

The Swine Flu Immunization Program: Scientific Venture or Political Folly?

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ABSTRACT

The author of this Article, an internationally recognized coroner perhaps best known among laymen for his incisive and tenacious criticism of the Warren Commission report on the Kennedy assassination, turns his attention to the federal government's 1976–1977 Swine Flu Immunization Program. Dr. Wecht contends that although this program may have been viewed by its key proponents as having great public health importance, or perhaps even political value, its creation and continuation nevertheless were scientifically unjustified. Furthermore, he contends, the federal government failed to inform the public adequately of important facts about the program's origins and progress, and it mismanaged the program in several important respects. Among the topics he discusses are swine flu's epidemiological history (including the 1976 Fort Dix outbreak that propelled swine flu into the national consciousness); the key elements leading to the government's decision to immunize; the government's failure to reevaluate the program seriously as problems arose; the shortcomings of the federal swine flu statute; the inadequacy of the government's investigation of the deaths of three persons in Pittsburgh within a few hours after being vaccinated (a matter that was of immediate concern to the author in his role as Coroner of Allegheny County, Pennsylvania); the long-delayed termination of the program following the emergence of a possible statistical link between the immunizations and an increase in the incidence of the Guillain-Barré Syndrome; the financial and human costs of the program; and the need for calmer, more objective decision making in future situations where immunization of the general populace is being considered.

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I. THE SWINE FLU FIASCO

During the fall and winter seasons of 1976–1977, the American public was the target population of the most ambitious—and most misguided—vaccination program ever attempted: the federal government's Swine Flu Immunization Program. The program began with a legitimate objective ("what's best for the country"). But it unfolded in a series of events that at the time were absurd and in retrospect are frightening.

A study of the Swine Flu Immunization Program is a study of the strange workings of the human mind. Fueled by fear of the unknown, and also, one suspects, by ambition, politics, and pride, a program based upon meager or nonexistent scientific evidence began, and, once started, continued even in the face of failures in program management, adverse facts, adverse expert opinions, and human disaster.

Most frightening of all, the evidence suggests that many of those agencies entrusted with the health of the American public apparently felt justified both in ignoring or hiding facts, and in disseminating information of doubtful objectivity in order to achieve their goal of continuing a floundering program. The evidence also suggests that saving face became paramount, even though it posed serious risk to the lives of many Americans.

This Article will explore some of the questions about the Swine Flu Immunization Program that have been asked, but were never answered, and those that should have been asked, but were not. What is swine flu? Why, how, and by whom was the decision made to implement an immunization program? Did that decision make sense? Why was there no periodic reevaluation of the program in light of increasingly adverse facts and opinions? What were the financial and human costs of the program, and what are its lessons?

II. THE EPIDEMIOLOGICAL HISTORY

A. BACKGROUND¹

In 1918–1919, two waves of influenza swept the world in the worst flu pandemic in recorded history. Twenty million people died; almost 600,000 were Americans. Because of a concurrent viral pandemic affecting large numbers of United States hogs, the human flu became generally known as "swine flu." Although there was never an isolation of the human virus in 1918–1919, it is generally accepted that, because of its virulence, the virus was of the more serious type A genre. The first wave of the

¹ This background information is based upon historical material provided in Sabin, *Swine Flu: What Happened? The Sciences*, March/April 1977, at 14.

1918–1919 pandemic was very mild. Scientists were unable to discover any cause at that time. However, during the second “killer” wave, a previously unknown bacillus was isolated. There also was evidence that those infected during the first wave of the pandemic had developed immunity to the disease’s second wave.

Medical technology subsequently improved, and in 1931 Richard Shope isolated the virus that had remained prevalent in swine after the 1918–1919 pandemic. Shope, experimenting with the bacillus (*Haemophilus influenzae suis*) isolated in 1918–1919 and with the swine virus he had isolated, showed that each by itself was fairly harmless. He concluded that it was only the combination of the two that produced the serious clinical illness and death observed in 1918–1919. Shope was also able to show that swine infected with the virus alone were immune to the virus-bacillus combination. When he compared his tests to the evidence suggesting that humans infected in the first wave of the 1918–1919 pandemic were immune in the second wave, Shope hypothesized that his virus was the same as that which had caused the human pandemic in 1918–1919.

Further experiments showed that humans alive during the 1918–1919 pandemic had a high level of immunity to Shope’s swine virus, presumably due to exposure to it during that period. Finally, in 1933, a human flu virus was isolated that was very similar to the swine virus isolated two years earlier. Experts reached the conclusion that the swine virus and the human virus were the same. It therefore can reasonably be assumed that the human swine flu virus is lethal only when it acts in combination with the bacillus isolated in the second wave of the 1918–1919 pandemic. This conclusion was corroborated in March 1976, when experiments showed that persons alive during the period from 1919 to 1929, a decade of many flu epidemics without massive numbers of deaths, had antibodies for the now infamous Fort Dix virus discussed below.

B. THE FORT DIX OUTBREAK²

Late in January 1976, one Private Lewis of Fort Dix, New Jersey, reported to sick call with an upper respiratory infection. After an examination, Lewis was released from the infirmary with orders to remain in bed for 48 hours. Private Lewis disobeyed orders and participated in a forced march that same night. He began to have trouble on the march, and finally he collapsed. A sergeant gave him mouth-to-mouth resuscitation, temporarily saving his life. Lewis was returned to the infirmary, where he died on February 4, 1976. Colonel Joseph Bartley, M.D., Chief of Preventive Medicine at Fort Dix, later speculated that had Private Lewis

² This description of the Fort Dix incident is based upon the account provided in Boffey, *Anatomy of a Decision: How the Nation Declared War on Swine Flu*, 192 SCIENCE 636 (1976).

not subjected himself to the extreme cold and physical exertion of the march, he would have lived.

