adapt to that process. For U.S. policy, especially in scientific and technological education, these recommendations would require the Office of Education and the National Science Foundation to develop joint plans for long-term development. The information systems stimulated by the National Science Foundation have heretofore focused primarily on the needs of research specialists; greater attention should be paid to the life-long educational process of nonspecialists. The network of educational resource information centers sponsored by the Office of Education is an increasingly important mechanism for getting appropriate information collected, digested, interpreted, and placed into the hands of a variety of users. An extension of this concept, as needed, would be consistent with the recommendations and the spirit of the OECD report.

Finally, the last two recommendations of the OECD ad hoc group deal with international cooperation. They urge increased and strengthened international cooperation, pointing out that reliance upon national self-sufficiency has never been a realistic policy. The United States, while still the single largest contributor to the world's new knowledge, is seeing its relative contribution shrink steadily. In most fields of science and technology, the U.S. contribution is now from 20 to 30 percent of the total, down from 25 to 50 percent several years ago. We can no longer assume, as many U.S. scientists and engineers have up to now, that any paper worth reading will appear in the English language. The situation calls for more vigorous development of the information analysis center concept, relying upon such centers to collect relevant literature from the entire world's output, index it, store, evaluate, and condense it into reports on the state of the art, critical reviews, and compilations of data. The smaller nations, especially those whose mother tongue is not a major world language, must take special care to ensure that they have access to that portion of the world's information that they need, taking into account the importance of concentrating their R & D programs on a limited number of technical areas in which they can hope to make a contribution.

We do not claim to have done full justice in this article to the series of conclusions and recommendations produced by the OECD committee. They are worthy of serious consideration by all those governmental and nongovernmental officials concerned with policy decisions on science and technology and with the effective use of the world's greatest natural resource—information.

References and Notes

1. *Information for a Changing Society* (Organization for Economic Cooperation and Development, Paris, France, 1971. Available from OECD Publications Center, 1750 Pennsylvania Avenue NW, Washington, D.C.)
2. Members were Pierre Piganiol (France), S. Balke (Germany), L. M. Branscomb (United States), S. Hamada (Japan), H. T. Hookway (United Kingdom), B. V. Tell (Sweden), and J. R. Whitehead (Canada).

NEWS AND COMMENT

Division of Biologics Standards: Scientific Management Questioned

"The Division of Biologics Standards should be in the forefront of efforts to present the public with the best and most effective and safest vaccines possible. Unfortunately the Division is not in the forefront. Rather it lags so far behind as to be jeopardizing the very concept of vaccine therapy by its scientific mismanagement. The following events suggest a major breakdown in the scientific integrity of the DBS. . . ."

So runs the preamble to a menacing dossier of charges drawn up against the government agency responsible for vaccine regulation by J. Anthony Morris, a DBS research scientist, and James S. Turner, an attorney and former consultant to Ralph Nader's Center for the Study of Responsive Law. The importance of the charges is that they have set in motion thorough investigations of the DBS's affairs by Congress and by the National Institutes of Health, of which the DBS is a part. The precise merit of the Morris-Turner indictment is harder to assess, and the DBS management should be regarded as innocent of the specific charges until and unless the various studies in progress show otherwise.

The charges and the response to them are part of an involved and continuing campaign waged by Morris and Turner against both the DBS and the front office on the NIH campus. The opening round of the campaign was a Civil Service grievance proceeding held early last year, in which Morris, ably represented by Turner, claimed he had been harassed by the DBS management (*Science*, 25 February 1972, page 861). The grievance committee upheld Morris's claim and round one went decisively to Morris and Turner. NIH Director Robert Q. Marston accepted the grievance committee's finding that Morris had been harassed and ordered facilities for scientific work to be restored to him. Marston rejected the committee's recommendation that the DBS management be censured, but he appointed in August last year a group of NIH management consultants to review the administrative affairs of the DBS. (Headed by an NIH management specialist, James W. Schriver, the group's report is still in draft form and has not yet been released by the NIH.)

