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OVERWHELMING 89 TO 7 VOTE BY SENATE OVERTURNS PRESIDENT REAGAN'S VETO OF NIH REAUTHORIZATION

The overwhelming votes in Congress to override President Reagan's veto of the Health Research Extension Act of 1985 were resounding victories for Sen. Orrin Hatch and Congressman Henry Waxman, and especially for National Cancer Program advocates led by the Coalition for Cancer Research and the American Cancer Society. The Senate's vote

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In Brief

NCAB DEC. MEETING INCLUDES BIOLOGICS SYMPOSIUM; EPIDEMIOLOGY CENTER GRANT PROGRAM DISAPPROVED

NATIONAL CANCER Advisory Board's December meeting will include a symposium on biologics Dec. 3 and 4. Topics to be addressed include cytokines, lymphokines, and modulators such as tumor necrosis factor, combined modality treatment, interferon in hairy cell leukemia and Steven Rosenberg's LAK plus IL-2 therapy. The symposium's session on monoclonal antibodies will include presentations on marrow purging, human use of anti-idiotype and anti-GD3 antibodies, antibodies conjugated to toxins, and imaging... **EPIDEMIOLOGY CENTER** grant program was not approved by NCI's Executive Committee because of budget constraints. The Executive Committee, however, will review the PO1 guidelines to ascertain which might be limiting to the epidemiology community, Div. of Cancer Etiology Director Richard Adamson told the division's Board of Scientific Counselors. The Preventive Oncology Academic Award has been rewritten to give equal weight to cancer etiology and cancer prevention and control, Adamson reported. Core grant guidelines will allow for epidemiologic and biometric resources, he said. A small grants program designed to support innovative studies in cancer etiology as well as dissertation research has been established .... **JOHN CARBONNEAU,** VP for medical affairs of ACS-Florida Div., will retire at the end of January. He will continue to work part time with the Florida Cancer Council, Florida Society of Clinical Oncology, and ACS-Florida.... **HOWARD OZER** has been appointed professor of medicine, chief of the Div. of medical oncology in the Univ. of North Carolina- Chapel Hill School of Medicine, and associate director of clinical affairs of the Lineberger Cancer Research Center. Ozer was formerly associate chief of the medical oncology department at Roswell Park aand associate professor of medicine and microbiology at State Univ. of New York at Buffalo.... **ISIAH FIDLER,** chairman of the department of cell biology and director of the interferon research program at the Univ. of Texas System Cancer Center, has been named the winner of the 1985 Alexandre Besredka Prize by the French-German foundation Journees immunologique - Immunologische Tage.

ACS, COALITION FOR CANCER RESEARCH GENERATED SUPPORT FOR OVERRIDE

(Continued from page 1)

of 89-7 on Nov. 20, coming after an equally impressive 380-32 vote in the House, sent the nitpickers and cancer program opponents in the Dept. of Health & Human Services and the Office of Management & Budget reeling with the most lopsided legislative defeat in the history of the Reagan Administration.

This was not the first time those forces at OMB and HHS have been rebuffed. They opposed the National Cancer Act from its inception in 1971 and at every renewal. But previous Presidents always went along with Congress and signed the bills. Reagan pocket vetoed the NIH reauthorization bill last year, which included National Cancer Act renewal, and Congress was deprived of the opportunity to override. A pocket veto is one which occurs after Congress has adjourned.

Ironically, the only President to veto the National Cancer Act is the one who personally has benefitted the most from progress against cancer.

The original, near unanimous votes in favor of the bill, HR 2409, should have sent a signal to OMB and the department, but in their arrogance, they ignored it. If heads do not roll because of the bad advice they gave the President, they should at least be resoundly rapped.

The massive support for the legislation as expressed in appeals to individual members of the House and Senate was generated primarily by the Coalition and its member organizations and by ACS. They were aided by forces supporting increased attention to arthritis research, lobbying for the new National Institute of Arthritis & Musculoskeletal & Skin Diseases; those pressing for more money for Alzheimer's disease research; and by nurses backing for the National Center for Nursing Research.

The message could not be more clear to the White House: the American people through their representatives in Congress support federal funding of biomedical research, and especially cancer research, more avidly than any other federal program. The time has come for the Executive Branch, from the White House down, to recognize this and stop trying to ignore or subvert the provisions of the National Cancer Act.

