# 1 The Epidemic That Never Was

## *Policy-Making and the Swine Flu Scare**

*Richard E. Neustadt and Harvey V. Fineberg*

*editor's introduction:*

### Methodological Significance

If you are going to do a case study, you are likely to devote a significant portion of your time to that case study. To be avoided is committing much of your time and resources and then finding that the case study will not work out. Therefore, in using the case study method, your goal should be to select your case study carefully. Try to spot unrealistic or uninformative case studies as early as possible.

More ambitiously, try to select a significant or "special" case or cases for your case study. The more significant your case—combined with the use of other methodological features emphasized throughout the rest of this anthology—the more likely your case study will contribute to the research literature or to improvements in practice (or to the completion of a doctoral dissertation). Conversely, devoting your efforts to a fairly "mundane" case study may not even produce an acceptable

*__Editor's Note:__ Excerpted, with light editing, from *The Epidemic That Never Was: Policy-Making and the Swine Flu Scare* by Richard E. Neustadt and Harvey V. Fineberg. Vintage Books Edition, New York, NY, 1983, pp. 17–22, 46, 57–59, 95–97, and 105. 

study (or dissertation). If you do not have access to a special case, the recommended approach is to consider any candidate for your case study with great care and forethought, even if the process takes more time than you would have anticipated.

Set your goals high. You may only have a once-in-a-lifetime opportunity to contribute to case study research. Also consult actively with your peers and colleagues about your selection. Choose the most significant case possible. Your success might result in an exemplary study (or dissertation). Your study might present new theoretical or practical themes. It also might capture, as with the present selection, a case of lasting relevance—if not value—decades later.

## Substantive Note**

In the swine flu scare, the United States government tried to immunize its whole population against a threat of world epidemic from a potentially deathly and new influenza strain, known as "swine flu." The scale of the immunization effort was unprecedented, with more than 40 million citizens immunized in 10 weeks during the fall of 1976. The venture also was marked, not surprisingly, by controversy, delay, administrative troubles, legal complications, the threat of unforeseen medical side effects, and a progressive loss of credibility for public health authorities.

The entire experience echoes to the present time, about 30 years (a generation) later. The governments of the world are preoccupied with the threat of maverick countries using weapons of mass (biological) destruction. The biochemical defenses may have changed and even improved, but the political and community forces—at national, state, and local levels—may still be those at work in the "swine flu scare" years earlier. At that time, Neustadt and Fineberg already concluded their case study with such topics as "thinking twice about medical knowledge." In retrospect, wouldn't this earlier case study have been an excellent case study to have had on your resume?

**Some passages in this substantive note come from the authors' Introduction, p. xix.

## The New Flu

The proximate beginning of this story is abrupt. On the East Coast of the United States, January 1976 was very cold. At Fort Dix, New Jersey, the training center for Army recruits, new men fresh from civilian life got their first taste of barracks and basics. A draft of several thousand came in after New Year's Day to be instructed by a cadre back from Christmas leave. The fort had been almost emptied; now in the cold it was full again. By mid-January many men began reporting respiratory ailments. A relative handful was hospitalized. One, refusing hospitalization, went on an overnight hike and died.

After a county medical meeting on another subject, the state's chief epidemiologist bet the senior Army doctor that Fort Dix was in the midst of an influenza virus epidemic. To win, the latter sent a sample set of cultures for analysis in the state laboratory. He lost. The lab turned up several cases of flu traceable to the Victoria virus, which had been the dominant cause of human influenza since 1968. But the lab also found other cases of flu caused by a virus it could not identify. With foreboding, Dr. Martin Goldfield, the civilian epidemiologist, sent those cultures to Atlanta, to the Federal government's Centers for Disease Control (CDC). A similar virus, also unidentified, was isolated from the dead man, and a culture was sent to CDC. In the evening of February 12, the Center's Laboratory Chief, Dr. Walter Dowdle, reported the result to his superiors—in four cases, including the fatality, the unknown virus was swine flu. This caused more concern than surprise at CDC.

