

THE

CANCER LETTER

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ACS To Open Key Positions To Competition In Massive 'Reorganization For The '90s'

The housecleaning that the American Cancer Society calls its Reorganization for the 90's will not be a mere "rearrangement of deck chairs," the society's Executive Vice President John Seffrin said to *The Cancer Letter* last week.

Along with redrawing its box diagram, ACS intends to open its key professional positions to competition, in effect forcing the current
(Continued to page 2)

In Brief

CTEP Files IND For Antineoplaston, Mayo, MSK, Plan Trials; Researcher Escapes Bosnia

NCI CANCER Therapy Evaluation Program has filed an Investigational New Drug application with FDA for clinical trials of "antineoplaston," an agent administered in the Houston-area clinic of the unconventional practitioner **Stanislaw Burzinski**. NCI intends to evaluate the agent in the treatment of advanced primary glioblastoma. The Mayo Clinic and Memorial Sloan-Kettering Cancer Center plan to hold the trials. . . . **HAMZA MUJAGIC**, the cancer researcher who headed a cancer center in Bosnia after working at NCI, has made a successful journey from Banja Luka, where he has been under a house arrest. Mujagic, who is now staying in Zagreb, plans to come to the U.S. to take a temporary consulting job at NCI. . . . **HERBERT PINEDO**, head of the Dept. of Medical Oncology, Free Univ. Hospital Amsterdam, was awarded the Fourth International Chiron Award for Biomedical Research and Training for his research in chemotherapy and coordination of international educational projects. . . . **ROBERT COMIS** has been appointed director of clinical programs for the Jefferson Cancer Network and the Jefferson Cancer Center, Thomas Jefferson Univ. Comis was senior vice president for medical science at Fox Chase Cancer Center. . . . **HELENE BROWN**, UCLA Jonsson Comprehensive Cancer Center, received the Trend Setter Award for Volunteer Leadership, given by the National Health Council and Warner-Lambert Co. **SEN. TOM HARKIN (D-IA)**, received the Trend Setter Award for Public Policy. . . . "ON THE EDGE of Being..When Doctors Confront Cancer" is a continuing medical education film about six physicians who have personally, or in their immediate families, confronted cancer. The film is offered as a service to physicians with the support of Cerenex Pharmaceuticals, a division of Glaxo Inc. Contact 800/GLAXO to obtain a copy. The film is narrated by **Jason Robards**, with an introduction by former Surgeon General **C. Everett Koop**.

New ACS Structure
Proposed, Approved
Page 5

Seffrin: First Year
At ACS Shows 'Simple
Problems Aren't'
Page 5

Diet Supplements
Should Be Held
To Scientific Standard,
Broder Tells House
Page 7

NCI Awards Regional
CIS Contracts
Page 7

FDA Encourages Study
Of Gender Differences
Page 8

RFA Available
Page 8

Top ACS Jobs Considered Open In Reorganization, Seffrin Says

(Continued from page 1)

department heads to reapply for their jobs.

"We are doing something we have never done before," Seffrin said in an interview last week. "All those positions are considered open. We consider them as new positions."

Seffrin said the reorganization will be almost completely implemented before the November meeting of the society's Board of Directors.

Both the reorganization and the shakeup in the national headquarters staff are seen as a means for improving the society's service to its 57 divisions and more than 300 local units. The change is guided by the recommendations of the Arthur D. Little report, a management survey commissioned by the ACS Executive Committee (*The Cancer Letter*, July 3, 1992), Seffrin and others said.

The highlights of the expected changes follow:

▶ Adopting the recommendations in the Little report, ACS will group its divisions by size rather than geographically. Under the new arrangement, the divisions will be grouped into four categories, with each category receiving a different level of support from the national office.

▶ National initiatives will be coordinated with the divisions, and the divisions will be brought into the planning process.

▶ The society has instituted a program that will return \$1.2 million to finance projects initiated by the divisions this year.

▶ Divisions will be encouraged to shop around for materials and services ordinarily supplied by the national office.

