

HE1.2:SW 6



The Swine Flu Affair

Decision-Making on a
Slippery Disease

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With an introduction by
Joseph A. Califano, Jr.,
Secretary of Health, Education, and Welfare

Introduction

In early February 1977, less than two weeks after taking office as Secretary of Health, Education and Welfare, I was faced with a difficult health policy decision: Whether to release stocks of influenza vaccine that had been withheld after use of the vaccine was linked with the Guillain-Barré Syndrome—an often paralyzing and sometimes killing side effect.

In the fall of 1976, HEW had begun vaccinating millions of citizens in an unprecedented national influenza program—an attempt to vaccinate virtually the entire American population against swine flu, and to vaccinate high-risk persons against both swine flu and A/Victoria flu.

Two main formulations of vaccine had been produced for this nationwide immunization drive: one, monovalent—the swine flu vaccine alone; the other, bivalent—the swine flu vaccine combined with A/Victoria vaccine. But over a two-month period in the fall of 1976, use of these vaccines on millions of people had turned up a hitherto unrecognized association between flu vaccine and Guillain-Barré Syndrome. Was Guillain-Barré the result of the swine flu vaccine, the A/Victoria vaccine, or all flu vaccines? No one could be certain.

But we had to make a decision. On January 29, 1977, A/Victoria flu had erupted in a nursing home in Miami. There was the possibility that this flu could become widespread, endangering high risk groups such as the elderly and those with chronic lung disease. If it did spread, the risks of influenza would far outweigh the risk of Guillain-Barré. But there was no way to gauge the extent of the danger; and the A/Victoria vaccine was available only in the bivalent formulation: in combination with the swine-flu vaccine. Thus, a decision to release the A/Victoria vaccine was necessarily a decision to release the swine flu vaccine.

In the end, after much debate and on the advice of the experts, I decided to release the bivalent vaccine. But in the course of making this decision, I was impressed by the enormous difficulty that a lay official has in fulfilling his responsibility to make sound, balanced judgments about complex scientifically-based public health issues. From briefing papers I had read before becoming Secretary and discussions of other

issues, I knew I was soon to be faced with other difficult public health questions—ranging from setting guidelines for recombinant DNA research to issues relating to psychosurgery and sterilization—that would require a careful weighing of scientific fact, some of it speculative, with ethical and policy considerations.

As a lawyer and former special assistant to former Secretary of Defense Robert S. McNamara and President Lyndon Johnson, I had frequently faced situations with little or no initial knowledge of the complex substance of the events or subject matter involved. This swine flu situation surprised and bedeviled me, however, because I knew so little that it was difficult even to determine *the questions to ask* in an attempt to reach an intelligent decision.

During this experience—and the review of the swine flu program it occasioned—I was struck that those who might find themselves facing sensitive health policy decisions could benefit greatly from a careful study of that program.

If the swine flu experience had any lessons to teach, it was important that we learn them. If there had been mistakes or missteps—however well-intentioned—it was important to learn what they were so we might not repeat them, either in immunization policy or in other, similar decision-making contexts.

Indeed, the swine flu experience threw into sharp relief two questions that increasingly challenge officials at the high policy levels of government:

- First, how shall top lay officials, who are not themselves expert, deal with fundamental policy questions that are based, in part, on highly technical and complex expert knowledge—especially when that knowledge is speculative, or hotly debated, or when “the facts” are so uncertain? When such questions arise, with how much deference and how much skepticism should those whose business is doing things and making policy view those whose business is knowing things—the scientists and the experts?
- How should policymakers—and their expert advisers—seek to involve and to educate the public and relevant parties on such complicated and technical issues? To what extent can there be informed and robust public debate before the decision is reached?

Increasingly, the questions that Presidents, cabinet officers and other officials confront involve extraordinarily technical complexities and un-

certainties: defense policy and disarmament choices involving sophisticated and expensive weapons systems, for example; health policy decisions involving subtle questions of scientific possibility and probability.

With these questions in mind, I remembered an illuminating report I had read several years ago about another problem-laden episode, the Skybolt missile affair.

President John F. Kennedy, in a difficult and controversial decision, had canceled the Skybolt missile—setting off a chain of diplomatic consequences which, to the dismay of the President and his advisers, none of them seemed to have foreseen. Somewhat shaken, President Kennedy invited Professor Richard E. Neustadt of Harvard, a renowned scholar of the Presidency and the decision-making process in government, to trace the Skybolt affair and prepare a report that might draw some lessons for future policymaking. As a newcomer to the staff of Defense Secretary McNamara in the early 1960's, I read Neustadt's report to President Kennedy. I found it a fascinating narrative—and a sobering, cautionary tale.

