

RETROSPECTIVE REVIEW ESSAY

In the Age of Bioterrorism, an Affair to Remember: The Silver Anniversary of the Swine Flu Epidemic That Never Was

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Richard E. Neustadt and Harvey V. Fineberg (1978). *The Swine Flu Affair: Decision-Making on a Slippery Disease*, with an Introduction by Joseph A. Califano, Jr. Washington, DC: U.S. Department of Health Education and Welfare, ix + 189 pp. Reprinted in a Revised and Expanded Edition: *The Epidemic That Never Was: Policy-Making and the Swine Flu Affair*, with a Foreword by David A. Hamburg. New York: Vintage Books, 1983, xxvi + 293 pp.

Twenty-five years ago, in November 1976, a physician misunderstood a cassette-tape providing continuing education for family practitioners to say that the rare neurological complication called Guillain-Barré syndrome could be a side effect of flu vaccines. When a recently vaccinated patient developed the syndrome, the physician alerted public officials and thereby started the process that ultimately ended the government campaign to immunize all Americans against swine flu. The physician was right, but for the wrong reasons, as Neustadt and Fineberg point out in the introduction to the 1983 edition of their classic case study of the swine flu episode (1983:xxv).

On the basis of confidence by virologists and the U.S. Centers for Disease Control (CDC) in new scientific knowledge, the Ford administration had reacted to the death of

one soldier in Ft. Dix, New Jersey, by deciding to immunize all Americans against swine flu. Because the death occurred in February, late in the flu season, there was just enough time to plan a massive program, manufacture the vaccine, and immunize the population before the beginning of the 1976-1977 flu season. Only the United States chose to immunize its citizens rather than adopting a policy of preparation and watchful waiting. After numerous setbacks in implementing the program, the CDC was belatedly able to initiate mass immunization. However, the outcome was that Americans generally failed to respond to government calls to be vaccinated, unanticipated side effects emerged among a few of those who did receive the injection, and the swine flu did not appear in any human population.

Some might consider the ironic ending to be a fitting metaphor for the entire swine flu affair. But some strong supporters of public health and the individuals involved would contend that the judgment should be reversed: the public health establishment and the U.S. government did what turned out to be the wrong thing for the right reasons when they put the health of the public above other considerations. These voices (e.g., Silverstein, 1981) maintain that the decision to immunize all Americans turned out to be the “wrong thing” only because the planet had the great good fortune that no outbreak of a new flu virus occurred. Risk-averse public health officials remembered the devastating influenza pandemic of 1918-1919. The “killer flu” in those years caused the deaths of some 20 million or more worldwide and 675,000 in the United States, according to Alfred W. Crosby (1989), the leading historian of the pandemic. Its several waves were deadly for young adults 20-40 years old, as well as for the old and young who succumb in more typical influenza epidemics (Pyle, 1986).

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The silver anniversary of these events provides a useful occasion to reread *The Swine Flu Affair*, the brief case study by political scientist Richard Neustadt and physician Harvey Fineberg that was commissioned by Joseph Califano, Jr., incoming President Carter's Secretary of Health, Education, and Welfare (HEW). Neustadt had previously produced a very important book on the presidency (1960) that had made a great impact on the Kennedy administration and led to his involvement in evaluating U.S. policy on the Skybolt missile (Neustadt, 1999). As a young political appointee in McNamara's Pentagon, Califano had read Neustadt's classified Skybolt study; more than a decade later as a cabinet secretary himself, he wanted Neustadt to produce a similar "lessons learned" study of swine flu. Fineberg, a much younger academic who earned an M.D. from Harvard Medical School and a Ph.D. in Public Policy from Harvard's Kennedy School, later served as Dean of the Harvard School of Public Health, and in 1997 became the university's Provost.

What many in 1976 labeled as "the swine flu fiasco,"—the title of a 1976 op-ed piece by acerbic *New York Times* editorial writer Harry Schwartz—can now be recognized as the first manifestation of the complex interactions among biomedical science, preventive medicine, government decision-making, and media that mark current health policy.

In the mid-1970s, concern about swine flu or any acute infectious disease ran counter to the zeitgeist. Infectious diseases, the conventional wisdom went, had been conquered or would shortly succumb to biomedical knowledge. Chronic diseases and the accompanying aging of the population were supposed to generate the problems of the future. An entire theory of aging developed around the elimination of preventable death and the consequent "rectangularization of the survival curve" (Fries, 1980; see also Gruenberg, 1977). The belief that chronic disease would dominate the future was even reflected in Thomas McKeown's *Role of Medicine: Dream, Mirage or Nemesis?* (1979), although he made powerful arguments that infectious diseases had not in the main been tamed by biomedical interventions.

