THE CANCER
LETTER

P.O. Box 2370 Reston, Virginia 22090 Telephone 703-620-4646

# FREESTANDING CANCER CENTERS MAY BE THE "MISSING INGREDIENT IN CANCER TREATMENT," DEVITA BELIEVES

An emerging national phenomenon which NCI Director Vincent DeVita says may provide the "missing incredient in cancer treatment" is the development of "freestanding cancer centers" organized to provide comprehensive outpatient cancer diagnosis and treatment services in affiliation with university and teaching hospitals and large community hospitals. The freestanding cancer centers, or FCCs, are being seen as (Continued to page 2)

In Brief

10-8501-017908

### DIAGNOSTIC IMAGING COST DECLINES BY HALF AS PERCENTAGE OF HEALTH COST IN 10 YEARS

PERCENTAGE OF TOTAL health care costs attributable to diagnostic imaging has declined from 6.3 per cent 10 years ago to about 3 per cent now, according to David Bragg, chairman of the Dept. of Radiology at the Univ. of Utah Medical Center. Of that amount, less than 1 per cent can be charged to the new "high tech" equipment, Bragg told the National Cancer Advisory Board. "We've also been very effective in preventing unneeded surgery and hospitalization and in making possible better treatment planning." Application of film digitalization now permits radiologists to detect lung tumors up to four years earlier than in the past; and 50 per cent of clinically undetectable breast lesions were found only through mammography screening in the Breast Cancer Detection Demonstration Project, Bragg said. "We have a low risk, feasible, efficient means of detecting early breast cancer, occult lesions, at a cost that should be under \$40." Questioned by Board member Helene Brown on "where can you get a mammography examination for \$40?" Bragg said "that is based on our actual costs, direct and indirect. Forty dollars yields a small profit of \$1.25, if there is significant volume".... "FOR THE federal government to say DRG will not impact on the quality of care is an absurdity," Clifford Straehley, professor of surgery at John Burns Medical School, Kaiser Foundation Hospital, told members of the President's Cancer Panel in Honolulu. Straehley cited as a flagrant example a patient with a complete heart block who was denied \$7,000 reimbursement for a pacemaker....PETER ROSEN, a medical oncologist in private practice for the past 10 years, has been named director of clinical medical oncology at the Univ. of Southern California Cancer Center. He will direct patient care activities and medical oncology teaching at the Norris Cancer Hospital and the USC-Los Angeles County Medical Center....JEAN BERNARD, professor of hematology at the Univ. of Paris, will receive the Leukemia Society of America's Robert R. de Villier Award at the Society's national medical symposium in Las Vegas March 14-16. He will deliver the keynote address.

Vol. 11 No. 2 Jan. 11, 1985

© Copyright 1985 The Cancer Letter Inc. Subscription \$150 year North America \$175 year elsewhere

Y 27 - 1 - 1

NCAB Committee, SORDS Agree On New Training Grants In Surgical Oncology ...Page 7

Block, Committee
Agree: No New PDQ
For General Public
... Page 4

DCPC Board To Hear Concept For Contract To Develop Program For Heavy Smokers ... Page 5

## THREE FIRMS ENGAGED IN DEVELOPING FREESTANDING TREATMENT CENTERS

(Continued from page 1)

a means to achieve visibility and "presence," key marketing factors in the competition for cancer patients; and, for now, a way to avoid the prospective payment (DRG) reimbursement system. At present, outpatient services are not subject to the DRG limits.

Some hospitals may be establishing FCCs on their own, but most of the activity appears to have been generated so far by three firms which are organizing, designing, building and, in most cases, operating the centers. Each of the three are approaching the FCC market in a different way:

\*CDP Associates Inc., known for the last decade as a consultant in the design and construction of university based cancer centers and community based radiotherapy centers and in the management of medical facilities, is perhaps the best known of the three in the cancer field. CDP is based in La Jolla.

