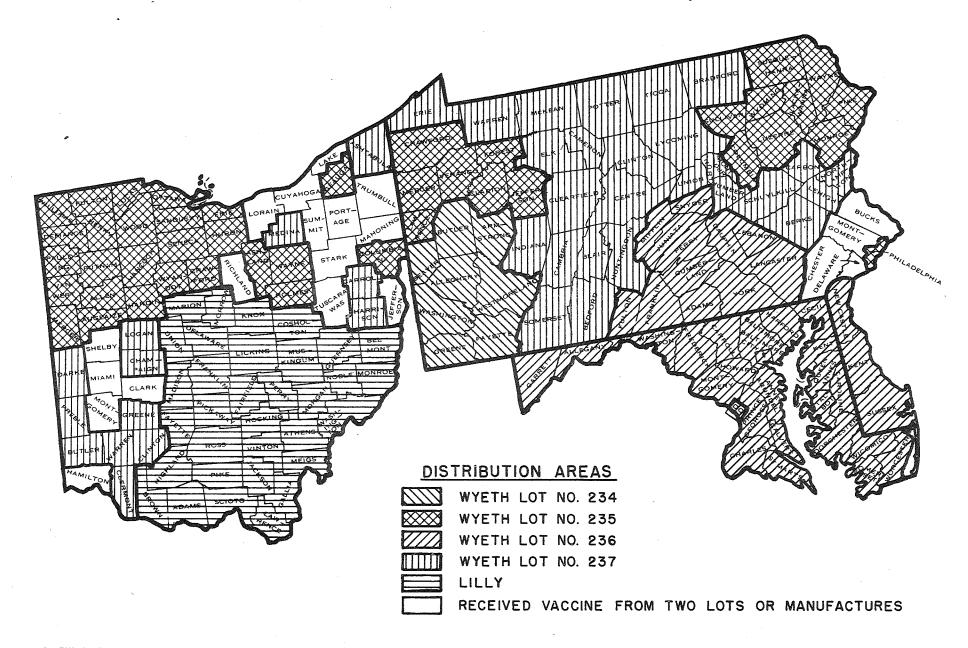
^{**}See footnote to Table 7 for data on six cases in which lot number data are incomplete.

PSU Accepted Cases of Poliomyelitis in Individuals Vaccinated with Wyeth and Lilly Vaccines in Four States and the District of Columbia for the Period April 3 to June 25, 1955 by Site of Inoculation and Site of First Paralysis

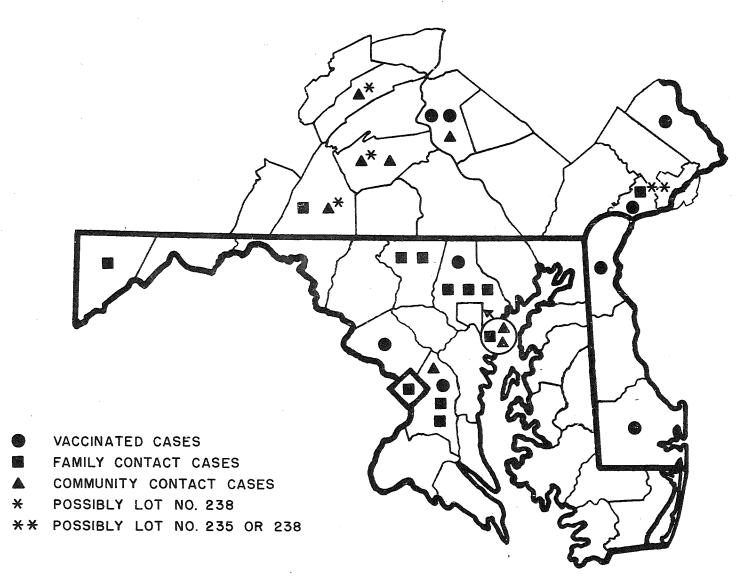
Site of	Site of	Wy		Lilly			
Inoculation	lst Paralysis	234	235	236	237	Incomplete*	Vaccine
Paralytic Cases	3						
left arm	left arm		1	2			
left arm	bulbar		1	2			
Left arm	leg(s)			3			
unknown	right arm and leg					1	1
unknown	legs			1			
Total Paral	ytic Cases	0	2	8	0	1	1
Non-Paralytic C	ases	0	3	1	2	1	2
Total	·	0	5	9	2	2	3

^{*}Includes one paralytic case vaccinated with Wyeth Vaccine of lot numbers 237 or 238 and one non-paralytic case vaccinated with Wyeth Vaccine of lot numbers 235 or 237.

