THE CANCER LETTER

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House Bill Provides 5.7% Increase To NIH, But Passage Threatened By Amendments

Laden with controversial amendments that threaten its passage, the proposed House appropriations bill for the Depts. of Labor, HHS and Education was scheduled for floor action later this week.

The bill, HR 2127, includes a 5.7 percent increase for NIH. That unexpected increase would boost the Institutes' budget by $642 million above this year's budget of $11.297 billion.

For NCI, the bill proposes an appropriation of $2.251 billion, an increase of $114.676 million over this year's budget.

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In Brief

ASCO Congratulates Klausner; UCLA Names Gasson Head Of Jonsson Center

AMERICAN SOCIETY of Clinical Oncology last week issued a statement congratulating **Richard Klausner** on his appointment as NCI director. "Dr. Klausner is a distinguished molecular biologist, and has an impressive record of scientific and administrative accomplishments at NIH," said ASCO President **John Glick**. "ASCO is looking forward to a productive dialogue with Dr. Klausner regarding policy issues of clinical investigation, the importance of translational research, third-party coverage for screening and clinical trials, and patient access to cancer centers and high-quality care." **John Durant**, ASCO executive vice president, said, "ASCO and NCI have always had a positive, interactive relationship. The recent location of ASCO headquarters to the Washington, DC area makes us particularly well positioned to work closely with Dr. Klausner to maintain and expand this constructive relationship." . . . **JUDITH GASSON** will become director of the Jonsson Comprehensive Cancer Center at the Univ. of California, Los Angeles, on Sept. 15. Gasson, 43, a molecular biologist, becomes the only woman currently to head an NCI-designated comprehensive cancer center, of which there are 26 in the US. Gasson joined UCLA in 1983. She was instrumental in purifying GM-CSF. She is studying factors that make leukemia cells grow, and ways to multiply cancer patients' blood cells in the laboratory prior to bone marrow transplantation. . . . **RAJKO MEDENICA**, the Hilton Head Island, SC, physician known for his unconventional cancer treatment methods and famous patients, was arrested in Germany last week, the Hilton Head Island Packet reported. Medenica was convicted in absentia in Switzerland in 1989 and sentenced

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Controversial House Bill Provides Increase To NCI, NIH

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The proposed increase also would make NIH a target for constituencies of other programs that the bill cuts. The bill terminates 66 programs in HHS, 93 programs in the Dept. of Education, and 11 programs in the Dept. of Labor.

Moreover, the bill is so laden with controversial features that Rep. John Porter (R-IL), chairman of the Labor, HHS & Education Subcommittee, described the bill as "overloaded."

"What we have already attached to this bill is going to bring it down, quite frankly," Porter said in an attempt to head off yet another controversial rider to the appropriations measure. Porter's comments first appeared in the Washington FAX.

The committee report and the bill it accompanies contain the following controversial provisions:

- Bars the use of federal funds for policy advocacy and requires each department to develop tests to assure that federal grantees and contractors are not using federal funds for advocacy.
- Gives states the option not to pay for abortions resulting from rape or incest and bars private accreditation organizations from requiring medical schools to include training in abortion procedures.
- Bans federal funding for human embryo research.
- Eliminates funds for family planning services.
- Does not provide a specific appropriation to the NIH Office of AIDS Research, instead allowing the NIH director to allocate funds for AIDS.
- Eliminates the offices of the HHS Assistant Secretary for Health and the Surgeon General.

In its language on NCI, the report states that the Institute crossed "the bounds of its portfolio" when it funded a project that included a study of the tobacco industry campaign contributions to state legislators and voting records by those legislators on tobacco control initiatives.

The language is aimed specifically at a study conducted by Stanton Glantz, professor of medicine at the Univ. of California at San Francisco. Glantz submitted his proposal in response to an NCI program announcement and received the grant following peer review. Glantz's work was subject of a series of articles and an editorial in the July 19 issue of the Journal of the American Medical Association.

