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RAUSCHER, ACS OPPOSE KENNEDY BILL, DEFEND NCI SPECIAL AUTHORITY, SAY FUNDING LEVEL INADEQUATE

"The proposed bill is regressive in its attempts to modify the status of the National Cancer Institute and would serve to jeopardize the programs with which it has been so successful," former NCI Director Frank Rauscher said at a hearing on S. 988, the "Health Science Promotion

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In Brief

BRINKLEY ASKS SUBCOMMITTEE TO ADD $62.5 MILLION TO NCI BUDGET FOR UNFUNDED GRANTS

NCI'S ESTIMATE that only 23% of approved research grant applications could be funded if Congress does not add money to the President's request for the 1980 fiscal year "is totally unacceptable to those 1,000 Americans who are going to die from cancer today, and it should be unacceptable—and I know it is—to the members who serve on this subcommittee and whose lives will be affected in one way or another by this disease," Congressman Jack Brinkley (D.-Ga.) told the House HEW Appropriations Subcommittee. "For the past five years, there have been comparable approved but unfunded research projects which continue to go unfunded. The hopes of the thousand Americans who die today (each day) from cancer may have been shattered upon inadequate funding decisions in the past. The lives of the thousand people who may die on a day three years from now may be sealed in these unfunded project applications. Their fate is in our hands. Considering the dramatic strides oncologists and other cancer researchers have made in the past several years, who knows which of these approved but unfunded projects might hold the key to the ultimate prevention or cure of the major types of cancer?" Brinkley asked the subcommittee to increase the budget by $62.5 million. . . . **"MEMORANDUM OF UNDERSTANDING"** published by FDA and NCI in the May 1 "Federal Register" formalized the agreement which the two agencies worked out more than a year ago to smooth out the problems between FDA's Bureau of Drugs and NCI's Div. of Cancer Treatment. The agreement has been working very well, according to DCT Director Vincent DeVita, because of the intelligence and cooperation of Richard Crout, Bureau of Drugs director, and Marion Finkel, associate director for new drug evaluation. . . . **RICHARD OMATA,** NCI international program specialist, and Patricia Newman, writer in the Office of Cancer Communications, were among 15 NIH staff members who received Public Health Service Honor Awards last week. Omata was cited "for development and management of six bilateral cancer research programs and an international scientist to speed the flow of research information." Newman was recognized "for outstanding initiative and performance in carrying out the HEW public awareness program on asbestos."

RAUSCHER SAYS BUDGET BYPASS KEY, CALLS KENNEDY BILL "REGRESSIVE"

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Act of 1979," before Sen. Edward Kennedy's Health Subcommittee last week.

Rauscher, now senior vice president for research of the American Cancer Society, objected to three major aspects of the bill:

- Elimination of NCI's budget bypass authority, which permits the agency to submit its budget request directly to the President without subjecting it to changes by NIH and HEW.
- Reducing the status of the NCI director and the National Cancer Advisory Board from that of Presidential appointees to appointment by the HEW secretary.
- Inadequate funding authorizations for the 1981, 1982 and 1983 fiscal years.

"It is of critical concern to the American Cancer Society that the priority status voted by Congress for the National Cancer Program in the National Cancer Act of 1971 be continued," Rauscher said. "The unique position that Congress gave to the National Cancer Institute in that act and in the two succeeding statutes that extended the program in 1974 and 1978 reflected the legitimate concern of Congress, the President and the American people that the efforts formerly made to eradicate the most dreaded of all diseases had been inadequate and that a renewed war on cancer mobilizing all of the resources of government and of the private sector was necessary. The Congress' own language for the effort was 'The Conquest of Cancer' program.

"The proposed bill is regressive in its attempts to modify the status of the National Cancer Institute and would serve to jeopardize the programs with which it has been so successful. Its effect is to repeal the National Cancer Act and not to extend it, and therefore the American Cancer Society must oppose the bill.