Through more than four years of discussions, hearings and negotiations, Hatch and Waxman have emerged as among the strongest friends the National Cancer Program has had in Congress. They managed to get almost everything in the bill asked by the various cancer constituencies, they were able to reach a compromise among themselves over several substantial differences in their respective versions, and they negotiated in good faith with the White House to meet Administration objections (to no avail, as it turned out).

Hatch had been ready to go to the Senate floor for an override vote as soon as the House had acted. However, Majority Leader Robert Dole (R.-Kan.) asked Hatch to wait until after President Reagan's meeting with USSR Leader Mikhail Gorbachev. Hatch agreed that many Republican senators might see a vote overriding the veto as weakening the President's hand during the summit and went along with Dole's request.

By the afternoon of Nov. 20, the substantive discussions at Geneva had been completed, with only the joint appearance of the two leaders and their summary statements scheduled for the last day. Hatch, Dole and other members of the leadership agreed an override at this point would not compromise the President's position, and they decided to move quickly, before OMB could start twisting some arms.

Discussion of the veto was opened at 7 p.m. and a vote was taken at 7:30. The seven who voted against overriding were all Republicans: John Danforth, Missouri; Jeremiah Denton, Alabama; Daniel Evans, Washington; Phil Gramm, Texas; Gordon Humphrey, New Hampshire; Paul Laxalt, Nevada; and Don Nickles, Oklahoma. Four were not present—John East (R.-N.C.), Daniel Inouye (D.-Hawaii), Arlen Specter (R.-Pa.), and Robert Stafford (R.-Vt.).

The remaining 89 voted to override, including Dole. It takes a powerful issue for a Senate majority leader to override a veto of his own party's President.

Not one word was uttered in support of the veto. Hatch disputed the President's arguments against the legislation, point by point. He said objections to the nursing center based on its $5 million a year cost were "preposterous. It is high time that nursing research took its rightful place in those NIH halls of ivy. A second reason that this bill should be signed into law is that without this legislation, the National Cancer Institute and the National Heart, Lung & Blood Institute are without authority in the law and are therefore subject to the whims of those who make budget policy only and who have no long term commitment to health policy."

Sen. Edward Kennedy (D.-Mass.), pointed out the bipartisan work that went into the legislation, disputed that it would lead to "micromanagement" of NIH as contended by the President, and supported the nursing center. He noted that Reagan had announced he would establish the arthritis institute by executive order. "My response to that . . . is that which is created by an executive order can be

destroyed by executive order.)"

Sens. John Heinz (R.-Pa.) and Slade Gorton (R.-Wash.) supported the legislation because of the nursing center, primarily. Sen. Bill Bradley (D.-N.J.) said he backed it because of the nursing center, arthritis institute and provisions emphasizing research on AIDS and Alzheimer's disease. Sen. Alan Cranston (D.-Calif.) supported the new institute, as did Lowell Weicker (R.-Conn.), who also liked the nursing center.

Even Barry Goldwater, a Reagan ally since the 1964 presidential campaign, urged an override, speaking eloquently for the arthritis institute.

Hatch closed out the debate by pointing out that the bill reauthorized the National Cancer Act. "It should be understood that this bill not only maintains the act and (NCI's) authorities but in fact strengthens and improves those authorities. For example, the bill improves the current cancer center core grant program, by extending to five years from three the life of the core grant, and continues intact the many authorities important to cancer centers. The bill improves the current NCI training authority, by clarifying that the authority specifically includes clinical research training, as well as continuing education and laboratory training. Many National Cancer Actw provisions have been continued or improved; the NCI director's peer review group appointment authority has been continued for specialized programs that do not fit the NIH peer review system well. Current law is maintained regarding the roles of the advisory councils and boards; the National Cancer Advisory Board members will continue to be appointed for six year terms; the President's Cancer Panel is continued with full responsibilities, and with the improvement that members' expired terms will be extended until new appointments are made; and the bill continues the NCI bypass budget and the Presidential appointment of the NCI director.

"There has been very strong support for this legislation from all elements of the cancer research and care community," Hatch continued. "The broad based Coalition for Cancer Research supports the bill strongly, as does the Assn.of American Cancer Institutes—cancer centers—and many cancer center directors individually. The American Society of Clinical Oncology, which has as its membership the great majority of physicians who provide clinical care and who harvest the research results to get them into the patient care system rapidly, strongly endorses the bill.

