THE CANCER RESEARCH EDUCATION CONTROL LETTER

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PENNSYLVANIA HOUSE APPROVES BILLS ESTABLISHING CONTROL, RESEARCH FUNDS WITH CIGARETTE TAX

Pennsylvania may soon join Kentucky as a state which has committed its government to support of cancer control and research. The Pennsylvania legislature's House of Representatives has passed a bill creating a Cancer Control and Research Advisory Board and Cancer Control and Research fund. The House also passed another bill adding one cent per pack to cigarette taxes and earmarking that revenue to fund the new program.

Both measures passed by overwhelming margins and are now awaiting action by the state Senate.

The cigarette tax is expected to raise as much as $12 million a year

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In Brief

LEAKS FROM COOPERATIVE GROUP SITE VISITS VEX CCIRC; TUMOR CELL CLONING WORKSHOP SET

CCIRC MEMBERS complained at the last meeting of the committee about leaks from site visitors reviewing cooperative group grant applications. Clair White, executive secretary of the Cancer Clinical Investigations Review Committee, agreed "there has been a breakdown of confidentiality. Nothing personal, but something is happening when people coast to coast know the result of a site visit the next day." Committee members also compalined about being loaded up with material relating to an application without sufficient time to absorb it. "Frequently the material is handed to us by the cooperative group the night before the visit, or sometimes even after the visit," said committee Chairman Jerome DeCosse. "This is unfair to the group being reviewed and to the group doing the reviewing" . . . . **CCIRC SPONSORED** symposium on sarcoma of soft tissues and bones in childhood is scheduled for Jan. 25-27 in Orlando. Committee member Arvin Glicksman reported the clinical trials design symposium in New Orleans was a success, with 310 registrants. DeCosse asked for topic suggestions for the 1980 symposium; mentioned were childhood and adult acute leukemia, chemotherapy monitoring, lung cancer therapy, ovarian cancer treatment advances, and late effects of chemotherapy. . . . **WORKSHOP ON CLONING** human tumor stem cells is planned by the Univ. of Arizona College of Medicine for Jan. 3-5 in Tucson. Sydney Salmon, Anne Hamburger, David Alberts, Ronald Buick and colleagues will discuss their methods of cultivating human tumor stem cells in soft agar. The process permits measurement of sensitivity of human tumor stem cells to anticancer drugs, may permit more efficacious selection of new agents and individualized chemotherapy regimens. A report on their work appeared in the *New England Journal of Medicine* June 15. Contact Cancer Center Division, Univ. of Arizona Health Sciences Center, Tucson 85724, phone Buick at 602-626-6408.

PENNSYLVANIA'S PROGRAM WOULD OFFER LONG TERM SUPPORT FOR CONTROL EFFORTS

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which would be distributed largely through grants and contracts to nonprofit organizations and government agencies "to plan, establish or conduct programs in cancer control or prevention, cancer education and training and cancer research," language in the act says.

The act would create in the state Dept. of Health the Pennsylvania Cancer Control and Research Advisory Board. It would consist of 11 members, all of whom would be Pennsylvania residents, and 10 of whom the governor would appoint with the consent of the Senate. Of the 10 appointed, five would be "distinguished scientists and physicians in the field of cancer, one shall be a qualified nurse oncologist, two shall be private citizens skilled in health care administration and two shall be private citizens." The 11th member would be the state secretary of health. The governor would designate one member as chairman for a term of four years.

The board would approve a program of cancer control and research each year, to be known as the "Pennsylvania Cancer Plan." The board would recommend to the secretary the awarding of grants and contracts.

Language in the act says that grants and contracts shall be distributed "so that neither extramural or intramural programs receive less than 25% or more than 75% of the moneys expended from the fund."