"In its realization of the need to embrace a total commitment to the conquest of cancer, Congress gave NCI its current status as a bureau within the National Institutes of Health with both its director and the National Cancer Advisory Board appointed by the President and its annual reports submitted directly to him. Most important, budgeting requests were to be submitted directly to the White House. NCI has been able to act and react quickly, effectively and free of political constraint because of its special structure.

"The new bill would make future progress more difficult. NCI would no longer maintain its priority status under a director a step removed from the President. Budget requests and annual reports would be submitted first to the NIH and then to the Secretary of Health, Education & Welfare and members of the National Cancer Advisory Board would be appointed by him, rather than by the President.

"Practically speaking NCI would no longer retain its close statutory relationship to the President and the sense of total commitment, flexibility of action and public image of NCI would be undermined. No longer would the intent of Congress that NCI be an equal partner with NIH in a joint effort to conquer cancer be realized. Indeed, the bill would contravene the expressed purpose of the National Cancer Act which was to enlarge the authority of the National Cancer Institute in order to advance the national effort against cancer most effectively.

"The budget bypass authority is perhaps the most important special authority given NCI. More important than the special access it assures regarding the NCI budget, is the special access it guarantees, when needed, to the highest levels of the Executive Branch on behalf of the National Cancer Program. This authority gives the President's Cancer Panel—another vital element of the Program—legal authority to work directly in behalf of the national cancer effort with the Congress as well as the White House.

"For instance, early in the National Cancer Program, an HEW department-wide order went out curtailing information office activity by departmental agencies just at the time when Congress, and the National Cancer Plan (originated by non-government scientists) determined that a prime way to reduce cancer deaths was to provide the public, and the medical profession more information. Another instance was the HEW department-wide move to reduce training programs, particularly the training of research personnel, on the theory that the more trained personnel there were, the more requests there would be for research grants. This came at a time when severe shortages were foreseen in epidemiologists, pathologists, and certain other areas of specialization. Many of these shortages are even worse today as a result of increased federal regulatory efforts.

"Benno Schmidt and the President's Cancer Panel were successfully able to appeal these departmental decisions on behalf of cancer. That kind of action has repeatedly proven the efficacy of the Congressional priority for cancer. I repeat, even when money was not the issue, the Panel-directed, cohesive, goal-oriented National Cancer Program was, and is something more than a government-as-usual activity. It has top flight, experienced overseers exercising oversight and administrative functions that most other government programs don't have, and such work cannot be done without the authority for direct access to top Executive Branch administration. The authority for budget bypass of the many levels of bureaucratic review and revision is the keystone of the National Cancer Program, and its success, thus far. Cancer administrators have not abused this special authority. They have used it discreetly, and with consideration of other health goals. They have used it as Congress originally intended it to be used. To remove it because of apparent disuse would be action based on a

NCI experienced significant delays between the time bioassays were completed and the time technical reports were published. The delay in publishing technical reports became a major concern to NCI. In 1976, NCI directed Tracor Jitco to develop a plan to produce draft reports on all completed bioassays in which the test animals were killed before July 15, 1976—207 bioassays were included in this category. NCI's goal was to publish technical reports on all 207 of these bioassays; in testimony before the Congress in early 1978, NCI said it would do this by the end of September 1978.

While the Tracor Jitco plan succeeded with providing NCI draft bioassay reports, NCI did not eliminate its backlog, the GAO report said.

NCI had published only 99 reports as of October 1978, and it had reduced its goal of publishing reports on all 207 bioassays to reporting only on 156 (NCI found the remaining 51 bioassays to be so deficient that it decided not to publish final reports on the results).

NCI stated that, while it did not complete its work on the backlog by September 1978 as it intended, the backlog was eliminated by December 1978. NCI's rationale for this was that it had provided preliminary results of the backlogged bioassays to the regulatory agencies by that time. However, the regulatory agencies are reluctant to act on data until it is finalized. Thus, we believe NCI's action to eliminate the backlog should not be considered complete until technical reports are published on the backlogged bioassays.

The bioassay backlog was caused by many factors; NCI could control some of them and could not control others. The National Cancer Act of 1971 provided the impetus and finances to increase efforts to identify chemical carcinogens. Since the legislation did not specify who was responsible for testing suspected carcinogenic chemicals, NCI assumed the burden for such efforts.

