9 Starting and Stopping

The terms on which the swine flu program had been rescued thereupon assured that nobody could get a shot before October 1, if then. This was not instantly apparent at the White House, or to Cooper, for that matter, but it should have been. Under congressional budget procedure, the new legislation became effective with the start of the new fiscal year. Until then, manufacturers and their insurers were determined that nobody would use swine vaccine on anybody. Production and distribution proceeded accordingly. Indeed it took a lot of pleas and promises to get enough deliveries before October 1 so immunization then could make a halting start.

Like it or not, this enforced interval afforded CDC a chance to carry through in style a number of administrative chores. Both with the manufacturers and with the states there was a lot of buttoning up to do and seven weeks to do it in. But Sencer's agency seems to have been all thumbs in this respect. Our inquiry is not definitive; what it suggests, however, is that CDC, though excellent at other things, was way over its head as an administrative center for a national program.

Three examples stake out the dimensions of the problem.

First is the matter of consent forms. As part of Millar's planning, spurred by Dull's awareness, CDC had written, printed and sent forward to the states some 60 million forms for use when vaccine was ready. Then the August legislation came along with a proviso, authored in the Kennedy Subcommittee, that a wholly separate body, the National Commission for the Protection of Human Subjects, should review and consult on consent forms. Already aggravated by delays, Sencer was furious, displaying a self-righteousness that some of his staff emulated. He reportedly announced, "I'll consult if they tell me I have to and then I'll do just what I want." This, in effect, is what happened. The National Commission was hard to assemble in August. When it did meet it was moderately critical. In retrospect its criticisms appear reasonable. Some were ignored. Others were slapped on top of CDC's form to make a two-page stapled document, with one page different for bivalent and monovalent shots. This was a messy product, hard to follow. We include it in Appendix D. Sencer and his people felt themselves unable, and

certainly were unwilling, to toss out their 60 million and start over. They pleaded lack of time.

Second is the matter of manufacturers' profits. The August legislation had barred profits on swine vaccine sold to the government (although allowing them on Victoria vaccine since that had been originally intended for the market). In a statute which had government absorbing the risks for profitable companies, this limit on their profits was of obvious importance, symbolically and otherwise, to many members of Congress. CDC was the contracting agency. $100 million worth of vaccine was by its standards a huge contract. Its contract office evidently lacked either the experience or the autonomy to frame provisions which could help police those profits (at best a problematic task). Nor were CDCers close enough to Congress to appreciate the symbolism. The administrative judgment—quickly made, so we are told—was that time was too short for fuss; post-audit would suffice. This left the symbols in prospective disarray, and since has drawn sharp questions from the Rogers subcommittee.[18]

Third is another contract problem, the amounts and timing of vaccine deliveries. Here the contract officers, plodding a straight and narrow path, made an egregious error in external relations. They did it the day after Ford had signed his legislation. By wire to the manufacturers, they cut in half (from 100 to 50 million) their minimum purchase guarantee on swine flu doses. And they set December 3 as the last date for deliveries. The theory, at least about the date, was defensible, given the lateness of the program's start and the imminence of flu season. The symbolism was intolerable, given Ford's and Cooper's pledges that there would be shots for everyone. Predictably the manufacturers protested, Sencer retorted, Mathews urged speed and Ford got sore: "That program damn well better run right." [19] Then Rogers held a hearing, the manufacturers made a case, Cooper overruled Sencer, and the deadline was extended to January 15. The cumulative total of swine doses would then be 146 million, enough for everyone over 18, however belated their shots.

Up the hill and down again. What was the point in all that?

Sencer, defending the performance of his people, told us that in these instances they were the prisoners of Feiner's lawyers and of local counsel who compounded indecisiveness with nitpicking. If so, two staffs in combination failed to cope with the dimensions of the work they had to do.

With each of these examples, the press could have had quite a lot of fun had not Ford's nomination and the start of the campaign preempted reportorial attention. Indeed, the large political events that summer had kept reportage down before as well as after Legionnaire's Disease. This

is particularly noticeable in the TV coverage of the insurance struggle and its sudden outcome. On their evening news shows NBC gave rather more attention than did CBS, perhaps for reasons running back to differences of emphasis in March. A non-political program, technically respectable, caught in a tussle between President and Congress may have more intrinsic interest to editors or producers than one thought to be politicized and rotten to the core. The coverage on those networks lends this speculation credence. At any rate there was a rather dry spell in July and then, after the early August flurry, still another. This was a boon for CDC. Had investigative reporters had time heavy on their hands that summer—as for instance the next summer—swine flu could have been a gold mine whichever way one's predilections ran, non-political, rotten, or both.