Shortly after Lewis reentered the infirmary, large numbers of soldiers began reporting to sick call with upper respiratory infections. (The sergeant who gave Lewis mouth-to-mouth resuscitation was not one of them.) Colonel Bartley felt those infections were something other than a flu. Because of the large numbers of sick soldiers, Colonel Bartley reported his situation to Martin Goldfield, M.D., Director of the Public Health Lab in New Jersey. Dr. Goldfield immediately suspected a flu and asked for throat swabs from the sick men. His laboratory personnel identified A/Victoria flu virus, and found another virus they were unable to identify. The specimens were sent to the Center for Disease Control (CDC) in Atlanta, which is the arm of the federal government responsible for control of epidemics. There the specimens were found to harbor swine flu virus à la 1933.

In all, only five confirmed cases of swine flu occurred at Fort Dix. There were eight other probable cases, and about 500 soldiers showed a rise in swine flu antibodies, but no illness.

From this epidemiological history the Swine Flu Immunization Program took birth.

III. THE DECISION TO IMMUNIZE

It cannot be denied that because of our knowledge of pandemics in general, and of the 1918–1919 pandemic specifically, the Fort Dix swine flu outbreak should have caused concern among public health officials. It is generally accepted among epidemiologists that pandemics occur periodically, in about 10- to 12-year cycles, as a result of virus mutations into a strain for which the world population has no immunities. According to the "cycle theory," a pandemic was due in 1976–1977. There is also evidence that new strains sometimes appear as old ones disappear.³ In this case, A/Hong Kong Flu was on the ebb. An FDA drug bulletin provided additional fuel for concern with its theory that the swine flu virus was lurking in the nation's hogs, ready to return to humans.⁴

Unfortunately, although concern was justified, the health officials responsible for instituting the immunization program seemed to disregard completely some crucial facts. First, the flu virus of 1918–1919 had never actually been isolated. Although believed to be the same, it was the 1933 virus to which personnel at the CDC were comparing the Fort Dix Virus, so they could not be positive that the Fort Dix virus and the 1918–1919

³ Marwick, *Swine Flu Immunization: 'Go' at Last*, MEDICAL WORLD NEWS, Sept. 6, 1976, at 60, 62.

⁴ FDA DRUG BULLETIN, August/October 1976, at 3.

virus were the same organisms. Second, conditions for a pandemic were ripe in 1918–1919. Massive troop movements facilitated the rapid spread of the virus, and no antibiotics existed at that time to combat the secondary infections that frequently were the actual cause of death. In 1976, neither of those situations existed. Third, the experiments already discussed strongly suggest that swine flu by itself is fairly harmless. The bacillus that seems necessary to produce serious swine flu results was not isolated from the Fort Dix throat swabs. Fourth, the sergeant who resuscitated Private Lewis did not become ill, suggesting that the virus Lewis carried might not have been especially prone to pass from human to human. This possibility seems plausible in light of the low number of confirmed cases of swine flu at Fort Dix. Fifth, as Colonel Bartley has speculated, Private Lewis might not have died if he had not gone on the march.⁵ Sixth, as to the FDA's theory that the swine flu virus was harbored in hogs and was waiting to strike humans, one must ask the obvious question—why now? The majority of the American public had not had immunity to swine flu for many years. Why should the swine flu virus pick 1976–1977 to reappear?

Clearly, in view of the *possibly* grave significance of the Fort Dix flu outbreak, public health officials should have reacted with concern and should have proceeded cautiously. Unfortunately, they instead reacted with alarm and proceeded headlong. On February 20, 1976, while the CDC was still involved in a search throughout the country for swine flu cases—a search that was yielding undefinitive results—the FDA's Bureau of Biologics held a workshop aimed at getting representatives of government, industry, and universities to begin preparations for undertaking a vaccination campaign should one be instituted.⁶ During that meeting, the date of April 1, 1976 was suggested as the latest time at which a “go, no go” decision could be made and still leave sufficient lead time for the necessary preparations. Next, on March 10, 1976, a meeting of the CDC's Advisory Committee on Immunization Practices convened. This group generally recommends to the CDC Director—Dr. David Sencer, at that time—whether, and, if so, precisely what type of, an immunization program should be undertaken by the federal government in response to a particular situation. It took the position that the government should stockpile a vaccine for swine flu and develop plans for administering it, but it did not make any statement as to whether the government should actually proceed yet with a mass vaccination program.⁷

⁵ Boffey, *supra* note 2, at 638.

⁶ The description, in the remainder of this Part, of the events leading up to the decision to immunize—although not necessarily the interpretation of those events—is based upon the account provided in Boffey, *supra* note 2.

⁷ Although the decision to stockpile was preferable to what later occurred, it was terribly unrealistic. The strategy was to wait and see if vaccination would be necessary. Vaccines,

A decision to stockpile and wait was made by the appropriate Committee. How, then, did we end up with a Swine Flu Immunization Program? Immediately following the Advisory Committee Meeting, Dr. Sencer prepared an "action memo" recommending a full-blown immunization program. The memo suggested the strong possibility of a swine flu pandemic and noted that ". . . the Administration can tolerate unnecessary health expenditures better than unnecessary death and illness. . . ."⁸ After the memo began to make its way through the HEW bureaucracy, Dr. Sencer contacted the Advisory Committee members and asked them if they agreed with it. According to Dr. Sencer, the majority did. The memo traveled to the White House rapidly. President Ford's reaction was to appoint a blue ribbon panel to meet, on 48 hours notice, to consider Dr. Sencer's proposal. That Committee met on March 24, and recommended that the President go ahead with an immunization program. Minutes after the meeting ended, President Ford appeared on national television and called for the vaccination against swine flu of every man, woman, and child in the United States.