▶ ACS rejected the Little report's recommendation

for a reduction of 10 percent in the national staff. "I did not find that that number was derived in any systematic way," Seffrin said to *The Cancer Letter*. "We are working on developing a sound rationale for the number of people we need."

Staff Changes

While current national staff department heads, most of them vice presidents, are regarded as front runners for the nearest related departmental leadership positions, Seffrin stressed that incumbents should not feel assured that they will be retained in those jobs.

Incumbents "are automatically considered finalists," for their jobs Seffrin said. However, they may be competing against other staff members and applicants from outside the society's headquarters. Seffrin said incumbents also have been invited to consider applying for other positions in the new arrangement.

"I think we have established an atmosphere in which it is not considered out of line to express a career interest in other positions," he said.

The first round of appointments to the new positions are expected to be made later this month.

New Division Groups

The most extensive and serious criticism of ACS in the Little report centered on the level of responsiveness by the national office to the needs of the divisions and in the relationship of national staff to division staff.

The Little report recommended that the divisions be grouped into four categories--mega, large, medium, and small--"for purposes of defining appropriate support from the national office."

Each group would have a national vice president for division services. In the present arrangement, divisions are grouped geographically, each group with a national staff member with the title of vice president.

The latest draft of the ACS national staff reorganization adopts the report's recommendation on the four groups, each with its own chief.

Seffrin said that position would be held by an individual or several persons acting as account managers, responsible for regular site visits and services to divisions.

According to the most recent recommendation of the Structure Modeling Work Group (a unit of a task force of 21 staff members who represented nearly all levels of the national headquarters staff and the divisions), the mega and small division groups would be placed under one division group manager while the large and medium groups would be placed under

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another division group manager.

One reason for locating the mega and small divisions in one group is that those with the larger staffs could provide assistance to the others on various projects or in dealing with certain problems, such as income development.

"They don't have to go through national for everything," Seffrin said. Divisions will be encouraged to swap ideas, resources, and even staff on occasions when they can help each other out.

However, Seffrin said ACS is also considering a structure under which all four groups would be working under one division group manager, but retain their own chiefs or account managers. Here is how the divisions were grouped in a recent ACS report:

Mega--Florida, Georgia, Texas, California, Illinois, Michigan, Ohio, Pennsylvania, New York State.

Large--Missouri, Indiana, Tennessee, North Carolina, Virginia, Maryland, New Jersey, Connecticut, Massachusetts, New York City, Philadelphia, Washington, Arkansas, Colorado, Minnesota, Wisconsin.

Medium--Oregon, Utah, Oklahoma, Nebraska, Kansas, Iowa, Long Island, Westchester, Queens, District of Columbia, New Hampshire, Hawaii, Arizona, Louisiana, Mississippi, Alabama, South Carolina, Kentucky.

Small--Alaska, Idaho, Montana, Wyoming, Vermont, Delaware, Rhode Island, West Virginia, North Dakota, South Dakota, Puerto Rico, New Mexico, Nevada, Maine.

An advisory group of division executive vice presidents, chaired by William Cockrell of the California division, has been working on the final alignment.

"I'm hoping that they can come up with some logical rationale" for placement of divisions within the four groups, Seffrin said to *The Cancer Letter*.

Greater Autonomy From National

For the first time in ACS history, divisions will be encouraged to seek alternative suppliers of materials and services ordinarily supplied by the national office.

"I think we can compete," Seffrin said.

The society's fund raising starts with the divisions, who by contract send 40 percent of the contributions they receive to the national headquarters.

They compete for grants to carry out projects initiated by national, and, sometimes, they receive material or staff services, mostly for national initiatives.

That aspect of the relationship will remain, but now the society will also offer a new mechanism for funding projects initiated by the divisions.

This year, the divisions will receive \$1.2 million in funding for such local projects. So far, divisions have submitted competitive applications totaling more than \$4 million.

A Field Advisory Council chaired by Charles Leiss, Maryland Div. EVP, graded the applications. "I took their recommendations and funded as far as the money went," Seffrin said. "So far, everyone is tickled pink, because they got help for something they wanted, and with the process."

