

The swine flu program ended, but in terms of Federal policy it left at least three legacies. With these the Secretary still is dealing or has yet to deal. One is a national commission on immunization policy. Another is liability policy. The third is an expanded Federal role in influenza immunization. The three interlock. They still evolve. They carry far beyond March 1977, the month we made our stopping-point for detailed reconstruction. But during 1977, while we worked on 1976, we tried to keep an eye on these three legacies. We offer a comment on each.

A National Commission

The idea of a commission on immunization policy is indistinguishable from the history of the two National Immunization Conferences, in November 1976 and in April 1977, which Cooper planned as the fulfillment of a pledge to Senator Kennedy. The pledge had been extracted during hearings in September 1976, after the tort claims statute had been followed by delivery delays. Kennedy seemed eager for a long-lasting body to review and pull together every aspect of the issues that had plagued the swine flu program.

... I do not really feel that a conference is sufficient to deal with the kind of problems we have here, the problems we are really concerned with and talking about and which are raised in this issue [availability of vaccine] here.

I think a conference can be useful under certain circumstances. . . . I think all of us who attend them do obtain some degree of information or knowledge; but due to the kind of indepth work that I think needs to be done, . . . I think it needs a commission.

...
We are really going to insist on this.⁸²

He settled for the promise of two conferences.

Cooper organized the first one as a sounding board for those who felt the swine flu program to have been at once desirable and problematical, problematic because unprecedented, hence underprepared. The whole influenza cast of characters turned out and more besides: CDC and NIAID and BoB staffs, with advisers, public health professionals, pediatricians, laboratory chiefs and some executives from the drug companies, epidemiologists from state health departments, even the likes of Leslie

Cheek, and better still, insurance company vice presidents, together with a scattering from voluntary agencies, public interest groups, congressional staffs, and press. After discussion, the Conference divided into six work groups which were asked to report four months hence at a second conference. These groups covered a lot of ground: Production, R & D, Consent, Liability, Public Awareness, and Policy. Their reports were duly printed and distributed three weeks before the second conference. At that affair, the same people, more or less, assembled again, discussed again, and adjourned, leaving the reports to work their way to agency or congressional action.

Cooper was ten weeks gone by the time of the April Conference, but Califano showed up full of expressed interest. This gained immediate approval followed by drawn-out disappointment. Califano's staff work at the time had not sufficed to count the cost of his expressiveness. He had already announced his immunization initiatives for children, incidentally over-promising in Cooper's wake. Now he went to this affair to demonstrate how much the general subject mattered to him and how differently he felt about such departmental doings than had Mathews, the phantom. But soon enough, staff found they disagreed with many portions of those working group reports. Califano was more than willing to hold still. At lower levels this appeared erratic.

Three of the six reports had featured a proposal eagerly accepted by most conferees, a National Immunization Commission or Policy Council. This was an adaptation of the Kennedy idea. Its authors meant to substitute for both the old ACIP and Califano-like *ad hoc*-ery a permanent body at the apex of decision-making:

The commission should have the responsibility for reviewing and advising the Secretary on all matters concerning immunization policies, priorities, and practices as they may affect the public health of the United States. . . . continuing awareness of the effectiveness, safety, need for the availability of existing . . . and additional vaccines. . . . stimulation and support of . . . research . . . training of personnel . . . public and professional education. . . . judgment of the need for public vaccination campaigns; review of the present system of vaccine administration, both public and private; and provision of long range support of programs to assure adequate immunization levels of the population. . . .³⁸

Many persons had combined to produce this proposal. Among them was Salk, for reasons running back to his original agenda of a year before. His interest was well known to Kennedy through Dr. Lawrence Horowitz, a subcommittee staffer. And the work groups that proposed it represented other interests too, ranging from the professors, researchers, and consumers who might sit on it to the three agencies whose stabilized relationships had barely been defense enough against recent upheavals: CDC,

BoB and NIAID. A National Commission could be counted on to spread stability one and two levels up, easing the way for them.

Two difficulties strike us but were not voiced at the Conference and perhaps struck no one there. One difficulty is that along with stability a body of this sort would also bring, in time, its members' own agendas and their mutual accommodations, turning into but another agency among the many predisposed in given ways. Its predispositions almost surely would include a growing role for federal immunization. They also almost surely would reflect the preferences of staff, and staffers more than likely would be drawn from the three agencies below: CDC, BoB and NIAID. Even if the higher level body had a wholly separate staff, it could not help but seek to bargain with those three for positions they could advocate together.