"I think it's amazing that this one grant has been singled out this way," Glantz said to **The Cancer Letter**. "I think it speaks volumes to the contributions to cancer control that our work has been making."

In other highlights, the committee report:

- Transfers responsibility to NIH for primary support of the extramural AIDS research program funded by the Dept. of the Army.
- Encourages NIH to strengthen basic, behavioral and clinical pediatric research and establish guidelines to include children in clinical trials.
- Endorses the expansion of clinical research training, the General Clinical Research Centers program, and development of a loan forgiveness program for health professionals who pursue clinical research careers, as outlined in a 1994 Institute of Medicine report.
- Encourages NCI to re-establish coordination of the National Cancer Program, including cancer activities of the Centers for Disease Control and Prevention and other federal agencies.
- Provides $2.125 billion for the Centers for Disease Control, $39 million above the current year's budget, and $97.7 million below the Administration's request. Disease prevention and cervical and breast cancer screening activities are to be increased.

The report includes an 85-page section devoted to dissenting views by Democratic members of the committee.

Text of Committee Report

The text of the House committee report on NIH and NCI follows:

The Committee views NIH as one of its very highest priorities and has made difficult resource

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allocation decisions throughout the bill to preserve what it believes is the minimum necessary funding level for NIH. NIH is the world's leading biomedical research institution; its investments in research save lives and reduce health care costs while creating jobs and economic growth in a global economy. In recent years, this research has produced major advances in the treatment of cancer, heart disease, diabetes, and mental illness that have helped save lives and improved quality of life. NIH supports over 50,000 scientists at 1,700 universities and research institutes across the US In 1993 alone, NIH contributed nearly $45 billion to the US economy and over 700,000 jobs. NIH research has spawned the biotechnology revolution, whose products are projected to grow into a $50 billion industry by the turn of the century. The US's ability to translate scientific discoveries into new product development has resulted in its lead over the European Community and Japan in pharmaceutical and biotechnology patents. While the Committee is firm in its commitment to deficit reduction, it believes that funding of biomedical research is an important investment in the future health and economic well-being of our nation.

Balance in the research portfolio.—The Committee believes that NIH should allocate the funding provided on the basis of scientific opportunity. The Committee heard compelling testimony from the Director of NIH during the appropriations hearings about the problems inherent in using other decision rules to allocate funding. While the Committee understands that other factors are relevant, such as the infectious nature of a disease, the Committee believes that judgments based on numeric measures or other factors are fraught with potential bias. The Committee wants to avoid endorsing any methodology that could be characterized as focusing on the "disease of the month." The Committee believes that the advances made in research areas like Parkinson's and Alzheimer's disease are largely due to NIH's flexibility to fund promising research on the basis of scientific opportunity.

As a result, the Committee has allocated the funding provided above the President's request consistent with the distribution reflected in the request, believing that it represents NIH's judgment of scientific opportunity. If NIH believes that adjustments to this allocation are necessary, the Committee would be pleased to consider them in later action on the bill. To enhance NIH's flexibility to allocate funding based on scientific opportunity, the Committee has attempted to minimize the amount of direction provided in the report accompanying the bill. For example, there are no directives to fund particular research mechanisms, such as centers or requests for applications. The Committee does believe it is appropriate to highlight disease areas of interest to Members of Congress, but does not intend for that to impede NIH's flexibility in decision-making.

AIDS Funding.—Consistent with the philosophy outlined above, the Committee has not earmarked a specific dollar amount for AIDS research and has not continued the procedure of establishing a single appropriation for the Office of AIDS Research. Especially since the total provided for NIH is different than the President's request, the Committee believes the Director of NIH, acting in conjunction with the Director of the Office of AIDS Research, should decide how much of the total NIH appropriation should be allocated to AIDS research. The Committee intends that the funds devoted to AIDS should continue fully to exploit scientific opportunities and to fulfill scientific objectives in this critically important research program. The Committee expects the Director of NIH, through the Director of the Office of AIDS Research, to identify the total allocated for AIDS and his intended distribution by Institute under the House funding level prior to conference on the 1996 bill. The Committee has provided the Director transfer authority to reallocate funds among appropriations accounts, subject to consultation with the House and Senate Appropriations Committees. The Committee encourages NIH to use this authority whenever it believes that an adjustment in the allocation of AIDS funding between Institutes is appropriate to achieve scientific objectives or to facilitate promising research efforts.

