

# A Premature Salk Vaccine April 19, 1956

## A Plea to the Illinois State Medical Society

THIS IS A PLEA to you not to commit the Illinois State Medical Society in any manner to any endorsement of the Salk poliomyelitis vaccination program promoted by the National Foundation for Infantile Paralysis (NFIP) and the United States Public Health Service (USPHS). You, as physicians, are only hearing what the NFIP and the USPHS want you to hear and are as a result no more knowledgeable than the layman, unless you are willing to do what the American Medical Association (AMA) has just done; namely, appoint a committee to carefully survey the literature and evaluate the vaccine. We are playing the NFIP's game when we unwittingly permit ourselves to sanction or promote the use of this vaccine. We worry about socialized medicine and yet hardly appreciate that it is the voluntary health agencies (and the NFIP is the striking example) who are slowly converting us into slave technicians and automatic vendors of drugs by developing great pressures on the medical profession through mass communication stimulation of the laity. Dr. William Bean, head of the Department of Medicine at Iowa, in an astutely conceived and executed article entitled "Recent Setbacks in Medicine" makes the point brilliantly re poliomyelitis in a paragraph entitled "Research-Trial by Mass Media." I quote in full:

One of the most spectacular setbacks has been the trial and determination by newspaper, radio and television of the effectiveness, safety and wisdom of using mass produced poliomyelitis vaccine. The unpreparedness of public health experts, confused federal measures to regulate manufacture and use of the vaccine, and the shambles of goggle-eyed publicity gained for voluntary health agencies and foundations, have lowered

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the medical profession in the public eye. Investigators suspected of being publicity hungry and laymen who become hysteria mongers seeking to gull the public by fear, to raise money by intellectual blackmail, and the natural complexity of a very complicated problem have added fuel to the flaming calls for federal regulation or state medicine. Here, as always, tragedy lurks in impatience. While the responsibility is collective the blame will concentrate on the physicians.<sup>1</sup>

As a result of my recent writings on the Salk vaccine ordered toward clarifying the scientific validity of the mass use of the Salk vaccine, I have been the recipient of much correspondence and information which leads me to believe that any individual physician, or any component of organized medicine, would be most foolish to sanction, promote, or advise the use of the vaccine. I give you, in part, some of my information pertaining to the safety and effectiveness of the vaccine.

### *Safety*

1. The most definitive attack against the Salk process and vaccine to date has been made by Dr. Sven Gard, a Rockefeller trained man, who is a Professor of Virology in Sweden and who was Vice-Chairman of the meeting of polio experts convened by the World Health Organization in Stockholm, November 21-25, 1955. In an article published in the Swedish physicians's journal, *Sartryck ur Svenska Lakartidningen*, January 1956, he states:

Honesty requires that we should give up the illusion that we can achieve a vaccine which can be said to be killed with 100 percent certainty.

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Absolute freedom from active virus can never be guaranteed. It appears, therefore, to be essential that notoriously highly pathogenic virus strains are not permitted to be used in the vaccine. Experience has shown that the Mahoney strain is the one most unsuitable and that its use should be prohibited. [Note: The Mahoney Strain was still used in 1956 in the U.S. However, it had already been replaced in Denmark, Sweden, England, Germany, etc.]

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It can therefore with good justification be assumed that in 1955 vaccination in the United States caused as many cases of poliomyelitis as it prevented.

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The whole interest has been centered around the protective effect of the vaccine while adverse effects have been neglected or explained away. What happened cannot be called an accident since this would signify that it could not have been foreseen. Well-founded warnings had been given half a year before mass inoculations were started but they were completely disregarded. A person gets an unpleasant impression of too many dollars and too much personal prestige having been invested in the Salk vaccine. When the American Polio Foundation communicated its decision to order 9 million dollars worth of vaccine, its President Basil O'Connor stated to the reporters: "We are gambling." He referred, of course, to the money. In fact, the gamble involved the life and health of an unknown number of children.<sup>2</sup>

Sven Gard has also written to me personally in a letter dated March 6, 1956:

As to the true cause of the Cutter incident, etc., I am afraid that the Technical Committee is barking up the wrong tree. Already in 1954 at the Congress in Rome, the proceedings of which were recently published by NFIP, I presented evidence to show that the Salk theory of formalin inactivation might be fundamentally wrong. We have been piling up new evidence ever since. I am now quite confident that the whole philosophy behind the Salk procedure. . . is wrong, indeed. When repeated filtrations are applied for removal of "aggregates" one is only hunting ghosts. The effect of filtration is nothing but a gradual removal of virus, live and dead alike. It could just as well be substituted by plain dilution of the vaccine.

Dr. Thomas Weller, of Harvard University, the Nobel prize winner, who, with Enders and Robbins, did the basic work in poliomyelitis which made the possibility of the vaccine possible, writes:

Thank you for the copies of the paper by Sven Gard. I had not seen Gard's summary and am most pleased to have it. He is certainly Scandinavia's outstanding virologist and is known to command great respect. I find myself in complete agreement with the viewpoint he expressed.

Dr. Maxwell Finland of the Thorndike Memorial Laboratory, Boston, writes: "This is about as clean-cut an indictment of the Salk vaccine as has yet been published."

2. The true story of Denmark's Salk vaccine program has been withheld in this country and the NFIP still propagandizes the

medical profession and the public about Denmark's safety record. Dr. Sven Gard, in the same article quoted above, writes:

Some time ago, Denmark stated that because of an accident in production they had no vaccine and therefore were forced for the time being to discontinue all further inoculations. This communication, however, most probably should be looked at from the background of the American experiences.<sup>3</sup>

Also, I can quote from a letter, dated January 12, 1956, sent by Hertis von Magnus, who has charge of the Denmark program, in answer to an inquiry from one of America's leading virologists: ". . . in the fall we have had all kinds of troubles with our inactivation procedure and have had to stop release of vaccine since November." It is understood that their troubles started after they introduced the careful safety testing procedures of Parke, Davis & Co.

3. Dr. S. Stephen Chapman of the University of Kentucky Medical School reported in a symposium of the Protein Foundation on January 6, 1956 that he had centrifuged the vaccine and had obtained live virus "more. . . than we theoretically ever could have anticipated having. . . . This brings up the problem of possible reactivation of the so called dead vaccine. . . ."

4. Reliable authorities have reported to me that in the past month Parke, Davis & Co., by using their more stringent safety tests, have found live virus in the Lilly Vaccine.

5. State health officers are beginning to get very concerned that the USPHS has dropped its safety testing as a means of expediting the production and distribution of the vaccine.

6. Cases of paresis shortly following the use of the vaccine are occurring completely out of proportion to the normal incidence of the disease for off season months but are not being accepted, recognized or publicized to the medical profession. One case, which I have examined myself, is the daughter of a neuro-psychiatrist and was attended by a former president of the Chicago Pediatric Society whose diagnosis was hemiparesis. This hemiparesis developed approximately 4-10 days following a third inoculation of vaccine (Lilly). I spoke to the father on April 15 and the child still had a residual paralysis in her left foot. Another case, inoculated with the same Lilly vaccine, was diagnosed as having paralytic poliomyelitis by Dr. Archibald Hoyne himself.

7. On April 14, 1956, I received an 86 page epidemiological analysis of the use of the Salk Vaccine in Germany and the United States by Professor Dr. Redeker, President of the Federal Health Ministry, Koblenz, West Germany. He concludes that the Salk Vac-

cine caused sharp increases of poliomyelitis shortly following its use in several cities in Germany and a number of states in this country as well as the U.S. as a whole, including the state of Illinois. He systematically corroborates the findings reported in the *Bulletin of the American Association of Public Health Physicians*, described under the heading of the Salk Vaccine Post Inoculation Poliomyelitis Phenomenon (See *CF*, 20:145-149). As far as can be determined from the *New York Times* of April 14, 1956, and from a letter of Dr. Redeker's accompanying the 86 page analysis, the 86 page analysis is part of a 480 page report by 7 leading West German scientists which was published in a Munich medical journal and which concluded that the Salk Vaccine is responsible for causing poliomyelitis.

8. The Poliomyelitis Technical Advisory Committee of the Illinois Department of Public Health recommended on April 13, 1956 "that in the light of present knowledge, physicians should be cautious about tonsillectomies and other nose and throat operations within one month of vaccinations against poliomyelitis."

It should be clearly understood here that if the Salk vaccine was a *killed virus* vaccine, tonsillectomy would not be cautioned against. The only possible reason that tonsillectomy is cautioned against is that the Committee believes there is live virus in the vaccine *but they don't say so*.

9. It should also be known that several leading authorities do not believe that the NFIP sponsored study claiming to prove that the Massachusetts epidemic was not caused by the vaccine proved what it intended to prove. There are many loopholes in this study and a criticism of this report is being prepared for publication. It is also of interest that a similar study was not made of the Wisconsin epidemic.

The above list is only part of the numerous scientific information now available that demonstrates that the NFIP literature is propaganda. It should be sufficient to warn you of the importance of approaching any decision involving the direct or indirect sanction of the Salk vaccine with great circumspection.

### *Effectiveness*

1. The data from the USPHS and from state health departments only proves *at best* that a vaccine known to have contained live virus (and it is commonly known that all of the vaccines used in the spring had varying amounts of live virus in them) is effective in protecting against poliomyelitis, *however*, at the price of causing poliomyelitis in the more susceptible children.

However, most statistics comparing vaccinated to non-vaccinated children of the same age groups are invalid. This holds for Illinois. The reason is that there are cases of poliomyelitis among the non-vaccinated that were *caused* by infected vaccinated children. This occurrence is well established. Furthermore, rates of polio were determined by using vaccine *distribution* figures rather than actual children vaccinated. In Illinois, I estimate this discrepancy to be up to 30 percent too high. This results in erroneously lower polio rates for vaccinated children and erroneously higher polio rates for non-vaccinated children (since distribution figures falsely high are subtracted from total children population to give the number of non-vaccinated children, numbers of non-vaccinated children are falsely low).

2. The German study includes an analysis of the *Francis Report* and the USPHS's "effectiveness" studies and demonstrates that these reports are invalid.

3. Dr. K. A. Brownlee, Professor of Statistics at the University of Chicago, in an invited review article on the *Francis Report* in the *Journal of the American Statistical Association*, concludes:

To summarize, 59% of the trial was worthless because of the lack of adequate controls. The remaining 41% may be all right but contains internal evidence of bias in favor of the vaccinated. There was hope that an independent trial would be run in Great Britain under the auspices of the Medical Research Council but this has been abandoned since they concluded that the vaccine was too dangerous. The reviewer may seem skeptical in feeling the need for an independent confirmation of a trial run on the scale of the present one, but he would point out that gamma globulin was triumphantly proclaimed effective by the NFIP after a similar trial, but now considerable doubt exists as to the correctness of this conclusion.<sup>4</sup> [Note: Corroboration of this latter point is to be found in the recommendation of the Polio Technical Advisory Committee of the Illinois State Health Department made on April 13, 1956, "...that gamma globulin not be distributed by the Illinois Department of Public Health for poliomyelitis cases contacts."]

4. Again, it should be recognized that national figures pertaining to effectiveness are biased because of the double standard of polio reporting that now exists. If a physician reports poliomyelitis in a *non-vaccinated* child, in practically all instances the diagnosis is automatically accepted. However, if poliomyelitis is reported in a *vaccinated* child, one—in most instances—has to prove the diagnosis by laboratory studies before it is accepted,

even though it is recognized that the laboratory diagnosis is a very hard one to make. Furthermore, neither the federal, nor the state health services, have established criteria for the clinical diagnosis of paralytic polio. This allows for all kinds of biases to operate. To date, these biases have operated to reduce the number of paralytic poliomyelitis cases, caused by or associated with the Salk vaccine, that have been accepted by official agencies. Canada, on the other hand, saw the need for being crystal clear about this. Canadian authorities, therefore, agreed among themselves that "the diagnosis of paralytic poliomyelitis is one in which muscular weakness was present for more than 24 hours, as determined by two successive examinations."<sup>5</sup> It is imperative, if we are ever to get a clear picture of what happens this summer, that the health department set up criteria for an acceptable clinical diagnosis of paralytic poliomyelitis to apply equally whether it be in the vaccinated or non-vaccinated child.

5. That the double standard of reporting is national in scope can be seen in an article by Dr. Fred R. Klenner. He states:

Nor were the previous listings the only "Vaccine Incidents." North Carolina, using Lilly vaccine, also had cases of polio following vaccinations. The North Carolina Public Health Office, Raleigh, published an account in the *Greensboro Daily News* that no cases appeared from the use of the vaccine in this state. I take this opportunity to challenge the accuracy of that press release. Rockingham County sent a sizeable number of cases to the polio hospital, Greensboro, NC, in 1955. Some of these children had received the vaccination; others certainly were from contact, although no effort was made to so classify.<sup>6</sup>

As in the previous list on safety, the above list is limited. The evidence indicating that we have no certain knowledge as to the effectiveness of the vaccine is greater than has been presented here. Perhaps we should recall, how a similar tragedy was handled before the days of the existence of the NFIP, when similar difficulties developed following the use of a Salk type formalin inactivated poliomyelitis vaccine. Dr. Klenner reports:

In spite of this evidence given by men from his own department, Surgeon General Scheele on May 6, 1955, said, "Although 44 vaccinated children have developed polio, this does not mean the Salk vaccine is not safe. They 'probably' had the disease already." In 1936, following cases of polio and deaths from the Kolmer vaccine (and later from the Brodie vaccine), the Senior Surgeon of the USPHS, Dr. James P. Leake, had enough intel-

ligence and "guts" to state publicly: "I beg you, Dr. Kolmer, to desist from the human use of your vaccine."<sup>7</sup>

Dr. Klenner goes on to quote an ambiguous and misleading statement of Dr. Van Riper's, after which he again brings in Dr. Leake for comparison. About this comparison Dr. Klenner states:

This is quite a contrast. The "double" talk issued regularly to physicians will be accepted by many, but in some it will "provoke" serious misgivings.<sup>8</sup>

It should be noted here that Dr. James P. Leake, quoted above, is a retired USPHS senior surgeon and is the same Dr. James P. Leake who has been appointed as a consulting member of the Salk Vaccine Committee of the American Medical Association recently appointed by Dr. Gunnar Gundersen, Chairman of the Board of Trustees and which includes four members of the Board of Trustees and whose purpose is to evaluate the Salk vaccine.

### *Conclusion*

May I state that this memorandum should be a sufficient warning to cause concern that you may end up unwittingly the pawns of the NFIP. No one knows what is going to happen this summer. It can very well be that we will witness a wide scale failure of the Salk vaccine. A 26 percent increase in paralytic polio has already been reported for 1956. And in the *Chicago Tribune* of April 8, the Chicago Health Department reported that "since January 1, Chicago has had only four polio cases. One of the victims, a boy, 8, received three shots of vaccine; another, a boy, 6, had two shots." A failure of the Salk vaccine is bound to result in a mass disillusionment on the part of the public which may very well be directed at organized medicine. It seems very improbable that the Salk vaccine will turn out to be dramatically effective.

I cannot emphasize enough, therefore, the caution with which the Illinois State Medical Society should approach this program. It seems to me highly unwise for the Society to be jockeyed into any position in which the public is permitted to think that they approve of the vaccine. Equally, I believe that it is a tenable position that you do not publicly disapprove of the vaccine. Actually, since the authorities and the sponsors of the vaccine have not seen fit to give physicians and the public an accurate and unbiased account of what has happened, and have flooded physicians and the public with a partisan and one sided account of the existing literature, it seems that in some manner it should be made clear



to the public that you are not in a position to make any recommendations. Obviously, a stronger position to take would be to make clear, the experimental nature of this program and the many unknowns that exist. □

#### REFERENCES

1. Bean, Wm. Recent Setbacks in Medicine. *Northwest Medicine*, Feb., 1956.
2. Gard, S. Prophylactic vaccination against poliomyelitis. *Sartryck ur Svenska Lakartidningen* (the Swedish physician's journal), 53:121, 1956.
3. *Ibid.*
4. Brownlee, K.A. Statistics of the 1954 polio vaccine trials (The Francis Report). *J. of the Amer. Statistical Assoc.*, Dec., 1955.
5. Lossing, E.H. *Evaluation of Canadian poliomyelitis vaccination program, 1955*. A mimeographed report from the Dept. of National Health and Welfare, Epidemiology Division, Ottawa, Canada on a meeting of Provincial Epidemiologists and Communicable Disease Control Directors held in Ottawa, May, 1955.
6. Klenner, F.R. Poliomyelitis vaccine: The authorities speak! *Tri-State Medical J.*, March, 1956.
7. Klenner, F.R. Poliomyelitis vaccine: Brodie vs. Salk. *Tri-State Medical J.*, July, 1955.
8. *Ibid.*

The program was initiated with the alleged demonstration that the vaccine was absolutely safe, that it contained built-in-safety, and that it was "one of the simplest biological preparations to make" (Salk). Shortly after the launching of the mass inoculation program in 1955, however, it was evident that these claims were not true. The vaccine was not safe. All spring of 1955, the Salk vaccine had variable amounts of live virus in it. It did not contain a "built-in" safety factor (Scheele, Shannon, Gard, Stokes, Guenther, Timm) and it was found to be "one of the most complex biological preparations ever to be made." (Scheele and Folsom).

Herbert Ratner, M.D.  
*GP*, May, 1957.

# The Untold Vaccine Story

THE PRECEDING PLEA of April 12, 1956 urged the leadership of the Illinois State Medical Society (ISMS) to dissociate the ISMS from the Salk vaccination program promoted by the United States Public Health Service (USPHS), the National Foundation of Infantile Paralysis (NFIP) and the City of Chicago and the Illinois State Health Department (ISHD), all of whom held that the Salk Vaccine (SV) was safe and effective. My plea stating that the SV, as then constituted, was neither safe nor effective was disregarded by the ISMS, but it turned out to be prophetic! Shortly after the vaccinations started, the City of Chicago began experiencing the second worst poliomyelitis epidemic in its history. Actually it was Chicago's worst epidemic and would have measured so if the standards for the diagnosis of polio that were used in 1952, the worst year, had also been used in 1956.

The question to be asked, then, is why a local health officer of a small suburban community in metropolitan Chicago (Oak Park, Pop. 60,000) was proven to be right, whereas the top echelons of experts of the USPHS, NFIP, the ISMS and the City of Chicago were proven to be wrong. If good science is measured by its ability to predict, the top echelons of experts proved themselves to be bad scientists and were, in fact, untrustworthy. Everything I knew, they knew or should have known. Additionally they knew things that local health officers, practicing physicians and even some of the consultants to the program did not know, since the inner circle of USPHS and NFIP experts kept to themselves virtually anything that raised doubts about the safety and effectiveness of the SV. An early example of the secrecy surrounding the SV came to light with the *White Paper* issued by the USPHS on June 7, 1955. It was necessitated by the outbreaks and epidemics which occurred immediately following the use of the SV shortly after it was licensed on April 12, 1955. With the *White Paper*, we were informed for the first time that the manufacturers of the

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SV in 1954 and in 1955 had much difficulty producing a vaccine free of live virulent polio viruses and were apparently still having difficulty. The function of the *White Paper* apparently was to extricate the USPHS from blame for a SV that was developed and accelerated in its production by the NFIP.

