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User Fees Proposed For FDA Oversight Services; Industry Groups Call It "Tax On Innovation"

A Reagan Administration fiscal 1990 budget proposal would impose $100 million in fees on "users" of several Food & Drug Administration oversight functions, including medical product evaluations and application processing for new drugs.

The Administration proposal would seek to recover the cost of services provided by the federal government "when the

(Continued to page 2)

In Brief

Gregory Curt May Return As Director of COP; Koop Locked In As Surgeon General Until Nov.

GREGORY CURT, who left NCI last year to become chief of clinical pharmacology and director of medical education at Roger Williams General Hospital in Rhode Island, may return to fill the position left vacant when Samuel Broder was named NCI director. Curt, who was deputy director of the Div. of Cancer Treatment, would be DCT associate director and director of the Clinical Oncology Program. He would also assume the position of NCI clinical director, which was held by Vincent DeVita until he left, and has been held by DCT Director Bruce Chabner since. COP is the NCI intramural clinical research arm which includes the Medicine, Radiation Oncology, Surgery, NCI-Navy Medical Oncology and Pediatric branches. Chabner is also interviewing prospects for the job of DCT deputy director. He expects to make that appointment by the end of this month. . . **EVERETT KOOP**, the colorful, controversial and highly effective Surgeon General, cannot be forced out of office by the new Administration despite pressures generated by the fringe groups who would like to see him go. The Surgeon General appointment is for a specified term, and Koop's extends to November. He would consider reappointment if offered, or perhaps another job in government. . . . **NIH DIRECTOR** James Wyngaarden has been selected as the 1989 winner of the FASEB Public Service Award. The Federation of American Societies for Experimental Biology makes an annual award to individuals who have made outstanding contributions to biological and medical research. Wyngaarden has been NIH director since 1982. . . . **ANTHONY FAUCI**, director of the National Institute of Allergy & Infectious Diseases and director of AIDS research for NIH, has been named by the American Assn. for the Advancement of Science as winner of the second annual AAAS/Westinghouse Award for Public Understanding of Science and Technology.

User Fees Proposed For FDA Services, Associations Call It "Research Tax"

(Continued from page 1)
recipient of the service can be readily identified," according to the budget submitted to Congress earlier this month. "Those benefiting from a government service will have to pay for the service rather than being subsidized by the taxpayers."

Four trade associations that represent the biotechnology and pharmaceutical industry last week called the fee proposal a tax on research and innovation.

"User fees on FDA regulated medical technologies tax research, innovation and our competitive potential," said a statement by the Industrial Biotechnology Assn., Health Industry Manufacturers Assn., Pharmaceutical Manufacturers Assn. and the Proprietary Assn.

Specific fees for various FDA services have not been set, so it is difficult to gauge the effect of the proposal on sponsors of investigational new drug and new drug applications.

According to the budget proposal, the user fees would "benefit consumers and lessen the economic cost of FDA regulation by shortening the review time for drugs, medical devices and consumer safety activity."

Under the proposal, FDA would "establish several fees for a wide variety of services, including medical product evaluations, application processing for food additives and new drugs, and inspections of manufacturing establishments."

According to budget projections, FDA would receive $87 million in user fees in fiscal 1990, $97 million in 1991, $101 million in 1992, $103 million in 1993 and $104 million in 1994.

The proposal continued: "Federal agencies charge only nominal fees for services, so that the taxpayers end up subsidizing specific beneficiaries of services.

"These subsidies deter private firms from providing similar goods or services in some instances, precluding efficiency and innovation, and making it impossible to determine the real value of the service to the recipient.

"The proposed user fees would eliminate some of these taxpayer subsidies and facilitate more efficient provision and utilization of the services.

"As a result, the recipient would receive better quality service and the taxpayer would no longer be bearing the burden."

The four associations argued that FDA is charged by law with the task of protecting the public health from unsafe products.

"All new drugs or medical devices are required by law to go through an approval process at FDA before they can be marketed so that only safe and effective products are made available to the public," the groups said. "The benefit is to the American public, not to the individual companies which are regulated by FDA."

