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NCI GRANTS PAYLINE COULD REACH 175 UNDER FINAL FISCAL 1985 AWARDS LEVEL OF APPROXIMATELY 1,000

As Congress takes off on summer recess following final approval of the FY 1986 budget Aug. 1, the six month fight over forward funding of research grants has ended, with House and Senate conferees agreeing to fund 6,200 new and competing renewal grants for NIH in fiscal 1985. House and Senate conferees agreed July 30 to a 1985 supplemental appropriations bill that allows no fewer than 6,200 new and competing

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In Brief

GERALD MURPHY RESIGNS AS ROSWELL PARK DIRECTOR; PENN.'S RICHARD COOPER ACCEPTS WISCONSIN JOB

GERALD MURPHY, whose 15 years as director of Roswell Park Memorial Institute was longer in that position than any of the other six in the 87 year history of the Institute, resigned last week in the culmination of months of feuding with New York State Health Commissioner David Axelrod. Murphy has accepted the positions of director of the Center for Onology Research and professor of urology at State Univ. of New York at Buffalo. He also will continue as principal investigator for the NCI supported Organ Sytems Coordinating Center at RPMI and as head of the National Prostatic Cancer Treatment Group. John Wright, professor of pathology at SUNY Buffalo and a member of the RPMI Board of Visitors, was named interim director of the Institute. Murphy had been fighting with Axelrod over the latter's efforts to merge RPMI with Buffalo General Hospital. Murphy said his resignation was tendered only after securing a firm agreement with Axelrod that RPMI would continue as an independent institution. Murphy, 51, was the youngest director in RPMI's history when he was appointed in 1970. He had gone there two years before, from Johns Hopkins, as associate director for clinical oncology and chief of urology and experimental surgery. Murphy said he will continue his work with the International Union Against Cancer (UICC), which he has served as general secretary for the past several years .... **RICHARD COOPER** has resigned as director of the Univ. of Pennsylvania Cancer Center, effective Sept. 1, to accept the position of dean of the Medical College of Wisconsin. **JOHN GLICK,** professor of medicine in the Univ. of Pennsylvania School of Medicine section of hematology-oncology, has been named to succeed Cooper as director of the cancer center.... **DAMON BIOTECH,** in a joint venture with the Scotting Development Agency, the U.K. government and various European venture capitalists and banks, will construct and operate a biopharmaceutical facility near Edinburgh which Damon says will be the largest monoclonal antibody plant in the world. The development will cost about $40 million.

FORWARD FUNDING PROHIBITED IN FY 1985 UNDER SUPPLEMENTAL APPROPRIATIONS

(Continued from page 1)
renewals to be funded (**The Cancer Letter** Aug. 2).

NIH officials have not yet determined the exact number of grants to be allotted to individual institutes, but NCI budget officials expect to make approximately 1,000 awards in the current fiscal year, resulting in a payline that could be as high as 175.

John Hartinger, chief of NCI's Financial Management Branch, told **The Cancer Letter** that the Institute anticipates funding approximately 1,000 grants in FY 1985 , and that the priority score payline could be as high as the "mid 170s" range.

Under the administration's proposed forward funding of NIH awards, NCI would have been able to fund only 790 new and competing renewal RO1 and PO1 grants in 1985, with a projected cut in the Institute's priority score payline from 170 to 158 (**The Cancer Letter**, Feb. 8).

The Office of Management & Budget's proposal to fund only 5,000 NIH grants in fiscal 1985 in spite of Congressional appropriations for 6,526 grants encountered resistance both from the Hill and scientists alike. In a review conducted by the General Accounting Office at the request of Sen. Lowell Weicker (R-Conn.), GAO termed the multiyear funding not lawful.

Both Weicker, who chairs the Senate Appropriations HHS Subcommittee, and Congressman William Natcher (D-Ky.), chairman of the House Appropriations HHS Subcommittee, extracted promises from HHS Secretary Margaret Heckler that the department would not forward fund any awards until the matter was resolved.

Forward funding of awards is specifically prohibited under the 1985 supplemental appropriations bill, but unused fiscal 1985 funds may be carried over to FY 1986.

The resolution contains no commitment for grant levels in FY 1986. Although Weicker's Senate subcommittee proposed that 6,200 grants be funded in fiscal 1986, Natcher's House subcommittee reportedly believes that the funding of 6,200 awards in FY 1985 could impose a second year burden that would preclude the same number in FY 1986 without a big increase in budget.