Despite the manufacturing difficulties, the USPHS and the NFIP refused to fully face up to the basic defects and dangers of the prematurely introduced SV. They did not withdraw the SV from the market even though it was not determined that the SV was truly safe and effective. Instead they decided to continue the vaccinations and brazen out the criticisms while making efforts to patch up the defects of the manufacturing and testing procedures of an ongoing program. Once this course of action was taken, the die was cast. This difficulty concerning the safety and the effectiveness of the vaccine was to haunt them for the next six years until the SV was finally displaced by the newly licensed Sabin attenuated live virus vaccine in 1961. In the years before 1961, going back to 1955, the promoters of the vaccine ignored, denied, or avoided the hard fact that the Salk inactivation recipe was faulty. When safety was sought effectiveness was lost and when effectiveness was sought safety was lost (*CF*, 19:281-285, 20:50). The problem was compounded by the inclusion in the SV of the highly virulent Mahoney strain for the Type I antigen, traces of which, if they escaped the inactivation process, would be able to cause paralytic poliomyelitis in inoculees, which, in turn, would spread the polio virus to others (*CF*, 19:209).

In choosing to continue the program the promoters ignored the early 1955 evidence that outbreaks and epidemics of polio occurred pre-seasonally following mass vaccinations, an occurrence which was later named the Salk Vaccine Post Inoculation Poliomyelitis Phenomenon (*CF*, 20:145-149). This phenomenon was independently recognized by epidemiologists of the Federal Health Ministry of West Germany (*CF*, 20:55-60).

When the sponsors of the SV were forced to take action in November, 1955 because testing continued to detect live polio viruses in the SV, the USPHS issued a manufacturing requirement effective November 11, 1955, which declared the "absolute need for. . . suitably spaced filtration procedures" so as to remove live virulent polio viruses which had escaped the Salk inactivation process (*CF*, 19:208-209). Unfortunately, these additional filtration steps reduced but did not eliminate the live viruses. At the same time the added filtrations sharply reduced the effectiveness of the vaccine by also removing dead polio viruses, the antigen that stimulated the protective antibodies (*Ibid.*).

These difficulties with the manufacture of the SV remained through at least 1959 as seen from the following account in *Time*, January 19, 1959 entitled "Calling the Shots."

. . . much of the [SV] material used in about 200 million U.S. inoculations has been no good. As a result, an all-out effort to improve the commercially produced vaccine is now being made.

This was the word last week at a University of Michigan Symposium with which the National Foundation launched its 1959 March of Dimes. The vaccin inventor, Jonas Salk, was more frank than ever before in conceding the ineffectiveness. . . of the commercial vaccine released.

*Time* further reported that ". . . Dr. Salk also conceded defects in the design of the vaccine itself" and emphasized the need to replace two of the three strains of polio virus in the SV. One of them was the Mahoney strain.

The need to replace the highly dangerous and highly virulent Mahoney strain had been raised four years earlier following the 1955 post vaccination outbreaks and epidemics caused by the SV (*CF*, 20:67-81). The critics' concern was that the Mahoney strain was so virulent that even if only traces of the strain survived the questionable Salk inactivation process, it would be sufficient to cause paralytic polio and spread polio to others. But their repeated criticisms were ignored by the promoters of the vaccine. The issue, however, was of sufficient concern that a congressional hearing was called for June 22 and 23, 1955 to address the problem. At this hearing Nobel Laureates John Enders of Harvard and Wendell M. Stanley of Berkeley and Dr. Albert Sabin of Cincinnati, all eminent virologists, voted for the interim termination of the vaccine program, but they were outvoted by eight representatives from the USPHS and the NFIP who wanted the program retained (*CF*, 20:57-58). An important item to note at this point is that most countries manufacturing the polio vaccine in the western world had either not included the Mahoney strain or had replaced it in the vaccine. Virtually all western countries discontinued importing the Salk vaccine following the 1955 epidemics (*CF*, 20:62). Their concern was that as long as the Mahoney strain remained in the vaccine the vaccine was a potential threat to the vaccinated. The United States, however, stubbornly resisted its removal until some time after the middle of 1959 when, perhaps, the NFIP began to fear the competition of the live attenuated poliomyelitis vaccine which did not contain the Mahoney strain (*Ibid.*).

At this point the reader should be astute enough to recognize that once the die is cast, once organizations and the experts representing them overcommit themselves to a product or program, they are going to defend their stand to the bitter end regardless of risks and professional objections. For them it would be difficult if not impossible to render an objective evaluation, when major reputations, both personal and organizational are at stake. A prestigious organization like the NFIP whose annual March of Dimes Collection took in \$57,000,000 dollars in one year's collection, which was more than the Heart and Cancer associations combined collected, is not going to admit failures or that they had lost a gamble. Neither will the USPHS. Physicians who had used the SV and health officers who had sponsored and executed a community vaccination program were not interested in having their misjudgments uncovered and publicized. This particularly holds when what has gone wrong is not obvious to the lay person and talented and inventive epidemiologists and skilled public relation departments fronting for their organizations can paint the picture otherwise. This is especially the case with a low incidence disease like polio which permits a lot of leeway for epidemiologists to rationalize and "stack" the data. Perhaps one should use the word manipulate. Everyone should be sufficiently sophisticated by now to know that professionals receive honors not only for successes but also for failures which are made to look like successes.

Concerning the 1956 Chicago epidemic this is not the occasion to analyze in detail what happened in Chicago. Summary remarks, however, are in order. In 1956 I was still immersed in the continuing story of what increasingly seemed was a failed mass vaccination program. It was one which was setting a dangerous precedent for future mass health programs. At the time, I kept track of what was happening, particularly since, as the health officer of Oak Park which was contiguous with Chicago, I had to make recommendations to Oak Park residents. By 1956 Oak Parkers were appreciative of my earlier cautious position on the SV which saved many from being vaccinated with a hazardous SV. This resulted in a lower vaccination rate compared to Chicago. Oak Park residents fared better with fewer vaccinations than Chicago did with many vaccinations. Out-of-towners interested in the SV controversy made enquiries about the Chicago epidemic, which I responded to with lengthy letters. These letters function today as useful records of what went on. I also analyzed the Chicago epidemic for an invitational article I had prepared for the New England Journal of Medicine. Accordingly, what I have to write now about the Chicago epidemic has substance. Two preliminary items should first be mentioned.

They give a sense of the games that were being played at the public relations level.

Both the Chicago Health Department and the president of the NFIP, using semantics, minimized the *epidemic* by calling it an *outbreak*. Prior to the introduction of the SV by the NFIP in 1955, the definition of a polio epidemic was that which reached 20 polio cases or more per 100,000 in a year. With the introduction of the SV the NFIP upped the definition of a polio epidemic to one that reached 35 cases of polio or more per 100,000. Using the latter definition the health officer of Chicago and the president of the NFIP kept insisting that the *epidemic* was only an *outbreak*. With the new definition, Chicago never had a polio epidemic in its entire recorded history going back to 1911! This was one of several devices the NFIP and its followers used for wiping out epidemics. The game of the NFIP was to maximize the disease in the pre-SV era and following its introduction to minimize the disease in the post-SV era. The former definition helped raise funds, the latter helped portray successes.

Again, through press conferences and releases and an acquiescent press, the public, including physicians, were gulled into believing that the emergency vaccination program had stopped the epidemic. A typical headline read "Why City Expects Victory Over Polio" (*Sun Times*, 8/2/56). A feature magazine article that came out later was entitled "How Chicago Blitzed Polio" (*Today's Health*, 3/59). The USPHS study of the Chicago Cook County 1956 Epidemic (*Am. J. of Hygiene*, 70:107-168, Sept. 1959), however, nowhere even suggested that Chicago's mass immunization program shortened the epidemic. Chicago also kept boasting that among those paralytic polio cases that had been inoculated "not one had received the recommended full course of *three correctly spaced doses* of Salk poliomyelitis vaccine." But extremely few who were inoculated in Chicago in 1956 had three doses of the SV and virtually none had received three correctly spaced doses (*J.A.M.A.*, April 27, 1957). Also, in a person who had received three shots, it was very difficult to get a diagnosis of paralytic polio accepted by health departments. This is another story to be told at a later time.

A capsulated analysis of the 1956 Chicago epidemic follows. For the most part, the SV used in the first half of 1956 was a 1955 SV which did not conform to the Nov. 11, 1955 requirements for the "absolute need for. . . suitably spaced filtration procedures" and the new safety tests. This 1955 SV contained traces of live polio viruses including the highly virulent Type I Mahoney strain capable of starting polio outbreaks and epidemics as it had in 1955. The SV had piled up in health departments throughout the country because

of the widespread reluctance of the public to use it due to the confused situation regarding the safety and effectiveness of the vaccine through most of 1955. This 1955 SV was not recalled or destroyed by the USPHS even though it did not meet the new Nov. 11, 1955 requirements. (The same thing happened when manufacturers were required to remove oncogenic Simian Virus 40 from the vaccine in May of 1961.) Either the USPHS was afraid of not having SV on hand for carrying out vaccination campaigns throughout the country or it was currying favor with the vaccine manufacturers by protecting their financial interests. The old, risky, 1955 vaccine at the earliest would not be replaced until close to mid-1956. A sharp rise of polio cases centered about the west side of Chicago during the week ending June 11, 1956 was said to be the start of the Chicago epidemic (Bundesen et al. *J.A.M.A.*, 4/27/57). This had just been preceded by a crash vaccination program of west side elementary school children to get them vaccinated before school let out for the summer. This intensive vaccination program and the subsequent sharp increase in polio cannot simply be ignored as coincidental.

By the time the epidemic was in full swing and the Chicago Health Department was trying to get as many people vaccinated as possible, Chicago was using the new vaccine which did conform to the Nov. 11th regulations. Unfortunately, though safer, the vaccine was robbed of most of its potency. As reported by *Time*, July 12, 1957, "some of the vaccine already used may have been no more potent than colored water in conferring protection against paralytic polio." In other words, the epidemic was preceded by an unsafe vaccine and then combatted with an ineffective one. Whether the latter vaccine made the epidemic worse still awaits a proper analysis.

It should be evident that had physicians developed a sophistication about the 1956 SV program which my plea to the officers of the ISMS tried to communicate, physicians would have dissociated themselves from the Chicago charade and the debacle that followed. □

*Editor's Comment:*

On 1/15/57 a *Chicago Tribune* caption read, "Honor Chicago Physicians for Halting Polio." It exemplified "that professionals receive honors . . . for failures which are made to look like successes." The story relates that at a fund raising NFIP luncheon, its President presented citations to the heads of Chicago's Board of Health and Medical Society "for their efforts in stemming the polio upsurge [sic] . . . last summer." Then it stated, "Current March of Dimes funds . . . are desperately needed." This was to buy an ineffective and unsafe SV, and as discovered later a SV contaminated with monkey viruses (*CF*, 20:134-138). HR

*Child  
and  
Family*



# An Untold Vaccine Story

## The Poliomyelitis Surveillance Unit

ON APRIL 12, 1955 the conclusions from the 1954 field trials of the Salk inactivated poliovirus vaccine (SV) were televised and broadcast worldwide from Ann Arbor, Michigan. Known as the Francis Report, the first words heard were, "It works." The distributed press release added that the vaccine "is 80 to 90% effective. It is safe, potent and effective." This was a misleading figure since it was only 60 to 70% effective against the most common cause of paralytic polio, poliovirus Type I.<sup>1</sup> The vaccine was licensed the same day by the United States Public Health Service (USPHS) before the full report was available to them. Presuming beforehand that the vaccine would be approved as effective and safe, the National Foundation of Infantile Paralysis (NFIP), in 1954, had "gambled" and contracted with five commercial vaccine companies to produce 27 million one-cubic centimeter doses of the vaccine at a cost of nine million dollars.<sup>2</sup> This vaccine was planned as a gift for the vaccination of all first and second grade students in the United States, both public and private schools, for which the NFIP had extensively prepared school personnel with massive educational materials and authorization slips for parents to sign. The first lots of Salk vaccine were released for immediate use on April 12th and 13th. By April 27, 10.9 million doses had been distributed throughout the United States, virtually all of which had been inoculated into the school children. The speed with which this was accomplished related to the oncoming poliomyelitis season which usually starts at the beginning of July. Sufficient time was needed for a second inoculation and for adequate development of protective,

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immunizing antibodies. On April 26 an ominous note was struck. Six cases of paralytic polio were reported, following Salk vaccine inoculations: five occurred in California, one in Chicago, both from the same manufacturer (Cutter) and from the same lot number. As paralytic polio cases began to mount, mostly in Idaho and Utah<sup>3</sup> whose major vaccine allotments were from Cutter, a California firm, it became apparent even to the public that something was awry. On April 27, following late emergency telephone consultations, Surgeon General of the USPHS, Leonard A. Scheele, M.D., asked Cutter, but not other manufacturers, to voluntarily withdraw its vaccine from use on the hypothesis that the difficulty was accidental, not intrinsic to the SV. The medical profession, public health personnel and the public at large, and at least one of the consultants<sup>4</sup> were not to know until June, when the USPHS's White Paper made it public, that all companies had been having difficulty in 1954 and 1955 in manufacturing a vaccine free of live virulent viruses.<sup>5</sup>

On April 28, the Surgeon General set up an official Poliomyelitis Surveillance Unit (PSU) in the Center for Disease Control in Atlanta, Georgia. Its function was "the surveillance of the disease and the field evaluation of the safety and effectiveness of vaccines." The unit was headed by Alexander D. Langmuir, M.D., a government epidemiologist who stated, "The purpose of the program was to provide a clearinghouse for collection, consolidation and dissemination of all pertinent epidemiologic information regarding the poliomyelitis problems confronting the nation."<sup>6</sup> The unit consisted of a total of 42 epidemic intelligence services officers. This included 29 physicians. Most of these, however, were recent medical school graduates who joined the USPHS to discharge their two year draft obligation (*Newsweek*, July 30, 1956) and, despite their impressive titles, were inexperienced in public health. Each state was asked to appoint a poliomyelitis reporting officer through whom all cases of polio following inoculations would be cleared before reporting them to the PSU. In Illinois the appointee was Dr. Ruth Church, Chief of the Illinois Bureau of Communicable Disease Control. Shortly after her appointment on May 3rd, 1955, Dr. Church attended a conference in Atlanta, Georgia of all nationwide poliomyelitis reporting officers, organized by Dr. Langmuir. Upon her return, Dr. Church, at a meeting of the Illinois State local health officers, relayed to them the warning that all public health officers would be responsible for any cases of paralytic polio that developed from inoculations given under public health jurisdic-

tion; that accordingly we were to be extremely cautious in diagnosing poliomyelitis in SV inoculees; and that special criteria had to be fulfilled before cases were "accepted by the PSU." As a result this reduced the number of cases subsequently reported to the PSU.<sup>7</sup> These reports were independent of the regular weekly reports to the National Office of Vital Statistics.

By May 7, when it became evident to the PSU and others that other vaccine producers besides Cutter were having trouble turning out a safe vaccine, Dr. Scheele suspended all vaccinations in order to reexamine the "margin of safety" of the SV inactivation process and to explore the adequacy of the safety tests which turned out to be of greater importance than previously believed.

On May 27 the ban was lifted with the claim that the SV was now "safer."<sup>8</sup> Manufacturers now had to follow new minimal manufacturing requirements and "more stringent" safety testing because the faultiness of the SV inactivation process did not assure safety, i.e. that all live poliovirus was killed. Before 1955 was over, two new testing procedures and more testing samples were required. The first new test involved use of monkeys treated with cortisone which increased their susceptibility to infection. On November 11, in a new statement of minimum requirements, a new filtration step was added which was represented as an "absolute need"<sup>9</sup> in order to remove clumps of protein in the vaccine which enclosed live virus. This not only had the effect of reducing the amount of live virus in the vaccine, it also reduced the vaccine's potency by filtering out the dead poliovirus antigen.<sup>10</sup> At no time did the USPHS withdraw the pre-November 11th vaccine which was already distributed and which continued to be highly promoted and used. It took several months before the "safer" vaccine was available for use.<sup>11</sup> As a result the leftover pre-November 11th unsafe vaccine was used in the early part of 1956. It started new epidemics in 1956. The Chicago epidemic exemplified this.<sup>12</sup> The problem of safety remained a continuing problem for the next several years. In effect the prematurely introduced SV vaccination program from its inception to the end of the decade can best be characterized as exigent, expedient and experimental. Notwithstanding, the fear of polio engendered by the promoters of the SV combined with continuing false assurances of safety and effectiveness managed to keep the program afloat.

The reduced effectiveness of the new, safer vaccine was not publicly admitted until 1959, when Dr. Langmuir, at an international

poliomyelitis conference held in Copenhagen, stated that the SV was not curbing poliomyelitis.<sup>13</sup> Leading up to this delayed admittance, the SV program and the promotion of SV as safe and effective<sup>14</sup> continued unchecked. However, because of the public's doubts as to the SV's safety and effectiveness, much unused vaccine piled up on the shelves in '56 and '57. This activated Basil O'Connor, President of the National Foundation, to use his influence in 1957 to get states to pass laws making Salk vaccination compulsory. The first state to make the SV obligatory was Pennsylvania.<sup>15</sup> Others followed.<sup>16</sup> This led to the notion that all vaccines for children should be compulsory which went counter to the then current public health practice that the best way to achieve effective vaccination protection was to target the preschool years through public health education rather than condition parents to await entrance into school.

The Polio Surveillance Unit, by a series of questionable techniques, played an instrumental role in keeping the vaccine on the market<sup>17</sup> — a vaccine which produced the very disease it was supposed to prevent. One can ask what prompted the PSU, the NFIP, and the USPHS to do so. Presumably, they held to the belief that the benefits of the vaccine in protecting against paralytic polio were so great that it justified exposing children and others to the dangers of the vaccine. Other concerns also played a role. Some are recorded in a 419 page book entitled *A Breakthrough: The Saga of Jonas Salk*<sup>18</sup> which has been described "outspoken, hard-hitting, penetrating . . . and always superbly documented." It was published in 1965 and included numerous interviews with all of the main characters associated with the behind-the-scenes development of the SV and the SV program. For instance, when experts were consulted on the morning of April 27th to decide whether the vaccine program should continue, "The consensus of the polio experts was that Scheele should 'do something' short of cutting off the entire vaccination program" (p. 313). Later a participant recalls that "Much of the discussion was at least implicitly concerned with the hot water in which the Cutter cases had dumped the government. If word ever got out that the Public Health Service actually had done something damaging to the health of the American people, the consequences would be terrible." Many were in sympathy with the government, "We felt that no lasting good could come to science or the public if the Public Health Services were discredited" (pp. 318-319). But several outstanding experts did not hold this position.

John Paul, John Enders, Bill Hammon and Howard Shaughnessy<sup>19</sup> were dead set against continuing the program. They wanted the entire program to be cancelled outright. Cutter cases were continuing to pile up, and these men genuinely feared that the vaccine manufactured by their firms would cause illness . . . . Scientifically, they just couldn't see the Salk vaccine. Neither could some of the government people . . . . But to accept the Paul-Enders recommendations and cancel all vaccinations would give the public the idea that the vaccine never should have been licensed in the first place. People like Bodian<sup>20</sup> and Langmuir sided with Salk, pointing out that no other manufacturer's product had yet caused paralysis and that there was no reason to expect such disaster. (p. 319)

And later when it was clear that paralytic cases were being caused by other manufacturer's vaccines, the PSU either preferred to remain ignorant or keep the findings to itself while reiterating that the SV was safe and effective. It only admitted what was already evident to the public. Even more scandalous was Surgeon General Scheele's closing statement in his address at the Annual Meeting of the American Medical Association on June 7, 1955. He took the self-serving position that the "Final decisions on the use of the vaccine remain the responsibilities of individual physicians and health officers."<sup>21</sup> By withholding from doctors the knowledge needed to make an intelligent, informed decision, the USPHS in effect was converting doctors into dupes and automaton technicians. This represented a dangerous form of governmental paternalism — some would call it an infringement of the principle of informed consent — in which the PSU decided what public health doctors and the public should know or not know. Plato would have likened the PSU to the 5th Century B.C. Greek doctor who took care of slaves and was very presumptuous and tyrannical in contrast to the doctor who attended freemen and was persuasive rather than dictatorial (Plato *Laws* Book III, 720 Jowett). The fact is that many epidemiological gimmicks and recurrent false health slogans were used by the P.S.U. to mislead colleagues and recipients of the vaccine.