Calling on the Bush Administration to drop the fee proposal, the associations said the fees "will severely impact smaller, entrepreneurial companies and will negatively affect our competitive position internationally. As they discourage innovation, the public will be the loser."

The FDA fee proposal is part of a larger budget recommendation to charge user fees for a variety of federal services. Fees would also be imposed on users of some services of the U.S. Coast Guard, the Army Corps of Engineers and the U.S. Forest Service.

Robert Wood Johnson Wins $5M Grant For Environmental Center

The health effects of synthetic environmental chemicals and the relationship between nutrition and cancer are two main topics that will be studied under a new five year, $5 million grant creating an environmental health sciences center at the Univ. of Medicine and Dentistry of the New Jersey-Robert Wood Johnson Medical School in Piscataway, N.J.

The granting agency, the National Institute of Environmental Health Sciences in Research Triangle Park, N.C., is the principal federal agency for basic biomedical research on the health effects of environmental contaminants.

The New Jersey center is the 11th

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environmental health sciences center funded by NIEHS. Bernard Goldstein will be the center's director.

"Center grants allow the integration of a number of research and program projects," said David Rall, NIEHS director, in announcing the new center. "Each center defines certain areas of research interest, and the establishment of a center allows unity of purpose and central administration under a center director."

The new center will coordinate the work of 30 scientists conducting research five major areas:

--Studies of the metabolism of benzene in the body, and the mechanisms by which it causes diseases such as leukemia and anemia.

--Investigation of the effects on liver function of polycyclic hydrocarbons, chemicals emitted from vehicle exhausts, combustion and industrial processes.

--A project to monitor contaminants in blood and urine correlated with levels in food, water and air.

--Studies of the role of nutrition in inhibiting and promoting the development of malignant tumors.

--Research on how toxins affect nerve cell transmission.

Center grants provide funding for administrative costs, capital equipment, general services, core support and feasibility studies. Other NIEHS centers are located at Mount Sinai Medical Center, New York Univ., Johns Hopkins, Harvard, MIT, Univ. of Rochester, Vanderbilt, Oregon State Univ., Univ. of California (Berkeley), and Univ. of Cincinnati.

Bypass Budget: Ignored By OMB, Needs More Attention From Congress

The present time "is a time of high momentum, a time when progress can be pushed rapidly ahead or slowed immeasurably. Many findings from basic research are ready for translation into practical measures. It is a time when intellectual resources must be matched and supported by technical resources."

That theme was struck by Vincent DeVita in his message accompanying the FY 1990 NCI bypass budget, his final submission of that unique, potentially powerful but highly underutilized document.

No other agency in the federal government has the authority to go public with its own budget requests and send them directly to the President without interference or changes by the intervening heirarchy. That authority was granted NCI by the National Cancer Act of 1971 as part of the compromise which kept NCI within NIH and the Dept. of Health & Human Services.

Cancer program advocates who had lobbied for an independent NCI accepted the compromise in the belief that the bypass budget would be the budget submitted to Congress, possibly with some reductions by the President, but with the priorities and program areas intact. They were encouraged in that belief by President Richard Nixon, who said when he signed the Act that cancer research "will get all the money it needs."

Neither Nixon nor his successors kept that promise, and all of them and their staffs at the Office of Management & Budget have ignored the bypass budget. Instead, they consider a budget developed within NIH and HHS, with all the restrictions and competing advocacies. That is the budget that goes to Congress, such as the $1.6 billion request submitted last week. The bypass budget asked for $2.2 billion.

The bypass budget has been usefull, in that it has provided a figure to present to Congress, through unofficial channels or by the NCI director when specifically asked for the bypass figure by a congressman. It probably has helped encourage Congress to add money over the Administration requests, which has happened in all but the last year.

Considering the potential impact of the bypass budget, however, its value is far less than those who fought for the Cancer Act in 1971 had envisioned.

Enrico Mihich, associate director of Roswell Park Memorial Institute and a member of the National Cancer Advisory Board, has urged his fellow scientists to use the bypass budget in presenting their cases to Congress for cancer program funding. As 1987-88 president of the American Assn. for Cancer Research, Mihich tried to take his message to the key congressmen, senators and their staff members.

