Kennedy School of Government
Case Program

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Swine Flu (A)

> In the world I deal with every day, there are so many things you do that are not terribly interesting, but which are called "real chores." To have a challenge of something that is a real public health interest is really stimulating.
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> So perhaps it is bad to have these things happen in one respect, but it is kind of stimulating to those of us who are in public health in another respect.[1]

The speaker was Dr. Harry Meyer, director of the Food and Drug Administration's (FDA) Bureau of Biologics, and the occasion the opening of a hurriedly convened workshop sponsored by that bureau in conjunction with two other agencies, the Center for Disease Control (CDC) and the National Institute of Allergy and Infectious Diseases (NIAID), on February 20, 1976. Another participant, Dr. Maurice Hilleman, vice president of Merck, Sharpe and Dohme Laboratories, sounded repeatedly on the theme that the situation called for "heroism" on several fronts; he added, "There [will] have to be some very heroic decision-making very soon."*[2] The topic of the day was influenza—four specific cases, out of the tens of thousands of cases that had occurred in the US during the 1975-1976 winter flu season—and about one month later, the hour for decision-making had arrived.

In mid-February 1976, Dr. David Sencer, director of the Center for Disease Control in Atlanta called his superior, Dr. Theodore Cooper, HEW assistant secretary for health, to inform him that CDC's laboratories had determined that four cases of influenza, one of them fatal,** at Fort Dix, New Jersey, were caused by a virus other than the "Victoria flu," which had caused a small epidemic among Army recruits at Fort Dix and had been the dominant influenza strain in the US for the past several years. CDC's analysis of cultures from throat washings, identified a swine-like flu virus which was believed to have been inactive in the human population since 1930 with the exception of a handful of cases of swine-to-person transmission. The Fort Dix evidence was more than an item of medical curiosity to Sencer, Cooper and the rest of the public health community, since it appeared that human-to-human transmission had occurred in this instance; this in turn suggested that an "antigenic shift"***

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* Several Public Health Service officials picked up on the idea of "heroic" policymaking some six weeks later in their congressional testimony on appropriations for the swine flu immunization program.

** The fatality was an eighteen-year old recruit who, against medical advice, left his bed and participated in a forced five-mile march at night, during which he collapsed and died.

*** Influenza viruses are identified by their surface proteins or "antigens." When a virus appears with antigens differing in composition from those of the virus previously circulating in the population, an "antigenic shift" is said to have occurred.

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had occurred or was occurring in the human influenza virus—an event which in the past had always been followed by a worldwide "pandemic" of influenza. Moreover, swine flu was believed to have been the agent of the century's worst flu pandemic, that of 1918-1919, in which 500,000 Americans died.

The purpose of Sencer's call to Cooper was simply informational—to alert Cooper that farther down the road a major decision might be necessary. As assistant secretary for health, Cooper, a cardiovascular surgeon, directed the National Public Health Service (PHS), which comprised the National Institute of Health (including NIAID), the FDA, CDC, and three other line health agencies. Sencer assured the assistant secretary that CDC would investigate the situation further through the ordinary review processes, which involved consultation with other component agencies of the Public Health Service and external scientific advisory groups, and would keep him informed of any new developments. At that point, neither saw cause for any immediate involvement on the part of HEW leadership. Cooper recalled that this was the usual route through which a line agency responded to a new, potentially troublesome situation.

> The six major operating agencies [in PHS] purely do their regular business, and the secretariat doesn't get involved—it would be paralyzed with inactivity [if it did]. What happens is that the agency's chief will let up the line know that there is a potential threat. ... Dr. Sencer let me know that there was a possibility that there would be a need for some urgent action but they didn't really know.

During the next few weeks, the investigation of the Fort Dix swine flu outbreak was a major item of business for CDC and its sibling agencies, NIAID and the Bureau of Biologics.* These agencies and their leaders had over the years apparently evolved a comfortable division of territory** so that close collaboration among them required no direction or coordination from above. On February 14, two days after the identification of the swine flu virus, their officials and civilian and military health officials from New Jersey met in Atlanta at CDC headquarters to discuss the findings and to chart further investigation. All parties agreed that more data was needed to determine whether the outbreak at Fort Dix was a harbinger of an epidemic or merely an isolated incident; they further agreed that, while uncertainty was so strong, there should be no publicity, which might prematurely and unnecessarily raise public concern. However, a few days later, fearful of uninformed press leaks, Sencer

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* Actually both of these were fairly autonomous subdivisions of larger line agencies—NIAID of the National Institute of Health (NIH) and the Bureau of Biologics of the FDA; the Bureau had recently been moved to the FDA from NIH.

** NIAID, "the delineation, support, and stimulation of the research aspects;" the Bureau of Biologics, "identification of strains, licensure, and all contacts with industry;" CDC, "the epidemiology, the surveillance, the reagent production, and use and developing recommendations for use of vaccine." Center for Disease Control, Bureau of Biologics/National Institute of Allergy and Infectious Disease, *Influenza Workshop* (Bethesda, Maryland, February 20, 1976), transcript, p. 8. In other words, NIAID's role was basically confined to research, and the Bureau of Biologics to testing and regulating a particular product, the vaccine. CDC was the federal government's "preventative medicine" organization, with responsibility for tracking the course of diseases through the population, offering recommendations as to whether a new vaccine was needed and if so what kind, and dealing with the state and local health departments.

changed his mind and on February 19 CDC went public with its information. CDC assistant director Dr. Bruce Dull summarized to the press what was known of the New Jersey cases, and added that "it should be possible to judge within several weeks whether or not there will be a need for a vaccine against swine-type influenza virus of man."[3] *The New York Times* accorded to "US flu alert" front-page coverage and noted the potential similarity to the 1918-19 virus.

On February 20 the group that had conferred at CDC the previous week was joined by scientists from state and local health departments, universities, and vaccine manufacturing companies at the Bureau of Biologics workshop mentioned earlier. The conference reviewed previous research and epidemiological data on swine flu. Thus far, intensive surveillance of influenza activity throughout the country had shown only Victoria strain virus. Nonetheless, the human-to-human transmission in the four swine flu cases at Fort Dix was confirmed: none of the diseased recruits had had any contact with pigs; laboratory contamination of the cultures had also been ruled out.

During the following weeks no new swine flu cases were reported at Fort Dix, elsewhere in the US, or (according to the World Health Organization) in the world. (There were new influenza cases reported at Fort Dix, but, according to an Army investigation, they were caused by the Victoria strain.) Not enough was known about how flu epidemics spread to interpret the absence of further swine flu outbreaks, especially in and around Fort Dix. It was possible that this meant that the swine virus had simply "sunk" back into the pig population; it was also possible that it was spreading through the human population without giving off clinical symptoms ("subclinical spread") and would erupt in pandemic proportions the next winter. Some scientists, including CDC's own laboratory chief, felt that a swine flu virus so quickly dominated by the Victoria strain at Fort Dix would not pose the threat of subclinical spread; but others argued persuasively that it could happen. In the meantime, disturbing news continued to flow out of Fort Dix. Tests on recruits who had been sick in January and early February revealed nine "old" cases of swine flu, bringing the total who had fallen ill to thirteen. Finally, extrapolating from tests of antibody levels on a sample of recruits, the Army estimated that up to 500 persons on the base had been infected by but apparently resisted the swine virus.*

Dr. Sencer scheduled for March 10 an emergency meeting of the Advisory Committee on Immunization Practices (ACIP), a seven-member "external" scientific panel which Sencer, as CDC director, chaired. In January that committee had passed on to the drug manufacturers its recommendation that they produce enough Victoria flu vaccine—about 40 million doses—to immunize the "high risk" population of elderly and infirm persons through the conventional private health care delivery channels during the 1976-77 flu season. The purpose of the March meeting was to consider revising both the scale and vaccine type of the original recommendation. If any vaccine for swine flu were to be produced in time for the 1976-77 flu season, regardless of the quantity sought, the ACIP would have to act almost immediately so that the manufacturers could begin the production process. On the eve of the ACIP meeting, Sencer and Cooper again spoke on the phone; Sencer warned that the

* While only thirteen men actually were stricken with swine flu at Fort Dix, the information form that accompanied the vaccine in the Fall 1976 immunization program described it as "an outbreak of several hundred cases"—apparently this referred to the antibody levels.

committee might propose major federal vaccination initiatives, something he had discussed with his division chiefs earlier that day, and promised to get back to Cooper immediately after the meeting.