"It is essential that our past investments in the war on cancer, begun almost 15 years ago, be continued with strong and vigorous support."

After the Senate vote, John Ultmann, director of the Univ. of Chicago Cancer Center and chairman of the National Coalition for Cancer Research, said the override "is a momentous occasion in that both the House and Senate expressed endorsement of current efforts by NIH in general and specifically the strengthened organizational pattern of the National Cancer Institute. The reauthorization act meets all the concerns of the the cancer community expressed in the past year or two and allows NCI to carry out its mission. It's fortunate that Congress understands the public's concern for adequate support of cancer research."

John Grupenhoff, whose firm of Grupenhoff, Endicott, Maldonado & Fenninger represents AACI and ASCO, said "Senator Hatch is the hero of this override vote, just as Chairman Waxman was in the House. Hatch has become a powerful advocate of cancer research, and his top health aide, Dr. David Sundwall, did a superb job of pulling together the Senate and professional and lay resources for the override."

Grupenhoff added that "the important thing that happened was that ASCO and AACI leaders and the leaders of the Coalition for Cancer Research, instead of taking a confrontational attitude toward the situation which would have hurt in the long run, took a very professional and constructive attitude and worked with, rather than against, the congressional leadership and staff. The result in terms of cooperation and friendships that have developed between congressional leaders and the cancer research community has been astonishing. I believe that we are going to see a sort of era of good feeling for the next couple of years which we so badly need, in regard to congressional activity."

In addition to points cited by Hatch which extend or improve on the National Cancer Act, the law now:

*Maintains the NCI director's authority to collect, identify, analyze, and disseminate information on cancer research, diagnosis, prevention and treatment. The bill which Reagan pocket vetoed last year would have given the authority to the HHS secretary who could, but was not required to, delegate it to the NCI director. That authority, as granted in the National Cancer Act, has protected NCI in the past from OMB publication moratoriums.

*The new bill retains the language in the Cancer Act regarding mandated authorities of the NCI director, using the term "shall" where appropriate. Last year's bill would have changed that to "may" in many instances, thus giving the Administration the opening to order the NCI director not to carry out those activities, such as training, support of foreign research, large scale production of specialized biological materials and other therapeutic substances for cancer research.

*The bill extends to all NIH institute directors the NCI director's current authority to establish peer review groups when needed, i.e., specialized programs that do not fit the NIH peer review system well, such as cancer center core grants, cooperative groups, training, etc. That authority was left out of last year's bill.

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NCI GETS $1.258 BILLION IN FINAL APPROPRIATIONS FOR FISCAL '86

NCI will receive $1 billion $258 million in fiscal 1986 under final budget figures reached late last week in a House/Senate conference on appropriations. The figure reflects a $132 million increase over the administration's budget request of $1.126 billion for FY '86. The House's version of its appropriations bill would have given NCI $1.221 billion in 1986. The Senate version, which would have given NCI $1.271 billion in FY 1986, included an additional $17.1 million for AIDS research by NCI.

Although the Senate/House conference report on the appropriations bill was not available at press time, the bill does contain additional funding for AIDS research. The additional money is slated to go to NIH Director Wyngaarden's office for distribution within NIH. NCI officials, however, have emphasized that drug development efforts planned in conjunction with the National Institute for Allergy & Infectious Diseases will be funded by the additional funds earmarked for AIDS research.

A specific breakdown of the number of grants allocated to each institute is not yet available, but the final legislation will fund 6,100 grants for NIH as a whole.

NCI's grants payline will probably reach at least 165 under the new FY 1986 budget level, based on payline projections by NCI officials earlier in the year. At the National Cancer Advisory Board's October meeting, NCI Director Vincent DeVita presented grants projections based on the administration's 1986 budget request, the House appropriations bill, and an appropriations proposal passed by the Senate Appropriations HHS Subcommittee.

The early Senate version that would have given NCI $1.254 billion is closest to the final appropriations figure of $1.258 billion. Institute officials estimated that NCI could fund 982 new and competing research grants under the proposed $1.254 billion budget. The figure would have resulted in the institute's being able to fund approximately 31% of approved grants, at a priority score of 165.