"Most of them had not heard of the bypass budget, and those that had said they did not think it was important," Mihich said.

That has to be corrected. The message must get through, that the bypass budget spells out the resources that are needed to build and maintain the most effective cancer research and control program possible. It is not pie in the sky. It is an annual presentation to the President and, indirectly, to Congress and the people of the United States, describing the efforts which can be made to reduce the toll

cancer exacts--500,000 American deaths a year--and how much those efforts will cost.

Copies of the 1990 bypass budget, 210 pages soft bound, are available at no charge from the NCI Financial Management Branch, NIH Bldg 31 Rm 11A18, Bethesda, MD 20892. The phone is 301/496-5803. It is a government publication with no copyright involved, so they may be reproduced in unlimited numbers.

Copies sent to congressional members and staff, and to other influential individuals, should be accompanied by a letter explaining the importance of the bypass budget.

The preface of the 1990 bypass budget notes that "it not only conveys the accomplishments that have been achieved by the National Cancer Program to date, but also presents the challenges that remain and the resources necessary to take full advantage of today's exceptional opportunities in order to successfully attain these goals.

"The bypass budget is a true reflection of the professional judgment of the Institute [and is reviewed and approved by the National Cancer Advisory Board], and represents a realistic appraisal of the scientific opportunities currently available. Given the achievements to date and the challenges ahead, it presents an opportunity for continued progress to achieve the ultimate goal of a world without cancer."

DeVita's message, as always, presents the case eloquently:

"The 1990 bypass budget conveys the challenges, accomplishments and opportunities that face cancer researchers. This budget is based on full exploitation of important scientific opportunities, with the inevitable and very real issue of cost being held just for the moment in abeyance. It is at the same time a realistic document and, if all the funds requested were to be made available, they could be put to immediate and valuable use.

"We have an enormous sense of urgency. Despite many major achievements, hundreds of thousands of people die each year of cancer. We know that many thousands of lives have already been saved by advances in diagnosis and treatment. We know, for instance, that if people didn't begin to smoke or stopped smoking totally that cancer rates would be reduced in 20 years by almost a third. We know that lives can be saved by early detection of many cancers such as breast cancer.

"Furthermore, despite rapid progress in cancer research and reasonably effective efforts at prevention, cancer will soon become the foremost killer in the United States. This is due to a combination of facts: there has been progress in treating and preventing cardiovascular disease; half of all cancers occur in people aged 65 and over; and our population is aging. So inevitably, there will be increases.

"There is good reason to take pride in the many important achievements of the National Cancer Program. These range from new insights into biological processes at the most minute molecular level of the cell to the establishment of a network of medical centers and community oncology groups which stretch across the nation that quickly bring the latest advances to the public.

"Since 1971, when the National Cancer Act was passed, many wise investments have been made in both basic research programs and in programs to apply the results of that research. The National Cancer Act was an extraordinary experiment in biomedical science. Through the Act, Congress and the American people made a farsighted investment in cancer research which has paid off handsomely. Scientists in 1971 were convinced that more basic research would make it possible to achieve an understanding of what makes a normal cell malignant. It was obvious to them that this detailed knowledge of the cancer cell was necessary to create realistic strategies for prevention as well as to improve cancer treatments. The alternative was to exhaust resources in random attempts to control cancer by making alterations in the environment.

"Knowledge does not always accrue in a predictable fashion. As the old saying goes, 'The wind favors the prepared sailor.' The United States was fortunate that the search for a viral cause of cancer had led to well established cancer virus research programs which have not only revealed information about the specific genes involved in the development of cancers, namely oncogenes, but have also established the intellectual and technical groundwork for the entire field of biotechnology. If this were all that had evolved from the cancer virus studies, that would be sufficient. These same studies, however, have yielded vital information about retroviruses and have ultimately saved lives by quickly giving the nation essential information about the AIDS viruses.

