

Federal Vaccine Agency: Critic Fired After Bitter Conflict

J. Anthony Morris, the scientist who triggered an investigation and massive reorganization of the federal government's vaccine regulation programs, was fired for "insubordination and inefficiency," effective 16 July.

The action was taken after lengthy proceedings in which a panel of scientific advisers judged that Morris had demonstrated "incompetence of a high order," but a hearing examiner concluded that Morris's sins were of such minimal seriousness that he should not be fired for them. The hearing examiner's recommendation—which was not followed—was that Morris should merely be suspended for 5 days without pay.

Morris had been serving as director of the slow, latent, and temperate virus section at the Bureau of Biologics in the Food and Drug Administration, the agency charged with regulating the safety and efficacy of vaccines. Over the years, Morris has been a persistent critic of federal vaccine programs. He and his attorney, James S. Turner, a leading consumer advocate, were the key figures in instigating congressional hearings on the management of those programs in the early 1970's. The upshot of those hearings and of an investigation by the General Accounting Office was that the agency responsible for vaccine regulation—then the Division of Biologics Standards in the National Institutes of Health—was transferred to the jurisdiction of the Food and Drug Administration, its management ranks were revamped, and it was rechristened the Bureau of Biologics.

Meanwhile, from a personal point of view, Morris won a favorable verdict in a grievance case in which he claimed that he had been harassed and pressured to leave his job because of his doubts about the efficacy of influenza vaccines. A three-member grievance panel found in 1972 that Morris had indeed been harassed by his superiors over an extended period of time and that the "entire management" of the vaccine agency "should be censured" for allowing the harassment to continue.

In the immediate aftermath of that grievance verdict and the agency's reorganization, there was a period of relative peace between Morris and his superiors, but soon they were battling again

over a host of issues, large and small. Morris has continued to play the critical gadfly role. This year, for example, he has opposed the federal campaign to vaccinate the American public against the "swine flu" on the grounds that influenza vaccines do not work well and that there is little danger of an epidemic. On other issues, he has argued that one proposed vaccine for influenza may cause tumors in mice; that influenza, mumps, and measles vaccines may induce hypersensitivity in guinea pigs; and that the WI-38 cell line used to manufacture live polio vaccine is contaminated.

Thus, the firing of Morris is only the latest episode in a struggle that dates back for at least a decade. Morris's supporters see his dismissal as the culmination of a long line of attempts to harass and silence him for speaking out on important public health issues. But Morris's superiors at the Bureau of Biologics contend that they bent over backward to accommodate Morris until they finally had no choice but to fire him because he was not performing his job well and was disrupting the whole agency by refusing to accept supervision.

In recent months, the anger and hostility between the two camps has been publicly visible. At one well-attended scientific meeting on the swine flu issue, for example, Morris, who often appears abrasive and contentious in argument, asked a seemingly hostile question of Harry Meyer, director of the Bureau of Biologics, and Meyer refused to answer, with a rude comment.

The decision to fire Morris was made by Food and Drug Commissioner Alexander M. Schmidt after lengthy hearings on the case. The proceedings were initiated early last year when Morris filed a grievance alleging that his superiors had again been harassing him, either intentionally or inadvertently, thereby interfering with his research program. Those charges were eventually aired before an "employee appeals examiner" within the Department of Health, Education, and Welfare, the parent department of the Food and Drug Administration. On 20 May 1976 the examiner issued a somewhat murky report that seemed to indicate that Morris had not really proved his charges. In no case was the examiner able to conclude that Morris

had been subjected to harassment, although he did find that Morris's superiors at the Bureau of Biologics were guilty of poor judgment in some instances.

Meanwhile, a parallel proceeding—the one that led to Morris's dismissal—was launched in mid-1975 by Meyer, the Bureau director, who proposed formally that Morris be removed from the federal service for reasons of "insubordination" and "inefficiency." The action was filed after Meyer had received a report highly critical of Morris's work from an advisory committee of outside experts, known as the Panel on Review of Viral Vaccines and Rickettsial Vaccines. The panel was asked to look into some of the questions raised by Morris in his grievance complaint because some of those questions involved scientific and public health issues that did not seem to fit easily into the usual personnel grievance proceeding.

The panel's report, submitted on 27 June 1975 but only recently made public, was remarkably harsh in its judgments and phraseology. It concluded that most of the research projects carried out by Morris were "either not relevant to currently licensed or potential future vaccines [the mission of the Bureau of Biologics] or . . . poorly designed and implemented." Although the panel acknowledged that Morris had "in the past conducted productive and valid scientific studies," it said he "has not advanced his competence in the past 15 years" in crucial areas and is thus unable to pursue certain technologically demanding investigations. The panel expressed "serious reservations" about Morris's choice of animal models for his studies, found that he used "a limited range of techniques," and applied even these with "unacceptable perfunctoriness," and complained that he failed to make up for his own lack of experience by collaborating with other scientists with the requisite skills. The panel also found "no evidence that Dr. Morris has read or knows significantly the literature in his area of interest." As for the actual conduct of experiments, the panel found "serious difficulties" with Morris's understanding of what constitutes a control and it found "incompetence of a high order" in Morris's "repeated failure to randomize test animals." The panel was "especially concerned" about Morris's failure to provide the original records for his experiments, a failure which raised "serious questions" in the panel's mind "as to the representation" of the experimental results.

