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# Stop Suffering And Death *All Around Us*? Von Eschenbach FDA Speeches Omit 2015

*By Paul Goldberg*

As NCI director, Andrew von Eschenbach unabashedly pursues his goal to "eliminate suffering and death due to cancer by 2015."

In his second job, as acting FDA commissioner, he omits one detail: his self-imposed deadline.

Earlier this week, as he announced FDA's collaboration with NCI and Centers for Medicare and Medicaid Services to validate biomarkers for development of cancer drugs, von Eschenbach rephrased the goal on which he has gambled his credibility:

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*In the Cancer Centers:*

## Baylor Receives $100 Million For Center; M.D. Anderson Wins 10th SPORE Grant

**BAYLOR COLLEGE of Medicine** has received a $100 million gift from **Dan Duncan** and his family, a majority of which is earmarked for the Dan L. Duncan Cancer Center. Duncan is a member of the board of trustees and head of Enterprise Products Partners. The gift adds to the $37 million the Duncan family has given over the past two years to support other initiatives. Last year, the family gave $35 million for the Baylor Clinic, ambulatory care facility, and $2 million for prostate cancer research. The most recent gift increases the probability the center will be designated an NCI comprehensive cancer center when the application is submitted this month, said **C. Kent Osborne**, director of the cancer center. The center has eight programs that include cell therapy, cancer prevention and population sciences, molecular carcinogenesis, nuclear receptor biology, breast cancer, pediatric oncology, cancer biology and prostate cancer, he said. . . . **M. D. ANDERSON Cancer Center** received a three-year $4.6 million NCI Specialized Programs of Research Excellence grant for breast cancer research, the center's 10th SPORE grant since 1996. **Gabriel Hortobagyi**, professor and chairman of the Department of Breast Medical Oncology, is the principal investigator, and co-PI is **Mien-Chie Hung**, professor and chairman of the Department of Molecular and Cellular Oncology. The SPORE includes five projects: 1) molecular and epidemiologic classification of early-stage breast cancer tumors; 2) cyclin E as a prognosticator for breast cancer; 3) treatment of metastatic breast cancer with gene-modified mesenchymal stem cells; 4) PTEN deficiency and Herceptin resistance; and 5) targeting breast cancer-specific gene therapy. The grant brings together 28 M. D. Anderson faculty

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## White House Must Nominate An FDA Head In Two Months

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"This has the potential… to impact upon the problem of cancer in a way that will *eliminate the suffering and death we see all around us*."

A Feb. 14 press release issued by HHS similarly didn't mention the 2015 goal. When a reporter at the telephone press conference asked von Eschenbach about the controversial goal, he was told that the acting commissioner "had to leave."

Meanwhile, at NCI, politicization around the 2015 goal intensified as the institute sets "strategic priorities" in the face of budget cuts. The strategy appears to include continuing funding of research in areas von Eschenbach regards as key to accomplishing the goal, even as the payline for investigator-initiated grants threatens to slip below the 11th percentile (The Cancer Letter, Feb. 10.)

It is unclear why von Eschenbach toned down his rhetoric at FDA. However, it is certain that in the next two months, the Bush administration will have to make a decision about his future. Under the federal Vacancies Reform Act, von Eschenbach can stay in the interim job at FDA no longer than 210 days. The clock began to tick on Sept. 23, 2005, when his predecessor Lester Crawford submitted his resignation. By April 21, the administration will have to nominate a permanent head of the agency.

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Last year, HHS Secretary Mike Leavitt said that von Eschenbach is unlikely to get the nomination (The Cancer Letter, Oct. 7, 2005). If he is nonetheless picked for the job, his chances of confirmation could be hampered by his disregard of criticism by members of Congress. One key legislator, Sen. Chuck Grassley (R-Iowa), has written two letters to the White House objecting to von Eschenbach's dual role.

**Von Eschenbach With and Without 2015**

Initially, von Eschenbach's speeches at FDA were indistinguishable from his speeches at NCI.

Last October, he told directors of the cancer centers that as a consequence of his dual appointment, the research institute and the regulatory agency had joined forces in pursuit of the 2015 goal.