Four things combined to create the concern. First, these four recruits could have been infected through human-to-human transmission. Not since the late 1920s had this form of influenza been reported in as many persons out of touch with pigs. There might have been a number of occasions unreported; no one knew. Second, for a decade after World War I a virus of this sort was believed to have been the chief cause of flu in human beings. Since then it had confined itself to pigs. Were it returning now to humans, none younger than 50 would have built up specific antibodies from previous infection. Third, the Fort Dix virus differed in both its surface proteins, termed "antigens," from the influenza virus then circulating in the human population. This difference, in expert terms an "antigenic shift," would negate any resistance carried over from exposure to the other current viruses. In 1976, leading experts assumed that pandemics follow antigenic shifts as night follows day.

And finally, in 1918, a pandemic of the swine flu virus, the most virulent influenza known to modern medicine, had, in a so-called "killer wave," been associated with some 20 million deaths worldwide, 500,000 here in the United States. Many were taken by bacterial pneumonia, a complication of influenza now treatable with antibiotics, but an unknown number succumbed to the flu itself. Among the hardest hit then had been

able-bodied persons in their twenties and early thirties. Parents of small children died in droves. So did young men in uniform. Virulence cannot as yet be tested in the lab. Could the Fort Dix swine flu be a comparable killer? No one at CDC had any reason to suppose it was—contrasting the 1920s to the circumstances of the one death now—but still. . . .

The absence of surprise reflected expert views at that time about epidemic cycles and about the reappearance of particular types of viruses in people. It was widely thought—on rather scanty evidence—that antigenic shifts were likely about once a decade (interspersed with slighter changes, "drifts," each second or third year). There had been shifts in 1957 and in 1968, both followed by pandemics—Asian flu and Hong Kong flu respectively—and public health officials were expecting another by, say, 1978 or 1979. 1976 was close. The very day the Fort Dix cases were identified at CDC, *The New York Times* carried an Op Ed piece by Dr. Edwin D. Kilbourne, one of the country's most respected influenza specialists, extolling cycles and affirming that pandemics occur every 11 years—another one of which, he warned, was surely coming soon:

> Worldwide epidemics, or pandemics, of influenza have marked the end of every decade since the 1940s—at intervals of exactly eleven years—1946, 1957, 1968. A perhaps simplistic reading of this immediate past tells us that 11 plus 1968 is 1979, and urgently suggests that those concerned with public health had best plan without further delay for an imminent natural disaster.[1]

In addition, an influenza virus recycling theory was just then receiving attention, and this suggested swine-type as a likely next strain to appear. The idea was that the flu virus had a restricted antigenic repertoire and a limited number of possible forms, requiring repetition after a time period sufficient for a large new crop of vulnerable people to accumulate. The Asian flu of 1957 was thought to have resembled flu in the pandemic year of 1889. The Hong Kong flu of 1968 was thought to be like that of 1898. Swine flu, absent for 50 years, fit well enough, no surprise. The theory had been originally proposed by two doctors who wrote in 1973:

> A logical sequel to the data presented and supported here would be the emergence in man of a swine-like virus about 1985–1991. . . . Regardless of one's view as to the origin of recycling of human strains of influenza, the matter of being prepared to produce swine virus vaccine rapidly should receive consideration by epidemiologists. Man has never been ably to intervene effectively to prevent morbidity and mortality accompanying the emergence of a major influenza variant, but the opportunity may come soon.[2]

Although some experts were skeptical about the regularity with which previous strains might be expected to reappear, no one doubted that a swine flu virus might well re-emerge in the human population.

On February 12, alerted by preliminary lab reports, Dr. David Sencer, CDC's director, asked a number of officials from outside his agency to join him there for a full lab report on February 14. The Army responded, as did Goldfield from New Jersey. And from two other parts of CDC's parent entity in HEW [now the U.S. Department of Health and Human Services, HHS], the Public Health Service (PHS), Dr. Harry Meyer and Dr. John Seal came as a matter of course. Meyer was director of the Bureau of Biologics (BoB) in the Food and Drug Administration; Seal was the deputy director of the National Institute for Allergy and Infectious Diseases (NIAID) in the National Institutes of Health. (NIAID's director left these relations to Seal.) The BoB was responsible for licensing and testing flu vaccines, the NIAID for federally sponsored flu research. The duties of Meyer and Seal overlapped, but they were accustomed collaborators. Both were accustomed also to work closely with CDC, its labs and its state services.

