The Congressional Polio Vaccine Hearings of 1955

A landmark in biomedical research

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In the spring of 1955, the Congressional Committee on Interstate and Foreign Commerce held two separate hearings concerning proposed poliomyelitis vaccine legislation. During the first session, the committee called together a group of leading health care administrators, including officials from the Department of Health, Education, and Welfare, the Food and Drug Administration, and the National Institutes of Health to give their advice concerning the proposal to expand the role of the federal government in the manufacture, distribution, and allocation of a polio vaccine. During the second session, the committee gathered a distinguished panel of fifteen leading researchers to answer medical questions concerning the safety of the vaccine and the advisability of distributing it throughout the nation. Three years prior to these hearings, the United States had witnessed the worst epidemic of paralytic poliomyelitis in its history, an outbreak that had claimed 58,000 victims by the end of 1952. In 1954, the National Foundation for Infantile Paralysis (NFIP), the leading private biomedical research foundation in America at that time, sponsored an unprecedented field trial of a vaccine developed by Jonas Salk, one of its researchers, on over two million schoolchildren. The vaccine was the product of nearly twenty-five years of massive research efforts by the NFIP, whose programs and policies involved citizens from every segment of American society and transformed the dynamics and structure of biomedical research and public health.
In April 1955, the Vaccine Review Board, under the leadership of respected epidemiologist Dr. Thomas Francis, Jr., announced the successful results of the test. Following Dr. Francis’s announcement, the Department of Health, Education, and Welfare licensed six pharmaceutical manufacturers to produce the Salk vaccine.

Although the vaccine trials were successful, certain lots of the vaccine produced by Cutter Laboratories in California were found to contain small amounts of live virus that had escaped inactivation. More than fifty California children and members of their families developed paralytic poliomyelitis shortly after the first inoculations in April 1955. Public anxiety about the safety of the polio vaccine was widespread, and was one of the factors precipitating the hearings.

The development of the polio vaccine was a turning point in American medical research, particularly in the relationship among scientists, private medical research organizations, and the federal government. During the first half of the twentieth century, colossal leaps occurred in national patient care, medical knowledge, and scientific technology, and American lay organizations and charities forged many of these advances. During the decades leading up to the Congressional Poliomyelitis Vaccine Hearings in 1955, poliomyelitis research was conducted almost exclusively by the NFIP. By the 1950s, however, the scale and cost of new developments and treatments began to exceed the abilities and resources of the nation’s philanthropic groups. The NFIP-sponsored trial of Salk’s vaccine represented both the NFIP’s greatest achievement and its swan song. Even as the Vaccine Review Board announced the successful results of the trials in April 1955, it was clear that the federal government would need to assume responsibility for bringing the vaccine to the general public. Positioning itself to take command of the rapidly expanding medical infrastructure developed by these lay organizations, the government sought the counsel of the scientific and business communities largely responsible for this growth. Thus, in May and June of 1955, the House Committee of Interstate and Foreign Commerce called in scientists, government administrators, and representatives from medical and pharmaceutical associations to advise it on proposed legislation designed to significantly expand federal involvement in national medicine.

The transcripts of the Congressional hearings of 1955 concerning the poliomyelitis vaccine (the Polio Hearings) serve as an unique telescope through which to view the tensions and questions dominating the burgeoning field of biomedical research at that critical moment in American history, questions about “the interrelationship of popular philanthropy, scientific research, the allocations of resources, and the cultural configurations of disease.” These hearings represented a fundamental transition point in biomedical research and health care policy in the United States.
By and about Samantha Williamson

I grew up in Baltimore, Maryland, and attended Princeton University, where I majored in history and wrote my senior thesis on American identity and ethnic tensions in the U.S. boxing world of the 1920s through 1940s. As a medical student at Johns Hopkins University, I have enjoyed the strong sense of tradition and history proudly embraced by professors and students alike. As someone interested in both medicine and the humanities, I am interested in situations in which the two intersect and must co-exist. I found the development of the poliomyelitis vaccination to be an unparalleled example through which to explore this interplay.

Following hard on the Cutter Laboratories disaster, the hearings not only restored the confidence of the American people in the polio vaccination program, they also implicitly established the national government as the ultimate guardian of health care in America. Prior to the hearings, health care policy was largely dictated by state and local governments and private research organizations.

