THE CANCER LETTER

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CMS Proposes To End Automatic Coverage Of Clinical Trials For Medicare Patients

By Paul Goldberg

Six months before leaving office, President Bill Clinton issued an executive order that resolved one of the most stubborn problems in oncology: Medicare's refusal to cover routine care provided to patients involved in clinical trials.

Overruling bureaucratic opposition at the agency, the Clinton policy provided coverage for all clinical trials sponsored by federal agencies as well as those reviewed by FDA. Over the following seven years, the number of elderly Americans taking part in cancer clinical trials appears to have increased.

However, this access to Medicare is now jeopardized, oncology and

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In the Cancer Centers:

NCAB Member David Koch Gives $100 Million To MIT For New Cancer Research Institute

DAVID KOCH, executive vice president and board member of Koch Industries Inc. and a member of the National Cancer Advisory Board, has given $100 million to the Massachusetts Institute of Technology for cancer research. With the gift, MIT will build the David H. Koch Institute for Integrative Cancer Research, scheduled to open in 2010.

The institute will pool MIT's molecular geneticists and cell biologists with engineers. "This is a new approach to cancer research with the potential to uncover breakthroughs in therapies and diagnostics," Koch said. "Conquering cancer will require multi-disciplined initiatives and MIT is positioned to enable that collaboration. As a cancer survivor, I feel especially fortunate to be able to help advance this effort."

Koch, an MIT alumnus, is a prostate cancer survivor. He was appointed to the NCAB in 2004 by President **George W. Bush**.

"The David H. Koch Institute for Integrative Cancer Research will harness the power of MIT scientists and engineers to address one of the most pressing challenges to human health: The ultimate eradication of cancer, starting with real improvements in detection, treatment and prevention," MIT President **Susan Hockfield** said. "David Koch's extraordinary generosity will make possible a level of collaborative, cross-disciplinary research and training unparalleled in the world. The convergence of life sciences and engineering enabled by his gift will chart a new course for cancer research,

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CMS Proposes 13 Points To Establish Trial Eligibility

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pharmaceutical industry say. On Oct. 17, the Centers for Medicare and Medicaid Services is expected to publish the final version of a revision of the standing policy on clinical trials.

Instead of continuing to accept review by other government entities, standards recently proposed by CMS list 13 characteristics of clinical trials that would merit coverage. To qualify for Medicare payments, clinical investigators would have to certify that their studies are consistent with all these characteristics—and, presumably, accept legal consequences if this certification is challenged.

"This is just one more assault on a clinical investigator," said Nancy Davidson, president of the American Society of Clinical Oncology and a breast cancer expert at Johns Hopkins University's Sidney Kimmel Cancer Center. "These are passionate people who want to do the right thing for their patients and for our field, and every time you put up another barrier that blocks research and doesn't help patients in clinical trial accrual, it's a huge hurt."

Under its existing policy, CMS presumes that trials sponsored by NIH, VA, and other federal agencies are eligible for coverage. Trials conducted under Investigational New Drug licenses from FDA or those exempt from the IND requirement have to be covered, too.

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According to critics, the requirement now proposed by CMS is duplicative, vague, burdensome—and legally risky for clinical researchers and their institutions. Several observers said they were particularly puzzled by one of the 13 criteria that new research wouldn't "unjustifiably duplicate existing studies."

"How is a sponsor or principal investigator going to be sure that a study isn't duplicative?" asked Kirk Dobbins, at attorney with King & Spalding FDA and Healthcare Practice who has worked at the HHS Office of General Counsel CMS Division. "Often, you are studying various aspects of a particular product either for a new indication or to clarify its effect on a particular population. Is it truly possible to make sure that you are not duplicating some aspect of another clinical trial?"

Besides, duplication is a fundamental premise in science, Dobbins said. "That's a basic premise of the scientific method: You should be able to demonstrate reproducible results," he said.

Though it's possible that the final version of the CMS policy would differ from the published proposal, oncology groups are gearing up for a fight.

Even before CMS releases its final coverage decision, members of Congress are urging the agency not to change its clinical trials coverage. Sens. Benjamin Cardin (D-Md.) and Sam Brownback (R-Kan.) are circulating a "dear-colleague" sign-on letters urging CMS to keep its 2000 coverage policy. In the House, Deborah Pryce (R-Ohio) and Lois Capps (D-Calif) are expected to send a letter to the agency, sources said.

Though Congress can vacate actions of federal agencies, this authority is rarely used. Currently, bills that seek to overturn the new CMS policy for coverage of erythropoiesis-stimulating agents are pending in the House and Senate.