That was a rather devastating indictment from a group that claims to

"represent, in the aggregate, nationally recognized competence in virology, rickettsiology, immunology, epidemiology, pediatrics, and microbiology."* But Morris contends that the panel was not an appropriate body to review his work because it was dominated by scientists who receive grant support from the Bureau of Biologics or other federal sources and are thus, in his eyes, compromised in their ability to act independently of the Bureau of Biologics management, with whom Morris is at war.

The proposal to remove Morris was heard by a second employee appeals examiner. At issue, in addition to the charges of scientific "inefficiency," were allegations that Morris was guilty of "insubordination" because he failed to attend and participate in meetings as required, to furnish information requested by his supervisors, and to submit protocols. In a report issued on 24 May 1976, the examiner sustained many of the specific charges and rejected the others. On the insubordination issue, for example, he agreed that Morris had willfully refused to give his superior a scientific paper that supposedly supported his position and that Morris had willfully failed to make presentations at two meetings as directed. And on the question of scientific inefficiency, the examiner agreed with

five specific charges about inadequacies in Morris's research, including the failure to keep proper records and to exercise sufficient caution in randomizing and housing mice.

But the examiner, who was not a scientist himself, did not view these transgressions as serious. He found the insubordination, "while in some instances willful, to be generally lacking in malice, and in most instances of minimal seriousness." And he found the scientific inadequacies "to be less substantial even than the reasons related to insubordination. Many are only marginally supported by the evidence and are sustained to a large degree solely on the basis of overwhelming peer opinions rather than conclusive hard (best) evidence of inefficiency." As a result, the examiner concluded that the proposed removal was "excessively severe"; he recommended downgrading the punishment to "a suspension of 5 days without pay."

But Food and Drug Commissioner Schmidt saw the matter differently. In a letter to Morris dated 12 July, he said that those charges which had been sustained by the examiner were ample reason to dismiss Morris. "I cannot agree," he wrote, "... to the characterization of the sustained charges of insubordination as being 'of minimal seriousness.' On the contrary, the kind of behavior exhibited by you toward your scientific colleagues and administrative superiors directly challenges the integrity of scientific progress and the ability of the Food and Drug Administration to carry out its mission." Noting that peer re-

view at scientific conferences is one of the principal quality control mechanisms in science, Schmidt added: "The sustained charges of insubordination amply document your blatant disregard for the required participation in scientific conferences and, indeed, your direct disobedience of your immediate supervisor. In such circumstances, there can be no effective quality control of your research program."

Schmidt went on to "most emphatically disagree" with the examiner's contention that Morris's scientific inadequacies were insubstantial. Noting that failure to observe the "rules of good science" can render an entire study useless, Schmidt admonished Morris: "The sustained reasons for your inefficiency include violations of many, if not most, of these elemental rules, including poor experimental design, improper selection and randomization of test animals, poorly controlled experiments or no controls, poorly kept or nonexistent records, and inadequate measuring techniques. In some instances, these flaws were such as to render the experimental results, not to mention the original experimental purpose, meaningless to your scientific peers."

As a result of the sustained charges, Schmidt removed Morris from his position on 16 July. At this writing, Morris is pondering whether to exercise his rights to appeal or take some other step. But he vows never to give up his fight to influence federal vaccine policies along lines that he believes necessary to protect the public health.—PHILIP M. BOFFEY

*Members of the panel who prepared the report included Saul Krugman, New York University School of Medicine (chairman); John P. Fox, University of Washington; William S. Jordan, Jr., University of Kentucky College of Medicine; Edwin H. Lennette, California State Department of Health; Kenneth McIntosh, University of Colorado Medical Center; June Osborn, University of Wisconsin Medical School; and Wade P. Parks, National Cancer Institute.

Venoms: Extracting Healing from the Serpent's Tooth

Jack Kilmon was standing around his lab in Baltimore talking about snakes when from the corner of his eye he saw something moving outside. He trotted down the hall, out the open door, and onto the parking lot, a distance of about 40 yards. An intruder? No, a 3-inch-long fuzzy caterpillar. Kilmon is an alert character, and alert is what he very much needs to be in his line of work, which involves daily handling of hundreds of venomous snakes as well as scorpions, black widow spiders, toads—in short, any beast that's poisonous.

Kilmon, 35, has always loved reptiles, particularly snakes, and he has parlayed this devotion into a rapidly growing business which involves the extraction, processing, and sale of venoms to medical researchers around the world. He claims to be the leading producer of venoms in the country, which is probably true since he only has one serious competitor, the Miami Serpentarium. The 12-year-old company, Biologicals Unlimited, is run by Kilmon, his wife, his best friend, and a 19-year-old herpetology student. His menagerie includes anywhere from 500

to 2000 cobras, vipers, and pit vipers (the three families of poisonous snakes), and sundry other creatures including five electric eels (their electric organs are sold for isolation of acetylcholine) and an alligator named Clyde who launches into a terrifying heavy breathing routine whenever anyone approaches the metal bathtub in which he resides. Clyde, who is there mainly for educational purposes (Kilmon gives tours to Boy Scouts and other groups) serves as the house garbage disposal and crematorium—when ever one of the other residents "croaks," as Kilmon puts it, it is delivered after autopsy to the alligator.

As for the venoms: they are becoming rather big in biomedical research, explains Kilmon, owing to rapid advances in molecular biology. Now that researchers are getting close to finding out what happens in nerve transmission, the many enzymes contained in snake venom are