The minutes of the ACIP meeting gave this report of the deliberations:

> Based on previous experience with new influenza strains, it is unlikely that a single outbreak will conclude the activities of this strain. ... It was, therefore, agreed that the production of vaccine must proceed and that a plan for vaccine administration be developed.
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> The committee felt that such a program should be encouraged under federal auspices to involve vaccine purchase as well as a delivery mechanism.[4]

The vagueness of this account regarding the dimensions of both the adversary and the recommended response is not surprising. No one was willing to predict a pandemic in the next year or even to estimate the probability of such an event. Moreover, although the panel was apparently unanimous in its support of a federal program aimed at producing vaccine for the entire population, at least one member, Dr. Russell Alexander, spoke for separating the production and vaccine administration decisions—holding off on using the vaccine unless there was another outbreak somewhere in the world. Sencer and the others from CDC opposed this approach primarily on logistic grounds; they felt that if the virus reappeared it would spread more rapidly than vaccine could be distributed, shots administered, and immunity built up. In any event, the ACIP's function was to offer medical recommendations, not to design administrative machinery.*

Sencer called Cooper after the meeting and reported that the ACIP unanimously felt the possibility of a major outbreak could not be dismissed and that an extraordinary federal response was probably in order. Sencer added that he and his aides were preparing a more specific memorandum to that effect—in all likelihood recommending a national immunization drive—which he would bring to Washington that weekend. Cooper asked what he called "the usual administrative questions," such as whether CDC had conferred with outside authorities and with the other relevant PHS agencies. Of course, since the actual content of the CDC proposal had not yet been worked out, Cooper did not, at that point, endorse a full-scale immunization drive. Nonetheless, convinced of both the seriousness and urgency of the situation, he believed that some action would be necessary before he returned from the eight-day trip to Egypt on which he was about to depart. Consequently, he took several actions to guarantee that the recommendation Sencer was preparing would receive expeditious consideration. First, so that time would not be lost while the proposal idled in HEW's paper mill, he told Sencer and his own staff to "make sure that Jim Dickson gets it." (James Dickson, the deputy assistant secretary for health—and like most PHS officials, an M.D.—would be in charge of PHS during Cooper's absence.) Cooper wanted Dickson, in turn, to pass CDC's proposal on to David Mathews, the secretary of HEW,

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* Also, by some accounts, the ACIP was practically a house organ and generally satisfied Sencer's wishes; by the time the meeting had concluded, Sencer was convinced that the only feasible approach would be a program involving federal purchase of flu vaccine and its administration before the onset of the flu season.

and see that Sencer had the opportunity to present his case to the secretary. Cooper also brought the matter up himself, before leaving for Egypt, during one of Mathews' full staff meetings. By Cooper's report, Mathews, who the previous year had left his position as president of the University of Alabama to join the Ford administration, responded very calmly to the news that the government might have to act rapidly to head off a flu epidemic.

> I said that it is my understanding that there may be a need for a recommendation from CDC for a large-scale immunization program in influenza, based on some findings that they are getting from Fort Dix. I said that if that were the case, that would be a rather important discussion, which Dr. Sencer feels needs immediate attention. ... His reaction was, "Well, we will be pleased to hear it." He was a rather low-keyed gentleman who wasn't excitable, and there was no great discussion about it that I recall.

Finally, Cooper mentioned to Dr. James Cavanaugh, deputy director of the White House staff, that a flu immunization proposal was in the pipeline. A former HEW official, Cavanaugh had, until recently, been deputy director of the White House Domestic Council and in charge of the Council's health and welfare staff; he continued to exercise considerable responsibility in these fields for the White House. As Cavanaugh recalled, Cooper said that he felt a full-scale immunization program might be necessary, but that he wanted to be certain first that CDC and the other line health agencies had adequately documented the need for and feasibility of such a program.

Beyond these groundwork-laying activities, Cooper felt no other immediate action at the HEW level, (i.e., the secretary, the assistant secretaries and their staff, as opposed to the line agencies) was either necessary or appropriate. In Cooper's estimation, Sencer and CDC were both trustworthy and technically competent; hence, he saw no reason to try to second-guess their conclusions or to reanalyze their raw findings. Moreover, neither his office nor other analysis-and-review operations within the department were set up to undertake that type of medical and epidemiological investigation. As Cooper elaborated:

> And what could they evaluate? ... The evaluation staff wouldn't have a prayer understanding things like that ["jet spread" of an influenza epidemic]. If you want to make government decisions by cross-checking everybody, what you do is set up a long enough lead time that you could set up an evaluation of the proposal, a study time for people to go out and do that. For what was being proposed, that is not a very practical option.
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> The point is this: if you want to put layers of everything over everything to double-check everybody, then you might as well

> fire the whole goddamn thing—it ain't worth a damn. The technical expertise is down in the agencies.

Although he did not approve any particular course of action before he left the country, by directing Dickson to go to the secretary with Sencer's recommendation, Cooper, in effect, signed off on the general direction Sencer had discussed over the phone.

From March 11-13, Sencer prepared a memorandum bearing the heading "Swine Influenza: ACTION." After the fashion of most government documents, the memo did not bear the name of its author but that of the official at the next higher level of authority; hence, it was written in the form of a recommendation from Cooper to Mathews. The seven "Facts" which introduced the paper built the case for a swine flu epidemic in 1976-77 as a serious possibility. Fact #2 was, so to speak, the killer:

> The virus isolated at Fort Dix is antigenically related to the influenza virus which has been implicated as the cause of the 1918-19 pandemic which killed 450,000 people—more than 400 out of every 100,000 Americans.*[5]

Also included among the "Facts" was a widely accepted generalization concerning the behavior of influenza strains: "Severe epidemics, or pandemics, of influenza occur at approximately 10-year intervals."[6] The most recent such event had occurred in 1968-69; consequently, by this timetable, swine flu was apparently coming to call only a trifle earlier than expected.** The Sencer memo proceeded to its "Assumptions"—beginning with the medical ones and building up to their policy implications. An antigenic shift made "widespread" influenza in 1976-77 a "strong possibility"; this plus the fact that no one under the age of fifty was likely to have antibodies against this specific strain constituted "the ingredients for a pandemic."[7] There followed a number of statements constructing the framework within which a decision would have to be made: for swine flu vaccine to be produced in time for the next flu season (i.e., by fall), its manufacture must commence almost immediately; to prevent a pandemic, an immunization program must be targeted to the entire population, not only the traditional "high risk" groups; and a "public health undertaking of this magnitude cannot succeed without federal leadership, sponsorship, and some level of financial support."[8]

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* This sentence contains two very important qualifiers—"antigenically related" and "implicated." Since viruses were not isolated until the 1930s, knowledge regarding the composition of the 1918-19 virus was based not on hard medical data but on a conventional wisdom which held that the virus that had caused the 1918-19 pandemic subsequently sank into pigs, where it also caused widespread influenza. After about 1930, the virus ceased to circulate among humans but remained in the pig population.

** Ironically, on February 13, just as the CDC laboratories were concluding that the unknown isolates from Fort Dix were swine flu, an Op-Ed piece appeared in the New York Times warning that the federal government would have to be ready to respond to an "imminent national disaster"—a new influenza pandemic—within the next couple of years. (Edwin D. Kilbourne, "Flu to Starboard! Man the Harpoons! Fill 'Em With Vaccine! Get the Captain! Hurry!" *New York Times*, February 13, 1976, p. 33. (Its author, Dr. Edwin Kilbourne, a very well respected virologist, subsequently participated in the March 10 ACIP meeting, where he emerged as one of those convinced that a 1976-77 pandemic was not only possible but likely.) However, the evidence for 10-year intervals between pandemics was scanty. While worldwide epidemics have occurred approximately every 10 years in the decades since the 1940s, one recent historical review concluded that the incidence of pandemics over the last 250 years has been very irregular, with the average interval between them ranging from 12 to 24 years.

Sencer identified four possible courses of action and their respective pros and cons. First the federal government could take "no extraordinary action" and depend upon the private health care market to service those customers who wished to be immunized. In what was perhaps a dig at the interest shown in public health initiatives during the Nixon and Ford years, Sencer included among the pros of this approach: "Any real action would require direct federal intervention which is contrary to current Administration philosophy."[9] Among the objections was an idea that became a litany of the immunization program (especially when it was criticized on the grounds that a pandemic was not a certainty): "The Administration can tolerate unnecessary health expenditures better than unnecessary death and illness, particularly if a flu pandemic should occur."[10] The second option was a "Minimum Response" in which the government would recommend to vaccine manufacturers that they produce enough doses to immunize the entire population, but would confine its own activities to public awareness campaigns, research and monitoring, and purchase of vaccine for federal beneficiaries. Drawbacks mentioned here were the likelihood that manufacturers would not produce sufficient quantities and that much of the population (particularly low-income groups who are generally underserviced by the private health market) would not be immunized. The third possibility discussed in the memo was a program carried out entirely by the public sector—the federal government would purchase enough vaccine for the entire population; it would be administered to the public by federal agencies and state health departments. Sencer cautioned, "The approach is inefficient to the extent that it fails to take advantage of the private sector health delivery system, placing too much reliance on public clinics and government action."[11]

The fourth and recommended option was described as a "combined approach" in which the US would still purchase all the vaccine, but distribute it through a variety of channels, ranging from physician offices to community clinics:

> In essence, the plan would rely on the federal government for its technical leadership and coordination, and its purchase power; state health agencies for their experience in conducting immunization programs and as logical distribution centers for vaccine; and on the private sector for its medical and other resources which must be mobilized.[12]

Sencer's position, as expounded in the memo, was that the only way a pandemic could be halted was through a program that would immunize most of the population; a half-hearted or more conservative vaccination effort would be little better than none at all. "The magnitude of the challenge suggests that the Department [of HEW] must either be willing to take extraordinary steps or be willing to accept an approach to the problem that cannot succeed."[13] The Sencer memo aimed two criticisms at the "Combined Approach," both of which tended to glance off it harmlessly—it would be expensive ($134 million),* and some people might be "needlessly re-immunized."**

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* Actually, to the Washington decisionmakers subsequently involved in the matter, its cost was one of its selling points. Relative to many of the major programs with which they dealt, $134 million for a nationwide *anything* was a major deal.