House and Senate leaders did not get around to holding a conference on the NIH reauthorization bill prior to recessing for the summer, but will meet in September when Congress reconvenes. Senate conferees for the bill are Orrin Hatch (R-Utah), Edward Kennedy (D-Mass.), Don Nickles (R-Okla.) and Dan Quayle (R-Ind.). House conferees have yet to be named.

Both the House and Senate measures would establish a separate National Institute of Arthritis, Musculoskeletal & Skin Disease. The House bill would also create a National Institute of Nursing Research, a provision not contained in the Senate bill.

The Senate bill also includes renewal of the National Cancer Act, and calls for a three year authorization period vs. one year in the House measure.

The major differences conferees will address in September are the establishment of a nursing institute and the three-year vs. one-year authorization period.

President Reagan pocket vetoed similar NIH reauthorization legislation last year. Although Reagan cited the creation of two new institutes as the reason for not approving the bill, Congressional leaders expect the President to sign a new reauthorization bill as long as it does not include a new nursing institute.

ACCC MEETING/ONCOLOGY ECONOMICS '85 TO STRESS DRGs, FCCs, QUALITY ISSUES

The Assn. of Community Cancer Centers midyear meeting will be held in conjunction with "Oncology Economics" '85 Sept. 17-21 in Los Angeles.

Speakers at the Oncology Economics sessions will address such issues as economics and quality, freestanding cancer centers, cancer DRGs, breast cancer screening clinics, and the potential impact of health care systems on cancer care. Speakers include John Moxley, senior VP for strategic planning and alternative services at American Medical International; American Cancer Society President Robert McKenna; FCC developers Dennis Birenbaum and C.D. Pruett; and Mammatech Corp. chief executive officer Henry Pennypacker.

The impact of severity of illness on tertiary care and cancer care will be discussed by Susan Horn, author of a recent "New England Journal of Medicine" article on the special problems tertiary care hospitals may face under prospective payment.

Research and reimbursement in relation to the prospective payment system will be addressed by David Sundwall, professional staff member with the Senate Labor & Human Resources Committee.

Other presentations scheduled for the meeting include how to make hospice and home care financially viable; joint ventures; how to make rehabilitation and counseling financially viable; and the future of health care and oncology. The conference will be chaired by Lee Mortenson, executive director of ACCC.

ACCC's mid-year meeting will stress the developing guidelines and standards for community cancer programs, efforts with the Prospective

Payment Assessment Commission to change DRGs for cancer, and other efforts by the association in such areas as hospice, clinical research, clinical practice, patient advocacy, and governmental relations.

For more information, contact ELM Services Inc., 1160 Nebel St., Rockville, Md. 20852 (301) 984-1242.

NCI's GALLO TO GIVE SCHWARTZ LECTURE AT SCRIPPS NINTH CANCER SYMPOSIUM

Robert Gallo, chief of NCI's Laboratory of Tumor Cell Biology, will give the Bernard Lee Schwartz Memorial Lecture at the ninth annual Scripps Memorial Hospital Cancer Symposium Oct. 21 in San Diego. Gallo, who identified the HTLV-3 virus associated with acquired immune deficiency syndrome, will speak on "Retroviruses of Man: Their Role in AIDS and Leukemia."

Other presentations scheduled for the three-day meeting from Oct. 21-23, include a discussion of new concepts such as MRI, flow cytometry, cell markers, new drug development and oncogenes. Evolving therapies to be presented include those for non-small cell lung cancer; chemotherapy in head and neck cancer; innovative radiation fractionation; gonadotrophin releasing factors in tumor therapy; Goldie-Coltman Hypothesis; and clinical aspects of AIDS.

Second-day discussions include panels and presentations on hematology, including the management of aplastic anemia; immune thrombocytopenia; myelodysplastic diseases; chronic leukemias; management of high-grade lymphomas; and radiation therapy for non-Hodgkins lymphoma.

Dilemmas in Oncology to be discussed include: "dealing with our losses;" the alternative therapy seeker; rational analgesia; pulmonary infiltrates in oncology; and leukopenia and fever.

Topics relating to gynecological cancer include: primary chemotherapy of ovarian cancer; "second look laparotomy - is it worth doing?;" post PAC chemotherapy; surgical management of endometrial cancer; as well as the systemic managment of and radiation therapy in endometrial cancer.