Extramural programs were defined as: "Programs in cancer research, cancer education and training and control conducted by qualified nonprofit associations receiving grants and contracts from the Div. of Research Resources & Centers and the Div. of Cancer Control of the National Cancer Institute, the American Cancer Society, the Damon Runyon-Walter Winchell Fund and other national sponsoring agencies with a proven capacity for peer review of cancer research and cancer control grants and contracts."

Intramural programs were defined as: "Programs for the planning, clinical research and testing, investigating inauguration, establishment and conduct of programs in cancer control, cancer information and education, and cancer prevention conducted by qualified nonprofit associations or governmental agencies including but not limited to (1) cancer screening and detection; (2) cancer epidemiology and biostatistical studies; (3) cancer community outreach programs; (4) cancer rehabilitation; (5) tumor registry system; (6) communications between cancer institutions; (7) cancer education and information; (8) cancer training."

The act spells out criteria which "shall be given consideration for recommending grants and contracts for extramural and intramural programs:

- "The relevancy of applicant's proposal to the Pennsylvania Cancer Plan.
- "The feasibility of the applicant's proposal.
- "For extramural programs, the eligible institution's proportion of the total private and federal governmental cancer research and control funds annually expended by the applicant in relationship to all such funds expended by the applicant in relationship to all such funds expended by eligible Pennsylvania research institutions."

The secretary of health would be authorized to provide staff and other assistance he deems necessary to support the board.

According to the bill's definition of "extramural," only those institutions receiving grants or contracts in cancer research or control from organizations (NCI, ACS, etc.) which have established peer review mechanisms would be considered eligible for the program's "extramural" funds. Other nonprofit institutions and government agencies would be considered "intramural."

The amount of money an extramural institution receives would depend to some extent on how much it receives through other, peer review sources.

Most if not all research projects supported by the program would be in the extramural institutions. Both extra- and intramural institutions would be eligible for cancer control funds.

The bill does not specifically provide a peer review mechanism to consider applications submitted to the board. Presumably, the board or the secretary of health could establish such procedures if they determine it is necessary.

NCI's Div. of Cancer Control & Rehabilitation is limited for the most part to support of demonstration programs of up to five years. With very few exceptions, NCI cannot be expected to provide long term funds for programs beyond that time; nor can it be counted upon to support implementation everywhere of programs proven successful in limited demonstrations.

The problem of how successful programs can be continued and broadened has not been resolved. Third party payers and volunteer organizations are being counted upon to help in some instances. The involvement of state governments, as Pennsylvania and Kentucky are doing, could provide the substantial, stable, long term support needed to realize the full benefits of the national cancer control effort.

A pamphlet produced by an organization called "Cancer Cause–The Environmental Connection" to stir up support for the bill lists eight "immediate steps for better understanding of cancer in Pennsylvania" which are cited as major goals of the legislation:

"1. Mass detection screening programs to reach people nearer their homes, especially in smaller towns and rural areas away from the large medical facilities.

"2. Studies made in the geographic locations

where deaths occur, in the identification of tumor sites in the body, and in the possible sources of carcinogens in patients' environments (i.e., in the field investigation of epidemics).

"3. Cancer community outreach and help programs.

"4. Cancer rehabilitation for victims.

"5. A central data dollection of all cancer deaths (i.e., a cancer registry).

"6. Speeded up and improved communications between medical personnel—doctors (general, family, oncology), dentists, nurses, social workers and allied health personnel.

"7. Cancer education and information to all Pennsylvania citizens.

"8. Better training for all persons involved in cancer care and services."

Samuel Fisher, Philadelphia CPA who is one of the leaders in the effort to get the bills through the legislature, has offered to send copies of them to anyone in other states considering similar programs. Write to Samuel M. Fisher & Co., GSB Bldg. Suite 800, City Line and Belmont Avenues, Philadelphia 19131, or phone 215-877-7500.

CANCER ACT RENEWAL CLEARED FOR EARLY VOTE BY HOUSE; SENATE BILL DIFFERS

Renewal of the National Cancer Act inched along this week when the House Rules Committee cleared for floor action H.R. 12347 which would renew various biomedical research authorities and the National Research Service Awards Act.