\*Health Corp. is a CDP spinoff, headquartered in Atlanta and staffed largely with former CDP executives. Both firms are headed by C.D. (Dunc) Pruitt.

\*Comprehensive Cancer Centers Inc., headquartered in Los Angeles, is a wholly owned subsidiary of Salick Health Care Inc., which operates a string of outpatient dialysis centers in the Los Angeles area and provides inpatient dialysis facilities for hospitals there. The companies are headed by Bernard Salick, with Gerald Rosen, one of the nation's premier clinical investigators, as medical director.

CDP contracts with institutions interested in developing FCCs, providing some or all of such services as analysis of market factors, feasibility studies, design, construction and equipment selection and purchase. The firm, which has been involved in the development of 40 freestanding facilities, most of them limited to radiotherapy, since 1976, will contract to remain on to manage the facility if that is what the organization desires.

Most of those 40 have incorporated chemotherapy and diagnosis into their services and now provide comprehensive cancer care. All 13 of CDP's active projects, in varying stages of development, will offer the full range of services.

Richard Allen, CDP vice president for corporate development, said that the firm's recent advertisements in national publications and a direct mailing to selected institutions have resulted in more than 200 responses. "We think the market is just starting to be tapped," Allen said. CDP has been promoting the FCC concept for less than a year.

Among CDP's clients, some hospitals own and manage their FCCs, some run them as joint ventures

ventures with limited partnerships, sometimes with a physician as a general partner, and at least one has been established with a nonprofit foundation as the owner.

Allen noted that FCCs now in development are including full diagnostic facilities, including CT scanning and magnetic resonance imaging.

What does it cost to develop a freestanding cancer center? Allen said that can range from \$600,000 to a little more than \$1 million, not including cost of land and equipment. That would be for a modest sized facility. One 27,000 gross square foot center CDP is developing in the South is costing \$4 million, not including land or equipment (Salick's centers are substantially larger and costlier). Another CDP developed center, with a building with 4,512 gsf cost \$752,810 for the building, \$886,000 for the equipment (not including CT or MRI, obviously), and \$413,800 in other costs, including \$150,000 for working capital. CDP also will assist with fundraising.

Health Corp., unlike CDP, works on the premise that it will own and operate the FCC as well as develop it. Health Corp. has completed five centers which are now in operation, five others are in development, and the firm is engaged in negotiations for six or seven more. That may have been a little too fast of a pace, however. The company has experienced some financial difficulties recently, caused at least in part by the failure of its major banking partner to meet its commitment.

Pruitt, who had given up active management of Health Corp. while remaining on its board, has resumed chief executive officer duties and remains confident of the company's future. "There has been a tremendous surge of interest," he said. "It has been a big problem just to keep up. Hospitals are recognizing the need for freestanding cancer centers. The concept is really catching on."

Pruitt said that Health Corp. had intended to complete 60 FCCs within five years, but estimated it would be seven years before that many are in operation.

Bernard Salick decided to get into the cancer business after his daughter was successfully treated for osteogenic sarcoma by Rosen at Memorial Sloan-Kettering. Rosen had developed some highly successful protocols for the disease, achieving cure rates approaching 100 per cent for early stages and 80-90 per cent or better for later stages with aggressive chemotherapy. Other investigators also had obtained striking results with chemotherapy; Rosen was most successful with his cisplatinum regimen.

Salick was impressed that Rosen was able to administer such powerful drugs, in heavy doses, to

outpatients. "Their facility (at Memorial) was similar to our outpatient dialysis centers. There was no such facility for cancer patients in Los Angeles, where patients could be treated in a suitable environment, a safe setting, with quality professionals, 24 hours a day, seven days a week."

Salick said he knew from his experience in running the dialysis centers that optimal care could be given on a 24 hour day, seven day week, "if it is structured properly and managed effectively, and can

financially viable."