Because of the unparalleled national attention focused on the polio vaccination program, and the widespread fear and uncertainty caused by the Cutter incident, the hearings were a key event in fostering public acceptance of greater federal involvement in health care.

The Polio Hearings also provided a dramatic public forum for the larger ongoing national debate among legislators, administrators, and the scientific and business communities over the appropriate role of the federal government in regulating the production, use, and distribution of biological products. The testimony and comments of the participating legislators, administrators, and scientists clearly show that most participants fully understood this larger context.

The Polio Hearings made it obvious that the model of biomedical research in the United States during the previous fifty years—the private funding of research by philanthropic organizations such as the NFIP and the National Tuberculosis Association—was insufficient to meet the needs of understanding and combating disease on a national scale. For perhaps the first time, federal legislators were publicly confronted with the complex financial, scientific, and logistical issues involved in developing and administering vaccines to a population that had grown to 150 million. The costs involved in privately underwriting the development and testing of the polio vaccine and distributing it across the nation provided compelling evidence that the federal government would thereafter need to play a central and active role in funding such research.

The Congressional hearings shortly followed the April 1955 announcement of the successful results of the Salk field trial. The hearings were convened to provide information to the House of Representatives on two proposed bills designed to give the federal government greater financial responsibility in the distribution of polio vaccine and other biologics. The first bill proposed a budget of $28 million for a federal poliomyelitis immunization assistance program that would ensure the distribution and allocation of the vaccine to those who could not afford vaccinations for their children. The second proposed an amendment to the existing Biologics Control Law that would grant the Secretary of Health, Education, and Welfare broad discretionary authority to supervise and control the distribution and use of all biological products with the intent “of protecting and preserving the health of the American people.”

The proposed legislation represented a substantial departure from the govern-
ment’s historical role. During the first half of the century, the federal government limited itself to licensing the commercial manufacture of biological products under the Biologics Control Law (Section 361 of the Public Health Services Act). This licensing authority was first established in the Pure Food and Drug Act of 1902. Other than ensuring that proposed drugs met safety and potency standards as a prelude to commercial production, the government up to the time of the hearings played no role in the manufacture, distribution, or use of such products.

The hearings before the House Committee on Interstate and Foreign Commerce, the committee with jurisdiction over all commercial goods sold in interstate commerce, including pharmaceutical products, were held at the New House Office Building in Washington, DC. The committee was composed of thirty representatives from twenty-three states. The Honorable J. Percy Priest from Tennessee served as chairman for both two-day sessions.

The Cutter disaster had created widespread fear and uncertainty among America’s parents. Was the problem limited to a manufacturing defect, or was the Salk vaccine itself unsafe? Should the government insist that the inoculations be discontinued until safer vaccines could be developed, or should the Salk vaccination program continue without delay?

The committee asked several senior members of the Department of Health, Education, and Welfare to attend, including Secretary Oveta Culp Hobby, General Counsel Parke Banta, Special Assistant for Health and Medical Affairs Dr. Chester Keefer, and two assistant secretaries. Their testimony would help to guide the committee in defining and developing the federal government’s role in biological research.

Contrary to the expectation of some, the panel was not comprised exclusively of poliomyelitis virologists, but rather contained an assortment of chemists, biologists, immunologists, physicians, administrative doctors, and virologists. Throughout the hearings, their different perspectives led to disagreement about various aspects of the vaccine development program.

Indicative of the dominance of the NFIP in all aspects of polio research in the first half of the twentieth century, every scientist on the panel had at one time received a grant from
the NFIP’s Committee on Research, and several had served as medical consultants on various executive boards of the NFIP. Dr. Thomas M. Rivers, commonly viewed as the father of virology and for many years chair of the Committee on Research, had worked closely with many of the scientists on the panel. Rivers was, to many, the NFIP’s “official keeper of the flame of Sacred Science.” Before becoming associate director of the NIH, Dr. James A. Shannon spent several years leading the NFIP’s Virus Research Grant commission. Dr. Thomas Francis, of the School of Public Health at the University of Michigan, conducted the evaluation of the field test. His vaccine report, known commonly as the Francis Report, outlined the evidence for the effectiveness of Salk’s vaccine, and was referred to frequently throughout the hearings.

Clearly the most famous member of the panel was Dr. Jonas E. Salk from the virus research laboratory at the University of Pittsburgh, who instantly became a household name following the field trial. Among those in the medical profession, Dr. Albert B. Sabin of the Children’s Research Hospital Foundation in Cincinnati, Ohio, was an equal or greater star. Sabin was considered a giant in the field of poliomyelitis research, and his continuing efforts to develop a live-virus oral vaccine were well-known to the public.

