

DRAFT
Polio Vaccine
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Legislation now before Congress seeks funds to assist the States in the purchase of a new vaccine against poliomyelitis.

This legislation has strong bipartisan support. Congress has always responded affirmatively when it has an opportunity to improve the health and well-being of the American people. This vaccine represents one more advance in medicine and public health by providing a weapon which will lead to the prevention and ultimate eradication of this tragic disease which kills and cripples so many of our children and young adults.

Like most Americans, I have been extremely concerned with the events that have taken place since the Public Health Service released the first polio vaccine for general use on April 12. I was disturbed as a parent, and as the elected representative of many thousands of parents, over questions that were raised concerning the safety of the vaccine. But I was confident that those who were studying the problems and trying to find the answers were people of great scientific and professional

stature. They were the outstanding experts in the country, including key staff from a government agency that has an unparalleled record of public service for more than 150 years. I knew that we could rely on their judgment and should follow their recommendations.

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Thus I was totally unprepared for the vicious public and political attack that has been made, not only on the professional competence of these men but even on their motives. These attacks and accusations left me at first puzzled, then irritated, then angry. I sincerely believe in the right and indeed the obligation of any individual to have and state his own opinions. But I believe equally that a responsible individual should make sure he has facts before he speaks his mind.

The several hearings on the polio vaccine situation conducted during the last several months by the Committee on Interstate and Foreign Commerce of the House of Representatives provide a splendid illustration of thoughtful and objective inquiry. Congressman Priest and his colleagues on that Committee have a distinguished record of service and are a credit to

the Congress because it is in this vein that they approach all of the issues that come before them. They heard and evaluated all of the facts and opinions on the Salk vaccine. Then they reported out a bill to assist in its widespread distribution and use. By so doing, they indicated their confidence in the Public Health Service and its advisors, who have certified to the safety and effectiveness of the vaccine.

Yet there remains an apparently widespread opinion that the government, notably the Public Health Service, has "bungled" the polio vaccine program. I would like to correct this impression, or at least put it in perspective.

I have been very much concerned by these attempts of possibly well-meaning but certainly misguided individuals to attribute political significance to the purely medical and scientific triumphs and failures accompanying the development of a vaccine to provide immunization against poliomyelitis.

In connection with this vaccine, two problems, totally unrelated in principle, have emerged. These are, first, the question of allocation and distribution of vaccine, and, second, the purely technical problems concerning the safety and effectiveness of the vaccine.

At the outset, I concede that the problem of how available supplies of vaccine should be distributed is one with which legislative and administrative branches of Federal, State and local governments legitimately concern themselves. ~~[Honest differences of opinion may exist regarding this question, and such differences of opinion may tend to divide along partisan lines.]~~

However, I think it should be made crystal clear to every man, woman, and child in this country that the research, medical, and public health aspects of the development and application of the poliomyelitis vaccine are totally devoid of political significance. ~~[Any member of any party who, through blame or claim, attempts to distort facts in order to make political capital of the failures or triumphs of any scientific~~

~~effort to combat any disease is doing a great disservice to himself, his party, the people of America, and the entire cause of mankind's timeless fight against disease. Medical science follows a timetable that is unrelated to politics.~~

Thus although last year's field trials of the Salk poliomyelitis vaccine were conducted, and their encouraging results this year were announced, during the time that a Republican administration happened to hold office, no credit whatsoever can be attributed to that administration for these achievements. In the same way, the great disappointment of a limited failure of the vaccine and the consequent necessity for slowing down the nationwide immunization program cannot be attributed to that administration.

The development of the Salk vaccine represents the application and extension of knowledge which has been gained over a period of decades by research workers throughout the world. This specific vaccine itself was developed, tested, and evaluated by competent medical and other scientific men outside the Federal Government, largely without federal financial support. This has been true of many of the most important achievements of medical science, and it will continue to be true of many developments in the future, although during recent years research workers and research establishments, supported in whole or in part by Federal appropriations,

have contributed increasingly to the total intensive research attack on the cause, prevention, and cure of all kinds of physical and mental disorders.