To lose *ad hoc*-ery for that strikes us as a poor bargain.

Moreover, such a body would, we think, be bound in time to fall into the orbit of the congressional subcommittees. Ultimately, Kennedy and Rogers with their staffs would be better able than a transient Secretary to affect the course of "national immunization policy." Whether this is good or bad depends on where one sits.

In a June conversation with his then special assistant, Dr. Michael McGinnis (now a Deputy Assistant Secretary for Health), Secretary Califano indicated his preference for dispensing with a commission or council. His reasons were his own, not ours. In ordinary times he saw it duplicating work that PHS executives and their advisers, or his office, ought to do. Should an emergency like swine flu arise, he might turn to his recently created Ethics Advisory Board. The Board was chaired by James Gaither, a San Francisco lawyer and a former aide in Califano's White House years. If special talents were required they could find them as before, *ad hoc*.

In our opinion there is nothing wrong with this, except that Messrs. Kennedy and Horowitz may not have got a national commission off their minds. Salk has not, as he told us in December, 1977. The second-level bureaucrats assuredly have not. They raise it still at any opportunity. And various consumer groups still have it on their lists, joined happily by the Pharmaceutical Manufacturers Association eager for alliances across the market.

Liability Legislation

The liability problem remains at the heart of immunization policy so

long as manufacturers and their insurers insist on special treatment for Federally sponsored programs. Either such programs are circumscribed, if not ruled out, or duty to warn and legal costs are federalized. As Dull had done in 1976 and others earlier, the National Immunization Conference and its work group on the subject naturally put immunization first: to preserve options and facilitate development of Federal programs, the private sector *ought* to have its way. Whether this meant tort claims procedure as with swine flu, or indemnification, or some way of compensating victims, was subsidiary. The sooner a choice was made, and legislation passed, the better for immunization.

That there is an array of other issues, quite apart from immunization, issues of precedent, of equity, of cost, of public-private balance, of administrative and judicial roles, has never impressed persons who put immunizing first.

In 1977, the new hands at HEW were in no hurry to dig into this one. Childhood immunization they found could be pursued by contractual assumption of the duty to warn, provided that the states assumed it, rather than HEW, even though the vaccines were procured with Federal dollars. The manufacturers and their insurers went along with that. It eased their fears of baseless suits. The states, they felt, would rouse less public ire and state laws in many places would discourage suits in general. Best of all, the childhood programs were small-scale compared to swine flu.

Califano thus was able to pursue immediate concerns through spring and summer without facing the hard issues embedded in long-term solutions.

The tort claims legislation of the year before had mandated from HEW a report on alternatives after its expiration. This had been a Rogers interest. The report was expected by his subcommittee. Mindful of that, Cooper had set up in PHS an interagency committee, chaired by Dr. James Cooper, with representation from OGC. When the new regime came in, Cooper proceeded more or less alone. His office served as a convenient place to send the liability report from April's Immunization Conference. Through the next months, Califano's staff and OGC alike assumed that somehow James Cooper was coping. He wasn't. In late July his draft report from the Secretary to Congress reached Rick Cotton of the HEW Executive Secretariat. Cotton considered it unsatisfactory. He sounded an alarm and forced a search for substitutes, turning among others, to McGinnis and to Richard Beattie, Barrett's successor as Deputy General Counsel.

McGinnis thereupon took up the task of getting a respectable report prepared, and pulled together a scratch team to do it. He seized the incoming White House Fellow, Dr. Louise Liang, and he talked one of Beattie's newest lawyers, Linda Donaldson, into "part-time" commitment. Beattie was resistant. Donaldson had been recruited as a general-purpose aide to help with matters of immediate concern to Califano. As Beattie put it to us:

I told her not to let herself get sucked into anything. But she did. I was concerned about her. She was new; it was a new issue to her. And we needed her on other things. I felt that the laboring oar in drafting the report should have been carried by Health. Given Joe's own demands on us we were trying to run a special "law firm for the Secretary," and we only had about six lawyers free for the work. She was supposed to be one of them. . . .

