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# Swine Flu Chronology

January 1976—March 1977

## January 1976

- 5 - Dr. Bruce Dull, Assistant Director for Programs of the Center for Disease Control (CDC), submits a memo to HEW Secretary David Mathews, sent via CDC director Dr. David Sencer and Assistant HEW Secretary for Health, Dr. Theodore Cooper; Dull states that liability problems may drive vaccine manufacturers out of business, and recommends that the Secretary support legislation to indemnify the manufacturers or to compensate all victims of vaccine
- mid-January - large number of cases of respiratory disease are reported among Army recruits at Fort Dix, New Jersey; Walter Reed Army Laboratory identifies adenovirus as cause of earlier outbreak of respiratory disease at Fort Meade, Md.
- 22 - Donald Carmody, a staff officer for Cooper in the Public Health Service, writes memo to his superior in the Office of Policy Development and Planning, emphasizing the problems in the Dull proposal and suggesting that it be sent up to Cooper without recommendation
- 27 - Colonel Joseph Bartley, chief of preventive medicine at Fort Dix, reports outbreak of illness, presumed due to adenovirus, to local health department
- 28 - Dr. Martin Goldfield, director of the New Jersey Public Health labs, contacts Bartley, gets briefing on the outbreak of respiratory disease, suspects influenza, and requests that throat washings be sent to the New Jersey state labs
- 29 - eight throat washings from Fort Dix delivered to virus lab at N.J. Health Department
- 30 - 11 additional specimens from Fort Dix delivered to N.J. lab

## February 1976

- 3 - at the N.J. lab, 11 isolates are made from the 19 throat washings sent by Bartley from Fort Dix; most of these are identifiable as A Victoria or A Port Chalmers virus, but scientists are unable to identify two of the isolates and unsure about five others, so Goldfield sends these seven on

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- to CDC and calls CDC's Dr. Gary Noble to report his findings
- 4 - after leaving his sick bed and making a forced, five-mile, night march, Private David Lewis, Fort Dix recruit, collapses and dies
  - 5 - the 7 isolates mailed from New Jersey lab arrive at CDC's Bureau of Laboratories
  - 5 - CDC confirms that five of the seven New Jersey isolates are A Victoria; and other two appear to be influenza but do not type as A Victoria
  - 10 - the New Jersey lab sends to CDC two more unidentifiable isolates from Fort Dix, one of them taken from the deceased Lewis; N.J. lab finds soluble influenza A antigen in one unidentified isolate
  - 11 - CDC receives the second group of isolates
  - 12 - double immunodiffusion confirms two original untyped viruses are a type of influenza A; hemagglutinin inhibition tests indicate four of the Fort Dix isolates contain swine flu type hemagglutinin; CDC lab communicates this finding to Sencer in the evening
  - 12 - Goldfield telephones virologist Dr. Edwin Kilbourne of Mt. Sinai Hospital in New York City with the news that he possesses a virus he cannot type; Kilbourne asks Goldfield to send him some specimens
  - 13 - N.J. lab mails quantity of the Fort Dix virus to Kilbourne
  - 13 - scientists at CDC confirm that the isolates are indeed swine-type influenza A viruses; at Sencer's request, Dr. Walter Dowdle, head of CDC's labs, notifies scientists and health officials across the country of the A swine discovery, and invites them to a meeting at CDC the next day
  - 14 - emergency meeting is held at CDC to discuss the Fort Dix finding; in attendance are representatives of the Army (Dr. Philip Russell, Dr. Frank Top), the New Jersey Department of Health (Goldfield), FDA's Bureau of Biologics (Dr. Harry Meyer, Jr.), NIH's National Institute of Allergy and Infectious Diseases (Dr. John Seal), and CDC (Sencer-chairman, Dull, Dr. William Foege, Noble, Dr. Michael Hattwick, Dowdle, Dr. Alan Kendal); conferees discuss need to develop vaccine; also decide not to publicize swine virus finding
  - 14 - 16 - CDC reconfirms isolation and identification of swine flu virus from original throat swabs brought from N.J. Health Dept.
  - 16 - Sencer and Dowdle inform Dr. Charles Cockburn of the World Health Organization (Geneva) of swine virus finding; Dowdle informs Kilbourne
  - 17 - Kilbourne receives samples of the virus mailed from New Jersey; his lab begins to develop a fast-growing "recombinant" for use in vaccine
  - 18 - CDC notifies state health officials of swine flu finding
  - 19 - CDC calls press conference; Dull announces swine virus has been discovered at Fort Dix; makes no reference to the 1918 pandemic in his prepared remarks, but does in response to questions from reporters

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- 20 - first media coverage of swine flu focuses on CDC's announcement of the previous day; coverage links the Fort Dix virus to the 1918 pandemic
- 20 - BoB hosts open workshop in Bethesda, Maryland, with representatives from the Armed Forces Epidemiological Board (AFEB), NIAID, CDC, the press, the scientific community, and all four vaccine manufacturing companies; conferees discuss preparations for a swine flu immunization campaign; second meeting held in the afternoon to discuss surveillance plans
- 20 - quantities of Fort Dix virus delivered to vaccine manufacturers, but virus grows poorly in their labs; companies await Kilbourne's recombinant strain and some work on preparing their own
- 20 - 26 - CDC alerts state epidemiologists in nationwide search for other cases of swine flu; besides earlier cases in Minnesota and Wisconsin, already known to CDC, the investigation turns up other isolated occurrences in Pennsylvania, Virginia, and Mississippi, although all but a questionable Virginia case involved human-pig contact
- 27 - informal meetings are held at BoB; Sencer, Dowdle, Meyer, Seal, and Noble review status of swine flu investigation and discuss candidates for vaccine strain