The U. S. Public Health Service and its scientific and research facilities necessarily have participated in the immediate events leading to the beginning of this year's nationwide poliomyelitis immunization program, as well as in events since the program got under way. The Surgeon General of the U. S. Public Health Service and the Director of the National Institutes of Health (who happens to be retiring today after 30 years of service) are career public servants; they and their scientific colleagues are concerned with matters of public health, not politics. In their response to the problems that have arisen in connection with the polio vaccine, there is every reason to believe that they have acted with courage and integrity.

It would be tragic indeed if the time ever arrived when medical and scientific workers in this country would find it necessary to make their decisions on the basis of any factors other than the medical and scientific facts that are available.

It is important for us to make a calm, objective appraisal of what has been going on in this country with respect to poliomyelitis. The broad program seeking to protect large numbers of children against this disease, as it has advanced, has encountered serious obstacles, delays, and disappointments. But these reverses have not invalidated the program, nor do they preclude its ultimate success. Such difficulties as have been encountered are inherent in the early phases of any optimistic nationwide health program. Briefly, this is what has happened.

More than 400,000 children received poliomyelitis vaccine last year, and the results indicated that the Salk vaccine used was both effective and safe.

Millions of children have been vaccinated this year. As yet, there have been fewer cases of poliomyelitis than in a normal year. The only cloud has been that early in the program, an unusual number of children who had received certain lots of the product of a single laboratory were stricken with paralytic poliomyelitis.

The unexpected development of these cases caused a suspension of the product of that laboratory and a review of the manufacturing and testing procedures in the production of the vaccine by all companies. This study revealed that modified technical procedures might increase the safety of all poliomyelitis vaccine.

The Public Health Service recommended that further vaccinations be held up pending the reappraisal of existing vaccine in the light of this new knowledge, and the standards for production and testing of the vaccine were revised. This suspension of immunization resulted in a delay which was obviously necessary and warranted to assure the utmost of safety on the basis of existing knowledge.

The vaccination program was resumed, using vaccine which met the revised criteria. As manufacturers were progressively better able to produce under these criteria, the volume of available vaccine increased.

It is predictable that there will be enough vaccine available in the next twelve months to vaccinate a large part of the most susceptible age group. In the meantime, further improvements in the vaccine are being sought through research, and when they are found, they too, will be applied.

It is much easier to summarize these developments after they have occurred. It was not so easy to state them at the time they were happening. This, indeed, seems to be one of the principal points raised by those who have chosen to be critical of the government's handling of the polio vaccine problem this year. Why, they ask, did the Public Health Service not state the facts? Why did they withhold information which properly should have been given to the American public? A corollary point of attack by critics is on the point of seeming vacillation on the part of the Public Health Service. Why, they ask, didn't someone make up his mind? Was the vaccine safe, or wasn't it?

I am a Congressman, not a scientist. ~~I have not heard, nor could I state, the technical answers to these questions.~~ But I have followed the situation very closely. I have asked the Public Health Service some questions that have arisen in my mind. And I have concluded that -- much as it has been misunderstood and misinterpreted-- the Public Health Service has once again demonstrated its capacity for strong and affirmative action on matters affecting the health of our people. Let me tell you how I have reached that conclusion.

The Public Health Service had strong evidence that the Salk vaccine is a good vaccine--not a perfect one, perhaps, and certainly not one that could not be improved--but good in the sense that it could be made safe enough and effective enough so that its use was fully warranted. Thus, even when there was temporary trouble with it, the Public Health Service -- in the absence of cold scientific evidence of a basic rather than a temporary defect -- had an obligation to sustain instead of destroy public confidence in the vaccine. This fact must be kept in mind when one looks at the other parts of the

problem. As the nation's official health agency, it was confident that use of the vaccine would prevent many cases of paralytic polio that otherwise would occur. Yet--still believing this--the Public Health Service was forced to suspend the vaccination program and establish more stringent safety requirements. This posed an awkward seeming contradiction: the vaccine was known to be good on the basis of 1954 trials, but it could now be tested to give greater assurance of safety, and so the program should mark time until changes could be made.

Why did this happen? Who was at fault? The Public Health Service has freely stated its role and documented its actions, leaving it for others to assess the blame. It is possible to see this matter so much more clearly in retrospect.

