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The Trials and Triumphs of the American Polio Vaccine

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Introduction:

Vaccination is one of mankind’s most influential scientific advances. It is only the past couple hundreds of years that humans have been able to thwart the illnesses that have plagued our population since the beginning of human existence. In the 14th century the Black Plague is responsive for killing millions people; over 50% of European population at the time.\(^1\) In the colonial era, small pox was killing most children less than 10 years old or leaving the survivors disfigured.\(^2\) With the developmental advances in immunology, the discovery of vaccines is responsible for saving millions of lives and pushing back the illnesses that used to spur so much fear, into the shadows.

Today’s generations will never know a person who perished from tuberculosis or have a classmate crippled by poliomyelitis. This is a fact for which the human race should be eternally grateful. There was a time that parents were so terrorized by these illnesses that they would volunteer their children for experimental treatment, a time where countless prayers were said to beg for a cure or to plead to a greater power to spare your family from harm. This fear has enormous power. It can drive a society into madness- the aftermath of the AIDS epidemic is still evident today with the stigmatization of HIV+ individuals- or it can unity a community against a common enemy.

The story of the development of the polio vaccination is a tale of dread, scientific endeavor, trials, and triumph. It is a story about how fear was harnessed to fuel the greatest scientific experiment in American history and a story of how man rid the earth of a frightening, child paralyzing, microscopic monster.

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\(^1\) Oshinsky, David M. *Polio: An American story*. Oxford: Oxford University Press, 2006. 8

\(^2\) Ibid.
The History of Poliomyelitis

The disease we know as poliomyelitis has been terrorizing humans for thousands of years. Archeologist have unearthed Ancient Egyptian paintings and carvings that depict healthy adults with withered limbs. There are of paintings of Ancient Egyptian children using canes to walk. The earliest example is depicted on a freestanding stone tablet, believed to be from 1500 BC. On the tablet, there is a carving of a man, whom archeologist believe to have been a priest based on his wardrobe, with a withered right leg who is using a cane to support his weight.

Throughout early human history, poliomyelitis was a disease that primary affected individuals, not a population. The disease most often effected children and therefore was referred to as infantile paralysis. Some of the most famous, ancient physicians in Europe, including Hippocrates, wrote about deformities that are indicative of poliomyelitis. The name polio itself comes from the word poliomyelitis, which is a combination of Greek words; “polios” meaning gray and “myelos” meaning marrow in addition to the Latin suffix “-itis” which means inflammation. Progressing forward in time, there are sporadic references to paralyzed children in the Middle Ages and more detailed historical accounts come from the 17th and 18th centuries.

In the mid 1800s, small population of infantile paralysis cases were speckled around Western Europe and the United States of America. In the summer of 1894, the first American polio epidemic was record was in Otter Valley, Vermont. In total, 123 children were affected. A meticulous and observant family physician named Charles Caverly carefully recorded information about each case and discovered public health trends about polio that would be useful for future outbreaks. He noted that the majority of polio victims were male and under 6 years

4 Ibid.
old. He also observed that most of the cases occurred in the summer and began the same way, with a headache, fever, nausea, fatigue, and a stiff neck. These vague signs could be interpreted as simply a bad case of the flu, but in reality, there was something more sinister happening to these young people.6

In 1916, a quickly growing epidemic of weakness in young children in a section of Brooklyn caught the attention of the Health Department. Pigtown, the area affected, was known for being a heavily populated immigrant community. Local newspapers at the time interviewed frightened Italian parents who reported that their children where too weak to hold a bottle or that their “legs seemed limp”. The Health Department sent dozens of investigators to Pigtown to conduct door-to-door inspections. Polio was found to be accountable.7

Up until the late 18th century, New York had a higher mortality rate than other comparable metropolises like Paris, London, Boston, and Philadelphia. It is estimated that 20 percent of New York babies died before their first birthday and of those that did survive, 25 percent of them would die before adulthood. The polio epidemic of 1916 was of immense significance. It is estimated that New York City had 8,900 cases and 2,400 deaths from polio. Of those reported cases 80 percent were children under five years old.8 Public health officials and federal authorities took desperate measures to contain the epidemic. They declared quarantines, banned public gatherings, killed up to 450 domestic cats and dogs every day, and dowsed the streets with 4 million gallons of water in an effort to abate the disease.9 But their efforts were