Breast cancer issues to be discussed include adjuvant chemotherapy in perspective; and lessons from the National Surgical Adjuvant Breast & Bowel Project. The NSABP's lessons will also be discussed in relation to adjuvant therapy for colon/rectal cancer. Other topics relating to the disease include alternatives to abdominoperneal resection, and "5FU - Myth or Magic?"

Physicians attending all three days of the symposium will receive 21 credit hours of Category I of the AMA's Physician Recognition Award and the California Medical Assn.'s certification program continuing medical education credits.

Scripps' fifth annual Cancer Symposium for Nurses will be held concurrently, with 23.5 contact hours available for continuing education credits.

For more information on either meeting, contact Nomi Feldman, Conference Coordinator, 3770 Tansy, San Diego 92121, 619-453-6222.

ACS' CANCER RESPONSE SYSTEM BUDGET REQUEST OF $185,140 TO BE REVIEWED

The American Cancer Society's Finance Committee will review a $185,140 request for first year funding of ACS' Cancer Response System (CRS) when the committee meets this month. National implementation of the cancer information program recently was approved by the society's Board of Directors (**The Cancer Letter**, Aug. 2).

According to a recent ACS report detailing the program, the budget request includes $48,000 for telephone costs for an estimated 12,000 toll free calls. CRS received a total of 9,008 calls in its one year National Feasibility Study conducted between March 1, 1984 and April 30, 1985.

An accompanying memo from ACS Vice President Diane Fink to ACS President Arthur Holleb notes that "it is expected that personnel costs will drop in the second year as additional divisions enter the system and take over national call answering activities."

The national feasibility study area included a total population of approximately 16 million people in four states—Missouri, Kentucky, Indiana and Kansas. Promotion for the study began in a small area of Missouri in March 1984, and expanded slowly, with all feasibility divisions promoting the system in January 1985.

While calls totaled 3,044 to the four division area, an additional 3,053 calls were made by persons outside the study areas who obtained ACS' toll free number 800-ACS-2345 by calling 800 Directory Assistance.

Two ACS divisions, Illinois and Milwaukee, chose a decentralized answering system in which division volunteers utilized CRS' computerized data base and the 800 number, but answered inquiries from callers in their own geographic area. A total of 2,911 calls were handled by those divisions between March 1, 1984 and April 30, 1985.

The budget request also includes $77,500 for salaries for three full time CRS employees at ACS' national office.

According to the memo, the national CRS staff

consists of three full time operators handling two incoming 800 lines. In Milwaukee, 16 volunteers and one volunteer coordinator were recruited to staff the phones, working four shifts a week.

In Illinois, exisiting staff answer calls using the computerized data base. The Illinois division, which didn't begin active promotion of CRS until May of 1985, received 1,511 calls before April 30, 1985.

Promotional material development funds requested for the fiscal 1985-86 year are $34,500 for the development of one public brochure, a physician brochure, a pay roll stuffer, an ad, and a TV spot.

The budget also asks for $7,200 for the rental of three computers; $4,440 for postage and materials; $3,500 for office supplies; and $10,000 for travel expenses to newly acquired divisions for CRD orientation, implementation and training.

Promotional materials developed by the national office and used by ACS divisions participating in the feasibility study included consumer and health professional brochures, TV and radio spots, posters and assorted ads, a promotional stuffer insert, and billboard ad.

Divisions participating in the program developed materials specific to their community and also employed strategies such as placing materials in community publications; and arranging appearances of key local ACS volunteers on local radio and TV talk and news shows. Billboards advertising the toll free number and the use of CRS spots on local TV and radio programs were also used, as was the dissemination of information materials to target groups such as physicians, hospitals, employers, labor unions, community organizations, government officials, industrial nurses, pharmacists ,the media and the public at large.

According to the memo, 15% of callers to CRS were patients; 8% were possible patients; 32% were friends or relatives; 29% the general public; 7% health professionals; 5% were "others" such as students; and 4% unknown. The majority of callers (71%) were female with only 27% of calls made by males.

Overall, general inquiries tied with questions about cancer sites, each representing 21% of calls. Treatment questions and inquiries about detection and diagnosis were also tied, with each accounting for 13% of calls made. Questions relating to the cause and prevention of cancer accounted for 11% of calls; services for 8%; rehabilitation, 5%; and unproven methods, 4%.