DISTRIBUTION AREAS FOR WYETH POLIOMYELITIS VACCINE USED IN NFIP CLINICS APRIL 24 TO MAY 7, 1955



MAP 2
POLIOMYELITIS CASES ASSOCIATED WITH WYETH VACCINE, LOT NO. 236
(PSU ACCEPTED CASES WITH ONSETS ON OR BEFORE JUNE 25, 1955)



DISTRIBUTION AREA FOR WYETH POLIOMYELITIS VACCINE, LOT NO. 236

Listing of PSU Accepted Policmyelitis Cases Associated with Vaccine for Four States and the District of Columbia (Cases with Onsets on or before June 25 and Inoculated on or before May 7)

APPENDIX A

PSU Case No.*	County	Age	Sex	Date Inoc.	Date 1st Symptoms	Site Inoc.	Site 1st Paralysis	Virus Isolation Case Contact		. Remarks
			V	'A CIC TINA 'I	ED CASES A	SSOCTAT	ED WITH WY	ETH VACCINE		
Pa-2	Delaware	7	F	4-27	5-6	IA	IA	Type I	236	
Pa-3	Philadelphia	7	M	4-27	5-6	IA	IA	Type I Type I	235	
Pa -l ı	Bucks	7	F	5–2	5-7	IA	IA	Type I	236	Died 5-25, bulbar
Pa-5	Philadelphia	7	M	5-2	5-12	IA	None		235	CSF 94 cells
Pa-6	Dauphin	6	M	4-28	5-14	IA ·	None	Type II	236	CSF 38 cells
Pa-7	Dauphin	7	M	4-28	5-15	IA	LL		236	
Pa-10	Clinton	7	M	5-5	6-6	?	RA,RL		7237,7238	
Del-l	New Castle	8	M	4-29	4-30	IA	LL.		236	l day interval to 1st
							•			symptoms; 1st paralysis on 5-6.
De1-2	Sussex	7	F	4-21	5–10	IA	Legs		236	post dray barb our you
Md-l	Montgomery	6	M	5-3	5-21	LIA	Bulbar	Type I	236	
Md-2	Prince George	6	F	4-26	5-25	?	Legs	Type I	236	
Md-3	Baltimore Co.	8	F	4-27	6-2	IA	Bulbar		236	

^{*} PSU cases numbers are assigned in order of acceptance; case numbers missing here are due either to case being revoked after acceptance or to dates falling outside Study Period.

- 2 -

APPENDIX A (Continued)

PSU Case No.*	County	Age	Sex	Date Inoc.	Date 1st Symptoms	Site Inoc.	Site lst Paralysis	Virus Case	Isolation Contact	Lot No.		Remarks
Ohio-2	Hamilton	7	VA CC M	INATED 4-27	CASES ASSO 5-17	CIATED IA	WITH WYETH None	VACCINI	E (Continue	ed) 237	CSF	7 20 cells
Ohio-3	Wood	8	M	4-28	5-17	IA	Bulbar			235		
Ohio-11	Columbiana	8	M	4-28	6-20	IA	None			235		
Ohio-14	Cla rk	7	M	5-3	6-20	Arm	None			237	CSE	7 102 cells
Ohio-152	Montgomery	6	M	4-27	6-17	RA	None			7235,7237	CSF	58 cells
Ohio-16	Henry	7	M	4-25	6–20	RA	None			235	CSF	81 cells
				VIA CC	፣ ተለነለ ጥርጥን . ሶለ ፍ	STO ACC	OCIATED WITH	I TTTTV	WA COTHE			
Ohio-4	Hamilton	8	F	5 -1 6	5 –3 0	IA	None	ı ıırıırı	•	?8124 – 6493 ?8125 – 6493	-	CSF? Stiff neck and abdominal
Ohio-5	Miami	8	F	5-3	5–15	?	RA,RL			? 8124 - 6493 ?8125 - 6493		weakness 6-3
Ohio-6	Cuyahoga	8	M	4-29	5-5	IA	None			?8124-6493 ?8125-6493		
	•			VACC	CINATED CAS	SES ASS	OCIATED VIT	H CUTTE	R VACCINE			
Ohio-l	Hamilton	1	M	4-17	?4-20 ?4-21	?RL	RL			Е6044		
		, ,	٠	•	i e	. 12 -						