## March 1976

- 1 - 9 - Army conducts serosurveys at Fort Dix while CDC does the same in surrounding civilian populations; Army estimates as many as 500 recruits at Fort Dix may have been exposed to swine virus
- 9 - as a prelude to the next day's meeting of the Advisory Committee on Immunization Practices (ACIP), Sencer meets Dowdle, Dull, Foege, and other staff from CDC's Epidemiology Bureau for an informal discussion regarding options; stockpiling of vaccine is discussed at some length
- 10 - at an open meeting in Atlanta, CDC briefs the ACIP on the results of its preliminary investigations; ACIP members concur in need for major action, support production of vaccine and formulation of a plan to administer; stockpiling option is briefly mentioned; afterwards, Sencer telephones Cooper in Washington and summarizes meeting
- 12 - AFEB holds meeting at Walter Reed Army Institute of Research to determine vaccine formulation for the military; Board recommends that swine component be incorporated into trivalent vaccine, along with A Victoria and B Hong Kong
- 13 - Sencer finishes action-memorandum which he had prepared in the previous two days; memo calls for mass immunization campaign aimed at vaccinating all Americans, and recommends that Administration ask Congress for \$134 million appropriation; proposes plan with Federal Government buying and testing the vaccine and setting dosage levels, the

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- states distributing the vaccine, and public health agencies and private physicians administering it
- 13 - Sencer asks Dr. Donald Millar, director of CDC's Bureau of State Services, to form a Program Implementation Group
  - 13 - Cooper leaves for eight-day trip to Egypt, with Acting Assistant Secretary James Dickson tending to affairs in his absence
  - 15 - At Secretary's morning staff meeting, Dickson, briefed by Sencer, summarizes swine flu problem
  - 15 - Dickson, Sencer and Meyer meet with Mathews for further discussion of problem; Sencer recommends mass immunization
  - 15 - Mathews sends brief note to James Lynn, Director of the Office of Management and Budget (OMB) informing him of the threat of a major flu epidemic; mentions that a supplementary appropriation may be needed in near future; requests the presence of OMB representatives at an afternoon meeting in his office
  - 15 - Sencer, Meyer and Seal brief Victor Zafra and assistants from OMB
  - 15 - President Gerald R. Ford first hears of the swine flu program from Lynn and Paul O'Neill, deputy director of OMB, along with James Cavanaugh, deputy director of the Domestic Council, in afternoon meetings on other subjects
  - 17 - 18 - Sencer telephones ACIP members to advise them of program specifics as set forth in his action-memorandum; invites their comments and gets unanimous assent
  - 21 - Cooper returns from Egypt
  - 22 - President meets with Mathews, Cooper and Dickson from HEW, Lynn and O'Neill from OMB, and Cavanaugh, James Cannon, Richard Cheney, and Spencer Johnson from the White House to discuss swine virus finding; mass vaccination program is recommended to the President, but he postpones decision until he meets with leading scientists; schedules meeting for Wednesday, the 24th
  - 24 - President meets at White House with "blue-ribbon" panel of experts, including Dr. Jonas Salk, Dr. Albert Sabin, Dr. Fred Davenport, Kilbourne, Dr. Reuel Stallones, Sencer, and Meyer; following meeting, President goes before television cameras to announce that he is recommending a mass vaccination program for all Americans and urges that Congress immediately pass a special \$135 million appropriation; afterwards, Mathews and Cooper conduct press conference
  - 24 - CDC initiates work on a "PERT" chart, plotting out steps and relationships in the swine flu program
  - 25 - Mathews sends memo to Cooper suggesting that he chair a coordinating Task Force for the "National Influenza Immunization Program"
  - 25 - BoB hosts open workshop in Bethesda; conferees include HEW officials,

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scientists from CDC, NIAID, Department of Defense (DoD), and Veterans Administration (VA), university investigators, and drug company representatives, among others; group reviews developments relevant to program; vaccine trials discussed

- 30 - hearing is held before the House Appropriations Subcommittee on Labor-Health, Education and Welfare (Rep. Daniel J. Flood, chairman); drug company spokesman, C. Joseph Stetler, talks of impending liability troubles and recommends government indemnification of vaccine manufacturers; subcommittee unanimously approves special appropriations (HJ Res 890)
- 31 - hearing conducted before House Interstate and Foreign Commerce Subcommittee on Health and the Environment (Rep. Paul G. Rogers, chairman); need for authorization bill discussed
- 31 - White House sends memo to all Federal departments and agencies, requesting support for the immunization program

### April 1976

- 1 - Senate Labor and Public Welfare Subcommittee on Health (Sen. Edward M. Kennedy, chairman) holds hearings on swine flu program; Kennedy presses hard on lagging immunization rates for childhood diseases
- 2 - CDC conducts large meeting in Atlanta with state health officers and representatives of private medicine to explain proposed swine flu program; Sencer outlines desired state participation; state officials question CDC hard on funding of local programs; Goldfield challenges wisdom of decision to mass immunize; TV Evening News broadcasts his dissent
- 2 - House Appropriations Committee reports out special appropriations bill (HJ Res 890) containing \$135 million for swine flu program
- 5 - Richard Friedman, HEW Regional Director (Chicago), sends memo to Cooper in which he suggests that PHS seriously consider stockpiling, avoid "scare tactics," and provide more financial support for state programs
- 5 - Rogers subcommittee approves authorization bill (HR 13012); in the press for time, bill is not sent to full Commerce Committee, but directly to the House floor
- 5 - House approves authorization bill by voice vote, and then, after limited debate, approves appropriations resolution, 354-12
- 5 - in a letter to the Pharmaceutical Manufacturers Association (PMA) Cooper says that the manufacturers' concern over liability should be alleviated by the Federal Government's assuming the duty to warn
- 6 - Senate Appropriations Committee (Sen. Warren Magnuson, chairman) conducts a hearing on the special appropriation
- 7 - Veterans Administration gives CDC the authority to negotiate and admin-