The Committee wants to make clear that it continues to support the Office of AIDS Research (OAR), its leadership, and its coordinated budget planning process and that it expects the individual institutes, centers and divisions to fully cooperate with OAR's work. The Committee assumes that the NIH Director's decisions on allocating AIDS funding will be fully consistent with the plan developed by the OAR and that he will ensure that the Institutes allocate their budgets accordingly. The Committee particularly applauds the formation of the OAR external review panel which is conducting a broad-based evaluation

of the NIH AIDS research portfolio. The Committee would expect the recommendations of this panel to guide and inform the NIH Director's allocation of AIDS funding. Lastly, the Committee assumes that the OAR will maintain its current structure and responsibilities, including the allocation of an emergency discretionary fund.

Management improvements.—Despite the Committee's wholehearted support of NIH's research efforts, it believes that improvements can and should be made to the management of its research enterprise, both in the administrative operations on the NIH campus and in its funding of extramural grants. The Committee believes that increased efficiencies are important to expand the share of funding actually going to research rather than administration, particularly in an environment of constrained resources. In later years, as spending caps government-wide continue to decline, the pressures to maximize the share of NIH funding going directly to research will be even greater. To that end, the Committee directs that research management and support costs at NIH will be reduced 7.5 percent below 1995 levels, and that costs associated with congressional and public affairs functions will be reduced a total of 10 percent below 1995 levels. The calculation of research management and support costs should include those expenses at the National Library of Medicine, as well as within the Office of the Director, excluding the Director's discretionary fund and the Women's and Minority Health Initiatives. This is consistent with that policy followed throughout the bill by the Committee, except that in this case, the Committee has not reduced overall funding, instead preserving it within the NIH accounts to increase the amount of research supported. Any funding of research and management support costs in excess of these levels should be treated by NIH as a reprogramming subject to the approval of the House and Senate Appropriations Committees. The Committee does not direct NIH to take particular approaches in achieving these reductions, but does encourage NIH to consider two areas: (1) consolidation of certain functions across Institutes, such as personnel, legislation, planning and evaluation, and communications; and (2) dismantling issue- or constituent-specific offices within the Office of the Director or the individual Institutes which are not mandated by law.

Indirect costs.—The Committee has expressed its concerns in the past about the current method for reimbursing the indirect costs associated with research. It continues to be an area of great concern. The Committee believes this is a key area in which savings could be generated, which could then be plowed back into the direct costs of research. It could also have the welcome side benefit of reducing administrative burdens, both for the Department and the institutions receiving NIH grants. The Committee views the Administration's indirect cost proposal as a useful start—particularly its proposal to end reimbursement for tuition payments for university employee dependents, which the Committee urges the Administration to finalize—but believes the system needs more fundamental reform. The Committee is intrigued by the development of the so-called "Phoenix Plan" by a group of university officials, which explores the potential of moving from a cost-based to a price-based system of reimbursement, comparable to the reforms implemented in the Medicare program in the 1980s. The Committee encourages the creators of the Phoenix Plan to conclude their study as quickly as they can, and urges NIH and the Office of Management and Budget to fully cooperate with their efforts. The Committee also notes that the House Science Committee is drafting legislation to require the Office of Science Technology and Policy to complete a study by the end of the year identifying the best ways to achieve a ten percent reduction in indirect cost reimbursement government-wide. The Committee awaits the outcome of that study with interest. In short, the Committee believes it is important to continue to scrutinize the current indirect cost system. While it is aware of the complexity and the controversy of the issue, it does not believe the status quo is sustainable or defensible in an environment of steady or declining resources.

