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Centers Network Releases "Version 1.0" Of Clinical Guidelines For Eight Cancers

Ft. Lauderdale, FL—A group of researchers and administrators at 13 major cancer centers spent more than 18 months compiling clinical guidelines for the treatment of cancer.

For the centers that comprise the National Comprehensive Cancer Network, the guidelines are no small matter. Ultimately, they are expected to offer an approach to pricing and measurement of outcomes.

Thus, it would have seemed reasonable for NCCN to regard the guidelines as proprietary documents, shielding them from the prying eyes of competing institutions.

NCCN did exactly the opposite. It presented the documents at a
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In Brief

USC Norris Opens Topping Tower March 21; Postal Service To Sell Breast Cancer Stamps

UNIVERSITY OF SOUTHERN CALIFORNIA Norris Comprehensive Cancer Center plans the official opening of the Dr. Norman Topping Tower on March 21. Topping was president of USC from 1958 to 1970. A scientific symposium, "New Frontiers in Cancer Research," is scheduled for March 22-23. Guest speakers include **Leroy Hood**, Univ. of Washington; **Peter Vogt**, Scripps Clinic; **Mary-Claire King**, Univ. of Washington; **Robert Gallo**, Univ. of Maryland Biotechnology Institute; **Luca Gianni**, Instituto Nazionale Tumori, Milan, Italy; and **Stanley Hamilton**, Johns Hopkins Univ., as well as 26 USC faculty members. For information, contact 213/342-1088. . . . **BREAST CANCER AWARENESS** stamps will be issued by the U.S. Postal Service starting June 15 in conjunction with the National Race for the Cure. The 32-cent stamp pictures a stylized woman and a pink ribbon. NCI's Cancer Information Service number, 1-800-4-CANCER, will be printed on the top border of each sheet of 20 stamps. The Postal Service also developed a breast cancer awareness brochure that will be made available in post offices beginning May 10, two days before Mother's Day. . . . **ONCOLOGY NURSING SOCIETY** has established Oncology Education Services, a division that provides consultation services in the area of oncology education. OES services include educational products and program development, event planning, development and management, marketing and evaluation. For information, contact OES, tel: 412/921-1929. . . . **FIVE NATIONAL** Cancer Advisory Board members have

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Guidelines Are About Process, Not Documents, NCCN Says

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conference attended by over 500 physicians, nurses and administrators, most of whom are affiliated with institutions that do not belong to the network. The guidelines are expected to be published in the September issue of the journal *Oncology*.

Did NCCN give away the store?

Not really. Rather, the network offered a graphic demonstration of its definition of clinical guidelines: The guidelines are not a document. The guidelines are a process.

"What you see today is version 1.0," Joseph Simone, chairman of the board of NCCN and physician-in-chief at Memorial Sloan-Kettering Cancer Center, said at the opening of the conference March 3.

"These guidelines represent the collective wisdom of 13 institutions. However, it would be misleading to say that everyone will treat their patients exactly in this manner."

In a nutshell, the NCCN approach was to form guideline panels that charted areas of consensus and disagreement in the treatment of eight types of cancer. The guidelines are brief. Breast cancer guidelines, for instance, fit loosely onto 25 pages.

Certainly, 250 or even 2,500 pages could have been devoted to breast cancer. However, a long,

detailed guideline would be unusable, said Robert Young, vice chairman of the NCCN board, co-chairman of its outcomes committee, and president of Fox Chase Cancer Center.

"That's the beauty of this kind of guidelines," Young said to **The Cancer Letter**. "They don't require that you know how every single patient is treated."

The NCCN guidelines apply to standard, rather than innovative treatments.

"We assumed that investigational care will always take precedence over the guidelines," said Robert Carlson, chairman of the breast cancer guidelines panel and an oncologist at Stanford University.

With investigational care not addressed, the writing of guidelines does not have to grind to a halt over controversial modalities including high dose chemotherapy and bone marrow transplantation for breast cancer. Thus, after what some expected to be a stormy presentation of breast cancer guidelines, Carlson was able to say: "While our guidelines are going to require some modification, we didn't have people telling us that we are crazy."

Even in the initial version, the guidelines have the potential of improving the quality of care, said Rodger Winn, chairman of the NCCN Guidelines Steering Committee and chief of the section of community oncology at M.D. Anderson Cancer Center.

"The guidelines we are talking about tell us that there is [consensus] on how the majority of patients should be treated by the majority of practitioners," Winn said.