The conventional wisdom even overstated its best case in suggesting that biomedical knowledge suffices to conquer infectious disease. To achieve this utopia, where populations largely live to the limits of supposed natural life spans, will depend upon the application of biomedical knowledge in such practical public health campaigns as the swine flu immunization. The swine flu episode of 1976 showed both that biomedical knowledge was inadequate for the actions taken (viz., the theory was wrong in assessing the risk of further cases) and that the U.S. government was unable to secure compliance of the American people in a seemingly straightforward preventive health program. The U.S. Comptroller General documented the shortcomings in implementing the swine flu program in rich detail in a notable 1977 Report to Congress.

In light of increased concern about bioterrorism emerging from investigations of attacks against the World Trade

Center and the Pentagon in September 2001, infectious disease is clearly back on the national agenda (U.S. General Accounting Office, 2001a). Advances in reverse genetics provide "the knowledge and the tools to assemble [influenza] viruses that are tailored for virulence in the desired host" (Webster, 2001). Studies of government decision-making and implementation during our first effort to head off an epidemic have clear relevance to current debates about protection against potential man-made epidemics. The decline in public health capability in the United States in the second half of the last century has been the focus of a number of media stories (e.g., "Bioterrorism Acquires New Dimension," 2001; Nesmith, 2001; McGinley, 2001; see also Garrett, 2000).

Policy Analysis v. Politics and Administration

The principal underlying theme of the Neustadt and Fineberg volume is that systematic decision-making of the sort advocated by policy analysts would have been more likely to lead the United States to adopt better swine flu policy—to do the right thing for the right reasons. In an understated way, the authors champion the formalized decision-making developed at the Rand Corporation and other think tanks and academic centers in the 1950s and 1960s. The analytical approaches (e.g., planning, programming, budgeting systems [PPBS]) that had made such a splash during the Kennedy and Johnson years were not yet fully incorporated into academic and practical public administration in the mid-1970s (Rivlin, 1971).

Traditions of medical administration were also not sympathetic to probabilistic decision theory. The Assistant Secretary for Health had little use for elaborate planning: he "trusted his capacity to doctor his way through" (Neustadt and Fineberg, 1983:53). The inadequacy of "doctoring through" becomes patently obvious in the Neustadt and Fineberg chronicle. In terms of specific alternatives to mass immunization, Neustadt and Fineberg suggest a policy of producing and stockpiling swine flu vaccine while waiting for evidence of human transmission before starting large-scale immunization.

In urging the value of policy analysis, this swine flu case study differs from studies such as Lawrence D. Brown's book on the federal health maintenance organization (HMO) policy (1983). That volume blames economics-based policy analysis for "the slim accomplishments of the federal HMO effort....A political process as decentralized and multistaged as that in the United States and a policy proposal as fragile and multitermed as the HMO initiative could not be happily united" (1983:475-76).

Arguments for using formal decision theory as *part* of the process of formulating policy gain strength from the fact that three young academics conducted a cost-benefit analysis of the swine flu immunization decision in "real" time (Schoenbaum, McNeil, and Kavet, 1976). The au-

thors pointed out that the entire analysis was completed in four weeks commencing on April 15, 1976, although the *New England Journal of Medicine* did not publish the article until the end of September, just before immunization began. Moreover, the swine flu decision-makers were aware of this study, because many of them agreed to help the authors estimate values for disease variables. Had federal policymakers heeded the findings of this study, they would have pursued very different immunization strategies. Moreover, the rapid execution of this study would have given federal decision-makers sufficient time to change their minds if they had wished to do so.

The argument between policy analysis and politics continues to be relevant to health policymaking. The “political tin ear” of Ira Magaziner, the chief architect of the Clinton health plan, goes hand in hand with his acknowledged mastery of policy nuance and detail, which was exhibited in proposed legislation of almost 2000 pages (Johnson and Broder, 1996). In fact, Magaziner should have taken as advice what might now be read as an epitaph for the failed Clinton health reform:

It might be a useful analytic exercise to ask that policy analysts append to their proposals “political impact statements” gauging the obstacles the proposals are likely to meet as they make their way from theory to program, and the damage the literal theories that support them are likely to sustain in and from the process (Brown, 1983:476).

In contrast to Neustadt and Fineberg’s understated criticisms and explicit disavowal of assigning blame, an interesting new book pulls no punches in faulting both policymaking and program management of the swine flu immunization program (Levin and Sanger, 2000). Its chapter-length case study of the swine flu program, which is based on the Neustadt and Fineberg volume and other published sources, is part of a larger argument that government will mismanage the dissemination of an effective AIDS vaccine when it is developed. The authors’ prediction of the many serious problems that will be generated by an effective AIDS vaccine seems largely to be a repeat of the history of the swine flu immunization program:

We predict a pattern of implementation marked by management problems and delays resulting from many serious conflicts: scientific controversy and competition over the vaccine’s effectiveness and safety; threats of lawsuits over side effects and demands from the manufacturers and developers for indemnification from lawsuits; professional and institutional timidity and conflict among health care providers; tensions between treatment and prevention advocates; tensions over priorities for groups and individuals receiving the vaccine; tensions be-

tween private interests and the public interest; and media sensationalization, especially of rare cases (Levin and Sanger, 2000:vii).

