Sencer Decides

Sencer was an able, wily autocrat with a devoted staff. The CDC was wholly his. He knew everything about it, everybody in it, and took care to put his own imprint on policy. Swine flu was no exception.

He spent March 9 preparing for the ACIP meeting in informal gettogethers with his laboratory people and some other senior aides. Dowdle recalled when we interviewed him:

It was clear we could not say the virus would spread. But it was clear that there had been human-to-human spread at Fort Dix. It was also clear that there was not any immunity in the population to this virus, not if you were under 50 (or maybe 62). Usual "high risk" categories did not apply. Most people were at risk, especially young adults. An epidemic spreading into a pandemic had to be anticipated as a possibility.

... Army recruits were a unique population group ... maybe they would be the only ones affected. But the current disappearance of the virus did not prove that. Flu could do strange things. Six weeks was a short time. We had to report our fundamental belief that a pandemic was

indeed a possibility.

This was the scientist speaking. What could not be disproved must be allowed for. Dowdle also recalls his frustration with the lack of data and his sadness at the thought of "changing all those lives," disrupting CDC by action on so little information. Influenza was a slippery phenomenon. Not much was known about pandemic spread. Aside from the three years of 1918, 1957, 1968, the past was mostly conjecture. And recorded spread in those years varied quite enough to buttress contradictory arguments about what now was happening. Since February, swine flu might have sunk back into pigs. Or was it spreading in humans subclinically, "seeding itself" to erupt explosively next flu season? Nothing quite like Fort Dix and the lack of spread beyond it had been seen before. One could guess but not know. And even among specialists, guesses diverged. Dowdle reportedly was cool to claims that a swine virus readily dominated by Victoria at Fort Dix would shortly arise and sweep around the world. In the circumstances he was not much afraid of subclinical spread. But others were. Kilbourne, for one, who would be with them the next day.

In the then hierarchy of virologists, as several tell us now, Dowdle was the Coming Man but Kilbourne an Old Great, while Sencer was a well-

informed bystander. Of the few generally acknowledged "Greats" in Kilbourne's class, none was a current member of the ACIP and he himself would be there out of interest, not entitlement (he had just been appointed for a term not yet begun). His presence was to count. It counted more as others recall it than as he does.

Save for some epidemiologists, whose eyes shine even yet with remembered excitement, many CDC-ers were at least as cool as Dowdle on March 9. More precisely they remember being at once apprehensive and resigned. As one of those who sat through Sencer's staff sessions explained to us:

There was nothing in this for CDC except trouble. Here we were at the end of one flu season with time to try to do something before the next flu season. The obvious thing to do was immunize everybody. But if we tried to do that, guide it, help it along, we might have to interrupt a hell of a lot of work on other diseases . . . work here, and in the states, a lot of places.

Then if a pandemic came, lots of people—maybe millions—would be angry . . . because they couldn't get shots when they wanted. . . . Or they got sick of something else that they mistook for flu and thought our shots weren't working. Most people in this country (including half the doctors) call all kinds of things flu that aren't. As for "another 1918," I didn't expect that, but who could be sure? . . . It would wreck us.

Yet, on the other hand, if there weren't a pandemic we'd be charged with wasting public money . . . crying wolf . . . causing all that inconvenience for nothing . . . and not only the people who got shots . . . the people who administered the shots . . . our friends out in the states . . . what would they think of us? It was a no-win situation . . . we saw that . . . talked about it

But institutional protection could not override the ethic of preventive medicine. Disease prevention was the professional commitment of them all, including those who cared for CDC the most. They felt themselves trapped. With a pandemic possible and time to do something about it, and lacking the time to disprove it, then something would have to be done. So ran the logic of what Sencer heard from his staff.

The next day, at the March 10 ACIP meeting, staff spelled out the situation (couched of course in Dowdle's terms, not those of institutional protection). It was an open meeting, though with minimal press attendance. After hours of discussion a consensus emerged:

First, the possibility of pandemic existed. None thought it negligible. Kilbourne thought it very likely. Most seem to have thought privately of likelihoods within a range from two to twenty percent; each was prepared to bet, however, with nobody but himself. These probabilities, after all, were based on personal judgment, not scientific fact. They voice them to us now, they did not argue them then.4

Second, while severity could not be estimated, one death in a dozen

was worrisome. Besides, somewhere in everybody's mind lurked 1918. No one thought there literally could be a repetition; antibiotics would hold down the death rate. Deaths aside, few thought the virus would be so severe. When last seen in the '20's it was mild. But nobody could bring himself to argue that such mildness was assured. It wasn't.

