THE CANCER LETTER

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FDA To Reorganize Oncology Office Into Four Divisions By Disease Type

By Paul Goldberg

FDA is in the process of reorganizing its oncology unit to integrate the review of small molecule and biologic products.

Abandoning its current structure, which evaluates cancer drugs separately from biologics, the office will now be broken up into four divisions focused on specific malignancies. Changes will include the renaming the office from the Office of Oncology Drug Products to the Office of Hematology and Oncology Products.

The reorganization, which will take effect in 2011, will create a structure of four divisions: the Division of Hematology Products, the Division

(Continued to page 2)

In the Cancer Centers:

Lawrence Corey Named President, Director Of Hutchinson Center, Succeeding Hartwell

FRED HUTCHINSON CANCER RESEARCH CENTER board of trustees announced the selection of **Lawrence Corey**, an expert in virology, immunology and vaccine development, as its new president and director, effective Jan. 1.

The board selected Corey for his leadership and expertise on a number of fronts, including scientific accomplishments and vision, management record, ability to foster partnerships and leadership style. As a scientist he is known internationally for his research in infectious disease-related cancers, HIV infection and medical complications of patients with compromised immune systems.

"The Hutchinson Center is a premier research institution and we needed someone with outstanding scientific and leadership credentials to take on this role. I am extremely pleased that Larry has decided to lend his vision and talent to advance the Center to the next level; he's an outstanding leader and can really represent the Center on a world stage," said Doug Walker, chairman of the Hutchinson Center's board.

Corey's research focuses on novel therapies and vaccines for human viral infections, in particular herpes viruses, HIV and infections related to cancer. He is also interested in expanding the center's research in understanding the role cancer plays in global health.

Under his leadership, and with partial funding from the U.S. Agency

(Continued to page 7)

FDA News:
Oncology Review Staff Will Specialize In Specific Diseases
. . . Page 2

NCI Programs:
Advisors Approve Research Network On Screening
. . . Page 4

Letter to the Editors:
Society of Toxicology On President's Cancer Panel Report
. . . Page 7

NCI Personnel:
Eric Hale Named Acting Director, NCI Ethics Office
. . . Page 9

To Our Subscribers:
No Issues For Next Three Weeks, Barring Important News Events
. . . Page 9

Review Staff Will Specialize In Specific Oncologic Diseases

(Continued from page 1)

of Hematology Oncology Toxicology, and two separate divisions of oncology products.

FDA officials said the review staff within the two divisions of oncology products will specialize in specific oncologic diseases, such as breast cancer, gastrointestinal cancer, and melanoma. This focus on specific diseases is similar to that of leading cancer centers, academic programs, and NCI.

There will be a distinct division, DHOT, dedicated to reviewing the non-clinical pharmacology and toxicology of oncology products. This change recognizes the increased importance of these disciplines as the science of oncology drug development becomes more complex, officials aid.

The Cancer Letter asked Richard Pazdur, director of the Office of Oncology Drug Products, to address several questions about the reorganization.

TCL: What is the proposed structure?

RP: FDA's Center for Drug Evaluation and Research's Office of Oncology Drug Products (OODP) will be reorganized and renamed the Office of Hematology and Oncology Products (OHOP). Expected to take effect in the first Quarter of 2011, the new office will expand from three to four divisions, with a focus on disease-specific hematologic and oncologic conditions.

OODP's current structure contains three divisions: Division of Hematology Products (DHP), Division of Drug Oncology Products (DDOP), Division of Biologic Oncology Products (DBOP)OHOP's new structure will contain four Divisions: Division of Hematology Products (DHP), Division of Oncology Products 1 (DOP 1), Division of Oncology Products 2 (DOP 2), and the Division of Hematology Oncology Toxicology (DHOT).

In addition, the Immediate Office of OODP contains the Oncology Program, which coordinates the oncology activities within the FDA and with external stakeholders.

Under OHOP's new structure, the Oncology Program will remain in the Immediate Office.