The bill was not scheduled by the House leadership for floor action this week but could be brought up next week, in time for a vote before Congress recesses Aug. 18. If it is not, no action will be possible before Congress returns after Labor Day, putting final approval dangerously close to the end of the fiscal year, Sept. 30, when the Cancer Act and other authorities will expire.

The Senate has already approved a one year renewal of the Act. The House version extends the Cancer Act for three years. Sen. Edward Kennedy, chairman of the Health Subcommittee, feels that some substantial revisions in the Act may be desirable next year and has held firmly to the one year renewal for now. Congressman Paul Rogers, chairman of the House Health Subcommittee, has gone along with requests from the National Cancer Advisory Board and other Cancer Program advocates for a three year renewal. A compromise in conference at two years is possible but not assured.

The House bill differs significantly in other ways from the Senate bill, primarily in redefining and expanding cancer control authority and authorizing increased funds for cancer control. The Kennedy bill would authorize $925 million for NCI in fiscal 1979 plus $85 million for control; Rogers' bill would authorize $924 million and $96 million, respectively.

The House bill includes provisions pushed through by Rep. Andrew Maguire aimed at forcing NCI to become more aggressive in stirring up regulatory action on carcinogens. Kennedy's bill has no such provision.

Most of the other changes in the Cancer Act are similar in both bills or close enough not to present problems—authorizing all of NIH to hire expert consultants, a privilege now limited to NCI; downgrading appointment of NCAB members from the Presidential to HEW secretarial level; and permitting NIH and NCI to distribute reference chemicals as well as living organisms and research animals to grantees and others in addition to contractors.

The Kennedy bill was approved by voice vote in the Senate, with no opposition recorded. In discussion before the vote, Kennedy commented, "We have heard criticism but also strong support for the Cancer Program, and it is premature to cut back on the cancer budget before the Subcommittee on Health & Scientific Research has completed its biomedical research review. Nutrition and prevention are clearly important areas, and we are going to work closely with the Agriculture Committee. I was a member of the Nutrition Committee, and we will continue to work with Sen. McGovern, Sen. Dole and other members of the Agriculture Committee to provide an appropriate nutritional allocation in the future."

Sen. Robert Dole (R.-Kan.) inserted remarks in the record which typify much of the criticism of the Cancer Program. Some of his criticism is based on material taken out of context; some is the repetition of unproven charges which, having been repeated often enough, are now being accepted by Congress and the press as facts; and some merely reflects ignorance of the Cancer Program.

Dole's statement said in part:

"First let me say I am glad to see the single one-year extension for funding to the National Cancer Institute, at a time when many are questioning the course and direction of NCI's research activities. Just two weeks ago today, Monday, June 11, I and other members of the Senate Nutrition subcommittee heard five key witnesses express their views on the research programs and priorities at NCI. One can only conclude from their testimony that the federal government is not adequately responding to public outcry for more and better information about the role of diet in the prevention and cure of the dreadful disease cancer.

"The witnesses spoke of the wide gap between what is already known and well documented about nutrition and cancer, but has not yet been put into clinical practice. The director of nutrition support services at the New England Deaconess Hospital's Cancer Research Institute, Dr. George Blackburn, cited a pattern observed in his terminally ill patients,

lingering with this bedridden illness, as definitely malnutrition—depression, weakness, and mean weight losses of 18%. He questioned why there is so little research emphasis on just how to keep patients from starving to death. . . .

"I think these comments were made based on the fact that we have spent billions and billions of dollars in the past seven years and really do not have a great deal to show for it insofar as a prevention is concerned, and, of course, still not much to show as far as cure is concerned.

"Research in the preparation of the hearings revealed alarming statistics about the diet-cancer relationships:

"40% of the cancer in men and 60% in women are nutrition related;

"Although NCI's budget has grown from $200 million to almost $900 million this current fiscal year, the institute continues to address the same areas of research: Immunology, virology and chemotherapy; and

"The institute is spending only 1% of its total budget on the role of diet in cancer.