At the outset Chairman Priest explained to both the committee and the scientific panel that the consideration of the legislative proposal for immunization assistance raised both a social question and a scientific, or medical, one. Congress needed to decide whether to support immediate inoculation of children with the Salk vaccine or, in light of the Cutter Laboratories disaster, to halt public vaccination until the development of both advanced safety tests and vaccine improvements. The committee needed to know: Was the Salk vaccine safe?

The hearings represented an important first test for the expanding federal government. While the NFIP had sponsored research laboratories at universities across the country, the NIH, founded in 1887 as a single-room laboratory and then known only as the National Institute of Health (rather than the future “Institutes,” which would include various research arms), funded its own laboratories exclusively. In 1945, NIH grants to scientists outside the Public Health Service totaled a paltry $180,000. The NFIP, by comparison, had an annual 1945 budget of $38 million. The CDC, then an acronym for Communicable Disease Center, spent nearly all of its efforts tracking malarial threats to U.S. military bases. The health care industry was also radically less developed. Health insurance was essentially unheard of, the concept of medical specialties was just catching on, and childhood diseases were held to be tragic but unavoidable.

The two primary areas of debate among the panel’s scientists concerned the need for advanced safety testing and modifications of the existing vaccine. Panel members argued about whether these changes represented merely improvements or rather the removal of serious safety hazards. Some viewed the Cutter incident as an unfortunate side effect of the complex new vaccine production process and believed that the knowledge gained from such mistakes could be incorporated into the vaccine without halting production. Others, however, saw the incident as a symbol of the dangerous inadequacies of the existing vaccine and believed it signified the need for further study.

Throughout the hearings, misunderstanding existed between the committee and the scientific panel. Each group felt the other lacked the necessary facts to make a decision. Politicians and policy makers felt that the scientists and researchers were often unable to see the broader picture. Compromise and imperfection went hand in hand with progress, and time was not a limitless commodity. At the same time, the scientists felt that the administrators were in danger of rushing into decisions while glossing over crucial facts. In continually pushing scientists to reach a conclusion, administrators and politicians seemed to forget that science was not a matter of more work or more money, and its debates were no more black and white than those in politics.

The discussion about whether impurities in the Salk vaccine posed a safety risk illustrates these tensions. When prodded by Chairman Priest to resolve the seemingly conflicting opinions among panel members about whether impurities such as monkey kidney proteins could be removed from

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* For an extended discussion of panel scientists, see Smith, Part II: Laboratory Life, and later chapters of John Rodman Paul’s A History of Poliomyelitis.
the vaccine, Dr. Joseph Smadel of the Army Medical Service School replied:

I think in attempting to simplify the scientific data, both Dr. [Wendell] Stanley [of the Biochemistry and Virus Laboratory, University of California, Berkeley] and I have been led down alleys in which neither of us are in an entirely defensible position. When I said that [the impurity] must still be there, I was speaking in general. When Dr. Stanley said that it is possible to remove it, he was speaking from the theoretical point of view. Somewhere in the middle line is where we belong.\textsuperscript{1p144}

Congressman Springer of Illinois asked whether there was a maximum safety tolerance for such impurities in the vaccine. Dr. Smadel again avoided taking a firm position:

I will answer that by saying that I am sure that there is no consensus about the maximum that is necessary in the final product or the maximum that can be tolerated.\textsuperscript{1p145}

The legislators had particular difficulty parsing the statistical data used by the scientists. Frustrated by what he perceived to be equivocation on the part of the doctors, Congressman Charles Wolverton of New Jersey demanded,

I am trying to put the question in a plain way so that I think it could be answered “Yes” or “No.” . . . After all, these phrases that are used, these terms that are used, are so confusing that I am not able to gather their full significance to the extent the members of the panel would.

However, I could understand if somebody said “Yes, I agree with Dr. Sabin; I think that is what ought to be done.” Or if somebody says “No, I don’t agree with him,” I can understand the word “No” and I can understand the word “Yes.”