- 3 APPENDIX A (Continued)

PSU Case No.	County	Age (Case)	Sex (Case)	Date Contact Inoc.	Date 1st Symptoms (Case)	Site lst Paralysis (Case)	Illness in Vaccinated Contact	Virus Case	Isolation Contact		Remarks
Pa-Xl	Franklin	29	F	FAMILY COI 4-25	NTACT CASE 5-25	S ASSOCIATE Leg	D WITH WYETH ?	VACCIN	E	236	
Pa-X2	Delaware	3	M	5 - 9	5-23	Bulbar	None		?	235,?2 ?238	
Pa-X3	Delaware	33	M	4-28	6-19	IA	Fever, vomits			236	Paralyzed 5-19
Md-X2	Carroll	14	F	4–26	?5-1	IA	None		Type I	236	LL and trunk also partially
Md-X3	Garrett	9	M	4-25	5-16	?	Fever Malaise		Type I	236	paralyzed. Paraplegia
Md-X4	Prince Geor	rge 4	M	?4-25	5-21	RA	Malaise Headache	Type I	Type I	236	
Md-X5	Carroll	10	F	4-26	5-21	RA	?	Type I	Type I	236	•
Md-X6	Balto.Co.	10	F	4-25	5-14	RA	None	Type I	Type I	236	IA also paralyzed
Md-X7	Balto.Co.	3	M	4-22	5-27	LL	Fever,	Type I	Type I	236	
Md-X8	Balto.City	2	M	4-28	6-5	None	None			236	CSF 23 cells.
Md-X9	Prince Georg	ge l	F	4-22	5-28	Legs	Severe	Type I		236	
Md-X10	Balto.Co.	3	M	4-25	6-10	?Arms,RL	cold			236	:
MC-X1	Washington	1,	M	4-27	5-16	Bulbar	None	Type I		236	

- 4 APPENDIX A (Continued)

PSU Case No.	County	Age (Case)	Sex (Case)			Site 1st Paralysis (Case)	Illness in Vaccinated Contact			Lot No.	Remarks
FAMILY CONTACT CASES ASSOCIATED WITH WYETH VACCINE (Continued)											
Ohio-X2	Hamilton	14	M	5– 6	5-24	None	None		,	237	CSF 19 cells.
Ohio-X3	Holmes	5	M	4-25	5-12	?	fever, h				RA,RL,LL paralyzed in family 5-12.
Ohio-X5	Hancock	3	M	4-27	5-27	RL	fever, s	ore throat	t	235	
Ohio-X8	Hancock	5	Ą	?	5–30	None	fever, he	eadache		235	Positive Pandy CSF 192 cells.
FAMILY CONTACT CASES ASSOCIATED WITH LILLY VACCINE											
Ohio-X1	Franklin	26	F	4-25	5–3	?	None		81 649		Spinal paralytic
Ohio-X6	Cuyahoga	5	F	5-4	5-29	None	None		81 649		CSF 90 cells.
Ohio-X7	Cuyahoga	33	$ec{F} \!$	5-4 6	5–26	Trunk	None			.25 - :337	Same Contact as Ohio-X6.
•				FAMILY CO	NTACT CAS	SES ASSOCIA	ATED WITH CU	TTER VACC	INE		
Md-Xl	Balto.Co.	23	F	4-16	5-8	?	None	Type I 1	[ype]∵Ie ∷	Е6041	Bulbar,RA,RL, LL paralysis
Ohio-X4	Trumbull	29	F	4-27	5-23	Arms	None		1	Е 60Ш	!