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8 Ibid.
null. The epidemic quickly outgrew New York, lasted from July to October, and claimed 27,000 lives in the United States. At its peak, a child died from polio every twenty-six minutes.\textsuperscript{10}

While the significant impact of the 1916 epidemic may have been overshadowed by World War I, medical researchers at the time were asking the pertinent questions: how does polio spread? How can we stop it? Unlike other infectious epidemics, it seems that polio did not respond to the typical public health measures of quarantine and sanitation. Polio was different.\textsuperscript{11}

While scientific curiosities about polio where challenging the nation’s brightest minds, the public could not afford to wait for the mysteries of polio to be solved as their children withered and died.

At the time, there were multiple theories about what caused polio. The community blamed fish, rats, cats, horses, mosquitos, chickens, shark vapors, pasteurized milk, wireless electricity, radio waves, tobacco smoke, automobile exhaust, the beards of doctors, and poisonous gases permeating from Europe. They blamed tarantulas for injecting their salivary poisons into bananas. They blamed parents for ticking their children. They blamed immigrant populations and they blamed the will of God. Desperate and scared, residents tried everything to prevent the illness. They ate catnip, skullcap, lady’s slipper, earthworm oils, blackberry brandy, and the blood of animals. People hung charms around their necks of garlic, pepper, camphor, and onions. Charlatans enticed terrified parents with potions of sassafras and alcohol or magic wood.


chips, promising protection and cure from poliomyelitis.\textsuperscript{12} Despite these measures, no one was safe from the reach of polio as it did not discriminate against gender, age, race, or religion.

Poliomyelitis is a virus that can take up residence in the anterior horn of the spinal cord and cause paralysis. It is an enteric infection, that is spread among individuals due to contact with fecal waste. Polio enters the body through the mouth and is ultimately excreted in stool. Replication of the virus occurs primarily in the small intestine, but can also occur at various points throughout the body, including the lymph nodes that are along the digestive tract. Once the virus is absorbed into the bloodstream it travels to the spinal cord where it damages motor neurons, the nerves that communicate to the muscles, inducing paralysis. Most deaths that occur due to poliomyelitis occur when the paralysis involves the diaphragm and other breathing muscles.\textsuperscript{13}

While paralysis is the most feared symptom of poliomyelitis it only occurs in about one in a hundred cases. Most often, polio infected individuals experience a minor illness with minimal discomfort. A short course of headache, nausea, and malaise are common and then the individual acquires protective immunity. But about 1 percent of people infected with poliomyelitis end up with an illness that causes variable paralysis.\textsuperscript{14} It is this drastic symptom that society and parents feared the most. Paralysis changes the polio survivor’s life forever.

\textbf{FDR and the March of Dimes}

Perhaps the most famous and influential individual affected by poliomyelitis was the United States of America’s thirty second president, Franklin Delano Roosevelt. At the age of thirty-nine, Franklin Delano Roosevelt, FDR, was a powerful, promising figure in the political

world. By 1921, he was a nominee for vice president, secretary of the navy, and a successful lawyer. The New York legislator was described as a “flamboyant and charismatic” individual who liked to stay active through swimming, sailing, running, and playing tennis.\textsuperscript{15}

In August of 1921, FDR was vacationing in the family’s summer home on Campobello Island, a small island off the coast of New Brunswick, Canada, when he started to experience muscle weakness. By the end of the day on August 10th, 1921, he was unable to stand or walk. When the doctors arrived to examine FDR, he was given a diagnosis of poliomyelitis.\textsuperscript{16}

At close to 40 years old, FDR did not fit the typical depiction of a polio victim. It is hypothesized that his wealthy upbringing may have sheltered him from naturally acquiring immunity to polio like the majority of children.\textsuperscript{17} In addition, the natural history of polio infections shows that older victims usually acquire a more severe course of the disease. FDR was completely paralyzed from the waist down with little to no use of his lower extremities.