Among their recent objects of collaboration had been workshops held at intervals since 1971 on how to better the quite dismal record of 1957 and of 1968 in getting vaccine to Americans ahead of a pandemic. This matter was much on Seal's mind and especially on Meyer's. His bureau had been the subject of a Senate inquiry three years before and needed nothing less than the black-marketing and discrimination characteristic of vaccine distribution in 1957.

To this group, enlarged by CDC staff, Dowdle reported his laboratory findings. The question at once became whether four human cases were the first appearance of incipient pandemic or a fluke of some kind, a limited transfer to a few humans of what remained an animal disease that would not thrive in people. All agreed that based on the present evidence there was no means of knowing. Surveillance was the task at hand. Since their uncertainty was real, they also agreed that there should be no publicity until there were more data: Why raise public concern about what might turn out an isolated incident? Some days later CDC scrapped this agreement on the plea that uninformed press leaks were imminent, and Sencer called a press conference for February 19. He must have hated the thought that an announcement might come from some place other than CDC. However that may be, the press conference got national attention:

In *The New York Times,* Harold Schmeck reported, February 20:

> The possibility was raised today that the virus that caused the greatest world epidemic of influenza in modern history—the pandemic of 1918–19—may have returned.

This story (on Page 1) was headed: *U.S. Calls Flu Alert on Possible Return of Epidemic Virus.*

The 1918 reference was included in brief notices that night, on CBS and ABC news telecasts. NBC went them one better and showed 1918 still

pictures of persons wearing masks. Lacking further information, the media did not follow up on the story for a month. But 1918 left a trace in certain minds—some of them TV producers and reporters. From within CDC, we have encountered a good deal of retrospective criticism at press tendencies to "harp" on 1918 prematurely, with no evidence whatsoever about prospective virulence or even spread through 1976. These NBC pictures are cited along with *The New York Times* headline. But the reference was included in the CDC press briefing, and indeed without it, what was known about Fort Dix so far was scarcely news at all. Publicity had no effect on the effort to establish what the Fort Dix outbreak meant. In Fort Dix itself, where the Army conducted its own investigation shielded from civilians, the Victoria strain proved dominant, at least for the time being. There were plenty of new influenza cases; none was caused by the swine virus. On the other hand, that virus was isolated from a fifth soldier who had been sick in early February, and blood tests confirmed eight more old cases of swine flu, none of them fatal. Moreover, a sampling of antibody levels among recruits suggested that as many as 500 had been infected by swine flu. This implied human transmission on a scale that could not reasonably be viewed lightly. Around Fort Dix, however, in the civilian population—which was Goldfield's territory for investigation—analysis of every case of flu reported, by a medical community on the alert, showed only the Victoria strain. Elsewhere in New Jersey, Goldfield's inquiries turned up no swine flu. The Army's inquiries turned up none at camps other than Fort Dix. The NIAID network of university researchers and the state epidemiologists in touch with CDC reported none untraceable to pigs. The World Health Organization, pressed by CDC, could learn of none abroad. One death, 13 sick men, and up to 500 recruits who evidently had caught and resisted the disease—all in one Army camp—were the only established instances of human-to-human swine flu found around the world as February turned into March, the last month of flu season in the Northern Hemisphere.

On March 10 the group that had met February 14 reassembled at CDC and under Sencer's chairmanship reviewed its findings with the Advisory Committee on Immunization Practices (ACIP). That committee consisted of a set of outside experts appointed by the U.S. Surgeon General, independently advising CDC; in fact, it was almost a part of CDC—nominated, chaired, and staffed at Sencer's discretion. BoB deadlines now forced his pace. One ACIP function was to make vaccine recommendations for the next flu season available to manufacturers. The annual questions were: vaccine against what viruses, aimed at which population groups? For 1976 these questions had already been reviewed in a January ACIP meeting. The committee had recommended Victoria vaccine for the "high-risk groups" as then defined, some 40 million people over 65 in age or with certain chronic diseases. By March 10, the four active manufacturers had produced in bulk form about 20 million doses of Victoria

vaccine for the civilian market. If Fort Dix meant a change or addition, now was the time to decide. Indeed, for a regulatory body like the BoB, responsible for setting standards and for quality control, March was already late. Vaccine is grown in eggs; a vaccine against swine flu would require new supplies replacing those just used for the Victoria vaccine. Then immunization trials would be needed if there was a new vaccine; also extensive testing would be necessary. And what about the vaccine now in bulk? Whatever surveillance had turned up by now would have to suffice for some sort of decision. . . .