"Dr. Theodore Cooper, now the dean of Cornell University's Medical College summed up the half day of testimony when he stated:

" 'Why, after seven years have our magnificent efforts not conquered those fearful diseases that we call cancer? Why have we spent such a small percentage of our resources on nutritional and environmental activities? Why so little on prevention?'

"It appears to me," Dole continued, "that:

"Enough time has been passed since the 1971 act to warrant better answers to the questions the public is asking;

"Enough money has been appropriated to warrant more and better research for prevention-oriented research like diet and nutrition; and

"Enough shortsightedness has taken place during the appropriations process to now warrant better accountability of the funding to date.

"Since our hearings and broadcasts news programs following the hearings my office has received dozens of letters commending the subcommittee members for their oversight into federal funding for cancer research. I am glad to see that Dr. Arthur Upton, the director of NCI, on record as acknowledging that more money ought to be spent on preventing cancer by changing the environment, especially diet, and less on unproved hypotheses such as the idea that many cancers are caused by viruses.

"This past June 16 I wrote Dr. Upton a letter suggesting to him several things which might be done immediately to lend cridibility to this statement, and let the public know that something will be done and done immediately. Three such actions he can perform are: filling the terms of this year's five cancer advisory board members with persons holding educational backgrounds in nutrition; awarding more research grants in the applied nutrition field; and developing and distributing to the public materials describing the relationships we know documented to date about diet and cancer.

"As a public official entrusted with the leadership of the institute, certainly these are actions he can implement immediately. They can help us better address the need for more and better information to the public about nutrition's role in cancer prevention, rehabilitation, and maintenance.

"I again congratulate the Human Resources Committee for limiting this extension to one year. This year will provide us with ample opportunity to review the activities of the National Cancer Institute and in doing so, design for the future a program more responsive to the needs of our citizens. I trust we will find that an increased emphasis on the issues I have raised today will be appropriate.

"It seems to me that the American public has a right to know what has happened and what has not happened and what progress has been made. I suggest that, after all the billions of dollars have been spent, I do not know of one single pamphlet, one single piece of information, that has gone to the American public about how to prevent cancer, how it may be prevented through diet or through nutrition."

Dole erred on a number of points:

1. Cooper's remarks were taken totally out of context. The former assistant secretary for health was generally supportive of the Cancer Program as conducted by NCI and the cancer research community.

2. The statistics that 40-60% of cancer is nutrition related may well be true but are no less "unproved hypotheses" than viral etiology for some cancers.

3. He wasted his time urging Upton to fill the vacant seats on the National Cancer Advisory Board with nutrition experts. The President (until the Act renewal is passed) has that authority, and HEW Secretary Joseph Califano probably will be the one making those appointments.

4. If Dole couldn't find a single pamphlet or piece of information produced by NCI on prevention, it is because he did not try. NCI's Office of Cancer Communications has produced an impressive list of such material, particularly on smoking (interestingly enough, Dole never mentioned smoking, although a far stronger case can be made against cigarette smoking than against diet), NCI in fact has produced or supported these publications in the nutrition field: "Diet and Nutrition: A Resource for Parents of Children with Cancer;" "Diet and Nutrition for Cancer Patients and Their Families;" "Feeding the Sick Child;" "Nutrition in Cancer Therapy and Rehabilitation: A Guide for Health Professionals;" and five technical reports in the nutrition field.

That list, incidentally, was presented by Upton to the Senate at the same hearing before the McGovern

Nutrition Committee from which Dole collected most of his criticism. Dole (or his staff member who wrote the statement) apparently wasn't listening.

DOLE RAPS HEW FOR HOLDING UP ACTION ON PATENTS, INCLUDING SOME IN CANCER

Sen. Dole stirred up another controversy last week, this time coming down on NCI's side, sort of.