There probably were two main reasons why the majority of the members of the Advisory Committee on Immunization Practices supported Dr. Sencer's memo. First, even though they may have felt that the possibility of a pandemic was slight, the members must have known that upper-level federal bureaucrats already had the memo, and the members may have felt that it was better to agree and protect themselves than to disagree and leave themselves open to attack from above should a pandemic actually occur. A second probable reason for their assent is suggested by a candid comment made by Harry Meyers, Director of the Bureau of Biologics. He has been quoted as saying, after the Bureau's February 20 workshop, "In the world I deal with every day, there are so many things you do that are not terribly interesting. . . . To have a challenge of something that is a real public health interest is really stimulating."⁹ Perhaps this comment reflected an atmosphere in the public health community that was highly receptive to a major public health challenge—whether the catastrophic threat to the health of the American public was real or imagined.

Dr. Sencer's memo moved quickly through the bureaucracy because of the fear it produced in laymen with such ominous phrases as "strong possibility [of a pandemic]" and "unnecessary death and illness."¹⁰ President Ford did not have sufficient specialized knowledge to doubt Dr. Sencer. Furthermore, by this time, wild rumors concerning an imminent

however, are not effective immediately. Therefore, by the time a plan for implementation could have been completed and implemented, the results undoubtedly would have fallen far short of the need.

⁸ Quoted at Boffey, *supra* note 2, at 640.

⁹ Quoted at *id.* at 638.

¹⁰ Quoted at *id.* at 640.

epidemic were circulating around Washington. The upcoming election doubtlessly caused President Ford to be very receptive to the Swine Flu Immunization Program. It was a natural headline grabber. If a 1977 swine flu pandemic had occurred, but Americans had been spared due to the efforts of President Ford, he might have emerged as a national hero.

The members of the blue ribbon panel really had no other choice but to recommend as they did. On 48 hours notice, they had no time to research the situation. The scientists on the panel were chosen by those proposing the program. Besides, by the time the question reached the panel, it had such political momentum that the decision was for all practical purposes already made. If the Committee *had* been free to explore the situation, hopefully it would have taken cognizance of two very important facts: (1) the supposed outbreak of swine flu at Fort Dix had limited itself to the military installation (not one case had been reported elsewhere); and (2) not a single case of swine flu had been reported in the six weeks since Private Lewis died at Fort Dix. These facts alone were sufficient to require limiting the decision to beginning the process of stockpiling and of planning a method for implementation of an immunization program if one later appeared essential. There was simply no indication that the Fort Dix virus had the potential to cause a pandemic.

Upon analyzing the governmental decision-making process that led to the commitment of 135 million tax dollars, it becomes apparent that no attempt was made to utilize a formal decision-making model. Yet such a model would have been relatively easy to develop. For example, subsequent to the March 24 decision, three experts from Harvard University developed a formal model that rationally and objectively evaluated the desirability of the Swine Flu Immunization Program; and they did it in less time (three weeks) than the actual decision took (February 20, 1976 to March 24, 1976).¹¹ By identifying various components of the program, any one of which would have changed the decision, they established that the Swine Flu Program would have been desirable only if: (1) the vaccine was highly effective; (2) the cost per vaccination was below \$50; (3) there was a minimum of 59 percent population participation; and (4) there was a high probability of dealing with a pandemic strain of virus. Although information sufficient for reaching a decision through examination of all of these factors was not available when the decision was made, using a comparable model drawing on such information as *was* available would have lent order, reason, and credibility to the decision.¹² Instead, the

¹¹ Schoenbaum, McNeil, and Kavett, *Swine Flu Decision*, 295 *NEW ENG. J. MED.* 759 (1976).

¹² The Schoenbaum model itself could have been utilized—but was not—later in the program, when the necessary information became available, as an aid in deciding whether to continue the program.

decision was haphazard, emotional, and questionable in the public eye. It was strong-armed into being and had a political taint.

IV. THE GOVERNMENT'S FAILURE TO REEVALUATE THE PROGRAM

The Swine Flu Immunization Program was plagued with problems even before the first inoculation was given. Shortly after the March 24 decision was made, one of the four manufacturers selected to produce the swine flu vaccine produced two million doses of the wrong vaccine.¹³ The CDC had supplied the manufacturers with the wrong virus.

Once the proper vaccine began to be produced, more serious problems occurred. First, testing to determine the proper dosage ran into trouble. If enough vaccine was used to produce sufficient antibodies to the flu virus, the reaction to inoculation was too common and too great. On the other hand, a dosage that did not produce so much reaction produced insufficient antibodies to be effective.

When a relatively acceptable dosage was finally found, it still produced considerable adverse reactions. Studies showed that 1 to 5 percent of those inoculated could expect to develop a fever of 100 degrees F. or higher; 20 to 40 percent could expect swelling, tenderness, and redness at the point of inoculation; and 20 percent could expect systemic reactions such as headache and general malaise.¹⁴ As testing continued, a minimum of 1.9 percent of the inoculated individuals experienced severe reactions to the vaccine.¹⁵

When this last figure came to light, the Swine Flu Program hit its toughest preliminary snag. The insurance companies carrying the manufacturers' liability insurance refused to underwrite production and sale of the vaccine. Insurance representatives based their decisions on three factors, which, along with the insurers' fears attributable to the sheer magnitude of the program, made their nonparticipation inevitable. First, the companies had limited experience with large scale single disease vaccination programs, and none on the scale projected for the Swine Flu Program. Thus, they found it impossible to come up with a reasonably accurate prediction of what premiums they should charge.

Second, the companies estimated that even if the 1.9 percent severe reaction rate found in the preliminary studies held true in the general populace, and if the affected 1.9 percent were the only claimants, and if they based their claims only on strict liability (excluding negligence, etc.),

¹³ *The Latest Victim of Murphy's Law—Flu Vaccine Program*, AM. MEDICAL NEWS, Jan. 17, 1977, at 20.

¹⁴ Marwick, *supra* note 3, at 64.

¹⁵ Zimmerly, *Legislative Boost for Swine Flu Program*, J. LEGAL MED., Oct. 1976, at 20.

the insurers' costs still could run as high as \$5 billion. Premiums to cover such a possibility would be close to \$341 million, or 2½ times the cost of the program itself.