[On March 24, President Gerald Ford announced:]

> I have been advised that there is a very real possibility that unless we take effective counteractions, there could be an epidemic of this dangerous disease next fall and winter here in the United States. Let me state clearly at this time: No one knows exactly how serious this threat could be. Nevertheless, we cannot afford to take a chance with the health of our nation. Accordingly, I am today announcing the following actions.
>
> . . . I am asking the Congress to appropriate $135 million, prior to their April recess, for the production of sufficient vaccine to inoculate every man, woman, and child in the United States. . . .

## Field Trials

On March 25, the day after the President's announcement, a meeting chaired by Meyer at the BoB—with CDC and NIAID and the producing laboratories represented—drew several key conclusions. These had been in the air March 10 or even earlier; this meeting tacked them down.

*First,* manufacturers should produce enough swine vaccine for everyone—roughly 200 million doses—and start deliveries in June for use from July on. Neither now nor later were dates for the mass immunization made precise. The aim was to start before August—as early in July as deliveries allowed—and to finish before winter. (In their April testimony, Sencer and Cooper said November; whereas Meyer, closer to production, said late December.)

*Second,* since this would fully occupy available facilities of active manufacturers, no more Victoria vaccine should be produced. What was at hand would be made bivalent by adding swine vaccine in bulk. This would produce some 30 million bivalent doses, to be used for high-risk groups, mainly the elderly.

*Third,* the rest of the swine flu vaccine would be turned into monovalent doses and used on a one-person, one-dose basis, thus ensuring wide availability. This assumed that one dose would give adequate protection

without bothersome effects on adults and children alike. The assumption was colored by recent improvements in vaccine purification. But it rested fundamentally on logistical concerns: How could one hope to get vaccine and kids together twice?

*Fourth,* the needs of the armed forces, also those of the Veterans Administration, although separately determined and contracted for (as usual), had to fit inside these targets, with deliveries coordinated in a fashion to which military doctors were distinctly unaccustomed. Production orders from still other sources, including other countries if they came, had to wait for American deliveries. Diversions of American supplies would be a matter for the White House. (So, indeed, was the compliance of DoD: Cavanaugh later got stuck with both.)

Another assumption was hidden, or more precisely muffled, in these calculations, namely that the manufacturers would grow the monovalent vaccine fast enough to guard against an early fall pandemic. In 1918, the virulent phase had begun in August. The manufacturers now argued, in Hilleman's words at the meeting:

> . . . you couldn't possibly have 200 million doses by fall . . . If you are talking about one dose per egg, which is more what it looks like [instead of the hoped-for two doses] you are talking about a different situation.[3]

The day before, the President had pledged vaccine to everyone. A week later, Cooper, on the Hill, would state his goal as "95 percent of all Americans." Hilleman's discrepancy seems to have left Meyer untroubled.

On April 2, Sencer in Atlanta hosted a monster meeting to acquaint state health officials and representatives of private medicine with these targets (Congress willing) and with CDC's conception of administrative follow-through based on state immunization plans. Prompt filing of these plans was sought by CDC. Funding and technical assistance were to follow. Vaccine distribution would begin as soon as field trials, tests, and bottling allowed, and states should start at once to put it into people. Taking maximum advantage of the time at hand, the states now had a chance to immunize the country, or most of it, before the next flu season.

Here was a challenge for the Public Health officialdom from coast to coast, an opportunity to do in 1976 precisely what had not been done in 1968 or 1957—and at Federal expense with the President responsible. Energy and time and personnel might have to be withdrawn from other uses, to be sure, but not much money begged from any legislature except Congress; his trouble, not theirs. Besides, there was the vision of the Kilbournes and the Coopers: Preventive medicine raised high in public consciousness. Who could be against that? . . .