** Apparently this referred to people over the age of fifty who might or might not still have swine flu antibodies.

That weekend Sencer arrived in Washington, memo in hand. Since Cooper had made clear that he wanted the recommendation passed on to Mathews, Dickson signed it on his behalf and set up a briefing with the secretary for Monday morning March 15. Dickson regarded Sencer as "a very strong man": "It's good to get the strongest man to run something under you—someone who isn't going to destroy the whole operation." He also believed that Sencer's organizational talents had paid off at CDC; he felt Cooper regarded CDC as "a 4+ organization on a 1-4 scale." Perhaps in order to have a counter-balance to Sencer (who was, by some accounts, widely perceived as manipulative as well as well-organized), Dickson invited to the meeting with Mathews the head of another PHS agency, Harry Meyer of the FDA's Bureau of Biologics. Meyer's Bureau would have a crucial role—licensing and testing the vaccine and dealing with the manufacturers—in the event of a "go" decision.

Dickson and Sencer talked very briefly Monday morning and then, along with Meyer, proceeded to the briefing with Mathews. The meeting lasted only about thirty-five minutes but ranged over several topics. Basically repeating the contents of his memo, Sencer took the lead in aggressively advocating a joint public/private program aimed at the entire population, his option #4. Sencer also hinted that Congress (in the person of Representative Daniel Flood) might act on its own and hold appropriations hearings on swine flu if no immunization initiative emerged from the department.[14] Mathews' principal question (and the one that most frequently would be posed to *him* over the next 10 days) was, "What is the probability of an epidemic?" To this, Dickson, Sencer and Meyer unanimously responded, "Unknown." The severity of an epidemic or a pandemic, were it to occur, was also a topic marked by uncertainty, since the virulence of a strain of virus cannot be reliably predicted through laboratory tests. Dickson remarked that the example of 1918-19 served as a "ghastly vignette" to the discussion. Apparently the possibility of one million deaths—an extrapolation, based on the current US population, from the 400,000 deaths of 1918-19—was brought up by someone, despite the fact that today antibiotics could be used during any outbreak;* at any rate, that estimate found its way into a memo later that day from Mathews to the budget director.**

Beyond the question of the necessity of a full-scale immunization program was that of its feasibility. As Dickson recalled, they were in a "time-bind"—one of the biggest concerns was chickens, not swine. Flu vaccine is made from killed virus which is grown in eggs. In accordance with the ACIP's January recommendation, the manufacturers had already gone ahead with production of Victoria flu vaccine. Producing swine flu vaccine—on a scale ten times greater than usual—meant making sure the manufacturers could get a whole new batch of eggs; that, in turn, would require above-the-call-of-duty dedication on the part of the chickens.*** Meyer believed that, with some difficulty, it could be done and that vaccine would be ready for distribution by mid-summer. The next major hurdle, also considered "do-able," was to administer the shots before the onset of winter. Sencer thought the

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* Although influenza itself is a viral infection, the actual cause of death in many cases was bacterial pneumonia, brought on by the weakening of the respiratory system.

** Other HEW officials recall that the number being "thrown around" most frequently at that time was half a million.

*** It was also necessary to act before the food companies made hash out of the roosters as they ordinarily did in the spring.

program could be completed by sometime in November; Meyer thought "by Christmas" a more realistic estimate.[15]

Although the logistics of the program would be challenging, it was felt certain that a safe and effective vaccine could be developed. Vaccine for other influenza strains had been in use for a quarter of a century, with about 20 million doses administered annually; side effects were anticipated—many arms would be sore and some people would experience fever and chills for a couple of days—but no serious ones. Moreover, two failsafe devices for detecting serious adverse reactions would be put into effect if a program were adopted. First, the Bureau of Biologics would conduct extensive field tests with volunteers before any vaccine was administered to the general population. Second, the CDC would set up an elaborate epidemiological surveillance system to monitor both the course of influenza (both swine and Victoria) throughout the season and the incidence of side effects. (Cooper, when he returned, put particular stress on the importance of instituting the surveillance system.)

Meyer did not contradict any of Sencer's hard-sell points but took a more cautious tone. His key caveat to Mathews was that "this is a social and not a scientific decision."[16] All science could do was ascertain that there was a risk of a swine flu pandemic, not how great that risk was. Since criticism could be expected whichever way the secretary decided, it was important to "bring everybody into the act," to broaden the decisionmaking beyond the administration in both the scientific and political communities.

Mathews did not announce a definite decision by the end of the meeting, but judging from the secretary's reactions, Dickson was convinced that Mathews had concluded it was his responsibility to launch an immunization program. Dickson noted that once officials knew that a pandemic was possible, they could not justify taking no action. Even though the probability of a pandemic (which no one was willing to estimate) could be very low, their concern had to focus on how serious the damage would be if it did occur—and a half million to a million deaths had been mentioned as possible. Dickson commented: "David Mathews was a very sensitive human being and a *historian*. He was not a callous general sending people into battle." He added, "In a political sense, the man didn't exist who could have said 'No.'"

By close of business on Monday, swine flu policymaking outbreaks had occurred in numerous parts of Washington. It was not certain whether HEW would require new authorization legislation in order to launch a swine flu vaccination—that point would have to be explored with its lawyers—but a supplemental appropriation was definitely necessary. That meant that the proposal would have to go through the Executive Office of the president; moreover, getting vaccine production started in time required a more expeditious approach than the usual interagency arrangement for processing requests for supplemental budgets. As Cooper explained the situation:

> There is a regular process which is moderately time-consuming ... regular times when we anticipate the president will consider supplementals. ... This was outside that time frame. And it would be so unusual we felt it had to be called specially to his attention.

After the meeting with the PHS officials, Mathews sent a short note to James Lynn, director of the Office of Management and Budget (OMB) inviting him to send someone over to HEW to attend an afternoon briefing on the swine flu threat. The doctor's statements of the uncertainty of a flu outbreak or of its severity somehow did not make it into this memo:

> There is evidence there will be a major flu epidemic this coming fall. The indication is that we will see a return of the 1918 flu virus. ... The projections are that this virus will kill one million Americans in 1976.
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> The decision will have to be made in the next week or so.[17]

The OMB people were apparently the only officials treated to so strong a statement of the likelihood of a severe epidemic; they also were (and remained) most doubtful among the federal participants that an outbreak would occur. Even before Mathews formally notified Lynn, OMB staff were working on a swine flu memo of their own. Victor Zafra, chief of the health branch, had read the press accounts in February about the Fort Dix events and the possible return on the 1918-19 virus; his reaction was "healthy skepticism—I didn't believe them." Around the time of the ACIP meeting, the health staff got word from their HEW counterparts of the probable content of CDC's recommendation. On Saturday, March 13, OMB Deputy Director Paul O'Neill, who was to become the key high-level participant from his agency in the swine flu deliberations, returned to Washington from an out of town business trip to find his health staff busy developing their memo:

> Here were two or three people involved and when I got there they were whirling around the director's office—which includes my office and a couple of secretaries' offices—preparing this memorandum; that's when I first started getting briefed on the issue.

On Monday afternoon, Zafra and his colleagues from OMB, as well as people from the office of Bill Morrill the HEW assistant secretary for planning and evaluation, were briefed by the Public Health Service officials (Sencer, Meyer, etc.). Both OMB and Morrill's office pressed the question of probability and were met with the same response Mathews had received—that it was unknown and there was no way of placing a figure on it. Zafra thought that they hadn't made their case." (He also thought that, in general, the "incentive system" in HEW and in most of the bureaucracy discouraged "asking hard questions," that knowing the conventional wisdom was rewarded only in places like OMB, which incubated skepticism.) Zafra felt a number of aspects of the Fort Dix outbreak suggested that the virus there had neither the spread nor virulence traits of the 1918 disease. First, the outbreak had occurred under unusual circumstances that made people especially susceptible to infectious disease—a crowded living situation and a pool of recruits not yet adjusted to the physical rigours of military life. Second, even under these conditions, only a handful on the entire base had been stricken

with swine flu; many others had apparently been exposed but successfully resisted it.* Nonetheless, the tone of the internal OMB memorandum on the subject was cautious. Nancy Bateman, a budget examiner, noted that extensive epidemiological surveillance had turned up no outbreak other than at Fort Dix and also suggested that CDC might have overestimated the budget required for an immunization program.[18] Zafra recalled that OMB staff "did not know enough to say [a program] was definitely bad." Of course, OMB's reservations (which it tactfully labeled "Uncertainties") did not really puncture HEW's position since Zafra *et al* could not rule out the possibility of a pandemic.