The deceptively simple fact is this: the assumption had been, based on earlier experience, that all live virus particles in the vaccine would be inactivated by treatment with formaldehyde under certain conditions. After a careful and detailed inquiry this spring, this turned out to be in error; instead, it appeared that even with the best of

manufacturing processes, a

few virus particles could and often did resist treatment with formaldehyde. This imposed an unexpected burden on the safety tests.

The evidence was that they were not adequate to establish with certainty the absence of live virus in trace amounts. So the safety tests had to be strengthened. They have been, and now the whole program is back in gear.

There was a period of many weeks, then, when the Public Health Service and its talented group of advisors simply did not know what had gone wrong with the inactivation process in large-scale manufacture and what needed to be done to correct this unexpected development. Yet answers were demanded on an almost hourly basis. The demand for "action" reached hysterical proportions. And, because there was no "action," there was widespread criticism.

In truth, there was plenty of action. The nation's outstanding scientific experts on immunization and poliomyelitis, and representatives of all companies manufacturing poliomyelitis vaccine, were literally working night and day trying to find an explanation

for the relationship between the vaccine and the occurrence of the cases of poliomyelitis. Even today, the full meaning of this is not understood. The subject remains under study, but it may be months or even years before every factor is completely understood. No amount of insistence or clamor is going to hasten that understanding.

In the meantime, it is well to remember that mechanized, push-button medicine and public health can never be attained. The very nature of every being in the biological world precludes this--and this includes man, as well as the microorganisms that cause many of man's diseases.

Throughout the history of medicine and public health, every great advance has been accomplished a step at a time, with each new and unforeseen obstacle overcome as it has been encountered. This has always involved a certain amount of trial, error, discovery of new knowledge, correction of error, and continued movement forward. This process will characterize the ultimate control of poliomyelitis as it has characterized all other great achievements in medicine and public health.

It would be wonderful, indeed, if there were available unlimited quantities of an absolutely effective, absolutely safe vaccine to provide absolutely assured immunity against poliomyelitis for every person in the United States--or throughout the world, for that matter. The fact is, however, that with existing knowledge it is not possible to produce unlimited quantities of an ideal product with infinite speed.

The history of the present immunization program reveals that competent, conscientious workers have labored earnestly, diligently, and as rapidly as they could to achieve effective, safe immunization of a maximum number of people. They are to be praised rather than censured for their work.

The U. S. Public Health Service is concerned primarily with the prevention and control of disease. [As a government agency under the Department of Health, Education, and Welfare,] It serves no interests except those of the American people. The action the Service has taken with respect to poliomyelitis vaccine, and the action that it will take in the future stems only from its purpose to serve the people well.

It would be tragic indeed if the Public Health Service programs or the individuals who direct them should suffer because of their intelligent, conscientious, and -- it now proves -- successful efforts to sustain the Salk vaccine during ^{THE} ~~this~~ critical period.

My work as chairman and member of the appropriations subcommittee dealing in part with the Public Health Service, including the National Institutes of Health, has kept me in close touch with their work and their leaders for nearly ten years. Theirs is a vital, complex function of the Federal government. As might be expected, they sometimes make mistakes which are discernible in retrospect and thus became fair game for the second-guessers. But -- to my knowledge -- they have never made a serious one, and never made one which stemmed from an improper motive.

In the polio matter, the Surgeon General of the Public Health

Service, Dr. Leonard A. Scheele, has come under special attack, although he has a distinguished record of nearly twenty-five years of public service, the last eight as the nation's senior health officer. His record demonstrates, and all those who work with him and for him know, that he is diligent, conscientious, alert, and capable. He seeks out the best advice he can get on critical issues, since matters of health are rarely matters of pure logic. Then, with this advice, he makes his decision -- and stands by it as his, instead of running away from his responsibilities.

He had the courage to take an unpopular course of action in connection with the Salk vaccine. He took this action having first secured the advice and judgment of everyone who could possibly have anything of substance to contribute -- the scientists of the nation (including those who had been critics of the Salk vaccine even before it was licensed); those who were intimately connected with the development of the vaccine, including Salk himself; the highly competent representatives of the

vaccine manufacturers; and his own scientific and professional staff at the National Institutes of Health.

