Academy Food Committees: New Criticism of Industry Ties

The National Academy of Sciences (NAS), whose scientific advisory panels have been criticized on more than one occasion lately for a seeming alliance with industry, took another sharp rap on the knuckles last week from a new critic, Senator Charles H. Percy (R–Ill.). In Senate hearings, Percy said the academy had been "insensitive" to conflicts of interest among the scientists it picked to advise the government on such controversial subjects as the safety of food additives. And he suggested that the NAS would do well to follow the example of the American Bar Association, whose code of ethics forbids judges from hearing cases involving parties to whom they have financial or personal ties.

Percy's criticism came during 3 days of hearings on food additive legislation, which were held last week by the Select Committee on Nutrition and Human Needs. His remarks were prompted by disclosures that two of seven scientists appointed by the NAS in 1970 to investigate possible hazards of monosodium glutamate (MSG) had received research funds from major users and manufacturers of the widely used "flavor enhancer." In addition, witnesses told the committee that two other members of the MSG panel were employed at the time by major chemical companies. And on top of this, a fifth member of the NAS panel showed up at the same Senate hearing to testify in behalf of the Grocery Manufacturers of America, a lobbying organization that opposes stricter regulation of food additives.

The MSG study panel's financial ties to the food industry emerged from testimony by James W. Olney, an associate professor of psychiatry and a neurophysiologist at the Washington University Medical School in St. Louis. In 1969, Olney's own published research on MSG reported that massive subcutaneous doses of the additive had caused visible brain lesions in infant mice, rats, and one newborn monkey.

Partly as a result of Olney's work, the Food and Drug Administration in 1970 asked the NAS to organize a special study panel to determine whether MSG ought to be banned from baby food. The seven-man panel, headed by Lloyd J. Filer, Jr., a professor of pediatrics at the University of Iowa Medical School, began its work early in 1970 and handed in its 42-page final report that July. The panel concluded that animal studies and observations of human MSG eaters "confirmed the high degree of safety" of the additive. The panel did recommend that MSG be removed from baby food —a decision already made voluntarily by manufacturers—on the ground that, while MSG posed only an "extremely small risk," it also conferred no benefits. But the panel advised the FDA not to restrict supermarket sales of packaged MSG.

Last week, Olney charged that the panel's report smacked of an "industry-arranged whitewash" by a group of scientists with almost no experience in neuropathology. Olney said a reading of the report, and his experience with the panel, suggested that it had based its conclusions largely on what seemed to be negative evidence hastily produced by small laboratories dependent for their livelihood on—and therefore sympathetic to—the food and drug industries.

"Those who were unable to confirm the findings [of neurological damage in infant animals] turned out to be almost exclusively from a certain element of the scientific community . . . who maintain close ties to the food and drug industries," Olney said. "Some members of the team specialize in generating made-to-order evidence, while others are asked by FDA through the NAS to evaluate the evidence."

In his prepared testimony, Olney refrained from mentioning names. But, under questioning by the Senate committee, he let it drop that during the summer of 1970, Filer, the chairman of the MSG committee, had taken part in research on MSG supported partly by Gerber Products, Inc., a leading baby food manufacturer, and partly by the International Mineral and Chemical Corporation, which, at the time, produced most of the nation's monosodium glutamate.

In addition, Olney said, George M. Owen, a researcher in pediatric nutrition at Children's Hospital in Columbus, Ohio, had also been supported by Gerber not long before his appointment to the MSG panel. Two other members were employed by the toxicological units of major chemical companies, although their work had no obvious connection with MSG; one was John A. Zapp, Jr., of DuPont in Wilmington, Delaware, and the other was Virgil B. Robinson, a veterinary researcher with Dow Chemical Company in Zionsville, Indiana. Robinson is currently a member of the academy's Committee on Food Protection, which is a principal target of critics who allege industry bias on the part of the NAS.

A fifth panel member with a prior and conceivably vested interest in monosodium glutamate was Lloyd W. Hazelton, the founder of a research and testing laboratory in Falls Church, Virginia, that, on occasion, has performed animal studies of MSG under contract to International Mineral and Chemical.

Filer, who is currently chairman of the academy's Food and Nutrition Board, could not be reached for comment. It was subsequently learned, however, that he and three co-workers had obtained grants and equipment worth about $5000 from Gerber and International Mineral for feeding studies of MSG as early as April or May of 1970 —3 months after Filer's appointment as chairman of the MSG panel, but more than 2 months before the panel released its report. During that summer, some new data from this study was hurriedly relayed to the NAS panel before the FDA received its report. The following June, Filer and his three coworkers published a paper describing their work and reporting that they could find no evidence that massive oral doses of MSG had caused brain lesions in the infant monkeys at their disposal. They suggested that earlier reports to the contrary, Olney's among them, may have been based on improperly prepared tissue specimens.