March 15 also saw greater involvement with the swine flu issue on the part of the White House. At 7:00 that morning Paul O'Neill of OMB brought up the subject over breakfast at the White House with James Cannon, a former Rockefeller aide who was executive director of the Domestic Council in the Ford administration. Later that morning Cannon and O'Neill mentioned it to President Ford while meeting with him on another subject. In the afternoon, Dr. Dickson called the deputy director of the Domestic Council, James Cavanaugh (whom Cooper alerted before his departure), and filled him in on the day's events at HEW. Dickson said that Mathews seemed receptive to CDC's immunization proposal and would probably be seeking executive approval for a supplemental appropriation request very soon. He also transmitted to the White House a copy of Sencer's memorandum. Cavanaugh's reaction to the news was, by Dickson's recollection, characteristically brief and noncommittal: "Okay, Jim, thanks." Dr. Cavanaugh also had conversations that day with both O'Neill and Mathews during which the topic of swine flu came up. The rest of the week saw further internal consultations and memo-trading within HEW, OMB and the White House; meanwhile, Dickson, O'Neill and Cavanaugh emerged as the principal "trouble-shooters" for their respective departments in anticipation of what they all saw as an inevitable need to involve the president in the decision very soon. The questions being asked all around fell roughly into four categories: probability, production, administration and legal issues. The probability issue was no clearer than it had been on Monday or, for that matter, in the CDC/NIAID/Bureau of Biologics meetings the previous month; it was "between 1 and 99 percent," and that was as close as science could come to an estimate. The production issue came down to the availability of roosters, chickens, and cooperative, efficient manufacturers. The organizational capability of CDC and, ultimately, of the state and local health departments to administer twice as many vaccinations in half as much time as the largest previous federal immunization campaign (the Sabin polio vaccine) also required investigation. Finally, was authorizing legislation necessary before undertaking the campaign, and would the program expose the federal government to frivolous or legitimate lawsuits alleging injuries from vaccinations?

At HEW Mathews relied on a number of what he called "defensive secondaries" to detect any gaps in the lone agencies' analysis and recommendations in these areas.[19] Bill Morrill, assistant secretary for planning and evaluation at HEW, commented on Mathews' operating style in cases like this:

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* In fact, it later came to light that after the recruit who died of swine flu had collapsed (during a forced march which he had joined against doctor's orders), his sergeant had administered mouth-to-mouth resuscitation, but had not subsequently contracted the disease.

> David more nearly reacted to than drove the process. He did not view his role, as a general matter, as being involved in activities that were particular to a given assistant secretary. He was much more a delegator. ... He'd have his own agenda of things that he was particularly interested in that he was working on.

Morrill was one of the people Mathews turned to for advice. Since this was not the long-range "policy development" type of question that normally concerned his office, Morrill's involvement was more personal than institutional. Lacking time to launch a formal feasibility study of the proposed program, Mathews basically asked Morrill (and subsequently others) if he thought, on the basis of his own administrative experience and the known facts about flu and vaccinations, a full-scale program could be pulled off operationally:

> There was not then, or indeed very much later, the kind of official involvement with the planning and evaluation offices that pertained to some other issues, because this was more nearly considered an operational matter that was right on top of us. So the involvement was for the most part by me individually and to a somewhat lesser degree a few of my people. ... But it was, particularly at that stage, a very fast moving set of events.

Morrill's view of the situation, for the most part, coincided with that of PHS; since this was reportedly often not the case, his concurrence probably carried added weight. As Morrill recalled:

> There wasn't anything in this particular undertaking other than sheer size that would lead one to think you couldn't do it. The manufacturing capability [was there] if you got it going; there was clearly a timing issue about whether you could get it all done fast enough. The distributional systems were all in place—the volume of stuff was not so large that it was overtaxed. ... There didn't seem to be any intrinsic flaws.

In much the same way as with Morrill, Mathews turned to Jack Young, the Comptroller of the department, for advice. Since this was, in part, a budgetary matter, Young's office was involved in an official capacity. Nonetheless, Young, like Cooper, Dickson, Mathews, Morrill, *et al*, did not feel he was in a position to second-guess what appeared to be the consensus of scientific opinion. At the end of the week, he responded through a memorandum to Mathews' query:

> I concur with Dr. Cooper's recommendation that you adopt a combined approach to the Swine influenza problem as detailed in alternative number 4. In situations such as this, I see no alternative but to rely upon the advice of our health professionals.[20]

In the meantime, HEW Deputy General Counsel St. John Barrett (who was in charge of the Office of the General Counsel [OGC] while William H. Taft III awaited confirmation as the new general counsel) told Mathews and Dickson that "under existing statutory authority they could go ahead" with a federally sponsored influenza immunization program; HEW would have to go to Congress only with a request for a supplemental appropriation, not authorization legislation as well. A second area of potential legal difficulties was liability. Both the lawyers and non-lawyers in the department were aware that a trend in court decisions over the past several years was to hold manufacturers "strictly liable" for injuries relating to risks inherent in the product even where there was no defect or negligence involved; producers could shield themselves only by informing the consumer beforehand of any risks associated with the product. Another court decision, dealing with the "duty to warn," was also of particular interest to HEW officials, even before the swine flu issue came up. In 1974, in *Reyes v. Wyeth*, the court held that although warnings—to the effect that in very rare instances live-virus vaccine could cause polio—were included in the shipping cartons containing the vaccine, the manufacturer was still liable in a case in which this occurred because the warning had not been communicated directly to the vaccine recipient.

Since the manufacturers would be producing swine flu vaccine to government specifications, federal assumption of the "duty to warn" seemed the easiest solution; both Taft and Barrett thought this would assauge any fears on the part of the manufacturers. The federal government, in turn, could protect itself by writing a warning that accurately communicated the risks associated with the vaccine: sore arms, occasional fever symptoms for a day or two and any other adverse reactions revealed by the vaccine field tests. The only unusual legal step anticipated at that point was that OGC, rather than the lone agencies, would be responsible for drafting and negotiating the vaccine purchase contracts with the manufacturers; language pertaining to the government's assumption of the duty to warn would be inserted in the contracts.[21] In retrospect, HEW officials felt they were too complacent in believing that no extraordinary measures for handling liability in a massive federally sponsored immunization program were necessary. Barrett remarked: "We were aware of *Reyes* but didn't regard it [liability] as as serious a problem as it later developed to be. ... We didn't anticipate the extreme sensitivity of the manufacturers regarding their insurance." At that stage, of course, OGC had simply been consulted by Mathews and Dickson and was not in direct contact with the manufacturers. Dickson was in touch with CDC and the Bureau of Biologics, which informed him that the manufacturers indicated they saw no problems with the immunization program as recommended in the Sencer memo.

Mathews' base-touching within his department had not turned up either opposition to a mass immunization program or evidence of any insurmountable operational obstacles. Also, Sencer, at Mathews' and Dickson's behest, had polled by telephone his outside panel, the ACIP, and filled them in on the details of the vaccination proposal and the status of the federal decision-making; Sencer reported back their unanimous concurrence. Although Cooper, the nation's principal health officer, was in Egypt at the time, he remained something of an invisible presence both inside and outside the department. The immunization program was perceived as Cooper's recommendation and Dickson as Cooper's agent. (If anyone had doubts as to whether Cooper strongly endorsed the proposal, these were

certainly dispelled when he returned to Washington at the beginning of the next week.) By the end of the week, a consensus of sorts had evolved among the HEW officials. Morrill summarized:

> The secretary sort of polled, and I can remember myself saying, "Yes, I think you can't just sit on this. You've got to do something." Indeed, what characterized the whole set of situations is that the people at the top of the department came pretty quickly to a belief that inaction—to take this report that this thing might happen and do nothing—was simply untenable. ... And people were mindful of the fact that it was a presidential election year and that made the thing dreadfully more difficult in a sense—the consequences of doing nothing and then having it later come to light.

The seriousness of the swine flu threat—and the fact that its likelihood couldn't be quantified—weighed heavily on the non-medical officials. A comment of William Taft, the general counsel, indicates how this matter filtered up to those regions of the department most distant from CDC's epidemiologists: "The chances seemed to be 1 in 2 that swine flu would come." An unknown probability translated into an even bet. Participants agreed that it was very unusual for the HEW bureaucracy to arrive at a common understanding of a problem (and to act on it as well) within only a week's time. Nonetheless, as one reflected:

> HEW, with all its lumbering glacial qualities was and is able under certain kinds of circumstances to move very fast about some things. ... If there's potential life threatening things involved, that agency, and indeed most big agencies like that, can move with surprising, lighting-like speed.

At OMB, Victor Zafra remained very skeptical of the likelihood of a swine flu epidemic; was also not happy that CDC had gone public with its epidemic warnings considerably before the matter had received any presidential attention. Likewise, Paul O'Neill was not convinced that there would be a swine flu epidemic, but he did believe that the possibility was serious enough to worry about. According to him, the safety and effectiveness of a vaccine were not considered problem areas by OMB:

> I think there was an acceptance of the capability of the scientists. While I don't think it was ever spoken explicitly, there was an assumption that if the immunologists could produce a polio vaccine that could stop the tragedy of polio epidemic, then they certainly would produce a [swine flu] vaccine. They said they could produce a successful vaccine—very quickly and with no problems. There was an acceptance of the notion of scientific credentials.

During the course of swine flu discussions at OMB, an issue resurfaced that had been discussed in Atlanta, both within CDC and in the ACIP meeting, but had not made it into Sencer's memorandum.