The second round of the campaign was initiated when Morris and Turner indicted scientific management in the DBS in a document that was delivered simultaneously to Marston and Senator Abraham Ribicoff (D–Conn.) on 27 September last year. When Ribicoff read the document into the *Congressional Record* 3 weeks later, NIH had lost the opportunity of conducting a deliberate in-house review of the charges; instead, Marston appointed a committee of outside academic experts to make an urgent study of the Morris-Turner indictment. Chaired by Abram S. Benenson, professor of medicine at the University of Kentucky, the committee reported on 9 November that, save for a few minor irregularities of no relevance to the public health, it could confirm none of the specific charges raised by Morris and Turner. Round two to the NIH, but by 6 December, within a week of seeing the Benenson report, Morris and Turner had prepared a detailed re-

buttal in which they argued that the report "either sidesteps, corroborates or expands the seriousness of the situation described in our [original] memorandum."

Neither the NIH nor the DBS has commented publicly on the Morris-Turner rebuttal, and DBS Director Roderick Murray is reserving his defense for the hearings that will be held shortly by Ribicoff's subcommittee. The merit of the 12 specific charges raised by Morris and Turner is the harder to evaluate because neither side has played a completely straight hand. The original Morris-Turner document, for example, contains several serious implications that go some way beyond the facts presented. When the Benenson committee tried to answer the implications, it was slapped down in the Morris-Turner rebuttal for having ignored the facts and answered charges of its own invention. On the other hand, the Benenson committee, although instructed by Marston to make a completely objective review, came up with a document that reads more like a partisan defense of the DBS.

The Benenson committee met only twice, relied almost exclusively on information supplied by the DBS management, and, apart from two telephone calls made by the chairman, interviewed no witnesses. More than half of the 11 members of the Benenson committee are present or past members of the DBS's board of scientific counselors. But despite this familiarity with the division's affairs, the committee's self-imposed handicaps made difficult a complete and impartial review of the 12 charges with their 200-odd pages of supporting documents. In fact, the committee worked in such a hurry that the final report was signed only by the chairman, who stated that the other members had indicated to him by telephone that they "approved in principle" of the report. Despite their approval in principle, some members still have certain reservations about the report. For example, Paul S. Moorhead of the University of Pennsylvania School of Medicine believes that, although in general terms the DBS has done a "fairly good job," some of the Morris-Turner charges "might actually be true but they are not well documented." Benenson turned the heat on the committee, and at first some members "felt it was their duty to defend the DBS." But in view of the shortness of the committee's meetings, Moorhead was "surprised at how good the final report was."

Another committee member, S. P. Masouredis of the University of California at San Diego, notes that "the committee was obviously under the shadow that it would have been a disservice to shatter the public's confidence in the DBS. But on the basis of the information provided to the committee, I would not reverse my signature on that report at this time."

Pattern of Insensitivity

The common theme of the Morris-Turner charges is that in numerous instances, amounting to a "pattern of administrative insensitivity," the DBS management has suppressed or ignored scientific findings that would adversely affect the vaccine market. The motive for this alleged behavior is ascribed at one place in the Morris-Turner memorandum to a "passionate commitment to vaccine therapy" on the part of the DBS leadership. The 12 charges concern a hodgepodge of incidents ranging from 1954 to the present, several of which were the subject of evidence given in Morris's grievance hearing. The relevance of delving so far back into history is that the DBS has been under the directorship of one man, Roderick Murray, since 1955. The salient issues raised are as follows.

The early polio vaccines. The first polio vaccine, marketed in 1955, consisted of polio virus killed by treatment with formaldehyde. The treatment was not wholly effective, and the live virus that escaped caused nearly 200 cases of paralytic polio. Bernice Eddy, the polio control officer in the Laboratory of Biologics Control (as the DBS was then known), had in fact detected live polio virus in certain vaccine lots in November 1954, but her findings did not lead to discovery of the true cause of the problem, which was corrected only after the first outbreaks of polio in April 1955. Morris and Turner claim that "if Eddy's information had been heeded when it was discovered," the disaster could have been avoided.

To this the Benenson committee replied, in essence, that, since the DBS was created precisely because of the polio disaster, it was unfair to blame the DBS for the incident.

The reorganization of the Laboratory of Biologics Standards into the DBS was a change in name only, the Morris-Turner rebuttal argues, and the assistant chief of the laboratory became the current director of the DBS.