As a result of the increased emphasis to identify environmental carcinogens, NCI began a large number of bioassays through contracts with private laboratories between 1971 and 1973. The results of these bioassays became available to NCI between 1973 and 1976. . . . The NCI unit that was to administer the bioassays was severely understaffed, and it could not properly monitor the bioassays while they were underway or deal with the results as they became available. These factors caused the bioassay backlog.

Several causes contributed to NCI's delay in eliminating the backlog, according to a report by the Clearinghouse on Environmental Carcinogens. The Tracor Jitco plan was premised on having no problems at any point, but many problems developed. The plan did not allow time for teams at the laboratories that performed the bioassays to be assembled and trained to write draft reports; ultimately, this approach did not work, and Tracor Jitco was assigned the responsibility of preparing draft technical reports.

Since NCI had not required laboratories to prepare bioassay reports, Tracor Jitco experienced significant difficulty when it attempted to do this. In many instances, considerable time had passed since the laboratories completed the bioassays, records had been placed in storage, and personnel changes had occurred. Thus, efforts to gather test data to prepare reports were difficult. Other delays in preparing reports occurred because scientists attempted to analyze and interpret the data from early tests by using more advanced techniques which could not always be easily applied to the data from these earlier tests.

NCI staff for reviewing bioassay results was also limited. One person was responsible for reviewing most of the draft bioassays—the head of the Data Evaluation Group. Further delays with eliminating the backlog occurred because of the time needed for review by the Clearinghouse on Environmental Carcinogens and because of the few staff assigned by NCI's Office of Cancer Communications to process draft reports.

We found that other existing completed bioassays fit the definition NCI used with identifying bioassays included in the backlog, the GAO report said.

These bioassays have not been reported to the Congress. We identified 223 such bioassays that were performed by the Frederick Cancer Research Center, the Eppley Institute for Research in Cancer, and NCI's inhouse Carcinogenesis Research Program. However, we are not certain that these are the only bioassays. NCI officials stated that these tests were not included in the backlog because NCI included only those for which Tracor Jitco was responsible.

NCI awarded a competitive prime contract to Tracor Jitco Inc. in March 1974 to manage its bioassay activities. NCI subsequently extended the contract without competition from May 1975 to May 1979. The contract is a cost-plus-award-fee type which allows Tracor Jitco to recover its costs of performing the agreed upon work ($39.7 million) plus a fixed fee of about $198,000. In addition, Tracor Jitco can earn an award fee of about $3.2 million if NCI determines that its performance is satisfactory. NCI plans to extend the contract for a short period beyond May 1979 to allow Tracor Jitco to complete certain agreed upon work; NCI will then assume the responsibilities previously assigned to Tracor Jitco for all future bioassays.

NCI has relied primarily on Tracor Jitco to provide information on the bioassays by the subcontractor laboratories. However, Tracor Jitco has not informed NCI of all the deficiencies it found during its inspections of subcontractors' activities, nor has it required the subcontractors to correct the deficiencies. NCI was not aware of this situation because it had not adequately monitored Tracor Jitco's efforts in review-

ing subcontractor activities, nor had NCI done its own verification of the adequacy of Tracor Jitco's reports.

To determine conditions at the laboratories that subcontract with Tracor Jitco, we developed a method for inspecting laboratory conditions. This method was based on NIH, NCI, and FDA guidelines and procedures developed by Tracor Jitco; we tested the methodology and had it approved by NCI, FDA, and industry officials. We hired experts who were recognized as qualified by both NCI and Tracor Jitco to assist with our inspections.

Even though NCI required Tracor Jitco to increase both the quantity and quality of its laboratory inspections, numerous deficiencies still existed at the laboratories that could affect the quality of bioassays. One of these deficiencies—the testing of more than one chemical in a room—was our most serious concern. In some cases, our inspection revealed laboratory deficiencies which Tracor Jitco did not detect.

Recommendations

We recommend that the secretary of HEW require the director of NCI to determine the total number of bioassays completed before July 15, 1976, for which results have not been reported by NCI and to submit a plan for bringing a timely end to this situation and preventing a recurrence.