Third, the insurance companies greatly feared strict liability. A recent case, *Reyes v. Wyeth Laboratories*,¹⁶ clearly illustrates the companies' predicament. In that case, a child received standard trivalent polio vaccine, and subsequently developed polio. In a suit brought by the child's father against the manufacturer of the vaccine, a jury found that the vaccine had caused the child's polio, and reached a verdict against the manufacturer. The U.S. Court of Appeals, Fifth Circuit, in affirming the verdict, stated that the vaccine, although not "unreasonably dangerous" per se, was "unreasonably dangerous" as marketed, because the manufacturer had not met its duty to warn the child's parents of the risks of the vaccine. Insurance representatives felt the swine flu vaccine was unreasonably dangerous (that is, in the *Reyes* court's words, "dangerous beyond the contemplation of the ordinary consumer") on at least one, and perhaps two, counts. First, without a doubt the vaccine was unreasonably dangerous because the experts themselves were not sure about its effects. Second, if the reaction rate was as predicted, it may also have qualified as unreasonably dangerous.

The pullout by those who make a living at studying risks should have been enough by itself to make the government pause. By late July, there should have been a reevaluation of the program. But additional facts, even more persuasive, should have militated against continuing the program. Not one case of swine flu had been reported in the five months since the Fort Dix episode. As a result, many early proponents of the immunization program, the eminent Dr. Albert Sabin of polio fame among them, were calling for stockpiling the vaccine and waiting, rather than proceeding with the actual inoculation program.¹⁷ Additionally, an experiment had been performed wherein the virus from Fort Dix was injected into monkeys at a laboratory in Fort Detrick. The clinical reaction had been negligible.¹⁸

Tragically, a reevaluation did not occur. President Ford and HEW apparently were too committed to turn back. For them, it probably had

¹⁶ 498 F.2d 1264 (1977). The manufacturer argued that under the "prescription drug" exception, it had no duty to warn the ultimate consumer of the risks of the vaccine and that it had satisfied its duty to warn because it had described those risks in a package insert that was sent with the vaccine to the health center that was carrying out the vaccination program. The court said, however, that the prescription drug exception did not apply in this case, because the manufacturer should have known that the vaccine would not be administered as a prescription drug—specifically, there would be no physician present who could explain the risks to the consumer.

¹⁷ *Lessons of the Swine Flu Debacle*, MEDICAL WORLD NEWS, March 7, 1977, at 33, 34.

¹⁸ This information was supplied by Dr. J. Anthony Morris, who, as noted in Part VIII of this Article, was studying flu vaccines at the FDA at the time of the Fort Dix outbreak.

become a basic matter of politics and saving face. The fear used as one of the devices to push the program through had been capitalized upon. What can only be described as propaganda had elicited such pervasive fear of swine flu that the public demanded the program. Had President Ford backed out in the heat of his election campaign, he might well have sunk his political ship. If viewed in this light, his decision to expend extraordinary effort to salvage the Swine Flu Program would not be difficult to understand.

V. THE FEDERAL SWINE FLU STATUTE: ADDING INSULT TO INJURY

President Ford's response to the liability dilemma, and apparently to any doubts he may have had about the inoculation program's value and safety, was to promote legislation whereby the federal government not only would finance the manufacturing of vaccine and administer the inoculation program, but in addition would act, in essence, as its own insurance and reinsurance carrier against future claims and lawsuits. His swine flu bill immediately met opposition for the same reasons that *ought* to have sparked a reevaluation. Primarily, legislators were skeptical because of the lack of reappearance of the swine flu. The bill stalled in committee and almost died until the Philadelphia Legionnaires' Disease hit the press. Many people thought that Legionnaires' Disease and Swine Flu were the same thing; therefore the demand for the Swine Flu Program intensified. President Ford met privately with several Congressional leaders to make a pitch for his swine flu bill. They agreed that there was a need and rewrote the original bill. The new edition was pushed through Congress through informal routes in record time; on August 12, 1976, President Ford signed into law P.L. 94-380, the National Swine Flu Immunization Program of 1976.¹⁹

The thrust of the statute was that the federal government became the liability insurer for the program. Vaccine manufacturers were relieved of liability for claims not based upon negligence. Although the consumers' sole remedy was against the government, the government could subrogate claims caused by any participant's negligence.²⁰

¹⁹ 42 U.S.C.A. § 247b(j).

²⁰ Some of the stated objectives of the statute were: (1) to develop a safe and effective swine flu vaccine; (2) to facilitate the vaccination of the population of the United States; (3) to research the nature, cause, and effect of swine flu; (4) to research the nature and effect of the vaccine; and (5) to determine the cost and effectiveness of the immunization program. It is interesting to note how closely these objectives resemble the decision-making model mentioned earlier. If numbers 1, 3, 4, or 5 had been handled as the bill ordered, the program might never have gotten off the ground.

The most unfortunate aspect of the statute was that it underwrote only those physicians and other providers who participated in the program free of charge. This, of course, tended to discourage private physicians' participation. Patients, therefore, frequently did not even consult their personal physicians because they knew the physicians would not administer the vaccine. If private physicians had been underwritten, more patients, especially high risk patients, probably would have consulted their personal physicians. Many of the untoward results could, thus, have been obviated, because most private physicians simply were not recommending the vaccine. Public physicians were.

Recent cases concerning required warnings and informed consent "appeared" in the statute in the form of a provision requiring²¹

[the] development, in consultation with the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and implementation of a written informed consent form and procedures for assuring that the risks and benefits from the swine flu vaccine are fully explained to each individual to whom such vaccine is to be administered. . . . Such procedures shall include the information necessary to advise [sic] individuals with respect to their rights and remedies arising out of the administration of such vaccine.