Now Professor Neustadt and his able colleague, Dr. Harvey V. Fineberg, at my request, have anatomized the swine flu affair—in search of lessons for the future, not of fault in the past. I asked them to give me as objective and clinical report as they could write. This book is their report. The views and observations they express here, I should stress, are their own. I sought neither to direct nor to influence the report—only to learn from it.

Their narrative will prove enormously valuable to policymakers in this Department facing difficult decisions in the future—and needing to steer by the light that a clear, objective history can shed upon their way. Indeed, this study can have great meaning for all citizens, within government and outside it, who are interested in the process by which large decisions are made—and who are eager to improve that process.

JOSEPH A. CALIFANO, JR.
Secretary,
Department of Health,
Education, and Welfare

July 1978

Letter of Transmittal

Honorable JOSEPH A. CALIFANO, JR.
Secretary of Health, Education and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

We present to you our study, done at your request, of Federal decision-making on the swine flu program from March 1976 to March 1977. We include the program's legacies of policy in the year after and our own retrospective reflections, along with a technical afterword. The study's coverage runs to March 1978. The study's terms are indicated further in our foreword.

We have sought details for the sake of lessons. The search was educational for us, but that is not the point. We hope it proves useful to you.

Sincerely,

RICHARD E. NEUSTADT

HARVEY V. FINEBERG

Harvard University
June 1978

Acknowledgements

Four of the principal participants in the swine flu program came to Cambridge at our invitation to review the first draft of this study. They commented freely, we listened attentively, then made what seems to us a careful judgment on each point. Whether they will agree is not for us to say. But what we can say is that we appreciate their courtesy, applaud their candor, and consider ourselves fortunate to have had their counsel.

Several Harvard colleagues and a few outside observers read and commented on chapters in draft. We are grateful to all, especially to those who offered criticism. We may not have taken it to their satisfaction, but we certainly thought about it, with benefit on almost every page.

We are grateful also to the many HEW officials who cheerfully responded to requests for files, and to the GAO officials who let us review some of their workpapers on state plans. We are grateful to still larger numbers of present and former officials from many parts of government who made themselves available for interviews. Our gratitude extends no less to persons in the private sector, scientific advisers, drug company officers, insurance executives and members of the press, both print and electronic, who let *us* interview *them*. To the Columbia Broadcasting System, which made TV transcripts available, and to Vanderbilt University, which lent us tapes, we offer thanks as well.

We have done this work part-time during the academic year 1977-78 and have been helped by two extraordinary research assistants, Thomas Kinsock of the Harvard Law School, class of 1979, and Michael Holt of the Harvard Medical School, class of 1980. Our files are extensive, our interviews many; these two know everything and can find anything. They also are severe at copy-editing, and in the realm of policy they make, we think, sophisticated judgments. We are grateful to them. And to our secretary, Sally Makacynas, goes our gratitude on behalf of our readers.

H.V.F.

R.E.N.

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Foreword

The swine flu program of the Federal government was launched in March 1976 with a White House announcement by President Gerald R. Ford. The program was finally set aside in March 1977, when HEW Secretary Joseph A. Califano, Jr. stated influenza prospects for the coming year. These did not include swine flu. The program thus outlasted, although not for long, the Ford Administration.

The National Influenza Immunization Program, the official title for this venture, was unprecedented in intended timing and in scope among American immunization efforts. It aimed at inoculating everyone before December 1976 against a new flu strain that might conceivably become as big a killer as the flu of 1918, the worst ever. The program was funded by Congress through a \$135 million appropriation, and it was later buttressed by special legislation in the field of liability. It was conducted through state health departments, with technical assistance from health agencies in HEW. Inoculations started late, October 1, 1976. They had been slowed somewhat by difficulties in deciding children's dosages and seriously stalled by liability issues. On December 16, the program was suspended to assess statistical evidence of a serious side-effect. Mass immunization never started up again. As a full-scale operation, the program's life was thus not twelve months but two and a half.

The killer never came. The fact that it was feared is one of many things to show how little experts understand the flu, and thus how shaky are the health initiatives launched in its name. What influenza needs, above all, is research.

Decision-making for the swine flu program had seven leading features. To simplify somewhat, they are:

- Overconfidence by specialists in theories spun from meagre evidence.
- Conviction fueled by a conjunction of some preexisting personal agendas.
- Zeal by health professionals to make their lay superiors do right.
- Premature commitment to deciding more than had to be decided.

- Failure to address uncertainties in such a way as to prepare for reconsideration.
- Insufficient questioning of scientific logic and of implementation prospects.
- Insensitivity to media relations and the long-term credibility of institutions.

These and other features are discussed and qualified below.