## April 1976 Contd.

- ister vaccine contracts for VA staff and patients; requests 1.5 million doses
- 7-8 - WHO holds meeting in Geneva with consultants from 15 countries; conferees discuss implications of swine outbreak and recommend that worldwide surveillance be increased, that poorer nations devise contingency plans, and that countries with production capability decide for themselves whether or not to produce swine vaccine
- 8 - Senate Appropriations Committee approves HJ Res 890 and reports it out, after adding \$1.8 billion of job support funds; Committee Report indicates that no Federal agency is to assume liability which it had not assumed for previous immunization programs; PMA telegrams a protest to the President
- 8 - An unidentified senior official of the Federal Insurance Company (Chubb Corporation) advises corporate headquarters of Merck, the parent company of Merck, Sharp & Dohme (one of the vaccine manufacturers), that effective July 1 it will exclude from Merck's product liability coverage all indemnity and defense costs associated with claims arising out of the swine flu program
- 9 - Senate Labor and Public Welfare Committee does not act on the House authorization bill (HR 13012), nor does it pass an authorization measure of its own; after a minor floor amendment is added, the full Senate approves the appropriations bill, 61-7
- 9 - Cooper announces Dr. W. Delano Meriwether as director of the National Influenza Immunization Program
- 9 - Meyer sends memo to Cooper in which he estimates production timetable for vaccine; says manufacturers will begin to produce in June and should be able to turn out 24-30 million doses per month, provided they are able to get 2 doses per egg
- 12 - House passes the amended appropriations bill by voice vote; thus, no authorization bill is passed, and appropriation is made under Title III of the Public Health Service Act. Colloquies on the Senate floor and a statement on the House floor by Congressman Robert H. Michel of Illinois tend to negate effect of the language on liability in Senate Committee report
- 12 - Cavanaugh chairs a White House meeting on the swine flu program
- 12 - T. Lawrence Jones, president of the American Insurance Association (casualty insurers), meets with Lynn of OMB; at end of session, Jones mentions that the insurance industry will not insure the manufacturers for swine vaccine unless the Government extends further liability protection
- 13 - the President and Chairman of Merck writes to Secretary Mathews, copies to White House and CDC, among others, stressing that liability will become a critical problem if the drug companies do not receive additional protection; emphasis is on duty-to-warn; warning from insurers is included but not headlined

## **April 1976 Contd.**

- 14 - CDC issues to the states its "Immunization Program Guidelines for Grant Applications"
- 14 - HEW Office of General Counsel (OGC) holds first meeting with Washington counsel to the drug manufacturers; antitrust and liability problems are discussed, particularly the Federal Government's assumption of the duty to warn
- 15 - President signs the special appropriations bill into law (PL 94-266)
- 15 - NIAID hosts workshop in Bethesda to discuss plans for flu vaccine trials
- 20 - Cavanaugh chairs another meeting at the White House on the progress of immunization plans
- 21 - press conference is held at HEW to announce the beginning of vaccine field trials; 3000 volunteers are to be involved
- 27 - CDC completes its PERT chart
- 30 - HEW Press Analysis tracks news coverage from 111 newspapers in 60 cities; shows that editorial response to the swine flu program in April has been 88% favorable

## **May 1976**

- 1 - other manufacturers of swine flu vaccine (Merrell, Parke-Davis, Wyeth) receive notice from casualty insurers about cancellation of liability coverage for swine vaccine
- 5 - at a meeting between OGC negotiators and attorneys for the drug companies, Stanley Temko, counsel to Merck, urges Administration to press for legislation which would indemnify the manufacturers for all costs not directly tied to their own negligence in production
- 6 - St. John Barrett of OGC sends memo to Cooper setting forth bargaining positions of OGC and the manufacturers; advises against the Federal Government's doing more than assuming the duty to warn
- 6 - Cooper sends letter to selected newspapers, explaining the swine flu program and urging favorable public response
- 6-7 - ACIP meets in Atlanta to review progress of program; committee agrees that full preparations should continue, although Dr. Russell Alexander suggests that the final decision to vaccinate might be postponed pending further swine flu outbreak; consensus still opposes stockpiling, however; committee also approves risk-benefit statement for use in Vaccinee Consent Form
- 14 - information packet mailed to Immunization Project directors in states
- 15 - CDC asks state health officials to contribute to development of informed consent procedures
- 17 - in an address delivered at the College of Pharmacy at the University of Toledo, Sabin suggests that the vaccine ought to be stockpiled pending a new outbreak

## May 1976 Contd.

- 18 - CDC signs a contract for the purchase of 1400-2000 jet injectors
- 19 - first technical meeting at BoB with manufacturers regarding production of vaccine
- 21,24 - meeting held between Washington counsel to the manufacturers and OGC negotiators, including General Counsel William Howard Taft IV; William P. Rogers, representing Merrell, informs OGC that Merrell will not participate unless it is assured of complete indemnity for those functions assumed by the Government
- 24 - Mathews delegates authority to CDC to award flu grants to states
- 25 - OGC memo to Mathews through Cooper traces difficulty with manufacturers over liability issue; sets forth contract clause representing maximum Government concession within existing law; mentions Merrell's refusal to proceed without indemnification
- 26 - conference of State and Territorial Health Epidemiologists is held at Cherry Hill, N.J.; immunization program is discussed
- 27 - CDC issues requests to the four manufacturers for "Vaccine Production Proposals," to be submitted by June 15; cover letter sets goal of initial deliveries in July, with all 40 million bivalent doses delivered by September 1, 120 of the 160 million monovalent doses delivered by September 1, and the rest of the monovalent by November 15
- 27 - HEW begins to prepare legislation authorizing indemnification of the manufacturers against all claims other than those based on negligence
- 27 - CDC representatives (Foege, Wendell Bradford) consult with DoD on vaccine for the armed forces
- 28 - in a conference call with Cooper, Sencer and Seal, Meyer estimates that 196 million doses of vaccine will be available by November 1
- 31 - HEW Press Analysis for May shows a slight drop-off in the amount of coverage for the swine flu program; indicates that editorial approval of the program has waned, from 88% favorable to 66% favorable

## June 1976

- 2 - Cooper announces that Parke-Davis used the wrong virus in the manufacture of 2 million doses; implies that this alone may result in 4-6 week delay for the start of vaccinations
- 2 - second technical meeting at BoB with manufacturers regarding production of the vaccine; Meyer estimates that 288 million doses could be available by January 1, 1977
- 2 - Cooper sends memo through Mathews' office to the White House stating that legislation would be needed to secure Merrell's participation, which is necessary to program
- 8 - DoD makes known to CDC its preferred dosage specifications for monovalent and bivalent vaccine (600 CCA swine, 400 CCA Victoria)