"There is always going to be variation in clinical practice that shows valid alternatives," Winn said at the conference. "But some variation leads to inappropriate interventions, and it's obviously what we want to attack with the guidelines."

The guidelines presented at the meeting covered cancers of the breast, colon, prostate, ovaries and lungs (both small-cell and non-small-cell), as well as acute leukemia and pediatric cancers. Altogether, these disease sites account for 51 percent of cancers.

Next, NCCN will take up the guidelines on melanoma, lymphomas, sarcomas, head-and-neck and CNS malignancies, and cancer of the bladder. Also planned is a guideline on antiemetics.

Clinical Trials Group Planned

In other developments at the meeting, NCCN



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officials announced plans to form a new, privately funded clinical trials group.

"Part of my job is to help our members leverage their strength, and one of the things that we believe we do well is clinical research," Bruce Ross, CEO of the network, said at the meeting.

"We have a serious interest in creating a clinical trials network within our membership and affiliated institutions, and we are in the midst of developing a business plan to create such a network," Ross said.

The group could be used for conducting drug company-sponsored clinical trials, Ross said.

"The guidelines presented at this meeting are a work in progress—they will be continually revised and updated, based on new findings," Ross said. "It's highly likely that data presented at [the annual meeting of the American Society for Clinical Oncology] just two months from now will result in substantial revisions."

Ross also announced that Roswell Park Cancer Institute has joined the network, bringing its membership to 14.

Other members are City of Hope National Medical Center, Dana-Farber Cancer Center, Fred Hutchinson Cancer Research Center, Fox Chase Cancer Center, Johns Hopkins Oncology Center, M.D. Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, Northwestern University/Lurie Cancer Center, Ohio State University Comprehensive Cancer Center, Stanford University Medical Center, St. Jude Children's Research Hospital, University of Michigan Comprehensive Cancer Center and University of Nebraska Medical Center.

Negotiations are underway with two other centers, sources said. The network's potential for expansion is, by design, limited. Members have to be located in areas not served by the network, and they have to accept the strategy adopted by other NCCN members.

"We have always talked, in general terms, about 15 to 20 institutions and their regional networks," Young said in an interview.

Current dues for NCCN institutions are \$132,000 a year.

Challenge: Pooling Data From 28 Data Systems

Observers and insiders agree that to succeed, NCCN will have to link the disparate information systems at its member institutions and form an

integrated system for measuring outcomes and monitoring adherence to the guidelines.

NCCN has carried out pilot studies in the treatment of cancer of the larynx at member institutions and a comprehensive survey of the institutions' mechanisms for measuring patient satisfaction.

Next, the group will start work on a multi-institutional outcomes database, a project that will begin by determining the patterns of care and outcomes for one or two diseases at three or four institutions.

In another project, NCCN plans to analyze the patterns of care and outcomes by using data submitted by its member institutions to the National Cancer Data Base administered by the American College of Surgeons.

The network's ultimate goal is to design a system for monitoring adherence to guidelines, conducting outcomes studies and costing out oncology carve-outs.

That promises to be a gargantuan task.

"Encouragingly, there is an enormous amount of data being collected for 13 institutions now," said Jane Weeks, assistant professor of medicine at Harvard Medical School and director of the Center for Outcomes and Policy Research.

Weeks said she and other members of the NCCN outcomes committee began their work by surveying the medical records systems, hospital information systems, clinical information systems, tumor registries, data warehouses and patient satisfaction surveys at the 13 institutions.

"It was very clear that data being collected by one person at a given institution was often unfamiliar to another person at that same institution," Weeks said.

"So the mere act of collecting the data and teaching each person the name of another person in their institution who also had good data was useful.

"There was an enormous heterogeneity in the systems used to collect data," Weeks said.

At the 13 centers, hospital information systems were based on 19 different vendor products. These were augmented by nine "home-grown" systems, Weeks said.

"This makes it hard to pool data, as you can imagine," Weeks said.

Patient satisfaction, too, was being measured in a variety of ways. "Four cancer centers are using

commercial firms—four different commercial firms, and nine are using internally developed surveys,” Weeks said.

“They are now submitting their data and their forms centrally, and we have an effort underway to generate some collective data out of that,” Weeks said.

Announcing Appropriate Standards

Clinical guidelines and the monitoring of outcomes has been on the minds of virtually everyone involved in medicine for quite some time.