Salick is an M.D., a member of the UCLA faculty and is affiliated with Cedars-Sinai Hospital. He sold the hospital on his free standing cancer center concept, and a 40-50,000 square foot building is in the design stage. It will contain 40 outpatient stations for administering chemotherapy, complete diagnostic facilities including CT scanning and MRI equipment, full laboratory facility, pharmacy, a surgicenter for minor surgical procedures, blood handling capability, office space for physicians, and of course complete radiotherapy facilities. Patients needing major surgery will continue to be hospitalized.

is it really necessary to have cancer treatment outpatient facilities open around the clock? DeVita thinks so. "It doesn't make sense to insist that chemotherapy can be given only 9 to 5, Monday to Friday," he said. "That makes the giving of chemotherapy fit our schedule and not what may be the

best treatment."

Pruitt said he the outpatient centers CDP and Health Corp. have been involved with "are day hospitals. If it turns out that seven days a week is important, we could adjust. But it seems to me that patients who need availability of treatment 24 hours should be hospitalized. If Dr. DeVita thinks being open around the clock is important, I wish he would make that known."

Salick said that patients requiring blood counts at night, or other attention related to their treatment or condition, "get a run around at hospitals. Emergency rooms never have anyone immediately available who knowns anything about cancer. They are not geared up for it."

Although administration of kidney dialysis is something that can be scheduled, Salick said he found that many patients who work day shifts or who for other reasons find it more convenient to receive the treatment at night appreciate the flexibility. Availability on weekends is also important, he said.

Salick and Rosen do not intend to stop with one center. They envision a network of 20 freestanding comprehensive outpatient centers across the country, all connected to computers, and each with its own network of small satellite centers in their communities. The satellites, "extended doctors'

offices," would be 1-2,000 square feet in size, probably located in professional buildings, also linked by computer to the comprehensive center. They would be primarily a screening type of facility, from which patients would be sent to the main center to establish diagnosis, for initiation of therapy, and for attention to any problems that arise. They would then go back to the satellite where their own physicians would administer treatment.

With increasing numbers of practicing oncologists available in communities, "there is fierce competition for patients," Salick said. "We intend to open our centers to all oncologists who wish to participate. We will provide free office space and the facilities where they can work and treat their patients. We do not intend to take patients away from anyone. Private practice and academic oncologists will work side by side. We want to become part of the NCI program of clinical research, and participate in their protocols."

Salick and Rosen have discussed their plans with DeVita, who later said it was his understanding they wanted their centers to be recognized "as CCOPs without NCI funds. They feel if we endorse them and monitor them, their quality of care will improve by

delivering protocol therapy."

DeVita said the prospect of privately owned, for profit freestanding outpatient cancer centers "was presented to me as a problem, but I kind of like the idea. This is a very interesting organization. One way or another, whether we endorse the idea or not, we will need to monitor it."

Executives of many nonprofit hospitals, especially the community hospitals without the resources of the large, university based institutions, at first saw privately owned FCCs as a threat to them—the problem referred to by DeVita. Others felt FCCs might further erode the patient base available for clinical trials. Judging from the response seen by CDP, Health Corp. and Salick from university and the nonprofit community hospitals, their attitude now has completely turned around. "They see the freestanding cancer center as a profitable operation," CDP's Allen said. "It can make money for them which many of them desperately need to keep the hospitals going."

As for draining patients away from clinical trials, the reverse might well happen. All three firms have indicated they will encourage their participating physicians to join in clinical studies, as full Community Clinical Oncology Program members or affiliates of cooperative groups, or through less formal arrangements with CCOPs, cooperative groups and university centers.

Allen, Pruitt, Salick and Rosen all agree that the most important advantage offered by FCCs is the prospect of improving the quality of cancer care, offering patients optimal treatment with the best facilities in the hands of the most competent oncologists and other professionals, in "one stop" pleasant surroundings, easy to find and easy to reach.

"There is an increasing desire on the part of patients to be treated in a center," Allen said. Even where hospitals have first rate cancer programs, there usually is "no identity visible to referring physicians or patients, no day hospital for outpatients."