We also recommend that the secretary of HEW require the director of NCI: (1) to more closely monitor the performance of Tracor Jitco Inc. by making more frequent site visits to the subcontractors' laboratories and by verifying that Tracor Jitco has required the laboratories to correct deficiencies found during inspections and (2) to use the information from NCI's site visits and inspections of the laboratories as part of the basis for determining the amount of the award fee.

NCI responded with considerably more backbone than agencies generally display when dealing with Congress:

It is important to consider the GAO report in its proper context, namely, that it takes NCI to task for past performance extending back to 1972. Although the report in fact acknowledges improvements and corrective action taken during the review, these actions got little notice in Congressman Waxman's news release or in press accounts of it.

Two additional points relating to context need to be addressed. GAO is highly critical of NCI's management of its chemical testing programs. It should be kept in mind that these programs have evolved since 1968 from research activities primarily intended to develop testing systems. It was only after they had been long underway in that setting that public interest, and the recognition that no other agency was testing chemicals for regulatory purposes, that NCI undertook to convert the programs to a "production" or "service" mode. Thus, activities designed to meet one need (research) had to be converted to meet another need (service to regulators). The problems described by GAO are primarily the result of this difficult conversion process.

Another matter relating to context needs mention. The GAO report states that NCI has failed, since 1972, to increase the proportion of its budget allocated to "carcinogenesis activities." Its conclusion is based on analysis of accurate data supplied by NCI in response to a specific GAO request. Both the request and the conclusion, however, miss a critically important point: namely, all activities of NCI directed towards environmental carcinogenesis or prevention are not classified within the accounting category stated by GAO to be of interest. Specifically, substantial portions of NCI's programs in epidemiology, nutrition, viral oncology, cancer control and tumor biology are clearly related to environmental carcinogenesis and prevention. These amounts were not requested by GAO and are therefore not taken into account in their conclusion. The data. . . clearly demonstrate that there have been substantial increases in the proportion of NCI's budget devoted to these areas since 1974.

Secondly, it should be noted that dollar allocations are a poor measure of program balance in cancer research. If one were to measure the units of research purchased per dollar in various NCI programs, it would be apparent that the costs of treatment research are much higher than those for carcinogenesis research. This is readily understandable given two facts: treatment research involves research on humans in a clinical setting, whereas carcinogenesis research involves research in laboratory settings utilizing small animals. Obviously, the former is more costly than the latter.

Overall, GAO reports accurately and fairly problems NCI has had in the testing of chemicals for carcinogenesis. It pinpoints a number of areas in which NCI performance has been improved or needs further improvement. The primary problem inhibiting NCI performance has been our inability to attract and retain adequate numbers of well qualified toxicologists and veterinary pathologists. This task has no quick or easy solutions, but we are doing everything we can to solve it.

We do not agree with every finding or conclusion of the report, and we believe that certain findings or conclusions misstate the facts.

Difficulty in recruiting scientists for testing program

GAO is generally correct in its conclusions. Testing of chemicals is a comparatively routine undertaking (i.e. compared to basic research) but requires just as highly qualified and talented scientists for performance. The national shortage of the two most vital professions (toxicologists and veterinary pathologists) severely hampers recruitment: those few people available would rather conduct basic research, and those

qualified and interested in testing chemicals can demand higher salaries than NCI can offer.

Since completion of GAO's review NCI has, however, filled most of its vacancies for toxicologists. There remain several vacancies for veterinary pathologists which will be extremely difficult to fill.

Our approach now is to sponsor specific extramural training programs to increase the supply. These programs will not solve the problem for three to 10 years, but it is the only solution we deem practical. Meanwhile, we will do the best we can given constraints.

Internal training programs, as suggested by CSC, are deemed impractical because they would require diversion of such qualified staff as we can attract from the production aspects. It is difficult enough to deny such scientists the opportunity to perform research, without also requiring them to take on burdensome training responsibilities.