"In the end, when those two agencies… are successful, then we will see a world in which no one will suffer and die from cancer, a world in which the full fruits of the era of molecular biology and molecular medicine are made available to patients and to the public in a safe and effective, rapid, and cost-effective manner, and we will not only have changed the future of cancer, but we will have changed and improved the health care for the entire nation and for our world," he said at a meeting of the Association of American Cancer Institutes (The Cancer Letter, Oct. 21, 2005).

The change in von Eschenbach's rhetoric became apparent at an FDA news conference Jan. 12, when he extolled the life-saving potential of new rules for early-stage clinical trials, but, surprisingly, refrained from mentioning the 2015 goal (The Cancer Letter, Jan 13).

However, just eight days later, on Jan. 20, von Eschenbach appeared—as NCI director—in southern Florida with Republican Rep. E. Clay Shaw Jr., a cancer survivor and a key Congressional supporter of the 2015 goal. Von Eschenbach praised Shaw's "leadership" to find resources to pursue the goal, endorsing the legislator in the midst of a reelection campaign (The Cancer Letter, Feb. 3).

Getting involved in a Congressional race is an unusual move for an NCI director. Von Eschenbach's predecessors have maintained at least an appearance of political neutrality, and in return, they were usually allowed to keep their jobs when administrations changed.

Shaw's health status is unpredictable, lung cancer experts say. His disease, bronchoalveolar carcinoma, progresses slower than more common forms of non-small cell lung cancer, but it appears to be clinically significant.

Far from going away, the story of the endorsement was picked up by the Miami Herald on Feb. 11: http://www.miami.com/mld/miamiherald/13845321.htm.

**Alliteration Survives**

Even when he omits the 2015 goal, von Eschenbach's remains true to his sermon-like speaking style.

"To go from the discovery and the development to really the most important part of the equation, the delivery of those intervention to patients in a way that truly will improve their outcome and ensure their freedom from suffering and death," von Eschenbach said Feb. 14.

The alliterations he crafted at NCI are intact: "collaboration and cooperation," "discovery, development, and delivery," "progress and a promise," "progress with a purpose," and "seamless and synergistic integration." Also, he is not averse to making promises to "save many lives."

"For me, this is much about progress, but it's much about the fulfillment of the promise of that progress, the ability to integrate discovery, development, and delivery by three federal agencies who have functioned and worked individually across these three missions, but now are committed to working collaboratively and cooperatively together to make this a seamless and integrated effort," he said at the recent press conference. "Seamless and integrated in that it will be synergistic, the whole will be greater than the sum of its parts, and the promise will be fulfilled, but even more importantly, it will be fulfilled sooner and earlier.

"That translates into many, many more lives saved that otherwise would have been lost."

At the same conference, NCI Deputy Director Anna Barker, an architect of von Eschenbach's reconfiguring of the institute, similarly refrained from saying "2015."

"Biomarkers… are key technology foundations for how we are going to deal with eliminating suffering and death due to cancer," Barker said at the Feb. 14 press conference. "It's one of those huge areas that have enormous promise, but we need to set the foundation for this."

Later, she added that biomarkers offer "enormous advantages we believe would accelerate the progress that we need to eliminate the suffering and death due to this disease in a decade." This, statement, too, introduced a contingency—successful use of biomarkers—into the promise to make cancer a manageable disease.

**Biomarker Rush At FDA**

At FDA, von Eschenbach's vision of the future appears to dovetail with a separate plan that, in part, aims to incorporate biomarkers into the drug development process.

The plan, called the Critical Path Initiative, developed by former FDA Commissioner Mark McClellan in 2004, was never accompanied by either promises or deadlines for eradication of disease.

Now, the FDA plan is being implemented by Janet Woodcock, deputy commissioner for operations, who is working closely with NCI and appears to envision methods for attacking cancer as something akin to an engineering problem. The President's budget proposal for FDA includes a $5.9 million for the initiative.

McClellan's report was titled, "Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products." Now, von Eschenbach calls the initiative the "Critical Path to Personalized Medicine."

"From FDA's standpoint, I can't emphasize enough how we need to move the paradigm toward scientific drug and device development," Woodcock said at the Feb. 14 conference. "Right now, the development process is fraught with uncertainty. And that is because of a lack of enough scientific markers and mechanistic predictions that we can make about treatments.… FDA has a tremendous stake in this, because this will improve our understanding of products during the development process."