Interestingly enough, however, at least one of Filer's co-authors now thinks these conclusions may have been in error—that they somehow missed seeing microscopic brain lesions in their monkeys after all. One coauthor, who asked not to be identified, also conceded in a telephone interview that the use of industry money under

World Ethics Body Proposed

A United Nations group concerned with medical sciences has recommended the creation of an international, nongovernmental body to explore the moral and social issues raised by new and forthcoming developments in biology and medicine.

The Council for International Organizations of Medical Sciences (CIOMS), an offspring of the World Health Organization (WHO) and Unesco, passed the resolution at a Round Table Conference held in Paris early this month.

The proposed body would be a step toward recognizing and attempting to cope with—on an international basis—pressing ethical problems relating to abortion, prolongation of life, utilization of scarce medical resources, and priorities in medical research and technology.

Amitai Etzioni, director of the Center for Policy Studies in New York, says the new body would be made up of equal parts biologists and medical people, humanists and social scientists, and theologians.

A typical question the organization might ponder, says Etzioni, is the circumstances under which amniocentesis (drawing fluid out of the womb to determine whether the fetus has a genetic disorder) should be performed. The organization might lay down the principle that all pregnant women over age 40 (when the chances of bearing a Mongoloid child are high) should be told—in countries where abortion is legal—that amniocentesis is advisable. There might also be guidelines to prevent a woman who wanted a child of a certain sex from using the procedure with the intention of getting an abortion if the sex didn't suit her.

The commission might also influence policy-makers in determining biomedical research priorities. A country might not be so quick to support research on in vitro fertilization of eggs or technology leading to a new life-prolonging device if it were advised by a prestigious international body of the dangerous ramifications and new ethical dilemmas such research would open up.

The commission would have only its prestige to lend force to its guidance, but Etzioni thinks its existence would encourage governments to sponsor similar efforts on a national basis. At present, many private groups, particularly in England and the United States, are attempting to foster interdisciplinary studies of ethics in science and medicine. But only in the United States, where technology assessment is further advanced than it is anywhere else, are serious efforts being made to make bioethics a national concern. Last December, the Senate passed a bill to create a 2-year National Advisory Commission on Health Science and Society. The commission would be given $2 million to contract out studies and make recommendations on the advisability of creating a permanent national body of some sort. But even this relatively small investment may not be made soon—the bill is now bottled up in the House health subcommittee, chaired by Representative Paul Rogers (D–Fla.), from whence it is unlikely to emerge this year. This means the Senate will have to start over again next year.

An international commission has even darker chances of becoming a reality in the near future. The president of CIOMS, Alfred Gellhorn of the University of Pennsylvania Medical School, says outside financial support would have to be found because WHO and Unesco would not want to be associated with a group that would inevitably be grappling with some inflammatory political and social questions.

CIOMS is a nongovernmental organization created in 1949 by grants from WHO and Unesco. Its membership includes 50 or so international medical and scientific societies and 17 national members, such as the U.S. National Academy of Sciences. Its initial charge was to reestablish war-torn communications in the world scientific community; now it has turned its attention to interdisciplinary conferences for the purpose of discussing sensitive topics such as heart transplants and human experimentation.—CONSTANCE HOLDEN

the circumstances "looked like hell." Filer's colleague, however, was nevertheless quick to insist that Filer was a man of great integrity who had "never, *never* asked us to color or manipulate data."

As for Olney, the scientist said, "He's a very reputable researcher, although he's getting a bit paranoid about all this. Still, he's right in saying that a lot of people doing nutritional research have a vested interest in the food and drug industries."

George Owen, for his part, readily admits that he received research funds not only from Gerber but from Wyeth Laboratories (also a manufacturer of baby food). He says the grants preceded his appointment to the MSG panel by about a year, but that the work they supported had nothing to do with this particular additive. He too expressed dismay that anyone could think that "Jack Filer was in someone's pocket." He said that while he had been associated with Filer at the University of Iowa, companies like Gerber, Wyeth, and Mead Johnson & Co. had been generous in their support of pediatric research, but the money had always been given and accepted on the understanding that data would be reported factually.

At first, Olney's allegations met with something approaching disbelief by the Senate committee, partly because not all the details of the academy panel's financial connections were immediately available. Senator Percy, for one, observed skeptically that Olney seemed to imply "collusion" between industry and a scientific body that was "beyond reproach."

That was on Tuesday, 19 September. On Wednesday, the committee grew more reproachful as other witnesses tended to corroborate what Olney had said, if only in a general way.

First came Samuel S. Epstein, a professor of environmental health at Case Western Reserve University and an outspoken advocate of stronger controls on food additives, drugs, and pesticides. Epstein contended that "close identification of the NAS-NRC Food Protection Committee with industrial interests makes it singularly inappropriate as a major source of 'independent' advice" to the Food and Drug Administration. He told the hearing that "anyone can buy the data to support his case" and that the academy committee—of which the MSG panel was an ad hoc offshoot—was supported "strongly by the food, chemical, and packaging industries."

(Indeed, during 1970–71, academy records show that these industries paid $68,000 of the food protection committee's general administrative expenses.)