One thing we are convinced the program was not. Whatever the contemporary notions from outside, it wasn't party politics; President Ford wanted to protect the public health.

In the year of its formal existence from March to March, the swine flu program chalked up numbers of accomplishments which give it weight historically. In these terms it may go down as a qualified success. More than 40 million civilians were inoculated, twice the number ever reached before in one flu season. A notable surveillance system was developed, better than anything before. A serious side-effect of influenza vaccination, Guillain-Barré syndrome, occasionally fatal, was tracked by that system and remains under investigation. A critical policy problem for all public health interventions and research, the problem of liability, was brought into sharp focus for the first time; it is now being addressed at policy levels both in HEW and in Congress. The flu as a disease and shots as a preventive were dramatized sufficiently so that a permanent program aimed at high risk groups is now in view. With that comes what the influenza specialists in public health have long desired, recognition for the flu alongside polio or measles among Federally-supported immunization initiatives.

While media attention focused on the troubles of the swine flu program—which were many—net effects on general public consciousness seem small. Possibly, indeed, they will turn out on balance to have been more positive than negative for public health. Swine flu may have a bad ring in public ears, but millions may have heard of flu shots for the first time. On this nobody has good information.

Yet to attentive publics in and near the Washington community, to doctors in the country's schools of medicine and public health, to professionals in print and electronic journalism, to members of Congress and the Carter Administration, also to most members of the Ford Administration, the swine flu program was once widely seen and now is overwhelmingly recalled as a "fiasco," a "disaster," or a "tragedy."

More interesting still, it was and is a trauma to the government offi-

ials most involved and to their scientific advisers. A year and more later, cheeks flush, brows furrow, voices crack.

In February 1977, as the program waned, Secretary Califano asked us to review and reconstruct it in detail for his own education. His purpose was managerial. He sought lessons for the future useful to a man in his position. He had just authorized a limited resumption of the program through the rest of the flu season for the sake of high-risk groups. His position and its problems were vivid in his mind. Lessons were what he wanted, not a history; finger-pointing did not interest him in terms of last time; his concern was with next time.

Yet as he was aware, having read a comparable report by one of us done years ago for President Kennedy, we know no better way to draw most lessons than to tell the applicable portions of the story. We began with that bias. It was only reinforced when we discovered the persistence and pervasiveness of trauma. The lessons of this program, we believe, will be obscured for relative outsiders unless they understand why it had such profound effects, *not* on the country but rather on its own participants. That understanding is imparted best by a selective narrative.

This calls for a reconstruction of events, which we have undertaken by combining press accounts, hearings, official files, and interviews with participants, as many as we could reach during the time we had available. Our efforts still leave some participants unreached, some happenings unrepresented. We are sorry for that but time pressed. In establishing "what happened" we have sought not less than three and preferably five opinions when there were as many or more persons present. In the case of actions taken by one person we have sought both his account and the impressions of contemporary bystanders, along with written records if available. Throughout we have sought views from informed observers.

This remains a reconstruction. It cannot be "the" truth as actually experienced, for there were many truths then, all imperfectly recalled; we now select among them with the benefit of hindsight. We are surely not infallible; we seek to be responsible; the judgment is our own.

Many of our informants spoke for background only. All were offered confidentiality if they so chose. Therefore, attributed quotations from our interviews have all been checked with sources for accuracy and propriety. As cannot help but happen, checks produced some changes of memory, or concerns about good taste, or insistence on non-attribution. For quotation purposes we honor the source's preference. Readers need not fear. This does not change the substance of the story; it just makes for a little less enjoyment in the reading.

What follows is our response to the Secretary's request, written for him and for whomever else he chooses. There are ten chapters of narrative, ending in March 1977. We do not deal with everything. We deal with those things we believe can best help Califano think ahead. Chapter 11 sketches open issues in the swine flu program's wake: a national commission, liability legislation, and a new immunization initiative. These we watched while researching the earlier story. We are current through March 1978. We then stopped watching; for the last three months we have been editing. Those issues remain open but our text closed as of March, a year after the program's termination.

We conclude these chapters with our own reflections, placed in Chapter 12. They bring us to administrative issues and to realms of current policy for Russian flu and after. They bring us also to the underlying issues posed by current knowledge about influenza, and by ignorance as well. We deal here with a slippery disease. What makes it so we address in a technical afterword.

There follow five appendices. "A" is a "cast of characters" named in our narrative, and a chart of certain agency relationships. "B" is a glossary of abbreviations and "C" is a detailed chronology from January 1976 to mid-March 1977. "D" contains certain documents described in narrative chapters, and "E" offers questions useful for the next pandemic threat.

With preliminaries over we can now begin.