If somebody would be willing to express an opinion in that way, it would be very helpful.\textsuperscript{1p179–80}

Anxious for answers, the politicians seemed overly willing to ignore certain conflicting data and recommendations in the interest of time. Nevertheless, the panel members understood the hearing’s purpose. Concerned about the outcome, the scientists compromised. As long as the committee members understood that interpretations of scientific data could be argued both ways (a point many on the committee were beginning to comprehend quite well), the scientists agreed to give more conclusive personal opinions on the readiness of Salk’s vaccine.
The members of the panel who advised halting production until further development of Salk’s vaccine favored this position for different reasons. Dr. Manfred Mayer of the Johns Hopkins School of Hygiene and Public Health believed the experimental evidence supporting the safety of kidney tissue injection (the protein base of the vaccine) was insufficient for public inoculation. In his opinion, in considering the element of danger, one must evaluate in terms of the number of people involved. An experiment with 20 or 50 or even 100 animals does not furnish sufficient experience to extrapolate to 10 million or 20 million children.

The element of numbers must be considered very carefully. This is one reason why I believe our information at the moment is inadequate. For Mayer, the very fact that the decision represented, in panel chairman Dr. Paul’s words, “an interpretation of available data [emphasis added],” signaled the need for further testing. Mayer’s opinion directly followed Salk’s defense of his vaccine. Asked by a committee member if the question of purity was “really material,” Salk responded, I don’t think so. I think it is an interesting and academic question, and one might say how far does one want to gild the lily. . . .

I think it would be nice to purify vaccine further, but not for the reasons that have been implied. . . . let us not do it for the wrong reason. Let us not do it because we are afraid of kidney damage. The clinical evidence is against that. Thus, using identical data, purification of the vaccine represented two very different objectives for Salk and Mayer. For Salk, removing protein tissue constituted a “nice” improvement. For Mayer, introduction of foreign material into the human body posed a potentially grave health risk. With both researchers privy to the same information, the committee was left to reconcile the opposing interpretations.

Dr. Wendell Stanley of the Biochemistry and Virus Laboratory at Berkeley also expressed concerns regarding incomplete testing of the vaccine:

Thus this is the first time in history, so far as I know, when a scientific program has gone ahead pretty much on the basis of not completely unpublished work, but work which is not readily available to scientists generally. Scientists over the years have followed a procedure of experimentation, checking and double-checking within their own laboratory, and publication so that the scientific world is then able to judge
the results, and checking, and rechecking in laboratories throughout the world, and then decisions having been made upon that. . . .

Very frequently competency resides in some other area of the world.1p178

In Stanley's view, the debate between Mayer and Salk illustrated the crucial system of checks and balances in the scientific community. It was not missing data that worried him, but rather a lack of professional criticism and analysis of the existing information (although that process would generate its own data). The best approach to resolve the question of vaccine purification, or any issue, was to open the question to other scientists (on an international scale) and gather a variety of judgments and opinions. Perhaps collectively these personal assessments would point to a resolution or, alternatively, suggest the need for continued study. For Stanley, however, it seemed premature to make any decision regarding Salk's vaccine.

Perhaps the most vocal opponent of Salk's vaccine was Dr. Albert Sabin. Often known as Salk's “perennial rival,” Sabin had criticized both the safety and effectiveness of the vaccine, beginning from its initial discussions in NFIP meetings. Sabin was a firm believer in live-virus vaccines, in which strains of poliomyelitis were “attenuated” to very weak strengths, in contrast to killed-virus vaccines like that developed by Salk. At the time of the hearings, Sabin's strongest grounds for delay focused on the importance of public confidence and perception. In his words,

I know of nothing that would set . . . back [the program of vaccination] for more years and destroy public confidence more than another Cutter Incident. . . .

. . . in attempting to do it at a time when we cannot be absolutely certain of avoiding another incident such as has occurred, we may eventually do more harm than good by going too fast.1p169-70

Until the evidence more conclusively proved the vaccine's safety, Sabin voted to halt the program for six months.

The panel's decision turned on the scientists' definition of “safe.” Dr. Shannon, based on his intimate knowledge of the current state of manufacture and production development, supported maintaining production and inoculation of children with the current vaccine. Drs. Bergsma, MacLeod, and Horsfall agreed, voting to continue the vaccine program and incorporate the substitution of a milder but equally immunogenic strain as soon as possible. Dr. Rivers also opposed halting the program, firmly endorsing the safety of the current vaccine. As he explained to the chair,

Mr. Priest, Dr. Sabin has admitted that a safe vaccine can be made. Right after that he suggests that we stop making a safe vaccine and make a safer one.