**June 1976 Contd.**

- 10 - casualty insurer tells Parke-Davis that as of July 1 it will not be covered for swine vaccine; Merrell receives same message from its new insurer shortly after
- 11 - CDC mails "Weekend Flu Facts" to state health officers, informing them of continuing liability issues and denouncing editorial position of *New York Times*
- 14 - Parke-Davis executive writes to Cooper, warns that his company may lose insurance coverage on July 1 if not fully relieved of liability for vaccine damage; states unwillingness of Parke-Davis to self-insure
- 15 - E. Burke Giblin, Chairman of the Board of Parke-Davis, sends telegram to the President, Congress and other Federal officials, detailing the July 1 insurance cut-off and requesting legislative assistance
- 15 - Cooper announces that Administration will ask Congress to pass indemnification legislation
- 15-25 - manufacturers submit first production proposals, which suggest that only 80 million doses can be delivered by October 1, 146 million by December 1, with first shipments to be made in July
- 16 - Administration submits proposals to Congress (HR 14409) authorizing HEW to indemnify the manufacturers against damages attributed to swine flu vaccination, except for those claims involving charges of negligent manufacture or breach of contract
- 16 - CBS Evening News reports the manufacturers have given the Government notice that they will no longer be insured for production of swine vaccine as of July 1, and that the insurers are reluctant to extend such coverage because "they fear the costs involved in defending against claims resulting from unforeseen side effects"
- 17 - third technical meeting at BoB between manufacturers and virologists from CDC and BoB
- 18 - CDC issues Supplemental Guidelines for Influenza Immunization Project Grants, dealing specifically with informed consent problem; CDC also releases statement of risks and benefits for the informed consent form
- 21 - NIAID hosts meeting in Bethesda to review the results of field trials; results indicate that adults can be safely and effectively vaccinated with a 200 CCA dose of the swine vaccine, but that no acceptable dose has been found for young adults and children
- 22 - as a follow-up to the previous day, the ACIP meets in Bethesda with the BoB's Advisory Panel on Viral and Rickettsial Vaccines to make dosage recommendations; group recommends 200 CCA dose of monovalent for those over 25 (bivalent for those over 65 and others in high risk group); further tests will be needed before recommendations can be made for the sub-18 or 18-24 age groups
- 24 - meeting at CDC, with Sencer, Dowdle, and others, to review production schedules submitted by manufacturers

## June 1976 Contd.

- 25 - casualty spokesman, Leslie Cheek, Washington representative of AIA, places conference telephone call to Meriwether, Meyer, Sencer, and other CDC officials; announces that none of the manufacturers will be insured after July 1, and that, as matters stand, the drug companies will not be able to find insurance anywhere
- 28 - the Rogers subcommittee conducts hearing on the Administration's indemnification bill; committee members are unsympathetic to the proposal, Administration witnesses are lukewarm in their advocacy, and insurance spokesman Cheek is questioned hard
- 30 - HEW Press Analysis for June indicates that coverage of program in major newspapers has dropped some from May levels, but that percentage of favorable reports remains at two-thirds

## July 1976

- 1 - non-profit health group convenes a swine flu forum in New York City; Dull speaks, and says that parallels with 1918 are inappropriate, that there is no reason to fear that a 1976 epidemic would equal the 1918 pandemic in scale
- 1 - the Rogers subcommittee holds an informal session with drug company executives to analyze the lack of progress on the liability issue; subsequently, the subcommittee tables the Administration's indemnification bill, and Chairman Rogers tells HEW General Counsel Taft to reach a contractual solution with the manufacturers and insurers that will not require new legislation
- 2 - manufacturers meet with officials from the Justice Dept. and OGC to discuss possible contractual solutions; no progress is made, and Cooper subsequently releases press statement explaining the impasse
- 5-7 - OGC and the manufacturers agree on contract language, but manufacturers refuse to sign unless Justice Dept. officials approve the language; also, the manufacturers indicate that they will wait on the response of their insurers, to be forthcoming by July 13
- 7 - Cooper receives "Program Overview" from OGC outlining state and local liability problems
- 8 - HEW asks Justice Dept. for opinion on proposed contract language
- 9 - insurance representatives meet with the manufacturers to discuss the proposed language, and agree that it is not sufficient
- 9 - after meeting with the President, Mathews announces that he personally has offered to mediate between manufacturers and insurers, and has scheduled a meeting for the 13th
- 9 - Dull writes ACIP members, explaining problems in the determination of vaccine dosage levels for children, and setting forth possible solutions for their consideration

## July 1976 Contd.

- 11 - Justice Dept. tells Taft that the proposed contract language would not violate the Anti-Deficiency Act
- 12 - after three years of proceedings the FDA Administrator dismisses Dr. J. Anthony Morris, a researcher in BoB, charging insubordination and incompetent performance; Morris goes public, charging he is being punished for findings that cast doubt on safety of influenza vaccines and immunization
- 13 - insurance company officials participate in OGC-drug company meetings for the first time; manufacturers indicate willingness to give contract language a try but insurers demur; Mathews holds press conference
- 13 - Ad Hoc Committee of AFEB meets to discuss immunization program and vaccine composition for armed forces; afterwards, representatives of CDC and AFEB meet, and the latter request whole virus vaccine in 400 CCA doses; CDC defers final decision
- 13 - CDC meets with labor organizations and large industries to disseminate information and solicit their support
- 14 - staff meeting held at CDC with representatives of all PHS Regional Centers to discuss progress of state programs
- 15 - Merrell verbally notifies Cooper it will not purchase eggs after Tuesday, July 20, thus ceasing vaccine production. Cooper also learns that Parke-Davis will decide within weeks on termination of its own production
- 15 - CDC issues Revised Guidelines on Informed Consent, as well as Information Forms for monovalent and bivalent vaccine
- 16-19 - HEW staffers following liability meet to consider options for solving problem; consideration given to dropping program, but consensus reached that White House should be used to break deadlock
- 18-31 - CDC investigates reported outbreaks of swine flu elsewhere in the world, including Manila and Taiwan, but all leads are false
- 19 - drug companies inform HEW that they are still unable to obtain insurance, and will soon have to cease manufacture
- 19 - after meeting with Mathews, President Ford holds press conference and announces that Administration will find a way to carry out the immunization program "with or without the support of Congress"
- 19 - Cooper sends memo to the White House, listing the program's problems and reviewing available options to deal with each; raises termination of program as one option, and limitation to high risk group as another, but rejects both, and recommends continuation of mass immunization
- 20 - Rogers subcommittee conducts another hearing on the liability problem, examining the progress of negotiations among OGC, the manufacturers and the insurers
- 20 - CDC sends letter to state health departments urging continuation of plans