However, Roosevelt was determined to overcome his diagnosis. Each night, FDR would challenge himself to walk. With the assistance of a helping hand or a cane, he would painstakingly place one foot in front of the other while he was drenched in sweat and saturated with frustration. In addition, he tried salt water baths, positive thinking techniques, ultra-violet light therapy, extensive bed rest, deep tissue massage, and various forms for physical therapy. Nothing seemed to make a difference. Nonetheless, he refused to accept failure. In the fall of

\textsuperscript{15} Offit, Paul A. \textit{The Cutter incident: how Americas first polio vaccine led to the growing vaccine crisis}. New Haven, CT: Yale University Press, 2007.31-38.
\textsuperscript{16} Ibid.
\textsuperscript{17} Offit, Paul A. \textit{The Cutter incident: how Americas first polio vaccine led to the growing vaccine crisis}. New Haven, CT: Yale University Press, 2007. 40.
1924, Roosevelt became intrigued with the story of Louis Joseph, a polio survivor who was able to achieve complete recover after swimming at the Warm Springs Resort.18

Warm Springs Resort was a thousand-acre establishment nestled in the pine forest of rural Meriwether County, Georgia. The land first belonged to the Creek Indians, who believed in the spirit of the healing waters to cure ailments such as dyspepsia, rheumatisms, and other chronic conditions.19 The property was eventually acquired by a private investor and converted into a Victorian inn that was equipped with 46 rooms, 15 private cabins, tennis courts, spas, and of course, the spring-fed swimming pool.20

By the time Roosevelt came to visit Warm Springs in 1924, the resort had undergone financial difficulties and was struggling to fill vacancy. Not deterred by the condition of the establishment, FDR fell in love with the facility’s charm and promise. While the spring was not magical, it did consistently stay at a balmy 88 degrees Fahrenheit and have a high mineral content. The high concentrations of Calcium and Magnesium in the water are responsible for an increase in the water’s buoyance. The result being that patient felt a heightened feeling of weightlessness and could move their extremities with little effort.21 When FDR first experienced the waters at Warm Springs he yelled “How marvelous! I don’t think I’ll ever get out”.22

Subsequently, Roosevelt bought the Warm Springs resort in 1926 for $200,000, which was about two thirds of his personal fortune. Despite this being a risky investment, Eleanor Roosevelt recalled that FDR felt like “he’s trying to do a big thing which may be a financial

20 Ibid
22 Ibid
success and a medical and philanthropic opportunity for infantile paralysis”.\textsuperscript{23} He and his
colleague, Basil O’Connor, turned the resort into a nonprofit organization so that it could be
sustained with tax- free gifts and charitable grants. Renovations were made to the facilities and
people from all over the country flocked to Georgia to experience Warm Springs.\textsuperscript{24}

With FDR’s reemergence into the political world in 1928 New York Governor’s election, he needed someone to take over his administrative responsibilities at the Warm Springs Foundation. He asked his good friend and fellow lawyer Basil O’Connor to take over control of the estate. While O’Connor had little interests in running a nonprofit organization, his leadership is responsible for sponsoring the great American crusade against polio.\textsuperscript{25}

The stock market crash of 1929 plummeted the United States economy into the Great Depression. With a lack of wealthy donors and generous grants, Warm Springs experienced a severe cash flow problems. Over the course of a year contributions to the Warm Springs Foundation dropped by over tenfold. On the verge of bankruptcy, O’Connor and the leaders at Warm Springs brainstormed various fundraising techniques to save the organization. Taking advantage of the founder of Warm Spring’s presidential office, they decided to pitch the idea of a nationwide party to celebrate Roosevelt’s birthday. Thus, the President’s Birthday Ball was born. Across the nation, thousands of local Birthday Ball committees were founded, united by the slogan, “We Dance so that Others Might Walk”\textsuperscript{26}

The campaign was a soaring success. There were over 6,000 Birthday Ball celebrations all the way from the coast of Washington state, to the Florida Keys. Businesses closed early,

\begin{itemize}
\item \textsuperscript{26} Oshinsky, David M. \textit{Polio: An American story}. Oxford: Oxford University Press, 2006. 49.
\end{itemize}
fireworks were lit, and ballrooms across the country were overflowing with people wanting to show their support. In Washington D.C., FDR attended the Birthday Ball at the Waldorf- Astoria where over 5,000 people occupied four ballrooms and enjoyed a birthday cake with a 28-foot diameter. At the end of the night, the president addressed the nation through radio broadcast in which he said “This, is the happiest birthday I have ever known”. When contributions were tallied, the President’s Birthday Ball raised $1,016,443 for infantile paralysis, much exceeding everyone’s expectations.