The report includes recommendations for expansion of the program approved by ACS' Board of Directors in June. CRS'expansion plan includes the continution and expansion of divisions "handling their calls integrating the function into their usual day to day activities with the computerized data base and 800 telephone number."

ACS expects to add eight to 12 new divisions to the system in the first year, with further expansion dependent on the first year experience.

Other recommendations include that the national office "continue a central CRS operation to maintain and update the data base, to coordinate division activities, to provide training to area offices, division volunteers and staff and to maintain a quality assurance program."

Divisions choosing not to use the 800 phone number may continue to use the answering arrangement of their choice, and will be offered the CRS data base and training in its use, under the recommendations.

The report also recommends that ACS "actively seek the collaboration of NCI in its planning and undertake cojoint planning for a nationally integrated system." According to the report, NCI and ACS "have met regularly to coordinate the two systems" in the past nine months. "During the transition for ACS implementation into other divisions, NCI and the Society will continue to meet to share information and materials," it adds.

ACS' feasibility study of the program concluded that "CRS is feasible and can be integrated into the Society's organization by divisions handling their own inquiries with volunteers and staff or by dedicated national staff. Furthermore, divisions can operate the 200 plus page data base stored on a personal computer and handle their own calls," it advises.

Divisions "may use their existing staff and/or recruit additional volunteers and integrate both into day to day activities," it says, adding that "some divisions may wish to add part time staff to handle special division needs."

Noting that "the number of calls depends on promotion," the report says that "divisions may wish to design local promotion to stimulate call activity," and advises that "any division wishing to implement the system within their community should expect four to nine months for preparation."

In the memo accompanying the report, Fink notes that CRS "is designed to answer all public questions not just from specific groups, i.e., patients, students, etc.."

The Massachusetts division is currently developing and testing "an additional component for the CRS designed to provide information for primary health care professionals," she reports. "If the Massachusetts test is successful, this segment will be added to the CRS to provide the society with a comprehensive information system for the public and primary care health professionals."

The CRS data base currently includes the national ACS data base; local division information; call data collection, automated followup (correspondence and envelopes) and statistical reporting and special reports.

The national data base is derived from ACS sources such as pamphlets, policy statements, "Ca" articles, "Clinical Oncology," "Cancer Manual," and "articles from pertinent journals, etc."

Topics are outlined in the following areas: general topics; cause/ prevention; detection/ diagnosis; cancer sites; treatment; rehabilitation; ACS services; and unproven methods.

Local division information includes community resources information, division/unit programs, and the division's medical referral or second opinion policy.

The CRS data base is stored on an IBM PCXT computer with 256K memory and 10 megabytes of storage. The report notes that the data base requires approximately 50% of the computer storage capacity.

Specific policies followed by CRS in its day to day operations are:

1.CRS does not give medical information to individuals "which are in the domain of their responsible physician."

2.CRS "encourages callers to discuss medical matters with their responsible physician."

3.CRS uses division developed mechanisms and policies for medical referral and requests for second medical opinion. The report notes that "such requests constitute less than 10% of calls."

4.CRS refers all calls needing psychosocial counseling to local division/unit offices "immediately."

5. CRS maintains caller confidentiality.

6. CRS "supplies divisions with regular data base updates via floppy disks which can be easily installed locally."

7."The data base has been developed to answer calls from the public and cancer patients."

According to the report, objectives of the CRS program are:

"To provide the public and patients with consistent, accurate and up to date information about cancer and" ACS.

To provide ACS staff and volunteers "for response to inquiries using a computerized information data base and access through a single 800 telephone number, 1-800-ACS2345."

To develop ACS' "mechanisms for quality assurance and necessary modification to increase efficiency and effectiveness."

"To evaluate the system within the society's organization during" the feasibility study conducted between March 1984 and June 1985.

ST. JUDE BOARD CONSIDERS RELOCATING RESEARCH FACILITIES TO WASHINGTON U.

The Board of Governors of St. Jude Children's Research Hospital "is looking into the possibility of relocating our research efforts" at Washington Univ. in St. Louis, St. Jude Director Joseph Simone told **The Cancer Letter** last week.

St. Jude has been located in Memphis since it was founded there in 1962 by entertainer Danny Thomas.