Salick observed that patients living in the lower socioeconomic neighborhoods "usually do not make their way to academic institutions for treatment. The best protocols are not filtering down to them." By locating his small satellite offices in those areas, through which patients will be referred to the main Comprehensive Cancer Centers Inc. facility, those patients will be brought into the mainstream of optimal therapy, Salick believes.

Salick said that the firm intends to open 20 such centers, each with its own satellites, within the next two to three years. He estimated each will cost \$10-12 million to construct and equip. To finance that kind of program, the company "will go to the public marketplace for funds," he said.

The FCC concept depends entirely on continuing profitability, or at least breaking even in the case of those owned by nonprofit institutions. Profitability will depend on maintaining high volumes of traffic, and the trend to outpatients has been greatly accelerated by the fact that the DRG rates are at present in effect only for hospitalized patients.

What would it do to the balance sheets if Congress extended prospective payment to outpatients?

"We would welcome it," Salick said. He has managed to remain profitable with the dialysis centers despite the fact that reimbursement has been on a flat rate basis since 1973. The basic rate actually was lowered after national cost figures were available, with the basic rate now \$128 for outpatients and and \$131 for those in hospitals. The inefficient facilities, in hospitals and elsewhere, had to close.

The government will only be able to get a handle on the cost of cancer treatment when more patients are treated in outpatient facilities such as those being developed now, Salick said. "They are treated now in every type of facility. There is no comprehensive program to get these costs in line. By esablishing a network of centers and working with NCI and other government agencies, with our computer based data, we can develop that kind of information. If the government comes out with a prospective payment program for outpatients, it will be our

program that provides the numbers on which their payment schedules will be based. There will be dramatic cost savings to the government and other third party carriers, when cancer is diagnosed earlier and treated more aggressively. The savings will be astronomical. The only way to do it is by running an economically viable program."

Cost is not the only factor in favor of outpatient cancer care. Rosen started administering chemotherapy on that basis 10 years ago at Memorial. "There were no DRGs then, and we did have the problem of filling beds. But we found that outpatients received better care. Once you educate family members, and teach patients what to do, they can do a better job than some nurses. Nurses have to be responsible for several patients, and you have the problem with shift changes. We have found that family members are usually very good at supervising care at home. We found that we could teach patients on cisplatinum to hydrate themselves at home better than would have been done in the hospital."

Rosen intends to remain active as a clinical investigator in his specialty, and will participate in education programs. One of those will be an annual "Oncology Review" for practicing oncologists, sponsored by Comprehensive Cancer Centers Inc., along with UCLA Jonsson Cancer Center and Cedars-Sinai. Rosen will chair the first review, along with Frederick Eilber, professor of surgery at UCLA, Feb. 14-16 at the Century Plaza Hotel in Los Angeles. Rosen is also associate clinical professor of pediatrics at UCLA.

Rosen said he is convinced that the "idea of the truly comprehensive cancer center," Salick's dedication to it and his business expertise and demonstrated success with the dialysis centers "reassured me that our proposed centers will create the next generation in the delivery of health care to the cancer patient."

### NCAB COMMITTEE AGREES ON PDQ ISSUES; NO NEW, SEPARATE SYSTEM FOR PUBLIC

The National Cancer Advisory Board's Committee on Information agreed last week on recommendations it will make to the full Board to resolve Committee Chairman Richard Bloch's concerns over what he had felt was grossly inadequate use of NCI's PDQ system (The Cancer Letter, Dec. 7).

Bloch had urged the NCAB to change the policy it had previously adopted, limiting promotion of PDQ to health professionals. He contended that many physicians, most likely those who would benefit the most from the information available in PDQ, would not use it unless pressured to do so by their patients. After hearing arguments that PDQ as it now exists would not be very useful to lay persons,

Bloch suggested that a new system be considered, one especially designed for use by the general public. The Board agreed to hear such a proposal and referred the matter to the information Committee, along with a charge to look at all of NCI's information programs aimed at the public.