The President’s Birthday Ball Commission revolutionized fundraising efforts and philanthropy in the United States. When once, nonprofit organizations were so dependent on large lump sums of money from cooperate organization, they now focused on amassing thousands of small donations and adopting the notion that nothing is too little to give. They were able to reach millions of people though television and radio and incite the community to unify against infantile paralysis.

Out of the success of the President’s Birthday Ball Commission, the National Foundation for Infantile Paralysis (NFIP) was formed. The NFIP was a nonpartisan group created by FDR and headed by O’Connor that was devoted to finding the cure for polio while providing the best treatment for those already afflicted. With an incredible startup cost needed, the public relations department at the NFIP wasted no time reaching out to celebrities for support. At the top of their list was Eddie Cantor, the highest paid performer of the time. Cantor, best known for his

[28] Ibid
blackface comedic routines, silent films, musicals, and popular radio show was beloved by millions of Americans. As a devoted husband, father, and friend to the president, Cantor would be the perfect fit as the celebrity personality of the NFIP.  

It was Eddie Cantor who is credited with creating the March of Dimes campaign. Named after a famous news reel, “The March of Time,” that played in theaters before the feature production, Cantor suggested that the NFIP could ask the American public to send their dimes to the president at the White House in support of polio research. The day after Cantor broadcasted about the March of Dimes on his radio show, the White House reported that they received 30,000 letters, and then 50,000 the next day, and then 150,000 letters on the third day. For a mailroom that is used to handing 5,000 pieces of mail a day, the White House was overwhelmed. Ira T. Smith, who ran the White House mail room at the time recalled “We kept on getting incredible numbers, and the Government of the United States darned near stopped functioning because we couldn’t clear away enough dimes”.  

The end result of the March of Dimes was that 2,680,000 dimes made their way to the White House, along with numerous small bills and personal checks. The dime became a powerful symbol of the fight against polio, so much so that in 1946 the director of the U.S. Mint released the Roosevelt dime with FDR’s likeness on it, to mark the presidents 64th birthday and to be used in the infantile paralysis drive.  

With a successful fundraising technique, the NFIP focused on sponsoring medical research related to polio and providing treatment coverage for its victims. Between 1938 and 1962, the March of Dimes raised $630 million dollars, of which $70 million dollars was set aside.

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for research and the remainder went to providing financial assistance for the treatment and rehabilitation of every polio victim in the country. The NFIP sponsored many grants to established researchers interested in fighting polio. The grants ranged from as low as $2,000 to as high as $64,000 and sponsored everything from developing a nasal spray to protect against polio to studies to “examining the different degrees of virulence in the virus”. The top priority of the NFIP’s research efforts, however, was to fund the production of “a good vaccine”.

The Vaccine Race

A vaccine to prevent against polio was the golden goose of any researcher in the field of virology. Due to the degenerative nature of the illness, a treatment for paralysis caused by polio is next to impossible. The next best thing is to prevent polio from taking any more victims in the first place. In 1932, Dr. John Kolmer made one of the first attempts to create an effective polio vaccine. Seeing the success of the rabies and yellow fever virus vaccines by his colleagues, he hypothesized that a similar denaturing process could weaken the polio virus enough to decrease its virulence but induce protective immunity. To make his vaccine, Kolmer grounded up the spinal cords of monkeys infected with polio, soaked them in a salt solution, filtered them through a thin mesh, and then treated them with ricinolate, a substance found in castor oil, for 15 days. He declared his vaccine to be safe after he tested it on his 2 sons, his lab assistant, and twenty-five local children.