Could the government order production of vaccine now and agree to purchase enough for the whole population, but hold back on administering it until there was confirmed evidence of an outbreak? The word back from HEW on each occasion (Cavanaugh brought it up also) was that for both logistical and medical reasons there would not be sufficient time. It was estimated that an epidemic could spread throughout a city in about two weeks; because of air travel, it was conceivable that it could spread through the country almost as quickly. PHS contended that it would be impossible to distribute and administer it to all who wanted it in that amount of time—the public health network would be able to manage 200 million vaccinations, but only at a more leisurely pace. Moreover, even if the public and private health practitioners could get the vaccine into people's arms in a few weeks, still more time would be needed before the shots conferred immunity. As Cooper, who upon his return stood with the line agency chiefs in opposing stockpiling, elaborated:

> You thought you had a substance that was safe and effective. What you would want to do is get it out early enough because effective immunization at a biologic level requires several weeks to generate the antibody response. So the ideal time to do it would be to get it out and into the folks early and get the antibody response on board. That was the concept of prevention, not a reaction to a thing.

By the end of the week of March 15, the OMB leadership had arrived at much the same perspective as their HEW counterparts. "Ultimately," said O'Neill, "in our judgement—that is to say, mine and Jim Lynn's—the president didn't have much choice." Even Zafra agreed that although an epidemic might be technically unlikely, the government was by this time boxed in: "The president made the necessary political choice." It was also assumed by everyone involved with the issue that the final decision on swine flu immunization had to come from Gerald Ford. Simply as a procedural matter, he would have to sign the request for a supplemental appropriation. More importantly to Lynn and O'Neill, this was a decision on whether or not to launch a major new program with considerable implications for life and safety (the estimate of half a million deaths) as well as policy (setting precedents in federal preventive medicine programming). O'Neill commented:

> I guess it never occurred to me that, whoever the president might have been, he wouldn't have been deeply involved in this kind of a question. Because the national policy implications of a threat of a major epidemic are not the kind of thing that, in my judgement, ought to be left to HEW and OMB to decide between themselves.

At the White House, James Cannon and James Cavanaugh were equally certain that the president would have to act shortly. "It was a decision that only a president could make," remarked Cannon. Cavanaugh had some "real questions" about the whole immunization proposal after his initial discussions with Mathews and Dickson on March 15. Cavanaugh felt CDC was "historically a very strong advocacy agency"; he saw his own role as "staying on top of the issue" to be certain that the

case was backed up by a firm staff analysis. Therefore, Cannon, Cavanaugh and Spencer Johnson the health analyst on the Domestic Council, undertook a staff review of their own. This, said Cavanaugh, was the usual White House response, when a line agency pressed for a new program and marked it with an "urgent timeframe." "There was no 'rush to judgment.' ... We'd put the issue on a fast-track for decision but be damned sure we'd gotten a full staff review."

Cavanaugh's questions were basically the same as those being asked at HEW and OMB that week, although a few of his channels of investigation were different. As a former HEW man himself, he maintained that he "knew that department like the back of my hand" and that his contacts reached below the level of assistant secretaries and "down into the bowels of the agencies." The first concern, of course, was whether or not the threat was really serious and the immunization program necessary. Cavanaugh called around and did not turn up any criticism on this score; he did, however, encounter the PHS argument that tying the actual start of the vaccination program to evidence of an outbreak was not feasible because of time considerations. He also called an old HEW associate, Dr. Charles Edwards, a former FDA commissioner and assistant secretary for health. Edwards' line was the same as that of the current PHS leadership: given the available data, immunization directed at the entire population was the only alternative. In the course of Cannon's and Cavanaugh's inquiries, one potential production obstacle disappeared. The Agriculture Department assured them that there were enough chickens to produce enough eggs to produce enough vaccine doses for the country. On the question of liability, Cavanaugh went directly to Attorney General Edward Levi, who referred him to a staff attorney who basically agreed with the HEW attorneys that the liability issue could be managed by having the federal government assume the "duty to warn." Cavanaugh, nonetheless, remembered having some inkling at that point that perhaps some more drastic form of liability bail-out for the manufacturers, such as indemnification legislation, might be needed; in any event, he apparently did not see this as a prohibitive concern. By the end of the week Cavanaugh was resigned to the swine flu decision: "There was no choice."

At Mathews' request, Cavanaugh scheduled a meeting with President Ford for 11:00 a.m. Monday, March 22. Spencer Johnson of the Domestic Council prepared a briefing document, setting out the data about the flu outbreaks and the vaccine plans and including comments from the president's other advisers;* OMB also sent over a briefing paper of its own, signed by James Lynn, which contained Zafra's "uncertainties." No one offered any objections to the proposed mass immunization program. Nonetheless, the White House people probably would not have agreed with the attitude expressed at the public health workshop the previous month, that coping with an isolated outbreak of a new virus strain was exciting and "stimulating" rather than a "real chore." They insisted that no politics were involved in their support of an immunization program, they anticipated that, if anything, the program would be a political liability—if swine flu did not spread, the president might be cast in the role of a foolish alarmist. Cavanaugh said, "There were not politics; there was some concern that we'd scare a lot of people." Cannon recalled:

* Unfortunately, this document is not yet publicly available from the Ford Library, which is still in the process of archiving the presidential papers.

> It was going to cost a lot of money and a great inconvenience to people, and privately some of the political experts around thought that this might be very damaging to the president because people would have sore arms in October, just before the election. ... That was never a serious consideration, but someone did raise it as a possibility.

As a way of lessening the potential for political embarrassment, Mathews, and subsequently Cooper, offered to announce the program to the public. The suggestion was basically left up in the air, although Cannon's and Cavanaugh's feeling was that convincing people to line up for flu shots would probably require an exercise of presidential leadership. In any event, the immediate task was making the decision, not announcing it.

By this time the press, having learned something of the week's swine flu activity in the various federal agencies, renewed its interest in the Fort Dix outbreak, the 1918 analogy, and its policy implications. On Sunday, March 21, the day before the scheduled meeting with Ford, swine flu made its second appearance on the front page of *The New York Times*: "Flu Experts Soon to Rule on Need of New Vaccine." The article described the Fort Dix incident as "a single scream in the night and then silence" and reported (inaccurately), "Apparently no recommendation has yet been sent to F. David Mathews, Secretary of Health, Education, and Welfare." Both Drs. Sencer and Meyer, as well as several scientists outside the federal government, were quoted as saying that the US would probably have no choice but to mount a large-scale immunization, albeit on the basis of little evidence that a pandemic was actually on the way: "It's a choice between gambling with money or gambling with lives," declared Meyer.[22]

On the same day as *The New York Times* article, Dr. Theodore Cooper returned to the United States from Egypt. He had not been in touch with Washington during his trip (although he had arranged with Cavanaugh that he could be contacted through the White House switchboard if absolutely necessary), and was unaware of what had transpired during the week. His first piece of new information on the subject came in the form of a message that greeted him upon his arrival at John F. Kennedy Airport that he was to attend a meeting at the White House by 11:00 a.m. the next morning. Cooper was briefed on the status of the issue by Dickson and the rest of his staff early Monday morning, and was satisfied that all the potential pitfalls had been adequately explored during his absence. He concluded that there was no other option in the matter and became a forceful advocate of the position already generally supported by the other federal participants.

> I don't remember anyone saying "gun to the head" but I do feel that it was my perception that if anyone at the senior level presented that kind of an option, it is very difficult to say "no"—on the basis of the scientific evidence that was available and no other real data that could be used in counterbalancing it. The only other issues at that point were

> money and time because the questions of both liability and side effects were allegedly spoken to.

Mathews, Cooper, and Dickson proceeded to the meeting with President Ford. James Lynn and Paul O'Neill attended from OMB, and James Cannon, James Cavanaugh, Spencer Johnson and Richard Cheney (Ford's chief of staff) from the White House. The HEW group brought along some large briefing boards graphically depicting the swine flu problem and the proposed remedy; Ford, however, apparently preferred to stick to discussion. Mathews began with a general presentation and deferred to Dr. Cooper, as the government's chief medical official, for a more technical explanation of the subject. The president reportedly maintained a "typically Ford" demeanor—"a conservative, quiet listener," asking a few questions. For the most part, the questions and answers remained the same as the ones that had circulated through the agencies. The probability of an epidemic was unknown: no estimates were offered. Serious side effects were not anticipated—field tests and the extensive influenza and reaction surveillance system would detect any risks. Minor side effects such as sore arms and fevers would be common and might be particularly annoying (and possibly politically relevant) if no epidemic materialized. Production and distribution timetables had been mapped out, demonstrating that the project was feasible. Finally, liability concerns had been explored with the government's lawyers, and the line health agencies had reported no dissent on this score from the manufacturers. Mathews added that he knew the program could pose political problems—it was a "no-win situation" for the president whichever way he decided—and repeated his offer that he or Dr. Cooper could take responsibility for publicly announcing it.