Dole issued a news release blasting HEW for "stonewalling" petitions from NIH grantees and contractors, including some supported by NCI, for release of patents on drugs and devices they are developing.

The government retains the rights to inventions developed through its support, but HEW in the past has attempted to encourage private sector development of drugs and medical devices by offering either nonexclusive or in some cases exclusive patent rights when requested.

Dole charged that HEW has reversed this policy and cited 29 examples of requests which have gone to the HEW general counsel without action, some of them a year ago. "HEW's decision to effectively suppress these medical breakthroughs is without precedent and is so unconscionable that I feel they are properly designated horror stories," Dole said.

"During the past year, the delivery to the public of potentially lifesaving drugs and medical devices developed under the auspices of HEW has been dealt a crippling blow. In clear violation of federal regulations governing disposition of inventions, HEW has reversed its long standing policy of permitting universities and medical research institutes to collaborate with the private sector for purposes of developing medical advances for diagnosing and treating such diseases as cancer, arthritis, hepatitis and muscular dystrophy," Dole charged.

Dole overstated the situation as far as the NCI supported projects are concerned. None of them could be considered "breakthroughs," although they do represent advances and some of them are very promising. NCI staff members supported the patent requests and are puzzled and annoyed over the HEW delays.

Dole chose as chief example the request of Michael Sela and his colleagues at Weizmann Institute for a patent on their carcinoembryonic antigens process as a diagnostic marker.

"Initial evaluation of this new assay has revealed it is superior to existing procedures for detecting cancer of the digestive tract," Dole said. "The advantages of diagnosing and evaluating cancer with blood samples were felt to be so significant that the professor promptly brought his research findings to the attention of the administration of the medical school as well as to his project manager at NIH. NIH as well as the university informed the professor that funds for clinical evaluation, running into the millions of dollars, were unavailable and suggested that he seek support from a private firm interested in marketing the device. Several companies were contacted in an effort to establish a collaboration with the university. At least one firm expressed a willingness to commit the necessary capital for development, but pointed out that even if the assay turns out to be as effective as the present evidence indicates, the company has no protection against its competitors copying the technique. Were this to take place, not only would the competitor have saved itself millions of dollars of risk capital, but in light of the limited market the firm could never recoup its investment. It therefore insisted on patent rights for a reasonable period of time as a shield against unscrupulous practices of other firms.

"Believing this to be a reasonable request, the professor petitioned HEW for rights to the invention so that patent protection could be extended to the private firm. After going many months without receiving word from HEW, the university requested a status report. It was informed the petition was under study.

"Several more months have gone by and it is a year and a half since the initial petition was submitted. The university was recently informed by the company that it no longer can commit its funds and must rescind the agreement. The professor has essentially given up on HEW and is back in his laboratory working on other projects. Interest in this once promising cancer diagnosis breakthrough has almost totally dissipated, and the assay is little more than an idle curiosity in the professor's laboratory notebook."

Ronald Herberman, chief of NCI's Laboratory of Immunodiagnosis, and Barbara Sanford, chief of the Cancer Biology Branch which administered Sela's grant, both supported the petition. Herberman told ***The Cancer Letter*** that Sela's method "had some promise, although there were some problems with false positives. It was not clear that it really was better, but we felt it would be worthwhile to explore it further."

Dole selected two other examples from the Cancer Program to include in what he called "HEW horror stories." One was the system using human tumor cells from individual patients to help plan individualized chemotherapy developed by Sydney Salmon and associates at the Univ. of Arizona (see In Brief, this issue). Another was the blood test for tumor related viral proteins developed by Solomon Spiegelman at Columbia Univ. Salmon's petition was sent to HEW Dec. 29, 1977, and Spiegelman's last April 11.

Other petitions by cancer investigators listed by Dole included:

Remers & Kumar, Univ. of Arizona, for new mitomycin anticancer agents (supported by the National Institute of Allergy & Infectious Diseases, according to Dole), filed Oct. 6, 1977.