Why Revisit Old Policy?

Several features explain why the swine flu episode deserves to be studied by students of health policy, in addition to its role as a cautionary precedent in current efforts to organize a defense against bioterrorism. Part of the attraction of this very readable case study comes from its brevity: Neustadt and Fineberg tell the story in a mere 103 pages in the original HEW edition (excluding the introduction, “Technical Afterword,” appendices, etc.) The narrative also benefits from the fact that the swine flu episode had a clear beginning and end, unlike the more typical unending health policy issues, such as the annual health budget, cost-containment, and regulation of nursing homes.

Lessons from the swine flu episode continue to be germane to current health policy:

- It was the first time biomedical knowledge promised to give government the power to prevent a potential *pending* catastrophe.
- It marked the advent of liability coverage and other insurance issues as major constraints on health policymaking.
- It illustrated the necessity of developing an effective media strategy to communicate in the new age of television.
- It demonstrated the potential for disaster when responsible officials and stakeholders erect a dichotomy between decision-making that is science- or policy-based versus *mere* political decisions.

The first three of these points marked a departure from the comfortable world before TV became the dominant medium and when medical authority—especially that of public health officials—was largely unquestioned. In that world, public health was primed to *react* quickly to outbreaks of infectious disease or food poisoning, but anticipating a crisis was not considered possible. One only needs to compare the swine flu episode with the orderly way in which the polio vaccine was tested and then given to American children to see how contentious public health policy had become (Paul, 1971; Levin and Sanger, 2000; Institute of Medicine, 2000:23-26, 126).

Indeed, Neustadt and Fineberg emphasize that damage to the credibility of the U.S. Public Health Service (PHS) was one of the major casualties of the swine flu episode. The PHS had been one of few federal components to remain untainted by the Watergate scandals and the Vietnam controversies. Its reputation for unbiased, apolitical scientific expertise was an important, if unrecognized, asset that was squandered by the Centers for Disease Control (CDC).

The swine flu episode itself ended when it became clear in late 1976 or early 1977 that no epidemic would occur in human populations. Yet the swine flu episode led directly to the first efforts to prepare in advance for large-scale immunization to forestall a threatening epidemic (U.S. General Accounting Office, 2000:22). Such efforts continue to this day. Thus, considerable consternation was created in the 2000-2001 flu season by production delays and distribution of vaccine without regard to risk status (U.S. General Accounting Office, 2001b). And after the attacks of September 11, 2001, research and planning to protect against man-made as well as natural biological agents received greater attention in a number of federal departments and agencies (U.S. General Accounting Office, 2001a).

Neustadt and Fineberg concentrated on administrative decision-making in the executive branch. Congress, state-level agencies, and the private sector only entered the story when they became important for a narrative that was written for the edification of the HEW secretary. Without contradicting the story told by Neustadt and Fineberg, award-winning science journalist Laurie Garrett (1995:153-91, 633-37; 2000:365-73, 666-69) has provided a much broader review of the swine flu episode. She incorporates international as well as nonfederal perspectives. Arthur M. Silverstein, M.D., an immunologist at Johns Hopkins Medical School who was on what turned out to be a busman's sabbatical in 1975-1976 as a Congressional Science Fellow on the staff of the Senate Health Subcommittee chaired by Ted Kennedy, supplements *The Swine Flu Affair* with trenchant and thoughtful insights into the congressional actions on swine flu (1981). His book, *Pure Politics and Impure Science: The Swine Flu Affair*, disputes the somewhat negative conclusions of Neustadt and Fineberg.

In addition to *The Swine Flu Affair* and Silverstein's book, a GAO Report to Congress provides a third account of the episode that is based on independent research. *The Swine Flu Program: An Unprecedented Venture In Preventive Medicine* details the shortcomings in implementation (U.S. Comptroller General, 1977). It constitutes the best published source on the liability issue, vaccine regulation, testing and acquisition, and failures in administering the delivery of the vaccine. Together, these three sources provide the basis for most of the material found in other publications relating to the swine flu episode.

Public Health Policy and Scientific Knowledge

Medical advances reducing mortality in flu victims from pneumococcal pneumonia and other secondary infections were available in 1976 and would likely have caused mortality rates in any pandemic to be much lower than the mortality of the 1918-1919 pandemic (Garrett

1995:169). Antiviral drugs that are claimed to be as effective as vaccines both in preventing flu and treating it if administered within 48 hours of the onset of symptoms have become widely available since the swine flu scare. Unlike vaccines that must be specific to particular influenza viruses, antiviral drug therapy is effective against all strains of human influenza. However, federal health officials wish to discourage widespread use of antiviral drugs in an epidemic, because of their side effects and the danger that profligate use will cause drug-resistant viruses to emerge. They do support "targeted" use, which presumably means appropriate therapeutic use (U.S. General Accounting Office, 2000:14-18, 34).