In summary, the crucial issue is whether or not the expert committees advising on polio were informed by the Laboratory's management of Eddy's findings. On the basis of summaries of the discussions of the expert committees during 1954 and 1955, Morris and Turner claim that the expert committees were apparently not informed by the Laboratory's management of Eddy's November 1954 findings. Even if the committees were informed, it seems clear that they and the Laboratory's management failed to make the correct deductions from Eddy's finding of live polio virus.

Although the Benenson committee argues that the DBS cannot be held responsible for the polio disaster, the committee nevertheless makes a point of stating that all the decisions on the polio vaccine were "arrived at with the assistance of the best experts available and the mistakes reflect deficiencies in the state of the art at the time rather than conscious suppression or neglect of available data." Another verdict on the polio episode is this: "Investigation by various workers [in the 2 years following the incident] revealed the limitations of formaldehyde as a disinfectant in the presence of protein. This was largely a rediscovery of what was already known but had been overlooked or forgotten." *

SV40 virus in polio and adenovirus vaccines. The next and only serious vaccine crisis that has occurred since the polio episode was the realization in mid-1961 that a monkey virus later shown to cause tumors in hamsters was contaminating both polio and adenovirus vaccines. The virus, known as SV40, was entering the vaccines and, just as in the polio case, was surviving the formalin treatment. (Large numbers of people were presumably injected with live SV40 virus, but so far it appears that man is not one of the species in which SV40 is tumorigenic.)

There were several stages by which the full extent of the SV40 problem became known. First was the discovery in 1959–1960 by a DBS scientist, once again Bernice Eddy, that an unknown agent in the monkey kidney cells used to produce polio and adenovirus vaccines would cause tumors when the cells were injected into hamsters. In September 1960, Maurice R. Hilleman, a scientist with the vaccine manufacturer Merck Sharp and Dohme, discovered in monkey kidney cells a new virus that he named simian virus 40, or SV40; the virus, he reported, "is effectively dealt with in killed virus vaccines

* G. S. Wilson, *The Hazards of Immunization* (Athlone Press, London, 1967), p. 46.

by virtue of its susceptibility to formalin."

By July 1961, Eddy had proved that the tumorigenic agent in monkey kidney cells and Hilleman's SV40 virus were one and the same. Morris and Turner, in essence, criticize the DBS's handling of the episode on two counts. First, they document the fact that, in both steps of her discovery, Eddy faced severe and probably excessive criticism of her manuscripts from her supervisor Joseph E. Smadel. However it is not clear that Smadel's obstruction of Eddy's findings made any difference to regulatory action, since this was spurred in April 1961 by an altogether separate event, the discovery of live SV40 in certain polio vaccines and the finding by another DBS scientist, Paul Gerber, that, contrary to Hilleman's claim, SV40 is not completely inactivated by formaldehyde.

Based on these observations, the DBS promptly ordered manufacturers to screen their finished polio and adenovirus vaccines for SV40. According to NIH officials, no vaccine containing live SV40 was released after April 1961. Morris and Turner claim, however, that adenovirus cannot be grown in monkey kidney cells in the absence of SV40 and that, therefore, all adenovirus vaccines must have been contaminated with SV40 up until August 1964 (when, for other reasons, adenovirus vaccines were discontinued). There is no direct evidence to support this claim.

In summary, Morris and Turner prove their first point, that Eddy was harshly treated by her supervisor, but their second point remains unresolved. It is not clear that the two issues in themselves add up to a deliberate suppression of data by the DBS management.

Assessment of the potency of influenza vaccine. The third charge in the Morris-Turner indictment concerns the fact that there exist two tests to measure the strength of influenza vaccine, neither of which is satisfactory. The first is a physical test known as the chicken cell agglutinating (CCA) test, and the second is a biological assay known as the mouse potency test. In 1960 Eddy, once again, obtained results indicating that the CCA test was inaccurate, but her supervisor, Smadel, refused her permission to discuss her results publicly. From 1960 to 1966, during which period Morris was influenza control officer, the DBS certified the potency of influenza vaccines on the basis of the mouse potency test; in 1967 all potency tests were suspended; and in 1968 the CCA test was instated as the required test. During the Morris grievance hearing it emerged that the present influenza control officer, Nicola M. Tauraso, believed that up until 1968 the manufacturers had been submitting, and the DBS certifying vaccines of less and less potency.