Simone said that Washington Univ. representatives approached St. Jude about six months ago on the possibility of joining forces. Last month, the Board of Governors "agreed to look into it," Simone said.

If the research component of St. Jude is moved, a clinical operation would be continued in Memphis, Simone said.

St. Jude executives have been working on a long, range expansion and development plan, an effort Simone initiated when he became director two years ago. Expansion will continue, whatever the outcome of the Washington Univ. offer "which came out of the blue," Simone said.

That offer interests St. Jude officials because the Washington Univ. School of Medicine has a very large and respected research base, Simone said. "That is not in any way a reflection on the Univ. of Tennessee Medical School. That is not an issue. That school is a very good one. My daughter goes there, and I have a strong affection for it. But it does not have the research activity that Washington Univ. has. The issue is the research environment. We are looking 20 years ahead."

St. Jude said in a news release that it is "exploring the possibility of establishing a research center" at Washington Univ. "Although the facility would have a patient care component, the initial effort would be research ranging from fundamental to applied. The initial research staff would be drawn from the Memphis facility.

"The basis for such a proposal is a strong desire to have a greater influence on child health around the country and to take advantage of expertise in existing major biomedical research facilities."

The news release went on to say that Simone and the Board of Governors "feel the biomedical research areas of interest to SJH's faculty are moving rapidly and that a strong desire exists to join forces with a larger center involved in similar work."

Preliminary discussions have included a review of site possibilities for the St. Jude research facility in St. Louis. Andrew Newman, chairman of the board of St. Louis Children's Hospital, has expressed willingness to help seek the financial

support necessary for the building of the new facility in St. Louis, the St. Jude news release said. It quoted Newman as saying, "The addition of St. Jude's expertise to our city's already outstanding pediatric facilities could only further enhance the quality of available medical care."

Albert Joseph, chairman of the St. Jude Board of Governors, emphasized that should SJH become a participating member of the Washington Univ. Medical Center, the hospital would insist on retaining its autonomy in name, fund raising, total governance, as well as maintaining its relationship with Danny Thomas and the Arabic speaking people of the United States.

St. Jude Hospital would continue to be home for the 1,000 children and young adults currently receiving treatment for cancer and other catostrophic diseases, and the 1,400 being followed after successful treatment for their disease, St. Jude said. "The St. Jude Hospital expansion in St. Louis would include outpatient clinics, but future patients requiring hospitalization would be admitted to St. Louis Children's Hospital."

"This is merely an investigation and we could learn at any time, at any point, that there is no basis for continuing those discussions," said Thomas, who established the hospital with his own money and continues to lead its fund raising efforts. "Yet our scientists and our board feel we owe it to the children of the world to explore the invitation thoroughly. Part of St. Jude Hospital's contribution to pediatric research is its constant cooperation with other scientific groups and institutions. We have added to that a new awareness of the need to reach out and extend our facility and our programs. That is what triggered the invitation from Washington Univ., but there will always be an important St. Jude Hospital presence in Memphis."

In commenting on the possible move, William Danforth, chancellor of Washington Univ., said, "These preliminary discussions are viewed as a beginning of what could be a great opportunity for the Medical Center and for St. Jude Hospital. The SJH faculty performs superb research and provides wonderful care for children. With the opening of the new St. Louis Children's Hospital last year, our Medical Center has facilities and programs equal to the best in the world for improving the health of children. Combined, these institutions would have the size and critical mass that would provide the opportunity to mount world class research programs for the last decades of the century."

"Such a plan expresses in a tangible way the deep concern felt by the staff of St. Jude Hospital at the progressive worldwide decline in the number and support of medical scientists working on children's problems," Simone said. SJH feels a responsibility to keep children's problems before the public, to solicit its support for this work and to expand those resources in the most responsible and efficient manner. There is no issue more important to the future of our society than the health and welfare of our children."

St. Jude said that completion of the new facility and move of scientists from Memphis probably could not be accomplished before 1990.

BIOTHERAPEUTICS OFFERS EXPERIMENTAL "CUSTOM MADE" THERAPY FOR A PRICE

"Custom tailored approaches to cancer research and treatment."

"New company offers custom tailored research services to cancer patients."

—From promotional material distributed by Biotherapeutics Inc., of Franklin, Tenn.