In a deposition Dr. Langmuir gave at one of the Cutter trials he properly defined the science of epidemiology as follows:

The epidemiologist deals with the observations and associations that he finds from the cases in the field, and regardless of the findings in the laboratory concerning presence or the absence of

live virus in the vaccine, it wouldn't change my judgement regarding my analysis of the epidemiological evidence.<sup>22</sup>

One of Langmuir's major transgression of the science of epidemiology was to redefine the diagnosis of paralytic polio (PP). The pre-SV, World Health Association definition of PP as weakness of any degree as detected by two examinations spaced 24 hours or more apart was replaced with a new definition restricted to those cases who had residual PP after 60 days. This reduced the number of PP cases by over 50%, not by virtue of the effectiveness of the SV but by a stroke of the pen.<sup>23</sup> Furthermore, no attempt was made to follow-up on acute non-paralytic polio cases to see if undetected muscular paralysis was present. Apparently, in Dr. Langmuir's eagerness to prove effectiveness, he was indifferent to the fact that any paralysis, even transient, was a clinical index to the presence of live virus in the SV just as much as those who had residual paralysis. In this as elsewhere, Dr. Langmuir failed to carry out his own description of the function of the PSU to collect all "pertinent information."

In the November, 1955 issue of the *Bulletin of the American Association of Public Health Physicians* in an article entitled "The Devil's Advocate and the 1955 Salk Poliomyelitis Vaccine Program," I described and defined the Salk Vaccine Post Inoculation Poliomyelitis Phenomenon (SVPIPP) as a pre-seasonal rise of poliomyelitis cases following SV inoculations which subsided before the onset of the polio season. This phenomenon, first discovered in Illinois, was found in Pennsylvania, Louisiana, California, Idaho and other states.<sup>24</sup> This *Bulletin* was distributed at the Annual Meeting of the Public Health Association held in Kansas City in November of 1955 and was available to all of the participants of a panel evaluating, or more properly, defending the SV. Dr. Langmuir was also there. During the meeting some U.S. public health officers singled me out thanking and congratulating me for the exposé.<sup>25</sup> It was later distributed nationwide to colleagues and to correspondents overseas. Subsequently, several local health officers (e.g. Brookline, Massachusetts and Denver, Colorado) wrote to say that it occurred in their jurisdictions.

In December, 1955 and early in 1956, the SVPIPP received unexpected support from Germany. First, I received an urgent request from Professor Dr. H. Redeker, President of the West Germany Federal Health Ministry, for the Annotated Notes of the Devil's Advocate article which appeared in the December, 1955 issue of the *Bulletin*.

This was forwarded. In return, early in 1956, Dr. Redeker mailed to me his 86 page document which independently, and more thoroughly, confirmed the SVPIPP. It was labelled Part B and was accompanied by two tables and twenty-two charts and was entitled "Experiences with the Salk Vaccine in the United States and a Critical Evaluation of the Results."<sup>26</sup> He not only confirmed the SVPIPP in the United States as a whole but detailed it in 12 states, and in Hamburg and Berlin in which the SV was used. He also found signs of it in the *Francis Report* on the 1954 Field Trials.

This document was part of a larger study written by seven leading German virologists, both of which were suppressed by the West German Minister of the Interior. It is not known what specific pressure and by whom caused the German government to suppress this report. The general impression was that the US played a role. Notwithstanding, we had the Redeker Report (Part B), which he made available to me, translated and distributed to colleagues. What Dr. Redeker induced from American epidemiologic data was either not induced by the PSU or ignored. That it did this fit in with their goal of keeping the Salk vaccine program viable even though it caused deaths and paralysis in many recipients and their family and community contacts. Presumably it permitted itself to hold on to the belief that the benefits exceeded the risks. What must be kept in mind is that during these very rocky months and years very few medical scientists felt they were in a position to publicly disagree, since virtually all virologists in the field of polio virus research were dependent on the NFIP for their research grants. In general they had to be beholden to NFIP policies. Those working for the USPHS were also under comparable constraints.

It was not until the early 1990s, that a restricted, confidential 17 page report submitted by Dr. Langmuir September 6, 1956 was uncovered through the Freedom of Information Act. The report was an answer to a July 25th request from his superior in the National Institutes of Health to comment on the Maryland pre-seasonal paralytic polio cases that followed the Salk vaccinations. Dr. Langmuir concluded that "In Maryland . . . 15 cases associated with [a particular lot of the Salk vaccine other than Cutter] occurred under circumstances which can only be accounted for on the basis of infective amounts of live virus being present in the vaccine."<sup>27</sup> In his covering letter he stated that he was reluctant to pursue such matters further since his personnel were placing "special emphasis on evaluation of the effectiveness of the vaccine."<sup>28</sup> The admission of the USPHS that another

firm's vaccine besides Cutter caused paralytic polio was elicited only upon request by a superior and the information was never released to the medical profession and the public. This enabled the USPHS to maintain the fiction that the only unsafe vaccine marketed had been Cutter's. To this day the USPHS still maintains this charade. The adjoining chart of the *Maryland State Department of Health Monthly Bulletin* shows how self-evident it is that the SVPIPP occurred in Maryland in May, 1955. Both the Maryland Health Department and the PSU ignored this occurrence in their end of the year reports.

Perhaps it would be appropriate in closing to quote Congressman J. Percy Priest who spoke at the Albert Lasker Journalism Awards Luncheon, May 24, 1956. The *New York Times* reported him as saying that the federal government should keep citizens informed on medical research and not try to hide "uncomfortable scientific facts or controversies." Congressman Priest stated further that in the previous year (1955) many responsible persons had felt that the public should be spared the ordeal of "knowledge about controversy." In 1955 Congressman Priest had ordered and chaired a full investigation of the vaccine controversy.

A further installment of the Untold Vaccine Story and the workings of the PSU will appear in the next issue of *CF*.

#### REFERENCES AND NOTES

1. Root, Lin. The polio gamble. *The Reporter* (Max Ascoli, Editor), July 14, 1955. In it she quotes William J. Laurence, science reporter of the *NY Times* as follows: "I've never seen a report of this importance more calculated to mislead people."
2. *Ibid.*
3. It should be noted that the states of Idaho and Utah had lower natural immunity to polio compared to the more highly urbanized eastern and midwestern states in which polio immunizing epidemics were more frequent. Customarily, one clinical case of poliomyelitis subclinically infects and immunizes one hundred or more others.
4. Shaughnessy, Howard B. (Ph.D., Chief of Laboratories, Illinois Department of Public Health) Personal Communication.
5. Scheele, Leonard H. (Surgeon-General of the Public Health Service) *Technical Report*, June, 1955. (See also *Child and Family*, 19:208-209, 1980 & 20:264-65, 1988).
6. Langmuir, A.; Nathanson, N. & Hall, W.J. *Current Report on Poliomyelitis Surveillance*, 5/29/56. A report prepared for presentation at Section on Preventive and Industrial Medicine and Public Health, American Medical Association, Chicago, June 4, 1956.
7. Ratner, H. The devil's advocate and the Salk vaccine program. *Bulletin of The American Association of Public Health Physicians*, Vol. 2, No. 5 (Nov.), 1955, pp. 3-8; Vol. 2, No. 6 (Dec.), 1955, pp. 5-8. Reprinted in *Child and Family*, 20:143-44, 1988.



8. If "safe" means "free from harm or risk" (Webster) what does "safer" mean in the lexicon of science? It simply means that what was dangerous to begin with is now less dangerous.
9. a) Technical Committee on Poliomyelitis Vaccine. Interim report. *JAMA*, 159:1444, 1955. (See *Child and Family*, 19:201, 1980.)  
b) Ratner, H. Poliomyelitis vaccine. *JAMA*, 160:231-232, 1956. (Reprinted in *Child and Family*, 19:281-285, 1980.)
10. *Ibid.* The pre-November 11 SV was highly effective (initial vaccine-caused paralysis cases excepted) because of the presence of small amounts of live virus. The post-November 11 filtrated SV, though more or less "safe", was highly ineffective. The USPHS never succeeded in getting safety and effectiveness in the same vial.
11. *Supra* 9.
12. Ratner, H. The untold vaccine story: The Chicago epidemic. *Child and Family*, 20:322-327, 1988.
13. Langmuir, A. Inactivated virus vaccines: Protective efficacy. In *Poliomyelitis: Papers and Discussions Presented at the Fifth International Poliomyelitis Conference*, J. B. Lippincott Co., Philadelphia, 1964, p. 105.  
"The increased incidence of poliomyelitis in the United States during the past 2 years has been a sobering experience for health officers and epidemiologists alike. Many had enthusiastically anticipated a progressive disappearance of this disease following the introduction and the general use of Salk vaccine in 1955. However, during 1959 more than 5,000 paralytic cases occurred. The figure is 50 per cent above that of 1958 and more than double the figure for the record low year of 1957.  
"This rising trend has appeared in spite of the continued use of Salk vaccine which had cumulated to a total of approximately 300 million doses distributed in the United States by the end of 1959. Clearly, the control of poliomyelitis is unfinished business."
14. *Ibid.*, p. 110. Langmuir extols the long duration of immunity conferred by the SV on the basis of a four-year follow up on the 1955 vaccinated 7 and 8 year old group. But the vaccine used in early spring, 1955 had demonstrable live poliovirus in it and hasn't been on the market since.
15. *Drug Topics*, Sept. 2, 1957.
16. North Carolina, California and others followed.
17. Ratner, H. *A critical review of the Salk vaccine program: Epidemiological Considerations*. Unpublished Study, pp. 1-71, 1956.
18. Carter, Richard. *Breakthrough: The Saga of Jonas Salk*. Trident Press: New York, 1966.
19. John R. Paul, M.D., Professor of Preventive Medicine, Yale University Medical School. Serological epidemiologist.  
John F. Enders, Ph.D., Head, Department of Bacteriology and Immunology, Harvard University Medical School. Nobel Laureate, 1954, for development of poliomyelitis tissue culture methods.  
William McD. Hammon, M.D., Head, Department of Epidemiology and Microbiology, Graduate School of Public Health, University of Pittsburgh. Authority on prophylaxis of poliomyelitis with gamma globulin.  
Howard J. Shaughnessy, Ph.D., Chief of Laboratories, Illinois Department of Public Health.
20. David Bodian, M.D., Poliomyelitis Laboratory, School of Hygiene and Public Health, Johns Hopkins University. Authority on immunogenesis and pathogenesis of poliomyelitis.

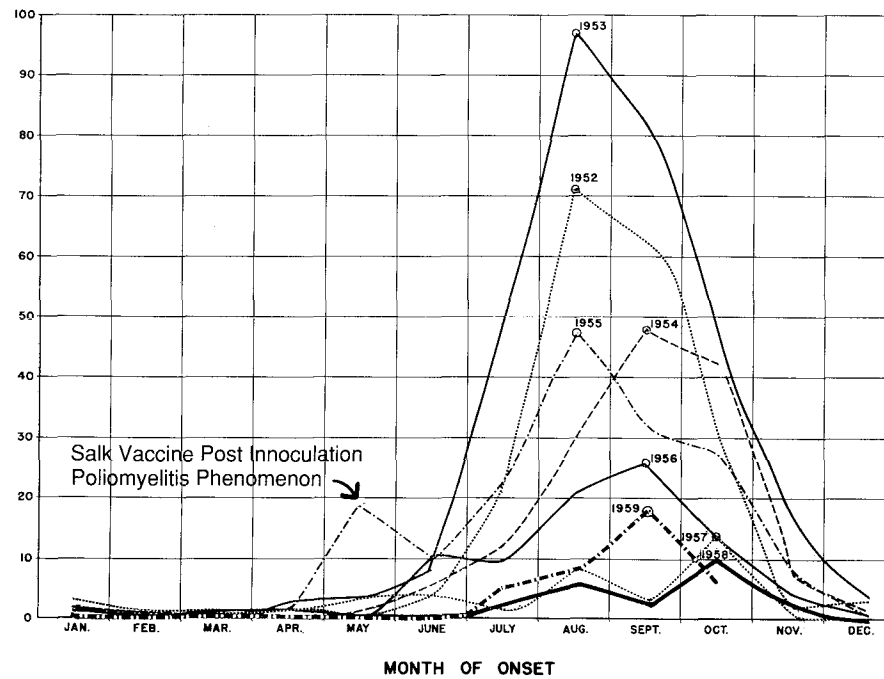
21. Scheele, L. & Shannon, J. Public health implications in a program of vaccination against poliomyelitis. *JAMA*, 158:1258, 1955.
22. Langmuir, A. Deposition in the Superior Court of the State of California -- Brian John May vs. Cutter Laboratories, June 13, 1960, pp. 42-43.
23. *Supra* 9a, p. 203.
24. *Supra* 7, pp. 145-149.
25. Their response was of interest in the light of a story on the USPHS that was published in *Newsweek*, July 30, 1956. It was entitled "Unhealthy Sequence" and recorded that a "Secret revolt is seething in the USPHS. Since June, 1955 the service has lost 240 doctors through resignation. Of the young interns...only 20% have decided to stay... 'Recruiting'...has gone haywire.' Following the resignation in late June of Surgeon General Leonard A. Scheele...word leaked out that the 158-year-old service was in real trouble."
26. Redeker, Dr. Experiences with the Salk vaccine in the United States and a critical evaluation of the results. Report of the Federated Health Board of West Germany, pp. 1-86, 22 charts, Coblenz, West Germany, Feb. 1956.  
 Later a summary of Part A of the 400 page German evaluation of polio was published in the *Munchener Medizinische Wochenschrift*, April 6, 1956. See the conclusion of this report in *Child and Family*, 20:60, 1988.
27. Langmuir, A.; Nathanson, N. & Hall, W. *The Wyeth Problem*. Prepared by the Poliomyelitis Surveillance Unit, Epidemiology Branch of the Communicable Disease Center, Dept of Health, Education and Welfare, 9/6/55.
28. Langmuir, Alexander D. Cover letter for the report described in note 27. The letter was addressed to the director of the National Institutes of Health and dated September 6, 1955.

Are we so socialized that we must argue that saving five children at the expense of two who are killed who otherwise would have lived is a legitimate move? There are persons who so argue and who are even surprised that there is disagreement. All proper medical men and a large number of others will realize immediately that this outlook, whatever its social propriety, impropriety, or inhumanity, sets up a dictator, a man whose decisions are sacrosanct, the man who decides to kill some to save others. (*California Medicine*, November, 1955)

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**PARALYTIC POLIOMYELITIS CASES IN MARYLAND 1952 – 1959**  
 (Maryland State Department of Health Monthly Bulletin, November, 1959.)

**REPORTED CASES**



*Child  
and  
Family*

# An Untold Vaccine Story

(CONTINUED)

IN 1955 the National Foundation of Infantile Paralysis (NF)—the March of Dimes organization—launched a nationwide immunization program against poliomyelitis thereby marking the year as the most distressing year in the history of twentieth century American medicine. The NF had selected, developed, and subsidized Salk's Inactivated Poliomyelitis Vaccine (SV), a vaccine which turned out to be inadequately studied, seriously flawed and prematurely introduced. When effective, SV was unsafe because of the presence of residual virulent live poliovirus; when safe SV was ineffective because of the excessive removal of poliovirus antigen. It was a year of withholding vital information from physicians and the public. The immunization program was abetted by the United States Public Health Service (USPHS), which licensed the vaccine on April 12, 1955 the same day the Francis Report of the 1954 field trials claimed it to be "effective, safe and potent" on a national telecast from Ann Arbor, Michigan. However, the scientific study on which this claim was

made was not made available to the USPHS at the time. The USPHS's Poliomyelitis Surveillance Unit of the Centers for Disease Control also abetted the program but instead of using the tools of epidemiology to safeguard the health and life of the people, it used the tools to make failure look like success. Perhaps it is more to the point to state that a reluctant and nervous USPHS was browbeaten into maintaining the overpublicized program because it was overshadowed by a powerful voluntary health agency's program whose president at the time, the dynamic Basil O'Connor, was a dominant national medical figure. His highly skilled promotion and promulgation of the national Salk vaccine program exemplified what was described in the Center for the Study of Democratic Institutions' 1962 American Character Critique of American Medicine as "mass manipulation by hand-selected, well subsidized, overly committed scientists backed by powerful public relations departments of wealthy national health agencies" (CF 11:10).

The *Devil's Advocate* article (DA) which follows documents in part the deceptions, self-decep-

verse. Human infancy is governed by natural law but it has its own significance. Montessori writes, "The child is born amidst love, his very origin is by love, and once born he is surrounded by the love of the mother and father. This love which parents make is natural; it makes joy . . . it does not feel sacrificial." Thus the presentation of "sex education" is really an education for love and not merely an exercise in avoiding pregnancy out-of-wedlock or how long to kiss without succumbing to temptation.

If a child witnesses from early childhood the respect and compatibility of his parents; their tenderness, their affection—these will be the most significant exam-

ples of serious and beautiful relations between a man and woman. But the "book of nature" then takes the family experience of love and being loved into a wider, more universal understanding that no matter what the norms may be for a sick society—nature teaches us that the spiritual task of making babies and raising our young is a most definitive act. This gives a kind of sanity and hope for the future. Human love then becomes not a lesson by imperative or the law—but rather our reason for existence which goes to the essence of what it means to be human in relation to the natural world which is our best teacher and our most enlightening subject. □

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*Editor's Comment:*

Sorokin, the famous Harvard sociologist, introduced the concepts "sensate" and "ideational" to the analysis of historical social systems. The sensate culture is characterized by materialism and sensualism and an inability to sustain a viable society. Today we live in a sensate culture marked by widespread sexual promiscuity and a sex addiction not unlike the addiction to drugs, and by sex educators who, with the exception of unwanted pregnancies and sexually transmitted diseases, teach value free sex in the schools. With the claim of reducing pregnancies and disease,

their educational programs are easy to foister on anxious and unreflecting parents. The preceding six articles critiquing current sex education programs, one by implication, are offered as an antidote. The authors, each of high standing professionally, are not dismissable by *ad hominem* aspersions. None are rigid religious fundamentalists, pro-life zealots, Comstockians or fanatics of any kind. They speak from a wide educational background and with the wisdom of the well educated adult. They speak up because they recognize a bankrupt program which is doing much harm to our youth and society. HR

tions, subterfuges, half-truths and double talk which backers of the vaccine employed in their attempt to keep the SV program viable throughout 1955 and thereafter. It is the third of a continuing series of reprinted articles and documents published in *Child and Family (CF)* whose aim is not only to correct an infamous chapter in the history of science, but also to increase the sophistication of the public in regard to nationally instituted health programs, and to awaken physicians working in national health agencies to the danger of becoming mere dutiful instruments of high echelon establishment thinking. The series also intends to help physicians protect their patients, to whom they have a primary obligation, from the blandishments of national voluntary and governmental health agencies and drug companies and from the bandwagon enthusiasm of the mass media.

The crass manipulation of the public by establishment professionals in 1955 was a turning point in the history of modern medicine. It was a time when activism was substituted for a re-examination of assumptions, and when expediency superceded courage and truth. It requires courage and honesty to discontinue a highly publicized program once started. Not to do so, however, may have long range deleterious consequences and set a corruptive example for generations. This is illustrated by the Asian Flu vaccine program of 1957

when the United States Public Health Service (USPHS) foisted off on doctors and the public 50 million doses of poor potency vaccine to combat a mild epidemic which had almost run its course. The promotion's main purpose seemed to have been to protect the financial interest of the vaccine manufacturers. The lack of courage to correct an earlier decision is also illustrated by the Swine Flu vaccine program of 1976. Here a widely promoted and widespread immunization program was still continued for months even after it had become evident that a Swine Flu epidemic would not materialize. The vaccine subsequently resulted in paralytic side effects in significant numbers of recipients. Another example, this one at the level of a voluntary health agency, is the continuation of Planned Parenthood's program for reducing teenage pregnancies, a program that is bankrupt and whose chief justification seems to be the protection of the jobs of numerous public relations and clinical staff personnel.