"Information about the genesis and development of cancer continues to unfold. Each finding moves us nearer to our goal of reducing morbidity and mortality from cancer. The

identification of the oncogene known as src, from a chicken virus and its counterpart in normal human tissues, suggested that cancer was the result of normal genes gone astray. Today, over 40 oncogenes have been identified, their protein products isolated and their various mechanisms elucidated. Also, in the past two years, an appreciation has developed of the function of not only oncogenes but of other genes which suppress the development of cancer. This will increasingly allow for more specific interventions to be designed.

"Similarly, research in cancer causation and prevention has moved forward rapidly. Cancer causation research and epidemiologic research have identified a wide variety of materials known to cause cancer in humans, starting with cigarette smoke in smokers, side stream smoke in nonsmokers, carcinogens in chewing tobacco, numerous occupational chemicals, viruses and, more recently, macro and micronutrients which accelerate or inhibit the development of cancer. As knowledge of the initiators of cancer is added to information about the development of cancer, the stage is set not only for effective prevention, but also for intervention even after hazardous exposure.

"In 1971, only 35 percent of patients were cured of cancer--primarily those who had cancers sufficiently localized to be cured by surgery or radiation. Fortunately, advances in cancer treatment have been remarkable, and today, half of all cancer patients can be cured. The investment in basic research in biochemistry, pharmacology and biology has provided a solid structure for modern systemic cancer treatment.

"Today, we see that the investment in basic research in cancer biology has also brought improvements in diagnosis. New and sensitive diagnostic tests have been developed which not only identify a tumor but allow an assessment of its state of development and its risk of spreading. Increasingly this allows physicians to prescribe therapies on a highly individual basis.

"The recent development of the biological response modifiers, the actual use of natural body substances such as colony stimulating factors and interleukin-2, has added a fourth modality to the three traditional methods of cancer treatment, namely, surgery, radiation and chemotherapy. Experience with biological response modifiers is rapidly accumulating, new combinations are being tried and the successes to date, particularly in previously intractable cancers such as renal cell and melanoma, are encouraging. It is nothing short of thrilling to look at the before and after treatment photographs of some of these patients and to see the reduction in their tumors. Although no one underestimates the need for extensive continued work, the promise of the biological modifiers program is bright.

"Clinical trials, carefully designed studies of new therapies or combinations of therapies in patients, are the means of both testing the new approaches and for gathering the type of information necessary to make a successful transition from the laboratory to the community. A major effort to expand clinical trials is in progress. The increased number of patients enrolled in these studies will speed information about new therapies and at the same time ensure that more patients will receive state of the art treatment or a therapy anticipated to be more effective. Clinical trials are carried out in cancer centers and through community oncology groups across the country.

"Each research advance brings the necessity for detailed exploration of the clinical implications and applications as well as the dissemination of the knowledge to health care professionals and the public. In this last year, advances in adjuvant treatment of very early breast cancer were obvious from the results of ongoing clinical trials. The designs of the ongoing clinical trials were shifted to give more women the advantage of this new knowledge of adjuvant treatment. A clinical alert was initiated to communicate to physicians the important information that had been gathered. It was recognized that delay of even a month could be measured in less positive outcome for thousands of women with breast cancer.

"Today, as a consequence of clinical trials, new high tech methods of drug development, the elaboration of biological response modifiers, and more sophisticated radiotherapy, we have new and better treatments for almost all the major cancer killers, including cancers of the breast, colon, rectum, lung, bladder, prostate, kidney, melanoma and bone and soft tissue sarcoma. Furthermore, treatments are both more effective and less difficult to tolerate. Consider that equal or better survival results can be obtained while preserving breasts, avoiding colostomies, avoiding impotence, and sparing limbs.

"The challenge is to amplify these results nationwide through more efficient technology transfer. Nor is it sufficient to reach only health professionals, as much of what has to

be done to prevent or detect cancer involves lifestyle changes such as improved diet or smoking cessation. In many cases it involves an individual decision to seek regular testing or to have a specific treatment. Information must be effectively communicated to the public so that individuals can be well informed.

"It is a time when useful results have come out of investigations of basic mechanisms, it is a time of high momentum, a time when progress can be pushed rapidly ahead aor slowed immeasurably. Many findings from basic research are ready for translation into practical measures. It is a time when intellectual resources must be matched and supported by technical resources.