NIH has been operating under continuing resolutions since fiscal year 1985 ended on Oct. 31. NCI Deputy Director Peter Fischinger told the Frederick Cancer Research Facility Advisory Committee that the institute has been operating on a month by month basis utilizing a very conservative payline during the past two months because of the uncertain budget picture. Fischinger reported that by the time final '85 awards were made, NCI funded 1,017 competing projects at a payline of 175, resulting in 30% funding of approved grants.

NIH officials have yet to determine a mechanisms distribution for awards under the new appropriations measure.

Although the bill does not contain language about positions at NIH, it is expected to be included in the conference report. Reports for both the original Senate and House appropriations bills discuss staffing levels NIH wide.

The House Appropriations Committee noted in its report that it "is aware that employment at NIH has been drastically reduced in recent years. Since 1984 staffing at NIH has decreased from 13,661 to 13,116, and further reductions are planned in 1986. In the same period, appropriations for NIH will increase from $4.5 billion to $5.5 billion."

The report advised that "employment ceilings have been imposed in total disregard of Congressional intent. The committee recognizes that the management of federal programs is primarily the responsibility of the Executive Branch, and that programs should be administered as economically as possible. On the other hand, inadequate staffing may lead to inefficiency and waste in the administration of public funds."

The House bill also directed HHS Secretary Margaret Heckler to "take immediate steps to correct" understaffing at the NIH Clinical Center, citing reports that "the patient care activities" are seriously understaffed.

Apparently, the joint version of the bill also avoids writing staffing levels into law, but will emphasize Congress' intent that staffing levels be increased throughout NIH.

PB-8511-018971

NCI CONSIDERS LEASING CHIMPANZEES TO TEST AIDS VACCINE CANDIDATES

NCI may pursue a "Rent-A-Chimp" operation in order to test candidate vaccines for AIDS, NCI Deputy Director Peter Fischinger told a meeting of the Frederick Cancer Research Facility's Advisory Committee. Problems encountered with attempts to use rhesus monkeys as an animal model for acquired immune deficiency syndrome, such as difficulties in infecting the monkeys with the HTLV-3 virus, have led investigators to conclude that chimpanzees are the only animal model left

in which to study candidates for an AIDS vaccine.

Although NCI has not conducted any AIDS related experiments with chimpanzees, Fischinger reported that other agencies have innoculated the animals with HTLV-3. Chimpanzees are easily infected, and once infected, the virus appears to persist for life, resembling its behavior in humans.

The use of chimpanzees "will have to be considered" once investigators have developed a good vaccine candidate, he advised.

NCI hopes to lease a number of the animals for a three year period in order to avoid the long term cost of maintaining the animals. Noting that "no chimps have ever been euthanized," Fischinger told the committee that it costs about $175,000 to maintain one chimpanzee for life. The chimps to be used would be obtained from a group that has already been infected with hepatitis, and therefore can't be used for any other kind of research, he said. Fischinger noted, however, that the animals' history of hepatitis shouldn't have an adverse effect on their suitability for AIDS vaccine testing since many people in high risk categories for AIDS have an increased incidence of hepatitis infection as well.

The institute may be able to access as many as 100 chimpanzees. Special considerations in the effort include the availability of P2 and P3 level containment facilities for the infected chimps.

Discussing other AIDS efforts by NCI, Fischinger reported "positive excitement" over preliminary results with the drug azido-thymidine currently being studied at the Clinical Center and Duke Univ.

"There has been really a definite improvement in a number of these patients" treated with the drug, he said. For example, one patient's T cells have increased 10 fold, although the count has not yet returned to normal. Other observations include weight gain (10 lbs. in one patient) and a decrease in ulcerations of AIDS patients. In addition, "mental functioning is actually coming back" in some patients treated with the drug, he said. For example, one patient, a neurosurgical nurse who developed AIDS following a blood transfusion, has demonstrated a significant improvement in mental functioning and has regained the ability to communicate that had been lost due to the disease.

Discussing the joint drug discovery and development project planned by NCI and the National Institute of Allergy & Infectious Disease, Fischinger noted that NCI's 25 years of experience in drug development has contributed to a computerized repository of more than 600,000 different agents that have been investigated. Many of those compounds are being looked at again as part of efforts to develop antiviral agents for the treatment of AIDS.