TCL: How will the workload be re-structured?

RP: Currently, OODP's two Divisions (DDOP and DBOP) that are responsible for reviewing oncology products for FDA approval divide their review responsibilities according to whether a product is a drug or a biologic. Drug products are approved under New Drug Applications and biologic products are approved under Biologics License Applications.

After the reorganization, OHOP's two review divisions for oncology products (DOP 1 and DOP 2) will divide their review responsibilities according to the specific cancers the products are intended to treat, regardless of whether a product is a drug or biologic. This will effectively integrate review of NDAs and BLAs across the office's review divisions.

The reorganization in OHOP is a continuation of the OND reorganization of 2005 in that the review of biologics and drugs will be integrated into each Oncology division. This has been successfully accomplished in the other Offices in CDER.

The disease-specific assignments for the two divisions have not been made yet; however, the categories will include breast cancer; gastrointestinal cancers; lung, head and neck cancers; neuro-oncology; melanoma and sarcoma; pediatric solid tumors; and supportive care products (other than hematologic growth factors).

The new Division of Hematology Oncology Toxicology will be dedicated to reviewing the non-clinical pharmacology and toxicology of oncology products. This change recognizes the increased importance of these disciplines as the science of oncology drug development becomes more complex.

The Division of Hematology Products will continue to review all hematology drugs, including those for benign and malignant hematological disorders. It will

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also continue to review all hematologic growth factors and products for pediatric hematologic malignancies.

TCL: What is the rationale for the re-structuring?

RP: Short answer--Consistency. Efficiency. Career Development. Integration of drugs and biologics. Equal workload.

As the practice of oncology and the treatments available to treat cancer become more complex, FDA recognizes the importance of organizing its oncologic product approval approach around the specific disease conditions, as opposed to the product's chemical composition. Treatments for oncologic diseases have become more complex and it's increasingly important for a reviewer to have strong expertise in the specific condition the drug is intended to treat.

Disease-specific orientation of the review staff will also lead to greater consistency in regulatory advice and decisions. It will enable greater efficiency in product review, since the same staff will be reviewing all applications for the same disease categories.

Reorganization based on disease-specific expertise also aligns FDA oncology review with the organizational structure of leading cancer centers, academic programs, and the National Cancer Institute. I believe this restructuring will also provide our review staff with opportunities to develop their careers and we will be emphasizing their participation in external stakeholders, including the NCI, professional groups, patient groups, and cooperative groups.

Although there was discussion in the re-organization plans to focus on molecular targets, we felt it was premature to base a reorganization on evolving molecular targets. Drugs that are currently being developed need to evaluated in the context of existing treatments for specific diseases. We would be interested in evaluating this structure as the scientific understanding of malignant diseases progresses.

We also had an uneven workload distribution. DODP had a far greater workload than the other components of the Office. With the re-structuring we will attempt to equalize the workload.

TCL: Will the management change?

RP: The division directors in the clinical divisions will not change. Dr. Ann Farrell will remain as acting division director for DHP. Drs. Bob Justice and Pat Keegan will remain division directors; however, the decision has not yet been made as to which division either will head. Dr. John Leighton will be acting director of the new Division of Hematology Oncology Toxicology. I will remain the Office Director.

The size of the divisions will largely depend on the number of applications in a disease-group. OODP will then allocate solid tumor disease groups to DOP 1 or DOP 2 in a manner that will balance the size of each division. Staff will be allocated to each division based on disease interest and regulatory experience in dealing with biologics or small molecules. In addition, we will assign pediatric oncologist to all three of the clinical review divisions.

TCL: How will the change affect operations?

RP: A plan to handle Investigational New Drug applications, New Drug Applications, and Biologic License Applications within the Oncology divisions is being developed.

Since the Oncology divisions will be structured in disease-specific groups, instead of by biologic or drug application, IND applications will be identified by indication and will be assigned to the division which houses the disease-specific group. A plan to handle existing INDs with multiple indications will be provided at a later date.