Professional societies, hospital chains, insurers, and for-profit providers are capturing, linking and analyzing costs and outcomes data. Many of these players regard their guidelines as proprietary, shielding them from public view.

The American Cancer Society is working on guidelines on screening and prevention. The Association of Community Cancer Centers recently conducted a survey of “critical pathways” its member institutions use in the treatment of cancer.

The American Society for Clinical Oncology is compiling guidelines based on clinical issues and treatment modalities, including growth factors, genetic testing, tumor markers, follow-up diagnostic care for breast and colon cancer and the treatment of metastatic non-resectable lung cancer.

While the impact of these varied approaches remains to be seen, NCCN is likely to influence the standards of physicians and the expectations of patients nationwide.

“The underlying reason for the guidelines is to make a statement that there are certain acceptable standards for cancer care that cannot be compromised because of the payment system, and that the providers—rather than the purchasers—are the people who should come up with those standards,” said Catherine Harvey, chief operating officer of the network.

“Everything we did at the conference reflected the importance of clinical guidelines and the establishment of expert-based standards of care for assuring that the patients get the appropriate level of care,” Harvey said. “We thought the best way to do it is in a consensus-building manner in a public forum.”

John Kovach, executive vice president, medical and scientific affairs at City of Hope, said the establishment of standards could help the cancer centers win the support of an increasingly influential lobby: the patients.

“Patients are becoming increasingly frustrated by lack of access to even a second opinion, let alone primary treatment at centers of excellence in cancer care,” Kovach, president of the Association of American Cancer Institutes, said at the NCCN conference.

“Despite an abundance of data showing the critical role of optimal treatment of cancers as initial treatment, the public is not yet as aware as it should be of this phenomenon,” Kovach said.

“This will certainly change. Patients are insisting on access to providers who can be relied upon to provide appropriate care without compromise. Increasing pressure from consumers is inevitable.

“In anticipation of this pressure, health care systems responsible for cancer care should develop mechanisms to assure implementation of and adherence to appropriate clinical pathways as proof of delivery of quality care,” Kovach said.

Goal To Make “Version 1.0” Obsolete

The network may have a lot to gain and little to lose by releasing its guidelines, said Fox Chase president Young.

“There is certainly a strong feeling that we do not want for-profit corporations and large organizations to simply take all this work, change the headlines on it and say, These are our guidelines,” Young said to **The Cancer Letter**.

“Our intent is to constantly update these guidelines for participating institutions as new information develops. We have made a lot of disclaimers that if somebody sits around with version 1.0, and five years from now, or three years from now, they are still using 1.0, it’s no longer going to be the gold standard.

“The gold standard will change on a constant basis. And that’s where we think patients are best served in NCCN institutions and their network hospitals,” Young said.

Search For Operating Officer

NCCN announced a search for chief operating officer, a post vacated by Harvey, who is leaving the network to become vice president at Axion Health Care Inc., a disease management company based in South San Francisco.

For additional information, contact NCCN, 50 Huntingdon Pike, Suite 200, Rockledge, PA 19046. Tel.: 215/728-4788, Fax: 215/728-3877.

GM Corp. To Pay For Marrow Transplants For Breast Cancer

General Motors Corp. has agreed to use its corporate philanthropic funds to reimburse bone marrow transplantation and high dose chemotherapy for breast cancer, the company said.

In a two-year pilot program that does not alter the company's health care plan, patients enrolled in the GM's self-insured programs will be given the option of undergoing the investigational treatment.

The company would reimburse treatment for patients with primary and metastatic breast cancer who are eligible for studies using high dose chemotherapy supported by bone marrow or peripheral blood cell transplantation.

Altogether, about 1.3 million people are insured through the GM self-insured health care programs. According to the company, 60 to 200 women a year may become eligible for the treatment. The estimated 300,000 GM employees insured through HMOs will not be affected by the new policy, the company said.

"Often, the most appropriate treatment option for a cancer patient is this kind of clinical research study," said William Peters, director and CEO of the Karmanos Cancer Institute, who worked with GM to develop the program. "The medical community, GM, and, ultimately society, gain when technology is improved through this kind of medical research."

The research initiative is expected to last for two years.

Peters and his institute, an affiliate of the Detroit Medical Center and Wayne State University, have organized an advisory panel in bone marrow transplantation, and will be working with GM program carriers to identify appropriate institutions, and match candidates to facilities.