PROGRAM ANNOUNCEMENT

Title: Small grants program for epidemiology
Application receipt dates: Feb. 1, June 1, Oct. 1

NCI's Div. of Cancer Etiology invites small grant applications relating to cancer epidemiology beginning with the Feb. 1 receipt date in 1986. This is a short term award, not to exceed two years, intended to provide support for pilot projects, testing of new techniques, or innovative or high risk projects which could provide a basis for more extended research.

Investigators are eligible to apply for a small grant to support research on a topic relevant to cancer etiology if they are interested in planning a complex epidemiologic investigation; developing or validating a laboratory procedure for the ultimate purpose of applying it in cancer epidemiologic research; or carrying out an innovative epidemiologic research project not related to ongoing supported research, for which rapid funding is justified (the availability of special personnel for limited time periods is considered to be an important factor in evaluating the need for rapid funding). If the research will constitute a doctoral dissertation, a written statement from the applicant's dissertation chairperson or equivalent academic supervisor that the project proposal has his/her approval must accompoany the application.

The award will provide a maximum of $25,000 in direct costs. These funds may be used for technical assistance, supplies, small equipment, and travel required by the project. Salary support for the principal investigator will not be allowed. The normal duration of support is one year but applications may be made for longer periods (up to two years) if the limit on total funding noted above is not exceeded. NCI expects to make approximately eight awards from each review cycle.

Prospective applicants are encouraged to contact Dr. Genrose Copley, Landow Bldg Rm 8C16, NCI, Bethesda, Md. 20892, phone 301-496-960.

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NCI ADVISORY GROUP, OTHER CANCER MEETINGS FOR DECEMBER, JANUARY

National Cancer Advisory Board Committee on Organ Systems Programs—Dec. 1, NIH Bldg 31 Rm 8, 1 p.m.

NCAB Committee on Cancer Control & Year 2000--Dec. 1, NIH Bldg 31 Rm 3, 7 p.m.

National Cancer Advisory Board—Dec. 2-4, NIH Bldg 31 Rm 6, 8:30 a.m., all open. Annual program review.

Idiotype Networks and Immune Regulation: Potential Uses in Vaccines and Understanding Human Diseases—Dec. 4-6, La Mansion Del Rio Hotel, San

Antonio. Contact Dr. Daniel Watanabe, Interface, International Conferences, 1212 Cedar Post, Suite D, Houston 77055, phone 713-973-2870.

Chronic Health Hazard Risk Assessment: Improving the Science Review Process—Dec. 4, Mayflower Hotel, Washington D.C. Contact American Industrial Health Council, 1330 Connecticut Ave. NW, Washington 20036, phone 202-659-0060.

Cancer Centers Support Grant Review Committee--Dec. 5, Holiday Inn Plaza, Rockville, Md., open 8:30-9:30 a.m.

Cancer Therapy Program Project Review Committee--Dec. 5-6, NIH Bldg 31 Rm 8, open Dec. 5 8:30-9 a.m.

American Society of Hematology—Dec. 7-10, Hilton Hotel, New Orleans. Contact ASH at 609-848-1000.

Ovarian Cancer: Therapeutic Results and Exciting New Leads—Dec. 13-14, NYU Medical Center, New York. Contact Registration Office, NYU Postgraduate Medical School, 550 First Ave., New York 10016.

Developmental Therapeutics Contract Review Committee--Dec. 16, NIH Bldg 31 Rm 7, open 8-8:30 a.m.

Cancer Biology & Immunology Contract Review Committee—Jan. 8-10, NIH Bldg 31 Rm 8, open Jan. 8 and 10 9-9:30 a.m.

Health Implications of Smokeless Tobacco Use--Jan. 13-15, NIH Clinical Center, Masur Auditorium, 9 a.m. NIH consensus conference.

Current Therapy of Gastrointestinal Malignancies—Jan. 18, Cleveland. Contact Barbara Guy, Lowman 211, University Hospitals of Cleveland, 2074 Abington Rd., Cleveland 44106, phone 216-844-7856.

Div. of Cancer Prevention & Control Board of Scientific Counselors--Jan. 23-24, NIH Bldg 1 Wilson Hall, 8:30 a.m.