This program was launched at the time national was trimming its budget as a result of collecting an income that fell below projections. Earlier this year, Seffrin directed his department heads to trim \$7 million from their budgets approved in June 1992, then cut another two percent across the board.

National is tightening the belt even more, and although the budget is estimated at \$1 million less than last year, another \$1.2 million will be set aside for the division projects.

No Reduction in Workforce

Seffrin said he "categorically rejected" Little's recommendation for a reduction of 10 percent in the national staff.

"I did not find that that number was derived in any systematic way," he said. "They performed a wonderful service in many ways, but I take issue with that recommendation. It was not based on any empirical evidence but on the opinions of some individuals. We're working on developing a sound rationale for the number of people we need."

Seffrin said that in 1990, the national office was authorized 440 full time equivalent positions, though not all were filled. As of last week, the number of full time equivalents was down to 364, a level Seffrin described as an "all-time low."

"We do have some departments that are strapped," Seffrin said. "We will have to redeploy, find out where we need more, where less. I would not have taken this job if I hadn't believed that we had the best core staff in the business."

"In the last few years, their mettle has been tested, with all the changes and turmoil (Seffrin is the third EVP since the late Lane Adams retired; ACS last year completed reorganization of its volunteer governance structure, a highly controversial action)."

Seffrin insisted that "we have addressed all the Arthur D. Little recommendations, either directly or indirectly."

Seffrin's Mandate

When he was hired by the ACS board last year,

Seffrin was given the mandate to build his staff and reorganize the national office as he saw fit.

However, Seffrin maintains that he chose not to use his mandate to its full extent.

"Unilateral and arbitrary decision making is not my style," Seffrin wrote in a letter sent to board members last month. "I am committed to the team approach as the most effective way to find the best solutions to problems and challenges facing our organization. The synergy of skilled and committed staff working toward a common goal is powerful indeed. I am pleased to report that the American Cancer Society has been able to benefit from this process in the development of our reorganization plan.

"An empowered group of 21 staff representing virtually all levels and departments in the national home office as well as divisions, worked nearly full time for six months. They researched, analyzed data and developed a functional, structural schematic with major innovations which will allow us to move ahead into the next century. They also produced a national home office purpose and operating philosophy and a strategy document for organizational development. This new operating philosophy outlines organizational values and a work environment to help change behaviors that have kept the society from reaching its full potential, both in accomplishing our mission and in empowering employees to do their best. . .

"While functional and structural changes were of critical importance, I believe that it is the new philosophical and cultural norms that will have the most profound and positive impact on the society's ability to prosper in the future."

The mission statement:

"The American Cancer Society is the nationwide community based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives from cancer, and diminishing suffering from cancer through research, education, and service."

The purpose and operating philosophy of the national home office:

"The national home office is committed to providing leadership and quality service in support of the mission of the American Cancer Society. This commitment is based on the following set of values:

"We are responsible and accountable; we listen to understand; we are responsive; we operate with integrity and consistency; we respect the individual; we facilitate professional growth and personal development; we promote partnerships and teamwork; we are stewards of the public trust and will spend all contributions wisely."

In that letter, Seffrin summarized what he termed as "major innovations" in the reorganization:

▶ A unit on voluntarism and the volunteer-staff partnership. This area will focus on ensuring that the latest methods of involving and developing volunteers are implemented throughout the society.

▶ Creation of an information center which would combine several current areas that provide information on cancer and American Cancer Society programs. They would coordinate a nationwide clearinghouse of best practices and provide, perhaps through an 800 number, a single inquiry point for divisions.

▶ Professional and technical specialties would be combined to provide expert services to divisions and other entities of the national home office. This would include such areas as training design, meeting coordination, planning support, marketing and product production.

▶ Divisions are divided into groups through a customer service manager concept. This individual would coordinate the determination of specific services needed by the group. The divisions would have direct control of some national funds to allow them to purchase the services they require. The customer service managers would also coordinate the identification of division needs and ensure their participation in strategic and operational planning.

▶ A strategic planning team would be established which, in conjunction with the executive team, will focus on the long term growth and health of the organization. Members would represent the major functioning areas and ensure coordination of operational planning within the national home office and the field.