The clinical trials decision could also be challenged in courts, as the agency may need to go through additional rulemaking under the federal Administrative Procedure Act. This could require a new public comment period and would take months to complete before the policy could be enforced.

If the proposal is implemented in its current form, attorneys for institutions that take part in clinical trials would likely recommend against enrolling Medicare patients, the agency's critics say. "This is like cold water for every institution, because they are concerned that they will be left with some kind of liability at a later time," ASCO's Davidson said. "This affects Medicare patients. So, individuals who are statistically the most likely to get cancer, the most likely to benefit from trials that have to do with cancer treatment, and are in

this way perhaps the least likely to be empowered to participate."

Historically, Medicare patients have been in the minority of clinical trials participants. However, according to a recently published study by the Southwest Oncology Group, the year 2000 change in coverage boosted clinical trials enrollment for patients who have Medicare coverage augmented by supplemental insurance.

In the Jan. 1, 2006, issue of the Journal of Clinical Oncology, Joseph Unger *et al.* reported that enrollment of Medicare-eligible patients went up from 31 percent between 1997 and 2000 to 38 percent between 2001 and 2003. The percentage of patients using Medicare alone remained unchanged.

"This proposal represents a significant reversal of the standards for Medicare coverage of clinical trials that have been effective since 2000, and it poses a threat to the ability of Medicare beneficiaries to receive care in clinical trials," the patient-run Cancer Leadership Council wrote in a recent letter to CMS.

"This coverage policy was essential for ensuring that cancer patients have access to quality care in a clinical trial (perhaps their best or only treatment option); furthering our knowledge about the best cancer therapies for senior citizens; and accelerating accrual to and completion of clinical trials answering important treatment questions for cancer patients of all ages."

Fran Visco, president of the National Breast Cancer Coalition, said the CMS criteria are reasonable and could discourage poor-quality research.

"These are people's lives we are talking about," said Visco, who lobbied to change the Medicare policy seven years ago and supports the agency's recent proposal. "We are also talking about taxpayer dollars, in an incredibly overburdened healthcare system. We need to make certain that every resource—lives, dollars, attention—is spent appropriately.

"These are strong criteria that clinical trials should meet before they move forward," Visco said. "Trials that do not are a waste of time, lives, and money, and if we can get rid of those trials and focus our efforts on the trials that should be going on, that's a good thing. And if this helps us get there, that's also a good thing. But it should not just add another clerical step in the process, there should be meaningful accountability involved."

CMS first implemented the coverage policy in September 2000 and launched its first attempt to revise that policy last April.

The agency said that in the process of preparing that review it received "several comments from hospitals and others suggesting that Medicare contractors had been paying claims involving patients in various types of clinical research outside the terms of the clinical trial policy."

These comments convinced the agency that broad changes in defining trials that merited coverage would be required. The current proposal was published on July 19, and the public comment period ended a month later.

"I think CMS's intent was not necessarily to make it burdensome, but to clarify the various elements of the policy, so that agency requirements are more transparent," said Dobbins. "But what is lost in implementation is what are the implications for clinical research that doesn't have all those elements, some of which are unclear, then the policy potentially unnecessarily complicates the research process."

Additional review would be counterproductive, ASCO's Davidson said. "I pulled out one of the clinical trials one of our young people put through here and looked at the steps she had to go through to get this from idea to opening the trial, and it's six months of enormous review," Davidson said. "It went through review by NIH, it went through the scientific review in our cancer center, the IRB review. It had to be reviewed by FDA, it was reviewed by several corporate partners who are providing drugs for part of the trial. What more is there? And every time you put on another layer of review, you discourage a clinical investigator a little bit more."

CMS Proposed Certification Criteria

The CMS document states that "the principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes."

The proposed certification criteria follow:

—The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

—The research study does not unjustifiably duplicate existing studies.

—The research study design is appropriate to answer the research question being asked in the study.

—The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

—The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.

—All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

—The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.

—The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.

—The clinical research study is registered on the ClinicalTrials.gov website by the study sponsor/principal investigator prior to the enrollment of the first study subject.

—The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

—The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

—The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

The proposed decision is posted at http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210.

The final decision will be posted at the same address.

Medicare:

Access To Care Unaffected By MMA, Duke Study Finds

Cancer patients receiving chemotherapy have not noticed a restriction in their access to treatment following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, despite the act's significant reduction in government reimbursement to oncologists, according to a study led by researchers in the Duke Clinical Research Institute.