Meeting last week in Ft. Lauderdale, the committee decided to recommend, essentially, that PDQ proceed under current policy with some important changes regarding promotion and vendor licensing, and that no separate PDQ for the public be established at this time.

"If the Board accepts our recommendations and if NCI does everything we recommended, then I will be very happy with the situation," Bloch told The Cancer Letter.

The committee's recommendations were in four parts:

\*Promotion of PDQ. How it is promoted will be left to NCI, but with the recommendation that some promotional efforts be directed to cancer patients encouraging them to urge their physicians to use PDQ. Patients also would be informed that they may ask through Cancer Information System phone services for PDQ printouts to be sent to their physicians.

A nationwide promotional effort aimed at cancer patients would have to be in all likelihood directed to the general public, so this point is a compromise weighted to Bloch's position.

\*Should PDQ as it now exists be open to public access? If not, should a second system be developed for the public? The committee recommended negative answers to both questions, but added that PDQ should be available to patients if their physicians so request. Also, patients should be encouraged to use the Cancer Information System; since CIS has access to PDQ, CIS could relay information from the PDQ data base to patients when appropriate.

\*The disputed directory files. PDQ contains the entire membership lists of all professional oncologic societies which agreed to allow such listing. In addition, names of other physicians and surgeons who treat cancer patients are listed, those coming from a variety of sources. The American Medical Assn., which has agreed to make the PDQ data base available through its computer system, objected to the name files, contending that it would inevitably leave some out who should be included. AMA also has traditionally objected to anything which may encourage "self referrals" by patients.

The committee decided that there was no way to resolve this issue, and accepted NCI Director Vincent DeVita's determination that the names be left in. However, the committee did recommend that any vendor—AMA or any other vendor with which NCI reaches an agreement for PDQ distribution—be

permitted to delete the files if it so desires. That position was taken over the objection of NCAB and committee member Ed Calhoon. He was outvoted by the other members present—Bloch, Helene Brown and Rose Kushner. Ann Landers, another committee member, did not attend. A vendor wishing to delete the names would have to seek NCI's permission, which would not be unreasonably withheld, the committee recommended.

\*Vendor licensing agreements. Bloch had objected to NCI's insistence that it must have the right of prior approval of private vendor PDQ promotional plans. NCI contended that it should be able to determine that promotions fit NCI policy but did not intend to seek prior approval of individual promotional items or articles. The committee recommended that the language of that restriction be reviewed and reworded if necessary to make, it more flexible, and that vendors should be permitted to work out any promotional plan as long as it does not conflict with NCI policy.

Bloch also objected to the fees that NCI requires from private vendors (the only one of which now is B.F. Saunders, although NCI is in negotiations with others). NCI is to receive \$7,500 as an annual fee from each vendor, plus \$5 per user connect hour which is to be charged against the annual fee. In other words, the hourly charge does not go into effect until a vendor has sold 1,500 user hours.

"I don't think we should charge the vendor anything," Bloch said. He feels that vendors would reduce their fees if they did not have to pay NCI anything, and that that would encourage more use of the system.

The committee recommended only that the issue of fees be examined.

NCI requires that vendors do not add or delete any information from the data base, and Bloch interpreted that as an impediment to the development by vendors of user friendly software. The committee supported NCI's effort to maintain the quality of the data base but suggested adding language to vendor agreements which would make it clear that software development is permitted.

NCI has scheduled a press conference for Jan. 31, to launch the B.F. Saunders service.

## DCPC BOARD TO HEAR CONCEPT FOR NEW CONTRACT AIMED AT HEAVY SMOKERS

NCI's Smoking, Tobacco & Cancer Program will present to the Board of Scientific Counselors of the Div. of Cancer Prevention & Control a concept for a two part contract to develop interventions aimed at heavy smokers.

The first part of the contract will be for development of a protocol for the study. That would then be brought back to the Board for concept

2478

approval of a large intervention trial. The Board meets Jan. 28-29.