∞ 5 **∞**

APPENDIX A (Continued)

PSU Case No.	County	Age (Case)	Sex (Case)		Date 1st Symptoms (Case)		Illness in Vaccinated Contact	Virus Is Case	olation Contact		Remarks
Pa-Cl	Franklin	17	COMMUN F	IITY CONTA 4–28 4–28	CT CASES . 5 -9	associate RL	D WITH WYETH Sore throat None			?236,?2 ?236,?2	
Pa-C2	Dauphin	5	M	4-28	5-17	None	None			236	SF 94 cells.
Pa-C3	Cumberland	15	F	4-28	5-13	LL	None			?236,?2	38
Pa-C4	Juniata	123	M	4-27	5-2	None	Fever			?236,?2	238
Pa-C6	Cumberland	5	M	4-27	5-8	None	Fever	Type I		236	
Md-C5	Baltimore Co	• 9	M	?	6-1	IA	None			236 F	A also para.
Md-C7	Prince Georg	e 7	F	?	5-24	RL	?			236	
Md-C8	Baltimore Co	. 6	M	4-29 5-2	6 - 5	LL	None	Type I		236 2	vaccinated
			COMMUN		CT CASES	ASSOCIA TE	None D WITH LILLY	VACCINE			contacts.
						NONE					
		••					D WITH CUTTE			m(a))	
Md-Cl	Baltimore Co	. 33	F	l ₁ –16	5-19	RA.	None	Type I	Type I	Е 6044	Contact of Md-Xl
Md-C2	Baltimore CC	2. 28	M	4-16	5-21	RL	None	Type I	Type I	E60111	it it it
Md-C3	Baltimore Co.	. 2	F	4-16	5-25	RL	None	Type I	Type I	E6044	n n n
Md-C4	Baltimore Co.	. 1	M	4-16	5-22	LL	None	Type I	Type I	E6044	21 17 25
Md-C6	Baltimore Co.	. 9	M	4-16	6-3	None	None		Type I	Е 6044	u u u CSF 98 cells.

APPENDIX B

Listing of Vaccine Associated Cases Reported to PSU but Not Accepted by PSU in Four States and the District of Columbia (Cases with Onsets on or before June 25 and Inoculated on or before May 7)

State	County	Age	Sex	Date Inoc.	Date 1st Symptoms	Site Inoc.	Site lst Paralysis	Virus Case	Isolation Contact	Lot	No. Remarks
VACCINATED CASES ASSOCIATED WITH WYETH VACCINE											
Pal	Erie	7	M	4-26	5-1	LA	?Legs	Neg.	Neg.	237	Accepted by PSU, revised to non-paralytic and later revoked by State as not polio following negative laboratory findings.
Pa.	Bradford	7	F	4-27	5-18	LA	None			237	Revoked by State as not polio.
Pa.	Montgomery	8	M	4-26	5-19	RA	None			235	Revoked by State as not polio following insignificant CSF findings.
Pa.	Delaware	7	M	5-3	5-4	LA	LL			236	Revoked upon final diagnosis of mumps encephalitis.
Pa.	Dauphin	7	M	4-27	5-16	LA	None			236	CSF 1117 cells, ?lymphocytic choriomeningitis.
Pa.	Fulton	8	F	4-28	6-25	LA	None			236	CSF?