With the AIDS threat upon us, the untold story of the polio immunization program of the fifties is more topical than ever. Having Dr. Jonas Salk, who better than anyone else knows the pitfalls of a vaccine rushed to market, state at a recent meeting of leading AIDS researchers that stronger leadership by the Federal Government is needed if a vaccine is to be developed quickly and having him

ask, "Where is the Basil O'Connor for AIDS?" (*New York Times*, 3/31/87) is both alarming and foreboding. Even Dr. Shannon of the USPHS, who had originally been a backer of the SV, admitted six years after its introduction that "a substantial number of vaccine candidates were placed at serious risk" by the premature introduction of the Basil O'Connor sponsored SV. Shannon's discussion of the 1955 SV mistake is reprinted in this issue of *CF*. Surely we do not want this mistake to be repeated with an AIDS vaccine which, if it were to cause AIDS, would be more deadly than the SV that caused poliomyelitis.

Our interest in the SV which led to the subsequent writing of the *Devil's Advocate* article came from the decision by the Oak Park, Illinois Health Department (OPHD), of which I was then the full-time public health director in the spring of 1955, to delay by three weeks the beginning of its vaccination program. The prime reason for postponement was that the OPHD believed that to be asked to consent to the vaccination, parents deserved something more substantial than the April 12, 1955 telecast from Ann Arbor, about which the *New York Times* wrote, "The formal verdict on the Salk Vaccine was disclosed today (April 12) amid fanfare and drama far more typical of a Hollywood premiere than a scientific meeting" (5/13/55). William Lawrence, the *Time's* science writer, stated, "I've never seen a report of

this importance more calculated to mislead people" (*Editor & Publisher*, April 16, 1955).

The telecast created a parents' stampede for the vaccine. For reasons not made public at the time, there was a shortage of the vaccine. The supply was sufficient only to launch NF's free national vaccination program for first and second grade elementary school children. Whereas other health jurisdictions overwhelmed by media pressure and tempted by the opportunity to impress tax payers had rushed into the immunization program, the OPHD delayed immunizations so that parents could ask questions of a public health official in a setting conducive to sober inquiry. Moreover, delaying the start of the program by several weeks could prove advantageous by learning from the experience of others who had given the vaccine.

During the week of the eleven meetings (April 25-28) the news broke Wednesday noon, April 27, that six cases of paralytic polio (PP) had developed after SV immunization: five in California and one in Chicago—the lot number of the vaccine was the same in each case. At this time the OPHD was the only health jurisdiction in the U.S. which, although it had stocked the vaccine, had not as yet administered it. All first and second graders in the state of Illinois, for instance, had been vaccinated. In Oak Park the eleven sessions held with parents during the week of April 25 had dis-



turbed parents as well as school and village officials and created adverse newspaper publicity. Though I had not opposed the SV, it was claimed that the discussions left parents uncertain and confused. Interestingly, news of the outbreak of PP following the vaccinations came from a Chicago newspaper science writer, Arthur Snider, who had covered an Oak Park parent session the day before to see what the fuss was about. In a telephone call to me he confided, "You are more right than you know."

The unexpected outbreak of six cases of PP following vaccinations foreshadowed an impending catastrophe. Other cases were subsequently reported. This forced the USPHS to take action. Rather than suspending the entire program, the agency banned the use of the one manufacturer's vaccine which was obviously implicated. That decision resulted from the Surgeon General's emergency telephone poll of his consultants. Later, one consultant who had never been told of past manufacturing difficulties in producing a safe vaccine, the knowledge of which was restricted to an inner group of NF and USPHS experts, informed me that had he known of the previous problems he would have voted to suspend the entire program (Howard J. Shaughnessy - Personal communication). The widening outbreak of cases enabled the OPHD to postpone the start of its vaccination program from May 2 to May 9, four weeks

after the rest of the country had begun vaccination. During this time, promotion of the vaccine continued unabated with mass media daily reiterations that the SV was "safe and effective." Even President Eisenhower was pressed into service to give his assurance over national television that the vaccine remaining on the market was "absolutely safe." The OPHD became the target of a concerted attack from other health officials, who had already given the vaccine. Pressures developed locally and ultimately led to the demand publicized by a local newspaper that the OPHD director be replaced. Fortunately, as cases of PP mounted the USPHS suspended the entire program on May 7. This saved my job and thereafter gave me the freedom and some protection to continue my objective evaluation of the SV and the SV program.

Though the national vaccination program was not fully restored until May 24, continuing difficulties in producing a vaccine which was simultaneously safe and effective persisted (see CF 19:281-4) as did the controversy over SV. The debates, most of which went on behind closed doors were cloaked by a steady barrage of public reiterations that the vaccine was safe and effective. Any public health officer who had doubts about the SV and who had to defend his position and post now found it necessary to keep knowledgeable of the true facts in order to survive. The

many hours devoted to the unravelling of the events of the year resulted in the *Devil's Advocate* article (*DA*) which was published November 1, 1955. It was the only major critique of the SV published in the U.S. that year. It was widely distributed at the Annual Meeting of the American Public Health Association, November 14-20, 1955, a highlight at which a panel of prominent SV advocates was to report on the turbulent course of the past year. Since the establishment experts reaffirmed their "faith" in the safety and effectiveness of the vaccine, it should not come as a surprise that the *DA* critique was ignored at the meeting and the author studiously avoided not only by polio luminaries but by science writers and the mass media as well. The latter preferred the conference statements of establishment figures and public relation handouts of the NF and the USPHS. No one seemed to be interested in questioning their pronouncements and releases. Furthermore, public health physicians and health department personnel attending the meeting, who had earlier executed widespread vaccination in bursts of glory and who had establishment backing, were not interested in hearing that the vaccine actually used was, in large part, either unsafe or ineffective. In this connection it should be noted that research by the majority of virologists in the U.S. was funded by the NF and that the researchers

thought it prudent to remain silent so as not to jeopardize future grants. Later, however, Maxwell Finland, an editor of the *New England Journal of Medicine* and a leading authority on infectious diseases, did invite me to prepare an article for the *New England Journal of Medicine* based on the *DA* article.

Officers of the USPHS not associated with the department's SV program were one major exception to the negative response of people attending the meeting. One after another singled me out to thank and congratulate me for the exposé. Later *Newsweek* reported July 30, 1956, on an "unhealthy sequence" to the SV fiasco stating that a "secret revolt is seething in the U.S. Public Health Service. Since June, 1955, the service has lost 240 doctors through resignations." Additional support came to me in personal letters from international experts and others.

The *DA* article not only received the cold shoulder at the APHA meeting by the public health establishment, but it resulted in my being fired as editor of the *Bulletin of the American Association of Public Health Physicians* at the very next meeting of the Executive Board of the Association. The President of the Association was the Public Health Director of the State of Florida and deeply supportive of the SV program. Three officers of the USPHS abstained from voting. Another member of the Exec-

utive Board, who was the president-elect, had earlier been told by the leading manufacturer of the SV for whom a major investment was at stake that if the editor wasn't replaced, he himself would be replaced as the public health director of the city in which the manufacturer was located.

The blow by blow account of the events of 1955, of the government threats that were made, and of the voices of support that emerged, many of them international, will be recounted in subsequent issues of *CF*.

Telling the story of the early history of the SV is imperative not only because it will reveal and correct one of the saddest chapters in the history of American science, but also because it will alert the public that health is not sacrosanct or free from vested interests. The traditional grandeur of the learned profession of medicine cannot be taken for granted. It has to be earned by every new generation of physicians.

For those who find it difficult to believe that the *DA* account of what happened in 1955 is true, namely, that an unsafe SV which was responsible for setting off epidemics of poliomyelitis was permitted to remain on the market, and that physicians and laity were kept in the dark as to the SV's defects, two companion pieces join the *DA* article in this issue of *CF*. One is a 1961 paper by Dr. James Shannon of the USPHS referred to above which

recounts how the prematurely introduced SV placed "a substantial number of vaccine candidates . . . at serious risk." In 1955, however, with the same insider's knowledge that had led him to condemn the SV in 1966, Shannon voted at a crucial congressional hearing with the majority to continue the SV immunization. He could have voted with the minority to immediately discontinue the program so that the serious problems associated with the SV could be resolved. Had he done so, he would have joined the distinguished, independent company of Nobel Laureate John Enders of Harvard whose pioneering work in polio made future polio vaccines possible, as well as William McD Hammon, an outstanding epidemiologist from the University of Pittsburgh where Dr. Jonas Salk did his work, and Albert B. Sabin of the University of Cincinnati whose attenuated live poliovirus vaccine was to replace the inadequate Salk Vaccine in 1961.

The second companion piece to the *DA* article is a letter from Prof. Dr. Redeker (R), President of the Federal Health Ministry of West Germany, which was mailed from Koblenz March 26, 1956. His letter confirmed what several of us suspected, i.e., that there were outside pressures which suppressed the Health Ministry's comprehensive critique of the Francis Report and the SV. Here I quote from my letter to Professor David D. Rutstein of Harvard University Medical School writ-

ten prior to receiving R's letter.

I particularly want to call your attention to the suppression by the West German Minister of the Interior of a 400(?) page critical survey of the Salk Vaccine made by seven leading West German authorities on the invitation of Prof. Dr. Redeker of Koblenz, President of the Federated Health Departments. This was done last February. One wonders whether the State Department or the Army has anything to do with the suppression. At the least, it seems scandalous that a scholarly study which bears on the health of American children has not been obtainable for our consideration by American authorities. . . .

Prof. Redeker sent me his contribution early summer [actually early Spring]. It is 86 single lined mimeographed pages. It seems to do a pretty demolishing job of [the work of] Drs. Francis and Langmuir. In it he confirms—independently—the SVPIPP [Salk Vaccine Post Inoculation Poliomyelitis Phenomenon] including the charts of numerous states in this country illustrating the phenomenon. I finally have gotten it translated and expect to receive the translation in long hand the middle part of next week [Nov. 30, 1956].

The events leading up to the receipt of R's letter started with an

air-mail request from R. on December 1, 1955 that I send him "as soon as possible," the bibliography for the *DA* article. It was sent to him in early April. R. responded by mailing his section of the complete Ministry of Health study, an 86 page document labelled Part B accompanied by two tables and twenty-two charts and entitled *Experiences with the Salk Vaccine in the United States and a Critical Evaluation of the Results* (see *CF* 19:275 Note 37). R's analysis independently confirmed the Salk Vaccine Post Inoculation Poliomyelitis Phenomenon (SVPIPP) described in the *DA* article. Whereas I illustrated the phenomenon in five states, in what was a preliminary report, R. demonstrated the phenomenon in ten to twelve states. He also detected the phenomenon in the Francis Report on the 1954 Field Trials.

Later, in response to directives by the Secretary of the Interior issued in the Bulletin of the Federal Government on February 16, 1956, "which led to misunderstandings" by the readers, R's seven collaborators published, independently of the government, an article entitled, *An Evaluation of the Protective Immunization against Poliomyelitis* in *Münchener Medizinische Wochenschrift*, April 6, 1956. The immediate response of American officials to this article was to denounce and belittle its conclusions which were critical of the SV. The critical findings that affected the life

and limbs of American children were ignored.

The Army of Occupation response is reported in a *New York Times* story from Frankfurt, Germany dated April 14, 1956. It stated that "Seven West German medical advisers say U.S. & German children inoculated with Salk Vaccine or a German serum may have been turned into spreading of Polio." The story then quoted two Major Generals holding top medical posts who preemptively stated that "All research to date has shown the vaccine to be safe and effective." These generals, who would know next to nothing of the difficulties the USPHS and the NF were having regarding safety and effectiveness of the SV, simply echoed the establishment line. In actuality the vaccine the army was using at the time was potentially unsafe and could not have conformed to the new safety requirements promulgated in November 1955.

More illustrative of the American party-line, brushing off the German condemnation of the SV, was the automatic response of Dr. David E. Price (P), acting chief of the USPHS. Though admitting in the *Chicago Sunday Tribune*, 4/15/56, that, "He was not familiar with details of the situation in Germany and could comment only on experience in the U.S.," P. went on to say that there was "great public and professional confidence" in the SV and that there is "overwhelming evidence"

that the SV was "safe and effective." This was in contradiction to the German report, unread and unstudied by him, which concluded that the "mass inoculation in the United States in 1955 resulted in what possibly was the greatest 'catastrophe' in the history of protective inoculations."

For P. to respond as above could only mean that he was either abysmally ignorant of the problems associated with the manufacture of the SV at the time, or if not ignorant felt himself justified in using the big lie. It was the use of the term "overwhelming" which made it a big lie since not even ardent establishment experts advocating the SV would have made that claim. Indeed, at that time the Massachusetts State Polio Advisory Committee, which consisted of 22 leading physicians including two Nobel Polio Prize winners, took a contrary position. In a statement published in the *New England Journal of Medicine* (12/1/55) the Committee concluded: (1) there was no assurance "that all viral infectivity had been destroyed" in the SV; (2) that safety tests were not dependable; and (3) that the highly virulent Mahoney polio virus strain remained a component of the SV despite the unanimous opinion of experts testifying before Congress (*Priest Report*, June 22 & 23, 1955) that the strain should be replaced since with it the SV was not only a threat to inoculated persons but also caused inoculated persons

themselves to become a source of infection to household and community contacts. Furthermore, many European countries who had planned or started SV immunizations dropped their plans because of the American difficulties with the SV. For example, the *Chicago Tribune* reported that Britain "has rejected the American Salk anti-polio vaccine in its present form as being too dangerous and has cancelled plans for trying it out" (7/16/55). P's other gross exaggeration was that there was "great public and professional confidence" in the SV. The truth, however, was that the public was refusing vaccination in large numbers and that professionals not beholden to the USPHS or the NF were increasingly voicing their distrust of the SV.

The political reason for rejecting the German study given by P., when he stated that the acceptance of the German criticism of the SV would play into the hands of the West German communists and their "Ami [American] Go Home" campaign, reveals the tactic the US employed to bring about the suppression of the German report as indicated by R. That it indeed had been suppressed became evident at the time. During an attempt to get a copy of the issue of the publication containing the indictment of the SV by the seven German experts, an agent representing German periodicals reported back to me that remaining copies of the

issue were stamped "Secret" and were not available. For an internationally respected German medical periodical to have one of its issues suppressed was virtually unheard of. Clearly it was an action taken by the Minister of the Interior of Germany who was under pressure to do so.

As R. indicates in his letter, the attack came from industrial special interest groups who were in some way involved in the SV. Presumably this included the German manufacturer of the SV since a large investment and large profits were at stake. The special interest groups may or may not have included the NF. It was reported that Doctors Thomas Francis Jr. and Robert F. Korn of the Francis Report, whose work was sponsored by the NF, went to Germany at the time. In the November 30, 1986 letter to Professor Rutstein of Harvard I also observed "... it seems scandalous that a scholarly study which bears on the health of American children has not been obtainable for our consideration by American authorities. I also know that Drs. Francis and Korn were sent to Germany to liquidate—silence—or answer the opposition—one hardly knows the verb to be used."

That West Germany bowed to pressure from the U.S. at that time is understandable. The fear of the Russian threat overlaid Germany and she was utterly dependent on the U.S. for protection. From 1949, when West Germany introduced its own consti-

tution, until 1956 the Communist Party maintained a 6 to 7 percent vote in the West German parliament. On May 5, 1955 West Germany became a sovereign state and in 1956 banned the Communist Party. It was the hot point of the cold war and was the year that Hungary (and Poland) revolted and the Russians countered with Soviet tanks. In this atmosphere the mention of a Communist threat justified virtually any action by the German government. The fact is that the USPHS

made no attempt to make R's Health Ministry collective study available in the U.S.

None of the foregoing suggests that the USPHS and the NF were interested in being candid with the public which was being injected, nor with physicians who were doing the injections. On the contrary it is not too harsh to say that the attitude of the USPHS was callous and was characterized by an elitist and rationalized disregard for the principle of informed consent. □

*Child & Family*, 20:59-60, 1988

PROF. DR. REDEKER

## A German Official Indicts the Salk Vaccine

Translation of a letter from Dr. Redeker, President of the Federal Health Ministry, West Germany, mailed from Koblenz, March 26, 1956

March 26, 1956

Most honored Dr. Ratner!  
Your reports at the convention of medical administrators and your kindness in sending me your collection of literature have rendered me a great service. On the basis of a mathematical-statistical analysis of the Francis Reports, I myself had already arrived, in late

summer of 1955, at the same conclusions to which you had come on the basis of your experiences with the mass vaccinations in 1955. In September 1955 I reported in Stuttgart on this analysis of the Francis Reports in detail. Since then I am the target of a counter-propaganda directed by involved industrial special-interest groups. The inability of the American scientific press to recognize these weaknesses in their evaluation of the Francis Reports was for me a cause of continuous brooding until your report of December 1955 came to my attention.

In January 1956 we submitted here a comprehensive evaluation dealing with the complex of problems inherent in polio vaccination with formalin-inactivated virus. The pertinent ministry has been unable so far to bring itself to publishing this report, which comprises about 400 typewritten pages, for reasons that by no means lie in a scientific rejection of the views presented in our report. For this reason I cannot yet send you a copy of this evaluation. However, I am taking the liberty of sending you from this evaluation an excerpt which I have written myself and which deals with the current situation of the critical evaluation of the American vaccinations.

I should like to emphasize that our evaluation (as well as all the scientists who participated in it) affirms the fundamental principle of a preventive vaccination

against polio, and that we look upon the development of a perfect and effective vaccine optimistically and with the greatest hope. We believe, however, that this development cannot occur when it is being fostered by some industrial or other agency working in isolation and excluding, more or less obviously, free scientific examination and cooperation. Replacing free scientific critique and review with a propagandistic implementation of a certain stage in the development of the vaccine seems to us particularly dangerous. We are convinced that, despite these difficulties and delaying tactics, the development of immunization against polio can and will be continued to the point where it will become a blessing for humanity.

My best greetings, and again many thanks for your support.

Yours faithfully,

1. The mass trial conducted in 1954 in the U.S.A. did not establish the effectiveness or safety of the vaccine. 2. The immunization incidents of 1955 cannot be traced exclusively to one manufacturer. There exists no proof that the more stringent manufacturing and control regulations assure the absence of pathogenic viruses in the vaccine. 3. The epidemic development of polio in the U.S.A. during 1954 and 1955 revealed that symptom-free, vaccinated children endanger the environment by the excretion of active virus.

From an independently published summary of the Federated Health Departments' suppressed 400 page polio vaccine evaluation, Eyer (Bonn), Herken (Berlin), Horing (Berlin), Pette (Hamburg), Seiffert (Munich), Traub (Tubingen), Weber (Munich). An Evaluation of the Protective Immunization Against Poliomyelitis—Report of the Scientific Committee. *Munchener Medizinische Wochenschrift*, April 6, 1956.



# The Devil's Advocate and the Salk Vaccine Program: 1955\*

A Contribution Toward an Objective Evaluation

## INTRODUCTION

NOT ALL public health physicians have the certainty that they are receiving an adequate evaluation of the events and experiences that have transpired and are transpiring in connection with the poliomyelitis vaccine program of 1955. Nor have they the certainty that the program is on a solid and secure scientific footing. Without these they cannot proceed with the execution of the program at the regional and local level with the same wholeheartedness and single heartedness that characterizes the national protagonists of the presently constituted poliomyelitis program. To attain this certainty something more is needed than the repetition of verbal reaffirmations of faith or undocumented accounts of safety and effectiveness. Man is a reasoning animal. He has a need to have his questions answered, his doubts resolved, and above all, to know

that all of the facts of a given issue are being placed on the table for examination and evaluation. It is the general purpose of this paper to contribute to the resolution of prevalent uncertainties by pinpointing the need for more explicit, frank and comprehensive expositions. It is the immediate specific purpose of this paper to raise a series of thoughts and questions for the consideration of the panel on poliomyelitis vaccine which will be held at the APHA meeting in Kansas City.