## **July 1976 Contd.**

- to vaccinate entire population; letter contains ACIP's recommendations on dosages for the 18-to-24 age group
- 21 - in response to White House query, the manufacturers explain their objections to "contract solution;" letters sent to Cooper, then forwarded to White House
- 21-23 - CDC holds meetings at its Regional Offices with state health officers, Immunization Project Directors, and Public Health Advisors
- 22 - American Insurance Association sends memo to Cooper; explains that the industry refuses to provide coverage because: (1) the legal climate is too unsettled to permit actuarial calculation, (2) the casualty insurance industry lost more than \$7 billion worldwide underwriting product liability in 1974 and 1975, and (3) the insurers feel that the Federal Government ought to defend all claims
- 22-23 - ACIP meets in Atlanta and recommends that program continue as planned
- 23 - Rogers subcommittee continues hearings; insurance executives appear, and are widely assailed for non-support; one of them suggests an insurance pool, but the others are not receptive to the idea
- 23 - President sends letter to Rogers urging that Congress pass indemnification legislation quickly
- 23, 26 - at the urging of Mathews, insurers formulate private insurance plans; insurers' discussions with OGC negotiators produce no solutions
- 27 - insurers offer three private plans; OGC and the drug companies veto two of the proposals, but ask the insurers to obtain industry commitments for full participation in the third
- 30 - insurers, manufacturers, and HEW officials meet to make final decision on private insurance program; insurers report failure to fully subscribe excess levels of plan; when pressured, three manufacturers promise to continue production in the immediate future, but Merrell, having already discontinued production, does not commit itself to resumption
- 30 - Mathews tells Rogers about the private insurance impasse and says legislation is needed

## **August 1976**

- 2 - outbreak of mysterious disease reported in Philadelphia; swine flu mentioned as possible cause of so-called Legionnaire's Disease
- 2 - HEW and subcommittee staff draft new bill, introduced as HR 15050 and S 3785; measure is modeled on Tort Claims Act and stipulates that all claims arising from the program are to be filed with the Federal Government
- 2 - after telephone calls to drug companies, Dowdle reports that 125 million doses are prepared in bulk

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- 3 - Rogers subcommittee conducts mark-up session of House bill; Mathews then speaks before subcommittee, and says that there is a "possibility" that swine flu is responsible for the Philadelphia deaths; subsequently, the subcommittee reports out HR 15050 by a 6-4 vote
- 5 - House Commerce Committee considers the Tort Claims bill, but decides not to report it after receiving word that Legionnaire's Disease is *not* swine flu; committee postpones further action until August 10
- 5 - Kennedy Subcommittee conducts hearing on Senate bill, S 3735; Sencer testifies that the mystery disease is almost certainly not swine flu; but members express concern about possibility of link; subcommittee approves the measure
- 6 - the President, alarmed by indications that congressional enthusiasm for the bill is waning, urges prompt passage before TV cameras; says he is "dumbfounded" by unwillingness of Congress to act
- 6 - Senate adopts resolution discharging S 3735 from the Labor and Public Welfare Committee and sending the measure directly to the Senate floor
- 6 - insurance executives begin to prepare an insurance program for the manufacturers which would extend \$220 million coverage, excess of \$10 million self-insured
- 7-8 - staffs of interested legislators and government consultants work on the bill, inserting a number of favorite provisions
- 9 - at a meeting of insurance company executives and brokers in Washington, the first layer of \$20 million is quickly subscribed; 25% of the second layer is also taken; industry officials are confident that the balance of the second level will be subscribed
- 10 - President telephones House Speaker Carl Albert and urges that the Tort Claims bill be reported to the House floor under a no-amendment rule
- 10 - after reviewing S 3735, the Senate Appropriations Committee clears it for floor consideration, without endorsement
- 10 - Rogers makes last-minute attempt to muster a quorum in the House Commerce Committee to report out the House version of the bill, but fails
- 10 - House proponents of the bill work with Senate sponsors to redraft S 3735, incorporating changes suggested by the House Commerce and Judiciary Committees
- 10 - by voice vote, Senate adopts the redrafted version of the Tort Claims bill; afterwards, the House approves the measure too, under a no-amendment rule
- 11 - representatives of HEW and the drug companies meet for the fourth time at BoB to make arrangements for the distribution of vaccine
- 11 - at a news conference, Meriwether announces the program is more than two months behind schedule and that immunization will start in late

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- September; says all states and 13 cities and territories have developed and submitted plans for vaccination programs
- 12 - President signs the Tort Claims bill into law, PL 94-380
  - 12 - manufacturers and HEW officials meet to work out final schedule of dosage levels for the vaccination of all those over 18
  - 13 - CDC telegrams vaccine manufacturers and asks them to submit revised proposals for vaccine delivery; accompanies request with two announcements: (1) CDC is reducing minimum guarantees for monovalent vaccine from 100 million to 50 million doses; (2) final delivery deadline has been set at December 3
  - 15 - contract is signed between CDC and Opinion Research Corporation to conduct monthly surveys of public attitudes toward program
  - 17 - meeting is held in Atlanta between CDC and members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to determine the adequacy of informed consent forms; commission disapproves CDC's format, offers suggestions
  - 18 - OGC negotiators Taft and Bernard Feiner along with Sencer and David K. Rowe, director of CDC's Procurement and Grants office, meet with counsel to the manufacturers in order to arrive at an understanding of the effects of PL 94-380; agreement reached in all areas except "limitation on contractor profit"
  - 19 - fifth technical meeting is held at BoB with representatives of NIAID and OGC, as well as the drug companies, present
  - 19 - having received notice of the December 3 deadline, Parke-Davis advises CDC that it will cease initiating production of new batches on August 21 unless the delivery deadline is extended; Sencer telegrams back, asking Parke-Davis not to stop production but requesting at the same time that the company aim at the announced December 3 deadline
  - 20 - final draft for vaccine labelling is delivered by BoB to the manufacturers
  - 20 - representatives from the four companies meet at CDC to review basis for determining "cost" of production
  - 20-24 - manufacturers submit revised production estimates, promising 20 million doses by October 1, 193 million by December 3
  - 28 - OGC approves an Introductory Statement Concerning Influenza Vaccination and announces that the Statement will be appended to the informed consent form previously developed by CDC
  - 30 - Merrell is first company to submit batches of vaccine to BoB for testing
  - 31 - Mathews sends letter to all manufacturers, asking them to redouble efforts to produce more vaccine earlier
  - 31 - Parke-Davis telegrams to CDC, explaining that it would no longer initiate new production of vaccine as of September 2 unless the December deadline were extended