Even so, the cumulative coverage of swine flu by all media, from February through the early August scare and legislation, produced an extraordinary result. The Gallup Poll reported August 31 that 93 percent of all Americans had heard about the swine flu program; 53 percent intended to get shots. This bore out a separate poll commissioned by CDC.

There, the 53 percent intention occasioned disappointment and some apprehension. Cooper, after all, had set their sights on 95 percent. Besides flu season would soon start and Kilbourne's expectation had still to be tested. In the absence of pandemic, they'd have done better to concern themselves about the challenge of that vast public awareness. It exposed them where their August flaps and fumbles showed them weak, on the external side of management, anticipating and adjusting to the public aspects. This was their blind side, as events would shortly emphasize again.

On October 1, mass-immunization started in the states that had vaccine; from week to week others joined in. After three changes of plan since June, some states were prepared to move fast while others were almost inactive. Still, in the first 10 days over a million Americans got shots. These were all adults, of course; the new set of field trials was still under way; children were still in abeyance.

On October 11, at Pittsburgh, Pennsylvania, three persons over 70, all with cardiac conditions, dropped dead shortly after receiving swine flu shots at the same clinic. An alert UPI reporter picked up the story from a local paper and sent it over the wires; subsequent stories featured the fact that the same batch of Parke-Davis vaccine was involved. Pittsburgh is close to TV network news bureaus. Mini-cameras and crews were soon on their way. On October 12, the Allegheny County Coroner, Dr. Cyril Wecht, stepped forward to meet them. He told CBS:

> I think that . . . [a bad batch] of vaccine is definitely one possibility that must be considered. And that is why we want to see the [Federal] people here. . . .

Thereupon, the Allegheny County Health Department suspended flu shots. Nine states followed at once: Alaska, Illinois, Louisiana, Maine, New Mexico, Texas, Vermont, Virginia and Wisconsin. The wire service began a national body count.

That evening, Sencer held a press conference and offered calming words:

> We have no evidence that there's anything wrong with the vaccine, but to be perfectly sure, the vaccine that is still in the field is being brought in for re-examination in Bethesda by the Bureau of Biologics. We are setting up a program to look into this in great depth, to reassure everyone that this is not a problem due to the vaccine, but just some of the inherent problems of providing preventative services to large numbers of people, particularly those who are elderly and have other underlying health problems.[20]

Wecht, the coroner, was not so easily put off. On October 13, he gave the autopsy results on two of his three corpses, heart failure, but hinted at negligence, not coincidence.

> We know that substances injected into the vascular system directly produce a more exaggerated and certainly a more rapid reaction than when those same substances are injected into the body fat or muscle mass.[21]

Millar at CDC leaped to the defense of coincidence, and offered up some figures he might better have provided in advance.

> We estimate . . . that among people 70-to-74-years of age something on the order of 10 to 12 deaths per 100,000 such people will occur every day. . . . We are seeing people who are dying within a day or so after vaccination. We expected to see that.[22]

CDC itself got into body-counting, and Millar competed with the wire services. For a while the number 33 was favored, later 41 on CDC's last count of Americans who had received flu shots and died of other causes. Meanwhile, for three straight days, swine flu was a big story on the network news, and safety questions were not left to eager coroners alone. The NBC Evening News of October 13 had Carole Simpson quoting a scientist recently identified in public with these matters: ". . . it's not safe." [23]

On October 14, the hullabaloo subsided. Ford and his family got televised flu shots. Cooper gave the press both lab reports establishing the vaccine's innocence and tough talk about "body count mentality."

