April 12, 1955 — Tommy Francis and the Salk Vaccine

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April 12, 1955, was supposed to be Tommy Francis’s day. At 10:20 a.m., the distinguished epidemiologist was scheduled to conduct an international press conference in Rackham Auditorium at the University of Michigan. The topic was the field trial he had just completed — the largest of its kind ever — evaluating the efficacy of the poliovirus vaccine developed by Jonas Salk at the University of Pittsburgh.

It is hardly hyperbole to note that the speech by Dr. Thomas Francis, Jr., was eagerly awaited by most of the world. Few diseases were capable of arousing more fear than poliomyelitis. Almost every summer, polio epidemics left behind a wake of paralysis and death; horrific images of children struggling to walk or trapped inside iron lungs were etched into every parent’s brain.

The U.S. fight against polio was significantly advanced by President Franklin Delano Roosevelt, the world’s most famous polio patient. In 1937, convinced that nothing short of the conquest of the disease was required, Roosevelt announced the formation of a National Foundation for Infantile Paralysis (NFIP) that would “lead, direct, and unify the fight of every phase of this sickness.” Soon, millions of Americans were responding to the pleas of the radio star Eddie Cantor to “send their dimes directly to the President at the White House...and we could call it the March of Dimes.”

Although we can justifiably recall the battle against polio as a huge success, it was not without its share of well-publicized and almost disastrous failures. Among the most notorious were two highly touted but flawed vaccines that appeared in the mid-1930s — one, a formalin-killed vaccine, developed by Maurice Brodie and William H. Park of the New York City Health Department, and another, a live attenuated vaccine, later derided as “a veritable witch’s brew,” concocted by John Kolmer of Temple University in Philadelphia. The Kolmer vaccine in particular, and perhaps the Brodie–Park vaccine as well, caused several cases of poliomyelitis but conferred no immunity. More than a decade later, the memory of the fiascoes still inspired widespread concern about the safety of polio vaccines.

These qualms had become tempered by the early 1950s, as scientists made considerable progress toward the creation of a safe vaccine. By the late 1940s, several groups of researchers had independently identified the three distinct types of poliovirus, a microbial distinction that was essential to the development of an effective vaccine.

At Harvard, John Enders, Frederick Robbins, and Thomas Weller developed a method of growing poliovirus in nonneural tissue using a tissue culture of monkey kidneys — a seminal achievement that won them the Nobel Prize in 1954. At the University of Cincinnati, Albert Sabin began work on a live attenuated oral vaccine that he insisted would provide better immunity than a killed-virus vaccine but that would not be ready for widespread use until 1961. Jonas Salk, who relied on older vaccine-production methods involving formalin-killed viral strains, was able to proceed more rapidly. By early 1953, Salk had begun campaigning relentlessly for a national field trial of his vaccine.

For this critical but unglamorous task, the NFIP turned to Salk’s former teacher, Thomas Francis, who had introduced Salk to the design of killed-virus vaccines, and his staff of epidemiologists at the University of Michigan School of Public Health. Francis had a sterling reputation as an investigator and was internationally known for his deft direction of complex field trials of influenzavirus vaccines during World War II. He agreed to conduct the polio-vaccine field trials if three inviolable rules were followed: there would have to be two study groups, one given vaccine and another, at least as large as the vaccine group, given placebo; the trial would have to be conducted in a double-blind manner; and the NFIP was not to interfere. The study formally began on April 26, 1954, when Randy Kerr, a six-year-old boy from McLean, Virginia, received the first inoculation.

No detail of the field trial escaped Francis’s watchful gaze — from complex issues of experimental design to such mundane matters as the pack-
aging of vaccine, the composition of safety instructions for parents, and the selection of the “Polio Pioneers,” the 650,000 children who received the vaccine and the 1.18 million who received a placebo. The trial relied for its implementation on some 150,000 volunteers, 15,000 schools, and 44 state departments of health. Francis admirably withstood the strain of conducting an extremely complex, high-stakes experiment in public. Thanks to the relentless campaign of the March of Dimes and the fear that polio and polio vaccines inspired, it was critical that Francis’s design be free of bias and confounding variables and that there be no ethical lapses in the conduct of the trial. Everything worked out beautifully.