After the restructuring of the Oncology divisions, INDs at the phase 2 stage should not contain multiple indications. A separate IND should be submitted if a new indication is being studied. Additional information regarding this will follow.

Existing NDAs and BLAs will be assigned to the oncology division that houses the disease-specific group for the first approved indication.

Consistent with Agency practice, new NDAs and BLAs with multiple indications (e.g., review across two divisions or offices) may be administratively split so that separate regulatory action for the different indications may be taken if necessary.

TCL: What's the rationale for the new toxicology division?

RP: The Division of Toxicology will focus on implementation of the ICH S9 guidance and developing consensus on new scientific and technical issues, particularly as the practice of oncology moves to more targeted therapeutics.

The organization of toxicology into its own division is unique in the Agency and is something that I strongly support. Currently, the pharm/tox reviewers are under the clinical division and with the new structure the leadership will be discipline-specific. I believe this new structure will provide greater consistency and enhanced career development of our nonclinical review staff.

TCL: If drugs shift from division to division, depending on indication, will there be a loss of intimate knowledge of the specific drug? Will there

be a learning curve for reviewers that will suddenly deal with small molecule or biologic reviews?

RP: Any type of loss of knowledge of a specific product would be offset by the expert knowledge of the disease as well as knowledge gained by understanding all products used for a given disease. Initially, there may be a learning curve for an individual reviewer when dealing with regulations governing BLAs and NDAs; however, OHOP plans to integrate the divisions by disease group interest (for medical officers), years of experience, and knowledge of NDAs and BLAs.

In a given review division, those experienced with BLAs and NDAs should be similar so knowledge of BLA and NDA regulations should be balanced--as a team, the learning curve should be diminished. Indication or disease-group specific teams are a model that is used within all OND review divisions and OHOP is carrying this model into Oncology. The integration of reviewing BLAs and NDAs within a review division has been successfully demonstrated in other OND offices with the OND reorganization in 2005.

NCI Programs:

Advisors Approve Network For Screening Research

By Kirsten Boyd Goldberg

NCI advisors have approved the institute's plan to use $15 million a year for five years to fund a network of up to 15 research centers to study optimal cancer screening processes and outcomes.

The new network builds on NCI's experience with the Breast Cancer Surveillance Consortium, a project that contributed data to two Institute of Medicine reports.

The NCI Board of Scientific Advisors also approved in concept the following grants programs:

• Advanced In Vivo Imaging to Understand Cancer Systems

• Comprehensive Partnership to Reduce Cancer Health Disparities

• NCI Tumor Microenvironment Network

• SBIR Phase II Bridge Awards to Accelerate the Development of Cancer Therapeutics, Imaging Technologies, Interventional Devices, Diagnostics, and Prognostics Toward Commercialization

Excerpted text from the concept statements follow:

Population-based Research Optimizing Screening Through Personalized Regimens. Concept for a new RFA cooperative agreement, first year set aside $15 million, total $75 million over five years; up to 15 research centers and one statistical coordinating center. Program director: Stephen Taplin, Division of Cancer Control and Population Sciences.

PROSPR's overall scientific goal is to develop multi-site, coordinated, transdisciplinary research to document the entire screening process to evaluate and improve it. The objectives are:

• Study the comparative effectiveness of existing and emerging screening processes in community practice.

• Study the balance of benefits and harms across recognized cancer risk profiles.

• Conduct preliminary studies to inform future research to optimize screening processes and outcomes.

• Actively share data and findings with potential collaborators through publications, web portals, and interaction with a consulting panel in order to foster related research.