There was no devil's advocate per se at the meeting; nonetheless, the OMB officials—although convinced by this time that, barring some unexpected development, the government would have to go ahead with a program—remained disturbed by HEW's refusal or inability to give a numerical probability for a pandemic, and hesitant about the program's feasibility. Cooper commented: "They were very leery. They were the most cautious of the group—on very sound and good grounds. They pushed for more broad scientific input." On this issue, the breadth of the scientific review, O'Neill struck a chord with the president. Ford asked, "How wide has the consultation been?" Cooper explained that CDC had followed the usual process of consulting with the other federal health agencies and putting the issue before its standing advisory panel, the ACIP, before bringing it to the level of the HEW secretariat—i.e., no new scientific review body had been set up for the special purpose of studying swine flu. O'Neill argued that such a review should take place at the presidential level; this was a final opportunity to ferret out any scientific objections to the proposal that had not been raised in HEW as well as a way of extending the decisionmaking beyond the bureaucracy and the administration:

> I felt very strongly that the president ought to hear from the outside people, and that we ought to marshal people who were—and who would be perceived to be—the leaders in immunology and virology from around the country, so that he had the value of advice from that independent source.

Ford apparently was enthusiastic about the idea of touching base directly with the "scientific community," and asked his aides to assemble a group of experts to meet with him in two days; a conference was scheduled for the afternoon of Wednesday, March 24. Ford deferred his final decision on swine flu immunization until then and did not indicate explicitly what his preferences were; nonetheless, the participants emerged from the Monday meeting with the feeling that the mass vaccination program was now a near-certainty. As James Cannon recounted:

> On the basis of the information we had at that time, it would have been in my judgment then, and in my retrospective view, absolutely criminal not to proceed to protect the public health—whatever the political consequences. ... There was literally time to save what we could extrapolate to be several hundred thousand lives. ... There was just no question about it.

At the same time, Cavanaugh and Cannon were convinced of the president's sincerity in getting a "spectrum" of scientific opinion and felt that their own role was to make certain he was exposed to any contrary viewpoints before he decided. Cavanaugh had the central task of putting together the "blue-ribbon" panel to meet with Ford. Most of the doctors and scientists he invited were drawn from a list submitted by Cooper, which he in turn had compiled primarily from the suggestions of Sencer and the other line agency heads; Cavanaugh also placed another call to Dr. Edwards, the former assistant secretary for health, who suggested a few more names. Cavanaugh ultimately lined up about thirty non-government scientists for the meeting. The group included several people—such as Maurice Hilleman of Merck, Sharpe and Dohme, Reul Stallones of the University of Texas, and Edwin Kilbourne of Mt. Sinai Medical School—who participated in either the Bethesda workshop or the Atlanta ACIP meeting. Officials of other pharmaceutical companies, state and local health departments, and the national medical associations were also invited, along with other sundry guests such as the mayor of Louisville, Kentucky (who happened to be an M.D.) and the governor of Rhode Island.

The real "coup," from the point of view of the White House, was Cavanaugh's success in securing the attendance of both Dr. Jonas Salk and Dr. Albert Sabin, developers respectively of the killed- and live-virus polio vaccines. To the public their names were probably synonymous with vaccinations. Moreover, it was no secret in the scientific community that there was little love lost between the two "pioneers" in virology, and they tended to square off against one another on most scientific issues. Possibly, Cavanaugh and the others at the White House saw the Salk-Sabin pairing as a final test; if there were faults in the proposal, one of them would be likely to find them. In any event, bringing Salk and Sabin into the decision was considered sufficiently important that the White House brought the latter up to Washington by military jet so that he would not have to bow out of the meeting with the president because of his commitment to address the South Carolina legislature earlier that day. Finally, the federal government would be represented at the meeting by President Ford and most of his staff, Lynn, and O'Neill, and a large delegation from HEW: Mathews, Cooper, Dickson, Sencer, Meyer, and the heads of the FDA, the National Institutes of Health and NIAID. No one from Capitol Hill was invited; to the White House aides, including congressmen would be a

political—not a bi-partisan—act. Said Cavanaugh, "These were scientific factual issues, not political ones." In retrospect, the organizers of the panel of experts saw only one serious omission. Cooper commented: "There was nobody there from the insurance industry. Perhaps that is a lesson for something of that order."

The various federal officials recalled this as *the* crucial meeting in swine flu decisionmaking. Nonetheless, the White House and PHS were sufficiently certain that the March 24 meeting would produce a "go-ahead" decision that they set in motion ahead of time the machinery for announcing the program. Earlier in the day, Jim Cannon sent Max Freidersdorf, the congressional liaison aide, a short memo concerning notification of the members of the House and Senate health authorization and appropriations subcommittees. Cannon explained:

> The president will brief the press at the conclusion of the meeting to announce his decision to give the go-ahead to pharmaceutical manufacturers to produce enough vaccine to immunize every American, at least 200 million doses.

Also, the PHS and White House press offices stood ready with swine flu "Fact Sheets" ("embargoed for release" until 5:00 pm) bearing the same message:

> The president ... is asking Congress to appropriate $135 million prior to their April recess to ensure the production of enough vaccine to inoculate every man, woman and child in the United States.[23]

The feeling of the White House aides was that only in the case of a serious negative response from some of the scientists, which on the basis of their advance checking they saw no reason to expect, would a mass immunization program not be announced officially later that day.

The meeting of the president and the scientists began at 3:30 pm in the Cabinet Room. Ford welcomed the group, briefly described the purpose of the meeting and, as planned, deferred to the HEW representatives. Mathews, Cooper and Sencer made presentations on the swine flu data and a strategy for preventing an epidemic. Following the presentations, first Salk and then Sabin very strongly urged the president to mount a mass immunization campaign such as Sencer had outlined; reportedly, neither failed to mention in passing the significance of his own work in laying the foundation for medical undertakings of this kind.[24] Ford asked for opinions from the other doctors, but apparently only about five of the outside scientists (including Salk and Sabin) participated very actively. The discussion touched on the same topics as the meeting on Monday—the non-government scientists agreed with PHS that no figure could be placed on the probability of an epidemic;* the 1918-19 disaster was another recurring topic. None of those who spoke up had a disparaging word for the immunization proposal.

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* Incidentally, about a month later one of the federal officials, Dr. John Seal, deputy director of NIAID, finally agreed to offer his own ballpark estimate of the probability of a swine flu epidemic as a sort of academic exercise for someone who was writing a journal article on the subject. His estimate was two percent. (From research notes lent by Professor Neustadt.)

President Ford asked at least twice whether anyone present had any reservations about this course of action. Cannon's description of this scene coincided with that of several other participants:

> He asked if it was the unanimous recommendation of this group that they proceed. The leading doctors said "Yes" and he said "Now, if any doctor here has a sense that this is not necessary, if there is any doubt in his mind about it, I would like him to tell me so now." And I remember that there was a very long silence that went on for what seemed minutes, and nobody said a word. President Ford broke the silence and raised some other questions which got the group talking again. He said a second time, some minutes later ... "If anyone has any doubt about this [and] would like to speak to me privately about this, I would like him to do so. I will be in my office for the next ten minutes if anyone wants to come in." He said to me, "Jim, you make sure that they come in."

Ford adjourned the meeting, went around the room shaking hands with the scientists, and retired to the Oval office to await any scientist with a dissenting view. None arrived. Much later some of the doctors expressed the view that the whole March 24 meeting was a "staged" or "orchestrated" event—House aides denied that the unanimous verdict of the blue ribbon panel had been "programmed" in advance by either them or Sencer, who had spoken with some of the scientists by phone the previous evening. Cavanaugh argued that any coaching Sencer might have done would have been far outweighed by Cavanaugh's own statements to the scientists when inviting them to the meeting, that the president was seeking their independent counsel, and by Ford's declarations during the meeting itself.

Ford felt that the absence of any criticism from the scientific group left no question as to the appropriate course of action. He told Mathews, Cooper, O'Neill and Cavanaugh to proceed with the program. As O'Neill saw it:

> Given that shoulder-to shoulder unanimity of the scientific community, the president really didn't have any choice. If he were to say, "We're not going to go ahead" in the face of that kind of block opinion, then it would be very difficult for him to convince the general public that his wisdom was better than that of all those scientists. ... Let's say we have some other kind of disease threat, similar to swine flu, but a different kind of virus, and the president was put into a position where he was told by all the scientific leaders in the country that for $135 million he could inoculate his population, and the trade

> off of that was a 10 percent probability of half a million dying.* He'd spend $135 million every single time.

The participants felt Ford acted out of a desire to do the right thing and to protect the public health rather than an intent to make political capital. Cooper mused:

> It was many times claimed that it was utilized for political purposes. I don't think that anyone can vindicate that position. I personally feel that it is completely wrong—having dealt with the president. I am not his personal friend. I was not of his party,** I was nothing of that order. ... I came out with the idea that he did this for the right reasons, and he was trying to do what was right.

Now that the decision was final, there remained the question of how to announce it. There appeared to be little maneuvering room here either. Since the president had already closely associated himself with the program by holding the meeting (as the press knew) with the scientists, delegating the responsibility for announcing it to HEW seemed pointless to White House aides. Ford apparently also felt that asking every citizen to receive a shot for the sake of the national health demanded the status of a presidential statement. Also, Cavanaugh felt that news of the decision should come directly and immediately from Ford, rather than through dozens of separate accounts from the scientists who attended the meeting with him.