## **August 1976 Contd.**

- 31 - a Gallup Poll conducted in late August corroborates the results of a National Survey taken early in August; Poll shows 93% of Americans aware of immunization program (same as in National Survey), and 52% intend to get shot (vs. 53% in Survey)

## **September 1976**

- 1 - HEW makes public the production estimates of the manufacturers, as revised in late August
- 1 - HEW gives CDC authority to sign "letter" contracts with the manufacturers, until such time as cost and pricing methods could be negotiated for use in final contracts
- 2 - President holds emergency meeting with Mathews, at which the Secretary guarantees that there will be enough vaccine to permit every American over age 18 who wishes to receive shot to do so by January or February
- 2 - CDC responds to Parke-Davis telegram of August 31 by stating that the company should try to increase production before December 3, as urged by Mathews
- 2 - BoB approves first batches of vaccine for release
- 3 - manufacturers answer charges that they delayed production by claiming that they are operating at full capacity, and have been for months; Merrell says it stopped production of bulk only upon fulfillment of its initial quota
- 3 - NIAID workshop is held in Bethesda to plan long-term surveillance of vaccine recipients
- 3 - brokers for insurance companies write participating companies, detailing procedures for insuring manufacturers
- 8 - Committee on Infectious Diseases of the American Academy of Pediatrics meets in Atlanta with officials from BoB, CDC, NIAID, and ACIP to make recommendation on vaccination of the 3-to-18 age group; committee recommends two doses of split virus, bivalent vaccine spaced four weeks apart, for high risk population only; committee declines to make recommendation for healthy youngsters, 3-18, pending further study
- 8 - CDC sends all manufacturers a letter asking them to ship available vaccine prior to October 1, with assurances that it will not be used until October 1.
- 8 - Cooper instructs CDC to extend delivery date for vaccine to January 15
- 10 - insurance company representatives inform House Health Subcommittee that the insurance program is fully subscribed
- 10 - Sencer, Meyer, and Seal agree to schedule an open meeting on children's vaccination as soon as possible after October 15
- 13 - Rogers subcommittee continues hearings; Administration officials admit

## September 1976 Contd.

that production is behind schedule, outline timetable for delivery of vaccine

- 13 - Mathews issues final "cost" and "profit" criteria for vaccine contracts
- 13-22 - letter contracts signed with all four vaccine manufacturers, stipulating that delivery deadline is to be extended to January 15
- 14 - Jones of the American Insurance Association writes Mathews to suggest he convene a national conference of interested parties to discuss liability problem in government-sponsored public health campaigns
- 17 - CDC issues revised Guidelines of Informed Consent, incorporating the "Introduction" approved by HEW on August 28
- 20 - the president of the National Commission for the Protection of Human Subjects writes to Sencer, expressing some reservation about the incorporation of the "Introduction" into the previously prepared consent form; says it is a "good faith" effort, but still worrisome
- 22 - letter contracts between manufacturers and CDC are completed; contracts contain the manufacturers' newly revised production estimates, which show further reduction in deliveries—only 109 million doses by December 1, 146 million by January 15
- 22 - Merck makes first shipment of vaccine to states
- 23 - Kennedy subcommittee conducts hearing on polio immunization and the need for a National Commission to set immunization policy; Dickson tells subcommittee that HEW will convene a National Immunization Conference to discuss long-range Federal immunization policy and draft recommendations
- 24 - CDC issues Supplemental Project Grant Guidelines, dealing with: (1) steps to be taken to notify persons in the 18-to-24 age bracket of need for second shot; (2) reiteration of high risk definition; and (3) a prohibition against giving vaccination before October 1
- 29 - CDC announces that immunization program will officially begin with vaccinations at the state fair in Indianapolis, Indiana

## October 1976

- 1 - first swine flu shots given
- 1 - Taft sends Cooper memo describing how contracts with vaccine manufacturers will include a fund to cover the \$2.5 million self-insurance retained by each manufacturer
- 11 - three elderly Pittsburgh people die shortly after receiving inoculation at same clinic
- 12 - Pittsburgh health officials decide to close down the immunization program in Allegheny County pending investigation of the deaths; health officials in nine states follow suit, and six other program areas suspend use of vaccine drawn from the same batch as used in the Pittsburgh clinic



## October 1976 Contd.

- 12 - at a news conference in Atlanta, Sencer says CDC has sent epidemiologists to investigate, but that thus far there is no evidence to suggest the deaths were caused by vaccine
- 12 - preliminary autopsy results are released on two of the three elderly persons whose deaths touched off the scare; results indicate that cause of death in each case was heart attack; however, Allegheny County Coroner Dr. Cyril Wecht sounds skeptical on the TV Evening News; suggests deaths may not have been coincidental
- 13 - body count begins; Millar issues press release saying that 14 persons in 9 states reportedly died after receiving shot; says numbers are well within range of the expected for first two weeks of the program and that no evidence has been found linking any of the deaths with vaccine
- 13 - BoB reports completed tests on the batch of vaccine used in the Pittsburgh clinic, with no finding of contamination
- 14 - 33 persons now reported as having died following vaccination
- 14 - President and family receive shots before television cameras
- 14 - Cooper holds news conference to summarize results of the investigation; says both vaccine and immunization program are exonerated, and decries "body count mentality;" all states which suspended either have resumed by now, or will soon; several areas report rapidly falling vaccination rate
- 14 - on his network radio broadcast, Walter Cronkite chides news media for coverage of Pittsburgh deaths
- 21 - Sencer writes to manufacturers, asking them to reassess production and delivery capabilities in light of extended deadline
- 22 - meeting sponsored by NIAID at Bethesda to review latest vaccine trials with the 3-to-18 age group; Seal announces that persons in this group can be safely and effectively immunized with 2 doses of split virus vaccine administered four weeks apart; says such administration will not begin until formal recommendation is made by ACIP sometime in next few weeks
- 22 - CDC announces 41 deceased vaccinees to date; still no known connection to vaccine
- 25 - Leslie Cheek of the AIA writes Rogers, summarizing the insurers' underwriting of program
- 29 - Sencer sends telegrams to states, explaining that final dosage recommendation for children is still pending