Third, traditional definition of high-risk groups did not apply. People under 50 had no natural protection, and young adults had suffered unusually high mortality in the 1918 pandemic. This argued for producing enough vaccine to inoculate them all before the next flu season. All meant all, or as many as possible, because one could not count on "herd" immunity to stifle epidemic spread. In influenza nothing on this scale had ever been attempted. But not since 1957 had the timing of discovery allowed for it. And then we did not have vaccines as safe or as effective as the ones developed since. Nor did we have the guns for swift injection. With a decision now the manufacturers could buy their eggs and make the vaccine fast enough so that inoculations could begin in summer, when the chance of flu was slightest and the risk of panic least. Meanwhile plans could be made for mass immunization.

Predisposition buttressed that consensus. It reflected the agendas several ACIP members drew from other aspects of their working lives. Kilbourne, for one, not only championed his theories, but was keen to make the country see the virtues of preventive medicine. Swine flu seemed to him a splendid opportunity. Others also saw the chance to demonstrate the value of public health practice. Dr. Reuel Stallones, Dean of the Public Health School at the University of Texas, recalled for us:

This was an opportunity to try to pay something back to society for the good life I've had as a public health doctor. Society has done a lot for me—this is sheer do-goodism. It was also an opportunity to strike a blow for epidemiology in the interest of humanity. The rewards have gone overwhelmingly to molecular biology which doesn't do much for humanity. Epidemiology ranks low in the hierarchy—in the pecking order, the rewards system. Yet it holds the key to reducing lots of human suffering.

Consensus thus supported might have dissolved over one issue which at this meeting was never joined: should one move automatically from ordering the vaccine and preparing for its use to using it? If so, what evidence about the spread of the disease would make one stop and stockpile it instead? If not, what evidence would make one move from stockpiling into mass immunization?

Dr. Russell Alexander of the Public Health School at the University of Washington was the principal proponent of a pause for further evidence. His concern was more medical than managerial. As he put it to us in retrospect:

My general view is that you should be conservative about putting foreign material into the human body. That's always true . . . especially when you are talking about 200 million bodies. The need should be estimated conservatively. If you don't need to give it, don't.

He also had a glimmering of one aspect of management, public understanding and acceptance. He told us:

If you have spread combined with high surveillance then the surrounding communities will really go to work and the public will really cooperate each time flu is reported in a new place. If it hit Denver you could immunize Seattle, because everybody would move fast.

Alexander did not make a speech. He put in questions or made comments when he could. An unimpassioned man, he was so mild that other members we have seen recall but vaguely something about "stockpiling." He himself makes light of it. Known as a voice of caution in past meetings, he was easy to discount on this occasion. But Schmeck, the New York Times man, there as an observer, stressed to us:

Alexander seemed serious about stockpiling. He wanted to know "at what point do we stop going on with our preparations to immunize everybody and turn to stockpiling instead—what point in terms both of progress of our preparations and progress of the disease." He asked this seriously. It was not answered.

If so, the term "stockpiling" trivializes, even distorts Alexander's suggestion, which embraced not alone the issue of a waiting game, but also the criteria for playing it. And failure to pursue them both, *especially* criteria, appears by hindsight sad, an opportunity lost. From this we draw a lesson for next time.

That they were not pursued in the ACIP meeting was Sencer's choice from the chair. It could not have escaped him that there was some nascent sentiment for separating manufacture from inoculation. Goldfield and a colleague, in particular, spoke for it from their vantage point, New Jersey, and were evidently bursting to elaborate, if asked. Sencer seems to have wanted none of that. The day before he had discussed stockpiling with his staff, and they had ended by dismissing it. Inoculation took two weeks to bring immunity. Infection brings on the disease within a few days. In two weeks flu could spread throughout a city. Add air travel and how prevent its spreading through the country unless everyone were immunized beforehand? Besides there was the issue of response-time by state clinics, private doctors, volunteers, and citizens at large, the objects of it all. Even a short lag could be too long. "Jet-spread" and slow response combined to make a stockpile option moot. So staff had said.

Staff aside, Seal tells us he and Meyer talked with Sencer at some

point. One of them, Seal no longer remembers which, observed for Sencer's benefit (one career executive to another):

Suppose there is a pandemic accompanied by deaths. Then it comes out: "They had the opportunity to save life; they made the vaccine, they put it in the refrigerator. . . ." That translates to "they did nothing." And worse "they didn't even recommend an immunization campaign to the Secretary."

When it came to the ACIP, whose first task was to ponder manufacture, Sencer did not insist on drawing Alexander out, much less encourage Goldfield, and the March 10 meeting ended with the issue of what happened after manufacture blurred. The minutes of the meeting state: "It was, therefore, agreed that the production of vaccine must proceed and that a plan for vaccine administration be developed." Everybody present we have talked to says the same. That is as far as they got. Sencer himself called it for us:

I went into the [ACIP] meeting with an open mind . . . We met all morning . . . By 2:00 or 2:30 a consensus had emerged . . . Stallones summed it up the best: First, there was evidence of a new strain with man-to-man transmission. Second, always before when a new strain was found there was a subsequent pandemic. And third, for the first time, there was both the knowledge and the time to provide for mass immunization. So, he said, "if we believe in preventive medicine we have no choice." I asked the committee to sleep on it and let us phone them the next day to make sure they still felt the same way, which we did—and they did.