Policy planning.—The Committee believes that the concept of a central planning authority, such as that vested in the OAR, could have broader applicability to other research areas in NIH with trans-Institute scope. The Committee would like the NIH Director's assessment of the utility of establishing a broader central policy office, perhaps through consolidating portions of the planning and evaluation functions in the individual Institutes, that would handle crosscutting issues. The assessment should address issues such as the potential cost-savings from consolidation and the appropriateness of more central policy planning for a range of NIH issues. The Committee would like to receive this

assessment prior to the 1997 appropriations hearings.

Communications.—The Committee continues last year's focus on NIH's external communications. The Committee believes it is critical for NIH to use all the media at its command to publicize the benefits and results of NIH research, in order to solidify the general public support of biomedical research and to identify NIH as the funding source for these breakthroughs in the public's mind. The Committee also urges NIH to take whatever steps are necessary to ensure that its grantees acknowledge NIH's funding contribution when they publicize their research findings. The Committee believes that these efforts can be supported within the funding levels already provided.

Report Language On NCI

The bill includes $2,251,084,000 for NCI, an increase of $31,287,000 over the amount requested and $114,676,000 over the comparable 1995 appropriation.

Breast cancer.—The Committee recognizes that breast cancer research continues to require a significant allocation of NCI resources in order to decipher the complex mysteries of this disease. The Committee agrees with NCI which places breast cancer research as a high priority within the Institute. Therefore, the Committee directs NCI to continue to strengthen its commitment to breast cancer research, including the National Action Plan on Breast Cancer.

Prostate cancer.—The Committee notes that the incidence of prostate cancer continues to rise, and urges that further effort be placed on research related to early detection, diagnosis, and treatment, particularly among minority Americans.

Minority populations.—The Committee continues to be concerned about the disproportionately high prevalence of cancer among disadvantaged and minority populations. Despite an overall drop in breast cancer rates, breast cancer rates for African American women continue to increase. Also, African-American males continue to experience the highest rate of prostate cancer of any population group in the world. The Committee encourages continued research emphasis in breast and prostate cancer and other high priority cancer areas in a concentrated effort to address the needs of minority populations.

Leukemia.—The Committee recognizes the importance of continued research and clinical trials for leukemia. Noting that changes in health care financing have slowed the development of more effective treatment for leukemia, the Committee urges NCI to support further leukemia-related translational research for innovative, peer-reviewed clinical trials.

Neurofibromatosis.—The Committee remains fully committed to continuation of an aggressive program of research on neurofibromatosis throughout NIH and urges NIH to ensure that funding levels reflect that priority. This work has already produced major breakthroughs, particularly in areas of genetics and the links between neurofibromatosis, various cancers, and other devastating diseases. The Committee encourages the Institutes at NIH with NF projects to work together with the extramural research community to develop a coordinated plan to move this research forward. The Committee encourages NIH in managing this effort to support a variety of collaborative approaches including the possibility of jointly sponsored requests for applications and an NIH-wide consensus conference to bring together experts from throughout the world to make recommendations on research opportunities and priorities.

Nutrition.—The Committee encourages NCI to continue its strong work in the nutrition field and to consider placing a priority within that field on breast cancer research and other research involved with women's health. Chemoprevention, an important activity of this Institute, often relates to substances in the diet. Support of clinical nutrition research units assures that basic information on chemoprevention is studied in the clinical arena.

Translational research.—The Committee notes the importance of translational research in moving research advances from the "bench to the bedside." The Committee encourages NCI to address to the extent it can [remove] some of the barriers to conducting translational research that were identified in the National Cancer Advisory Board's 1994 report.

Cancer coordination.—The 1994 report of the National Cancer Advisory Board entitled "Cancer at a Crossroads" outlined that the national cancer program suffered from an absence of a national coordination of cancer fighting efforts in the public, private and voluntary sectors. The Committee recommends that NCI take the leadership working in coordination with the CDC and other Federal agencies to re-establish coordination of the national cancer program. The Committee expects that other agencies

will work with NCI to facilitate this recommendation. Before hearings on the fiscal year 1997 budget, the Committee would like a brief report outlining the progress made to accomplish this recommendation.