Difficulties in eliminating the bioassay backlog

GAO disputes the NCI statement that the "backlog" was eliminated by December 1978 on the basis that not all test results were published in final form and sent to regulatory agencies, which are reluctant to act on data until they are finalized. While this is true, it misses the key point that the only test result data not turned into final reports were on tests either found to be inconclusive or no longer of concern. As stated later in GAO's report 51 of the 207 bioassays were found to be deficient in design or execution as a result of their having been undertaken as research projects rather than as tests for regulatory purposes. NCI would not expect regulatory agencies to take action on the basis of such findings, so we fail to see why final reports—preparation of which are costly and time-consuming—would be useful.

As to the fact that only 99 technical reports were published by October 1978, and only 139 by March 1979, we believe that GAO accurately portrays the difficulties NCI has faced in completing the task. Since the technical reports may well form the basis of regulatory actions, NCI considers it to be important to insure their adequacy and accuracy and holds that goal to be more important than speed at any cost. We believe that goal will have been met.

The statement that regulatory agencies are reluctant to act before receipt of formal, final reports is difficult to comprehend inasmuch as regulatory action was taken on TRIS, toxaphene, ethylene dibromide, and several other compounds based on the same kind of preliminary data the regulatories agencies have had on all "backlog" chemicals since last September, NCI said in its response.

Furthermore, it is not acknowledged in GAO's report that an additional 34 reports had been completed in camera ready (i.e. final) form and made available in that form to the regulatory agencies by October 1978, and 20 additional reports were in this final form by March 1978. The fact that final GPO printing and, therefore, publication had not been completed should have no bearing on the ability of regulatory agencies to act.

All bioassays completed but unreported were not included in the backlog reported to Congress

GAO's rationale for this contention, and NCI's response, are stated in the report. Our only additional comment is that publication of technical reports on the 207 bioassays performed under responsibility of the Tracor Jitco contract was deemed the highest priority because otherwise the results of these tests would have gone unpublished in any form. The other test results identified as "missing" by GAO had been reported in scientific literature, or were planned for such publication. Thus, regulatory agencies would have access to them in appropriate and adequate form.

The criteria used by NCI in defining the 207 chemical "backlog" in July 1976 were:

1. No contractual obligation to publish.
2. Test performed using a protocol consistent with definitive bioassay.
3. Animals on test had been sacrificed prior to July 15, 1976.

None of the "additional chemicals" identified by GAO met these criteria, and no other unpublished chemical tests fit them, either.

Twenty-one bioassays from FCRC were reported to the Clearinghouse by Dec. 13, 1978 and to the regulatory agencies prior to this date. FCRC did not publish these in the literature in timely fashion, so the testing program took them over to publish as technical reports. They were not included in the original 207 backlog. Eleven have already been printed and 10 are now at the printers. One of these 10 is due out May 4, 1979.

Thirty-seven research studies are in the intramural program. They did not meet bioassay criteria and were therefore not in the original 207 backlog. Twenty-one have already been published in the literature and manuscripts on the remaining 16 are in preparation.

At Eppley, 204 research studies on 155 chemicals have been completed and the findings published on 96 in scientific journal articles.

We reject outright the implication that there was any attempt to "hide" test results that should have been reported. Our goal remains one of providing accurate and adequate data to regulators in the quickest possible time within available resources.

NCI has not adequately monitored Tracor Jitco

GAO pointed out deficiencies in NCI's monitoring of the contractor during the course of its investigation. As noted by GAO in the report, many of these deficiencies are attributable to the lack of qualified NCI staff, the reasons for which are addressed elsewhere. When GAO informed NCI of the problems, corrective action was taken, as noted in the report.

Further improvements will be made as adequate staff are hired. We welcome the opportunity to improve offered by these GAO findings, the NCI response concluded.

Umberto Saffiotti, who was director of the Carcinogenesis Program in 1972 when the big push for testing chemicals began, told ***The Cancer Letter*** that bioassay contractors were not required to write technical reports on their findings because it was intended that that job would be done by NCI staff.