APPENDIX B (Continued)

State	County	Age	Sex	Date Inoc.	Date 1st Symptoms	Site Inoc.	Site lst Paralysis	Virus Case	Isolation Contact	Lot	No.	Remarks
				VACC	CINATED CAS	SES ASSC	CIATED WITH	WYETH	VACCINE (Conti	.nued)	
Md	Montgomery	?	?	4-29	5-7	?	?			236	susp	l cell; ect, wait for report.
DC	Washington	9	M	4-26	5-30	?	None			236	CSF?	
				VACO	CINATED CAS	SES ASSO	CIATED WITH	LILLY	VACCINE			
Ohio .	Delaware	7	M	4-27	4-27	LA	?RA,?LL		?8124-6493 ?8125-6493		late Stat	rted as suspect, or revoked by see as not polio, sibly rhuematic er.
Ohio	Washington	6	M	5–2	5-14	?	None		8125-6493	337		phocytic riomeningitis

VACCINATED CASES ASSOCIATED WITH CUTTER VACCINE

NONE

VACCINATED CASES -- VACCINE MANUFACTURER UNKNOWN

NONE

-3-

APPENDIX B (Continued)

State	County	Age (Case)	Sex (Case)	Date Contact Inoc.	Date 1st Symptom (Case)	Site 1st Paralysis (Case)	Illness in Vaccinated Contact	Virus Isolati Case Contac		narks	
Doade	Country	(case)							o No. Ren	IdIKS	
FAMILY CONTACT CASES ASSOCIATED WITH WYETH VACCINE											
Pa	Mercer	2	M	?	6-9	?	?		?235,?236 ?238 p	Dates?, paralysis?	
Pa	Westmoreland	1 6	F	<u>4</u> –26	6-8	None	None	· .	?234,?235 ?237,?238	CSF?	
Pa	Lebanon	28	M	4-26	6-21	None	None		?235,?236 ?238	CSF?	
Pa	Northampton	10	M	?	6-25	None	None		?234,?237 ?238	CSF?,Dates,?	
DC	Washington	9	M	4-27	5-26	None	None		236	CSF?	
			FAMI	LY CONTAC	T CASES AS	SOCIATED WI	TH LILLY VAC	CINE			
					NON	Œ					
			FAMI	LLY CONTAC	T CASES AS	SOCIATED WI	TH CUTTER VA	CCINE			
					NON	E					
			FAMI	LLY CONTAC	T CASES	- VACCINE MA	NUFACTURER U	nknown			
Pa	Venango	2	M	4-24	6-19	?	?			Paralysis?	
Ohio	Portage	14	M	4-28	5-18	Neck	None			Bulbar	

APPENDIX B (Continued)

State	County	(Case)	(Case)	Date Contact Inoc.	Date 1st Symptoms (Case)	Site lst Paralysis (Case)	Illness in Vaccinated Contact	Virus Case		ation L tact N	ot Remarks			
COMMUNITY CONTACT CASES ASSOCIATED WITH WYETH VACCINE														
Pa-C5	Franklin	9	M	4-28	5-4	None	Stomachache headache neck pains.	•		236	and later revoked upon final diagnosis of mumps-			
Pa	Allegheny	1	F	?	5-31	?	?			?	encephalitis. Revoked upon final diagnosis of tuberculosis			
Pa	Carbon	2	F	5-3	?	?	None	Туре	II	237				
Pa	Chester	5	F	4-28	5-17	?	?		?23	35,7236	Dates ? Paralytic			
Pa	?	3	M	4-28	5-21	?	3		?2	35,?236	•			
Pa	Crawford	6	M	4-27	5-21	?	None	Neg.	Type	II 235	from other contacts, paralysis			
Pa	Delaware	6	M	4-27	6–3	?	?	Туре	I ?2	36,?238	questionable. Paralysis questionable.			
			COMMUN	IITY CONTA		ASSOCIATED V	VITH LILLY VA	CCINE						
			COMMUN	NITY CONTA		ASSOCIATED V	WITH CUTTER V	ACC IN	3					
Pa	Cumberland .	11	COMMUN M	NITY CONTA ?	ACT CASES - 5-21	VACCINE N None	MANUFACTURER ?	UNKNO	N		CSF? Contact?			