▶ A functional structure would be created regarding advocacy and collaborative relationships. This area of activity would be charged with enhancing the society's leadership in the public policy area. They would also support the active pursuit of natural collaborations with other organizations to expand cancer control activities beyond the society. This would include coordinating relationships with health professional groups, other cancer groups and nonprofit organizations which share ACS goals. This would also include international activities.

▶ Commitment to cross functional teams. These teams would be given authority, accountability, and the resources necessary to take action. Use of these teams will ensure that a cross section of expertise is brought to bear in on creatively developing programs or problem solving.

ACS: New Organizational Structure Proposed By Work Group, Approved

Following is the organizational lineup proposed by the Structure Modeling Work Group and approved by Seffrin:

Detection. The unit will be responsible for breast, cervical, and skin cancer detection. It will also provide site specific guidelines and education for the public and health care professionals, monitor trends and research to maintain current knowledge of cancer detection, ensure division participation in program planning and evaluation, and provide support and training to divisions.

Patient Services/Treatment. This unit will engage in monitoring trends, planning, collaboration with the divisions. The unit's responsibilities will also include public and professional education, resources information guidance, direct services, education and support. Efforts in pain control will fall in this unit's jurisdiction.

Prevention: comprehensive school health education, tobacco use prevention and cessation, nutrition, and technology transfer.

Research: medical and scientific grants advice and review, epidemiology and statistics, and administration of research and cancer control grants.

Volunteerism/Volunteers/Staff Partnerships: trend analysis, door openings, recruitment, awards and recognition, volunteer development and program expansion, and an academy for new staff members.

Advocacy Relationship Management. This unit will include three separate offices--Public Policy/Legislation, which includes state initiatives and federal/government relations; Collaborative Relationships, which includes organizations, socio-economic disadvantaged, government agencies, international, and nursing; and Public Relations, which includes national media, and public relations.

The Public Policy/Legislation office will remain in Washington, and the media office will remain in New York, Seffrin said.

Income Development: annual, foundation, and development.

Finance: financial services, audit, accounting, cost accounting, investments, centralized purchasing, and facilities management.

Marketing: direct marketing, constituent research, marketing research, market analysis, and competitive analysis.

Information Center: library, internal communications, cancer referral service, clearinghouse, and archives.

Product Promotion: materials production management, editorial and creative service, printing, audio visual, distribution, medical writers expertise, mailroom, and publications.

Computer Systems Services: computer operations, software acquisition.

Professional Services: meetings logistics and travel, training design, evaluation skills, planning skills/expertise, and accreditation/CME.

Human Resources: benefits and personnel.

Seffrin: First Year As ACS Head Shows 'Simple Problems Aren't'

Last year, when John Seffrin took the job of the executive vice president of the American Cancer Society, the society's staff morale was low, annual contributions had leveled off, and the society's base--the 57 divisions, more than 300 local units, and about one million volunteers--were more than restless.

Seffrin knew what he was getting into.

He had just come off a two-year term as chairman of the ACS Board of Directors and had been active as a volunteer with the society's Indiana division and the national headquarters since the 1970s.

Seffrin was granted carte blanche by the board to do as he pleased in reorganizing the national office and building his staff.

"It's been an absolutely fantastic experience," he said, reflecting on his first full year in the job. "It is a wonderful challenge. I have never put in more hours or worked harder."

Chief among the lessons he has learned:

"Simple problems aren't."

In the past 12 months Seffrin has had input in decisions ranging from monumental to minute, "from how to answer the phones to reorganization, and everything in between."

"It's been a good year, and a growing year," he said to *The Cancer Letter*. "I'm thrilled with the progress we have made."

MA Cigarette Tax Victory

One of the society's accomplishments of which he is most proud was the Massachusetts division's victory in pushing through a 25-cent-per-pack cigarette tax increase in last November's election, raising the state tax there to 51 cents.

Faced with the tobacco industry's \$10 million effort to defeat the initiative, the division appealed to national for help. Seffrin authorized the spending of \$250,000, which, with the division's efforts, turned out to be enough to turn the tide.

"Every time we have rung the bell, it's been through a collaborative effort such as that," Seffrin said.