## November 1976

- 4-10 - CDC develops options for vaccinating children; also considers recommending second dose for the 18-to-24 age group
- 5 - *New York Times* prints article by Sabin criticizing the handling of the swine flu program; says decision to proceed in March was justifiable, but

## November 1976 Contd.

the use of 1918 "scare tactics" was not; favors a stockpiling, preparedness approach

- 6 - a National Survey is released, containing results of poll taken October 4-12; indicates that only 1% of eligible population had received shot by October 12, but that another 57% intended to receive shot in future
- 6 - alarmed by results of the October National Survey, which showed a particularly poor immunization rate in the black population, Cooper sends letters to managers of inner city radio stations, requesting support and providing sample copy for public service spots
- 12 - Millar writes to states, informing them of invigorated "Awareness" campaign
- 12 - case of Guillain-Barré syndrome in Minnesota vaccinee
- 12-14 - National Immunization Conference organized by Cooper is held at the National Institutes of Health in Bethesda to draft national policy on immunization; six major issues are identified; (1) development of policy, (2) consent, (3) production and supply, (4) liability, (5) research and development, and (6) health information and public awareness; it is decided that work groups will be formed to study these issues and report back at a second conference in March or April 1977
- 15 - ACIP recommends that healthy persons in the 3-18 age group be given two doses of split virus vaccine four weeks apart; also announces that only 8 million doses of such vaccine remain, and thus only 4 million of the 57 million persons in this category will be able to get shot; in addition, ACIP recommends that a second dose be given to those in 18-to-24 age group
- 15-19 - initial investigation by Minnesota Department of Health into occurrences of Guillain-Barré syndrome in vaccinees
- 17 - Taft writes the Internal Revenue Service concerning the tax status of the manufacturers' self-insurance fund
- 18 - Cooper expresses concern over the low level of participation nationwide; only four project areas over the 50% mark (Wyoming, Hawaii, Puerto Rico, and Trust Territories)
- 19 - report is made of seroconversion to swine virus in 32-year-old man in Concordia, Missouri
- 21 - *New York Times* poll shows that over half of those New York City residents who have not received shot feel it is unnecessary
- 22 - Missouri state health officials confirm the swine flu case in Concordia
- 22 - Parke-Davis submits official reply to the charge that it had negligently manufactured millions of doses of vaccine; in answer to HEW charge that it had carelessly used an A Shope strain instead of A swine, Parke-Davis claims total innocence, and suggests that CDC may have given it wrong strain at start

## **November 1976 Contd.**

- 23 - CDC epidemiologists report no evidence of human-to-human transmission of swine virus in Concordia
- 24 - New York City, New Jersey and Connecticut all report increases in vaccination rate following swine finding in Missouri
- 24 - Denton Peterson, Immunization Program Representative in the Minnesota Department of Health, calls CDC to discuss case of Guillain-Barré syndrome in vaccinee

## **December 1976**

- 2 - Minnesota reports three additional cases of Guillain-Barré at same time as Alabama reports three cases; CDC begins investigation
- 3 - isolate taken from a 23-year-old hog farmer in Wisconsin is identified as swine virus; subsequent search indicates sick swine the source and some secondary spread spotted
- 6 - CDC ships Public Awareness materials to project directors, and to radio and television stations
- 7 - CDC confirms that isolate taken from Wisconsin man is swine virus
- 9 - Lyle Conrad, assistant director of the Immunization Division at CDC, announces that measles cases are up 64% nationwide from last year; blames the swine flu program, which he claims has diverted resources from more needy programs
- 11 - investigation of Guillain-Barré is extended to eleven states
- 13 - Sencer makes a conference call to outside experts; reports preliminary data on the association of Guillain-Barré with the vaccine, and seeks their opinions; consensus is that program should not be halted
- 14 - CDC issues press release on Guillain-Barré; says that 54 cases in 10 states have thus far been reported, and of the 54, 30 received shot anywhere from one to thirty days before onset of symptoms
- 14 - Dowdle prepares a reply to Parke-Davis on the matter of the mistaken production of Shope vaccine; refutes the contention of Parke-Davis that CDC was at fault, and reiterates that the company must be held to have been negligent and not paid for the faulty doses
- 15 - Sencer makes second conference call regarding the Guillain-Barré problem
- 16 - Sencer conducts morning conference call, his third in four days, with 20 experts from NIAID, BoB and the states, conferees agree on recommendation of a one-month suspension to allow for investigation of link; Sencer calls Cooper with the recommendation; Cooper confers with Mathews and Cavanaugh; telephones Salk; President okays suspension
- 16 - subsequently, Sencer in Atlanta and Cooper in Washington announce suspension of the program

## **December 1976 Contd.**

- 16 - Rogers subcommittee conducts an emergency hearing to get explanation of moratorium from HEW officials
- 17 - Kennedy subcommittee holds a hearing; chairman says program is dead, and Cooper agrees that it would be difficult to get program started again, if and when such is recommended; Foege estimates incidence of Guillain-Barré in vaccinated group is about four times greater than normal
- 17 - Millar sends notice from CDC to all project areas explaining moratorium; Dr. Phil Brachman writes state epidemiologists, asking that they survey all Guillain-Barré reported after September 1
- 20 - swine virus is isolated from 13-year-old boy in Wisconsin; subsequent investigation indicates pigs are source of infection
- 23 - Cooper submits first of several weekly reports to Congress on the Guillain-Barré evidence
- 29 - ACIP advises against resuming the program since several more weeks may be needed to investigate; recommends that shot should be available to individual patients if both doctor and patient agree that vaccine is needed and if patient is fully informed
- 30 - HEW announces that the Federal Government has received a total of 31 claims valued at \$1.2 million under the Tort Claims bill
- 30 - in Vail, Colorado, President tells TV news reporters that he concurred in the December decision to suspend, but defends the original March decision to immunize everyone
- late December - HEW fills out the membership of the six work groups created at the Immunization Conference in November; broad cross-section of interests represented; work groups asked to submit reports by March 1 and plan on an early April conference