"There were plans to increase the staff to perform these jobs," Saffiotti said. The plans were frustrated by a series of events. FDA asked NCI to evaluate the cyclomate tests, a project that required a year and several of Saffiotti's staff to assist the scientists—non-government and government—who participated in that effort. Other key people were transferred to new jobs, one of them James Sontag, who became executive secretary of the Clearinghouse on Environmental Carcinogens.

Serious disagreements on management policies developed between Saffiotti and then DCCP Director James Peters. The result was that Peters, with the backing of Frank Rauscher, who was NCI director, split the program into two segments—carcinogenesis research and carcinogenesis testing. Richard Griesemer eventually became head of the testing program; Saffiotti was offered the chance to remain as head of carcinogenesis research, but he turned it down and went full time to the position he now holds, chief of the Laboratory of Experimental Pathology, which he had headed in a dual role as director of the Carcinogenesis Program.

Congressman David Obey attempted to solve the manpower problem when he wrote into an appropriation act a mandate for 60 or more positions earmarked for carcinogenesis. Even that did not help much, as GAO noted.

Saffiotti feels that splitting up the program contributed heavily to recruiting difficulties, agreeing with GAO that people qualified to conduct the tests, monitor contractors, analyze results and write reports are also qualified to do research. If they can't do the more intellectually satisfying research, they go to industry where at least they can make more money.

The roots of the backlog go deeper than that, however, Before 1972, the Carcinogenesis Program was devoted to research, and bioassays were directed at answering certain scientific questions, not at providing the regulatory agencies with the ammunition they need to make bans on carcinogens hold up in court. When it became clear in 1972 that Congress and the nation were relying on NCI for just that type of support, the program had to shift gears and develop a format for reports that would meet regulatory needs.

"It was trial and error," Saffiotti said. "Over three generations of bioassays, we improved the standards each time."

Finally, the Clearinghouse was established by Rauscher, on advice from the National Cancer Advisory Board, to provide a forum for non-NCI scientists and representatives of labor, consumers and industry, to render opinions on the bioassay reports. As GAO reported, this caused further delays, but it also strengthened the hand of the regulators, offered vast insights into the test data, helped improve test methods, sent compounds deemed inadequately tested back for another look—sometimes clashing with NCI staff in the process.

GAO apparently shares the opinion of some NCI staff members and also of many of the institute's advisors that placing Carcinogenesis Testing under the National Toxicology Program is probably not going to provide any benefits to the Carcinogenesis Program and could add to its problems.

HANDS OFF BOARD APPOINTMENTS, NCAB SUBCOMMITTEE TELLS JOE CALIFANO

The National Cancer Advisory Board's Subcommittee on the National Cancer Advisory Board—established to study problems, deficiencies and future directions of the Board—will recommend that the NCAB ask HEW Secretary Joseph Califano to keep his hands off future Board appointments.

William Baker, chairman of the subcommittee, pointed out at the group's recent meeting that when the NCAB was created by the National Cancer Act, it was the intent of Congress that Board appointments "not be controlled by the Department."

The six appointees, including four new members, made this month by President Carter (***The Cancer Letter***, May 4) were in reality selected by Califano, Baker pointed out.

Thomas King, director of the Div. of Extramural Activities and NCAB executive secretary, noted that six more vacancies will come up in 1980 and "they should be addressed right now." There also will be another vacancy on the President's Cancer Panel next year (Elizabeth Miller's term expires in February) and Carter still has not appointed anyone to succeed Panel Chairman Benno Schmidt, whose term expired in February 1978.

The Cancer Act also provides that the NCI director be appointed by the President, but Califano, not Carter, selected Arthur Upton.

Presidents Nixon and Ford bypassed HEW entirely in selecting Frank Rauscher as NCI director in 1972 and in making appointments to the NCAB and the Panel. No President, however, will make such appointments without some advice. Nixon built an organization within the White House which gathered up vast power from the departments. In health matters, James Cavanaugh was the chief advisor to both Nixon and Ford.

So far, no one has emerged in the Carter White House with the influence in health affairs that Cavanaugh wielded. Peter Bourne, who may have been

moving in that direction, was forced out after an indiscretion over a prescription for drugs. In any event, Carter made it clear from the start that his department heads would be his chief advisors.