Division executive vice presidents contacted by **The Cancer Letter** were pleased with Seffrin's performance.

"John has put together a great management team," William Barlow, Philadelphia Div. EVP, said, referring to the "triumvirate" of Seffrin and his two deputy EVPs, Richard McGuiness for operations and Harmon Eyre for research and medical affairs. "I'm excited about the new functions they are establishing. They are making changes that have been needed since Lane left."

Barlow said he liked the structure of the changes related to divisions, "but I would like to see who the players are" before reaching a conclusion on how effective they might be.

Many of the divisions "are stretched too much and need help," Barlow said.

"The national staff has experienced a real rough time," Massachusetts Div. EVP Donald Gudaitis said. "It has impacted on morale. I feel we're definitely moving in the right direction. The wholesale change in the national office is positive. I'm optimistic about where the organization is headed."

"The principles, philosophy, and credo that John has set for national is dead on," said Michael Dany, Texas Div. EVP. "The need for service to divisions is clearly recognized."

Among the changes Dany likes are the "customer based philosophy, more resources for division services, and the single stop information source at the national home office. Those are all very positive. I also like the organization of staff around our priorities, the staff focus on core programs and priorities and not on functional bases. Another is the concept of flexible working teams, where people participate on tasks based on their talents, pulling people from whatever departments they are in."

One EVP who asked not to be identified said that he had some doubts about Seffrin when he was hired. "We had no idea how effective he would be as a manager, coming from academia (Seffrin chaired the Dept. of Applied Health Sciences at Indiana Univ. and his PhD is in health education).

"He was coming into a large organization with very different and vocal constituents, at a time when the organization had stagnated," the EVP said.

"Some of us were frustrated because we felt we needed a Lee Iacocca to come in and kick some ass. Now that I have seen what he has accomplished, the changes undertaken, these are steps in the right direction. I like the changes and his style of leadership. He has been very effective," he said.

Role Of Physicians

Members of the ACS Board of Directors contacted by **The Cancer Letter** were supportive of the reorganization, but had some reservations. Their greatest concern had little to do with the reorganization itself but with what some of them felt has been a growing tendency to deemphasize the role of the society's medical and scientific staff and volunteer leaders.

"This has been a trend over the last three to four years," one board member commented (board members contacted by **The Cancer Letter** agreed to comment forthrightly provided their remarks were unattributed). "Many physicians (in the volunteer leadership and, possibly also on the national staff) feel the place of physicians in the society is being downplayed. The credibility of the society is not in fund raising, it is in the scientific and medical area. The medical side is the spearhead of the organization."

The board member said the trend may have started when responses to queries from the press and public were given by lay people without checking with the medical staff or physician volunteers.

The restructuring of the society's governance last year contributed to a diminished role for physicians, according to another board member. "The past officer directors and life members, (many of them physicians) now are not even allowed to sit with board members. I think we are losing a lot of help from those wise old heads when they are segregated from the board. They are the conscience of the society."

That restructuring also reduced the size of what had been the Medical & Scientific Committee, now the Medical Affairs Committee. That committee has provided much of the society's medical and scientific leadership; in fact, nearly all matters pertaining to medical and scientific issues are reviewed by the committee. Reducing it in size reduces the number of physicians who influence the society's direction, some board members felt.

The volunteer governance of the society traditionally has two top positions--the chairman of the board, elected to a two year term, is a lay volunteer; and the president, elected to a one year term, is a physician volunteer.

"There is a perception, which I don't believe is real but the perception exists nevertheless, that our executive vice presidents have believed that the chairman is more important than the president," one board member said. "Some of our presidents have had that feeling. Having a former president (Harmon Eyre) in the EVP's office (as deputy EVP for medical affairs

and research) should dilute that concern."

One board member feels that ACS "has been so involved in the process, so hung up on governance, that some have forgotten what they are there for. The rearrangement may not be as important as the fact that the process took place. Things might work better simply because we have looked at it so intently. But I hate to see us focus on structure and process, as if that's the main thing."