"Critics of the MMA often said that it would reduce patients' access to chemotherapy services, because doctors would receive 30 to 40 percent less reimbursement from the government for administering treatment," said Kevin Schulman, director of the DCRI's Center for Clinical and Genetic Economics, and senior investigator on the study. "Our study showed that patients actually do not perceive barriers to their access to chemotherapy and perceptions about access are really the same among patients who received treatment before the legislation went into effect, and those who received it afterwards."

The findings will be published in the Nov. 15 print edition of the journal Cancer, but also appeared in the journal's Oct. 8 online edition. The study was funded by a grant from the National Patient Advocate Foundation's Global Access Project, which includes pharmaceutical companies and advocacy groups, to fund health research.

The Duke researchers examined the results of 1,421 surveys completed on the Internet by 684 patients who had received chemotherapy prior to the enactment of the MMA and 737 patients who were treated after it went into effect. Respondents answered questions related to issues including the amount of time they waited to start chemotherapy after their initial cancer diagnosis, and how far they had to travel to get their treatments.

"When the act was passed in 2003, many doctors and patient advocates were concerned about the consolidation of services it might necessitate, such as the moving of chemotherapy services to hospital rather than outpatient settings and the elimination of staff positions," said Joelle Friedman, a DCRI researcher and lead author on the paper. "They were afraid these changes would affect patients' access to care, but our study showed that these concerns turned out to be largely unwarranted."

About half of the patients surveyed in each group were under the age of 65 and half were over 65. The

majority of patients in each group reported being either satisfied or very satisfied with the care they received from their oncologists, Friedman said.

The researchers also found no difference in the amount of time from diagnosis to initiation of chemotherapy between the two groups; the median lapse in time was 22 days in both groups, Friedman said.

Patients reported an average travel time of 30 minutes to the location of their chemotherapy appointments, both before and after the implementation of the act, she said.

The speculation that treatment location would change—that patients would either be forced to travel farther for therapy or switch treatment locations in the middle of therapy—also proved to be unfounded, Friedman said.

In a subgroup analysis, the researchers looked at respondents who were living in rural areas and Medicare beneficiaries without supplemental insurance. Among respondents in rural areas, waiting time for therapy was three weeks in the pre-MMA group and 3.9 weeks in the post-MMA group. Among respondents enrolled in Medicare without supplemental insurance, waiting time was 4.3 weeks in the pre-MMA group and four weeks in the post-MMA group.

There were differences in treatment location among respondents in rural areas and among Medicare beneficiaries without supplemental insurance. Among respondents in rural areas, 34 percent in the pre-MMA group received treatment in an outpatient hospital infusion center, compared to 22 percent in the post-MMA group. Fourteen percent of respondents in the pre-MMA group received treatment in a private doctor's office, compared to 30 percent in the post-MMA group.

The findings were similar among Medicare beneficiaries without supplemental insurance. Forty percent of these respondents in the pre-MMA group reported receiving chemotherapy in an outpatient hospital infusion center, compared to 21 percent in the post-MMA group; and 17 percent in the pre-MMA reported receiving chemotherapy in a private doctor's office, compared to 33 percent in the post-MMA group.

The researchers cautioned that the analysis may be confounded by payments to physicians in the CMS cancer demonstration project. These payments may have delayed changes in care. Also, the study cohort was a relatively high socioeconomic status, and further research is needed on the effects of the legislation in more vulnerable populations, they wrote.

The MMA represented the largest overhaul of the Medicare system since it was created in 1965. Changes included a new prescription drug benefit, and a $25 billion allocation of funds to rural hospitals. One key provision, however, was a significant reduction in Medicare reimbursement to healthcare providers. Oncologists were strongly affected, due to a perception that they had been over-compensated in the past.

Research Funding:

NIH Provides More Than Half Of U.S. Global Health Spending

NIH contributed more than half of the $9.3 billion the U.S. invested last year in global health research, according to a new report released today by Research!America.

The report calculates 2006 U.S. investment in research designed to address health conditions that primarily affect the poorest residents of low- and middle-income countries.

NIH provided nearly $5 billion to global health research in 2006. Other top contributors were:

—U.S. Agency for International Development, $152 million.

—Department of Defense, $64 million.

—Department of State, $39 million.

—Centers for Disease Control and Prevention, $32 million.

—Pharmaceutical and biotech companies, nearly $3.5 billion for research, exclusive of donations of materials, facilities or expertise for global health needs.