Laver and Garman (2001) argue for stockpiling "huge quantities" of two influenza-specific antiviral drugs that inhibit the enzyme (neuraminidase) which permits the virus to spread throughout the body. These recently developed drugs could be used to suppress an epidemic in a community if made available rapidly. Part of the problem is obtaining quick verification—through the use of accurate diagnostic tests—that influenza rather than other respiratory conditions with similar symptoms is in fact threatening the community. Such diagnostic tests have been developed; results can be available in 20 minutes (Laver and Garman, 2001). In his *Science* "perspective," Webster (2001) concurs with Laver and Garman: "It is gravely disquieting that no action has yet been taken to create strategic stockpiles of such drugs." However, the CDC and the HHS's Office of Emergency Preparedness report that they maintain "12-hour Push Packages" of drugs and other medical supplies that can be delivered anywhere in the United States within 12 hours (U.S. General Accounting Office, 2001a).

Protection against high mortality in an influenza epidemic might be better achieved by attaining the national immunization goals for pneumococcal pneumonia in advance of the epidemic, because subsequent infection by pneumonia is the most common mechanism leading to death. *Healthy People 2010* establishes these goals for the next decade as immunization of 90 percent of the high-risk populations 65 and over and 60 percent of other high-risk populations (U.S. Department of Health and Human Services, 2000:I:14/44-49; U.S. General Accounting Office, 2000). In 1999, immunization levels were thought to be 54 percent of those 65 and older and 13 percent of younger high-risk adults (U.S. General Accounting Office, 2001:21). With immunity that continues for 5 to 10 years, securing such protection against flu-caused mortality in advance is superior to stockpiling vaccines and drugs to be used in an epidemic. Indeed, maintaining high levels of immunization against pneumonia in at-risk populations can be thought of as "stockpiling" protection in the population rather than on warehouse shelves. Such a strategy leaves the CDC free to focus on the logistics of rapid manufacture or stockpiling different flu vaccines

every year and developing adequate stores of antiviral drugs. (The shelf life of antiviral neuraminidase inhibitors is not yet known, but Laver and Garman [2001] speculate that it is about five years.)

Even more promising is the prospect of applying the new DNA vaccine strategy to influenza. An Institute of Medicine (2000:223-31, 381-82) expert committee estimated that development of a generic vaccine capable of immunizing against all strains of human influenza for five years will require only seven years to develop and license and cost \$360 million. This estimate places development of such an influenza vaccine in the most cost-effective category.

Conclusion

Neustadt and Fineberg do include a brief but very comprehensible “Technical Afterword,” but some readers of *Politics and the Life Sciences* are likely to want to know more about the scientific issues surrounding swine flu. *New York Times* science writer Gina Kolata (1999) is the best popular source for a readable synthesis of this information. Knowledge of flu has advanced since the mid-1970s. In particular, questions about the nature of the organism causing the 1918-1919 epidemic have been answered with the mapping of significant portions of its genome (Taubenberger et al., 1997; Pennisi, 1997; Taubenberger, 1998; Reid et al., 1999). This work confirms that the 1918 virus was a form found in swine rather than in birds. However, intriguing questions relating to how it arose, why it was so virulent, and whether it might be associated with a form of encephalitis that also caused death are still unanswered (Kolata, 1999; Gibbs et al., 2001; Pickrell, 2001; Laver and Garman, 2001; Webster, 2001). Webster (2001) speculates that the 1918 virus might be recreated in vitro when the genetic sequencing is completed, but he urges caution in such a study!

These advances in genetic understanding underline the point made above about the Neustadt and Fineberg book's break with the seemingly quaint conventional wisdom of the 1970s, which claimed that the battle against infectious diseases had essentially been won and that future health care would be focused on chronic disease and lifestyle issues. It is eerie to read Neustadt and Fineberg's warning that

influenza may not be the source of the next hard case [of health care policymaking]. Indeed, it almost surely won't be....The flu-ologists have been cooled down. The next hard case is likelier to come from somewhere else and, superficially, seem different. (1978:91)

Only a scant three years later, CDC's *Morbidity and Mortality Weekly Report* published the first paper recogniz-

ing what was later named HIV/AIDS (Gottlieb, 1981). If the swine flu episode was a case of overreaction in the face of infectious disease, HIV/AIDS has been a sorry record of ideological paralysis and federal unwillingness to act effectively (Shilts, 1988; Garrett, 1995).

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