Goldstein, Univ. of Texas, for hormone treatment

of immune system diseases, including cancer, filed Dec. 20, 1977.

Townsend & Earl, Univ. of Utah, for synthesis of anticancer compounds, filed Jan. 26.

Pogell & McCann, St. Louis Univ., for pamamycin, new antibiotic, filed Jan. 27.

Apple & Formica, Univ. of California, for azetomicin, filed April 7.

Farnsworth, Univ. of Illinois, for Jacaranone, filed April 20.

Turcotte, Univ. of Rhode Island, for anticancer drugs, filed May 1.

Pettit & Ode, for anticancer drugs, filed May 26.

Gosalvez, Univ. of Madrid, for analogs of adriamycin, filed July 17.

An HEW spokesman told ***The Cancer Letter*** that "there has been no change in policy. We are looking at each request on a case by case basis." He acknowledged that some may have been slowed up in the review process.

SOURCES SOUGHT

Title: *Plan, organize and conduct a technical symposium to further investigate the characteristics and performance of reduced dose mammography systems*

This will include both the clinical and technical characteristics of the new reduced dose detectors and detector systems, as well as provide a forum for a multidisciplinary discussion and interchange of ideas between researchers and practitioners directly concerned with this field.

At this time, only one source is known to have laid the groundwork necessary to conduct this type of symposium in the near future; that source being Roswell Park Memorial Institute.

Specifically, respondents will be required to perform the following: 1. Furnish all the necessary personnel, materials, services, facilities and otherwise do all things necessary for or incidental to the conduct of this symposium; 2. The symposium should be designed to attract a highly specialized and qualified group of scientists from government, academic institutions, industry, and the public sector. 3. The symposium should serve as a forum at which to exchange information on state-of-the-art technology and to educate users. 4. The contractor will prepare and edit the proceedings of the symposium in a format suitable for publication as a Bureau of Radiological Health (BRH) report.

Organizations having demonstrated capabilities and experience in the specific areas mentioned above and desiring consideration for request for proposals are invited to submit a concise and complete resume describing: 1) organization background and experience; 2) qualification and experience of the proposed principal investigator and supporting personnel which would be assigned to the project. Unnecessarily elaborate brochures or other presentations of a general nature beyond that sufficient to provide the information called for herein are neither required nor desired.

This synopsis is not a request for proposal. If other qualified sources are identified as a result of this announcement, a competitive RFP will be issued at a later date to all interested offerors. Responses must be submitted in six copies. The government does not intend to award a contract on the basis of this request for sources, or to otherwise pay for the information solicited.

Negotiated Contracts Branch
Att: C. Murphy, HFA-514
Food & Drug Administration
5600 Fishers Ln.
Rockville, Md. 20857

NCI CONTRACT AWARDS

Title: Demonstration for reimbursement in cancer control, renewal
Contractor: Blue Cross Assn., $649,928.

Title: Breast Cancer Detection Demonstration Project, renewals
Contractors: Univ. of Louisville, $173,461; and Mountain States Tumor Institute, $204,372.

Title: Phase I studies of new anticancer agents, continuation
Contractor: Univ. of Kansas, $27,826.

Title: Cancer Information Dissemination and Analysis Centers (CIDAC) for cancer virology, immunology and basic cancer biology
Contractor: Franklin Institute, $844,527.

Title: Production, purification and concentration of potentially oncogenic DNA viruses
Contractor: Life Sciences Inc., $260,709.

Title: Production and maintenance of selected reagent grade SPF animals, continuation
Contractor: Life Sciences Inc., $404,307.

Title: Research on spontaneous and virus induced neoplastic transformation, continuation
Contractor: Meloy Laboratories, $47,547.

Title: Development of the NCP project analysis model, renewal
Contractor: TRW Systems Group, $123,110.

The Cancer Letter —*Editor* JERRY D. BOYD

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