## **January 1977**

- 5 - CBS Evening News airs a lengthy piece on the issue of declining immunization rates against childhood diseases
- 6 - Cooper announces resignation, effective Inauguration Day
- 11 - representatives of HEW and the Department of Justice meet to discuss procedure for handling claims filed under PL 94-380
- 11 - Minnesota Health Department reports case of swine flu in a 27-year-old man who has had contact with pigs; no human-to-human transmission is discovered
- 11 - Cooper asks Sencer and CDC for advice on reformulation of informed consent forms
- 14 - ACIP meets in Atlanta and concludes that the moratorium on all influenza vaccine ought to be lifted; observes that flu shots do appear to entail some slight additional risk of contracting Guillain-Barré (estimated at one case for every 100,000 to 200,000 vaccinations); recommends

**January 1977 Contd.**

that main focus of resumed program should be on high risk group

- 14 - subsequently, Sencer reads draft of recommendations over phone to Cooper, who concurs
- 16 - Sencer releases final ACIP recommendations after double-checking with members by telephone; group recommendation is resumption on limited scale, aimed at high risk group
- 17 - in deference to incoming Administration, Cooper declines to decide whether or not to lift the moratorium
- 18 - in response to Cooper's letter of January 11, Sencer sends memo to the Assistant Secretary setting forth the options for the future of the program, and strongly recommends that Cooper concur with the recommendation of the ACIP to resume on a limited scale
- 18 - Cooper responds immediately to Sencer, asking that he: (1) poll the states on their willingness to rejoin the battle, (2) estimate the cost of restarting the program, and (3) develop a new informed consent form, and get the concurrence of OGC and the National Commission for the Protection of Human Subjects
- 18 - CDC formulates new Informed Consent forms, incorporating a warning on the possibility of the vaccinee contracting Guillain-Barré
- 19 - Sencer responds to Cooper, listing the results of CDC's poll of the states; few expressed themselves as willing to resume a full-scale public program; Sencer estimates that the start-up cost would be between \$15,000 and \$30,000; Sencer also sends Cooper the new Informed Consent forms
- 19 - Cooper issues news release explaining his decision not to lift the moratorium; says that Informed Consent forms are still a problem, that the states must be consulted individually about scale of resumption, and that a proper scope and target had to be selected for revised program
- 20 - Califano sworn in as Secretary of HEW
- 20-21 - NIAID workshop on the vaccine test program is held in Bethesda; some criticism leveled on the limited amount of follow-up surveillance that is being done
- 25 - BoB workshop is held in Bethesda; in attendance are representatives from CDC, NIAID, DoD, and manufacturing firms; conferees discuss alternatives for vaccine composition for 1977-1978
- 26 - Acting Assistant Secretary for Health Dickson sends memo to Califano, sketching the history of the swine flu program and itemizing the major options for dealing with the current moratorium
- 28 - OMB approves a Department of Justice supplemental budget of \$1.2 million for swine flu litigation in 1977; Justice officials estimate that an equivalent appropriation will be needed for the same purpose through 1980
- 28 - World Health Organization announces its 1977-1978 recommendation for influenza vaccine composition

## February 1977

- 2 - BoB prepares reply to Parke-Davis on the Shope vaccine matter, claiming that Parke-Davis was negligent and that it ought not to be paid
- 2 - outbreak of Victoria flu is recorded among the patients and staff of a nursing home in Florida
- 4 - Justice Department reveals that 104 damage claims have been filed against the Federal Government under PL 94-380; total value is almost \$11 million
- 4 - Califano announces that a special meeting will be held on Monday the 7th to discuss the moratorium and recommend a course of action for the remainder of the 1976-1977 flu season
- 4 - Califano sends a memo to President Carter, summarizing the history of the moratorium, identifying the problem posed by the recent outbreak of Victoria flu, and stating his intention to meet with an *ad hoc* committee on Monday to discuss the options, after which he (Califano) would consult with the White House and make a decision; Califano closes by suggesting that he does not think the President should publicly make the decision
- 4 - Representatives Henry Waxman and Andrew Maguire of Rogers' subcommittee hold a morning press conference at which they voice their concern over the administration and implementation of the program
- 4 - HEW Undersecretary Hale Champion informs Sencer he will be replaced as head of CDC
- 7 - Califano convenes an open meeting to discuss resumption of influenza vaccination; *ad hoc* panel of academic, scientific, political and media experts, chaired by John Knowles, meets at HEW; panel recommends that Califano resume vaccination of the high risk group with bivalent vaccine, but reaches no agreement on general resumption
- 7 - During meeting it becomes known that Califano wants Sencer's resignation as director of CDC; Sencer confirms
- 7 - Acting General Counsel Barrett sends memo to Califano, enclosing the revised Informed Consent forms and advising that the Secretary invite comments thereon from Justice and from the National Commission for the Protection of Human Subjects
- 8 - at a news conference, Califano announces that he is lifting the ban on bivalent and B Hong Kong vaccines to help combat small outbreaks of Victoria and Hong Kong flu; moratorium is continued on swine monovalent vaccine; mass outreach campaign is not to be resumed
- 9 - health officials from a majority of states announce that bivalent vaccine will be made available to physicians and health clinics but that mass immunization programs will not be resumed
- 9 - an AFEB Ad Hoc Subcommittee on Influenza submits recommendations on vaccination of armed forces for the spring; advises that recruits be given the swine-Victoria bivalent vaccine, but that as soon as Victoria

## February 1977 Contd.

monovalent vaccine should become available, recruits be given that only;  
AFEB accepts the recommendation

- 14-15 - meeting is held at CDC with representatives of NIAID, BoB, and the Department of Agriculture to discuss swine flu in man and pigs and methods of control

## March 1977

- 11 - Califano convenes an *ad hoc*, advisory panel to make suggestions and recommendations on flu vaccine policy for the next year; at end of all-day meeting, the group concludes that only high risk group or those with important occupations (70 million in all) should be targets for flu vaccination next winter; vaccine will immunize against Victoria flu; swine flu vaccine is not recommended