It is disturbing to see scientists prematurely or overly committed to a program. To disengage oneself from a stand once taken is not easy for a human being. Yet, in science, we do not proceed proximately by commitments, by emotions or by faith and dreams. We proceed by reason. If we are to merit the name of scientist, we have the obligation to prescind from our hopes, enthusiasm, aspirations, and even public relations, to pursue objectively and with critical acumen the reality of the

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\*To be published in two parts.

experience we are trying to evaluate. Presumably this is the type of bias that the scientists in charge of the 1954 field trials tried to protect themselves from by their insistence on keeping from everyone but the IBM machine, so to speak, the knowledge of who received the vaccine and who received the placebo. Dr. Francis echoed this thought on May 7th, when, in comparing the carefully planned field trials of 1954 to the stepped up tempo of an accelerated mass inoculation program experiencing difficulties, he stated, "We have always insisted that any work done by the evaluation center was with last year's material and under last year's field trial conditions. (The field trials were conducted) under rigid test conditions. We have never felt that freehand projections could be made on the basis of our studies." (1)

Perhaps it is too much to expect those involved in the promotion of the 1955 Salk Vaccine program to play the devil's advocate. Their hearts and souls are too immersed in their endeavors. Public statements, news releases, and articles distributed have predominantly favored the Salk Vaccine program, practically to the exclusion

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DR. RATNER, at the time of this paper, was Director of Public Health, Oak Park, IL, Associate Clinical Professor of Preventive Medicine and Public Health, Stritch School of Medicine, Chicago, and Editor of The Bulletin of The American Association of Public Health Physicians.

of unfavorable items. One can but wonder parenthetically whether the voluntary and official health agencies do not have the specific responsibility of presenting the cons as well as the pros of a given medical procedure, and whether this isn't the mark that truly distinguishes the scientific from the commercial or partisan organization.

Lest some of the readers think these are picayunish or carping issues, a listing of some scarcely acknowledged items may be in order. We hope they will give the reader an awareness of the existence of a great debate.

1. English authorities in July, 1955, cancelled the Salk Vaccine program as too dangerous. Their director of the Public Health Laboratory Service, Dr. G. S. Wilson, stated, "I do not see how any vaccine prepared by Salk's method can be guaranteed to be safe." (2)

2. All European countries, with the exception of Denmark, have discontinued their programs. Even Denmark is reported to have found live virus in the Salk Vaccine. (3)

3. Canada, who has had no publicized trouble with the vaccine, decided as of July 29, 1955, to postpone its vaccination program until the early part of 1956, in keeping with its earlier prudent approach, to take advantage of expected advances in the development of safe and effective poliomyelitis vaccines. (4)

4. Two Nobel prize winners, Dr. John Enders and Dr. Wendel

M. Stanley, have both publicly indicated their uncertainties about the Salk Vaccine. Dr. Enders, since May 7th, has taken the position that it "is the part of wisdom to wait" in respect to the mass inoculation program. Dr. Enders also stated on June 22nd that he "agreed with everything that Dr. Sabin said" at the public hearings on that day in Washington. (5) (Dr. Albert Sabin has been an outspoken critic of the Salk Vaccine program).

5. The Polio Advisory Committee and health officials of at least one state, and an important state, Massachusetts, have advised against public inoculations and have withheld approval of the use of the vaccine until at least January 1st. (6)

6. Dr. M. V. Veldee of the Stanford Research Institute, a man "well qualified from his long experience in the field of biologic control," (7) has in a letter to the New England Journal of Medicine (9/15/55) concluded, after a long and careful analysis, that in his opinion "the formaldehyde-inactivation method as presently carried out cannot result in a vaccine that meets . . . prescribed standards for product safety. . . ." (8)

7. One of the two major pharmaceutical houses connected with the production of Salk Vaccine since the 1954 field trials, by establishing safety testing standards more stringent than those of the government, has recently found it necessary to withdraw their product from the market be-

cause of the presence of live virus. (9)

8. Leading polio authorities have unanimously agreed that the peripherally virulent Mahoney strain should be removed from the Salk Vaccine. (10) The Salk Vaccine presently being distributed, however, contains the Mahoney strain.

9. Dr. Joseph L. Melnick of Yale, an experienced poliomyelitis worker, stated on September 18th that "it is impossible to say with complete assurance that every lot of vaccine will be totally safe until after it has been used in children." (11)

Finally, to place all of the above items in their proper perspective, we should recall a fundamental principle enunciated by Dr. Salk on June 7th at the AMA meetings in Atlantic City. "The objective in the preparation of a poliomyelitis vaccine cannot include the knowing or willful acceptance of a risk that is tangible, or measurable to any degree. Any risk that is involved, so long as it is recognized, must be corrected, whatever may be its cause." (12)

#### THE HEALTH OFFICER AS DEVIL'S ADVOCATE

It is perhaps proper and logical for a local health officer to undertake the job of devil's advocate. The statements of Drs. Salk (13) and Sheele (14) on June 7th and the Foundation on June 18th (15) make it clear that the local health officer and local physicians have

the responsibility for final decisions on the use of the vaccine. The necessity that these decisions be informed and wise is apparent. The comments and questions that follow are those that have been expressed and shared by many. We think it healthy to record them in writing to make them part of the deliberations of the public health physician. We hope they will aid in resolving existing uncertainties.

Several things should be clear from the onset. The principles involved in the complex, trying and tragic drama that unfolded itself in the spring of 1955 transcend both the disease poliomyelitis and the year 1955. It will be a cause for double sorrow if the future does not learn from the immediate past and present. On a later occasion we hope to pursue this thought further.

As devil's advocate the writer would not want to be misconstrued nor open to any misconstruction that would reflect on the solid achievement of Dr. Salk, or on the self-sacrificing and noble goals of those fighting poliomyelitis or on their earnest pursuit of these goals. To be the man who calls the on the spot shots, in the quickened tempo of multiple pressures, is not easy nor necessarily rewarding. Who is there who would care to say "I could have done better." But a critic has his role to play. To assume that a person is less than infallible in matters of science is merely to acknowledge that he is a human be-

ing, and who would claim to be more?

#### KEEPING PHYSICIANS INFORMED

One must first take issue with the Foundation's July 1955 Report to Physicians on the Salk Vaccine where they commend themselves on their continuing policy of keeping physicians informed. They give as an example of prompt publication the Francis Report which reached the readers of the APHA in the middle of May. The fact is that by the middle of May the Foundation intended that all eligible children should have received their shots, and most of them had. What, therefore, was prompt about the distribution of the Francis Report? The Francis Report actually did make its appearance in printed form on April 12th, but apparently no one saw fit to distribute it in conjunction with the vaccine to the physicians or health officers responsible for giving the inoculations. Box loads of other Foundation materials were distributed. One questions the propriety of imposing upon the medical profession at large, and local health officers in particular, an "enforced" inoculation program in the absence of making available to them the written report on the basis of which the program was presumably launched. Such a failure has the effect of converting the medical profession into slave technicians.

The same point applies to the periodic reports of the Poliomyelitis Surveillance Unit. If the local health officer is responsible for decision making, why is the crucial data collected by the PSU not made available to him? What, also, prevents these reports from being brought out of the category of restricted material and made accessible to scientists at large? It seems the time has come for this. Supplementary deliberations, alternate hypotheses and fresh minds would greatly benefit a full and true evaluation of the 1955 experience.

Finally, we must realize that the Francis Report of April 12th was only a Summary Report. At least one state health director has expressed the need "to have the opportunity to study the detailed record of the experience gained in the vaccine trial program of 1954" and has stated he has "been attempting for some time to obtain this information without a great deal of success." (15\*) A "final complete report" (16) has been promised. It would be advantageous to know when we can expect this final report. Insofar as it casts light on the field trials of 1954, it should contribute to better understanding and better decisions on the part of the local health officer in 1955.

#### *Inoculation of Children 6 Years Old and Younger*

It has been stated by the Foundation prior to April 12th that

"Constructive advance planning had to be done under the assumption that the vaccine was significantly effective, but with full recognition that plans would have to be modified . . . if this did not turn out to be the case." (17) The Francis Report found no significant protection in six year olds and a "progressive increase in the protective effect as age increases." (18) Why, then, was not the Foundation's plan changed to inoculate second and third graders instead of first and second graders? Also, on what clinical evidence are we presently advised to inoculate five year olds, or to extend priorities to the preschool child? It is of interest that the effectiveness claimed for the Salk Vaccine used in 1955 is claimed for eight and nine year olds, but is admittedly slight for seven year olds. (19)

It has been said that the observation pertaining to six year olds "may be related to observation of too small a group." (20) There were, however, more cases of poliomyelitis in the six year old group than in the eight year old group and three times as many cases as in the nine year old group. Furthermore, there were more cases of poliomyelitis in the six year old group than the total number of virus positive cases that permitted the Francis Report to conclude that the vaccine was up to 90% or more effective. (21) This, of course, does not prove that these were not observations on too small a group, but it does prove that this group was

larger than many upon which conclusions were based. Are we ready to reject this conclusion and numerous other conclusions of the Francis Report because the observations are on too small a group?

(to be continued) □

## BIBLIOGRAPHY AND NOTES

EDITOR'S NOTE: The unexpected demand and continuing requests for the bibliography, as well as additional copies of the article, have necessitated the publication of the bibliography. There have been requests for over 300 copies of the bibliography and Bulletin to date. The requests extend from the Honolulu County Medical Library in Hawaii to Der Präsident des Bundesgesundheitsamtes, Koblenz, Germany. It retrospect, this demand is not too surprising.

There has been no project in recent public health history that has so taxed the time and minds of public health physicians as the 1955 Salk Vaccine Program. Neither has there been a project whose evaluation has rested so completely on that which is most central to the specialty of public health; namely, epidemiological analysis. It is in this light that public health physicians recognize that the scientific issues raised by this program are not resolvable in the public press. Ultimately, their solution must be sought in scientific journals.

## INTRODUCTION

1 N.Y. Herald Tribune, May 8, 1955 (AP release from Ann Arbor, May 7).

*This statement was released in the interim between the May 5-6 meetings of the Sub-Committee to Review Minimum Requirements of the Special Committee to Consider Problems Related to Poliomyelitis Vaccine and the report to the nation to be broadcast on May 8th by Surgeon General Scheele based on the recommendations of the Sub-Committee and other considerations.*

2 Time Magazine, July 25, 1955, p. 32. Foreign Letters—J.A.M.A. 159:394, Sept. 24, 1955.

3 *It should be understood here that we are referring to non-experimental mass inoculation programs.*

"The foreign visitors said that with the exception of Denmark production of Salk Vaccine had been suspended throughout Europe."—Chicago American, Nov. 8, 1955.

*One of the two foreign visitors to whom reference is made is Prof. H. Pette, the distinguished Prof. of Neurology of the University of Hamburg, Germany. His sagacity may be measured by an earlier observation: "The author advised to wait with propagation of active immunization against poliomyelitis in Germany until the results of the mass experiment in the USA are known, particularly as the initial enthusiasm from gamma globulin prophylaxis has given*

way to resignation." H. Pette, Vaccination Against Poliomyelitis. International Medical Digest, March 1955, p. 163. Abstracted from Deutsche Medizinische Wochenschrift 79:1664, Nov. 5, 1954.

4 "Resumption of Canada's antipolio immunization program will be delayed until early next year, Health Minister Martin announced today. He said in a statement that . . . Government health authorities and other experts in the field have decided this is the safest . . . way of attaining the objective of about 3,000,000 vaccinated children by the end of next March . . . Mr. Martin gave six reasons for delaying . . . '1 . . . The period of least risk extends from December to late Spring . . . 6. Connaught and the Institute of Microbiology in the next few months will be able to take full advantage of any new production techniques which might be developed as the result of studies now being made in Canada and the United States.' He added that the second phase will be carried out 'in the same orderly, prudent, effective and well-planned manner as this year's inoculations.'"—The Globe and Mail, Toronto, Canada, July 30, 1955.

5 N.Y. Herald Tribune, June 23, 1955.

"The unusual poll was taken before a House Interstate and Foreign Commerce sub-committee where the scientists actually divided 8 to 5 on the safety of the vaccine."—N.Y. Times, June 24, 1955.

6 Editorial: Poliomyelitis Vaccine Program Deferred.—New Eng. J. of Med. 253:790, Nov. 3, 1955.

7 Editorial Salk Vaccine: The Fundamental Problem.—Ibid. p. 481, Sept. 15, 1955.

8 Ibid. pp. 483-484.

9 *It should be understood that commercial firms are not more explicit than the occasion demands when discussing matters that lend themselves to misinterpretation by the public. It should be obvious that the reference to be cited can only have in mind the presence of live virus in Salk Vaccine, which in turn explains the fact why large amounts of processed Salk Vaccine have been withheld and continue to be withheld from the market by this firm.*

"The . . . pharmaceutical firm hasn't shipped any vaccine since June 3, said (the) company president . . . 'Improved procedures and extensive testing beyond normal requirements are insuring the highest purity and potency of our product . . . ' The serum ready for release, a company spokesman said, is not a new serum but one made by improved methods and given extensive testing well beyond the Government's standards for production of Salk vaccine."—Detroit Free Press, Oct. 11, 1955.

*It is also pertinent to add here that scientists operating on grants from some foundations are not free to publicize their findings without first clearing with the foundation which has made the grant. A foundation, which re-*

*minds its grantees of such stipulations during the height of a discussion on the pros and cons of a product sponsored by them, is not contributing to a free, open and objective evaluation of the product by scientists at large.*

10 "The group unanimously recommended the start immediately of a concentrated research effort to find equally effective but less virulent strains of virus for those now in the vaccine." N.Y. Times, June 24, 1955.

*The group consists of scientists that were invited to appear before a House Interstate and Foreign Commerce Committee investigating the safety of the Salk Vaccine. They include: Salk, Francis, Rivers, Smadel, Shannon, Enders, Sabin and others. Scientists expressed themselves similarly at the Panel Discussion on Poliomyelitis at the Atlantic City Meeting of the AMA on June 7, 1955. It should also be noted that Denmark started its program without the Mahoney strain and that Sweden subsequently replaced the Mahoney strain in its vaccine.*

11 From a television broadcast on September 18, 1955, as reported in the Chicago Daily Tribune, Sept. 19, 1955.

12 Jonas E. Salk, M.D., Considerations in the Preparation and Use of Poliomyelitis Virus Vaccine—as read and released in connection with the Panel Discussion on Prospects for the Control of Poliomyelitis at the 104th Annual Meeting of the AMA, Atlan-

tic City, June 7, 1955, and as published in the J.A.M.A., 158:1239-1248, Aug. 6, 1955.

#### THE HEALTH OFFICER AS DEVIL'S ADVOCATE

13 "The application of vaccination against poliomyelitis, which is a new procedure in the hands of most physicians, and with most patients, is fraught with feelings of uncertainty. These feelings are present, also, in some who must assume responsibility for vaccine certification . . . the decisions as to what should be done with such information must reside with those who must have the responsibility for the actions that are to be taken in connection with the application of vaccination against poliomyelitis." Ibid. As read and released but not published.

14 "Final decisions on the use of the vaccine remain the responsibilities of individual physicians and health officers."—Leonard A. Scheele, M.D., and James A. Shannon, M.D., Public Health Implications in a Program of Vaccination Against Poliomyelitis. As read and released on June 7, 1955 in Atlantic City and as published in the J.A.M.A. 158:1249-1258, Aug. 6, 1955.

15 Text of NFIP Statement following a meeting of experts. N.Y. Times, June 19, 1955.

#### KEEPING PHYSICIANS INFORMED

15\* U.S. News and World Re-



port, July 1, 1955, p. 32.

16 Thomas Francis, Jr., M.D. and Others: An Evaluation of the 1954 Poliomyelitis Vaccine Trials. Summary Report. AM. J. Pub. Health Vol. 45, No. 5, Part 2, May 1955. Introduction, p. xiv.

*Inoculation of Children 6 Years Old and Younger*

17 Hart E. Van Riper, M.D., and Kenneth S. Landauer, M.D. Annual Statement on Poliomyelitis. Poliomyelitis, 1955. Ped. Clinics N. America, 2:630, May, 1955.

18 Francis, op. cit., p. 39.

19 "Preliminary analyses, based on reports of 2,539 paralytic cases in all age groups, already show a distinct lowering of the incidence of paralytic polio in 8 and 9-year-olds, and a small reduction in 7-year-old children." This quotation is taken verbatim from the speech of Dr. Leonard A. Scheele prepared for presentation at the Economic Club of Detroit on

Monday noon, Oct. 3, 1955, as distributed by Dr. A. A. Langmuir, Chief, Epidemiological Branch of the Communicable Disease Center on Oct. 3, 1955.

20 Scheele and Shannon, op. cit., p. 1257.

*This statement was not present in the paper as read and released on June 7.*

21 These comparisons pertain to the paralytic poliomyelitis cases in the Placebo Study Areas in which "There is . . . greater confidence in the results obtained from the strictly controlled and almost identical test populations . . ." p. 50.

Cases	In vaccinated	In Placebo	Total
6 yr. old	16	23	39*
8 yr. old	4	29	33*
9 yr. old	1	9	10*
Virus pos.			
Type 2	0	6)	
Type 3	2	25)	33

\*Appendix, p. 12  
Francis, op. cit. □

*(To be Continued)*

*Reprinted from The Bulletin of The American Association of Public Health Physicians. Vol. 2, No. 5 (Nov.), 1955, pp. 3-8; Vol. 2, No. 6 (Dec.), 1955, pp. 5-8.*

The Salk Vaccine applies new practices in the production of viral medicine. The vaccine has progressed from the experimental level to large-scale production with unprecedented rapidity. This speed . . . created problems in biologics control amenable to solution only with the accumulation of knowledge and experience.

L. A. SCHEELE, M.D. and J. A. SHANNON, M.D.  
The White Paper on the Salk Poliomyelitis Vaccine  
June, 1955

## N.I.H.—Contribution to Biomedical Knowledge\*

SENATOR HARRIS and Members of the Seminar:

I am pleased to participate in this discussion of "Research in the Service of Man." I should like to congratulate Senator Harris and the Frontiers of Science Foundation of Oklahoma on providing a productive setting for a broad examination of an important series of questions relating to the advance of biomedical knowledge and extending its benefits to the nation.

We who serve in the Washington scene have been particularly impressed with the intelligence, vigor and fairmindedness with which the Senator has directed the inquiries of the Senate Subcommittee on Government Research into the complex and difficult question surrounding the development of constructive policies bearing on the conduct of Federal science programs in relationship to national needs and objectives. We are also aware of the important role that the Frontiers of Science Foundation of Oklaho-

ma is serving in encouraging and supporting an enlightened engagement with science and research in the Oklahoma area. Vigorous private action at the State and local scene is an essential complement to the conduct of national programs.

The preparation of this discussion required a choice be made between considering some important general issues or the substantive programs of our several Institutes. I chose the former as the most appropriate for me since a number of the substantive issues, will be dealt with by individual scientists actively engaged in the fields they will present.