Gastroenterology Update: 1986—Jan. 25-Feb. 1, Vail, Colorado. Johns Hopkins Univ. School of Medicine and Presbyterian Hospital of Oklahoma City. Contact Jeanne Ryan, Program Coordinator, Office of Continuing Education, Johns Hopkins Univ. School of Medicine, 720 Rutland Ave. Turner 22, Baltimore 21205, phone 301-955-6046.

20th Annual Vail Midwinter Seminar--Jan. 29-31, Mark Hotel, Vail. GU and GYN cancers. Contact Chris Heminway, American Cancer Society, Colorado Div. Inc., 2255 S. Oneida, Denver 80224, phone 303-758-2030.

Administrators' Challenge: Responding to Change--Jan. 30-31, Four Seasons Hotel, Houston. Third annual administrative conference. Contact Office of Conference Services, M.D. Anderson Hospital & Tumor Institute, 6723 Bertner Ave., Houston 77030, phone 713-792-2222.

FUTURE MEETINGS

Advances in Cancer Prevention & Treatment--Feb. 22, Toledo. Contact Teri Swimmer, M.S., Northwest Ohio Cancer Network, Medical College of Ohio Cancer Program, C.S. #10008, Toledo 43699, phone 419-381-3717.

Calories and Energy Expenditure in Carcinogenesis--Feb. 24-25, Capital Hilton, Washington D.C. Contact Wendy Gasch, ILSI-NF, 1126 16th St. NW, Suite 111, Washington 20036, phone 202-659-0074.

American Society of Preventive Oncology--March 5-7, Bethesda Hyatt, Maryland. Annual meeting will include presentations on the rationale and achievability of NCI's Year 2000 goals; unsettled issues relating to tobacco and cancer; role of behavioral research and modification in control of cancer; clinical observations pertinent to molecular biochemistry; risks and benefits of hormonal replacement therapy at menopause; and chemoprevention trials. Contact Richard Love, MD, ASPO, 1300 University Ave.-7C, Madison, WI 53706, phone 608-263-7066.

New Concepts in Breast Cancer Management—April 12, Cleveland. Contact Barbara Guy, Lowman 211, University Hospitals of Cleveland, 2074 Abington Rd., Cleveland, OH 44106, phone 216-844-7856.

Food Antioxidants: International Perspectives--April 21-23, Loews L'Enfant Plaza Hotel, Washington, D.C. Includes discussions on general toxicity, carcinogenicity and genotoxicity and on studies of mutagenicity, mechanisms of action and tumor promotion. Contact Elaine Auld, International Life Sciences Institute-Nutrition Foundation, 1126 16th St. NW Suite 111, Washington 20036, phone 202-659-0074 or 872-0778.

Freestanding Cancer Center Development--May 13-14, Fox Chase Cancer Center, Philadelphia. Current and future role of FCCs, including clinical issues, role of surgeons in FCCs, hospital relationships; economic issues, joint ventures, and marketing; community relations; and national networking. Sponsored by Fox Chase Cancer Center, Intercommunity Cancer Centers of America and CDP Associates. Contact Ron Gilden, CDP Group, 5901 Peachtree Dunwoody Rd. NE, Suite C-100, Atlanta 30328, phone 404-391-9872.

RFPs AVAILABLE

Requests for proposal described here pertain to contracts planned for award by the National Cancer Institute unless otherwise noted. NCI listings will show the phone number of the Contracting Officer or Contract Specialist who will respond to questions. Address requests for NCI RFPs, citing the RFP number, to the individual named, the Blair building room number shown, National Cancer Institute, NIH, Bethesda, Md. 20892. Proposals may be hand delivered to the Blair building, 8300 Colesville Rd., Silver Spring, Md., but the U.S. Postal Service will not deliver there. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-67865
Title: Development and production of parenteral dosage forms of anti-AIDS agents
Deadline: Approximately Jan. 17, 1986

The Pharmaceutical Resources Branch of the Developmental Therapeutics Program, Div. of Cancer Treatment, is seeking a contractor to develop and manufacture parenteral dosage forms of anti-AIDS agents in support of DCT's clinical programs. The

project will also involve a complete quality control evaluation of the products. Offerors may bid on one or both of the following annual levels of effort: Level A, 66,560 staff hours; Level B, 29,120 staff hours.