—Private foundations, $592 million.

The $9.3 billion represents 8 percent of the $116 billion that Research!America estimates U.S. sources spent overall on health research in 2006.

"From Research!America polls, we know Americans think that investing in global health research is the smart thing to do for America and the right thing to do for the world," said Mary Woolley, Research!America's president. "This report reinforces the direction Americans want, to place a higher priority on research to fight and prevent diseases that chiefly affect the world's poorest people."

Research!America compiled the data for the report in consultation with the federal agencies cited, the Pharmaceutical Research and Manufacturers of America, the Foundation Center and the Bill & Melinda Gates Foundation.

"Only with strong, sustained investment in health and medical research can we address the humanitarian,

economic and national security concerns within and beyond our borders," said John Edward Porter, Research!America board chairman and former member of Congress. "Our nation must ramp up investment in global health research to help prevent the emergence and spread of diseases that could endanger American children and families."

The global health R&D report is available at www.researchamerica.org.

Tobacco Control:

Tobacco Sales To Minors Drop As Result Of Synar Program

The Substance Abuse and Mental Health Services Administration said sales of tobacco to underage youth have declined under the Synar Amendment program—a federal and state partnership program aimed at ending illegal tobacco sales to minors.

For the first time, all 50 states and the District of Columbia have achieved a major Synar program goal—an 80 percent compliance rate among tobacco product retailers. Ten years ago, at the Synar program's inception, the compliance rate was 25 percent.

"This report on decreasing tobacco sales to minors shows state tobacco control efforts are working," said Terry Cline, SAMHSA administrator. "States have done an extraordinary job over the last 10 years in helping us stem illegal tobacco sales to minors. Together, we are making great strides in protecting our children from the death and disability that accompanies tobacco use."

The program is named for the late Rep. Mike Synar of Oklahoma.

SAMHSA's "FFY 2006 Annual Synar Reports: State Compliance" shows that the average national tobacco retailer violation rate dropped to 10.9 percent for federal fiscal year 2006, down from 40.1 percent in 1997. The national average is at its lowest point in Synar's 10-year history.

The SAMHSA report notes that states successfully implementing the program employed comprehensive strategies combining vigorous enforcement, supportive public policies, and development of social climates discouraging youth tobacco use.

Under regulations implementing the program, states and jurisdictions must report annually on their retailer violation rates, which represent the percentage of inspected retail outlets that sold tobacco products to a customer under age 18. The amendment requires that retailer violation rates not exceed 20 percent. States and jurisdictions measure their progress through unannounced inspections of tobacco retailers, and SAMHSA provides technical assistance.

The report is available at http://ncadistore.samhsa.gov/catalog/productDetails.aspx?ProductID=17719.

In the Cancer Centers:

MIT Institute To Combine Scientists And Engineers

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for which we are deeply grateful."

The new institute will house the laboratories of about 25 MIT faculty members from the School of Science and the School of Engineering. Among the scientists are **Angelika Amon**, winner of the Waterman Award from the National Science Foundation as the nation's top young scientist or engineer, and **Phillip Sharp**, winner of the 1993 Nobel Prize in Physiology or Medicine. Engineering faculty include **Angela Belcher**, a MacArthur Award winner who was named Scientific American's Researcher of the Year in 2006. MIT Professor **Robert Langer** will also conduct his engineering research within the new Koch Institute. Langer's collaborative research efforts have led to numerous patented discoveries and novel ways to improve the clinical management of cancer. He was awarded the 2006 National Medal of Science.

Building on the advances in traditional areas of cancer exploration such as molecular genetics and cellular biology, the state-of-the-art facility will focus on five target areas of research at the intersection of biology and engineering, including defining the specific vulnerabilities of cancer cells by creating a complete "wiring diagram" of the key pathways that allow cancer cells to keep dividing and remain alive; engineering entirely new nanotechnology paradigms for cancer treatment; understanding how tumors evade immune recognition and developing methods to overcome these avoidance mechanisms, including more effective anti-cancer vaccines and other forms of immunotherapy; using powerful new tools to dissect the molecular and cellular basis for metastasis; and shifting the curve of cancer diagnosis and prevention to earlier and earlier stages using advances such as genomics, novel imaging agents, and micro-scale monitoring devices.