Capitol Notes

Diet Supplements Should Be Held To Scientific Standard, Broder Says

Manufacturers of diet supplements should be required to provide a scientific justification if they claim that their products are active against cancer, NCI Director Samuel Broder said at a House hearing last week.

"When a manufacturer makes a commercial claim in terms of the capacity of an agent to bring about a therapy for cancer, there should be a scientific standard to defend the claim," Broder said at the hearing of the Subcommittee on Health and the Environment of the House Energy and Commerce Committee on legislation that seeks to relax the Food and Drug Administration's regulation of dietary supplements.

Cancer remedies advertised as having activity against cancer and marketed as diet supplements include shark cartilage, a substance that has been receiving both national publicity and attention on Capitol Hill.

"[Cancer patients] are extremely vulnerable, and I believe they make the implicit assumption that claims are not being made unless somebody somewhere has reviewed them and provided an imprimatur that they are accurate," Broder said.

Actually, even under existing rules, the diet supplement industry is virtually unregulated, said FDA commissioner David Kessler.

"When supplements are really drugs in disguise, promoted to treat serious diseases, we have a problem," Kessler said at the hearing. "Recognize that the dietary supplement industry is essentially unregulated. The marketplace is awash in unsubstantiated claims."

Kessler said that in a recent survey by FDA, 93 percent of health food stores recommended dietary supplements to treat cancer and fight infection and high blood pressure.

Sen. Orrin Hatch (R-UT) and Rep. Bill Richardson

(D-NM) have introduced corresponding bills that would classify dietary supplements as foods and relax the FDA standard for scientific proof of health claims made by food supplement manufacturers.

NCI Awards Regional Contracts For Cancer Information Service

NCI has awarded 17 new regional contracts to operate its Cancer Information Service.

The Institute has committed \$16.1 million in 1993 to support 19 regional CIS offices located at NCI-designated cancer centers and community hospitals across the U.S. Awards have not been finalized in two regions.

Through a national toll-free service, the CIS enables callers to 1-800-4-CANCER to ask information specialists questions on cancer prevention, detection, diagnosis, treatment, rehabilitation and community resources. CIS provides current treatment information to physicians through the Physicians' Data Query database.

Established in 1976, CIS has provided regional service to about 80 percent of the American public. The new awards expand the CIS program to ensure equal service to all geographic areas, NCI said.

Besides the new regional structure, the CIS is improving its communications technology, providing more staff and training, and beginning a national quality assurance program, according to Kate Duffy Mazan, chief of the CIS. More than 2,500 test calls will be placed each year to monitor the quality of information given to the public by the CIS.

Each regional office has local resource directories of cancer-related services and programs in its geographic area. In a new emphasis, the CIS will serve as NCI's primary outreach network. Outreach coordinators in each region will promote the use of NCI educational messages and materials to address specific cancer problems in their region.

The CIS currently responds to more than half a million requests annually for cancer information.

The regions, institutions receiving the five-year contracts, and the principal investigators follow:

Region 1: (CT, ME, MA, NH, RI, VT) Yale Univ., Vincent DeVita Jr.

Region 2: (New York City, Long Island, Westchester County, NY) Memorial Sloan-Kettering Cancer Center, Thomas Fahey.

Region 3: (NY, Western PA) Roswell Park Cancer Institute, Edwin Mirand.

Region 4: (DE, NJ, Eastern PA) Fox Chase Cancer Center, Paul Engstrom.

Region 5: (DC, MD, Northern VA) **Johns Hopkins Oncology Center**, Raymond Lenhard.

Region 6: (GA, NC, SC) **Duke Comprehensive Cancer Center**, Barbara Rimer.

Region 7: (FL, PR) **Sylvester Comprehensive Cancer Center**, Edward Trapido.

Region 8: (AL, LA, MS) **Univ. of Alabama at Birmingham Comprehensive Cancer Center**, Edward Partridge.

Region 9: (AR, KY, TN) **Lucille Parker Markey Cancer Center**, Gilbert Friedell.

Region 10: (OH, WV, Southern VA) **Randolph Cancer Center, West Virginia Univ.**, Fred Butcher.

Region 11: (IA, ND, MN, SD, WI) Not awarded yet.