The principal investigator should have at least three years experience in the development and manufacturing of sterile freeze dried dosage forms. Other personnel should possess suitable training and experience to insure satisfactory performance of all phases of work under their purview. The facilities and equipment must be adequate to develop, manufacture and quality control test sterile freeze dried dosage forms. The contractor(s) selected must be an FDA approved manufacturer of parenteral dosage forms at the time of cotract award. NCI expects to make either one award under Level A or two awards under Level B.

RFP NCI-CM-67864
Title: Analysis of chemicals and pharmaceutical formulations for anti-AIDS agents
Deadline: Approximately Jan. 17, 1986

NCI expects to award a cost reimbursement contract to a contractor with the capability to evaluate bulk chemicals and formulated drug products for identity, purity and drug content. Reports of the analytical testing on bulk rugs and dosage forms will be used as a bais for assessing the suitability of bulk drugs or finished dosage forms for use in screening, pharmacology studies, toxicological studies, formulation studies or for clinical trials. The data will also be supplied to FDA as part of IND filings for new anti-AIDS agents by NCI and the National Institute of Allergy & Infectious Diseases. Historical summaries of the data will be used in preparing specifications for the various bulk pharmaceutical substances. These specifications will be used in procurement actions, as well as for the routine quality control of these materials.

In addition, solubility and stability data will be developed, and selected assay methods will be adapted for the quantitation of drug in plasma. These data will be provided to other contract projects to facilitate formulation development, and to aid in the analytical aspects of pharmacology and toxicological testing.

The prinicpal investigator should be trained in chemistry (analytical, pharmaceutical, organic, etc.), preferably at the PhD level from an accredited school, and must be thoroughly familiar with the analysis and evaluation of bulk pharmaceutical substances and clinical dosage forms. Equivalent experience may be acceptable in lieu of the PhD.

RFP NCI-CM-67863
Title: Dosage form development of new agents for the treatment of AIDS
Deadline: Approximately Jan. 17, 1986

NCI is undertaking a drug development effort to evaluate new agents in the treatment of acquired immune deficiency syndrome (AIDS). A number of compounds are presumed to exhibit insufficient solubility and/or stability for intravenous administration. Therefore, NCI is seeking a contractor to 1) develop acceptable dosage forms of compounds to be subsequently evaluated in patients with AIDS; and 2) to carry out innovative studies leading to more effective approaches for the intravenous delivery of compounds that possess limited solubility and stability.

Three to four compounds will be assigned per year. NCI will select and provide the compounds to be studied. Most compounds will probably present significant solubility problems, but some comounds will exhibit adequate solubility and stability behavior and, thus, require only a straightforward dosage form development effort. These studies will also require considerable pharmaceutical analysis work including the development of a stability inducing assay applicable to the formulation. The following analytical equipment should be available: ultraviolet, infrared, and proton magnetic resonance spectroscopy; high pressure liquid chromatography with variable wavelength ultraviolet detection, optical rotation, and thermal analysis equipment.

The goals of the project are pharmaceutical dosage forms suitable for intravenous administration. The contractor wil provide a pilot batch (50-150 units) as a product of teh research effort for subsequent chemicl and/or biological evaluation at the discretion of NCI.

The principal investigator should possess a PhD in pharmaceutical or medicinal chemistry and have at least three years experience in the development of injectable formulations. The PI should devote about 500 hours each year to the project. About two staff years of effort wiull be required annually and 2400 direct labor hours should be at the PhD level. NCI expects to award a single contract on an incrementally funded basis. Each increment is for one year and the contract will be awarded for a three year period on or about July 21, 1986.

RFP NCI-CM-67862
Title: Development and manufacture of oral dosage forms of anti-AIDS agents
Deadline: Approximately Jan. 17, 1986

NCI's Pharmaceutical Resources Branch of the Div. of Cancer Treatment's Developmental Therapeutics Program is seeking a contractor to develop and manufacture oral dosage forms of anti-AIDS agents in support of DCT clinical programs. The project will also involve a complete quality control evalutaion of the products. Offerors may bid on one or both of the following annual levels of effort: Level A, 29,120 staff hours; Level B, 14,560 staff hours.