In respect to the matter at hand today, I speak, as you will recognize, as the head of an agency which has served a very significant role in the advancement of biomedical knowledge. The role and purpose of NIH in this development is misunderstood by some. NIH is too frequently perceived as a science agency interested in biological and medical problems in themselves, rather than a health agency utilizing science and research for the solution

\*Remarks presented by James A. Shannon at the Conference on Research in the Service of Man, Oklahoma City, October 25, 1966.

of disease and health problems. But permit me to rest any uncertainties that may exist in respect to this matter. The National Institutes of Health exists primarily to deal with disease and health problems. The Public Health Service Act under which NIH operates authorizes and instructs the Surgeon General to:

... conduct ... and encourage cooperation with and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordinaton of, research investigations, experiments, demonstrations, and studies relating to the cause, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man. . . .

Three major factors play a determining role in the form, content, and mechanisms of action of the NIH and its programs.

1. The rising social demand to diminish the hazard of serious disease.
2. The state of development of the biomedical sciences.
3. The inherent nature of scientific advance.

*First is the rising social demand*

DR. JAMES A. SHANNON at the time of this presentation was the Director of the National Institute of Health.

POLIO VACCINE MISTAKES

*to diminish the hazard of the major diseases.* This force has been given major expression in the several legislative acts creating the categorical disease institutes which now form the basic structure of the NIH. These acts have been complemented by generous and growing budgets in support of the institute programs and the establishment of other program authorizations essential for the success of the enterprise.

*Second is the state of development of the biomedical sciences.* The base of knowledge of life processes and the phenomena underlying health and disease is still grossly inadequate. Consequently the development of any diagnostic, therapeutic and preventive capability is still largely dependent upon what are basically empirical approaches, the movement of science in collateral fields, plus the accidents of serendipity and the intuitive brilliance of a too few gifted individuals. As a consequence of those hard realities, effort has had to be directed, on as broad a scale as resources would permit, to advancing the base of science upon which disease-oriented research efforts are entirely dependent. Thus a series of derivative missions—the operational imperatives to mounting a comprehensive attack upon health problems—has become an essential part of the activities of the National Institutes of Health.

\* \* \*

*The third determinant factor in the conduct of NIH programs has been the inherent nature of the process of scientific advance and the conditions for the solution of disease problems.*

The mechanics of scientific progress in medicine are complex, diverse, and often determined by unpredictable and seemingly wholly unrelated events. Ideally the process involves: 1) The emergency of broad generalizations relating to particular phenomena. 2) The direction of these generalizations to the study of a particular problem. 3) The intensive and sharpening pursuit of promising leads to solutions. 4) The appearance of a feasible course of action which may result in a useful result or end point. 5) Concentrated effort for the practical development of a program so perceived. 6) The broad application of the end product of the research to medical health practice.

This sequence is fraught with uncertainties, is often only visible in hindsight and the precipitating events often emerge from unforeseen developments in a wholly uncontrollable manner. The dominant factors in this process are the internal logic of science and the intrinsic purposeful nature of the medical sciences. Research in the medical sciences is pervaded by a concern for achieving mastery over the condition, of, and hazards to, human life. This circumstance assures a high component of practical and problem oriented research. The circum-

stances under which one intervenes in this natural process to accelerate or direct, in a highly organized fashion, the course of action is indeed a most critical consideration: Such action must be taken with caution since the state of knowledge is such that there are only limited opportunities for such deliberate action. Such intervention is apt to be expensive, and if undertaken in the absence of an adequate scientific base, is likely to be unproductive and thus wasteful of limited resources. Frequently too, programmed activity, but not programmed research, must be undertaken where the science base is perceived to be inadequate.

However, such selections must be made, and, as our understanding of the biological and behavioral bases of human health and disease becomes increasingly sophisticated the opportunities for such selections will inevitably increase. Consequently the functional organization of the NIH must reflect this need and contain such a capability.

I should first like to illustrate this process of scientific progress and the problems associated with attempting to accelerate or direct the course of action by purposeful intervention by reviewing the background and events which led up to what all acknowledge as one of the triumphs of postwar medical research—the development of the polio vaccine.

\* \* \*

In retrospect the 1935 attempt was bound to fail because of an inadequate amount of fundamental information upon which to base the targeted programs. The natural history of the disease was not fully understood, the complexity of the viral agents was not known, nor was the mode of transmission of the disease. Further the crude suspensions of monkey spinal cord did not permit, with the then current information, complete inactivation of infectivity and at the same time the retention of a capability of stimulating antibodies, simple safety tests could not be devised. The hazard of allergic encephalitis due to monkey cord preparations was not taken fully into account. By 1948 it was demonstrated that such immunization was possible in monkeys, a fact of fundamental, but not practical use.

\* \* \*

The most important act in the postwar period that led to the rapid evolution of the polio field was taken by the Polio Foundation shortly after the termination of World War II. Assessing the state of the art at that time the decision was made that saturation support of the nation's best virologists was required so that in addition to attention to the general field of virology, they could give some priority to the special problems of polio.

The general appreciation that more than a single agent was involved in disease causation was resolved by a coordinated collection and study of approximately 1,000 viral isolations from cases of polio. It was determined that paralytic polio could be caused by agents which antigenically can be grouped into three and no more than three types. This was a monumental task involving the use of some thousands of monkeys and was completed by Bodian in 1949.

Perhaps more important and in the same year, Enders adapted the then sophisticated field of tissue culture to the problem of the study and production of viruses. This latter tour de force for the first time made a practical viral technology available to the polio workers and others. It was then feasible to mount a vigorous and purposeful program in the fields of diagnosis, pathogenesis and epidemiology of the disease on the one hand and vaccine development on the other. . . .

The choice in the vaccine development portion of this overall activity was to emphasize, coordinate and fund again to saturation levels the development of an inactivated viral vaccine which came into being as a reasonable certainty about 1953 and into general use around 1955. . . .

As I will point out later, the decision of the Foundation to throw its resources behind the development of an inactivated vaccine markedly increased the difficulties and greatly protracted the

time required to develop the generally accepted polio vaccine we have today [Sabin]. Such acceptance is reflected best in the production figures of U.S. industry. In a most recent analysis of vaccine production, in terms of immunizing courses produced, there were 1.3 million for the inactivated Salk vaccine and 14.0 million for the attenuated Sabin vaccine. As I see it then there were three phases in this overall development.

I have portrayed them in outline by three slides which reflect scientific progress on the one hand and administrative judgments on the other.

#### *Polio Vaccine Development*

\* \* \*

#### PHASE III

1) Vaccine development was now deemed possible—1950. 2) Success of vaccine development was too uncertain to lessen saturation support for virology. 3) The preferred technique for vaccine development was inactivation of the polio vaccine by formaldehyde. 4) An effective vaccine seemed to be available—1953 [Salk]. Problems that arose [in the field in 1954 and in general use in 1955] were due to an inadequate science base.

Some of these judgments were made by the community of scientists, some made by a support

agency having a capability of modulating and hopefully accelerating the development of knowledge in a desired direction.

The essential steps by the foundation related to: 1) Broad support for virology—1946. 2) Definition of polio strains—1949. 3) Feasibility of vaccine development—1950. 4) Inactivated virus was the preferred choice for a vaccine—unclear date—1952? 5) Full development support was assured by 1953. 6) Finally vaccine was ready for distribution by 1955.

The consequences of this series of decisions made by the support agency had three consequences:

1. The final inactivated vaccine distributed and which came into general use required redesign of production methods and redesign of safety testing within three weeks after the vaccine went into initial use. This redesign required redefinition of the fundamental concepts upon which both inactivation and safety testing were based. In other words, the development had outrun its science base and a substantial number of vaccine candidates were placed at serious risk.
2. The late observation that at least one simian virus (SV-40) was inactivated at a slower rate than the polio virus was not recognized for many months. This virus, entering the vaccine production system via the monkey kidney tissue used in polio virus production, had the unfortunate capability

of producing tumors in experimental animals. Fortunately, once recognized, however late, it was relatively simple to eliminate the hazardous virus in the production and testing process. SV-40 was one of a number of monkey virus that was not recognized as potential hazards at the time the vaccine came into general use

and its discovery as a potential hazard is another example of how the vaccine development program outran its science base.

3. The selection of the inactivated product as the viral agent of choice greatly delayed what now appears to be the definitive product, the Sabin attenuated viral vaccine. □

*Reprinted from a paper published by the National Institutes of Health, a Division of the Dept. of Health, Education, and Welfare, Oct. 21, 1966.*

*Editor's Comment:*

S's admission of the flaws of the original Salk Vaccine (SV) was occasioned by his solicitation for governmental funding for basic scientific research. That something was wrong with the SV became apparent as polio outbreaks occurred shortly after its use in 1955. S. admits that its "development had outrun its scientific basis and a substantial number of vaccine candidates were placed at serious risk." The reality was that millions of children had received an unsafe SV which caused cases of paralysis, deaths and pre-seasonal polio epidemics. The dangers of rushing the SV to market to maintain a 1955 schedule was not unforeseeable. S. knew at the time, as evidenced by his testimony before a congressional hearing (Priest Report, June 22 & 23, 1955), that the inactivation process was unreliable and safety tests inadequate. But he did not vote with the minority who held that in the presence of the highly

virulent Mahoney strain and a deficient inactivation process the program had to be called off, at least until the Mahoney strain was replaced as was already occurring in other countries. By not agreeing to a prompt discontinuation of the program at the Hearings, S. seems to hold that when "a medical product outdistances its scientific basis" it need not be removed since bases can be acquired as problems surface. Re the eight to three vote to continue the use of the SV, Noble Laureate W. M. Stanley stated at the Hearings: "This voting . . . is not completely relevant because you can take any number of medical scientists and by selection you can get a preponderance of one side or a preponderance on the other side." The reputations of the National Foundation of Infantile Paralysis and the United States Public Health Service were at stake. The vote spelled out the bottom line. Reputations were more important than children's lives. HR

*Child  
and  
Family*



# An Untold Vaccine Story

(CONTINUED)

THE CONCLUDING part of "The Devil's Advocate" follows. It recounts the serious difficulties the National Foundation of Infantile Paralysis (NFIP) and the United States Public Health Service (USPHS) had with the Salk vaccine (SV) with its continuing improvisations. The period covered is from April 22, 1955 the day the SV was proclaimed safe and effective and licensed, to November 1955. It was a time of turmoil in which difficulties with the SV program dominated the mass media, in which the time and energies of public health personnel were preempted and in which the public was kept in a state of anxiety and indecision. It was also a period in which the powerful public relation resources of the NFIP and USPHS were utilized to the full in a do or die attempt to succor the SV program. The intelligent layman's reaction to this is found in prescient excerpts from pundit Walter Lippman's syndicated column: "There are those who have had great misgivings since April 12 (when) the effectiveness of the SV was proclaimed. The fact is that the responsible authorities were half-cocked. The real situation called for at least one more season devoted to an enlarged and fully controlled experiment. It was a case where the way to make genuine progress was to adhere to the strictest standards of scientific caution" (*NY Herald Tribune*, 5/10/55).

Rather than recalling the program, reiterated reassurances of the vaccine's safety and effectiveness were given. Faith was required of the public, in lieu of scientific evidence. For example, while taking the SV temporarily off the market the head of the USPHS "reiterated his faith in the serum" (*NY Herald Tribune*, 5/8/55). Two months later the NF gave every assurance that the vaccine is "now safe" (*Polio Postscripts*, July '55). Four months later, however, *Time* stated that the promoters of the SV "have had an exasperating way of reversing themselves. Now it's safe, now it isn't. Now it works, now it doesn't quite." (11/29/55). Two weeks thereafter *Time* also reported that "No sooner had the SV received an apparently clean bill of health than the Massachusetts State Poliomyelitis Advisory Committee dissented. State authorities, it ruled, are still not to use the vaccine until there is more convincing safety evidence" (12/12/55). (See *CF*, 19:281-5.) □

# The Devil's Advocate and the Salk Vaccine Program: 1955\*

## A Contribution Toward an Objective Evaluation

(Continued)

### *Is There One Salk Vaccine?*

WHETHER THERE is more than one Salk Vaccine is a crucial question. Its answer is necessary for an intelligent interpretation of data. We should be grateful for the astute observation of Dr. Francis who stated that the Salk Vaccine "is not one product but a series of vaccine preparations made on the same basic principle. It now appears that certain of these preparations are not safe."<sup>22</sup> If we are to avoid semantic confusion it seems that we must distinguish, at minimum, between three broadly different Salk Vaccines:

1. *The 1954 Field Trial Salk Vaccine.* In respect to safety, this vaccine was triple tested and contained merthiolate which has viricidal action.

2. *The pre-May 27th 1955 Salk Vaccine.* (May 27th was the date on which a new set of safety tests was promulgated, based on a new rationale and flowing from unexpected field experiences). This vaccine was an admittedly inadequately safety tested vaccine. Thus, on August 25th, it was stated that "prior to May 27th . . . there were . . . fundamental weaknesses in the safety testing procedures which failed to assure what is now believed to be a satisfactory degree of sensitivity."<sup>24</sup> This vaccine contained unknown amounts of live virulent virus varying with manufacturers and with lot numbers. The bulk of children who were inoculated with vaccine prepared prior to May 27th in preparation for the 1955 summer poliomyelitis season received this vaccine.

3. *The post-May 27th 1955 Salk Vaccine.* This vaccine is one which, according to theoretical considerations and within the limi-

\*The second of two parts

tations of present testing procedures, contains minimal amount of live virus. It, principally, has been used in late summer and fall inoculations. This category changes as additional safety tests are introduced. Such change may be on the part of the licensing agent; e.g., the September addition of the cortisone treated monkey test; or on the part of the manufacturer; e.g., when manufacturers voluntarily introduce additional testing procedures, such as increases in the incubation period on tissue culture safety testing.

Furthermore, countries like Canada, Sweden, Denmark and others have Salk Vaccines which for reasons other than those above must be thought of as different.<sup>25</sup>

There are some who think there are only two different kinds of Salk Vaccine: properly prepared vaccine and improperly prepared vaccine.<sup>26</sup> This division seems to beg the question at several levels. At one level it simply identified properly prepared Salk Vaccine with vaccine that does not cause poliomyelitis. At another level it side-steps the issue of whether there is a large margin of safety in the formalin inactivation process itself or whether there is no safety margin. The resolution of this issue radically changes the function of the safety tests. In the former, the safety tests become a means of finding "contamination and process failures from accidents in manufacture"<sup>27</sup>; in the latter, "principal reliance for the exclusion of live virus must be placed upon the safety test in the final vaccine."<sup>28</sup>

We hope that in future discussions on the effectiveness of the Salk Vaccine, authorities will specify which Salk Vaccine they are talking about. It should be evident at this point that reports now emanating on the effectiveness of the Salk Vaccine in 1955 have in mind the pre-May 27th 1955 Salk Vaccine. At best, when valid, they only demonstrate that an admittedly inadequately tested Salk Vaccine containing unknown amounts of live virulent virus shows signs of effectiveness. Such a finding is not necessarily confirmatory of the 1954 experience, nor does it necessarily bear on the effectiveness of the post-May 27th 1955 Salk Vaccine. We hope this semantic confusion will be avoided in future discussions.

#### *Live Virus in the 1955 Salk Vaccine*

The impression has been given that the only pre-May 27th 1955 Salk Vaccine which contained live virus was that in several lots

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DR. RATNER, at the time of this paper was Director of Public Health, Oak Park, IL, Associate Clinical Professor of Preventive Medicine and Public Health, Stritch School of Medicine, Chicago, and Editor of the Bulletin of the American Association of Public Health Physicians.

of one manufacturer's product.<sup>29</sup> It is common knowledge, however, amongst many working intimately in poliomyelitis that by additional testing live virus was detected by investigators in other manufacturers' products used in children. It would seem that physicians have a right to this scientific information. They are the ones inoculating children. What prevents authorities from collating this material and promptly making it available to the medical profession?

#### *Minimum Licensing Requirements*

Two of the minimum licensing requirements call for:

1. "... a preparation of poliomyelitis viruses... killed by a suitable method..."<sup>30</sup>
2. An inactivation of virus in which "all virus infectivity is destroyed with certainty by the use of an agent or method which has been demonstrated by the laboratory using the method to be consistently effective and reliable in inactivating a series of lots of poliomyelitis virus."<sup>31</sup>

The following questions seem to be order concerning the 1955 Salk Vaccine: 1. Are the viruses killed and is "all virus infectivity... destroyed with certainty"? 2. Is the method of inactivation "consistently effective and reliable in inactivating a series of lots of poliomyelitis virus" and how long is a series?

Concerning the second question, the irregular and unpredictable production of poliomyelitis vaccine manifested throughout 1955, as witnessed by the numerous erroneous predictions of expected supplies, is disturbing. Also disturbing is the fact that originally there were six "established and reputable (pharmaceutical manufacturers). The competence of the scientist in charge of production in each plant was known and respected."<sup>32</sup> At present, however, there are only three firms with a product on the market. Further, of the two firms who were finally selected to produce the vaccine for the 1954 field trials, and who supplied the bulk of the vaccine used in the spring of 1955, one firm has withdrawn its product from the market because, among other reasons, its more stringent than required safety tests have apparently detected live virus in the vaccine.<sup>33</sup>

We feel that the authorities owe it to the medical profession to list the consistency records to date (by code would be sufficient) of the six pharmaceutical firms associated with the production of this vaccine.

### *A Double Standard of Reporting*

A double standard of reporting poliomyelitis cases apparently had come into being by the week ended May 7th with the introduction of the term *accepted*. In the Communicable Disease Summary of the USPHS for the week ended April 20, 1955, A Poliomyelitis Surveillance Unit was announced. The same Summary also stated that 33 cases had been *reported* in which there was association with poliomyelitis vaccine. In the Summary of the week ended May 7th the new term *accepted* was introduced in the sentence reading, "To date, 62 cases of poliomyelitis have been accepted as occurring in persons who previously had received poliomyelitis vaccine." From that date on, when referring to post inoculation or associated cases, PSU had listed cases as *accepted* rather than *reported*.

Presumably, certain criteria have been established for the acceptance of *accepted* cases by PSU which are more rigid than those established for the acceptance of poliomyelitis cases by the National Office of Vital Statistics. This would seem to result in the following consequences:

1. It would delay and reduce the number of Salk Vaccine cases reported to and accepted by PSU by virtue of the need for the collection of additional data and the subsequent determination by state personnel, and then by PSU, of the acceptability and relevance of the interpretation of these data.
2. It would prevent a proper comparison between NOVS cases and PSU cases. NOVS accepts any case reported as poliomyelitis. This would include cases which might actually be Salk Vaccine cases but which were not accepted by PSU. Therefore, the ratio of Salk Vaccine cases accepted by PSU to total cases reported to NOVS would be decreased. This could mask the harmful effects, as well as enhance in some situations the protective effects of the Salk Vaccine.
3. It would hamper epidemic intelligence. Last spring it was crucial to know the incidence of Salk Vaccine cases at the time they were occurring to determine their casual relationship to poliomyelitis. If such cases were not *accepted* until a later period, the basic data necessary to determine such a relationship would not be available when needed.

The purpose of establishing the category of *accepted* cases is, therefore, not clear, if one has epidemic intelligence in mind. The writer can only speak from knowledge of his own state, Illinois. If a local health office in Illinois was concerned with determining and knowing whether the vaccine was causing poliomyelitis in the

state, it would not be of help to him if cases occurring in June were not accepted until Fall. This happened in at least five instances. If this were duplicated in other states, PSU would not be in a position to advise health officers at large, through their state health departments, that something untoward was happening at the time it was happening.

There are also several instances in Illinois in which cases obviously connected with the Salk Vaccine were not accepted. If such events transpired in Illinois, one can presume they happened elsewhere. Two questions are in order. What were the exact criteria used in April, May and June that may have limited the acceptance of reported cases? Which would have given us a more accurate picture of what was happening in the immediate post-inoculation period. (April, May and June) *reported* or accepted Salk Vaccine cases, and what would this picture have been?