Baker wondered if the President and his staff realize that it was the specific intent of Congress to make the Board—and even NCI to a certain extent—independent of HEW. He suggested that Gilbert Omenn, who is an ex-officio member of the Board as a representative of the White House Office of Science & Technology Policy, might be consulted on that point. Omenn is assistant director for human resources in that office; there has been speculation that that if anyone is going to assume the role Cavanaugh had as a Presidential health advisor, it would be Omenn.

Baker also pointed out that there was a move last year when legislation was being written to extend the Cancer Act to make Board members appointees of the secretary, but that it failed, thus strengthening the original intent of Congress.

"It seems to me that the HEW secretary has overview power and that nominations are not likely to get by him without his approval. That is not the intent of the legislation. Should we make a recommendation on a position for the Board to take?"

"I think we should recommend that the President follow the letter of the law," said Henry Pitot, who had just been appointed by Carter/Califano to be the new chairman of the Board.

Harold Amos, noting that it had taken the Administration more than a year to fill the six vacancies, said, "This has happened to other agencies, not just us. Is this just the way the Carter Administration works? It seems to be a sloppy, slovenly way to operate."

In Califano's defense, he had delayed making appointments until the Cancer Act renewal had been completed, since amendments had been proposed to change the composition of the Board. After some of those amendments were adopted, it required some time to find and recruit candidates who fit the new requirements, as King pointed out.

The Cancer Act also directs that the heads of certain agencies—FDA, EPA, NIOSH, NIEHS, Consumer Product Safety Commission and the Secretary of Labor are ex-officio Board members. Only David Rall, NIEHS director, has attended Board meetings; others have sent representatives.

"How far do we want to go in allowing the agency heads to send substitutes?" Baker asked. "Are there no constraints on who the agencies can send? Even someone inexperienced and junior?"

Advised that the Act permits the agency chiefs to send anyone they wish, Baker said, "That's a bad deal."

Pitot pointed out that ex-officio members cannot vote, but Baker said "they are bound to influence the direction things go."

"And they cannot make the positive contribution that the agency heads could make," Amos commented. "The directors of those agencies have a lot of power."

The secretary of HEW also is listed as an ex-officio member, and Amos noted that he has never attended a meeting nor sent a representative.

"Well, that we can salute," Baker said. "It's just as well that the director of NIH (another ex-officio member) and the secretary have not sent other folks."

King noted that when NIH Director Donald Fredrickson wanted to make some announcement to the Board or wanted his office to be represented for some other reason, he attended himself.

Baker agreed with Amos' suggestion that the issue be discussed at the Board meeting May 24-25 and the Board be asked to take a position on it.

The six Board members whose terms expire next year are Baker, Mary Lasker, Denman Hammond, Joseph Ogura, William Powers and William Shingleton.

Amos expressed concern about the number of new persons that will be on the Board if all six are replaced by others, combined with the four new members coming on this year. "We can't function with such a large number of new people. We ought to ask for a one year extension for those going off in 1980."

Amos also complained about some members "in times past who were reappointed and they had not done a damn thing. We ought to take a position on that."

"Also, some of those waiting around to be replaced are not adequately functioning," Shingleton said. "We can't get people to subcommittee meetings."

The subcommittee members agreed that two day Board meetings do not allow enough time to adequately review grants, the Board's primary function as a secondary review group. All NCI grants over $35,000 must be approved by the Board.

"We always have difficulty keeping enough members for a quorum for more than two days," King said.

Amos suggested that with a three day meeting, a quorum probably could be assured for the second day. That entire day should be reserved for grant review, and if extra time is needed, it could go over to the evening or to the next day.

"We can't do our mission in less than three days," Baker agreed.

Baker commented on the General Accounting Office report on the Carcinogenesis Testing Program. "The GAO seems to be expressing a lack of recognition of how the work is going. What's the explanation? Perhaps a bad word would express it."

Referring to the National Toxicology Program, Amos said, "That has a chance of being the biggest boondoggle of all time, and we're contributing $21

million to it."