Morris and Turner charge that, from 1960 on, the DBS failed to clear up the confusion surrounding the testing of influenza potency, an accusation that the Benenson committee answers by saying that the deficiencies of the CCA test have now been corrected. The Morris-Turner indictment also quotes correspondence between the DBS and the manufacturers, which "suggests that the DBS is more willing to respond to the probing of the industry it regulates than the scientists in its own laboratories."

Misbranded Vaccines

The point at issue concerns the preparation of a new reference lot of influenza vaccine in 1965. Because of the new lot's discrepancy with the previous reference lot, the DBS instructed manufacturers to assign a value more than double the true value to the new reference. According to the Morris-Turner indictment: "This meant that the labeled value of the potency of the vaccine would remain high (900 CCA units/ml) even though everyone recognized that the actual value, as nearly as could be determined by DBS laboratories, was much lower (317 CCA units/ml). This raises the question of why vaccines labeled in this way should not be considered misbranded under the Food, Drug and Cosmetic Act."

The value of the new reference lot was later adjusted downward after consultation with the manufacturers. A letter of 10 December 1965 from DBS Assistant Director John C. Wagner to the chairman of the Pharmaceutical Manufacturers Viral Study Group says: "We will begin by asking the question, are the manufacturers satisfied with the CCA value that is currently assigned to [the new reference lot]? If yes, we will continue to use this value. On the other hand, if the answer is no, then we must begin immediately to collect data upon which a new value can be established."

The Benenson committee's comment is that these negotiations represented not an accommodation to the manufacturers, but simply a "readjustment of arbitrary standards at a time when the standards themselves were under intensive scrutiny and revision."

In summary, the Morris-Turner memorandum would seem to substantiate the charge that DBS's methods for assessing the potency of influenza vaccine were subject to confusion over a considerable period of time. NIH officials point out that for a large part of this time Morris was the DBS scientist responsible for influenza testing; Morris, however, claims that he tried to improve the testing of influenza potency as far as he was able to do so under the conditions imposed by the DBS management. One verdict is that of C. W. Hiatt, a former DBS scientist who collaborated with Morris in assessing the CCA test. Hiatt, now at the University of Texas medical school in San Antonio, told *Science*: "The Morris-Turner statements on the flu vaccine tests were, for the most part, technically correct, but I objected to the general tone of their comments. It came out very accusative, but in fact much of the confusion arose from the uncertainty and technical difficulties at the time."

Virus-like particles in duck eggs. This incident concerned the discovery in 1969 of virus-like particles in duck eggs (used for the production of rubella vaccine) by both a DBS scientist and a research institute under contract to the DBS. The Morris-Turner indictment says that the DBS investigator "was told to abandon his studies of the particles because they were 'biologically inactive,' " and the $100,000 contract of the research institute was not renewed because its work was judged by the DBS management to be of poor quality.

The Benenson committee, because of its decision not to communicate with Morris and Turner, managed to fasten upon a quite separate incident in which another DBS scientist had sighted viral particles in duck eggs. The committee demolished that incident quite skillfully, but left unanswered the incident referred to by Morris and Turner.

Tests for avian leukosis virus in chicken eggs. The DBS requires live vaccines grown in eggs to be tested for the presence of a group of viruses, known as the avian leukosis complex, which cause leukemia in chickens. Morris and Turner state that the DBS accepts as satisfactory a procedure by Dow Chemical Company, a manufacturer of measles vaccine, which detects only a few of the viruses in the complex. "This major fault in the test system was brought to the attention of DBS administrators by [DBS scientist]

C. G. Aulisio in 1967 . . . but no action was taken to correct the deficiency then or since." Aulisio was told he could not seek collaborative help within or outside the DBS to evaluate the problem, the Morris-Turner indictment states.

The Benenson committee agrees that the test in question would not detect all the viruses concerned and admits that one lot of measles vaccine was passed by the DBS on the basis of this inadequate test. This, says the committee, was an "improper deviation from the published requirements."

Discouragement by the DBS management of important scientific work. The principal and most serious charge of the Morris-Turner indictment is that the DBS has deliberately discouraged research by DBS scientists which would adversely affect vaccines. This charge is documented by reference to three individual scientists—Eddy, Morris, and Aulisio. The indictment suggests that other scientists have left the DBS because they lost support after taking positions that were not in favor with the DBS leadership.