Study of campaign contributions.—The Committee was disturbed to learn that NCI has funded a research grant studying tobacco industry campaign contributions to State legislators and voting records by those individuals on tobacco control initiatives. While the Committee is not rendering judgment on the merits of the grant proposal, it feels strongly that such research projects do not properly fall within the boundaries of the NCI portfolio, especially when nearly three-quarters of approved research projects go unfunded.

Accordingly, the Committee does not provide any further funding for this research grant within the NCI appropriation.

ODAC Okays Gemcitabine For Pancreatic Cancer

The FDA Oncologic Drugs Advisory Committee last week recommended marketing approval for Gemzar (gemcitabine hydrochloride, Eli Lilly and Co.) for the treatment of locally advanced or metastatic pancreatic cancer.

The committee voted 8-3 to recommend approval of the drug after reviewing the results of two clinical trials.

The trials were unusual in that the company worked with FDA to establish a novel clinical endpoint with which to measure the efficacy of the drug.

Because pancreatic cancer is often difficult to diagnose and is diagnosed in advanced stages, traditional means for establishing the activity of a chemotherapy agent, such as the rate of tumor growth or shrinkage, often do not provide a meaningful analysis of a patient's overall health.

The novel endpoint, termed "clinical benefit," was designed to quantitatively measure the effect of Gemzar on patients' overall quality of life. The components include the patient's level of pain, need for pain medication, ability to perform daily activities and weight change.

"I want to congratulate the company on putting a lot of effort into a very difficult area (clinical benefit endpoints) in a manner that is conservative," said ODAC member Richard Gelber, professor of pediatrics, Dana Farber Cancer Institute.

Clinical Data

One phase III, multi-center, randomized trial compared Gemzar to 5-fluorouracil (5-FU). The study measured survival, an overall estimate of clinical benefit, and tumor shrinkage in patients who had not previously received chemotherapy.

In the study, 63 patients were treated with each compound. The six-month survival rates were 46 percent and 31 percent for Gemzar and 5-FU respectively, and the one-year survival rates were 18 percent and 2 percent for Gemzar and 5-FU respectively.

There was an approximately one and a half month improvement in median survival in patients who received Gemzar in this study.

In addition, 24 percent of patients who received Gemzar experienced "clinical benefit" compared with 5 percent of patients treated with 5-FU. The partial response rate (50 percent or greater decrease in tumor size) for patients treated with Gemzar was 5.4 percent compared with 0 patients treated with 5-FU.

Disease stabilization (a decrease of less than 50 percent and an increase of less than 25 percent in tumor size) for patients treated with Gemzar was approximately 39 percent compared with 19 percent for patients receiving 5-FU.

"This randomized study showed a 30 percent improvement in median survival, illustrating the potential benefit of Gemzar as the initial treatment for patients with advanced pancreatic cancer," according to lead investigator Malcolm Moore, Princess Margaret Hospital, Ontario, Canada, who presented the results to the committee.

A second phase II trial included 63 patients who had not responded to 5-FU treatment. Symptoms improved in 27 percent of patients, with a median survival time of 3.85 months, a six month survival rate of 31 percent and a one-year survival rate of 4 percent.

A partial response rate was observed in approximately 10 percent of patients, and disease stabilization was reported in approximately 30 percent of patients.

"This study demonstrates that objective criteria can be used to evaluate the clinical impact of therapies being evaluated for difficult to treat solid tumors like pancreatic cancer, a highly symptomatic disease that is difficult to assess by traditional tumor response parameters," according to lead investigator Mace Rothenberg, Univ. of Texas Health Science Center.