Around 4:50 pm the chief executive appeared in the White House press room, with Drs. Salk and Sabin on either side. Secretary Mathews and Drs. Cooper and Sencer stood respectfully in the background. President Ford said that the federal health officials and the "very outstanding technicians" who had just met with him had advised that a swine flu epidemic the following year was a "very real possibility."*** Consequently, he continued:

> I am asking the Congress to appropriate $135 million prior to the April recess to inoculate every man, woman and child in the United States. ... Finally, I am asking each and every American to make certain he or she receives an inoculation this fall.[25]

Ford turned the press briefing over to the HEW officials and Salk and Sabin returned to his office. (Cooper later told Ford that he was apparently the first person to get Salk and Sabin to agree on anything.) Ford soon learned that the relevant congressional committees were ready to act

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* O'Neill was well aware that the probability had been described as "unknown"; by the time of the March 24 meeting he had heard this dozens of times. Nonetheless, much like Taft, he apparently had his own estimate of what "unknown" meant. Possibly, it is a mark of OMB skepticism that O'Neill translated this into 10 percent while Taft, the HEW attorney, felt this meant it could as easily go one way as the other.

** A surprising number of the characters in the swine flu story were Democrats or had Democratic associations. According to Ford's memoirs, Mathews was selected as HEW secretary partly because he was a Southern Democrat and a university president. Also, Paul O'Neill had come to OMB—through the Civil Service, however, not appointment—during the Johnson administration.

*** Since no one could numerically estimate the probability, "a very real possibility" became a common description of the seriousness of the threat.

expeditiously on the supplemental appropriations request. The president was no doubt satisfied: he was successfully putting through an ambitious and refreshingly non-controversial program that was unquestionably in the public interest.

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Endnotes

1 Center for Disease Control, Bureau of Biologics/National Institute of Allergy and Infectious Disease, *Influenza Workshop* (Bethesda, Maryland, February 20, 1976), transcript, p. 9.
2 *Ibid.*, p. 103.
3 Harold M. Schmeck, "US Calls Flu Alert of Possible Return of Epidemic's Virus," *The New York Times*, February 20, 1976, p. 11.
4 Center for Disease Control, Summary Minutes of Meeting, Immunization Practices Advisory Committee, Atlanta, Georgia, March 10, 1976, pp. 4-5.
5 Memorandum signed by Dr. James Dickson on behalf of Dr. Theodore Cooper to David Mathews, secretary of HEW, March 18, 1976, p. 1.
6 *Ibid.*
7 Edwin D. Kilbourne, "Flu to Starboard! Man the Harpoons! Fill 'Em With Vaccine! Get the Captain! Hurry!" *The New York Times*, February 13, 1976, p. 2.
8 *Ibid.*
9 Memorandum signed by Dr. Dickson on behalf of Dr. Cooper, p. 3.
10 *Ibid, p. 4.*
11 *Ibid.*, p. 6.
12 *Ibid.*, p. 7.
13 *Ibid.*, p. 9.
14 Research notes lent to the Kennedy School Case Program by Professor Richard Neustadt.
15 *Ibid.*
16 *Ibid.*
17 Memorandum from David Mathews, secretary of HEW, to James Lynn, director of OMB, March 15, 1976.
18 Memorandum from Nancy Bateman, budget examiner, to Paul O'Neill, deputy director of OMB, March 15, 1976.
19 Research notes lent by Professor Neustadt.
20 Memorandum from John Young, comptroller of HEW, to Secretary Mathews, March 18, 1976.
21 Research notes from Professor Neustadt.
22 Harold Schmeck, "Flu Experts Soon to Rule on Need of New Vaccine," *The New York Times*, pp. 1, 39.
23 Office of the White House press secretary, *Fact Sheet, Swine Influenza Immunization Program*, March 24, 1976.
24 Research notes lent by Professor Neustadt.
25 "Swine Flu Inoculations," *Presidential Documents: Gerald Ford*, 1976, Vol. 12, No. 13, pp. 483-484.

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PAGES 15-23 FROM SWINE FLU(E)
SUMMARY CASE

EXHIBIT I

Principal Participants

James Cannon, Director of Domestic Council, Executive Office of the President, Ford Administration, to January 1977

James Cavanaugh, Deputy Chief of Staff in the White House and Deputy Director of the Domestic Council, Ford Administration, to January 1977

Theodore Cooper, M.D., Assistant Secretary for Health, HEW, Ford Administration, to January 1977

James F. Dickson, III, M.D., Deputy Assistant Secretary for Health under Cooper, Acting Assistant Secretary to June 1977

James T. Lynn, Director, Office of Management and Budget, Executive Office of the President, Ford Administration, to January 1977

David Mathews, Secretary of HEW, Ford Administration, to January 1977

Harry M. Meyer, Jr., M.D., Director, Bureau of Biologics, Food and Drug Administration

Paul O'Neill, Deputy Director, Office of Management and Budget, Executive Office of the President, Ford Administration, to January 1977

David J. Sencer, M.D., Director, Center for Disease Control, to April 1977

Victor Zafra, Division Chief, Office of Management and Budget

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All exhibits are excerpted from Richard E. Neustadt and Harvey V. Fineberg, M.D., The Swine Flu Affair: Decision-Making on a Slippery Disease, (Washington: Government Printing Office, 1978, Stock Number 017-000-00210-4)

EXHIBIT II

March 18, 1976
"Action Memo" on Swine Flu
(written by Dr. David Sencer on March 13 for
Submission to Sec. David Mathews by Asst. Sec. Theodore Cooper)

MEMORANDUM

Department of Health, Education and Welfare
Office of the Assistant Secretary for Health

Date: March 18, 1976

TO: The Secretary

FROM: Assistant Secretary for Health

SUBJECT: Swine Influenza--ACTION

ISSUE

How should the Federal Government respond to the influenza problem caused by a new virus?

FACTS

1. In February 1976 a new strain of influenza virus, designated as influenza A/New Jersey/76 (HswlNl), was isolated from an outbreak of disease among recruits in training at Fort Dix, New Jersey.

2. The virus is antigenically related to the influenza virus which has been implicated as the cause of the 1918-1919 pandemic which killed 450,000 people--more than 400 of every 100,000 Americans.

3. The entire U.S. population under the age of 50 is probably susceptible to this new strain.

4. Prior to 1930, this strain was the predominate cause of human influenza in the U.S. Since 1930, the virus has been limited to transmission among swine with only occasional transmission from swine to man--with no secondary person-to-person transmission.

5. In an average year, influenza caused about 17,000 deaths (9 per 100,000 population) and costs the nation approximately $500 million.

6. Severe epidemics, or pandemics, of influenza occur at approximately 10 year intervals. In 1968-69, influenza struct 20 percent of our population, causing more than 33,000 deaths (14 per 100,000) and cost an estimated $3.2 billion.

7. A vaccine to protect against swine influenza can be developed before the next flu season; however, the production of large quantities would require extraordinary efforts by drug manufacturers.

EXHIBIT II (con't)

ASSUMPTIONS

1. Although there has been only one outbreak of A/swine influenza, person-to-person spread has been proven and additional outbreaks cannot be ruled out. Present evidence and past experience indicate a strong possibility that this country will experience widespread A/swine influenza in 1976-77. Swine flu represents a major antigenic shift from recent viruses and the population under 50 is almost universally susceptible. These are the ingredients for a pandemic.

2. Routine public health influenza recommendations (immunization of the population at high risk--elderly and chronically ill persons) would not forestall a flu pandemic. Routine actions would have to be supplemented.

3. The situation is one of "go or no go." If extraordinary measures are to be undertaken there is barely enough time to assure adequate vaccine production and to mobilize the nation's health care delivery system. Any extensive immunization program would have to be in full scale operation by the beginning of September and should not last beyond the end of November 1976. A decision must be made now.

4. There is no medical epidemiologic basis for excluding any part of the population--swine flu vaccine will be recommended for the total population except in individual cases. Similarly there is no public health or epidemiologic rationale for narrowing down the targeted population. Further, it is assumed that it would be socially and politically unacceptable to plan for less than 100 percent coverage. Therefore, it is assumed that any recommendations for action must be directed toward the goal of immunizing 213 million people in three months (September through November 1976). The nation has never attempted an immunization program of such scope and intensity.

5. A public health undertaking of this magnitude cannot succeed without Federal leadership, sponsorship, and some level of financial support.

6. The vaccine when purchased in large quantities will cost around 50 cents per dose. Nationally, the vaccine will cost in excess of $100 million. To this total must be added delivery costs, as well as costs related to surveillance and monitoring. Part, but not all, of the costs can be considered sunk costs, or as non-additive. Regardless of what strategy is adopted, it will be extremely difficult to estimate the amount of additional costs that will result from a crash influenza immunization program.

7. The Advisory Committee on Immunization Practices will recommend formally and publicly, the immunization of the total U.S. population against A/swine influenza.

EXHIBIT II (con't)

8. Any recommended course of action, other than no action, must assure:

--that a supply of vaccine is produced which is adequate to immunize the whole population.

--that adequate supplies of vaccine are available as needed at health care delivery points.

--that the American people are made aware of the need for immunization against this flu virus.

--that the population systematically reach or be reached by the health system.

--that the Public Health Service maintain epidemiologic, laboratory, and immunization surveillance of the population for complications of vaccination, for influenza morbidity and mortality, and for vaccine effectiveness and efficacy.

--that the unique research opportunities be maximized.

--that evaluation of the effectiveness of the efforts is conducted.