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Kolmer went on to test his vaccine in ten thousand children in thirty-six states and in Canada. The three-dose vaccine trial did not have a control group which impeded the ability of researchers to tell if the vaccine was actually effective. Not long into the study several children began to develop polio after receiving Kolmer’s vaccine. Paralysis started in the arm where the child was inoculated and progressed throughout the body. Overall, Kolmer’s vaccine paralyzed ten children and killed five.\textsuperscript{36}

During this time, another researcher, Maurice Brodie, was working on a “killed virus vaccine”. Unlike Kolmer, who wanted to weaken the virus, Brodie wanted to destroy the virus’s ability to cause illness while maintaining properties that trigger the immune system’s ability to make antibodies against polio. Brodie made his vaccine by treating the spinal cords of paralyzed monkeys with polio and treating them for 25 days with formaldehyde. Brodie inoculated himself and 5 coworkers before he injected the vaccine into twelve children. All children produced polio antibodies without developing polio, a success. Brodie then proceeded to inoculate seven thousand children with his formaldehyde treated polio vaccine.\textsuperscript{37}

Brodie’s large-scale vaccine trial included vaccinated and nonvaccinated children from North Carolina, Virginia, and California. His research showed that 5 out of 4,500 children who did not receive the vaccine acquired polio, compared to only 1 of 7,000 children who received his vaccine. These results showed that the vaccine was 88 percent effective in preventing polio, but there was a serious complication.\textsuperscript{38} A previously healthy twenty-year-old who received

\footnotesize{\textsuperscript{36} Offit, Paul A. The Cutter incident: how Americas first polio vaccine led to the growing vaccine crisis. New Haven, CT: Yale University Press, 2007. 17.}  
\footnotesize{\textsuperscript{37} Offit, Paul A. The Cutter incident: how Americas first polio vaccine led to the growing vaccine crisis. New Haven, CT: Yale University Press, 2007. 15-18.}  
\footnotesize{\textsuperscript{38} Offit, Paul A. The Cutter incident: how Americas first polio vaccine led to the growing vaccine crisis. New Haven, CT: Yale University Press, 2007. 17.}
Brodie’s vaccine developed paralysis in his inoculated arm and died four days later. In addition, two children under the age of five, developed polio within two weeks of being inoculated with Brodie’s vaccine. These cases caused medical journals and researchers to question if Brodie’s vaccine was safe and if it even worked.39

The catastrophes that resulted from these early vaccine trials proved that developing a safe and effective polio vaccine would be no easy feat. Kolmer was accused of being a “murder” by another colleague and Brodie struggled to find work after his findings were presented. The effect that these trials had on polio research was so haunting that no one dared to develop another vaccine for another twenty years.40

In 1951, Basil O’Connor was sailing on the luxurious Queen Mary ocean liner when he met a young scientist who peaked his interest. He quickly realized that this scientist was unlike others he had interacted with through the NFIP and they struck up a casual friendship as they strolled the deck and talked about their philosophies on research, polio, and life. O’Connor recalled “Before that ship landed I knew this was one young man to keep an eye on”. That young scientist was Jonas Salk.41

Jonas Salk was born on October 28th 1914 to a pair of Russian immigrants in East Harlem, New York. Jonas was a quick and intelligent child. He was accepted to the Townsend Harris High School, a highly competitive public school for intellectually gifted students, at the age of 12. Salk graduated a year early from high school and went on the City College of New

40 Ibid.
York and then attended New York University (NYU) College of Medicine on a scholarship.\(^{42}\) During his time at NYU, Salk excelled in his classes and received top marks in most subjects. Salk even attended faculty lectures and seminars with permission from the medical school’s dean. It was here that he forged a love for the laboratory.\(^{43}\) Upon graduation from NYU, Salk entered residency at the prestigious Mt. Sinai Hospital in New York City. After completing his residency training, Salk joined forces with his former medical school mentor and virology expert Thomas Francis at the University of Michigan to study the influenza virus.\(^{44}\)

In 1947, Salk branched out on his own and took an associate professorship position at the University of Pittsburg. It is there that he got involved with NFIP to prove the validity of research that showed there were three types of polio viruses. In 1951, Salk received a generous grant of $200,000 from the NFIP to support his research by hiring over 50 personnel and expand his laboratory to previously three empty floors of Pittsburg’s Municipal Hospital.\(^{45}\)

Salk, and his partner Julius Youngner, worked to develop several advances that would be essential to vaccine production. They developed methods to grow polio viral particles on monkey testicles, providing an easy medium for researchers to replicate the virus. They also revolutionized polio virus typing. Salk and Younger worked to determine the characteristics and virulence of each strain of polio. This knowledge would be vital in the development of a vaccine strains would need to be chosen that could induce immunity and provide protection against all three types of polio viruses. Salk choose to work with MEF-I, the most common type of type 2