The concept came out of two workshops held last year by DCPC after Board members had expressed concern over the fact that there has been very little cessation of smoking among those at highest risk for tobacco related disease, the heavy smokers. In fact, those who smoke 40 or more cigarettes a day, the definition of a heavy smoker, actually increased between 1970 and and 1980 from 11.4 per cent of the population to 16.8 per cent, although overall smoking rates declined from more than 50 per cent to less than 40 per cent.

Reports from the workshops which defined the RFP workscope that will be issued if the Board approves

the concept follow in part:

Because of the considerable cancer consequences of heavy cigarette smoking, smoking cessation within this population is urgent. As the number of years of smoking cessation increases, there is a decline in the cancer death rate, which ultimately approaches that of nonsmokers. Prevention occurs predominantly through self motivated techniques; organized smoking programs are utilized only by about five per cent of those who quit smoking. Although this statistic gives rise to optimism because intervention approaches through self help, the mass media and health care professionals are in progress and easily disseminated, a cautionary note must be added: smokers who quit through these methods are usually those with lighter smoking habits.

There is a need to demonstrate that heavy smokers can be encouraged to join antismoking programs and to quit smoking, and that cancer risk can be reduced through smoking cessation. Experimental studies to address these problems must be designed.

Considerations to be addressed in designing a successful heavy smoker intervention trial:

\*Problem: Heavy smokers may be harder to recruit and retain in intervention programs, and they may be less likely to quit compared with light smokers. Heavy smokers also may be less likely to maintain cessation than light smokers. Few cessation programs report a relationship between an individual's initial smoking rate at the start of a program and the outcome at the end of the intervention.

\*Study participants: Heavy smokers should be the focus of an intervention study. The definition of heavy smoking, however, remains undetermined. Whether number of cigarettes smoked per day or a multifactorial definition of dosage should be used remains to be clarified. A representative sample should be used for the trial; a volunteer sample should be avoided. Males and females and blacks and whites should be included in the trial. A tentative agreement was reached to study heavy smokers in the 40-60 age range.

\*Treatment considerations—Treatment must be intensive; minimal interventions are ineffective with heavy smokers.

—Components of an intervention might include medical intervention delivered through existing health care services, behavioral approaches, community organization approaches, and political interventions, e.g., through taxation or legislative means.

—Process analysis of the intervention should be conducted to examine why heavy smokers are quitting less frequently than light smokers and to determine which intervention components are most effective with heavy smokers.

-Whether to use a single intervention strategy or a combination of treatment alternatives that might enhance the probability of success at the expense of experimental control has yet to be determined.

—Since it is imperative that the treatment be delivered to study participants as intended, an efficacy trial should test the impact of the intervention under a relatively idealized set of treatment delivery conditions.

—The intervention package must be generalizable and readily adoptable to other populations.

\*Length of treatment and followup. An examination of data from the Multiple Risk Factor Intervention Trial (MRFIT) suggests little advantage in continuing to treat people beyond two years of intervention. Although MRFIT data suggest a two year followup, other studies have followed patients for one year to determine behavioral endpoints. For cancer endpoints, at least 10 years of followup are required to evaluate the effects of smoking cessation.

\*Recruitment. How subjects are recruited depends on the intervention strategy chosen for the study. The three major sources for recruitment include the workplace, health care system and the community.

The workshop examined the need for and significance of conducting a study to achieve smoking reduction (behavioral endpoint study) or a study of the impact of smoking cessation on lung cancer (cancer endpoint study). It was concluded that both of these studies as well as a feasibility study for the cancer endpoint study should be carried out.

Behavioral endpoint study:

\*Problem: The prevalence of heavy smoking in the population is not changing despite the decline in the prevalence of smoking overall.

\*Research question: The purpose of a behavioral endpoint study is to test an optimum intervention package to identify the most effective way to reduce the prevalence of heavy smoking. An effective intervention should resolve questions relating to

Page 6 / Jan. 11, 1985

recruiting heavy smokers into a smoking cessation program, maintaining heavy smokers in a program, and demonstrating a significant change in smoking behavior.