"Francis Bacon said, almost 500 years ago, 'Nature to be commanded, must be obeyed.' The research effort that has brought us to this point has helped us understand the rules of cancer, the way that it works. It has given us insight into how to 'command' cancer to stop by 'obeying' its rules. The work is well under way; it must be confidently continued."

The 1990 bypass budget makes these major assumptions and increase requests:

* Research project grants (ROIs, POIs)--an increase of $221.4 million would fund 50 percent of approved competing grants at recommended levels. The President's request would fund only 21 percent, with reductions from recommended levels of two to 10 percent.

* Cancer centers--an increase of $35.1 million would fund up to five new centers, with the aim of increasing the number of centers by 50 percent by 1994. It would also provide funds for expanding the role of comprehensive centers, and full core grants at their full recommended levels. The President's request would result in a reduction in the number of funded core grants, plus sizeable reductions from recommended levels.

* Cancer prevention and control--an increase of $50.2 million would support prevention and control activities at an increase of approximately 70 percent over the current level, including doubling the number of Community Clinical Oncology Program awards. The President's budget calls for essentially a flat level for prevention and control, which considering inflation would reduce the level of activities.

* Clinical cooperative groups--an increase of $20.8 million would provide a start toward the goal of doubling patient accrual by 1992.

* Training--an increase of $15.9 million would support 1,800 trainees through the National REsearch Service Award program.

* Instrumentation--an increase of $20 million would provide for small instrumentation needs of the extramural community.

* Construction--an increase of $60 million would initiate a comprehensive program to upgrade and develop cancer research facilities including a five year plan for the modernization of the Frederick Cancer Research Facility. There is no money in the President's budget for construction.

* Two year authority--Increased availability for obligational authority is requested for construction funds to permit more prudent planning and utilization.

* Special initiative--an increase of $15 million would provide funds to upgrade biomedical research computing capabilities (supercomputer) at FCRF.

The bypass budget document includes progress reports and plans for new research in each of 11 research programs--biological carcinogenesis, chemical and physical carcinogenesis, tumor biology, diagnostic research, immunology, nutrition, preclinical treatment research, clinical treatment research, epidemiology, rehabilitation research and information dissemination.

It also includes reports on progress and needs involving cancer centers, research manpower development, construction, and cancer prevention and control.

A section on AIDS describes NCI's involvement in that research.

An appendix includes an NCI organizational chart, a summary of personnel requirements (the bypass requests 2,600 positions, while the President's budget authorizes only 2,000), a description of the NCI supported network cancer centers, clinical cooperative group members, cooperative group outreach program affiliates, CCOPs and Cancer Information Service offices, and current memberships of the National Cancer Advisory Board and the four program division Boards of Scientific Counselors.

A report by the National Academy of Sciences, National Academy of Engineering and Institute of Medicine calls for "cross agency perspectives" in funding science and technology budgets. The report was made to the House and Senate Budget Committees, as requested by those committees last year.

New Publications

New titles from Raven Press, 1185 Avenue of the Americas, New York, NY, 10036. Phone: 212/930-9500:

"Hormones and Cancer 3: Proceedings of the Third International Congress on Hormones And Cancer, (Progress in Cancer Research and Therapy, Vol. 35)" edited by Francesco Bresciani, Roger King, Marc Lippman and Jean-Pierre Raynaud. $90. Review of progress in the study of the endocrine control of cancer and the use of hormones in cancer diagnosis and treatment.

"Skin Tumors: Experimental and Clinical Aspects (Carcinogenesis: A Comprehensive Survey, Vol. 2)" edited by Claudio Conti, Thomas Slaga and Andres Klein-Szanto. $70. The biology of human and experimental skin tumors, including recent advances.

"Herpes and Papilloma Viruses: Their Role in the Carcinogenesis of the Lower Genital Tract (Vol.2)" edited by G. De Palo, F. Rilke and H. zur Hausen. $73.50. A sequel to a 1986 publication, this volume covers recent findings in molecular cloning, studies, and treatment for HPV, herpes and Epstein-Barr viruses.