\(^{43}\) oshinsky 98


polio, The Saukett strain, a sample of a type 3 polio virus isolated from a young boy in and to represent type 1 polio Salk picked The Mahoney strain, a virus that was isolated from a child in Akron, Ohio. The Mahoney strain portrayed incredible virulence, with the ability to paralyze monkeys at 1 to 10,000 parts diluted. To make his vaccine Salk grew the viruses in monkey kidney or testicular cells, then placed the viral suspension on ice, before finally treating the viruses with formaldehyde to weaken them, like his predecessor Maurice Brodie. During this process Salk took meticulous data about the inactivation time of each virus and constructed strict protocols for each step of virus inactivation.

Jonas Salk was not the only one with a horse in the race for the polio vaccine. In 1949 there were a reported 42,000 cases of polio, making it the worst epidemic thus far. With polio dominating the media, the public became more frightful and more desperate for a vaccine.

In early 1950, Hilary Koprowski, a physician who had excellent success reinventing Pastuaer’s rabies vaccine, was testing his oral polio vaccine in volunteers. Koprowski aimed to develop a vaccine that acquired immunity by mimicking the natural route of infection. Unlike Salk, he did not want to “kill” the virus, but instead introduce a weakened strain of the polio virus that could replicate in the gut and not have paralytic properties. He found his weakened polio virus in a strain that was adapted from rodents. His first test subject experienced no side effects and an analysis of his excrement showed that neutralizing, anti-poliovirus antibodies were

50 Ibid.
developed. He went on to test his oral polio vaccine in 19 children before presenting the results of his trial at the Round Table Conference on Immunization Against Polio in March of 1951. This conference was hosted by the NFIP and researchers from across the country were invited to participate and share their findings. No other researchers were relatively close to human trials at this time; Salk was still working on growing polio in monkey testicular tissue.\textsuperscript{51} Koprowski got mixed criticism on his results. Albert Sabin, a fellow researcher working on his own oral polio vaccine, accused Koprowski of cruelty to children and hinted that he might be prosecuted by the Society for the Prevention of Cruelty to Children for his trials. Others, found Koprowski’s results to be the competitive push that polio research needed. Dr. Howe of Johns Hopkins remarked “Koprowski has shown to us all that our experimental results of immunization of chimpanzees may also be expected in man”.\textsuperscript{52} Despite the positive initial results of Koprowski’s trial, the NFIP did not pursue the vaccine. Dr. Koprowski went on the further develop his oral polio virus vaccine and ultimately experienced great successes vaccinating over 13 million individuals from the jungles of the Congo to Poland and Croatia.\textsuperscript{53}

As previously mentioned, Albert Sabin was another contender in the race for a polio vaccine. Like Koprowski, he was working on an oral polio vaccine with a live virus. Sabin is most famous for his vaccination efforts in the Soviet Union and for his prickly opposition to Jonas Salk. While others felt the pressure to produce results at a demanding and fast pace, Sabin distasted the hastiness of the NFIP to indorse a vaccine. He criticized Koprowski for testing in his vaccine prematurely in children and he was skeptical of Salk’s ability to successfully kill the

\textsuperscript{51} Ibid.
\textsuperscript{52} Ibid.
\textsuperscript{53} Ibid.
polio virus. While Sabin was not the first to produce an effective vaccine, he would be the ultimate winner in the tortoise and the hare story of the polio vaccine.⁵⁴

The Field Trial

In the spring of 1953, Jonas Salk performed the time-honored ritual of inoculating himself and his family with his vaccine. Salk had three boys, under the age of ten, all of which had no adverse reactions to the vaccine.⁵⁵ With the polio epidemic of 1952 looming in the past, the NFIP and the public were eager for a vaccine. In the summer of 1952 over fifty-eight thousand people were affected by polio.⁵⁶ It was one of the worse polio epidemics yet. However, in order to produce adequate quantities of Salk’s vaccine to conduct a field trial the NFIP would have to turn to pharmaceutical companies for help. They were the ones with the proper equipment to mass produce the vaccine. O’Connor and the NFIP signed 5 pharmaceutical companies to produce the Salk vaccine, Parke-Davis of Detroit, Eli-Lilly of Indianapolis, Wyeth of Marietta, Pennsylvania, and Pitman-Moore of Zionville, Indiana, and Cutter Laboratories of Berkeley.⁵⁷