Another witness, Charles Edwards, the commissioner of the FDA, said the academy generally had done well by his agency in picking advisory panels. Nevertheless, Edwards said he thought the academy had, in the past, "not shown enough awareness of the problem" of conflicting interests.

The last straw, it seemed, was the appearance of Lloyd Hazelton, an alumnus of the MSG panel and now, or at least last week, a spokesman for the food industry lobby.

"Here is the same person acting as judge and jury," Percy commented. "Regardless of his objectivity and competence, it appears that there is a conflict of interest here. Aren't there enough scientists in the United States so we can select a panel that would be above reproach?"

The senator went on to say that he had the highest regard for members of the NAS, but that he thought the academy had been "insensitive to the fact that we have refused to seat a Supreme Court justice whose integrity no one could question, but who had experienced a conflict of interest." Percy suggested that this insensitivity might be a fit subject for hearings next year by the Government Operations subcommittee on research, of which he is a member.

The academy made no formal response to this criticism, but a spokesman noted that during the past year the academy had taken steps to avoid the appearance of conflicting interests among prospective panel members. Chief among these steps is a requirement that candidates for panels file a statement declaring potential conflicts. These "bias statements" are then used, the spokesman said, as a guide in achieving a balance of viewpoints among members of a given panel. In no case, however, are they used to disqualify a scientist from an advisory committee.

In spite of the academy's new precautions, the FDA has decided to go elsewhere for advice concerning the safety of some 600 food additives on the government's GRAS (or generally regarded as safe) list. Charles Edwards told the Senate committee that to carry out this large and highly sensitive review the FDA had turned instead to the Federation of American Societies for Experimental Biology (FASEB).

Edwards said the FDA had decided to pass over the academy in favor of FASEB partly because of industry representation on NAS panels. He was quick to add that the academy was being kept in reserve as an appeals body for judgments rendered by FASEB, but if the move was not a slap at the academy it certainly marked an important break with tradition.

Officials of FASEB, for their part, regard the job with eagerness tempered with more than a little trepidation. George Irving and C. Jelleff Carr, the two staff members who share responsibility for the project, agreed in an interview last week that reviewing the safety of food additives was a "new and unusual endeavor" both for the federation and the FDA, and one that could take several years.

Their plans call for a panel of nine scientists, Irving among them, to review the available literature on each additive as compiled in a series of monographs currently being prepared for the FDA under separate contracts. Research sponsored by the FDA will fill some of the gaps in the literature, and the NAS will compile data on dietary intakes of food additives, to help FASEB and the FDA assign priorities to individual chemicals.

How is the federation handling the problem of conflicting interests among its nine panelists? Like the academy, Carr said, they will require detailed statements of each member's connections with the food and chemical industries, if any. But unlike the academy, a panelist will be barred from sitting in judgment of a particular food additive if, for instance, companies using or manufacturing the additive have supported his research.—ROBERT GILLETTE

Hexachlorophene Curbed

Restrictions amounting to a virtual ban were announced last week for the antibacterial agent hexachlorophene, an ingredient of many soaps, shampoos, cosmetics, deodorants and numerous other products. The action of the Food and Drug Administration (FDA) was influenced by the death last month of some 40 French babies in a case involving hexachlorophene. Last December the FDA placed the first serious regulatory curb on the burgeoning use of hexachlorophene by recommending that hospitals refrain from bathing infants in strong (3 percent) solutions of the chemical.

The new regulations state that all products containing hexachlorophene as a principal ingredient will be limited to prescription sale only. (The chemical may be used as a preservative in drugs and cosmetics at levels no higher than 0.1 percent). All existing stocks containing more than 0.75 percent hexachlorophene must be either recalled or (in pharmacies) sold on prescription only.

First patented in 1941 by the Swiss company Givaudan, hexachlorophene has found its way into an increasing multitude of products, such that until recently some 4 million pounds a week were being used by American cosmetics and pharamaceutical companies. The first check on its use arose indirectly as the result of an application to use the chemical as a fungicide. Experiments by Renate D. Kimbrough and Thomas B. Gaines at the FDA toxicology center in Atlanta, Georgia, indicated the potential of hexachlorophene for damaging nervous tissue (*Science* 19 November 1971). The warning by the FDA in December last year that 3 percent hexachlorophene should not be used for routine bathing of infants evoked considerable criticism, particularly in light of several staphylococcus outbreaks in hospitals. But the deaths of the French babies reported last month seem to have been caused by a talcum powder to which hexachlorophene was added in excess but at a level of only 6 percent. The lesions in the infants' brains were identical to those caused by hexachlorophene in experimental animals. "There remains no doubt that hexachlorophene is a potent human neurotoxin, at high levels of use, e.g. 3 percent emulsion and 6 percent in powder," the FDA stated last week. For those exposed to hexachlorophene during the last 30 years, particularly the 3 percent solution, the margin of safety does not seem always to have been overwhelmingly great.—N.W.