#### *Expected and Reported Cases*

The original determination that one manufacturer's product was causing poliomyelitis in Idaho, California and elsewhere was based on a statistical demonstration in the manner of the Francis Report which established the effectiveness of the Salk Vaccine. This method was independent of the laboratory demonstration of live virus in the vaccine itself. A similar method was used to determine the safeness or unsafeness of other manufacturers' preparations of Salk Vaccine by comparing "reported cases" to "expected cases." "Expected numbers (were) calculated by applying the five-year (1950-1954) median attack rate in 6, 7 and 8-year-olds in the specified geographical areas to the numbers of first-grade and second-grade children vaccinated in 1955 in the corresponding areas." It was added that "This is a crude measure, for the incidence of poliomyelitis varies widely and unpredictably in successive years; but it is the best tool available under present conditions." (June 7th).<sup>34</sup>

If we extend the period analyzed on June 7th in Atlantic City (April 16-May 21) another two weeks, so that it covers the period from April 16 to June 4, we find, in a comparison of reported cases (as accepted by PSU) to expected cases, as calculated above, that the vaccine of each of the manufacturers showed reported cases higher than expected cases.<sup>35</sup> The *reported cases* of three manufacturers were more than 100% higher than *expected cases*. The *reported cases* of the manufacturer with the least number proportionately was 22% higher than *expected cases*.

There are further reasons why it is not possible to agree with the conclusion that the vaccine of all manufacturers was not associated with an increase in poliomyelitis.

1. We can now see that expectancy based on the 5 year median attack rate is a crude measure. The 1955 polio incidence is well below the 5 year median. It was more than 20% below the 5 year average prior to the inoculation period and more than 20% below the 5 year average following the immediate post-inoculation period.<sup>36</sup> This would reduce the expectancy rate more than 20% and make more significant the comparative increase in reported cases (as *accepted* by the PSU).
2. Not all cases of poliomyelitis associated with the Salk Vaccine were *accepted* by PSU.

Furthermore, any special criteria established by PSU for the 1955 diagnosis of paralytic and non-paralytic cases, insofar as they had not been used in the previous 5 years, would reduce the number of cases reported without reducing the number of cases expected. If these criteria were as successful as the Francis Report in ruling out cases that were definitely not poliomyelitis, this would reduce the number of reported cases (as accepted by PSU) approximately 15%. There is reason to think that these criteria and their interpretation were more efficient than the Francis Report in ruling out cases. This would further strengthen the belief that in actuality there were significantly more reported cases than expected cases.

#### *The Salk Vaccine Post Inoculation Poliomyelitis Phenomenon.*

If there is an increase in poliomyelitis in the population at large following the inoculation of part of that population with the Salk Vaccine, circumstances being right, this should manifest itself in a distinct rise of cases in the post-inoculation period. If the seeding of a population with poliomyelitis viruses does not lead to a progressive increase of cases; viz, an epidemic, then there should be a drop in cases following the immediate post-inoculation period. (The possibility of an epidemic must be kept in mind in those areas where the particular types and strains of virus introduced are not endemic to the area, or where the susceptibility rate is high).

This post-inoculation rise and fall of cases would become apparent under certain conditions:

1. When it occurred before the natural rise of cases in an area. (In situations where only parts of a population were inoculated, the normal seasonal increase in cases might mask the increase).

2. When it occurred after the natural decrease of cases in an area so that the number of cases were not sufficient to mask the increase of post-inoculation cases.
3. If the vaccine were given at a time when seasonal conditions were conducive to the development and spread of poliomyelitis.
4. When local episodic outbreaks within an area have been ruled out. The post-inoculation rise and fall of cases would be less manifest where small numbers of people were inoculated and where the inoculation period was spread over a greater period of time.

One of the set of circumstances that would permit the rise and fall of cases to be exhibited can be found in some of the NFIP Salk Vaccine programs of last spring. The inoculations were started after the beginning of the poliomyelitis year and, in many instances, before the progressive rise of summer cases had begun. Although only a small percent of the population was inoculated, this might still be sufficient in numbers to have a detectable effect. Since poliomyelitis tends to be unpredictable in its behavior, confirmatory evidence would be necessary to ascertain that the rise and fall is atypical, and to ascertain that the increase did consist, in significant part, of known Salk Vaccine associated cases. A preseasonal rise of cases should be looked upon, however, as a clue, to the phenomenon.

The atypical rise and fall of poliomyelitis cases following the inoculation of Salk Vaccine with the presence of a significant increase of known Salk Vaccine associated cases will be referred to as the Salk Vaccine Post Inoculation Poliomyelitis Phenomenon (SVPIPP). Post inoculation poliomyelitis is here intended to include known cases in vaccinated individuals, known cases amongst family contacts, and known cases amongst community contacts. It is not intended to exclude, however, cases of poliomyelitis in which the contact is unknown or indirect, for it should be recognized that these categories do not necessarily encompass all cases which may develop from a virus introduced by the vaccine. Poliomyelitis is a disease characterized by the interception of many unknown infected individuals between one clinical case and another. In Idaho, there were 8 cases out of 53 that did not have a well-established close contact with vaccinated children.<sup>37</sup>

The existence of this phenomenon is evident when one analyzes the weekly incidence of the disease in the United States, California and Idaho. In the U.S., following the initiation of the NFIP Salk Vaccine program, the 15th calendar week ended April 16th, a pronounced rise began with the 17th week ended April 30th, and



was reversed the 24th week ended June 18th. The phenomenon becomes striking when the incidence of 1955 is compared with 1954. Prior to and after this period, the poliomyelitis incidence of 1955 is below 1954. During the post-inoculation period the 1955 incidence is 25 to 40 percent higher than in 1954. Compared to the 5 year average, 1955 shows a similar contrast. In California, the phenomenon can be observed between the 16th week ended April 23rd and the 21st week ended May 28th. The contrast with 1954 and the 5 year average is as dramatic as in the U.S. as a whole. In Idaho, the phenomenon extends through June and is even more dramatic.

In the case of the U.S., California and Idaho, we are not pointing out anything new. Everyone concedes now the impact of one manufacturer's product on the rise and fall of cases in these areas. What is new is the recognition that this is a phenomenon which may be correlated to other than the one manufacturer's vaccine. The writer finds this phenomenon present in many other states. Since national authorities do not concede that Salk Vaccine products of other manufacturers used in the NFIP program were at fault, we shall demonstrate this phenomenon in a state in which, heretofore, no doubt has been expressed as to the safety of the vaccine. This should suffice to establish the phenomenon as being correlative with the Salk Vaccine and not simply with one manufacturer's product. As confirmatory, however, we shall list other states involving additional manufacturers' vaccines, in which available evidence suggests that these are true examples of the phenomenon.

It should be recognized that the writer does not have a choice of states with which to make his demonstration. He is by virtue of PSU restrictions limited perforce to the state in which he is a health officer, because this is the only state in which data is made available to him.

In Illinois, the phenomenon can be observed between the 18th week ended May 7th, and the 23rd week ended June 11th. (Actually the phenomenon, because of continual inoculations, repeats itself and terminates the 26th week ended July 2). It should be noted as background that the 1955 poliomyelitis season in Illinois is considerably below 1954, the five year average, and at least four of the individual five past years. The number of cases during the period of the week ended May 7th and the week ended June 11th of 1955 is 3 times the corresponding period in 1954 (which had an overall higher poliomyelitis incidence), 2½ times the 5 year average, and 2 times the highest single year within the 5 year average.

The pre-July 1st rise and fall of cases following the Salk Vaccine inoculations in Illinois is clearly atypical. The important question now arises.

Is there any evidence to indicate this rise is due to known Salk Vaccine associated cases? The answer is clear and will be made in terms of the cases in Cook County including Chicago. This county accounts for the majority of cases in the State of Illinois. During the period from April 1st to July 1st, Salk Vaccine associated cases by date of onset of symptoms accounted for more than 40% of the total number of cases reported in Chicago and approximately 31% in Suburban Cook County. Since some of these cases may be expected to occur independently of the vaccine, a similar period following July 1st was compared as a baseline. Here the Salk Vaccine associated cases accounted for only approximately 17% of the total cases in Chicago and only approximately 13% in Suburban Cook County. In other words, the Salk Vaccine associated cases during the immediate post-inoculation period were approximately 2½ times what could normally be expected in both Suburban Cook County and in Chicago. It should be noted here that two separate health departments with separate investigators are responsible for collecting the data.

The reality of the SVPIPP is thus confirmed in a state which used a manufacturer's product other than the one responsible for the increase of poliomyelitis in California, Idaho and elsewhere, and in which the rise and fall was atypical, and in which a good part of the rise was accounted for by known Salk Vaccine associated cases. The writer would like to make it known that only a brief resume establishing the phenomenon is intended here and that a more detailed report on the SVPIPP is in preparation.

Although the data is not available for making conclusive statements about the presence of the SVPIPP in other states, it is evident that this phenomenon exists elsewhere. Pennsylvania, which used a third manufacturer's product, and whose inoculation program started on April 25th, reports 1 case the week ended May 14th, 10 cases the week ended May 21st, and 3 cases the week ended May 28th. It seems clear from several published references<sup>38</sup> that the majority of the 10 cases were associated with the Salk Vaccine. The same can be said for Louisiana which used a fourth manufacturer's product. One can list other states where the SVPIPP is evident or suggestive.

The SVPIPP confirms the proposition that the pre-May 27th 1955 Salk Vaccine used on the majority of children in the NFIP program contained poliomyelitis producing virus. It is hoped that authorities who have the data at their disposal will study and make a

prompt report of the extent of the SVPIPP in the various states. In connection with the Fall inoculation program, it seems imperative that the medical profession at large should be promptly informed of any Salk Vaccine associated cases now occurring. One wonders why the reporting of family and community contact cases, which has great significance in demonstrating the presence of induced poliomyelitis carriers, has been dropped at this crucial point. Special note should be taken as to whether the SVPIPP is reappearing with the Fall inoculation program.

#### *Vaccine Protection of 1955*

The October 3rd USPHS press release<sup>39</sup> reporting on the efficacy of the pre-May 27th 1955 Salk Vaccine raises several questions in the reader's mind. The release states that the frequency of poliomyelitis in vaccinated children was substantially lower after the second month and that strong evidence of lessened severity of poliomyelitis also became apparent in vaccinated children after the second month. This finding seems to contradict earlier statements of the proponents of the vaccine who consistently claimed the presence of immunity at a much earlier time.<sup>40</sup> There is no laboratory or other clinical evidence pertaining to immunity which supports the finding that maximum immunity would only be achieved after the second month. The study period of the 1954 field trials which demonstrated the efficacy of the 1954 Salk Vaccine was initiated 2 weeks and not 8 weeks after the last injection.

It would seem that the reason protection was not claimed for the vaccine in the first month or two following injection was that in the first 2 months there were "about as many cases . . . reported in vaccinated children as were expected." Actually there were more cases reported than could be expected in the absence of the injection (see above). These cases were presumably caused by a live virus vaccine and occurred, for the most part, within the first month following the injections.

If these cases caused by the vaccine are deleted from the calculation, it can be shown (if the uncontrolled figures on protection were valid to begin with) that the pre-May 27th 1955 Salk Vaccine was actually even more protective than it was claimed to be in this release. In other words, those children who survived the disease effects of the live virus in the first two months could be expected to have an excellent immunity.

Such a finding would also be more in harmony with our immunological knowledge. It would also conform to the finding in Idaho, where it was demonstrated in a study of 160 representative chil-

dren receiving one inoculation of the live virus Salk vaccine, that by six weeks high levels of antibody were obtained.<sup>41</sup>

It seems evident that the better than expected results obtained throughout the country following one inoculation, if valid statistically, confirm the proposition that these children have been inoculated with a live virus vaccine. It is hoped that the correlation will be made between protection and the vaccine, in those states or areas which show the presence of the SVPIPP and in those areas which do not, to further establish the basis for the protective value of the pre-May 27th 1955 Salk Vaccine.

The press release of October 3rd also states that the reported cases of poliomyelitis among the 7 million children throughout the United States is now running 25 to 50% below the incidence expected without vaccination in the same age groups. Assuming that these figures are valid, the SVPIPP should be used to determine whether, in the areas where the phenomenon is present, the protection isn't greater and that the contrary is true where the phenomenon is absent. Areas where the phenomenon is either unequivocally present or absent should be used if valid correlations are to be expected.

The release also states that in several areas the paralytic rates among vaccinated children are strikingly lower than among unvaccinated children of the same ages. The question arises here, too, of a correlation with the SVPIPP. The release further states that among vaccinated children poliomyelitis is predominantly non-paralytic. Three questions come to mind. Because of the scare connected with the use of the poliomyelitis vaccine, is it possible that more non-paralytic cases are being detected in vaccinated children by virtue of closer observation? Can as much weight be placed on the diagnosis of non-paralytic poliomyelitis? Are these non-paralytic cases *reported* cases or *accepted* cases?

Finally, we feel that only one side of the ledger is being presented in this release. The price that has been paid and the risks that have been taken for the results that have been obtained are not mentioned. The price that we have paid goes beyond those vaccinated children who have come down with poliomyelitis. It includes the associated community cases and the presently unknown associated cases that have yet to be estimated.

Lastly, at best, this release can only validly conclude that the pre-May 27th 1955 Salk Vaccine, the product of a process in which there were "fundamental weaknesses in the safety testing procedures"<sup>42</sup> which resulted in the presence of unknown amounts of live virulent poliomyelitis viruses, is highly effective.

### *1955 As A Low Poliomyelitis Incidence Year*

Many published stories and reports<sup>43</sup> have stated, implied and have led professional people and the public to believe that the sharp reduction of cases (and of deaths) from poliomyelitis in 1955 as compared to 1954 is attributable to the Salk Vaccine. It is desirable that a definitive statement be made clarifying this misconception if only for the sake of sound health education. That it is a misconception follows from these considerations. The number of children inoculated has been too small to account for the decrease. The sharp decrease was apparent before the inoculations began or could take effect and was of the same order as the decrease following the immediate post-inoculation period. We should not be misled by the SVPIPP which makes the subsequent decrease in incidence look significant by comparison.

### *The Crucial Safety Test*

Because of the many doubts raised concerning the safety of an effective Salk Vaccine, it seems that authorities should no longer postpone the one crucial test that could determine the safety of an effective post 1954 Salk Vaccine; namely, to test the vaccine on children, on an experimental basis, to determine whether they are being converted into carriers of poliomyelitis virus.

Tissue culture tests are more sensitive than monkey tests. Children are more sensitive to poliomyelitis virus than tissue cultures. When we determine the absence of live virus by the tissue culture method, we are only determining the absence of live virus insofar as it is measurable by tissue culture methods. We are not, however, making the vaccine to protect tissue culture cells against poliomyelitis. We are making the vaccine to protect children against poliomyelitis. Obviously, it is a better public health practice to know that a vaccine is safe before one gives it to children rather than after one gives it to children.

The one crucial test that could determine the safety of an effective vaccine and permit us to set up standards for adequate laboratory tests is the final determination of the presence or absence of live virus in the stools of vaccinated children. Such a study would require large groups of vaccinated children with unvaccinated children as controls. It would also require serial studies of the stools of vaccinated and unvaccinated children. Antigenic effectiveness could then be determined by antibody studies and correlated with safety. We hope that officials will see fit to conduct this crucial study and to resolve the doubts that exist in lay and professional circles.

## CONCLUSION

The role of the devil's advocate has ended. Many more things could have been said. Many more things will be said. We hope that the temper of the times will not preclude a dispassionate reading of what has been said, for it is solely intended as a "wholesome contribution to the deepening of public health thinking and to the cause of sound and certain progress" in the recognition that "Community health is a precious possession and trust."<sup>44</sup>

The writer, as editor, wants to make it clear that this article in no way reflects the official thinking of the AAPHP. It should suffice that the article is signed. The Bulletin is open to further discussion on the issues raised in this article within the limitations of space and time.

No one knows what the future holds for the Salk Vaccine. It may be that careful deliberation will allow a continuation of the Salk Vaccine program. It may be that it will not. In either case it behooves us to remember the lines from *Murder In The Cathedral* by T.S. Eliot:

"The last temptation is the greatest treason to do the right deed for the wrong reason." □

## BIBLIOGRAPHY AND NOTES

EDITOR'S NOTE: The unexpected demand and continuing requests for the bibliography, as well as additional copies of the article, have necessitated the publication of the bibliography. There have been requests for over 300 copies of the bibliography and Bulletin to date. The requests extend from the Honolulu County Medical Library in Hawaii to Der Präsident des Bundesgesundheitsamtes, Koblenz, Germany. In retrospect, this demand is not too surprising.

There has been no project in recent public health history that has so taxed the time and minds of public health physicians as the 1955 Salk Vaccine Program. Neither has there been a project whose evaluation has rested so completely on that which is most central to the specialty of public health; namely, epidemiological analysis. It is in this light that public health physicians recognize that the scientific issues raised by this program are not resolvable in the public press. Ultimately, their solution must be sought in scientific journals.

### *Is There One Salk Vaccine?*

22. Chicago American, May 18, 1955. *This statement was made at a press conference by Dr. Francis on May 18, 1955, prior to the reading of a paper at the annual Meeting of the Illinois State Medical Society.*

23. Reference number not used.
24. Report on Poliomyelitis Vaccine Produced by the Cutter Laboratories, U.S. Dept. of Health, Ed. and Welfare, Public Health Service, Aug. 25, 1955, p. 5.
25. **Canada:** "In Canada safety tests have been applied to lots up to 120 liters . . . whereas in the United States these basically similar quantitative tests have been applied to lots up to 1200 liters . . . Because of certain special problems in the manufacture of Salk Vaccine, this difference becomes vitally important." p. 30. ". . . The possibility that some live virus can survive the formaldehyde "cooking" has convinced the Canadians that a complete double check is warranted even after the vaccine has passed stringent tests. They insist that this is not a luxury but a necessity if a vaccine is to be made as safe as humanly possible. As of this writing, four lots of carefully tested Connaught vaccine, enough to inoculate 400,000 children, have been rejected and dumped after double checks at the Health Department's Laboratory of Hygiene in Ottawa. Since U.S. manufacturers are not now required to double-check, these suspicious lots of vaccine would have in all probability been sent out for use in the United States. The Canadian experts (contrary to the U.S.) are convinced the double check is the backbone of their safety program." (Concerning protocols): "Particulars supplied by three (U.S.) firms (to Canada) were not adequate enough to warrant issuing a license at the time . . . The U.S. government did not bother to ask any searching questions such as these after the field trials . . . Only by complete records could any worthwhile yardstick be applied to test the effectiveness of production methods." p. 31.

Robert Crichton. How Canada Handled the Salk Vaccine. The Reporter. 13:28-32, July 14, 1955.

**Sweden:** "The Swedish Medical Board cancelled provisional orders for 254,000 c.c. of the Salk vaccine and cancelled planned vaccination of 350,000 children this Spring on the grounds of insufficient safety measures." -Chicago American, May 8, 1955.

**Denmark:** "Inasmuch as it seems that the addition of an antiseptic to the vaccine impairs its potency, the sponsors of the Danish vaccine have dispensed with antiseptics and as an additional precaution filter the vaccine again just before it is put up in ampules." Foreign Letters-J.A.M.A. 158:213, May 21, 1955.

" . . . the Mahoney strain . . . is characterized by great virulence because of its capacity to multiply rapidly in extraneural

tissues. Because of this characteristic, it is at least theoretically possible for a minute dose of living virus to produce incapacitating paralysis. . . This objection has led those responsible for vaccine development in Denmark to exclude it in their routine vaccine production this spring. They have used the Brunhilde strain. . .”—Scheele and Shannon, op. cit., p. 1251.