The principal investigator should have at least three years experience in the development and manufacturing of oral dosage forms. Other personnel should possess suitable training and experience to insure satisfactory performance of all phases of work under their purview. The facilities and equipment must be adequate to develop, manufacture, and quality control test oral dosage forms. The contractor(s) selected must be an FDA approved manufacturer of oral dosage forms at the time of contract award.

NCI expects to make either one award under Level A or two awards under Level B.

RFP NCI-CM-67867
Title: Large scale preparation of anti-AIDS bulk drugs for phase 2 and phase 3 clinical trials
Deadline: Approximately Jan. 17, 1986

NCI expects to award two cost reimbursement three year contracts to contractors with the capability to provide and operate a materials preparation laboratory for (a) the development of existing or new processes, procedures and techniques for the preparation of compounds, and (b) the synthesis of varying amounts of materials, not readily available from other sources in the quantity and/or quality needed by NCI.

The scale of the work to be performed under the solicitation is divided into two categories that relate primarily to the capacity of the offerors' facilities. Project A: An operating large scale facility with one small (20-50 gallons) and one large (100 galons or larger) glass lined reactor and the necessary supporting equipment and facilities. Project B: An operating pilot plant with a wide variety of glass lined reactors up to and including 500 gallons and the necessary supporting equipment and facilities.

Quantities of drugs requested will usually range from 50 grams to multi-kilograms. Process development for scale up and access to pilot plant equipment is essential. Specific assignment of the materials for preparation will be made by NCI, and may include synthesis of all types of chemicals and drugs. Quality specifications will be determined by NCI's Pharmaceutical Resources Branch. All materials must be evaluated by the synthesis laboratory for identity and purity before being submitted to NCI.

The principal investigator should be trained in organic or medicinal chemistry, preferably at the PhD level, or equivalent in experience and have extensive experience in chemical synthesis and synthetic process development.

AT the time of submission of proposal, the offeror must be registered with the FDA as a manufacturer of bulk drugs and shall have submitted a facilities drug master file to FDA. Facilities shall meet FDA standards in accordance with the current good manufacturing practices. Noncompliance with the above requirement shall immediately render the proposal technically unacceptable without the consideration of other evaluation criteria.

Two related RFPs are currently available. This RFP is an open competition. RFP NCI-CM-67871 (See following) is a 100% set aside for small business. Offerors who qualify as a small business are encouraged to submit proposals under both RFPs; however, not more than one award of the four awards available under both RFPs will be made to any single offering organization.

RFP NCI-CM-67871
Title: Large scale preparation of anti-AIDS bulk drugs by small business for phase 2 and 3 clinical trials
Deadline: Approximately Jan. 17, 1986

NCI expects to award two cost reimbursement contracts to small businesses with the capability to provide and operate a materials production laboratory for (a) the development of existing or new processes, procedures and techniques for the preparation of compounds, and (b) the synthesis of varying amounts of materials, not readily available from other sources in the quantity and/or quality needed by NCI.

The successful offeror shall provide an operating large scale facility with at least one small (20-50 gallons) and one large (100 gallons or larger) glass lined reactor, and the necessary supporting equipment and facilities.

The principal investigator should be trained in organic or medicinal chemistry, preferably at the PhD level, or equivalent in experience, and have extensive experience in chemical synthesis and synthetic process development.

At the time of submission of proposal, the offeror must be registered with FDA as a manufacturer of bulk drugs and shall have submitted a facilities drug master file to FDA. Facilities shall meet FDA standards in accordance with the current good manufacturing practices. Non-compliance with the above requirement shall immediately render the proposal technically unacceptable without the consideration of other evaluation criteria.

Contracting Officer
for above six RFPs: Edward Hodges
RCB Blair Bldg Rm 216
301-427-8737

RFP NCI-CN-65001-41
Title: Computing suppport for biometry branch
Tentative Deadline: mid-February, 1986

NCI is interested in soliciting proposals from small business organizations to provide all necessary personnel, facilities, equipment, materials and supplies, except as may otherwise be provided by the government, to provide programming and data management support for the research projects conducted by members of the Div. of Cancer Prevention and Control's Biometry Branch.

This procurement is a 100% set aside for small business. For the purpose of this procurement, a small business is classified as small if its average annual receipts for its preceding three fiscal years do not exceed $7 million.

Contract specialist: Susan Hoffman
RCB, Blair Bldg, Rm 2A07
301-427-8745

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