

### 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.

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.<sup>1</sup>

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."<sup>2</sup> 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,<sup>\*\*</sup> 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"<sup>\*\*\*</sup>

- \* 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

- \* 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."<sup>3</sup> *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.

The committee felt that such a program should be encouraged under federal auspices to involve vaccine purchase as well as a delivery mechanism.<sup>4</sup>

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,

\* 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.

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."<sup>6</sup> 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."<sup>7</sup> 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."<sup>8</sup>

\* 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."<sup>9</sup> 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."<sup>10</sup> 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 underserved 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."<sup>11</sup>

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.<sup>12</sup>

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."<sup>13</sup> 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."<sup>\*\*</sup>

\* 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.<sup>14</sup> 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.<sup>15</sup>

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."<sup>16</sup> 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.

The decision will have to be made in the next week or so.<sup>17</sup>

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.<sup>18</sup> 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.<sup>19</sup> Bill Morrill, assistant secretary for planning and evaluation at HEW, commented on Mathews' operating style in cases like this:

\* 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.