"Multimodal Treatment of Ovarian Cancer (European Organization for Research and Treatment of Cancer, Monograph Series, Vol. 20)" edited by Pier Franco Conte, Nicola Ragni, Riccardo Rosso and Jan Vermorken. $75. Current status of ovarian cancer treatment, diagnosis and staging.

New titles available from Alan R. Liss Inc., 41 East 11th St., New York, NY 10003. Outside U.S. order from bookseller; prices may be higher outside North America:

"Advances in Cancer Control: Cancer Control Research and the Emergence of the Oncology Product Line," edited by Paul Engstrom, Paul Anderson and Lee Mortenson. $50 U.S. New advances in cancer research that are having a major impact on the industrialization of health care and product line management.

"Prediction of Response to Cancer Therapy," edited by Thomas Hall. $60 U.S. Evaluation of completed clinical studies to understand testing methods for patient reaction to therapy.

"Management of Advanced Cancer of Prostate and Bladder (EORTC Genitourinary Group Monograph 4)" edited by Philip Smith and Michele Pavone-Macaluso. $120 U.S. Current concepts in the diagnosis and staging of prostate and bladder cancers.

"Progress and Controversies in Oncological Urology II (EORTC Genitourinary Group Monograph 5)" edited by Fritz Schroder, et. al. $140 U.S. An attempt to reach international consensus on aspects of prostatic carcinoma research.

"Advances in Neuroblastoma Research 2," edited by Audrey Evans, Giulio D'Angio, Alfred Knudson and Robert Seeger. $130 U.S. Recent advances in research concerning this malignant childhood solid tumor.

Oncology Nursing

"Instruments for Clinical Nursing Research," edited by Marilyn Frank-Stromborg. $39.95. Appleton & Lange, 25 Van Zant St., East Norwalk, CT 06855. Resource guide for measuring and assessing human functioning and client status.

"Pain: Clinical Manual for Nursing Practice," by Margo McCaffery and Alexandra Beebe. Available February 1989. No price listed. C.V. Mosby Co., St. Louis. Reference guide on tools and techniques to assess and care for the patient with pain.

New publications available from the Oncology Nursing Society, 1016 Greentree Rd., Pittsburgh, PA 15220-3125:

"Monograph of the Advanced Research Session at the 13th Annual ONS Congress (1988)" edited by Marilyn Dodd. $6 ONS members, $7.50 nonmembers. Includes four research papers judged to be most meritorious among abstracts submitted for the congress session.

"The Master's Degree with a Specialty in Oncology Nursing," published in cooperation with the American Cancer Society. $2 ONS members, $4 nonmembers. Curriculum guide for educators in planning graduate oncology nursing education and for prospective students in selecting graduate programs.

"Cancer: The Outlaw Cell (Second Edition)," edited by Richard LaFond. $29.95 U.S. and Canada, $35.95 elsewhere. American Chemical Society, 1155 16th St. N.W., Washington, D.C. 20036. 800/ACS-5558. Articles by scientists on some of the most promising aspects of cancer research and clinical treatment. First edition was published in 1978.

"How to Improve Your Odds Against Cancer," by John Potter. $15.95. Frederick Fell Publishers, 2131 Hollywood Blvd., Suite 204, Hollywood, FL 33020. Healthy lifestyles and a self-examination regimen to aid in prevention and early detection.

"What Asbestos-Exposed Workers Should Know," by Irving Selikoff. $2. Workplace

Health Fund, 815 16th St. N.W. Suite 301, Washington, D.C. 20006. Q&A format explaining symptoms associated with asbestos related diseases, information patients should provide doctors, and medical tests. Discounts for bulk orders. Proceeds support WHF research and education program.

"Chemical Carcinogens," edited by P. Politzer and F.J. Martin Jr. $147.25 U.S. Elsevier Science Publishing, P.O. Box 1663 Grand Central Station, New York, NY 10163. In Europe, Sara Burgerhartstaat 25, 1055 KV Amsterdam, P.O. Box 330, 1000 AH Amsterdam, The Netherlands. Material from participants of the Interdisciplinary Cancer Research Workshops held at the Univ. of New Orleans on current work in chemical carcinogenesis.