PROSPR builds on experience from the Breast Cancer Surveillance Consortium, in which five clinical networks comprising more than 60 radiology facilities and 100 radiologists collect mammography data on women in the course of their usual care. Since 1994, the BCSC has fostered research leading to 374 publications and affected mammography practice throughout the U.S. However, its work emphasizes the evaluation of only the mammography test. There is now a need to expand the scientific focus served by the BCSC beyond one test and one cancer. Such an expanded focus, encompassed by PROSPR, would evaluate the process for all currently recommended screening modalities for cervical (Pap), breast (mammogram), and colorectal cancer (fecal occult blood test, sigmoidoscopy, colonoscopy). It also would allow comparisons of current screening modalities with emerging technologies (e.g., human papillomavirus, digital mammography, fecal immunochemical testing, fedal DNA testing, computerized tomographic colonography). Using standards of NCI's Cancer Biomedical Informatics Grid, PROSPR data would be readily available to the investigators and the wider scientific community.

PROSPR will establish networks of existing clinical practices that provide cancer screening and follow-up evaluation and use them to collect longitudinal data on the screened population and screening process. These data will be linked to cancer occurrence through

existing cancer registries. Mutlidisciplinary teams of investigators with specific expertise in areas relevant to screening evaluation (e.g., epidemiology, decision analysis, imaging, mathematical modeling, behavioral science) will consider factors influencing the screening process. The emaphsis will be on evaluating the screening process in the average risk population, but an investigator group could choose particular subpopulations of interest, such as those served by Federally Qualified Health Centers or who are long term survivors of another cancer. The findings from this research will be used to consider ways of optimizing the screening process. Optimal screening would identify the most cancers using the least resources (time, testing) while minimizing morbidity (anxiety, false positive tests, unnecessary biopsies and treatment).

To optimize screening, proposals could include research to: 1) address deficiencies by proposing to assess the implementation of new screening tests or evaluative techniques, 2) develop and evaluate the consequences of personalized risk-based regimens by reducing screening frequency to lessen the chance of adverse consequences, and 3) address human factors in the screening process by testing systems that would help providers coordinate follow-up of all abnormal tests. New information from this research would inform the decisions of many cancer screening stakeholders, including patients making personal decisions about screening, providers offering screening tests, policy makers decision about screening recommendations, and investigators who develop subsequent intervention trials.

NCI is proposing that three to five teams of investigators per cancer type to develop registries for data collected in the course of care. The clinical network, registry, and investigators together comprise a research center. The teams would begin by developing, in conjunction with caBIG, the common data elements and data collection procedures for patient and test data.

The initiative includes a single statistical coordinating center with subgroups of personnel responsible for te pooled cervical, breast, and colorectal cancer data. Centers could report on one or ore cancers, but an SCC would pool their cancer-specific data with other data from other centers focused on the same cancer. The pooling of data within the SCC would allow adequate power for analyses of risk and rare outcomes and for comparisons across geographic sites. The SCC would maintain separate pooled data sets for each cancer. Those data sets would be built from common data elements submitted by each research center. The screening process data unique to a research center would remain at that research center.

PROSPR will include a consulting panel of experts from disease-specific clinical care, screening practice, imaging, and simulation modeling, biologic specimen collection, and representatives from relevant screening research efforts.

Selection criteria for the centers would include the quality of the investigators, the science proposed, and the viability of the proposed clinical network. Responsive projects could include evaluations such as, but not limited to, the following:

• The current effectiveness and cost-effectiveness of digital mammography and follow-up by different age, ethnic, and risk groups.

• The comparative effectiveness of diagnostic and treatment modalities for cervical abnormalities.

• The comparative effectiveness of CT colonography versus optical colonoscopy including the follow-up of extra-colonic lesions.

• The comparative effectiveness of screen-film versus digital versus magnetic resonance imaging mammography and follow-up.

• The comparative effectiveness of alternative methods of presenting to patients the relative merits and risks of screening in genral and its specific advantages and disadvantages.

• Comparison of the entire screening process among subpopulations differentially impacted by health care reform.

• Behavioral and/or health care organizational influences on screening and follow-up rates and comparative influence of each factor on the various steps in the screening process.

Advanced In Vivo Imaging to Understand Cancer Systems. Concept for a new RFA cooperative agreement, first year set aside $5 million, total $25 million over five years, four to six awards. Program director: Anne Menkens, Division of Cancer Treatment and Diagnosis.

