MEETING WITH PRESIDENT AND DR. COOPER
Friday, July 9, 1976
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NOTE:

On Wednesday, July 14, a report on the results of JNC, Secretary Mathews, and Dr. Cooper's meeting with the President should be given to the President.
Here is a comment on each of the points made in today's Newsweek piece:

1. One manufacturer inadvertently turned out 3 million doses of the wrong vaccine.

Parke-Davis did in fact produce 3 million doses of vaccine using the wrong seed virus before it was discovered by HEW. This will not cost the federal government anything, as the production costs are borne by the manufacturer. It appears that other manufacturers can produce an additional 3 million doses for the stockpile.

2. Various state and municipal health officers warn funds would be inadequate.

Some state and local health officers have indicated funds would be inadequate, as they want to finance a great deal of their overhead through this program.

Dr. Cooper and other HEW witnesses before the Appropriations Committee continue to indicate that the amount you requested is adequate.

3. Insurance companies refuse to cover the manufacturers against suits.

The insurance carriers have informed the vaccine manufacturers that they cannot cover them against suits that could arise from side effects caused by the vaccine beyond the scope of the manufacturers' delivering a safe and effective vaccine. HEW and the Justice Department feel that the manufacturers can be adequately protected by contract language between HEW and the manufacturers.

Representatives of HEW, Justice Department, the insurance companies, and the manufacturers are meeting this afternoon to continue to review this problem.

4. Albert Sabin backs off earlier recommendation for large-scale massive program for the entire population.

Dr. Sabin is now of the view that the inoculation
should be limited to high-risk groups and that the vaccine should be stockpiled for large-scale use only if an epidemic actually arises.

There is no general support for Dr. Sabin's view from the scientific community. They still back the recommendations that were made to you when you met with this group.

In summary, the program is still on track. The legal problems should be resolved in the next two weeks. The clinical trials of the vaccine will be completed in the next three weeks. Early results indicate that the vaccine is not as effective with children as it is with adults.
The Swine-Flu Snafu

During the past four months, the Federal government's unprecedented $135 million campaign to vaccinate virtually every American against swine influenza has suffered one setback after another, and last week there was a distinct possibility that the program wouldn't get going at all. First, one manufacturer inadvertently turned out 3 million doses of the wrong vaccine, delaying the entire production schedule. Then various state and municipal health officials warned that the funds voted by Congress would be woefully inadequate to finance the mass inoculations. More recently, insurance companies refused to cover the manufacturers against suits that might arise from side effects caused by the vaccine. And finally last week, one of the nation's leading virologists came out flatly against the idea of inoculating everyone in the U.S. against swine flu in the first place.

Dr. Albert Sabin, the 69-year-old developer of oral polio vaccine, raised doubts about the swine-flu program at a Congressional hearing. Sabin questioned whether the swine-flu virus, isolated last February at Fort Dix, N.J., was really as virulent as the supposedly similar virus that contributed to the deaths of 20 million people in 1918-19. Normally, an emerging flu-virus variant causes local outbreaks before it produces a worldwide epidemic. But no outbreaks of swine flu have been recorded anywhere since the Fort Dix episode.

Sabin: Major objection to mass inoculations was based on the results of the first clinical trials of the new vaccine, announced late last month. The tests, which involved more than 5,000 volunteers, showed that the vaccine produced good antibody responses in adults over the age of 23, but was not nearly so effective in children. The tests also showed that children were more likely than adults to develop fever, muscle aches and nausea as a result of the shots. One of the vaccines caused such side effects in 19 per cent of a group of 6- to 10-year-olds. "It is evident to me," said Sabin, "that the original plan for mass vaccination ... is no longer possible." Rather, he suggested, immunization should be limited to "high risk" groups, such as those over 60 and persons with debilitating illnesses. The rest of the vaccine, he said, should be stockpiled for large-scale use if an epidemic arises.

Old Rival: Dr. Jonas Salk, developer of the first polio vaccine, disagreed with his old medical rival and favored full-scale inoculations. The vaccine, said Salk, "does more good in people's sera than in the refrigerator."

But the dispute between the virus experts could become an academic exercise unless the question of the manufacturers' liability is settled somehow. The fear of suits stems from the case of a Texas girl who became paralyzed after receiving oral polio vaccine in a public program. The vaccine maker was held responsible for the failure of the people conducting the program to inform parents of the possible risks of the vaccine.

The four firms making the swine-flu vaccine sought legislation that would indemnify them against claims arising from vaccine reactions. But late in the week, a House subcommittee refused to consider such a proposal. This means that unless the manufacturers and federal health officials work out an alternate plan, the inoculation program may stop—at least for the time being.

July 12, 1976
All -

1) mention contact & support & call on management to act in July

2) need to report on where I am waiting