Allegheny County and five states announced resumption of inoculations; the other four said they would do so shortly. And, to top it all off, Walter Cronkite almost apologized. On his network radio broadcast he commented:

> The qualifiers [in a 'catastrophe' story like this one] never quite seem to repair the damage done by the initial statement. Many people are left with the distinct impression that the vaccine may be fatal. Health officials can talk until they are blue in the face but they so far have not been able to dispel that impression. . . .
>
> The scare was set off when Pittsburgh halted its immunization program while the deaths of three elderly persons were investigated. All three had been immunized at the same clinic. No connection was found but the word was out. The repetition of stories which appeared to link death and vaccination have spread that damage like wildfire. Hopefully it will all die down but it will take considerable public relations efforts such as the President's well-publicized vaccination today.[24]

This gave inordinate satisfaction for the moment to the Coopers, Meriwethers, Sencers and Millars, which is too bad. In our view they didn't deserve it.

For we think that the whole episode was perfectly predictable: the coincident deaths in some city, the wire services, the nearby mini-cameras, the eager coroner (or Mayor or what-have-you), the human interest, hence the body count, and so forth. We think, therefore, that Federal sponsors of the program should have predicted it, briefed the states about it, passed the word to medical practitioners, alerted health officials in all major cities, and sat down with network news bureaus and wire service bureaus, all handy at Atlanta, seeking counsel. In the prevailing climate of press pride and touchiness, counsel might have been refused, which is no reason not to ask.

Cooper at the time expressed somewhat these sentiments. On October 14, James McManus reported on CBS News:

> Dr. Cooper said he now wishes he had earlier and more strongly outlined possible events surrounding the program including deaths that might appear to be associated with the shots.[25]

So far as we can find, nothing of the sort was tried. "Temporally related deaths" were certainly anticipated in Hattwick's surveillance center. We understand that they had been discussed from time to time at higher levels. The problem loomed, but that was all; planning was discounted on the ground that information spreads, and to alert the public might reduce the numbers willing to be immunized.

However that may be, alerting the public in an *un*planned way probably did reduce those numbers. It also emphasized some troubling under-

currents: who would the program kill? old or young? poor or rich? black or white? All fall, ghetto acceptance rates were lower than suburban rates, for reasons obvious enough once stated, but again not worked through in advance. Although conscious of the problems of race and class, PHS and CDC made little impact on them—nor did they make provision for the public consequences of that failure.

From mid-October on, polls showed a downward drift of persons who intended to be immunized. Absolute numbers of those actually inoculated rose for a while as state plans took hold. During "Pittsburgh week" and despite it, 2.4 million people were immunized. A month later those numbers rose to 6.4 million for the second week of November. A month after that, however, they had dropped back to 2.3 million for the second week of December.

By then a number of factors other than fear were working to cut numbers. In November the children's dosage question was resolved precisely as had been foreseen in June: children should receive two doses of the split vaccine, but there was only enough of it to immunize one child in every dozen. Moreover, there was little participation from private physicians. They accounted, all told, for only 15 percent of inoculations, and were anything but vocal in support of immunization. Our unscientific sample suggests that many were indifferent, others confused, and most disgruntled: "Politics." Kilbourne had urged on Sencer weekly bulletins to every private doctor. Had Kilbourne's expected pandemic come to pass this would have been essential. But CDC had acted on the expectation, not the suggestion. Private physicians were, above all, uninformed.

And then, of course, there was no swine flu, or almost none. One case, not directly traceable to pigs, showed up in Concordia, Missouri. That was all. Millions came down with other respiratory ailments passed from human to human that fall. But with this one exception there were none the swine flu virus could have caused, or vaccine cured.

Between October 1 and December 16, more than 40 million Americans received swine flu shots through Sencer's program. (Defense and VA programs accounted for some millions more.) This is twice the number ever immunized before for any influenza virus in a single season. Considering the obstacles it is an impressive number. It also is a number oddly distributed. Some states, albeit small ones, inoculated 80 percent of their adults in that time period. Others immunized not more than 10 percent. Delaware was at the top of that range, New York City near the bottom. Variations in between are striking: Houston, Texas inoculated only 10 percent of its adults, while San Antonio, Texas immunized nearly one-third. Despite coincident deaths, Pittsburgh, Pennsylvania vaccinated

nearly 43 percent while Philadelphia, home of Legionnaire's Disease, managed but 23 percent. And so forth.[26] These variations cry out for explanation. So far as we know CDC has not pursued them and may lack the resources to do so. HEW would gain if Congress asked the GAO to do it.