To give the Donaldson-Liang team time, HEW twice asked for extensions of the statutory deadline. Substantively it was worth it. In little more than three months they, with Beattie's help, produced the first thoroughgoing brief on liability, assessing issues and detailing options, that HEW had ever had. In March 1976 it would have been an invaluable guide. In November 1977, Califano felt no need to act precipitately and he had incentives not to. The precedential effects of all alternatives were sobering. The issues were complex. Besides, the Donaldson report led logically toward compensation for the victim of immunization, removing redress from judicial to administrative process. At Justice, the Neil Petersons were sure to snicker: "Uncle Joe and the do-gooders." Califano's instincts pulled both ways. He thus forebore to make a rapid choice among alternatives, agreeing to give Congress in November only an analysis without recommendations. In his words to us:

The issues underlying . . . are very tough. . . . We still haven't enough information on some things. . . . The decisions will be tough. I need time to soak before I make them and take a stand. I know I'll have to do that but I certainly don't want to do it in a rush if I don't have to . . . and I don't unless we have another drastic antigenic shift, or if more manufacturers get out of the business, so we're down to one who's thinking about quitting, something like that.

We think the point well made. But CDCers, NIAIDers and the like have never heard it. The immunologists have frequently found Califano baffling (irritating, infuriating), never more than on this issue. To them he is no phantom, but instead a sort of cross between the "arbitrary" Tzar and the "impenetrable" sphinx.

There the matter rested at the turn of 1978, waiting on events.

A New Immunization Initiative

The reports of the Immunization Conference had implied an enlarged

Federal role in influenza immunization, not on the swine flu scale, except perhaps in an emergency, but larger than before. What was now suggested was Federal money for vaccine and technical assistance in its distribution. At Millar's level in CDC there was a lot of interest (if not active promotion).

CDC lives by a web of intricate relationships between its human cadres of epidemiologists and public health advisers, and the money it dispenses to the states for special projects. Here, in sight, was a new project grant.

But nothing came of those conference reports. They were released in March, 1977. The new Assistant Secretary, Dr. Julius Richmond, did not even take office until four months later. Califano showed no independent interest. McGinnis sat on them.

In the fall of 1977, the concerned CDCers took a new tack—pandemic planning. They joined counterparts in NIAID and BoB to urge on Richmond's deputy, Dr. Joyce Lashof, a working group to think about the coming of the antigenic shift which swine flu wasn't. When she agreed they constituted themselves as such. And when her office asked for a report (a query probably inspired), they drafted one proposing federally supported immunization every year for high-risk groups as the essential feature of pandemic planning. Generously defined and conscientiously pursued, this could bring a quarter of the population annually within the purview of routine delivery systems. With those systems oiled and ready, their expansion to meet a severe pandemic, even another 1918, should be simpler, more predictable and surer than the improvised and often-altered distribution schemes of 1976. Meanwhile CDC itself could weave a stronger web. And influenza immunization would be on the map among established Federal programs, ready for emergency enlargement.

This argument was in draft form by mid-November, 1977. Note that it rested on a chilling afterview, not previously expressed by CDC, of limited state capabilities in 1976. And the capacity of states to learn by doing was asserted, not assessed. That a delivery system for 200 million could expand from 50 million better than from nothing may not be as plain a proposition as it seems. At one extreme is Sabin arguing that nationwide immunization in good time could only be accomplished through locally organized volunteer brigades, prepared in advance. At the opposite extreme is Rockefeller evidently thinking that a dangerous pandemic calls for federalization, or resort to the armed forces. With no close analysis of capabilities, pandemic planning assumed state-run programs.

Planning was overtaken at the end of 1977 by the prospect of a new

pandemic from the Russian flu foreseen for 1978. That form of influenza, exactly like a mild virus last seen in the mid-fifties, had spread from east to west across the Soviet Union and seemed about to spread to Western Europe and America. The prospect was explored in successive *ad hoc* meetings, each open to the press with the third televised; the first in Atlanta, the second in Bethesda, and the third in Califano's conference room. This was *ad hoc*-ery carried to an extreme, but that is a matter of taste. Under Califano, public meetings become status symbols. By the time of the third meeting, January 30, 1978, an inspection team had returned from the Soviet Union and Russian flu had reached the United States. This facilitated a consensus on the likelihood of further outbreaks in this country all during 1978 and into 1979. Russian flu would be competing with and might replace the current strains of Texas and Victoria flu.