\*Sampling: To reduce heavy smoking in the population, an ideal strategy would be to recruit all heavy smokers in an intervention study. Alternatively, the study should strive to include the highest percentage of heavy smokers possible.

\*Intervention strategy: Based on an evaluation of currently available research results, a single intervention aimed at smoking cessation should be selected in a pilot test. If the pilot test appears to achieve the expected behavior change, it would be implemented on a larger scale. A stepped approach to intervention was suggested, ranging from applying the simplest intervention to the most complex. providing an opportunity to assess the various intervention components individually and identify the more successful parts.

\*Design considerations: Specifications regarding the optimum intervention package need to be delineated.

\*Other considerations: Two behavioral endpointsreducing the number of cigarettes smoked and complete smoking cessation—were considered. However, an explanation of study results that incorporated reduced smoking would require a reliable index of smoke exposure. Because such an index is not now available, it was concluded that smoking cessation would be the desired behavioral endpoint.

Cancer endpoint feasibility study:

\*Problem: The practicality of conducting a cancer

endpoint study is unknown.

\*Research question: Can an intervention program be specifically tailored to produce a significant difference between treatment and control groups to make the cancer endpoint study feasible?

\*Sample: The sampling procedure may use a MRFIT sampling frame. A feasibility study does not require a population based sample as does the behavioral endpoint study.

\*Design considerations: The use of a formative process evaluation allowing for adjust ments during the course of the study was suggested for developing of the most effective intervention strategy for heavy smokers in the feasibility study. Both the study cohort and the intervention should be designed to show differences most clearly.

Cancer endpoint study:

\*Problem: There is a significant incidence of lung cancer; 25 per cent of all cancer deaths is attributable to lung cancer.

\*Research question: Does smoking cessation reduce the incidence of lung cancer?

\*Sample: Sample size is crucial in determining

whether a major trial is a realistic undertaking. The sample must be representative of heavy smokers and requires a lower intensity of recruitment than the behavioral endpoint study.

\*Design considerations: A number of statistical and design issues must be addressed, including recruitment of subjects, delivery setting (worksite or community), cost effectiveness, sample size (based on age and quantity of cigarettes smoked). and eligibility criteria (such as excluding people with other diseases that would affect mortality and bias the study results). Careful projections on the expected range of effects of each variable must be estimated.

A controversial topic among workshop participants and NCI staff involved the issue of including the cancer endpoint in the program. A strong feeling persists that NCI does not need to spend more money to determine if smoking cessation reduces lung cancer; the benefits of smoking cessation have been well demonstrated, even if there is no statistical evidence that it will reduce lung cancer incidence.

That view prevailed in the development of the concept which will be presented to the DCPC Board. and the behavioral endpoint will be the only one recommended for inclusion in the RFP.

Another controversial point may be the focus on a community intervention rather than on individuals. The recommendation in the concept proposal will be on the community approach.

Thomas Clynn is DCPC program director for smoking research.

### NCAB COMMITTEE, SORDS AGREE ON NEW TRAINING PROGRAM IN SURGICAL ONCOLOGY

As the result of recommendations by the National Cancer Advisory Board Committee on Innovations in Surgical Oncology and the Surgical Oncology Research Development Subcommittee (SORDS) of the Board of Scientific Counselors of NCI's Div. of Cancer Treatment, a new institutional training program in surgical oncology will be proposed to the Div. of Cancer Prevention & Control Board of Scientific Counselors for concept approval.

The new program would support training grants to institutions which would select individuals for two to three years of training in surgical oncology after they have completed their internships.

The NCAB committee, chaired by Ed Calhoon, agreed on the following general concepts at its meeting last year:

1. There is a need for a defined post graduate training program in surgical oncology leading to either a certificate of competence or a more formal degree (e.g. masters in biomedical sciences).