Aulisio is the DBS scientist who Morris and Turner say was ordered to abandon his study of virus-like particles in duck eggs. Morris was relieved of his duties as influenza control officer in 1966, 2 days after he had informed DBS director Murray of the results of a field trial indicating that influenza vaccine was inefficacious. From then on, Morris's support was progressively whittled away by his supervisors, one of whom even ordered the destruction of some 5000 mice being held on long-term influenza and scrapie virus studies. A Civil Service grievance committee upheld Morris's claim that he had been harassed by the DBS management but made no finding on Morris's imputation of the DBS's motive in so treating him. (The DBS management claimed Morris's support had been removed because of his failure to communicate with his supervisors.)

The third instance, that of Bernice Eddy, is perhaps the most anomalous of the three. The harassment of Eddy at the time of the SV40 affair by her supervisor Smadel went to such lengths that a colleague, Lawrence Kilham, now at the Dartmouth Medical School in Hanover, New Hampshire, protested to the office of the Surgeon General. In a letter of 13 June 1961, Kilham wrote: "[Eddy's] work is more outstanding than that of any scientist in the DBS today and yet the proposition is to take away many facilities and trained personnel which she needs and at the crucial point when her main research is reaching fruition. . . . Many scientists at the NIH are extremely dissatisfied with the conditions that prevail. A true intellectual atmosphere is practically nonexistent."

The record of Eddy's treatment by the DBS management provides one of the stronger items of evidence in support of the Morris-Turner thesis. In 1954 Eddy, as polio control officer, found live virus in supposedly killed polio vaccine; in 1955 she was relieved of her duties as polio control officer. In 1960 Eddy, as influenza control officer, remarked on the inaccuracy of the CCA test for assessing influenza vaccine and was removed from the control duties on the vaccine, with which she had worked for the past 16 years. After her discoveries concerning the SV40 virus, her staff and animal space were reduced and she was demoted from head of a section to head of a unit. Eddy's supervisor during this time was Smadel, who died in 1963, but many of the memoranda of the period pass through or emanate from the present director of the DBS.

The Benenson committee, in effect, sidesteps this charge by saying that the personnel problems of the DBS fall within the purview of another group, the Schriver committee, which was appointed by Marston to examine the administrative affairs of the DBS. Nevertheless, the Benenson report assents to the important point that "such interpersonal difficulties must interfere with the effectiveness of the overall program."

The significance of the Benenson committee report was that it at least showed the existence of another side to some of the questions raised by Morris and Turner. But the committee seems to have believed that the weight of its collective authority would in part substitute for facts in denouncing the conclusions of the Morris-Turner indictment. Geoffrey Edsall, of the Massachusetts Department of Public Health, a member of the DBS board of scientific counselors, wrote to Senator Ribicoff on 26 January this year: "I am deeply concerned that you are willing to place your faith in three relatively unknown scientists and a young lawyer, and yet to apply the term 'whitewash' to the considered judgment and evaluation of the eleven able and distinguished scientists—professors, a Dean and a Nobel Prize winner—who conducted the formal review of the Morris-Turner charges."

Professors and deans, however, do not hold a monopoly on truth and the Morris-Turner indictment would seem at the least to substantiate that serious personnel problems have afflicted DBS scientists over a long period and that there was a lack of evident aggressiveness on the part of the DBS management in resolving scientific issues such as the testing of influenza potency. (Management of research in the DBS will be considered in a future article.) Whether or not the DBS management has deliberately discouraged research relevant to vaccine control is a harder issue to assess. But Morris and Turner at the least have done no harm to the public interest in asking that this and other issues at the DBS be looked into.

—NICHOLAS WADE

Office of Technology Assessment: Congress Smiles, Scientists Wince

In what can only be regarded as a minor miracle of legislative revival from the dead, the House of Representatives on 8 February approved former Congressman Emilio Q. Daddario's 1967 plan for an Office of Technology Assessment (OTA) for Congress.

The sudden introduction of the measure, the swift, hour-long debate, and the substantial (256 to 118) vote in favor of the bill was a revelation that technology assessment has been in recent years not dead but only sleeping. The legislative Lazarus is scheduled for immediate (2 March) hearings in the Senate, and floor debate and vote is likely to occur soon thereafter. But many high priests of science, with a bow to their old pal Daddario, are highly skeptical of the measure.