"It's appropriate to be funding this treatment through the research foundation," said Robert Carlson, associate professor of medicine, associate chief of the division of oncology at Stanford University, and chairman of the breast cancer guidelines committee of the National Comprehensive Cancer Network.

"It's an investigational treatment, so it's wonderful that GM is supporting clinical research," Carlson said.

The list of transplant centers chosen to take part in the program are University of Alabama Comprehensive Cancer Center, University of Arizona

Cancer Center, University of California at Los Angeles Jonsson Comprehensive Cancer Center, University of Colorado Cancer Center, University of Miami Sylvester Cancer Center, Loyola University Medical Center, University of Chicago Cancer Research Center, Johns Hopkins Oncology Center, Beth Israel Hospital in Boston and the Dana-Farber Cancer Institute, Barbara Ann Karmanos Cancer Institute, University of Michigan Comprehensive Cancer Center, Comprehensive Cancer Center of Wake Forest University, Duke University Cancer Center, University of North Carolina Lineberger Comprehensive Cancer Center, Ohio State University, Case Western Reserve University, Dartmouth University Norris Cotton Cancer Center, Columbia-Presbyterian Cancer Center, Memorial Sloan-Kettering Cancer Center, Roswell Park Cancer Institute, University of Pittsburgh Cancer Institute, San Antonio Cancer Institute, M. D. Anderson Cancer Center, Fred Hutchinson Cancer Research Center, and University of Wisconsin Comprehensive Cancer Center.

The advisory panel includes Peters, Frederick Appelbaum of Fred Hutchinson, Richard Champlin of M. D. Anderson, Emil Frei of Dana-Farber, Geoffrey Herzig of Roswell Park, David Hurd of Wake Forest, Laurence Norton of Memorial Sloan-Kettering and Samuel Silver of University of Michigan.

On Capitol Hill

NIH Says Earmarks Unwelcome Under "Steady State" Funding

In Senate hearings last week, NIH Director Harold Varmus urged Congress to impose no new mandates on the Institutes, allowing scientists to pursue the opportunities they consider most promising.

Testifying at a two-day hearing of the Senate Committee on Labor and Human Resources, Varmus said the growth of funding for biomedical research has reached a "steady state," and with appropriations flat, NIH should be given flexibility to set its research priorities.

"Growth cannot go on forever," Varmus said in testimony March 6. "I would prefer if the steady state were achieved at some higher level. But it's quite clear that we have approached that level now. We have been in steady state for five to eight years, and if this

is the steady state, then we should be preparing to adjust to it.

"Priority setting is best done in atmosphere in which scientists manage scientific programs are given maximum flexibility choose those that show the greatest interest and have the greatest importance.

"We are asking for as few earmarks as possible to allow us to make decisions about the scientific priorities," Varmus said. "We appreciate the language that urges us to consider certain problems. The difficulty arises when we are given extremely specific mandates."

The Message Is Unity

Throughout the hearing, Varmus sat at the witness table as institute directors and other senior officials presented testimony to the committee.

The format of the testimony conveyed the message of unity, as even NCI, the largest institute at NIH, did not submit separate testimony.

Instead, NCI Director Richard Klausner appeared on a panel with Francis Collins, director of the National Center for Human Genome Research, and Kenneth Olden, director of the National Institute of Environmental Health Sciences.

The testimony submitted by the three officials was organized around the same theme of new insights into cancer and other diseases, and was not differentiated by institute.

"Just as people will be able to read the entire human genome, our goal must be to read the individual cancer, a fingerprint that will tell us how quickly it will grow, whether it will respond to therapy, whether it will spread, whether it needs to be treated," Klausner said. "This is already happening in many of our clinical trials."

Detailed authorization proposals for NIH are expected to be sent to the committee by HHS Secretary Donna Shalala, Varmus said. Authorization for the Institutes is renewed every four years.

ACS Supports Provisions Of Kassebaum FDA Bill

In a statement last week, the American Cancer Society said legislative action "might be required" to bring about change at FDA.

Last month, representatives of other cancer advocacy groups challenged ACS to clarify its stance on FDA reform, citing the society's membership in a

patient coalition that argued against legislatively mandated changes at the agency.

In a statement submitted to the Senate Labor and Human Resources Committee, ACS said the goals of the goals of the Patients' Coalition were consistent with the society's policies.