We suggest a study by the GAO because our own informal sampling poses puzzles about what may actually have happened. We are wary of the future capabilities at state and local levels. We fear that Federal programs may be hollow shells. What we now think occurred, on insufficient evidence, is that Federal officials tried to influence state counterparts and they in turn tried variably to energize their local health departments. The locals, not the others, were decisive for most states. In each city and county, four things may have come together to determine performance: First was the availability of vaccine and consent forms, matters of complaint (along with children's dosages). Second was the underlying attitude of residents, welcoming or fearing mass immunization. Third was competence, indicated we think by relative success with immunization programs already in place. And fourth was conviction on the part of somebody at once willing and able to take local leadership. Believers in the threat of a pandemic did far more than non-believers. The counties of this country certainly were split between the two. And what divided them may rest on nothing more than faith, hunch, or contacts.

We do not suggest that strategies and planning, locally or statewide, made no difference to the variations in performance. But as of now we have no judgment on the point. Only a detailed investigation at both local and state levels can decide.

One state that was conscientious in its conduct of the national program was Minnesota, where nearly two-thirds of the eligible adults were immunized. In the third week of November, a physician there reported to his local health authorities a patient who had contracted an ascending paralysis, called Guillain-Barré syndrome, following immunization. The physician said he had just learned of this possible side-effect from a cassette-tape discussion of flu vaccination prepared for the continuing education of family practitioners by a California specialist. The Minnesota immunization program officer, Denton R. Peterson, dutifully called CDC and spoke to one of the surveillance physicians there. The latter expressed no interest in this single case, but Peterson was sufficiently bothered to conduct a literature search and did indeed discover previous case reports. "We felt we were sitting on a bomb," he told us. Within a week three more cases, one fatal, were reported to Peterson. Two came from a single neurologist who remarked that he had observed this complication of flu vaccine during his residency training. More anxious than

ever, Peterson again called CDC, where the surveillance center was just being told by phone of three more cases in Alabama. The next day they learned of an additional case in New Jersey. By then CDC was taking the problem seriously. Center staff surveyed neurologists in eleven states to ascertain the relative risk of this rare disease (estimated at 5000 cases annually) among vaccinated and unvaccinated. When the preliminary results suggested an increased risk among the vaccinated, Sencer sought advice from usual sources, NIAID, BoB, ACIP and his own people. The statistical association did not convince them all.

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

With some trepidation about White House willingness to stop, Sencer called Cooper on December 16, and fortuitously reached him in the White House Staff Mess, lunching with Cavanaugh. Mathews by chance was at another table. The three huddled quickly; Cooper then excused himself and made a call to Salk. The switchboard reached Salk in Paris. Without enthusiasm he concurred in Sencer's view. Cooper and the others then walked down the hall to Ford. He heard them out, sighed and agreed. For most intents and purposes the swine flu program was over. With no disease in sight nine months after Ford's announcement, even a rare side effect could turn him around.

That afternoon Cooper announced suspension of the swine flu program, saying that he was acting "in the interest of safety of the public, in the interest of credibility, and in the interest of the practice of good medicine." [27]

Press comments were not kind. The TV anchormen conveyed no sense of loss. And five days later Harry Schwartz contributed an Op Ed piece in the *New York Times*. Entitled, "Swine Flu Fiasco," it rounded off the points that he had previously made in anonymity:

> The sorry debacle of the swine flu vaccine program provides a fitting end point to the misunderstandings and misconceptions that have marked Government approaches to health care during the last eight years. . . .
>
> Any reasonable effort to assign responsibility for this state of affairs must call attention to at least the following elements:
>
> (1) The scarcity in the White House and in Congress of officials with sufficient sophistication in medical problems to be able to put biological reality before political expediency. . . .

(2) The excessive confidence of the Government medical bureaucracy and its outside experts in urging the vaccination program on the country while playing down the uncertainties arising from the fact that medical science still knows comparatively little about the origin and spread of influenza epidemics. . . .
(3) The self-interest of Government health bureaucracy which saw in the swine flu threat the ideal chance to impress the nation with the capabilities of saving money and lives by preventing disease.

In our view his first element overplays the politics. For the rest we offer a refinement. The "heavies" here were seven or eight personal agendas which happened to converge in the remembered light of 1918.