Advances in the development and application of in vivo cancer imaging tools demonstrate the power of these agents and technologies in the analysis of changes in tumor initiation, progression and response to therapy. However, to fully understand the cancer cell and its complex tumor environment, in vivo imaging data must be acquired, processed and integrated with state of the art biological and "-omic" information. Such integrated approaches will require sophisticated systems, computational and modeling advances. These

integrated approaches will provide an unprecedented understanding of the cancer cell and its enviorment at increasingly high temporal and spatial resolution. To realize the full potential of integrating data from these disparate sources, additional research is needed. Through a virtual workshop, extramural experts identified four interdisciplinary research areas that require additional focus in order to advance the field. Those research areas are:

1. Technologies and methods to advance high resolution intravital, in vivo microscopic imaging.

2. Development and validation of cancer-specific in vivo probe and reporter systems.

3. Integration of micro- and macroscopic data.

4. Development of new approaches of modeling, integrating, and visualizing multiscale imaging data.

NCI proposes to leverage and expand programs currently in place including: In Vivo Cellular and Molecular Imaging Centers, Integrative Cancer Biology Program, Tumor Microenvironment Network, Mouse Models of Human Cancer Consortium, and Centers of Cancer Nanotechnology Excellence.

The purpose of this concept is to provide an opportunity for new collaborative projects among cancer complexity researchers, cancer imagers, and experts in cutting edge applications such as nanotechnology that address the four major areas of research identified through the virtual workshop.

This RFA will use the model of collaborative U01s that are currently in use by the Division of Cancer Biology to fund synergistic linkages between ongoing funded programs. The new initiative will solicit U01 type research projects linked to the goals and expertise of these programs. Each U01 team will be required to have a PI who is formally identified as a key personnel of an ICMIC and a PI identified as key personnel of either an ICBP U54 Center, TMEN U54 or MMHCC project. They will also have the option of bringing in additional expertise outside of these major programs as necessary. It is envisioned that the expertise and technologies available through the funded CCNEs will be integral components of these collaborative efforts.

NCI anticipates that each collaborative U01 will range from $500,000 direct/$750,000 total (including consortium/contractual costs to $850,000 direct/$1.25 million total per year.

Comprehensive Partnerships to Reduce Cancer Health Disparities. Reissued RFA cooperative agreement, first year set aside $6.25 million, total $31.25 million over five years, for four to five awards. NCI Center to Reduce Cancer Health Disparities.

The purpose of the U54 Partnership is to foster and support intensive and mutually beneficial collaborations among the Minority-Serving Institutions and NCI-designated cancer centers for the development of strong national cancer programs. These cancer programs are aimed at understanding reasons behind the significant cancer disparities and related impacts on racial and ethnic minority and socioeconomically disadvantaged populations. The U54 focuses on four target areas: research, training, outreach, and education. Each U54 Partnership must address the first three target areas; cancer education is required for those training programs where curriculum development is part of the training activity. Other activities related to cancer education are optional.

The U54 enables MSIs and cancer centers to create stable, comprehensive, long term partnerships. Through these collaborations, MSIs and centers work together to develop research projects, train scientists in cancer research and effectively deliver cancer advances to underserved communities aiming to reduce cancer health disparities.

Since 2001, 90 (45 partnerships) applications have competed and 38 (19 partnerships) have been awarded. By the end of FY2009, the partnerships have generated 453 peer reviewed publications, and facilitated the training and education of 393 students and trainees.

The requested budget for FY2011 of $6.25 million would fund two partnerships (four to five grants).

Tumor Microenvironment Network. Concept for a reissued RFA, first year set aside $9 million, total $45.2 million over five years for nine awards. Program director: Suresh Mohla, Division of Cancer Biology.