Part of the consensus, as reported to the Secretary, was a Federal program funding state procurement for some 30 million doses of trivalent vaccine. This could assure that Russian vaccine (combined with others marketed in 1977) would be available for use in high risk groups.³⁴ If the *states* placed the orders, spokesmen for the manufacturers had said they would fill them without Federal liability legislation, provided the states assumed duty to warn. The states, it was thought, would attract fewer suits. There thus was no Federal procurement. But there would be Federal funding and some technical assistance in the form of a new project grant.

This program, not coincidentally, was a version of pandemic planning tailored to the worsened flu prospects for 1978. The justification became deaths attributed to influenza, focusing attention on the high risk groups. If good for 1978 this would be good in any year, since influenza was a source of deaths in every year. The program contemplated adaptation, year by year, to meet anticipated drifts and shifts of the flu virus. In the present state of knowledge, anticipations could be wrong, there was no help for that. But public understanding might be strengthened in the process and state capabilities as well. If planning for a bad year was not emphasized, neither was it forgotten. As one public health official said to us:

It will take maybe 25 years to get this right, to be wise in the spring about what's going to happen in the fall, but meanwhile lives will certainly be saved, everybody will be gaining valuable experience, and the public will get quite an education on influenza.

So Califano was told January 30. Behind the consensus of his public meeting there lay staff work and advocacy by the erstwhile pandemic planners. Foege, not a rash man, had already sounded out congressional

aides, citing costs of \$15-20 million. The Secretary, in response, questioned the willingness of states to take the funds, procure the vaccine and distribute it, while contracting to warn. A CDC round-up by phone showed two-thirds acquiescent, others possible. Califano also questioned definition of "high risk." He acknowledged those of any age with "chronic medical conditions"—mainly cardiac and respiratory illnesses—and everybody over 65. Age 65 was the conventional base for recognizing a statistical relationship between aging and death from influenza. The relationship starts to show at 50 and the pandemic planners would have liked to label all above that age "high risk." But after pressing senior PHS advisers, Califano got agreement on the higher base. This reduced from 66 to 42 million people those whom HEW defined as at high risk. Of these it expected 20 percent to be reached by existing services, and hoped that Federal grants could bring that up to 40 percent in one year's time, to 60 percent later. These targets translated into dollar costs of \$15 million for the first year, \$20 million for the second and unspecified amounts thereafter.

Satisfied with this, Califano did not try to find the funds internally. Dollar trade-off offends doctors. He didn't like it either. Instead, on February 16, he sent his people to the OMB for a supplemental appropriation. The Administration had changed, but not the government: Zafra, still suspicious, was waiting to receive them. This time Zafra had available to him, alongside OMB in the Executive Office of the President, the Science Adviser's Office (formally the Office of Science and Technology Policy, OSTP), with an assistant director in health-related matters. The latter strengthened Zafra's hand and sharpened budget questions, urging, among other things, that healthy people over 65 need not invariably be presumed high risks.

The OMB examiners thereupon recommended a still smaller program, and they wanted it absorbed without additional appropriations. The issue reached the Budget Director and Califano compromised (on paper). He got a program of his size but funded separately for only its first year; the second year costs were to be absorbed by PHS. This was agreed, Congress willing. OMB examiners assumed that Congress would be only too willing to undo the absorption scheme (trade-offs in public health were no more usual at the top of Capitol Hill than at the bottom). Thereupon the President included \$15 million for the first year in a supplemental appropriation request. It went to Congress February 23.

At the same time, with OMB clearance HEW asked Congress for a permanent authorization. This invoked the Kennedy and Rogers subcommittees. Their response turned out to be more problematical than

the Administration had foreseen. The Rogers subcommittee was insistent on receiving first a version of the liability report for which it had been waiting since the previous September. The Kennedy subcommittee had some members scoffing at a program ". . . from the same folks who brought us swine flu." As we write, neither subcommittee has reported out a bill; appropriations are remote without one.

Still, two years after Sencer's action-memorandum Califano has endorsed a long-term version of the "minimum response" Sencer rejected then. If Congress acts, influenza will have joined rubella, measles, polio, among continuing, accepted, Federal immunization initiatives. This offers a perspective on the swine flu story. At the least it indicates what CDC has learned.

It also shows what influenza specialists have gained. If Congress does not act the endorsement remains and flu is still a part of more agendas than before.