The plans for the field trial included 420,000 children to receive Salk’s polio vaccine (produced by Parke-Davis and Eli-Lilly), 200,000 children would receive a placebo saline injection, and 1.2 million children would act as controls and be given nothing. With a total of 1.8 million participants, the Salk Vaccine field trial was, and remains today, to be the largest, most comprehensive test of a medical product ever conducted in the United States. Over twenty

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thousand physicians and forty thousand registered nurses, fifty thousand teachers, and two hundred thousand members of the community from forty-four states volunteered their time to the trial. The trial was double-blinded, meaning the physicians administering the injection and participants did not know if they were given the vaccine or a placebo. On April 26\textsuperscript{th}, 1954, the first shot was given to six-year-old, Randy Kerr of McLean, Virginia in front of several reporters and cameramen.\textsuperscript{58}

When the data from the trial was analyzed, the results were clear: the vaccine worked. Sixteen children in the trial died from polio and none of them received Salk’s vaccine. Thirty-six participants developed polio and had to be placed in iron lungs. Of those thirty-six children, only two received the Salk vaccine. Overall, children who did not receive the Salk vaccine were 3.3 times more likely to be paralyzed from polio than those who were inoculated. The trial was a success and American had the vaccine it had worked so hard to fund.\textsuperscript{59}

On April 12\textsuperscript{th} 1955, Thomas Francis, Salk’s former mentor and director of the NFIP field trial prepared to share the results of the trial with the American public. Over five hundred people crammed into the auditorium at Rackham Hall on the campus of the University of Michigan. Over 150 reporters and 16 television cameras stood, waiting anxiously to hear Francis’s report. Across the country, movie theaters were broadcasting the event to thousands of physicians who filled their seats. For over an hour Thomas Francis stood at the podium and presented the

\textsuperscript{58} Offit, Paul A. \textit{The Cutter incident: how Americas first polio vaccine led to the growing vaccine crisis}. New Haven, CT: Yale University Press, 2007. 50-52.

scientific data from the trial. Behind all medical jargon the message was clear: the vaccine worked.\textsuperscript{60}

With the announcement of the successful vaccine trial, church bells rung across the country, factories held moments of silence, and it was not uncommon to see Americans with tears of joy in their eyes. It was as if a war had ended, and in some ways, one did. Salk was catapulted into the role of hero and became the public embodiment of the long crusade to eliminate polio from American soil.\textsuperscript{61}

The Cutter Incident

With the announcement of the success of the field trial, responsibility for the production of the vaccine was no longer managed by the NFIP, but instead by the government agencies that oversaw pharmaceutical companies once the vaccine was sold to the public.\textsuperscript{62} The Laboratory of Biologics Control (LBC) was the federal agency within the National Institutes of Health that was responsible for the licensing of vaccines. Up to that time, the LBC managed diphtheria toxin production and 200 other medical products. On April 13\textsuperscript{th}, one day after Thomas Francis’s announcement, the LBC granted licensing for the polio vaccine to the five original manufacturers and approved numerous lots of the polio vaccine for distribution.\textsuperscript{63}

Less than two weeks after vaccine production, phone calls were pouring into the office of the director of the LBC regarding cases of paralytic polio. On April 25\textsuperscript{th} he received a phone call

\begin{footnotesize}
\textsuperscript{60} Offit, Paul A. \textit{The Cutter incident: how Americas first polio vaccine led to the growing vaccine crisis}. New Haven, CT: Yale University Press, 2007. 54-55.
\end{footnotesize}
about a one year old child who experienced complete paralysis of his legs eight days after being
inoculated. The next day, two seven-year-old boys from California reported paralysis in their left
arms after receiving the polio vaccine. By the end of the day on April 26th, there were six
children who experienced paralysis after receiving the polio vaccine- and they all received
vaccines manufactured by Cutter Laboratories.64

This event was the start of what would come to be known as the Cutter Incident. The
decision was made to recall the Cutter vaccine forty-eight hours after the first cases of paralysis,
but the damage was already done; three hundred eighty thousand doses of the vaccine were given
to children across the country.65 In the two months that followed, 94 cases of poliomyelitis were
registered in children who were given Cutter vaccines.66 In addition, 126 cases of polio were
reported in family contacts of the vaccinees and 40 cases in community contacts. A total of 260
cases of polio were attributed to faulty Cutter vaccines. Of those 260 cases of polio, 192 were
paralytic, and 10 deaths occurred.67 As a result, the American public’s confidence in the Salk
polio vaccine was shaken.