ALTERNATIVE COURSES OF ACTION

1. No Action

An argument can be made for taking no extraordinary action beyond what would normally be recommended. To date there has been only one outbreak. The swine flu virus has been around, but has not caused a problem among humans since 1930.

Pro:

--The market place would prevail--private industry (drug manufacturers) would produce in accordance with its estimate of demand and the consumers would make their own decisions. Similarly, States would respond in accordance with their own sets of priorities.

--The "pandemic" might not occur and the Department would have avoided unnecessary health expenditures.

--Any real action would require direct Federal intervention which is contrary to current administration philosophy.

Con:

--Congress, the media, and the American people will expect some action.

--The Administration can tolerate unnecessary health expenditures better than unnecessary death and illness, particularly if a flu pandemic should occur.

EXHIBIT II (con't)

--In all likelihood, Congress will act on its own initiative.

2. Minimum Response

Under this option there would be a limited Federal role with primary reliance on delivery systems now in place and on spontaneous, non-governmental action.

a. The Federal Government would advise the drug industry to develop and produce A/swine vaccine sufficient to immunize the general population. The Federal Government would underwrite this effort by promising to purchase vaccine for the 58 million Federal beneficiaries.

b. A nationwide public awareness program would be undertaken to serve as general backdrop for local programs.

c. The Public Health Service would stimulate community programs sponsored by local organizations (medical societies, associations, industries, etc.)

d. The Center for Disease Control would maintain epidemiologic and laboratory surveillance of the population.

e. The National Institutes of Health would conduct studies and investigations, particularly on new and improved vaccines.

Pro:

--The approach is characterized by high visability, minimum Federal intervention, and diffused liability and responsibility. It is a partnership with the private sector that relies on Federal stimulation of nongovernmental action.

--The burden on the Federal budget would be minimal. Assuming purchase of vaccines for 58 million beneficiaries, plus additional costs related to c., d., and e., above the total new obligational authority requirement would not exceed $40 million ($32 million for vaccine; plus 8 million for surveillance, monitoring, evaluation, and research).

--Success would depend upon widespread voluntary action--in terms of individual choice to seek immunization and in terms of voluntary community programs not unlike the police programs of the past.

Con:

--There is little assurance that vaccine manufacturers will undertake the massive production effort that would be required to assure availability of vaccine for the entire nation.

--There would be no control over the distribution of vaccines to the extent that they are available; the poor, the near poor, and the aging usually get left out. Even under routine flu recommendations in which the elderly are a primary target, only about half the high risk population gets immunized against flu.

EXHIBIT II (con't)

--Probably only about half the population would get immunized.

3. Government Program

This alternative is based on virtually total government responsibility for the nationwide immunization program.

a. The Federal Government would advise vaccine manufacturers to embark on full scale production of vaccine with the expectation of Federal purchase of up to 200 million doses.

b. The Public Health Service, through the CDC would purchase the vaccines for distribution to State Health Departments.

c. In each State the health department would organize and carry out an immunization program designed to reach 100 percent of the State's population. Vaccine would be available only through programs carried out under the aegis of the State health department (or the Federal Government for direct Federal beneficiaries).

d. Primary reliance would be placed on systematic, planned delivery of vaccir in such a way as to make maximum use of intensive, high volume immunizatic techniques and procedures--particularly the use of jet-injector guns.

e. In addition to a general nationwide awareness program, intensive promotion and outreach activities would be carried out at the local level. Maximum use would be made of temporary employment of unemployed workers, high schc and college students, housewives, and retired people as outreach workers and for jobs requiring no special health skills.

f. The Center for Disease Control would maintain epidemiologic and laboratory surveillance of the population.

g. The National Institutes of Health would conduct studies and investigations particularly on new and improved vaccines.

h. The program would be evaluated to assess the effectiveness of the effort i reducing influenza associated morbidity, hospitalization, and mortality in a pandemic period.

Pro:

--Under this alternative adequate availability of vaccine would be closest to certainty, and the vaccine would be distributed throughout the nation most equitably.

--There would be greater certainty of participation of all States as well as a predictably more uniform level of intensity across the nation.

EXHIBIT II (con't)

--Accessibility to immunization services would not depend upon economic status.

--This approach would provide the framework for better planning - for example, the use of travelling immunization teams which could take the vaccine to the people; and greater use of the jet injector, and other mass immunization technique

--The Federal and State governments traditionally have been responsible for the control of communicable diseases; therefore, the strategy relies upon government action in an area of public health where the States are strong and where basic operating mechanisms exist.

Con:

--This alternative would be very costly and given the timing, the magnitude of the problem, and the status of State fiscal health, the costs would have to be borne by the Federal Government. The impact on the Federal budget would be an increase of $190 million in new obligational authority.

--The approach is inefficient to the extent that it fails to take advantage of the private sector health delivery system, placing too much reliance on public clinics and government action.

--While this approach would undoubtedly result in a higher percentage of the population being immunized than would be the case with the Minimum Response strategy (alternative 2), it is unlikely that the public sector could achieve uniform high levels of protection. Although socioeconomic barriers to immunization services would be virtually eliminated, breakdowns would occur because the program is beyond the scope of official agencies.

--A totally "public" program is contrary to the spirit and custom of health care delivery in this country and should only be considered if it is clearly the most effective approach.

4. Combined Approach

A program based on this strategy would take advantage of the strengths and resources of both the public and private sectors. Successful immunization of our population in three months' time can be accomplished only in this manner in this country. In essence, the plan would rely on: the Federal Government for its technical leadership and coordination, and its purchase power; State health agencies for their experience in conducting immunization programs and as logical distribution centers for vaccine; and on the private sector for its medical and other resources which must be mobilized.

a. The Federal Government would advise vaccine manufacturers to embark on full scale production of enough vaccine to immunize the American people. The Public Health Service would contract for 200 million doses of vaccine which would be made available at no cost through State health agencies.

EXHIBIT II (con't)

b. State health agencies would develop plans to immunize the people in their States through a combination of official and voluntary action - travelling immunization teams, community programs, private physician practices, as examples.

c. The strategy would be to tailor the approach to the situation or opportunity--using mass immunization techniques where appropriate, but also using delivery points already in place such as: physicians' offices, health department clinics, community health centers--any place with the competence to perform immunization services.

d. Awareness campaigns would be carried out at the local level against a broader, generalized nationwide effort. Use would be made of unemployed workers, students, etc., for certain jobs.

e. The Center for Disease Control would maintain epidemiologic and laboratory surveillance of the population.

f. The National Institutes of Health would conduct studies and investigations of vaccine effectiveness and efficacy.

g. The program would be evaluated to assess the effectiveness of the effort in reducing influenza associated morbidity, hospitalization, and mortality in a pandemic period.

Pro:

--Under this alternative adequate availability of vaccine would be closest to certainty, and the vaccine would be distributed throughout the nation most equitably.

--There would be greater certainty of participation of all States as well as a predictably more uniform level of intensity across the nation.

--Accessibility to immunization services would not depend upon socioeconomic factors.

--Making use of all delivery points better assures that the vaccine will get to more people.

--The approach provides the framework for planning and expands the scope of resources which can be applied.

--Undertaking the program in this manner provides a practical, contemporary example of government, industry, and private citizens cooperating to serve a common cause.

Con:

--This strategy would require substantial Federal expenditures. A supplemental request of approximately $134 million would be needed.

EXHIBIT II (con't)

--Under this alternative there is the greatest possibility of some people being needlessly reimmunized.

DISCUSSION

Any of the courses of action would raise budgetary and authorization questions and these will be discussed later. More important is the question of what the Federal Government is willing to invest if some action is deemed necessary to avert a possible influenza pandemic. We have not undertaken a health program of this scope and intensity before in our history. There are no precedents, nor mechanisms in place that are suited to an endeavor of this magnitude. Given this situation, can we afford the administrative and programatic inflexibility that would result from normal considerations about duplicative costs, third party reimbursements, and Federal-State or public-private relationships and responsibilities? The magnitude of the challenge suggests that the Department must either be willing to take extraordinary steps or be willing to accept an approach to the problem that cannot succeed.

It is recommended that the Department, through the Public Health Service and the Center for Disease Control, undertake an influenza immunization campaign as outlined in alternative 4, Combined Approach. This alternative best satisfies all of the minimum program requirements outlined earlier and more importantly, it is the most likely to succeed--more people would be protected.

The question of legislative authorization is not entirely clear. It would appear that Section 311 a. of the Public Health Service Act contains adequate authority to implement the recommended program. If 311 a. cannot be used, then it will be necessary to seek "point of order" authority in the supplemental appropriation act. It is anticipated that Congress would be receptive to "point of order" language in this instance.

It will be necessary to seek a supplemental appropriation so that all parties can begin to mobilize for the big push in the fall. It will also be necessary for the funds to be available until expended because the program, although time-limited, falls into fiscal year 1976, the transition quarter, and fiscal year 1977. In general terms the request would be for approximately $134 million made up as follows:

Immunization Programs (vaccines, supplies, temporary personnel, awareness)	$126 million
Surveillance and Research	8 million

RECOMMENDATION

It is recommended that the Secretary adopt alternative 4 as the Department's strategy and that the Public Health Service be given responsibility for the program and be directed to begin immediate implementation.

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(office of Theodore Cooper, M.D.)