"The Patients' Coalition has a broad-based set of principles which identify issues of concern to patients and offer a starting point for effecting desired changes without undermining the ability of the FDA to achieve its critical mission of protecting and promoting the public health," ACS said in a statement dated March 4. .

"The ACS has also worked with other cancer organizations, such as the American Society of Clinical Oncology and the National Coalition for Cancer Survivorship in identifying concerns specific to cancer patients," the statement read.

In recent testimony, Ellen Stovall, criticized the Patients' Coalition for its opposition to FDA reform (**The Cancer Letter**, March 1). NCCS and ASCO have been among strong proponents of several provisions of the FDA reform bill introduced by Sen. Nancy Kassebaum (R-KN).

"ACS believes FDA needs to continue the reforms that have already begun to speed the approval of safe and effective drugs for cancer patients," ACS said in a statement. "Continued agency action or legislative language might be required to address the concerns of the American Cancer Society."

In the statement, ACS said it supported the provision that would allow drug companies to disseminate information on off-label use of cancer drugs. Also, the society called for a more rapid approval of Supplemental New Drug Indications.

Committee markup of the Kassebaum bill was expected to begin later this week.

In Brief

Five On NCAB Finish Terms

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completed their six-year terms on the board: **Frederick Becker**, M.D. Anderson Cancer Center; **Kenneth Chan**, Ohio State University; **Marlene Malek**, Vincent Lombardi Cancer Center; **Deborah Mayer**, oncology clinical nurse specialist, Portland, OR; and **Sydney Salmon**, Arizona Cancer Center. . . **DAVID BACHRACH**, executive vice president for administration and finance and professor of health systems management at M.D. Anderson Cancer

Center, has been advanced to Fellow status in the American College of Healthcare Executives. Fellow status is the highest level of professional achievement in the college. Bachrach, a member of the center's staff since 1989, is responsible for administrative and financial functions. . . . **CORRECTION: William Benedict** was appointed professor of medicine in the Department of Hematology, University of Texas M.D. Anderson Cancer Center, not associate professor, as reported in the Nov. 17, 1995, issue of **The Cancer Letter**. Benedict was professor of biotechnology in the Center for Biotechnology at Baylor College of Medicine.

NIH Clinical Center Needs Own Budget, Report Says

The NIH Clinical Center should have its own budget and a centralized management structure headed by a board that would include experts from outside the federal government, a report concludes.

The report, by a panel appointed by HHS Secretary Donna Shalala, argues that the Clinical Center should not be privatized, as suggested last year by Vice President Albert Gore's Reinventing Government II initiative (**The Cancer Letter**, May 19, 1995).

Instead, the NIH Clinical Center Options Team said, the center should seek the status of a federal "reinvention laboratory," which would exempt it from certain procurement and personnel regulations and increase its flexibility.

"The center must be nimble enough to respond rapidly to new initiatives, cost-effective enough to undertake these changes with fewer resources than it has today, and innovative enough to serve as a national core of clinical research in the information age," the Options Team report said. "To achieve these goals, the Clinical Center must change the way it is governed, funded and managed."

Helen Smits, deputy administrator of the Health Care Financing Administration, was chairman of the Options Team.

"This is a rather remarkable document for us, because it provides a roadmap to get us into the next century," said John Gallin, director of the Clinical Center. "It represents major change for the Clinical Center."

Shalala has approved in concept the report's recommendations, Gallin said to **The Cancer Letter**.

The center is working with the Office of Management and Budget on implementing the report's fiscal recommendations, he said.

"We are going to get stable, independent funding for the Clinical Center, which we are hoping will start in FY97," Gallin said. "This will enable the re-engineering and the change of governance."

Governance of the center "always has been a bit awkward," with 15 of 23 institutes using the center, Gallin said. In accordance with the report's recommendations, the center will create a board of governors that will include experts in hospital management, he said.

The fiscal and governance changes are important for the center as it plans a new hospital building, Gallin said.

Earlier this year, an Oregon architectural firm, Zimmer, Gunsul and Frasca Partnership, won the design competition for the new building. The project is expected to cost about \$380 million, and if Congress approves the funding, construction could begin in three years.

The report, "Opportunity: Revitalizing the NIH Clinical Center for Tomorrow's Challenges," made the following major recommendations:

—A clear and logical governance structure should be developed for the Clinical Center that draws on the expertise of leaders of outside organizations and reflects the interests of the Institutes, which are the clients of the Center. A Board of Governors should be created to oversee the Clinical Center. The Board's responsibilities should include annual budgeting and strategic planning as well as oversight of operations. The majority of this Board and the chair should be individuals from outside government; the remainder of the Board should be representatives of NIH Institutes. Appointments to the Board should be made by the Director of NIH upon the recommendation of Institute directors and the Director of the Clinical Center.