This concept builds on the success of the current TMEN initiative by proposing to continue to foster research through resource and infrastructure development and through outreach. The concept proposes to pursue new scientific themes that have emerged from the current TMEN efforts. These include: the function and heterogeneity of bone marrow derived and myeloid derived suppressor cells; characterization of the premetastatic and stem cell niches; characterization of tumor dormancy; the emerging role of microbiome and viruses in cancer initiation and/or progression; metabolic dysregulation contributed by tumor and host cells; the roles of neurogenesis and axonogenesis in cancer progression; and cell fusion between tumor and host cells, and the role of tumor stroma in conferring therapeutic resistance.

The proposed RFA will use the U54 mechanism to fund individual multidisciplinary research programs, and collectively the programs will constitute the consortium. While each funded program will be largely self-sufficient, investigators will be expected to devote a portion of their efforts to participating in collaborative effort with other consortium members to improve existing technologies, develop novel reagents, and disseminate information.

SBIR Phase II Bridge Awards to Accelerate the Development of Cancer Therapeutics, Imaging Technologies, Interventional Devices, Diagnostics, and Prognostics Toward Commercialization. Concept for an RFA reissue, first year set aside $10 million, total $30 million over three years for five to 10 awards. Program director: Andrew Kurtz, NCI SBIR Development Center.

NCI proposes the reissuance of this RFA for the third consecutive year. The goal of this award is to bridge the funding gap, known as the "valley of death," that often exists between the end of the SBIR Phase II award and the next round of financing needed by a small business to advance a promising cancer technology toward commercialization. This RFA is designed to incentivize partnerships between SBIR Phase II awardees and third party investors or strategic partners.

The proposed FY2011 reissuance would retain the same technical scope as in FY10 and will again encourage the development of technologies that require preclinical and clinical evaluation and ultimate approval by an appropriate federal regulatory agency.

In the Cancer Centers:

Corey Named Director Of Hutchinson Center

(Continued from page 1)

for International Development, the center last year established the first American cancer clinic and medical training facility in Africa, a joint effort between the Hutchinson Center and the Uganda Cancer Institute for the study and treatment of cancer, including the childhood cancer Burkitt's lymphoma, a viral disease-related malignancy.

Corey also is principal investigator of the Hutchinson Center-based HIV Vaccine Trials Network, an international collaboration of scientists and institutions that combines clinical trials and laboratory-based research to accelerate the development of HIV vaccines. Under Corey's leadership, the network has evolved from nine U.S. research sites to 26 outposts in nine countries on four continents.

Corey also serves as an infectious disease physician at the Seattle Cancer Care Alliance.

Corey's selection caps a year-long search to fill the position of center leader and Nobel laureate **Lee Hartwell,** who will retire this fall after 13 years at the helm of the Hutchinson Center. Hartwell will continue to be involved with the center as director emeritus.

Corey will become the fourth president and director in the center's 35-year history. In addition to Hartwell, he is preceded by **Robert Day**, who led the center from 1981 to 1997; and center founder **Bill Hutchinson**, who served in that capacity from 1972 to 1981.

YALE CANCER CENTER and Smilow Cancer Hospital at Yale-New Haven appointed **Anees Chagpar** to the position of director of the Yale Breast Center at Smilow Cancer Hospital. Effective Sept. 1, Chagpar will also have an appointment in the section of surgical oncology in the Yale School of Medicine Department of Surgery. Chagpar joins Yale Cancer Center and Smilow Cancer Hospital from the University of Louisville School of Medicine, where she served as an associate professor in the Department of Surgery at the University of Louisville and director of the Multidisciplinary Breast Program at James Graham Brown Cancer Center

WINTHROP P. ROCKEFELLER CANCER INSTITUTE and the University of Arkansas for Medical Sciences dedicated its 12-story expansion. The 300,000-square-foot building will double the institute's capacity for research, treatment and outreach.

Participating in the dedication ceremony were former U.S. Sen. **David Pryor**; Gov. **Mike Beebe**; UAMS Chancellor **Dan Rahn**; and **Peter Emanuel**, WRCI director.