At the press conference, the agencies announced the Oncology Biomarker Qualification Initiative. The announcement was rich in promise and light on detail.

The initiative's pilot project would be to validate and standardize the use of fluorodeoxyglucose and positron emission tomography (FDG-PET) scanning as a predictor of tumor response in non-Hodgkin's lymphoma.

Scientists describe FDG-PET in this indication as a low-hanging fruit, a widely studied biomarker that seems more reliable than most. However, the announcement didn't include a plan for validation or any information on how CMS would pay for the PET scans in these trials.

"Over the next several months, the OBQI team will design a number of initiatives to identify and clinically qualify other cancer biomarkers," HHS said in a press release.

The press release cites the FDA Critical Path initiatives and the NIH Roadmap, but says nothing about von Eschenbach's 2015 goal. The document is posted

on the FDA website: http://www.fda.gov/bbs/topics/news/2006/NEW01316.html.

On the same day, von Eschenbach's "Director's Update" column in the NCI Cancer Bulletin, the institute's official publication, filled this void by announcing that a "strategic plan" for reaching the 2015 goal would be released in the near future.

"Over the past 15 months, each of NCI's divisions and centers worked to come up with almost 200 possible strategic goals, from which the NCI executive committee eventually agreed on eight strategic priorities," von Eschenbach wrote in his capacity as NCI director. "It's these priorities that comprise the soon-to-be-released 2015 strategic plan which will be instrumental in guiding our strategic choices."

**A Step Forward To "Save Lives"**

At the press conference, Barker said budget cuts wouldn't deter NCI from emphasizing research on biomarkers.

"The cuts are having an impact across the board," she said. "Virtually nothing within the cancer institute is being exempted from these kinds of cuts. Having said that, biomarkers are probably the key to many of the plans and visions and hopes that we have for moving toward personalized medicine, specifically in molecular oncology.

"So we believe this is an area of investment that we must make. So we are investing significantly in biomarkers, whether it's in genomics through the cancer genome atlas, or proteomics, by bringing some standardization to the field, advanced imaging, and projects like this," Barker said. "These are areas where we are selectively investing strategically to really have an impact in terms of qualifying biomarkers that are going to make a difference not only for drug discovery and development, but also for patient stratification and predicting outcomes, and, ultimately surrogate endpoints as well.

"Any of the initiatives that really are going to put patients first in terms of moving technology more efficiently and effectively into patients is certainly something that NCI will continue to focus on much more strategically in the future," she said.

Barker said the FDG-PET pilot project is a work in progress.

Though scientists at the institute have drafted a protocol, its details would likely change after the plan is reviewed by a group of experts who are scheduled to meet on March 20.

"There may be more than one trial, by the way," Barker said. "It's kind of unlikely that we will be able to answer all the questions we have with one trial.

"We do have good correlations in other types of lymphoma with disease-free survival and progression-free survival, so we are pretty hopeful that if we can develop the standards, that this is one of those areas where we can have very, very quick progress, in a sense that we would be able to use this as an endpoint for early response, which would save time and money and all the kinds of things we think about in terms of drug development."

Barker said she couldn't be certain that the validation project would address the use of FDG-PET in non-Hodgkin's lymphoma.

"The experts actually could change this as they come together," she said. "We believe that they will probably focus on FDG-PET as an endpoint for early response in non-Hodgkin's lymphoma, which we think is quite doable."

"We have a rough protocol, in a sense that we know what should be done overall, but this is a very technically challenging area and we want the best of the imagers and the best of the lymphoma experts, and sort out all of the issues that need to be considered when you design a trial like this."

Whatever the outcome, FDA's Woodcock said additional validation projects were certain to follow. The agency envisions playing a coordinating role in such studies, she said.

"FDA in general will not be funding clinical trials," Woodcock said. "We are going to look at leveraging the work that is going on right now and see how we can add on these types of studies.

"This is kind of big science. We have to pool our resources together to get it done. That's why we have been talking about consortia to get much of the work done. And we are not just talking drug companies. Private foundations of various kinds have indicated interest. We are working on different nonprofits around the country on different parts of the Critical Path initiative right now, and we expect more of that to happen."

On the way out, von Eschenbach assured reporters that the announced program represented "a major step forward."