The subcommittee discussed recommending a review or updating of the National Cancer Plan. A plan was first developed after the Cancer Act was first passed in 1971, and updated in 1974.

"If we decide to revise it, would we go through the same magnitude of effort that went into putting it together originally?" Pitot asked. More than 200 scientists participated in that.

Baker said he did not think a new review or update would require that kind of effort. Shingleton asked if it would be a useful exercise.

"We should make an effort to assess where we are," Amos said.

The plan "left a lot of questions," Pitot said. "Most are still not answered. In a way, it might be embarrassing to look at it again. But in 1981, someone is certain to look at it, and that could be even more embarrassing than if we look at it ourselves and update it."

"It was an admirable effort, and there was appeal in the objectives," Baker said. The plan "pointed out that certain objectives needed to be realized. We didn't know then the depth of the lack of our knowledge. There has been progress."

Pitot suggested that "if we do a new review we shoot for 1981. If we look carefully, we'll probably find areas where we have advanced tremendously, and others not at all. It could be used for and against us."

Pitot said that "NIEHS is doing a lot of carcinogenesis work. We can ask Rall about it when he does his spiel (he is on the agenda for the May 24-25 meeting). He may say it's none of our business. On the other hand, we can say it is."

"That's why he's on the Board," Amos said. "There's a lot of carcinogenesis work going on elsewhere. Maybe Congress was wise after all in providing for agency heads to be on the Board."

NO PROOF FIBER IS ANTICARCINOGENIC, BUT DIET SHOULD INCLUDE IT: NEWELL

Guy Newell, NCI deputy director who was an epidemiologist at Tulane Univ. before going to NCI in 1973, told science writers at an ACS seminar that dietary fiber "may act to minimize an individual's chances of acquiring cancer."

Newell's presentation, prepared with NCI staff member Neil Ellison, said that "one specific component of the diet that has received a large amount of publicity for the past decade regarding its possible protective effects against cancer is fiber. Yet, strict dietary recommendations concerning fiber are not appropriate at this time. Instead, an overview of the data suggests that general dietary adjustments concerning fiber be made.

"Broad epidemiological observations initially stimulated interest in the fiber and cancer relationship. Diseases of the intestines, including appendicitis, diverticulosis, colonic polyps and colon cancer were noted to occur less often in populations ingesting large amounts of fiber. These populations were usually found in less industrialized countries. When individual differences were investigated between geographic areas, Burkitt and others noted that high fiber intake was correlated with larger, softer stools, more frequent defecation, and more rapid intestinal transit times. They theorized that these effects could result in a decreased time exposure of the colonic mucosa to stool carcinogens as well as a relative decrease in the concentration of possible stool carcinogens. . . .

"The simplicity of the data just reviewed is misleading. Dietary fiber is complex. There are vast differences in the sources and types of fiber. A basic definition presented by Soest is that fiber consists of plant wall and non-nutritive residues. Non-nutritive residues include all substances resistant to animal digestive enzymes. Some of these residues may be fermented by colonic bacteria and the subsequent products absorbed. Alterations in food's initial fiber content may occur with their preparation. For example, browning of meats may make some proteins unavailable to digestion. . . .

"In spite of the data given, there is no general acceptance of the anticarcinogenic role of dietary fiber. This skepticism is appropriate since no direct cause-effect relationship has ever been shown in man for dietary fiber (or its lack) and cancer. In fact, animal studies by Cruse refute work by others and claim no protection of bran feeding in experimentally induced colon cancers in rats. Wynder also denies any correlation between fiber content of foods and the incidence of colon cancer when judged on a world wide basis.

"Clearly, other factors besides fiber must play a role in the possible diet and colon cancer relationship, which comprises just one small aspect of the total nutrition and cancer interaction. However, a generalized increase in dietary fiber has no known disadvantages for almost all normal individuals. This, along with the early suggestive data of a possible anticarcinogenic effect associated with increased dietary bulk, indicate that the simple addition of fresh fruits and vegetables to one's diet may act to minimize an individual's chances of acquiring cancer," Newell concluded.

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