Millions of consent forms were printed pursuant to these requirements; however, they did not meet even minimal ethical, let alone legal, requirements.²² The CDC itself did a survey which revealed that up to 13 percent (4.5 million) of the people who were vaccinated were not informed at all as to the possible side effects of the vaccine or as to their legal remedies.²³

It is important to realize that the swine flu statute differed significantly from other legislation dealing with remedies against the government. The Federal Tort Claims Act,²⁴ for example, limits liability of the United States to situations involving negligent acts of employees, and specifically excludes claims arising from acts or omissions of parties exercising due care. The swine flu statute specifically allowed claims based upon any theory in tort, including strict liability and breach of warranty. The result is that once a claimant establishes a causative link between the swine flu vaccine and his damages, the government is practically defenseless. It was for this very reason that insurance companies backed away from the program.

²¹ 42 U.S.C.A. § 247b(j)(1)(F).

²² Hines, *Small Things Build into Swine Flu Fiasco*, The Pittsburgh Press, Sept. 12, 1976, at 1-B.

²³ *Flu Shot Illegalities Reported*, The Pittsburgh Press, Dec. 15, 1976, at 39.

²⁴ 28 U.S.C. §§ 1346(b), 2671 (1970).

Much more thought should have been given to this aspect of the statute because, as will be seen later, the insurers' \$5 billion cost estimate is turning out to be less far-fetched than it may once have seemed.

VI. EXAMPLES OF GOVERNMENT DISTORTIONS

Despite some last-minute administrative problems,²⁵ on October 1, 1976, the Swine Flu Immunization Program began, largely because of the government's distortions and omissions of information. Had the news media lived up to their excellent showing in reporting the Watergate affair, perhaps these tactics could have been unmasked in time. Unfortunately, the media let the public down. At a recent meeting of the American College of Physicians, two New York University researchers blasted the media for their coverage of the Swine Flu Program.²⁶ The researchers charged that pertinent questions involving attendant risks of the program were not asked. There was never a report on what swine flu is, or if and how the vaccine works. Adversary reporting was minimal; that is, no one seemed to question the Ford Administration's motives. The conclusion of the researchers was that the reporters lacked sufficient medical knowledge to explore what was happening. They merely reported the events and information given to them, thus playing into the hands of the CDC.

For example, in late summer and fall of 1976, two very important studies were made which had the potential to cause the public to question the Swine Flu Program. Neither study was widely publicized by the CDC. Jerome C. Schulman and Peter Palesé, physicians who were located at the Mt. Sinai School of Medicine, concluded that the A/New Jersey flu virus was not a recombinant derived from current human strains of flu virus. Applying a widely accepted theory that recombination of human and animal strains of virus is necessary to produce a flu virus with pandemic potential, these two experts asserted that the Fort Dix virus probably could not cause a pandemic.²⁷ Their conclusion was corroborated by the most significant study carried out during the entire swine flu era. Drs. A. S. Beare and J. W. Craig of the Common Cold Research Unit at Salisbury, England imported some isolates of the A/New Jersey flu virus. They vaccinated six volunteers with the virus. Of the six, only four became ill.

²⁵ For example, on August 27, 1976, the manufacturers announced that instead of September 1, the intended date for beginning to inoculate, they would have no vaccine ready until October 1; and that even then, only 25 percent of what they had promised would be available. *The Latest Victim of Murphy's Law—Flu Vaccine Program*, AM. MEDICAL NEWS, Jan. 17, 1977, at 20.

²⁶ See *Media Blasted for Coverage of Swine Flu Program*, AM. MEDICAL NEWS, May 2, 1977, at 13.

²⁷ *Lessons of the Swine Flu Debacle*, MEDICAL WORLD NEWS, March 7, 1977, at 33.

Their symptoms were mild. The other two volunteers never got sick, even though they were always in close proximity to the four ill volunteers. The conclusion of the study was that the A/New Jersey virus was not especially contagious, and that its effects were much more mild than the currently common A/Victoria flu.²⁸

The CDC did not stop at omission; it apparently utilized some distortions as well. For example, in July, a public health booklet released in Pennsylvania contained the following report made by the CDC: "We now have adequate data to demonstrate that a *safe and effective* vaccine can be produced for adults. All products tested provided satisfactory immunity levels with only minimal side effects."²⁹ A similar release made in an FDA drug bulletin in August stated that ". . . clinical trials . . . have demonstrated that new monovalent swine flu vaccines produce significant antibody levels" ³⁰ Yet, as already stated, researchers in fact were having difficulty finding an effective, yet safe, dosage, and they knew that the side effects were not so minimal. Dr. Sabin recently stated that only one of the four manufacturers was producing a vaccine that provided an acceptable level of immunity, and that the effective vaccine worked in only a segment of the test population. Moreover, Dr. Sabin claims that the CDC was aware of this situation.³¹

The most pronounced misuse of the media by officials in charge of the program occurred on December 6, 1976. Two weeks after the inoculation program began, three deaths occurred in Pittsburgh, Pennsylvania. The three victims had received swine flu vaccine within an hour of one another at the same clinic and all three had died within the following six hours. The CDC "investigated" and concluded that the vaccinations were not the cause of the deaths. However, the Pittsburgh deaths caused the entire program to lag seriously. Then on December 6, 1976, Missouri public health officials and a CDC spokesman announced that a confirmed case of swine flu had occurred. A few days later, government spokesmen indicated that a mistake had been made. The patient in question did not have a confirmed case of swine flu. A number of officials remarked that they had not intended that the case be reported as a confirmed case of swine flu.

Why were these government actions objectionable? The reporting of the Missouri case by the CDC coincided exactly with a massive advertising campaign intended to bolster the diminished participation in the vaccination program. And although federal health officials knew a "mistake" had been made, they made no move to correct it. It was only after outside

²⁸ Beare and Craig, *Virulence for Man of a Human Influenza-A Virus Antigenically Similar to "Classical" Swine Viruses*, 1976 LANCET (VOL. II) 4 (1976).

²⁹ *Swine Flu Update*, PENNSYLVANIA HEALTH, Summer 1976, at 3 (emphasis added).

³⁰ FDA DRUG BULLETIN, August/October 1976.