"I know that we have used words that are of multi-syllables, but the message is really quite simple," he said. "This is about being more precise, more accurate, and more effective in being able to utilize the tools and therapies that we will be developing in a way that saves more lives."

*NCI Programs:*

# NCI Forming New Committees To Oversee Clinical Trials

*By Kirsten Boyd Goldberg*

NCI has begun to form the new organizational structure that will govern the federally-funded cancer clinical trials system, including a permanent external advisory committee that will have similar standing to the institute's Board of Scientific Advisors.

The reorganization is in response to recommendations by the Clinical Trials Working Group in a report to the National Cancer Advisory Board last June (The Cancer Letter, June 10, 2005).

Full implementation of the report's more than 20 recommendations will take four to five years, but most of the initiatives will be put in place by the end of 2008, James Doroshow, director of the Division of Cancer Treatment and Diagnosis, said to the NCAB at its Feb. 7 meeting.

The new groups to be formed this year include:

—Clinical Trials Advisory Committee (CTAC), NCI's first new external advisory committee in more than a decade. The committee, approved by HHS and NIH and governed by the provisions of the Federal Advisory Committee Act, will advise the NCI director on the clinical trials program, oversee the reorganization, and conduct reviews of the program. The committee will include members of NCAB, other NCI advisory boards, and cancer clinical trials investigators. CTAC also will provide advice on the use of funds for correlative science and quality-of-life studies. The first meeting is expected to be held in June.

—Clinical Trials Operations Committee (CTOC), an internal committee led by the NCI Deputy Director for Clinical and Translational Sciences, John Niederhuber. The committee includes the directors of NCI divisions, branches, and centers involved in clinical trials. The committee's role will be to review and prioritize clinical trial programs proposed by the NCI components, evaluate these programs to reduce duplication, advise on the development of informatics infrastructure to support clinical trials, and evaluate new Requests for Applications and Program Announcements for clinical trials prior to review by the NCI Executive Committee. This group met for the first time last December.

—Coordinating Center for Clinical Trials (CCCT), also led by Niederhuber, will provide the project management for implementation of the CTWG report's recommendations. This group will coordinate new disease-specific steering committees for prioritization of phase III trials, the investigational drug steering committee for phase I and II trials, and working groups designed to develop new tools for clinical investigators, as well as measures to improve clinical trial operational efficiency.

—Disease-specific steering committees: Two of these committees have been formed. The gastrointestinal steering committee met for the first time Jan. 26 at the American Society of Clinical Oncology Gastrointestinal Cancer Symposium, and the gynecologic malignancies committee met at the Gynecologic Oncology Group meeting last month. A third group, most likely for head and neck cancer, also would be formed this year. These committees will help design and prioritize clinical trials.

Last September, NCI established the Investigational Drug Steering Committee (IDSC) to provide extramural advice on the early phase development of agents for which NCI holds the IND. The committee's responsibilities include advising the NCI Investigational Drug Branch, reviewing the Cancer Therapy Evaluation Program's drug development plans, and evaluating unsolicited letters of intent for new grant studies. The policies and procedures for the group are under development, Doroshow said.

* * *

**Cancer Genetic Markers of Susceptibility**: NCI has funded a three-year, $14 million study to identify inherited genetic alterations in prostate and breast cancer.

The study will start by scanning 2,500 samples from men with and without prostate cancer. San Diego-based Illumina Inc. will conduct the rapid genotyping. The most promising single nucleotide polymorphisms will be analyzed and validated in a series of large, population-based studies.

The NCI Division of Cancer Epidemiology and Genetics will coordinate the study.

* * *

**Breast Cancer Stamp** funds will support a new NCI program in breast cancer premalignancy research, the institute said.

The Breast Cancer Premalignancy Program would support intramural and extramural research on breast cancer stem cells, pathways, the microenvironment, molecular target identification (biomarkers), imaging, drug discovery, and translation.

As of last November, the NCI had collected more than $33.5 million in stamp funds and awarded more than $25.4 million for grants and contracts, including Insight Awards and a research project grant exceptions.

*Professional Societies:*

# Quality Of Cancer Care Report Targets Areas For Improvement

Results of the first study on national cancer care quality found that the large majority of patients are receiving high-quality care, though certain areas need improvement.