Side effects of Gemzar include neutropenia, a decrease in white blood cells which may increase the susceptibility to infection, thrombocytopenia, a decrease in blood platelets which may cause excessive bleeding; and elevation of liver enzymes. Nausea, vomiting, rash and flu-like symptoms and traces of blood and protein in urine have been reported.

ODAC Backs New Use For Aredia

The committee also recommended that FDA approve a new indication for the Ciba-Geigy AG drug Aredia.

ODAC found the drug safe and effective to treat bone metastases associated with multiple myeloma.

Aredia is already approved in the US to treat *hypercalcemia of malignancy*, an abnormally high level of calcium in the blood sometimes caused by cancer.

In Brief

Medenica Arrested; Revised PHS Grant Form Available

(Continued from page 1)

to four years in prison for false billing practices. He was also convicted in the former Yugoslavia and sentenced to 20 years in prison. Medenica was arrested in the Munich airport as he was traveling to an AIDS conference in Austria, the paper reported. Last February, a jury awarded $14 million in damages to a Hilton Head couple who claimed Medenica was negligent in his treatment of a breast cancer patient (**The Cancer Letter**, Feb. 24). . . . **REVISED PHS 398** grant application form is now available, and should be used for receipt dates beginning Sept. 1, and must be used for the receipt date of Jan. 1, and thereafter. A major change in the new PHS 398 is the format of the application kit. To request two or more copies of the new PHS 398, contact: Administrative Services Office, Div. of Research Grants, NIH, 6701 Rockledge Drive MSC 7760, Bethesda, MD 20892-7760, email: amrg@drgpo.drg.nih.gov. Provide a complete mailing address, the number of copies needed, and an email address or telephone number. . . . **JOHNS HOPKINS HOSPITAL** has been pledged $20 million from the Harry and Jeanette Weinberg Foundation to support construction of a new comprehensive cancer center on the East Baltimore campus. The gift is the largest donation to any project in the hospital's history. The new building, estimated to cost $97.7 million, will expand clinical space and allow Hopkins to serve 15 percent more cancer patients each year, the hospital said. . . . **LAURENCE HURLEY**, of the Univ. of Texas at Austin, will direct the department of chemistry at the Institute for Drug Development, of the Cancer Therapy & Research Center, in San Antonio. Hurley, a medicinal chemist, is known for his work on drug-DNA interaction and drug design. . . . **ASSOCIATION OF** American Cancer Institutes has elected new officers for 1995-96. They are: president, **Paul Bunn**, Univ. of Colorado Cancer Center; vice president and president-elect, **Joseph Pagano**, UNC Lineberger Comprehensive Cancer Center; chairman of the board, **John Kovach**, City of Hope National Medical Center; secretary-treasurer, **Edwin Mirand**, Roswell Park Cancer Institute. Newly elected board members are: **Richard Schilsky**, Univ. of Chicago Cancer Research Center; **Robert Young**, Fox Chase Cancer Center; and **I. Bernard Weinstein**, Columbia-Presbyterian Cancer Center.

ORI Finds California Scientist Committed Misconduct

The Office of Research Integrity has made final findings of scientific misconduct in the following case:

—James Urban, California Institute of Technology. ORI has found that Urban engaged in scientific misconduct. This finding is based on an investigation by the California Institute of Technology, which concluded that Urban committed serious errors in judgment and serious scientific misconduct in connection with fabricating certain research data in two scientific papers that were published in the journal Cell.

The first paper is J. Urban, V. Kumar, D. Kono, C. Gomez, S. Horvath, J. Clayton, D. Ando, E. Sercarz, and L. Hood, "Restricted Use of T Cell Receptor V Genes on Murine Autoimmune Encephalomyelitis Raises Possibilities for Antibody Therapy," Cell 54: 577-592 (1988). The second paper at issue is J. L. Urban, S. J. Horvath and L. Hood, "Autoimmune T Cells: Immune Recognition of Normal and Variant Peptide Epitopes and Peptide-based Therapy," Cell 59: 257-271 (1989).