Then -- given all the facts -- he decided to stop the immunization program temporarily, to change the production and testing procedures, and to delay the availability of vaccine in quantity.

He of course knew he would be attacked for this course of action. But -- instead of indulging in the popular pastime of name-calling and excoriating bungling bureaucrat -- the American people should thank this man who kept the polio program alive when a single wrong decision or a single false move might have destroyed the program altogether and set back polio prevention by many years.

I want to speak, too, of the wisdom and competence and dedication of the scientists and scientific administrators at the National Institutes

of Health, where the medical and scientific part of the polio vaccine problem has been centered.

Dr. William H. Sebrell, Jr., who has just retired as Director of that great research institution, and Dr. James A. Shannon, his successor, have appeared before our committee on literally dozens of occasions. Dr. Sebrell has directed the building of the Institutes into an organization of which we as a nation can well be proud. This is not a matter of size or dollars, nor even merely a matter of scope and direction. The unique quality Dr. Sebrell has contributed to this institution is leadership to give emphasis to quality and research substance and results. Dr. Sebrell and his colleagues have given the Congress and the American people confidence that disease can be conquered by research brought to practical application -- in much the same way, strangely enough, as polio seems about to be conquered. It would be ironic indeed if the fine institution they represent ^{should} suffer in public and professional esteem because of their work to sustain the Salk vaccine in the face of the difficulties met by industry in

producing it consistently on a large scale in accordance with the theoretical and experimental calculations that had been the basis for its licensing. And it would be tragic if their larger research mission should be clouded by irresponsible attack based on misunderstanding of their role in one phase in the evolution of a vaccine against poliomyelitis.

The National Institutes of Health does polio research as one function of one of its Institutes, and it licenses and releases polio vaccine as one among hundreds of biological products produced by industry and regulated by government to protect the interests of the American public. We must not forget that the broad mission of the National Institutes of Health covers all of medical research. Cancer, heart disease, mental illness, arthritis, diabetes, cerebral palsy, epilepsy, blindness -- these and all the other major diseases which kill and ^{maim} ~~main~~ the American people are studied in an intensive research attack that represents the government's primary effort to find a way to achieve better health for more

Americans. The program supports a large part of the research that is conducted in the nation's medical schools and universities, and it gives special attention to providing training opportunities for young medical scientists so that progress will not be impeded by a shortage of trained research workers. The National Institutes of Health has been the subject of special Congressional interest since World War II. It has been built up on a solid basis, to take advantage of research opportunity and to meet the needs of medical science. It has already produced results of great consequence to the public health. We who have watched the Institutes carefully and participated in their development have full confidence in their programs and in the calibre and integrity of their leaders.

Dr. Shannon particularly, as Associate Director of the National Institutes of Health responsible for activities at Bethesda, had a direct, personal role in each step that was taken after the difficulty with polio vaccine first arose. The scientific decisions that affected Dr. Scheele's

administrative decisions were primarily his, based upon advice received from a committee of technical experts. Together, they achieved an understanding of the partial failure of what was presumed to be total virus inactivation, leading to the development of new testing procedures and the establishment of criteria to govern resumption of the polio vaccine program. The nation is fortunate indeed to have a man of such professional and administrative stature to head this, one of the most important of the governmental programs.

I am informed that the polio vaccine problems are pretty well over. There will be further improvements in the vaccine as the result of developmental research that is now in progress. It may be that ultimately there will be a different vaccine to replace the one which now bears the name of the gifted scientist from the University of Pittsburgh. But the end of polio as a major public health problem in this country is in sight. In the meantime, a safe and effective vaccine is being made available in ever-increasing amounts. The completion of most

of the generous immunization program under the auspices of the National Foundation for Infantile Paralysis is at hand. We go now into a period of broad use of the vaccine through Federally-aided State programs, and finally into a period of routine availability through private channels.

Medicine and public health have made a tangible advance against another disease, and have learned a great deal in the process.

Let us, too, view the health of the nation in perspective. Let us be grateful for the progress that has been made -- and let us, without expecting the impossible, give thoughtful and consistent support to those programs whose dedication is to a bright future for the health and well-being of all Americans.