The hard sell marketing approach for health care services now being adopted by providers, the not for profit as well as the for profit organizations, sometimes seems better suited to shopping center discount houses than to the lofty field of medicine, which used to be above such things. Those who are offended by that approach, however, might be even more put off by the basic philosophy behind the services offered by Biotherapeutics: That experimental treatment, in this case biological therapy still in the very early stages of development, is made available to cancer patients outside the context of organized clinical trials—if they can pay for it.

Biological Therapeutics Inc. was founded earlier this year by Robert Oldham, former director of NCI's Biological Response Modifiers Program, and William West, former NCI investigator involved in the development of monoclonal antibodies for cancer treatment and presently a medical oncologist in a Memphis private practice.

Patients are referred to Biological Therapeutics by their physicians. They are examined either by Oldham or West, who then discuss with the patient and referring physician the patient's situation and possible research approaches.

"Should the patient decide to contract with Biotherapeutics for individualized research services, our scientists will conduct the research work while (the referring physician) provides standard therapy," a pamphlet distributed by the company explains. "We will keep both you (the physician) and the patient informed on the progress of the research. Subsequently, should there be tumor recurrence or disease progression despite standard therapy, we will have established, in the

laboratory, the foundation for further therapeutic opptions."

Biotherapeutics provides research services, not patient care, the pamphlet emphasizes. "Once the research services are complete and if we have developed a therapeutic approach through those services, we will make available the developed biological substances to the patient and his consulting physician (Dr. Oldham or Dr. West). They will ultimately decide, with the patient and his personal physician, the feasibility of administering these treatment approaches."

What are the research services offered?

"Since certain cancers are likely to recur after initial treatment, we offer a tumor acquisition, processing and preservation program. Patients and physicians may choose to have a tumor specimen analyzed to determine optional treatment strategies and stored for possible future use should the patient experience recurrence or disease progression. For other patients, there may be compelling reasons to pursue an avenue of biological research without delay. For example, certain patients may be advised to participate in a research program to develop custom tailored monoclonal antibodies and immunoconjugates. Patients with compartmentalized disease (e.g. ovarian or colon cancer) may be advised to pursue adoptive cellular component research. Patients free of disease but at high risk of recurrence (e.g. melanoma) may choose to participate in research using active specific immunization with autologous or allogenic tumor cells. For other patients, it may be most appropriate to evaluate the susceptibility of their tumor cells to interferons and other lymphokines."

Patients are offered five levels of service, with a cost established for each level and spelled out in the contract. They are:

1. Tumor acquisition, processing and preservation—$1,500.

2. Monoclonal antibodies and immunoconjugates—$35,000.

3. Cellular component development (lymphokine activated killer cells)—$19,400.

4. Lymphokines/cytokines development—(price to be determined).

5. Specific immunization—(price to be determined).

The Biotherapeutics pamphlet poses the question, "How is this patient-centered research funded?", and gives the answer:

"Biotherapeutics has no source of funding for this research other than the individual patient. Obviously, since this research is being performed for the individual patient, it must be funded by the patient. The company is developing strategies which may make available some support for patients without the financial resources to fund this research. However, these are long term strategies and are not presently available to provide short term support for patients in need of our research capabilities."

The company acknowledges that third party reimbursement probably will not be available in most instances. "Each insurance company has its own guidelines for covering medical costs. However, we believe that the cost of these research services generally is not reimbursable under most medical insurance policies or government programs. These costs, however, may be tax deductible in accordance with Section 213 of the Internal Revenue Code."

Oldham said he is convinced that his firm's program "is feasible and doable," and once that has been demonstrated, "will become fashionable."

Using the present system established for developing and testing anticancer drugs to test biologicals "does not make sense," Oldham told **The Cancer Letter.** "It makes sense for drugs because of the toxicity, but that doesn't apply for the most part to biologicals. There is overwhelming evidence that biologicals can be transmitted faster into clinical use, but when I've tried to get that across, it's like talking to a brick wall."

As for the matter of offering a service in which only those patients with the financial ability can benefit, Oldham asked, "Why not come up with a system in which the patient pays for his own care? We make it clear from the start that our program uses the patient's own resources to help solve his problem."

Oldham insisted that patients are told they will be getting only halfway technology, that biological treatment of cancer is still very much in the formative stage. "What we are offering is sensible and reasonable. We have these concepts which might be useful." Clinical trials are being carried on with biologicals by NCI, by NCI supported studies and by university based investigators. "There is no reason why qualified people can't apply research in other than government or university laboratories, and in our case, commercial laboratories," Oldham said.