Between October 1 and December 16, more than 40 million Americans received swine flu shots through Sencer's program. (Defense and VA programs accounted for some millions more.) This is twice the number

ever immunized before for any influenza virus in a single season. Considering the obstacles, it is an impressive number. It also is a number oddly distributed. Some states, albeit small ones, inoculated 80 percent of their adults in that time period. Others immunized not more than 10 percent. Delaware was at the top of that range, New York City near the bottom. Variations in between are striking: Houston, Texas, inoculated only 10 percent of its adults, whereas San Antonio, Texas, immunized nearly one-third. Despite coincident deaths, Pittsburgh, Pennsylvania, vaccinated nearly 43 percent whereas Philadephia, home of Legionnaire's Disease, managed but 23 percent. And so forth.[4] These variations cry out for explanation. So far as we know, CDC has not pursued them and may lack the resources to do so. . . .

One state that was conscientious in its conduct of the national program was Minnesota, where nearly two-thirds of the eligible adults were immunized. In the third week of November, a physician there reported to his local health authorities a patient who had contracted an ascending paralysis, called Guillain-Barré syndrome, following immunization. The physician said he had just learned of this possible side effect from a cassette-tape discussion of flu vaccination prepared for the continuing education of family practitioners by a California specialist. The Minnesota immunization program officer, Denton R. Peterson, dutifully called CDC and spoke to one of the surveillance physicians there. The latter expressed no interest in this single case, but Peterson was sufficiently bothered to conduct a literature search and did indeed discover previous case reports. "We felt we were sitting on a bomb," he told us. Within a week three more cases, one fatal, were reported to Peterson. Two came from a single neurologist who remarked that he had observed this complication of flu vaccine during his residency training. More anxious than ever, Peterson again called CDC, where the surveillance center was just being told by phone of three more cases in Alabama. The next day they learned of an additional case in New Jersey. By then CDC was taking the problem seriously. Center staff surveyed neurologists in 11 states to ascertain the relative risk of this rare disease (estimated at five thousand cases annually) among the vaccinated and unvaccinated. When the preliminary results suggested an increased risk among the vaccinated, Sencer sought advice from usual sources: NIAID, BoB, ACIP, and his own people. The statistical association did not convince them all.

But what struck everybody, sensitized by their long summer, was the thought: Until the risk (if any) is established, it cannot be put into a consent form! The statistical relationship would have to be reviewed and immunization halted in the interim. After everything that had already happened, everybody took that to mean virtual termination. Even the least imaginative could conjure up the television shots of victims in their beds, wheel chairs, and respirators.

With some trepidation about White House willingness to stop, Sencer called Cooper on December 16, and fortuitously reached him in the White

House Staff Mess, lunching with Cavanaugh. Mathews by chance was at another table. The three huddled quickly; Cooper then excused himself and made a call to Salk. The switchboard reached Salk in Paris. Without enthusiasm he concurred with Sencer's view. Cooper and the others then walked down the hall to [President] Ford. He heard them out, sighed, and agreed. For most intents and purposes the swine flu program was over. With no disease in sight nine months after Ford's announcement, even a rare side effect could turn him around.

That afternoon Cooper announced suspension of the swine flu program, saying that he was acting "in the interest of safety of the public, in the interest of credibility, and in the interest of the practice of good medicine."[5] . . .

## Legacies

The swine flu program ended, but in terms of Federal policy it left at least three legacies. With these the Secretary [of HEW] still is dealing or has yet to deal. One is a national commission on immunization policy. Another is liability policy. The third is an expanded Federal role in influenza immunization. The three interlock. They still evolve. They carry far beyond March 1977, the month we made our stopping-point for detailed reconstruction. But during 1977, while we worked on 1976, we tried to keep an eye on these three legacies. . . .

## Notes

1. *The New York Times*, February 13, 1976, p. 33.

2. N. Masurel and W. M. Marine (1973). Recycling of Asian and Hong Kong Influenza A Virus Hemagglutinins in Man. *American Journal of Epidemiology, 97*, 48–49.

3. Bureau of Biologics Workshop, March 25, 1976, transcript, p. 128.

4. Figures are taken from unpublished data compiled by the CDC. Percentages are based on populations 18 years of age and older, as of the 1970 census. This means that for 1976, [the] percentages are overstated in areas of recent, rapid growth.

5. For the full text, see HEW press release, December 16, 1976.