³¹ Sabin, *supra* note 1, at 27.

pressure was brought to bear that the "mistake" came to light. The only reasonable conclusion that can be drawn from the incident is that the release was at best a case of government capitalizing on a known prior program mistake and was at worst a deliberate hoax promulgated to assist the advertising campaign.

Also glaringly omitted from the swine flu literature was the fact that an excellent alternative to mass vaccination existed: the therapeutic administration, following diagnosis of the disease, of the drug Amantadine. Vaccines have a number of drawbacks. First, they must be specifically formulated for each new flu strain. Second, because they require two to three weeks to take effect, they must be administered in advance of an epidemic. (The result of these two facts is a sort of epidemiological roulette. Scientists must guess what the upcoming flu strain will be and then formulate a vaccine. If the actual flu strain differs enough from that which was anticipated the vaccine will be ineffective). Third, vaccines are totally ineffective after exposure to a virus. Fourth, they produce relatively severe side effects and generally have a low rate of effectiveness. Amantadine was a drug that had been extensively tested for more than ten years and had received FDA approval at just about the time the swine flu decision was being made in the Spring of 1976. Amantadine suffers none of the drawbacks of vaccine mentioned above. In addition, Amantadine has important plusses: (1) it is not specific for any flu virus—that is, it is equally effective against all strains; and (2) it is therapeutic, usually reducing flu symptoms within 48 hours. When all the facts are considered, Amantadine shows itself to be far superior to vaccines. Its low incidence of mild side effects makes it especially appropriate for high-risk groups such as the chronically ill, the aged, and the very young. Amantadine's only apparent drawback is that it must be ingested daily. However, since it needs no lead time, the period during which it must be taken can be limited.³²

A review of the information made available, and not made available, by the CDC shows just how unprincipled the agency's actions apparently were. Half-truths and omissions seemed to come in a steady stream throughout the immunization program. Even demonstrable distortions occurred. By fall, certain key federal public health agencies had become more than misguided; they had begun what appears from a distance to have been a concerted effort to cover up the failings of the program by manipulating the media and duping the public.

VII. THE "INVESTIGATION" OF THE PITTSBURGH DEATHS

In the entire swine flu episode, never was the federal government's abuse of the public trust more obvious than during the "investigation" of

³² See Chanin, *Influenza: Vaccines or Amantadine?* 237 J. AM. MED. ASS'N 1445 (1977).

the three deaths that occurred in Pittsburgh during the first two weeks of the immunization program. This author, as Allegheny County Coroner, was directly involved in this "investigation."

Here is what happened. During a one hour period at a single clinic, five elderly inoculees suffered serious symptoms immediately following their swine flu vaccination. Three suffered reactions sufficiently severe to necessitate immediate hospitalization. Of those, one died within an hour of arrival at the hospital. Two others suffered side effects at the clinic, but were able to go home. They both died within approximately six hours. All five of the patients suffered the same symptoms: weakness, loss of color, dizziness, and difficulty in breathing. Autopsy findings at the Allegheny County Coroner's Office indicated that heart and lung problems caused the three deaths.

Thereupon, the Swine Flu Program was halted nationally during a whirlwind investigation of the deaths by CDC officials. First, the investigators conducted a telephone survey of local hospitals which revealed that no other persons with side effects from the vaccine had been admitted. Next, they turned to the clinic. They reported that it was well-organized, and was staffed by competent personnel who were using accepted procedures. That was essentially the extent of the investigation. Based upon it, the CDC purportedly cleared the vaccine as the cause of death, and the immunization program was resumed.

Although time was of the essence, the scope of the Swine Flu Program, and therefore of its potential consequences, demanded a much more in-depth investigation than that conducted. The evidence strongly suggested that there was a common thread among the deaths: five people with the same symptoms, all inoculated at the same clinic within an hour, including three sudden deaths from the same causes. The odds against such an occurrence being natural would seem astronomical. The CDC investigators pegged the possibility of three deaths occurring in this manner as only 1 in 50. One exhaustive statistical study has concluded that the probability was more on the order of 1 in 500,000.³³ Robert J. Armstrong, Chief of Mortality Statistics at the National Center for Health Statistics, has been reported as stating he had a gut feeling that the coincidental occurrence of three such deaths would be "... an extremely rare event—a tremendous longshot."³⁴

The attitude in Pittsburgh of Allegheny County and Pennsylvania health officials was much like that of the President's blue ribbon panel. The investigators hardly could have been expected to be objective; after all, they were sponsoring the program. Furthermore, the investigators

³³ See Gail, *Mass Vaccination: Probability of Three Sudden Deaths*, 195 *SCIENCE* 934 (1977).

³⁴ Boffey, *Swine Flu: Were the Three Deaths in Pittsburgh a Coincidence?* 194 *SCIENCE* 590, 648 (1976).

uniformly ignored or dismissed various theories presented by highly respected experts. This author, acting in his capacity as Coroner of Allegheny County, suggested that stress from standing in line and exposure to adverse weather conditions for hours may have been a factor. His theory was brushed aside. Not one month later, this author has learned, Dr. Hans Selye, widely regarded as the world's leading expert on human stress, commented that aged persons and chronically ill persons are particularly predisposed to have certain types of stress reactions, such as heart failure, following inoculations.

Two other possibilities suggested by this author also were dismissed lightly by investigators. One was the possible interaction between the vaccine and certain drugs that the deceased had been taking for various illnesses (*e.g.*, heart disease, hypertension, diabetes). The investigators could not imagine how such a possibility could occur; yet, no tests were performed. This author's suggestion that the vaccine might have been inadvertently injected into the victims' veins met a similar fate. Existing studies were similarly ignored—for example, reports in 1975 by several Russian scientists in three separate articles that they had found a relationship between myocarditis and vaccines.³⁵

Perhaps the most obvious possibility of all was never investigated by the CDC. It was widely known that the swine flu vaccine was the first flu vaccine ever produced not containing the enzyme neuraminidase. The role that the enzyme's absence might have played in the Pittsburgh deaths should have been explored immediately.