. . . . I do not know what is safer than safe. . . .

. . . . I think it would be tragic if we stopped the program now.1p173-74

Other members of the panel warned that halting the existing vaccine program would be harder than implied by Sabin and Hammon. In explaining his vote to continue production and use of the Salk vaccine, Dr. Francis cautioned members of the panel and committee alike that one could not simply implement substantial changes in the existing vaccine and jump directly to the physician's office. A new product demanded new tests and trials.

the suggestion is that this can all be done in 6 months. If one were to stop the present program, either substituting something which I think has been proved to be effective in the field . . . the suggestion would be that you would really substitute and remove a product which has been safe and effective and substitute for it an unknown, an idea which, at the present time, is still experimental. You would be substituting a proven product for something which is yet to be proven.1p199

Regardless of the panel's final tally of votes, the ultimate decision was left to the committee and Congress. Despite the scientists' efforts to include differing interpretations in their discussions, each panel member's comments were ultimately reduced to his “vote.” The committee members' need to condense the opinions of the scientific panel was understandable. The hearings were intended to clarify issues that would affect Congress's vote on the enormous budget for poliomyelitis vaccination assistance. The committee's task required the consideration of elements broader than that of the scientific inquiry and, simultaneously, the dismissal of certain standards and concerns central to the researchers. In this sense, the records of the Congressional hearings illustrate the tensions inherent between biomedical research and policy development. In the end, the scientific panel recommended that the government proceed with the Salk immunization program by a vote of 8 to 3.

Salk and Sabin—different approaches, rivals, but the heroes of the polio war

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Conclusion

The Congressional Committee on Interstate and Foreign Commerce voted to send the poliomyelitis legislation to the floor of the House of Representatives, where the two bills were approved. The vaccine program continued, and Congress authorized a $35 million budget for immunization assistance.

Four years later, Albert Sabin introduced an oral live-virus vaccine that promised lifetime immunity without the boosters necessary in the Salk vaccine. Within less than ten years of the NFIP field trial, the rates for paralytic poliomyelitis in the United States dropped from 13.9 per 100,000 to 0.5 per 100,000. By 1992, just five cases occurred throughout the country. On a broader scale, the Polio Hearings spotlight the transition that was occurring in biomedical research in the 1950s. The public outcry for answers from the government following the Cutter Laboratories incident, and the ensuing Polio Hearings forced the federal government to assert more direct and aggressive control over the manufacture, testing, and delivery of biological products and vaccines. Within two months of the hearings, many of the people and agencies that had been responsible for overseeing the vaccine program were replaced. In July, Secretary Hobby and her special assistant, Chester Kheer, resigned in the face of criticism for their handling of the vaccine program. That same month, William Serbell retired as director of the National Institutes of Health and was replaced by Assistant Director Shannon. On July 15, the Laboratory of Biologics Control was elevated from a subsidiary function within the National Institute of Microbiology to the status of a division within the NIH, under a new director. It was renamed the Bureau of Biologics, and acquired newly enlarged facilities for vaccine testing. Within a year, the bureau employed more than 100 people responsible for vaccine testing.

As a result of the Cutter incident, the U.S. surgeon general established a national surveillance program requiring all states to report cases of poliomyelitis directly to the CDC in Atlanta. Later renamed the Centers for Disease Control, the CDC today plays a pivotal role in tracking all forms of communicable diseases throughout the world. In the years following the Polio Hearings, Congress passed new legislation granting the federal government extensive regulatory powers over the distribution and use of all biologics. The Public Health Services were expanded to include twelve new subcommittees created to monitor and administer biomedical research and national health care.

The government’s assumption of control over the polio vaccine program also marked the end of independently financed research by organizations such as the NFIP, and ushered in the era of the government funded laboratory grant. During the ensuing years, the federal government took the reins of medical funding from the lay philanthropic organizations, prompting massive growth in federal health and research programs. By the 1960s, the National Institutes of Health, which in 1945 had dedicated less than $200,000 to independent research programs, had become the primary source of medical research grants in the nation. Today comprised of twenty-seven separate institutes and centers, the NIH conducts research in its own laboratories and supports the biomedical research of independent scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad. The transcripts of the Polio Hearings of 1955 provide an invaluable historical insight into the political, scientific, financial, and administrative issues and concerns that drove this dramatic transition.

References


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