The cost of the addition is $130 million, funded in part by $36 million in state general improvement funds that provided a dollar-for-dollar match of private donations. Beebe granted UAMS an additional $1.5 million from general improvement funds that had to be matched by private donations.

Another $12.3 million was donated by the Winthrop Rockefeller Foundation to honor the late Lt. Gov. Winthrop P. Rockefeller, who died in 2006 at age 57 from myeloproliferative disease. The foundation's gift was made to help fund the expansion and also to fund two endowed chairs in the lymphoma and leukemia program. Rockefeller was the son of former Arkansas

Gov. Winthrop Rockefeller. Other funding for the project includes $35 million from bonds paid for with the state's settlement with the tobacco industry.

Another two research floors are planned for completion in 2011, funded by a nearly $10.5 million NIH grant trhough the American Recovery and Reinvestment Act of 2009 stimulus monies allocated to the NIH for construction grants.

Reports:

Decrease In Cancer Incidence Not Reflected In All Groups

Fewer San Francisco Bay Area residents are being diagnosed with cancer and fewer of them are dying from it, according to the most recent data from the Cancer Prevention Institute of California, which runs the cancer registry charged with tracking cancer in the region.

New diagnoses of cancer in the Bay Area dropped by about 11 percent for men and 10 percent for women between 1988 and 2007. A closer examination of the data, however, reveals that the decrease does not apply equally to all demographic groups.

African American women did not experience declines in incidence rates of smoking-related cancers, lung cancer incidence or death, colorectal cancer incidence, or pancreatic cancer death. Hispanic men did not experience declines in their incidence rates of pancreatic cancer or non-Hodgkin lymphoma or in their death rates from colorectal cancer or liver cancer. Hispanic women did not show declines in their incidence rates of pancreatic or liver cancers. While death rates from lung cancer declined in some groups, these rates did not change for Hispanic women.

"Our data point to the need to target particular communities with prevention messages, as at least half of cancer can be prevented by changing health behaviors like quitting smoking and increasing physical activity," said Scarlett Gomez, CPIC research scientist and cancer registry associate director.

The CPIC's 2010 report, "The State of Cancer in the Greater Bay Area," is available at www.cpic.org/2010ReportGBA.

Letter to the Editors:

Society Of Toxicology Comments On Panel Report

To the Editors:

In April of this year, the President's Cancer Panel released its 2008–09 report titled "Reducing Environmental Cancer Risk: What We Can Do Now." This report discusses many important issues but none as important as the extent of the problem: "Over 1.5 million American men, women, and children were diagnosed with cancer in 2009 and over 562,000 have died." The report then goes on to say that there are many unknowns about what percentage of these cancers are associated with environmental factors, an uncertainty that is highly significant given that environmental factors represent a preventable cause of this disease.

The Society of Toxicology applauds this effort to raise awareness of environmental causes of cancer, and supports the need to understand the role that environmental factors play in this disease. In fact, toxicology, the study of the adverse effects of chemical, physical, and biological agents on health, is directly aimed at identifying environmental contributions to causes of adverse health effects and thus recognizes this importance for identifying preventable causes of cancer.

The President's Cancer Panel, created in 1971 to monitor the National Cancer Program, provides periodic reports on the nation's cancer programs and priorities. Earlier reports have addressed topics such as health disparities, translational research, cancer survivorship, barriers to care, cancer among Native American populations, and promotion of healthy lifestyles for reducing cancer risk. This most recent report summarizes the Panel's findings and conclusions based upon testimony from invited experts and additional information gathering, and provides recommendations for reducing environmental cancer risks. Besides issuing a call to action at several levels for reducing environmental exposures to potential carcinogens, the panel also calls for enforcing existing policies and regulations that protect workers and the public, implementing policy and regulatory changes that support public health and reduce the burden of cancer, and taking personal action.