The lack of in-depth investigation into the deaths of the three people in Pittsburgh was appalling. It was nothing short of a whitewash. The deaths highlighted how little was known about the swine flu vaccine in particular, and about mass inoculation programs in general.

VIII. THE PROGRAM ENDS: WHY NOT SOONER?

Ironically, it was the CDC itself that finally called a halt to the Swine Flu Immunization Program.

Through its "watchdog" activities, the CDC began to notice an unusually high incidence of Guillain-Barré Syndrome in inoculees. This rather rare disease causes varying degrees of temporary or sometimes permanent paralysis. It also occasionally affects the involuntary muscles of the heart and lungs, causing death. Although no definite link between the Swine Flu Program and Guillain-Barré Syndrome was established, there was enough evidence to justify calling a halt to the program.³⁶

³⁵ See Pavleev, *Myocardial Damage Syndrome in Allergic States*, *KARDIOLOGIA*, Nov. 1975, at 27; Semyonovich and Samoylova, *Allergic Injuries of the Myocardium with Drug Intolerance*, *id.* at 23; Yevleva, *Infectious Allergic Myocarditis and Rheumatic Carditis*, *id.* at 30.

³⁶ *Paralysis Cases Shut Flu Clinics Across Nation*, *The Pittsburgh Press*, Dec. 17, 1976, at 1.

It seems unlikely that the possibility (and that is all it was at the time) of Guillain-Barré Syndrome resulting from the vaccine was the principal and sole reason for calling off the program. As shown throughout this Article, the proponents of the program had been proceeding all along in the face of much more damaging evidence. Rather, the program collapsed of its own weight. All the negative factors taken together had finally become too much for Dr. Sencer and his colleagues to ignore any longer. In all likelihood, the “eye fake” created by the focus of national attention on Guillain-Barré Syndrome simply provided the CDC leadership with a convenient means of escape from an unconscionable situation.

To fully appreciate just how incredible it was that the Swine Flu Immunization Program got as far as it did, it is necessary to examine some adverse opinions expressed by medical experts during and after the vaccine campaign. For example, Dr. Martin Goldfield, the man who isolated the Fort Dix virus, and Colonel Joseph Bartley, M.D., Chief of Preventive Medicine at Fort Dix, both opposed the program.³⁷ They saw no evidence that swine flu was even as serious as A/Victoria flu. More importantly, they recognized that the risk to the public created by a mass vaccination program was unacceptable, and that the probability of a pandemic was small.

Dr. Albert Sabin, an early proponent of the Swine Flu Program, soon noticed the bizarre course the program was taking. Shortly after the March 24 announcement by President Ford, Dr. Sabin evaluated the current epidemiology of swine flu. There was none. Later, in April of 1977, he observed that once the program began no notice was taken of the significant shortage of reported swine flu cases. Dr. Sabin feels that the strategy used for the Swine Flu Program would be useless in the face of a real epidemic.³⁸

Dr. J. Anthony Morris thinks that flu vaccines may even be of no value. He had been doing extensive research on flu vaccines for the FDA when the Fort Dix outbreak occurred. Although not conclusive, Dr. Morris' research indicated that not only were vaccines ineffective against flu, they promoted flu. He bases his belief on statistics from the Hong Kong flu pandemic in the late 1960s, which he interprets as demonstrating that those countries employing flu vaccine actually suffered more widespread and more serious cases of the flu. Dr. Morris objected to the Swine Flu Program on other grounds. Early on, he objected to the incomplete testing of the vaccine, and argued that the government should not inoculate every man, woman, and child in the country with a vaccine about which little was known. During the testing to determine dosage, Dr. Morris noted (and his findings were corroborated by Dr. Robert Waldman, a leading virolo-

³⁷ See Randal, *Medical Politics Killed Swine Flu Effort*, The Miami Herald, Dec. 23, 1976, at 7-A.

³⁸ Sabin, *supra* note 1, at 30 (1977).

gist) that the proposed dosage of two hundred units was insufficient to produce immunity in most people. In fact, Dr. Morris told this author that the dosage was below government standards.

Dr. Morris finally was fired from the FDA because, he believes, of his outspoken criticism of the Swine Flu Program. In a recent interview with this author, Dr. Morris specifically criticized Dr. Sencer, and Dr. Edward Kilbourne of the Mt. Sinai School of Medicine (a key proponent of the program whose influence on it is discussed below), for engaging in excessive "medical politics," and for pushing the program in spite of such overwhelming circumstances opposing it as the following. First, the lack of infection in the sergeant who gave Private Lewis mouth-to-mouth resuscitation suggested that the Private's illness was not very contagious. Second, the British tests on humans mentioned earlier also showed lack of contagiousness. Third, the tests at Fort Detrick included injecting monkeys with isolates of the Fort Dix virus; most of the monkeys did not get sick and even those that did showed negligible clinical symptoms. Fourth, the CDC reported only nine cases of swine flu from February to December of 1976, none of which caused an outbreak of the disease.

A brief examination of the possible motives of Dr. Kilbourne may provide insight into the direction of the program. Dr. Kilbourne has spent the bulk of his professional life studying vaccines, vaccination programs, and flu viruses. He is a leading authority on mass immunization in the Armed Forces. Dr. Kilbourne repeatedly has proposed that mass immunization of general populations would be just as effective as it seems to be for the troops. He may have seen the opportunity to test this theory when the Fort Dix situation occurred. This supposition is supported by Dr. Kilbourne himself; in January 1976, he published a book in which he stated that he thinks that national, even global, vaccination against type A flu may eradicate it.³⁹

Dr. Kilbourne was in the unique position of having substantial influence upon the Director of the agency conducting the immunization campaign.⁴⁰ According to Dr. Morris, it was in fact Dr. Kilbourne who was the motivating force behind the immunization program. Just how committed Dr. Kilbourne was to the program was amply illustrated by his comments concerning the Guillain-Barré Syndrome. Twenty-four hours after the program was discontinued, Dr. Kilbourne, on national television, flatly denied any link between the Guillain-Barré Syndrome and flu vaccines.⁴¹ Could he really have investigated that possibility thoroughly in so short a time? Was he aware of a study published in the *Archives of Internal Medicine*

³⁹ Kilbourne, *The Influenza Viruses and Influenza* 530, 531 (1975).