"Making Intelligent Choices About Therapy," by the Leukemia Society of America, 733 Third Ave., New York, NY 10017, or through local chapters of the society. Brochure on unproven treatments and their warning signs to help patients of leukemia and related diseases avoid "quackery" treatment, and how to become involved in approved investigational treatment programs.

"The Structures of Life: Discovering the Molecular Shapes That Determine Health or Disease," booklet on research in structural biology. Office of Research Reports, National Institute of General Medical Sciences, Building 31, Room 4A52, Bethesda, MD 20892. Send self-addressed mailing label with request.

RFPs Available

Requests for proposals 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 Executive Plaza room number shown, National Cancer Institute, NIH, Bethesda, MD 20892. Proposals may be hand delivered to the Executive Plaza, 6130 Executive Blvd., Rockville, MD. RFP announcements from other agencies will include the complete mailing address at the end of each.

RFP NCI-CM-97596-19
Title: Provision, maintenance and transfer of tumor bearing animal models for investigation
Deadline: Approximately March 15

The Clinical Oncology Program of NCI's Div. of Cancer Treatment requires the maintenance of experimental labaoratory rodents for investigators located on the NIH campus. The contractor shall provide housing, handling and maintenance of both normal and experimental rodents, provide technical support in experimental manipulations, monitor health of animals, provide weekly health and mortality data of all animals, and record manipulations conducted.

The contractor shall provide daily transportation of animals between the contractor's facilities and the NIH campus including both a morning and an evening trip as necessary and provide 24 hour access, including weekends and holidays, to the animals by authorized NCI investigators.

As a minimum requirement, the contractor's animal facility must be within one hour travel of the NIH campus as NIH investigators will frequently transport chemical and pharmaceutical reagents as well as biological preparations from laboratories located on the NIH campus to the contractor's animal facility for experimental manipulations.

This is a recompetition of a contract held by Hazleton Laboratories America Inc. It is anticipated that one award will be made for a five year period and funded incrementally.
Contract Specialist: Zetherine Gore
RCB Executive Plaza South Rm 603
301/496-8620

NCI-CM-97579-48
Title: Production of antisense oligonucleotides for in vitro use and for animal studies
Deadline: Approximately March 1

This RFP is for competition for master agreements for the above named tasks. Master agreement is certification of eligibility, awarded to several organizations judged technically and scientifically qualified to compete for future master agreement orders.

NCI is seeking to identify those institutions with the capacity and expertise to provide oligodeoxynucleotides of given quality and of defined length, sequence and the desired chemical modifications as determined by the government. These shall include chemically unmodified sequences, phosphorothioates, methylphosphonates and ethyl phosphotriesters. These deoxynucleotides shall be manufactured by automated solid phase techniques, by standard solution chemical syntheses or by plasmid production or other technologies resulting in more efficient production of the materials. The master agreement holders shall also produce other chemically modified forms of oligodeoxynucleotides.
Contracting Officer: Thompkins Weaver
RCB Executive Plaza South Rm 617
301/496-8620

NCI-CN-95159-20
Title: Multidisciplinary technical resources and support for chemoprevention research
Deadline: Approximately March 25

NCI is issuing a RFP for master agreements to provide multidisciplinary technical resources and support for chemoprevention research according to the following tasks:

Task A: Drug development support for NCI chemoprevention programs. Provide for the assessment of status, progress and/or further evaluation of agents or technologies associated with the chemoprevention of cancer. May include the convening of expert panels and workshops.

Task B: Development of specialized products in support of the chemoprevention program. These products may include, but are not limited to, background documents, chemical worksheets, investigational drug brochures, FDA regulatory filings, patent support or customs support.

Offerors can submit proposals for either or both of the above tasks. Eacn task will be evaluated separately and two pools of master agreement holders will be awarded. All master agreement holders in each pool will be able to compete for master agreement orders issued during the five year period of performance. It is estimated that up to 10 master agreement orders will be awarded for Task A per year, and eight for Task B per year.
Contract Specialist: Charles Lerner
RCB EPS Rm 635
301/496-8603