Region 12: (IN, MI) **Meyer L. Prentis Comprehensive Cancer Center of Metropolitan Detroit**, Vainutis Vaitkevicius.

Region 13: (IL, KS, MO, NE) **Univ. of Kansas Medical Center**, Ace Allen.

Region 14: (OK, TX) **M.D. Anderson Cancer Center**, Stephen Stuyck.

Region 15: (AK, MT, OR, WA, Northern ID) **Fred Hutchinson Cancer Research Center**, Robert Day.

Region 16: (AZ, CO, NM, UT, WY, Southern ID) **The Penrose-St. Francis Healthcare System**, Charles Zinn.

Region 17: (NV, Northern CA) **Northern California Cancer Center**, Dee West.

Region 18: (Southern CA) Not awarded yet.

Region 19: (HI) **Cancer Research Center of Hawaii**, Brian Issell.

FDA Encourages Drug Developers To Examine Gender Differences

The Food and Drug Administration has published a guideline calling for better assessment of possible gender differences in responses to new medications.

The guideline, published in the July 22 "Federal Register," encourages companies to include patients of both sexes in drug development and to analyze the effectiveness and safety databases to look for significant differences in response between men and women.

At the same time, FDA revised a 1977 policy that had excluded women of childbearing potential from the early studies of most drugs.

The guideline directs particular attention to possible pharmacokinetic effects of the phases of the menstrual period, menopause and use of oral contraceptives or estrogens.

Elimination of the 1977 restriction on participation of women of childbearing potential in early clinical

studies reflects the agency's view that institutional review boards, investigators and patients should play a greater role in determining whether participation of women in trials is appropriate and how best to make sure there is no exposure of a fetus to potentially toxic agents, according to an FDA statement. In its review of the manufacturers' protocols, the agency will continue to evaluate the risks and benefits of drug studies in specific populations, including women.

Comments may be submitted to Dockets Management Branch, HFA-305, Rm. 1-23, 12420 Parklawn Drive, Rockville, MD 20857 by Nov. 19.

RFAs Available

RFA CA-93-036

Title: **Viral interactions with p53 in human cancer**

Letter of Intent Receipt Date: Sept. 15

Application Receipt Date: Nov. 23

NCI invites investigator-initiated research grant applications for support of basic studies on the molecular mechanisms by which DNA tumor viruses (such as papillomavirus, SV40, adenovirus) interact with p53, thereby providing new insight into viral oncology and human tumorigenesis.

Applications may be submitted by domestic and foreign for-profit and non-profit organizations. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Awards (R29). This RFA will use the NIH R01 and the FIRST Award (R29). Total project period may not exceed five years. Anticipated award date is July 1, 1994. Approximately \$1,000,000 in total costs per year for up to five years will be committed to fund applications. Five to six awards will be made.

Cancer is a multi-step process that is usually preceded by the accumulation of mutations in an assortment of genes. Until recently, the tumorigenic mutations that have been studied in detail are those that activate oncogenes. The discovery of anti-oncogenes or tumor suppressor genes, by which inactivating mutations elicit tumorigenesis, has added a new dimension to the understanding of neoplasia. The retinoblastoma susceptibility gene (RB) is the prototype tumor suppressor gene and has been shown to suppress the transformed phenotype for several different cancers. The p53 gene is a growth control gene that plays a key role in the suppression of abnormal cell proliferation and tumor development. Mutations in the p53 gene are becoming the most common genetic alterations in many human cancers. Genetic abnormalities of p53, some of which may be due to viral involvement, are functionally implicated in the development of a wide variety of human cancers, including breast, cervix, bone, colon, liver and lung. Many of the viral oncoproteins from DNA tumor viruses such as human papillomaviruses, simian virus 40 (SV40) and adenoviruses, which transform cells in culture and induce tumors in animals, act in part through the functional inactivation of p53 tumor suppressor gene products resulting in uncontrolled cell growth.

Inquiries: May Wong, PhD, Div. of Cancer Etiology, NCI, Executive Plaza North Rm 540, Bethesda, MD 20892, Tel. 301/496-1953.