Although nothing like randomized clinical trials will be carried out by Oldham, West and their colleagues, "everything we do will follow written protocols. We will collect, pool and analyze the information and we will publish it, like I have been doing for 15 years," Oldham said. "The only real difference here is that we are asking patients to participate in the funding."

Oldham said he thinks cancer research "has become too institutionalized. It is not serving patients. Patients are saying that they can't get TNF, or they aren't eligible for protocols. PDQ does help

disseminate information on new treatment but it does not make that treatment available."

The experimental therapy will not be offered to patients until they fail standard therapy, Oldham said. "When they fail, they will have these options—no further treatment; experimental drugs; experimental therapy at universities; our treatment."

Biologicals will not be used at this time for adjuvant therapy. "I wouldn't give it to patients without perceptible disease, or not before relapse." Adjuvant biological therapy may be useful in the future, Oldham said, but at the present time, it is very expensive, although he does agree that its use probably would be more effective when the tumor burden is smaller. "We have to show they work against advanced disease before we go with them as adjuvant therapy. I'm not interest in looking for small differences. Adjuvant biological trials will be done, but it will have to be by NCI supported cooperative groups.

"The key (after patients fail standard treatment) is to start earlier." The Biotherapeutics program of obtaining tumor tissue and doing the preliminary lab work immediately should make that possible, Oldham said.

The Biotherapeutics program offers patients who have failed standard therapy an alternative to the questionable practitioners in Tijuana, the Bahamas and elsewhere and to the laetrile advocates, Oldham agreed. "It makes sense to set up a facility where patients have access to treatment provided by credentialed people. If people are looking for an option, we are highly credentialed. We know what we are doing."

Oldham founded the Vanderbilt Univ. Medical Center Div. of Medical Oncology in 1975. He was the first director of NCI's Biological Response Modifiers Program and headed it for three years. He has authored eight books and more than 250 scientific papers, is president of the Society for Biological Therapy and editor in chief of the "Journal of Biological Response Modifiers."

West is a graduate of Johns Hopkins. After working in the early development of monoclonal antibodies at NCI, he established a medical oncology practice in association with Memphis Baptist Memorial Hospital. He also founded West Laboratories to pursue biological approaches to cancer management, which has become a component of Biotherapeutics. West has authored more than 25 scientific papers.

Biotherapeutics includes seven PhDs and more than 20 support people on its staff. Oldham expects those numbers to double within a year.

At present, 15 patients are on study. Oldham said that the company will reach the break even point when it has from 40 to 60 patients on study, depending on the level of service they receive.

Patients under study so far have lymphoma, melanoma, breast cancer and colon cancer. West has a special interest in lung cancer, but Oldham noted that the time available from disease progression to death may be too short to permit development of individualized biological treatment of that disease.

Patients are being referred from around the country. Although Oldham has a large local oncology practice, none so far have come through that. "Physicians who referred patients to me at NCI are still sending them to me here," Oldham said. "All of them are well informed about their diseases and the various treatment options, all have been treated at major institutions and all are under the care of oncologists."

Biotherapeutics was financed through a private stock sale which was oversubscribed by 50 per cent, Oldham said. "We were out to raise $2 million, and we wound up selling $3 million in stock. I don't believe we'll need to raise any more money. We plan to reach the break even point early in 1986."

The company presently is located in rented facilities in Franklin and Memphis but is preparing to build its own 3,000 square foot laboratory in Nashville.

Oldham admitted his program will be controversial, at least it some quarters. "But it's new, innovative, and the patients will like it. The opportunity ought to be there for patients who want to receive experimental therapy but for one reason or another can't participate in the existing system."

Oldham is chairman and scientific director of the company, and West is medical director. Other members of the board of directors are Louis Berneman, PhD, president; Cathie Oldham, M.D., vice president and corporate secretary; Michael Aiken, M.D., who is president of HealthStream Corp.; William Blalock, who is chairman and CEO of Hermitage Corp.; Frank Bumstead, who is managing partner of Rogers-Bumstead Interests Ltd.; Lowell Foster, PhD, who is president of International Clinical Laboratories East; Henry Herr, chief financial officer of American HealthCorp; realtor Boyce Magli and attorney Jackson Moore.

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