Sencer and his staff turned promptly to the practical effects of the consensus. This had never been considered ACIP business. Governmental consultation, legislation, budgeting, contracting and the like were not its charge. Implementation was Sencer's business. One ACIP member who stayed over for a day and called upon some senior CDC officials, commented to us: "I found them all busy with planning and mostly unable to talk to me."

Sencer himself went to work with one aide and wrote a nine-page paper, known to all and sundry as his "action-memorandum." In the process, he recalls, he made up his own mind precisely what the Federal government should do. His paper was designed at once to say it and to sell it.

In form this memorandum was addressed to David Mathews, Secretary of HEW, from Dr. Theodore Cooper, the Assistant Secretary for Health, Sencer's boss. In fact it was to go on up from Mathews to the Office of Management and Budget (OMB), to the Domestic Council, to the White House, to President Ford, as *the* decision paper in the case. It was written for that purpose and it served so. Thus it has a special place in our

decision-making story. It is worth reading in full and we include it in Appendix D.

Sencer began his memo with "Facts":

1. In February 1976 a new strain of influenza virus. . . .

2. The virus is antigenically related to the [one] implicated as the cause of the 1918-19 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.

6. Severe epidemics or pandemics of influenza recur at approximately 10

year intervals.... In 1968-69....
7. A vaccine... can be developed before the next flu season; however, the production of large quantities would require extraordinary efforts by drug manufacturers.

CDC officials present and past, Sencer included, have complained to us about the overemphasis on 1918 at the Secretary's level and the White House. Here is where it began.

Sencer turned next to "Assumptions":

1. Although there has been only one outbreak . . . [there is] a strong possibility that this country will experience widespread [swine] influenza in 1976-77. . . . major antigenic shift . . . population almost universally under 50 is susceptible . . . ingredients for a pandemic.

Routine actions would have to be supplemented.
 The situation is one of "go or no go." . . . there is barely enough time. . . . A decision must be made now.

4. There is no medical epidemiologic basis for excluding any part of the population . . . i.e., everyone can catch it and don't count on "herd effect."] . . . it is assumed . . . socially and politically unacceptable to plan for less than 100 percent coverage. Therefore . . . any recommendation for action must be directed toward the goal of immunizing 213 million people in three months.\...

Sencer still is seething about Ford and Cooper who were soon to make exaggerated pledges of vaccine for everybody. But the drafters of their statements following his lead.

The Sencer memorandum then got down to recommendations, offering four options of a common sort in government, three framed to be rejected by the reader, with the fourth the one desired by the writer. First was "do nothing," followed by a set of "pros" and "cons." Among the cons:

In all likelihood Congress will act on its own initiative.

⁻The Administration can tolerate unnecessary health expenditures better than unnecessary death and illness.

Second was "minimum response." This must have had some staff support in CDC. It proposed making vaccine for all, the government committed to buy part, whether used or not (for Federal beneficiaries in Medicare, Medicaid, Veterans Administration and Department of Defense), the other part available commercially, and everyone exhorted to get shots through normal channels. This was relatively cheap and also easy in administrative terms, nothing unprecedented about it (except numbers of doses and dollars). But among the "cons":

-There is little assurance that vaccine manufacturers will undertake the

... massive production effort ... required....

—... the poor, the near poor and the aging usually get left out....

—Probably only about half the population would be immunized.

Third was a "government program," federal and state, without private physicians, and fourth was a "combined approach" which added a role for the private sector.

The fourth option was recommended. It envisaged Federal purchase of vaccine for everybody, production by the private manufacturers, field trials through NIAID, licensing by BoB, planning through the states, immunization through a mix of public-private services and surveillance through CDC. The estimated cost was \$134 million, \$100 million for vaccine, the rest for operations and surveillance or research. Administratively, as Sencer warned, this was a leap into the dark, "no precedents, nor mechanisms in place," and an heroic response to a dire possibility.

Sencer, in so recommending, may have played the hero in his own mind; if so he was but the first who did. Mathews, Cooper and Ford, among others, would follow.

In retrospect, this action-memorandum reads as though it were deliberately designed to force a favorable response from a beset Administration that could not afford to turn it down and then to have it leak. The memorandum certainly had that effect, but CDC associates doubt Sencer was deliberate. They think him "a physician with a conscience." They think he simply meant to make the strongest case he could.

However that may be, Sencer rolled the felt need to do "something" into one decision: manufacture, planning, immunizing and surveillance all together, and tied the whole to Meyer's deadline for the manufacturers, those egg supplies. On their account the deadline was two weeks away, "go or no go."