The study, commissioned by the American Society of Clinical Oncology and undertaken by the Harvard School of Public Health and RAND Corp., analyzed data from nearly 1,800 patient surveys and medical records of people with early-stage breast and colorectal cancer.

The results of the National Initiative on Cancer Care Quality were published in the Feb. 1 issue of the Journal of Clinical Oncology.

Patients with early-stage breast cancer received 86 percent of generally recommended care, based on 36 quality-care measures, while patients with early-stage colorectal cancer received 78 percent of generally recommended care, based upon 25 quality-care measures. These overall rates of adherence suggest that the quality of care for cancer is better than that observed for other chronic medical conditions.

"We were very pleased to see such a high level of adherence to many quality care measures," said Ezekiel Emanuel, chairman of ASCO's Task Force on Quality Cancer Care, which oversaw the research. "However, a large part of our goal was to target areas for improvement, so ASCO, other professional societies, advocacy groups, the National Cancer Institute, and others could direct their attention to these areas."

The study examined the quality of care for patients diagnosed with stage I, II, or III breast cancer or stage II or III colorectal cancer an average of four years after diagnosis in five metropolitan areas: Atlanta, Cleveland, Houston, Kansas City, and Los Angeles.

The study sought to measure to what degree cancer patients received elements of care that were consistent with the best evidence in the literature and clinical practice guidelines.

The 36 quality measures for breast cancer included in the study were grouped into five areas: diagnostic evaluation, surgery, adjuvant therapy, managing toxicities, and surveillance. Adherence varied across the five areas, with adherence rates of 88 percent, 87 percent, 82 percent, 73 percent and 94 percent, respectively.

For colorectal cancer, the 25 quality measures were grouped into four areas: diagnostic evaluation, surgery, adjuvant therapy, and surveillance. Overall adherence was slightly lower in this disease, with adherence rates in the four areas of 87 percent, 93 percent, 64 percent, and 50 percent, respectively.

Examples of quality measures with adherence rates above 85 percent in each of the categories of care include the following :

—Diagnostic evaluation. Ninety-nine percent of newly diagnosed breast cancer patients underwent axillary lymph node sampling, as recommended by guidelines. For colon cancer patients who underwent surgery to remove tumors, 98 percent of pathology reports stated whether the cancer had spread to the lymph nodes.

—Surgery. For breast cancer patients undergoing surgery, 99 percent of patients had "clear margins," 98 percent received radiation therapy after breast-conserving surgery, and 96 percent of patients received the recommended dose of radiation. For colon cancer patients undergoing surgery, 89 percent of patients had clear margins.

—Adjuvant therapy. When chemotherapy after surgery was indicated as a preferred treatment option, 96 percent of eligible women with breast cancer received the treatment. Ninety-two percent of colon cancer patients received adjuvant therapy when indicated.

—Surveillance and follow-up. For breast cancer patients with tumors larger than one centimeter or those with cancers that have spread to the lymph nodes and are estrogen-receptor or progesterone-receptor positive, 92 percent received tamoxifen for five years after surgery, as recommended by quality care guidelines. For colorectal cancer patients who underwent an ileostomy or colostomy, 96 percent received instruction in enterostomy care following the procedure.

Examples of quality measures in the categories of care with adherence rates of less than 85 percent include:

—Surgery. Thirty percent of patients underwent mastectomy as their first procedure (the remaining 70 percent of patients received a lumpectomy, followed by radiation). Of the group of patients that underwent mastectomy as their first procedure, 30 percent were told that breast-conserving surgery was an option. This may be because the patient was not an appropriate candidate for a lumpectomy, the patient requested a mastectomy, or because the doctor did not document discussions with the patient in the medical record. Also, 49 percent of breast cancer patients who had a mastectomy were informed about the option of breast reconstruction prior to undergoing mastectomy.

—Adjuvant therapy. For breast cancer patients, the planned chemotherapy dose was consistent with published recommendations for 58 percent of patients (in most cases, the dose provided was low). For patients with colorectal cancer, the planned dose was consistent with published recommendations for 68 percent of patients. In addition, 79 percent of patients with colorectal cancer had begun adjuvant chemotherapy treatment within eight weeks of surgery, as recommended by treatment guidelines.