The CIT report states that Urban admitted that he fabricated two control lanes reported in Figure 5 of the Cell 54 paper. With respect to the Cell 59 paper, the CIT report states that Urban admitted that he

circulated draft copies of the manuscript that contained fabricated data in order to circumvent both the internal and external review processes.

Urban has accepted the ORI findings and agreed to exclude himself voluntarily, for a period of three years beginning June 2, from any contracting or subcontracting with any agency of the government and from eligibility for, or involvement in, nonprocurement transactions (grants and cooperative agreements). This voluntary exclusion does not apply to Urban's current or future practice of clinical medicine or training, whether as a resident, fellow, or licensed practitioner, unless that practice involves the proposing, conducting, or reporting of biomedical or behavioral research or research training. Urban also agreed to exclude himself voluntarily from serving on any PHS advisory committees or peer review committees for the same three-year period.

ORI acknowledges that Urban cooperated with the CIT Investigation Committee during its investigation of allegations of scientific misconduct and with ORI.

SAIC Frederick Offers Use Of Natural Products Plant

SAIC Frederick, the Operations and Technical Support Contractor to the National Cancer Institute-Frederick Cancer Research and Development Center (NCI-FCRDC) in Frederick, Maryland, seeks expressions of interest in use of the FCRDC Natural Products Pilot Plant (NPPP), a large-scale bioprocess facility. The NPPP is comprised of both fermentation and recovery plants. The fermentation plant has a maximum fermentation capacity of 2,000 gallons per batch (from a 3,000-gallon nominal volume production fermentor) with two 30-gallon and two 300-gallon fermentors for seed development, process development research, or intermediate scale production.

The recovery plant has the capability of performing large-scale solvent extraction, solid/liquid separation from fermentation broths or other feedstocks by several different methods, concentration of products of interest by controlled evaporation of solvent carriers, and provides equipment and facilities suitable for the recovery and isolation of crude, partially purified, and highly purified products derived from fermentation broths, plant materials, and other starting materials, The fermentation plant is designed for operation at a BL2 large-scale level of containment, and the recovery plant at a BLl large-scale level of containment, The NPPP has been used for fermentation process development, scale-up studies, production of purified natural and biological products from a variety of feedstocks in support of drug development research, and production of bulk cells and cell-derived products. The fermentation plant is primarily designed for the fermentation of bacteria, fungi, and yeasts and is not appropriate for growing mammalian or insect cell cultures. Renovations to the NPPP are nearing completion with availability for use expected in early 1996. Recent upgrades include a state-of-the-art data-acquisition system for monitoring and controlling the 30- and 300-gallon fermentors, a contained continuous decanter centrifuge, a large-scale HPEC system, new stainless steel process vessels, and a new double-pass reverse osmosis process water system.

SAIC Frederick provides skilled technical personnel with more than two decades of experience operating the pilot plant in support of drug discovery and development workscopes for NCI and the private sector. SAIC Frederick also provides experienced Quality Assurance, Quality Control and facility support staff for production of bulk chemicals and biologicals in support of pre-pivotal (phase I and phase II) clinical trials. All employees are trained in current Good Manufacturing Practices.

NPPP facilities will be committed in part to support NCI workscopes concurrent with availability to users outside of NCI. When necessary, accommodations will be made to ensure that NCI work receives the approprfate priority. Additionally, cancer- and AIDS-related work will be given preference in obtaining use of the facility in concert with the overall objectives of NCI-FCRDC. However, other work will not be precluded from consideration. Upon determining the level of interest in use of the facilities by responsible NCI officials, prospective users may be invited to NCI-FCRDC for a site visit at which time additonal information and conditions for use will be made available and a tour of the plant arranged. Detailed workscopes or project plans will then be requested and reviewed for a determination of consistency with the mission of NCI, an assessment of technical feasibil1ty, and development of formal cost estimates.

Contact: Terry Hebb, Contracts Administrator, 301/846-5416, or Donna Dawson, Contracting Officer, 301/846-1087.