26. Testimony by Dr. Salk before a House Commerce subcommittee. “It is clear that children who receive properly prepared vaccine do not transmit disease to adults. . .” St. Louis Post Dispatch, June 23, 1955. “What are the chances statistically that an immunized child will develop poliomyelitis from the vaccine? None from properly inactivated vaccine.”—From Questions and Answers prepared under the direction of Hart E. Van Riper, M.D., J.A.M.A. 158:1279, Aug. 6, 1955.
27. Scheele and Shannon, op. cit., p. 1252.
28. Ibid. p. 1253.

*Live Virus in The 1955 Salk Vaccine*

29. “Vaccine produced by all manufacturers has been proven to be safe except possibly two lots of Cutter Vaccine,” (Dr. Scheele). N.Y. Times, May 25, 1955.  
“These facts warrant a presumption that the cause of the disease in some of the individuals who received vaccine from these 6 lots was infection with poliomyelitis virus contained in these lots of vaccine produced by the Cutter Laboratories.”—Public Health Service, op. cit., p. 3.  
“In order to keep you informed on the Salk Vaccine picture, Mr. Basil O’Connor, president of the National Foundation for Infantile Paralysis has submitted the six questions and answers below which cover almost all of the points that have been confusing the public. . . “2. Is there any questions about the safety. . . of vaccine already used aside from the two batches of Cutter vaccine under study? No.”—Polio Postscripts, Chicago, Ill., Vol. 3, No. 3, July, 1955.

*Minimum Licensing Requirements*

30. Public Health Service Technical Report on Salk Poliomyelitis Vaccine. June 1955. U.S. Dept. of Health, Ed., and Welfare. Public Health Service. Appendix E. Minimum Requirements: Poliomyelitis Vaccine. 1. The Product, 1.2 Definition p. 1.
31. Ibid. 2. Production of Poliomyelitis Vaccine, 2.6 Inactivation of Virus, p. 2.



32. Scheele and Shannon, op. cit., p. 1250.

33. See reference 9.

*Expected and Reported Cases*

34. Scheele and Shannon, op. cit., p. 1256.

Mfgr.*	No. Vac**	No. Polio Cases 4/20-5/21***		No. Vac**	No. Polio Cases 4/16-6/4****	
		Rpt.	Expt.		Rpt.	Expt.
C	309,000	35	5	308,748	38	8
L	2,514,000	28	24	2,513,962	50	41
W	776,000	11	2	775,920	13	2
P.D.	834,000	2	3	834,148	8	5
P.M.	411,000	2	2	410,648	7	3

\*The initials signify Cutter, Lilly, Wyeth, Parke-Davis, Pitman-Moore, respectively.

\*\*Approximate numbers of persons receiving vaccine in NFIP clinics.

\*\*\*Scheele and Shannon, op. cit., Table 9 p. 1255.

\*\*\*\*Illinois Dept. of Public Health Release to Health Officers, July 15, 1955.

36. *The following table is based on poliomyelitis cases released weekly by the NFIP according to figures of the USPHS:*

Week Ended	No. Polio Cases		% Gain or Loss in 1955
	1955	Average 1950-54	
<i>Pre-inoculation 1/8-4/16</i>	1201	1546	-22.3%
<i>SVPIPP Period 4/23-6/11</i>	1628	1073	+51.7%
<i>Post SVPIPP 7/2-8/13</i>	6340	8055	-21.2%

*In the absence of Salk vaccination and the SVPIPP the number of cases in the period of weeks ended April 23-June 11, 1955, would be expected to match proportionately the preceding and the subsequent number of cases to give a typical curve. This curve would be approximately 20% below the corresponding 1950-1954 average. The increase due to the SVPIPP would then be approximately 72%, or roughly 770 cases. PSU "accepted" Cutter cases, including satellite cases, only amounted to a total of 142 cases by June 8. Whatever allowances one may feel impelled to make, by no stretch of the imagination could one assume with the USPHS and the NFIP that Cutter vaccine was responsible for this large atypical increase. PSU "accepted" cases associated with all vaccines, including satellite cases, only accounted for 245 cases by June 8, and some of these may be assumed to have occurred independently of the association with the vaccine. The discrepancy between this maximum figure of 245 cases and the 770 SVPIPP cases remains large. This discrepancy confirms our failure to achieve adequate surveillance for the country as a whole and to supply adequate epidemic intelligence.*

*The Salk Vaccine Post Inoculation Phenomenon*

37. L. J. Peterson, M.S.P.H., W. W. Benson, M.P.H., and F. O. Graeber, M.D.: Vaccination-Induced Poliomyelitis in Idaho. *J.A.M.A.* 159:242, Sept. 24, 1955.
38. The week end reports listed for Pennsylvania should be corrected to read as follows: May 7, 2 cases; May 14, 10 cases; May 21, 10 cases; May 28, 3 cases. These figures underscore even further the SVPIPP. *To simplify this reference to data which has been publicized in the newspapers in Pennsylvania and elsewhere, and which was responsible for the withdrawal of this manufacturer's vaccine from public health departments; e.g., New Jersey, it is sufficient to report that during this period, PSU accepted 7 cases of poliomyelitis in 7 year olds with onsets of symptoms varying from approximately 5 to 18 days following vaccination and in addition had accepted an equal number of satellite cases. In 3 cases, initial paralysis occurred at the site of inoculation. One doubts whether the Scheele-Shannon reference (supra 14, to the fact that with this manufacturer's vaccine only "11 cases have been reported from midwestern and eastern states," in a paper delivered on June 7, and published on August 6, accomplished the purpose of keeping physicians and local health officers, who have the responsibility of giving the inoculations, adequately informed.*
39. See reference 19.
40. "... minimally detectable levels of (polio) anti-body in the serum induced by active immunization are sufficient to prevent invasion of the central nervous system when the virus is blood borne. This has been shown also by Bodian in studies with passively administered antibody." p. 287.  
"... in most immunologic reactions there occurs a relatively large output of antibody shortly after the injection of antigen..." p. 290.  
Jonas E. Salk, M.D.,—Present Status of the Problem of Vaccination Against Poliomyelitis. *Am. J. Pub. Health*, 45:285-297, March 1955.  
"... the presence of demonstrable antibody in the serum is sufficient to prevent the development of paralytic poliomyelitis." p. 585.  
"... in such immunologically experienced individuals... a rise in antibody titer occurred, beginning sometime between the fourth and eighth day. By the latter time the maximum level appears to have been reached." p. 594.

“The geometric mean levels of antibody induced as a result of the first dose of vaccine was between 1:8 and 1:16 for the 1955 preparations . . . following primary vaccination measurable antibody appears in some individuals sometime between the sixth and ninth day . . . Therefore, the use of vaccine for the first time during the poliomyelitis season, or even in epidemic areas, could be expected to have a beneficial effect so long as one keeps in mind the limitations imposed by the time required to induce the immunologic effect in relation to the time of exposure to infection.” pp. 588-589.

Ibid. Vaccination Against Paralytic Poliomyelitis Performance and Prospects. 45:575-596, May 1955. Presented at a Convocation at Ann Arbor, Mich., April 12, 1955.

“Since it requires 7 to 10 days for the vaccine to produce antibody, the vaccine cannot be expected to protect the individual from paralytic infection . . . (in) an individual already infected.”

Hart E. Van Riper, M.D. Questions and Answers on Poliomyelitis. J.A.M.A. 158:1280, August 6, 1955. Information for Physicians on the Salk Poliomyelitis Vaccine. National Foundation for Infantile Paralysis. July 1955.

41. “A study of antibody response to the one injection of vaccine in a representative sample of the children receiving the vaccine has indicated that very high levels of antibody were obtained . . . The antibody response in these children who received one inoculation far exceeds the levels reached in Idaho children in the field trial vaccine program of 1954, after three inoculations over a five week period.”—Peterson-Benson-Graeber, op. cit., p. 243.
42. See reference 24.
43. *It should be sufficient to say that Time Magazine represents practically an isolated instance of a published report making clear the fact that the 1955 Salk Vaccination program could not have accounted for the low 1955 polio year. For a careful scientific approach to this problem the reader is referred to Bernard G. Greenberg, Ph.D., and Charles M. Cameron, Jr., M.D., M.P.H. The Probable Influence of Salk Poliomyelitis Vaccine on Reported Poliomyelitis in North Carolina. North Carolina Medical Journal 16:391-395, Sept. 1955. They state, “. . . there is every reason to believe that the use of Salk Vaccine among some first and second grade children will have little influence on the poliomyelitis rates recorded in this state in 1955. It may be suggested that even widespread inoculations among hundreds of thousands of residents of North Carolina may have no statistical impact on the disease for several years to come.”*

## CONCLUSION

44. Editorial Policy. Bulletin, AAPHP, Nov. 1955. □

*Reprinted from The Bulletin of The American Association of Public Health Physicians.  
Vol. 2, No. 5 (Nov.), 1955, pp. 3-8; Vol. 2, No. 6 (Dec.), 1955, pp. 5-8.*

The poem below expresses the thoughts of a teenage daughter of a public health physician who was exposed to her father's end of a stream of telephone conversations from anxiety ridden parents seeking advice during the on again off again hectic days of the 1955-6 years of the Salk vaccine program.

### My Daddy On Polio

There's three ways to catch the thing, or so my Daddy claims;  
Through normal means is the first; so don't play hard at games,  
Keep away from swimming pools, and be in bed at nine;  
Clean your hands most frequently, 'specially 'fore you dine.

Ninety per cent effective was Dr. Salk's vaccine;  
How sensational it is now, remains to be seen.  
Whether the Dr. meant effective *for* or *against*  
Is a question an observant public should raise next.

The second way to get it; perhaps as you have guessed;  
Is *because* of the vaccine, which prob'ly is the best.

*In spite of* the vaccine (regardless how much of it)  
Is the last way to get the germ—and that's all there is to it.

There's three ways to catch the thing, or so my Daddy says,  
One's as good as another, so take your choice he adds.

MARY TIM RATNER  
August 2, 1956

*Child  
and  
Family*

# Monkey Viruses, AIDS and the Salk Vaccine

(PART I)

July 17, 1987

To the Editor (*The Lancet*):

THE NOTION that AIDS viruses or their precursors were transmitted from monkey to man through monkey bites or the handling and consumption of monkey meats or by the aphrodisiacal injections of monkey blood (6/27/87) pales in significance when one recalls that in the United States and then throughout the world for over a seven year period from 1954 to 1961 millions and millions of children and adults were inoculated with poliovirus vaccines containing varying amounts of live monkey viruses derived from monkey kidney tissues on which polio viruses were cultured for use in polio vaccines.

This historical iatrogenic massive transmission of viruses from one animal species to another transgressed a species barrier—one of nature's great built-in protective biologic mechanisms against the inter-species spread of disease. Yet it seems that no one is interested in taking advantage of this fortuitous experiment. Of particular and topical interest is the widespread introduction of Simian Virus 40 (SV40) into *homo sapiens*.

SV40 was first discovered in monkeys in 1958.<sup>1</sup> By 1960 it was concluded that SV40 was a "common and essentially ubiquitous contaminant of rhesus monkey kidney cell cultures in which it developed high titers,"<sup>2</sup> that it was present in attenuated and in inactivated polio vaccines, and that it was capable of infecting man.<sup>3</sup> In May of 1961 it was reported that monkey kidney tissue extracts injected into hamsters induced cancerous tumors.<sup>4</sup> In 1962 the oncogenic agent in the extract was identified as SV40.<sup>5</sup>

Though the oncogenic SV40 was found in both live and "killed" vaccines, the inactivated Salk vaccine was the primary vehicle which transmitted SV40 from monkey to man. It was *injected* into

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millions of people from 1954 until 1961 when the presence of live SV40 in the Salk vaccine was established and when measures were taken to eliminate the SV40 from the Salk vaccine. The Sabin live attenuated polio vaccine in contrast was limited to field trials in most continents of the world in the late fifties. It was not licensed for use in the U.S. until 1961, whereas the Salk vaccine was licensed April 12, 1955, six years earlier. Furthermore, the Sabin vaccine was *ingested* not *injected*. Accordingly it had a minimal infectious rate compared to the Salk vaccine. That SV40 was found in the Salk vaccine came as a surprise because the Salk vaccine was thought to be a killed virus vaccine. It turned out, however, that SV40 was more resistant than poliovirus to inactivation by formaldehyde.

SV40 has been causally related to leukemia type diseases in man. Furthermore, given the established properties of the oncogenic SV40: that the DNA of its nucleic acid can combine with the RNA of host cells, that it can hybridize with other viruses, that it can enter a latent "virogenic state" and be reactivated, etc. and given the AIDS epidemic which first surfaced in the U.S. in 1981 as a lethal disease, it seems that virologists who still have so much to learn about human immune deficiency virus (HIV) should stop being innocent of or seemingly reluctant to study the relationship of SV40 to the AIDS pandemic. Certainly it is strange that in 1987 a leading virus expert on AIDS, discussing before a scientific gathering the origin of AIDS, still speaks about monkey bites and ignores the wholesale worldwide injection of monkey viruses, particularly SV40, into man via the poliovirus vaccines.<sup>6</sup>

#### REFERENCES

1. Hull, R.N. et al. *Am. J. Hygiene*, 68:31, 1958.
2. Sweet, P.H. & Hilleman, M.H. *Proc. Soc. Exp. Biol. and Med.*, 105:420-427, 1960.
3. a. *Ibid*  
b. Melnick, J.L. et al. *Proc. Soc. Exp. Biol. and Med.*, 109:965-968, 1962.
4. Eddy, B.H. et al. *Proc. Soc. Biol. and Med.*, 107:191-197, 1961.
5. Eddy, B.H. et al. *Virology*, 17:65-67, 1962.
6. Essex, M.L. *San Antonio Light*, April 12, 1987.

#### (PART II)

The above was rejected by the letter editor of England's prestigious medical journal, *The Lancet*. He either was opaque to its significance or perhaps preferred to let resting dogs lie. Throughout the world countries had participated in vaccination programs with the injectable Salk or Salk-like anti-polio vaccines. As of mid 1958, the United States had already exported close to a half a billion doses

of the Salk vaccine. England alone had imported over 10 million doses of the vaccine. Accordingly, the discovery of the oncogenic simian virus 40 (SV40) in the Salk vaccine (and perhaps other simian viruses yet to be discovered) caused great consternation in government circles. It was an inadvertent iatrogenic event of marked proportions, the long-range outcome of which was unknown. The National Foundation for Infantile Paralysis (NFIP) and the United States Public Health Service (USPHS), who were just recovering from their previous troubles with the Salk vaccine (*CF* 19:191-213, 259-285; 20:50-75), were well aware how upset parents would be to discover that Salk anti-polio vaccinators, like a horde of hungry mosquitoes, had descended on their children with African monkey viruses.

Accordingly, government virologists and administrators did what they could to suppress or minimize the discovery. The distinguished government researcher who had isolated SV40 from the Salk vaccine, was even persecuted and demoted by her superiors for sharing her findings with other scientists.<sup>1</sup>

I have heard . . . that you are rumored to have said in New York at a meeting of The Cancer Society, that you had experimental proof that normal monkey kidney tissue cultures contained a cancerous agent capable of inducing tumors in hamsters. Whether you yourself or the audience went the next step to imply that individuals receiving monkey kidney tissue culture material containing either live or dead viruses would develop cancer I do not know. In any case, you have apparently stirred up a hornets' nest, and there are some who are sufficiently credulous to believe that the use of monkey kidney tissue culture in man may induce cancer in them.

In August, I reviewed with you some of your experimental data which had to do with lumps in hamsters which had been inoculated with materials from monkey kidney tissue cultures. At that time, it was my conclusion, which I stated to you, that you had inadequate data to draw any conclusions whatever about the pathological nature of the lumps, the possible viral origin, the relation of the lesion to an indigenous condition in the hamsters, or the possible relation of the lumps to one or another of the extraneous monkey viruses. If I recall the conversation correctly, you were inclined to make, even in conversation, two entirely unwarranted statements. These two were: 1. You believed that the lumps might have something to do with the vacuolating agent and 2. that they might have something to do with cancer



in man. It is my recollection that I was not even diplomatic in telling you that you had no basis for either statement.

\* \* \*

In view of the apparent lack of critical scientific judgment and common sense on your part in this matter, I give you the following instructions. From now on, whenever you propose to speak before a scientific group outside of the LVR, you will submit a written manuscript for scientific review by me.<sup>2</sup>

At a later date, she became the subject of a Congressional investigation and was exonerated.<sup>3</sup>

Notwithstanding, the United States Public Health Service was so successful in soft pedalling the extent to which simian viruses were injected into human beings that two subsequent generations of virologists, most of whom are now working on the AIDS plague, are for the most part unaware of this widespread virus dissemination via the Salk vaccine. Were they more aware, there would have been a more intensive pursuit of the relationship of the Salk vaccine to AIDS, a new syndrome which first appeared on the scene twenty years after the world wide massive iatrogenic seeding of the public with the contaminated Salk vaccine. Virologists would also have been alert to the possible relationship of the Salk vaccine to other newly risen diseases such as Kawasaki disease.

Concerning simian viruses, Hilary Koprowski, of the Wistar Institute, Philadelphia, a world renowned virologist, had the following to say:

As a monkey kidney tissue is host to innumerable simian viruses, the number found, varying in relation to the amount of work expended to find them . . . the problem present to the manufacturer is considerable, if not insuperable . . . As our technical methods improve we may find fewer and fewer lots of vaccine which can be called free of simian viruses.<sup>4</sup>

Eleven years later *Science*, with great prescience, stated:

There can be few graver opportunities for man made disaster than the mass immunization campaigns that are now routine in many countries. Should the vaccine preparations become contaminated with an undetected agent present in the host cells, such as a cancer-causing virus, a whole generation of vaccinees could be put in jeopardy. This, of course, is no science fiction writer's horror story—it has already happened once; millions of people have been injected with a monkey virus known as SV40,

which was found in 1961 to be contaminating polio and adenovirus vaccines. The virus causes cancer in hamsters, no one yet knows what it may do in man.<sup>5</sup>

In 1962 it may have been justified for the National Cancer Institute (NCI) to have been "anxious not to push publicity on this problem because of the possibility of creating a real wave of popular hysteria (and though) no efforts (are being made) to keep their studies secret... (we) have tried to avoid giving the matter publicity."<sup>6</sup>

Today the NCI now knows or should know that Salk vaccine containing SV40 is associated with cancer in human beings. Today, 26 years later, with AIDS breathing down our neck, this is not the time for NCI and other governmental agencies to keep secret their earlier SV40 studies which they had pursued with "considerable vigor."<sup>7</sup> Today they have an obligation to inform the scientific establishment of the knowledge they are sitting on.

Serendipity apart, scientists are only going to find what they look for. Furthermore, as Louis Pasteur pointed out, the scientist with the prepared mind is in the best position to discover what there is to be found. □

#### REFERENCES

1. Hearings before the Subcommittee on Executive Reorganization and Government Research of the Committee on Government Operations. United States Senate, Ninety-Second Congress, second session, on Titles I and II of S. 3419, April 20, 21; and May 3, 4, 1972.
2. *Ibid.*, p. 549. A United States Government Memorandum from Dr. Joseph E. Smadel, Chief, Laboratory of Virology and Rickettsiology, to Dr. Bernice Eddy, Oct. 24, 1960, filed in the records of the Congressional Hearings.
3. *Supra* 1.
4. Hearings before a Subcommittee of the Committee on Interstate and Foreign Commerce. House of Representatives, Eighty-Seventh Congress, first session, on Developments with Respect to the Manufacture of Live Virus Polio Vaccine and Results of Utilization of Killed Virus Polio Vaccine, March 16 and 17, 1961.
5. *Science*, March 17, 1972.
6. Personal communication, May 21, 1962.
7. *Ibid.*