—Managing toxicities. Sixty-six percent of breast cancer patients receiving nausea-inducing therapy were treated with a potent anti-nausea drug, such as 5HT blockade.

—Surveillance and follow-up. Seventy-five percent of breast cancer patients who started taking tamoxifen continued taking it for the entire five-year course of treatment. Fifty percent of patients who had a removal of a stage II or stage III colorectal cancer were counseled about the need for first-degree relatives to undergo screening.

Additional findings of note include:

—Researchers found significant variations in care across the five metropolitan areas. For breast cancer patients, while the planned chemotherapy dose was consistent with published recommendations for 58 percent of patients overall, this ranged from 29 percent to 74 percent across the five cities. For patients with colorectal cancer, the planned dose was consistent with published recommendations for 68 percent of patients, ranging from 62 percent to 85 percent across the five cities.

—Lack of documentation of treatment in patients' medical records was a significant problem. Among women with breast cancer, the percentage of patients whose planned chemotherapy regimen was actually noted in their chart ranged from 46 percent to 78 percent across the five cities. For colorectal cancer patients, adherence rates ranged from 50 percent to 68 percent.

**National Monitoring of Cancer Care Quality**

ASCO said it plans to incorporate the study's findings into its educational programs. The society said it is taking steps to improve documentation for care provided, particularly in the area of chemotherapy administration, and is in the process of developing tools for clinicians.

"The NICCQ study provides valuable information that will enable us to better educate physicians about the best ways to treat cancer patients," said ASCO President Sandra Horning. "The quality measures identified in the NICCQ study can be incorporated into patients' medical records, so doctors will be able to better document the care patients are receiving through all stages of treatment."

Through the Quality Oncology Practice Initiative (QOPI), ASCO is applying the NICCQ measures and findings to practice-based quality improvement initiatives. Doctors will be able to assess the care that they are providing in their practices and compare it to what other practices are doing.

ASCO also is working with the National Comprehensive Cancer Network to use the NICCQ quality measures to develop a subset of measures to improve accountability for care for breast and colorectal cancer, which will be specified, pilot tested, and then disseminated.

ASCO commissioned the study after the 1999 Institute of Medicine report on cancer care quality.

## *In the Cancer Centers:*

# Center To Build New Hospital

(Continued from page 1)

in 13 disciplines. . . . **IRELAND CANCER CENTER of University Hospitals of Cleveland** will build a free-standing comprehensive cancer hospital as part of a $1 billion development plan, said **Stanton Gerson**, director of the cancer center. The development plan will include renovation, expansion and new construction on the campus itself as well as other system hospitals, ambulatory centers, and commitments to technological advancements. . . . **STEVEN HARTRANFT** was named vice president of quality improvement and patient safety at City of Hope Cancer Center. He was senior clinical quality improvement analyst at the University of Texas M.D. Anderson Cancer Center. . . . **MARIE JO CORRY** was appointed senior associate director of development in the Department of Radiation Oncology and Molecular Radiation Sciences, Kimmel Cancer Center at Johns Hopkins. She managed fundraising at the Hopkins Bloomberg School of Public Health. . . . **MOSHE TALPAZ** was named associate director for translational research at University of Michigan Comprehensive Cancer Center. Talpaz, was professor of medicine at M.D. Anderson Cancer Center.

## *Reports:*

**Central Brain Tumor Registry of the United States**, a non-profit statistical research organization, has published its 2005-2006 "Statistical Report, Primary Brain Tumors in the United States, 1998-2002."

Statistical analyses for the report were conducted under contract with the Centers for Disease Control and Prevention. The American Brain Tumor Association, The Pediatric Brain Tumor Foundation of the United States, and NeoPharm Inc. provided funding support.

The report is available at www.cbtrus.org.

## *Funding Opportunities:*

# RFA Available

**RFA-CA-07-004: Small Animal Imaging Resource Program.** Letters of Intent Receipt Date: April 18. Application Receipt Dates: May 18. NCI invites U24 applications for the SAIR Program for grants that will support: shared imaging resources to be used by cancer investigators; research related to small animal imaging technology or methodology; and training of both professional and technical support personnel interested in the science and techniques of small animal imaging. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-004.html. Inquiries: Barbara Croft, 301- 496-9531; bc129b@nih.gov.

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