2. These training programs should be developed at

major medical centers and cancer centers which have the resources for training surgical oncology fellows in tumor biology, immunology, biostatistics, diagnostic imaging, nutrition, rehabilitation, and broad exposure to radiation and chemotherapy.

3. A training grant should be established as a national focus for the development of clinical surgical oncology subspecialties. This grant would allow two to three years of post graduate board based clinical and scientific education as described above. The salary of the training would be commensurate with his/her post graduate experience. In addition to salary, a research stipend similar to KO8 awards (\$10,000) a year would be applied to support travel and research expenses.

4. Grantees would be considered NCI fellows in surgical oncology, but individual institutions would decide whether training would result in a specialized degree or a certificate of competence. There would be no exclusion for a graduate degree. However, any tuition costs would not be covered by

the training grant.

5. It was agreed that \$5 million should be reserved for the support of 100-125 such fellowships.

The NCAB committee later met with SORDS to develop details of the proposal which will be presented to the DCPC Board. NCI training programs are funded and administered by DCPC.

NCI's KO8 program, the clinical investigator awards, was designed to support training of recent medical school graduates in basic cancer research laboratory skills, including surgical oncologists. It pays salary support of \$40,000 a year plus \$10,000 for research support, allows for 25 per cent commitment to clinical activities to maintain clinical skills, encourages the selection of the strongest basic scientific mentor (including PhDs) and provides support for a training interval (three to five years) sufficient to develop independent laboratory skills.

NCI has committed funds to support up to eight surgeons through KO8 each year, which with funding for up to five years eventually support as many as

40 surgeons during a single year.

The NCAB committee decided that a program was needed for the training of the highest quality cancer surgeons, rather than surgical scientists as does KO8. The committee felt such a program is of critical importance to assure delivery of state of the art clinical care, since surgeons are integral to both cancer diagnosis and treatment.

Committee member LaSalle Leffall said there is at present less resistance in the American College of Surgeons to accepting surgical oncology as a subspecialty. However, he felt that recommendations concerning training requirements of the subspeciality should not interfere with the currently accepted period of general surgical training. Charles Sherman, committee consultant, noted that there was a precedent for this approach for vascular surgery and a stronger rationale could be made for surgical oncology.

Leffall later said, in discussion at the NCAB meeting, that his remarks should be construed as "implying that the American College of Surgeons Board of Certification is likely to certify surgical

oncology."

"We should look forward to certification of special qualifications in surgical oncology by the American Board of Surgeons," William Longmire, member of the President's Cancer Panel, commented.

"What is meant by surgical oncology?" Board member Enrico Mihich asked. "Is the purpose of the proposed training program) to improve an area of surgery in oncology? To improve the knowledge of surgeons in the biology of the disease so he can do his job better? Or to teach surgeons to work with other members of a team?"

"The biology is the important factor,"

Leffall answered.

"It is extremely important to educate some people in the problems we are having," Board member Geza Jako said.

"The practicing surgeon usually is not a member of the diagnostic team, and that is a problem," Board member Gale Katterhagen said.

DCT Director Bruce Chabner commented, "We have a very effective mechanism in the KO8 awards, but we are not getting enough applicants. It does not make sense to establish a \$5 million pool if we can't get enough surgeons to participate, and it does not seem now that they are willing to participate."

#### NCI CONTRACT AWARDS

TITLE: Epidemiological investigations of cancer in Utah (SEER program)
CONTRACTOR: Univ. of Utah, \$528,000.

TITLE: Support for a cancer surveillance system
CONTRACTOR: Fred Hutchinson Cancer Research
Center, \$889,150.

#### The Cancer Letter \_Editor Jerry D. Boyd

Published forty-eight times a year by The Cancer Letter, Inc., P.O. Box 2370, Reston, Virginia 22090. Also publisher of The Clinical Cancer Letter. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means (electronic, mechanical, photocopying, recording or otherwise) without the prior written permission of the publisher. Violators risk criminal penalties and \$50,000 damages.