—The Clinical Center should have a clearly defined budget of its own. The budget should be as stable as the NIH budget as a whole.

—The Clinical Center should have a means of retaining reserves from year to year. The Center should also be permitted to charge insurance companies for some services and to solicit donations. The new budgeting process should include methods to (1) ensure that all Institutes have continued access to a baseline level of activity at the Center, (2) permit

Institutes that improve the efficiency of their protocols to increase their overall activity, and (3) permit outside investigators to use the Clinical Center.

—As one of its first official actions, the new governing Board of the Clinical Center should direct development of a strategic plan with clear and measurable objectives. The plan should serve as the keystone by which managers can allocate and distribute resources. Clinical Center management should immediately begin to develop the background information upon which such a plan can be based.

—The Clinical Center should have more flexibility to improve its efficiency and effectiveness, particularly with regard to the procurement of goods and services, management of personnel, and use of operating savings. The Options Team evaluated several structural approaches as the means for obtaining such flexibility, including continuing to operate the Clinical Center as a federal organization, converting it to one of several types of federally sponsored organizational arrangements, and managing the Center by contract. The Options Team and external consultants recommend that the Clinical Center be designated a "Reinvention Laboratory," a federal demonstration site in which reduced regulation, enhanced local autonomy, and improved federal personnel and procurement practices are combined.

The Options Team also recommends that the Center do the following:

—Actively seek funding for a new Center facility that will be more efficient to run and maintain and that will permit more efficient use of staff.

—Explore increased contracting out of individual Clinical Center functions.

—Invest in integrated information systems that provide real-time information for managers about costs and human resources.

—Adopt an ongoing program of benchmarking, integrated with the strategic plan adopted by the new Board of Governors.

—Establish new methods for recruiting patients to protocols.

RFAs Available

RFA TW-96-002

Title: **Minority International Research Training Grants**

Application Receipt Date: May 7

The Fogarty International Center and the Office of Research on Minority Health will support the development of training programs that offer international research

training opportunities to qualified minorities (undergraduates, graduate students and faculty members) underrepresented in biomedical and behavioral research careers.

Funds will be awarded to support innovative approaches to research training with a focus on: 1) encouraging minority students to pursue post-baccalaureate degrees and consider research careers in the biomedical or behavioral sciences; 2) broadening minority student research training to include international issues and concerns; and 3) assisting the next generation of scientists to work effectively in the global environment by establishing international linkages on several levels—linkages between U.S. students and foreign scientists at centers of biomedical and behavioral research, between U.S. minority scientists and foreign scientists abroad, and between minority and minority-serving institutions and research institutions abroad.

Inquiries: Jean Flagg-Newton, Division of International Training and Research, Fogarty International Center, Building 31, Room B2C39-MSC 2220, Bethesda, MD 20892-2220, tel: 301/496-1653, fax: 301/402-0779, e-mail: flaggnej@ficod.fic.nih.gov

RFA ES-96-006

Title: **The Use Of Transgenic Model Systems In Molecular Toxicology**

Letter of Intent Receipt Date: May 10

Application Receipt Date: June 10

A major goal of the National Institute of Environmental Health Sciences is to foster research that will increase the knowledge of the diverse health effects of exposure to environmental agents. It is likely that many common diseases, including cancer, lung disease, neurodegenerative diseases, cardiovascular diseases, and developmental abnormalities or dysfunctions, have an environmental component. There is critical need for a thorough understanding of the action of environmental agents on human health at the genome level.

The objective of this RFA is to encourage innovative, mechanistically based research using transgenic technologies to investigate the alterations of gene expression induced by environmental agents in specific target cells and organs, and to determine how this response varies at critical times during exposure. The funds available for the first year of support for the entire program is \$1.5 million. The expected number of awards is six to eight research project (R01) grants.

Inquiries: Jose Velazquez, Chemical Exposures and Molecular Biology Branch, National Institute of Environmental Health Sciences, PO Box 12233, 104 Alexander Drive, MD 3-04, Research Triangle Park, NC 27709, tel: 919/541-4500, fax: 919/541-2843, e-mail: velazqu1@niehs.nih.gov