Repercussions of the Cutter Incident and the future of the polio vaccine

Extensive research and analysis of the Cutter Laboratory’s inactivation protocol revealed
two possible cause for the inactivated virus to be present in the vaccines. First, poor filtering
allowed viral clumps to form which could hid infectious particles, and secondly, Salk’s equation

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64 Offit, Paul A. The Cutter incident: how Americas first polio vaccine led to the growing vaccine
65 Offit, Paul A. The Cutter incident: how Americas first polio vaccine led to the growing vaccine
66 Koprowski, Hilary. "First decade (1950-1960) of studies and trials with the polio
67 Furesz, J. "Developments in the production and quality control of poliovirus vaccines-
for inactivation was difficult for Cutter (and other pharmaceutical companies) to replicate at high volumes.\textsuperscript{68} Investigations into the incident showed that there was evidence of the Cutter was struggling before cases of polio were reported; more than one third of the vaccine lots produced by Cutter had evidence of live virus particles.\textsuperscript{69} The addition of a Seitz filter midway during activation and an increase in the viral inactivation period provided easy solutions to the problem, making the Salk vaccine safe again, but the damage to the vaccine’s reputation had already been substantial.\textsuperscript{70}

The Cutter Incident could not have occurred at a worse time. On the brink of polio season with public panic over the Salk vaccine, government officials were in a difficult situation. This paved the way for Albert Sabin. Taking advantage of the fear of improper viral inactivation, Sabin proposed that his oral live virus was safer. The vaccine contained a weakened, but live version of the polio virus that was taken by mouth following the natural path of wild poliovirus. The vaccine would induce replication of polio virus in the gut and subsequent anti-poliovirus antibodies to be formed, providing lifelong immunity without the need for booster shots.\textsuperscript{71} Sabin tested his vaccine in inmates and the trials were a success. Sabin ran into a roadblock, however, when he went to do a large scale trial of his vaccine in the US; with most of the population, either having natural immunity of induced immunity due to the Salk vaccine field trial, he was lacking test subjects.\textsuperscript{72} Sabin found his solace in the Soviet Union where polio epidemics were

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growing larger each year. Russian officials invited Sabin to the USSR in 1959 where he inoculated 10 million children. The immense success of his Russian trials proved that Sabin’s live, oral polio vaccine held up against Salk’s inactivated vaccine. In 1960, Sabin was approved to conduct field trials in the United States and later that year, the surgeon general approved his vaccine for production. Just one year later, in 1961, the reported cases of polio in the United States dropped below 1,000, the lowest total ever. America was virtually eradicated of polio.

In 1987 the World Health Organization (WHO) launched a global initiative to eradicate polio from the planet. Backed by the Center for Disease Control (CDC) and the United Nations Children’s Fund (UNICEF), WHO administered the polio vaccine to high risk nations around the world. By 2000, the reported cases of polio worldwide had already been reduced from a thousand new cases a day to just two thousand cases a year. By 2005, 95% of polio only existed in small pockets of the world, like remote parts of Northern India, Nigeria, and Pakistan. Now, in 2017, with polio on the brink of eradication, the remaining handful of cases occur in areas that are hard to reach due to political conflicts. Last year’s data reports that there were only thirty-seven cases of polio reported worldwide.

Conclusion

The story of the polio vaccine is one of innovation, determination, and triumph. It captures the indefatigable human spirit to overcome challenges and powerful momentum of a society motivated by a common enemy. The polio vaccine should be a proud accomplishment of

77 Undark Podcast. MIT. November 2 2017.
the people; sponsored by a charitable organization, embodying the spirit of volunteerism, paid
for by millions of small contributions, and made possible by faith in scientific research.
When Salk was asked about who own the polio vaccine he replied “Well, the people (do), I
would say”.78 The polio vaccine truly belongs to the people of the Unites States, for without their
efforts eradication of one of the most terrifying and disfiguring diseases would not be possible.