⁴⁰ See Randal, *supra* note 37.

⁴¹ See *id.*

in 1966 that noted an association between various vaccines and Guillain-Barré?⁴²

Motives of participants in such a complex situation are, of course, difficult to assess. But, given the many factors that ought to have halted the program, is it unfair to speculate that Dr. Kilbourne may have sought to test his theories concerning influenza through his involvement in the Swine Flu Program, and that Dr. Sencer may have allowed himself to be influenced excessively by Dr. Kilbourne? Is it not reasonable to speculate that professional enthusiasm on their part, combined with political ambition on President Ford's part, contributed in great part to the swine flu debacle?

IX. THE PROGRAM'S HUMAN AND FINANCIAL COSTS

The final results of the Swine Flu Immunization Program may never be known. But this author's recent investigation of the current status of the aftermath shows many adverse sequellae and high costs. Recently, a CDC employee unhesitatingly answered "yes" when this author asked the question, "Is there a link between Guillain-Barré Syndrome and the Swine Flu Immunization Program?" He asserted that the CDC has established a definite statistical relationship between the two: one can expect an incidence of 10 cases of Guillain-Barré Syndrome per one million inoculees; 5 to 10 percent of those permanently affected with paralysis by the Syndrome die; and to date, there are 500-600 cases of Guillain-Barré Syndrome statistically associated with the Swine Flu Immunization Program.

The number of deaths acknowledged to have resulted from the program is not known; however, already 52 wrongful death claims have been filed with the Department of Justice. An additional 22 lawsuits also based on wrongful death have been filed in various courts around the country. A May 1977 decision by the United States District Court in Oklahoma, *Sparks v. Wyeth Laboratories, Inc.*,⁴³ determined that the Swine Flu Act of 1976 is constitutional. Therefore, the requirement that any lawsuits be preceded by an administrative claim filed with the Department of Justice will in all likelihood cause the above 22 suits filed with courts to be dismissed; but they can still be filed as administrative claims.

The money spent on the Swine Flu Program itself was \$135 million. This is only a fraction of what the final costs will be. Plaintiffs in the mentioned wrongful death actions are claiming \$1,023,139,657 in dam-

⁴² Leneman, *The Guillain-Barré Syndrome*, 118 ARCH. INTERNAL MED. 139, 142 (Table 2) (1966).

⁴³ 431 F. Supp. 411 (1977).

ages; in the 22 civil suits they are demanding \$287,590,529; and in personal injury claims filed with the Justice Department they are demanding \$260,070,134. The grand total from all the claims is \$1,675,800,320, a figure that does not include the salaries and incidental costs of the special Justice Department task force assigned to handle swine-flu-related claims. Furthermore, the three attorneys, three secretaries, and assorted part-time help of the task force have received 3,000 inquiries into claim procedures. It is beginning to look as if the insurance carriers' \$5 billion estimate of the likely dollar value of claims that might be paid because of the program is not totally out of line.

Furthermore, the ultimate dollar costs may be continuous. The federal government set a dangerous precedent by underwriting the immunization program. If it becomes necessary to underwrite all programs of this nature, the costs will be never-ending; and if the federal government refuses to underwrite future immunization programs, they may never become available.

Unfortunately, the dollar costs of the program may not be its most "expensive" result. Tragically, the diverting of our limited vaccine manufacturing capacity to the swine flu effort has caused a serious depletion in supplies of other vaccines. In May of 1977, the National Immunization Conference stated that we have a rapidly increasing need for mass polio, measles, and other inoculations that cannot be met. Vaccine is just not available because the swine flu effort diverted limited manufacturing capacity, thus preventing a buildup of other vaccines.⁴⁴ Even if the vaccines were available, the general public is now fearful—due to the swine flu debacle—of even the most proven vaccines, and might not use them. We may, as a result, be facing very serious related public health problems in the near future.

X. LESSONS FOR THE FUTURE

Hopefully, our swine flu experience has not been a total loss. First, experts in preventive medicine should take note that vaccines often cause untoward results in many persons and may not be particularly effective. A reevaluation of vaccines in general, and flu vaccines specifically, is in order. Second, public health officials should now realize that any kind of vaccination program on a national scale demands objective, sophisticated planning, utilizing rational decision-making models. We cannot again afford to overreact emotionally to a potential public health hazard. For instance, in 1976 the situation just was not similar to that during the 1918-1919 flu pandemic. There were no large troop movements, and we

⁴⁴ See *Immunization Experts Foresee Problems*, MEDICAL WORLD NEWS, May 2, 1977, at 31.

have developed various effective antibiotics to help flu victims cope with flu virus's bacterial sidekicks. Given these facts, we can afford to be calm and objective next time around. Third, people, especially high-risk individuals, must not be treated like cattle. The scenario of elderly persons standing in long lines in adverse weather for hours waiting to be vaccinated must not be repeated. Fourth, alternatives to a specific program must be built into any plan. The Swine Flu Program clearly showed us that a vaccine that is harmless to some persons may cause a catastrophe in others. Most importantly, the federal government must recognize its appropriate role in protecting the public health and must adhere to it with scientific caution. The government should limit itself to facilitating public programs. Employing high-pressure sales tactics like Madison Avenue mass media promoters to push a program is not commensurate with this objective. Certainly, when people's lives are at stake, cheap politics has no place.

In concluding, the author must point out that although the five objectives above are desirable and reasonable, experience tells us that none of them will be achieved unless there is sufficient prodding. We must rely on the news media to investigate, to probe, and to catalyze appropriate action. They must seek out and provide objective, constructive criticism for officials and the public to consider so that we will make better decisions in the future and avoid a repeat of the swine flu travesty.