Coincidentally, Francis’s announcement was to be made on the 10th anniversary of Franklin Roosevelt’s death, the earliest date by which the University of Michigan’s carpenters could complete construction of the long platform that would accommodate the battery of television cameras and radio microphones and the hundreds of photographers and journalists who would cover the event. Before a jam-packed audience of scientists and dignitaries, Francis approached the lectern. He began his speech with two simple declarative sentences: “The vaccine works. It is safe, effective, and potent.” He then explained that the Salk vaccine was 60 to 70 percent effective in preventing infection with type 1 poliovirus, the most prevalent strain, and at least 90 percent effective against types 2 and 3.

Thrilling as this news was, there was one person in the auditorium who was visibly unhappy with Francis’s report: Jonas Salk. As the diminutive virologist took the podium after Francis’s speech, an avalanche of applause greeted him. Yet this public show of appreciation on the part of his scientific peers — a group that had never been accused of being overly effusive — was not enough for Salk, who felt compelled to insist that he had created nothing less than the perfect vaccine. Too flustered even to mention the names of the colleagues who had worked with him at Pittsburgh, Salk assailed the accuracy of Francis’s findings. The failures encountered in the trial, he declared, were caused by Merthiolate, a mercury-based antiseptic that had been added to the batches of vaccine, against Salk’s wishes, at the express orders of the U.S. Laboratory of Biologics Control. With a dramatic flourish, Salk proclaimed that his new and improved (Merthiolate-free) vaccine might well be 100 percent effective.

Salk’s comments created a controversy that his critics used to disparage him for the rest of his career. Backstage, a furious Francis was heard scolding his former student. “What the hell did you have to say that for?” Francis railed. “You’re in no position to claim 100 percent effectiveness. What’s the matter with you?”

Salk’s failure to recognize the achievements of his coworkers and his injudicious (albeit ultimately correct) claims aside, the rest of the world was eager to lionize him as a bona fide medical hero. As the journalists scrambled out of the auditorium to call their editors, the spotlight of fame permanently shifted from the epidemiologist to the young creator of the polio vaccine. For many days, there wasn’t a front page of a newspaper, a television or radio
show, or a newsreel that did not shower Jonas Salk with praise and gratitude. For millions of parents and their children around the world, Salk became the avatar of medical progress. Even so, a decade later, Salk admitted, “I was not unscathed by Ann Arbor.”

I recently went to my medical school’s library to peruse Francis’s published, but rarely checked out, account of the 1954 field trial. The book is written in clear, elegant prose, and even a casual reader will recognize its author as a model of scientific integrity, ethical treatment of human subjects, and thorough attention to epidemiologic detail. Still, even in the face of this impressive historical document, it takes little imagination to understand why April 12, 1955, turned out to be Jonas Salk’s day. After all, he developed the first effective vaccine against polio; his teacher merely undertook the chore of testing its efficacy on a mass scale and then confirmed to the world that Salk had succeeded.

The annals of medical history are replete with such distinctions.

Yet one of the great benefits of reflecting on the past is the opportunity to adjust one’s understanding of events and human interactions. The morning after the announcement, the New York Times heralded Francis’s vaccine report as a “medical classic.” No one has ever refuted this conclusion. History would be well served, as we commemorate this 50th anniversary, if Tommy Francis’s contributions were restored to view.

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**Polio Update**

Map shows cases of poliomyelitis due to infection with wild poliovirus in 2004. Data are from the World Health Organization, as of February 22, 2005. Cases in countries without endemic poliovirus or reestablished transmission were imported. Cases caused by vaccine-derived polioviruses are excluded.