The Panel's report has been received with mixed reviews from some medical and scientific experts as well as several organizations and advocacy groups. For example, while experts generally believe that the increasing number of known or suspected environmental carcinogens warrants further study and action to reduce or eliminate these exposures, some are concerned that the report overstates the risk of environmentally-induced cancer and gives too little attention to the major known causes of cancer, including tobacco, obesity, sunlight, and alcohol. In this regard, we believe the current report on reducing environmental cancer risk should be viewed

in context with the preceding President's Cancer Panel's report, "Promoting Healthy Lifestyles" (2007), which was lauded for its conclusions and recommendations for reducing cancer risk through diet, nutrition, and physical exercise, and by eliminating tobacco use and exposure. These two reports together present a balanced picture of obesity and tobacco as major modifiable cancer risk factors with other sources of environmental pollution also being critically important to human health. A second criticism is that the report recommends a precautionary approach. The SOT is firmly committed to disease prevention as noted by one of the Society's strategic objectives, "Increase the impact of toxicology on human health and disease prevention." However at the heart of toxicological research is the premise that "the dose makes the poison" and we believe that current regulatory decisions should be based on well-informed safety assessments that emphasize appropriate dose-response data. The President's report makes an especially compelling plea, for example, for recognizing the potential for cumulative impacts from radiation exposures from unnecessary or overused CT scanning. Although medical imaging and nuclear medicine have become valued tools for facilitating diagnosis, their use has skyrocketed and application has been common place among individuals seeking early diagnosis. The report endorses recognition of radiation from each scan and promotes extra caution when multiple exposures are proposed for children. Promotion of a campaign to recognize the potential special vulnerability among children to cumulative scans acknowledges this cumulative exposure issue and also the importance of dose when balancing medical risks and benefits.

As noted above, the report's emphasis on the need to identify and prevent environmental exposures that can cause cancer is well aligned with a key component of the toxicological sciences, which is to identify potential toxic compounds prior to widespread use. Our scientists conduct many types of tests to ensure the safety of drugs and chemicals in common usage and thus we applaud the emphasis on prevention in the report. The report also emphasizes the need for both epidemiological and basic environmental cancer research (including innovative methods for going beyond our single chemical testing mentality) to understand these risks. The report makes an urgent plea for more research dollars for finding causes of cancer that are preventable and for identifying windows of susceptibility to environmental exposures. This call is significant and is critical to address one of the most controversial aspects of this report, "How many cancers are due to environmental factors and how many can be prevented?" The Society of Toxicology applauds that call for more research and challenges its members to come forth in this quest.

Michael P. Holsapple, SOT President; Jon C. Cook, SOT Vice President; Cheryl Walker, SOT Past President; and William Slikker, Vice President-Elect

NCI Personnel:

Hale Named Acting Director Of NCI Ethics Office

ERIC HALE has been appointed acting director of the NCI Office of Ethics until the selection of a permanent ethics director for the institute is named.

Hale has worked at NCI for 12 years. He is associate director for the Office of Policy and Intellectual Property in the Center for Cancer Research, where he will return upon the conclusion of this appointment.

Hale succeeds **Andrea Bernardo**, who will join the NIH Office of the Director in the NIH Ethics Office.

August Publication Break For The Cancer Letter

The Cancer Letter editors are planning to take their annual summer publication break starting next week, and do not expect to publish an issue of The Cancer Letter for two to three weeks, depending on the status of important news events in our field.

Subscribers who are worried about not receiving their weekly email notifications can always check the website at www.cancerletter.com to find out whether a new issue has been posted. Subscribers can log on and download the new issue from the Archive tab.

Funding Opportunity:

Lustgarten Foundation Awards

The Lustgarten Foundation announces its Innovator Awards Program to fund proposals for "out of the box" concepts in translational and basic research. These awards will be $100,000 for one year and may be renewable for an additional year.

Grants are open to domestic and foreign non-profit institutions. Applicants should submit a Concept Proposal. The foundation will contact the Principal Investigators of selected concepts to invite the submission of full proposals.

Concept proposal deadline is Sept. 13. For a full RFP announcement and a Proposal Template, visit: www.lustgarten.org.