Tyler Jacks, the David H. Koch Professor of Biology at MIT, will serve as the director of the Koch Institute at MIT. "By housing leading cancer biologists with world-class engineers, we are creating a formidable team motivated to understand cancer and to do something about it. We expect to rapidly deliver important new tools

for oncologists and their patients," Jacks said. "Our goal is to make the David H. Koch Institute for Integrative Cancer Research the gold standard in interdisciplinary disease-focused research. Our organization will build an expanding and highly effective relationship network that also involves other academic oncology centers, industrial partners and cancer-focused foundations. Together we will dramatically expand our research and training efforts and seek to deliver powerful clinical solutions."

Koch, who holds bachelor's and master's degrees in chemical engineering from MIT, has personally pledged and contributed more than $400 million to a wide variety of organizations and programs that further cancer research, enhance medical centers, and support educational institutions, and sustain arts and cultural institutions. His contributions to MIT established the David H. Koch School of Chemical Engineering Practice, and he has been honored with the dedication of the David H. Koch Biology Building at the university.

* * *

OHIO STATE University Medical Center's Wright Center of Innovation in Biomedical Imaging received a $1.5 million grant from the NIH Foundation to study and establish imaging biomarkers, said **Michael Caligiuri**, director of the Ohio State University Comprehensive Cancer Center. **Michael Knopp**, chairman of the Department of Radiology, is principal investigator of the study. The grant will support one of the first projects of the Biomarkers Consortium, a public-private biomedical research partnership formed in 2006 by NIH, FDA, Centers for Medicaid and Medicare Services, and other industry and advocacy groups. The Ohio State project is part of an effort by the Cancer and Leukemia Group B to expand use of imaging markers within cooperative group trials. . . . **UNIVERSITY OF ARKANSAS** for Medical Sciences honored the late **Winthrop Rockefeller** by renaming its Arkansas Cancer Research Center for him during a groundbreaking ceremony for a major expansion to the facility. He was former Arkansas lieutenant governor and great-grandson of John D. Rockefeller. The Winthrop P. Rockefeller Cancer Institute will include a 12-floor, 300,000-square-foot addition for treatment and research space. The addition is expected to open in 2010. Also, the Winthrop Rockefeller Foundation gave a $12 million gift to the cancer institute that will fund a new leukemia and lymphoma program, said **I. Dodd Wilson**, chancellor of UAMS. The expansion is being funded in part by a law signed earlier this year to provide up to $50 million in matching funds to build the expansion as well as support patient care and research programs. Act 838 created a $36 million fund to provide a dollar-for-dollar match of private donations in support of the cancer center expansion and program endowments. . . . **HOWARD HIATT**, oncologist, professor of medicine at Harvard Medical School, and senior physician at the Brigham and Women's Hospital, received the 2007 Gustav O. Lienhard Award for the advancement of health care services from the Institute of Medicine. The award honors Hiatt for improving the performance of personal health services in the U.S. and around the world, said **Harvey Fineberg**, IOM president. Hiatt received his M.D. from Harvard in 1948 and has been on the Harvard University faculty since 1955, and with the Brigham and Women's Hospital since 1985. He was the first Herrman L. Blumgart Professor of Medicine at Harvard Medical School and was dean from 1972 to 1984 of Harvard School of Public Health. The award includes a medal and a $25,000 prize. . . . **ANDRE KONSKI** was appointed chief medical officer of Fox Chase Cancer Center Partners to expand the ability of Fox Chase and its community hospital partners to deliver regional care. Konski will work with **Paul Engstrom**, senior vice president for extramural research at FCCC, and **Steven Cohen**, associate medical director for FCCC Partners. Konski, who has been at Fox Chase since 2002, is clinical research director for radiation oncology and clinical director for the prostate cancer risk assessment program. . . . **SURESH RAMALINGAM** was named director of the translational thoracic malignancies program and acting assistant professor of hematology and oncology at Emory Winship Cancer Institute, said **Brian Leyland-Jones**, institute director, and **Fadlo Khuri**, section head of hematology and oncology. Ramalingam, who was at the University of Pittsburgh School of Medicine, is known for his work in lung cancer, esophageal cancer, and other thoracic cancers. He is principal investigator on several early phase clinical trials in lung cancers. . . . **DENNIS RUSCH** was named chief financial officer for City of Hope. He was area and group chief financial officer at South Texas Health System. Prior to that he was chief financial officer and vice president of finance at Roswell Park Cancer Institute. . . . **LEONIDAS PLATANIAS**, deputy director of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, was elected president of the International Society for Interferon and Cytokine Research. Platanias, the Jesse, Sara, Andrew, Abigail, Benjamin and Elizabeth Lurie Professor of Oncology, also is professor in the Division of Hematology and Oncology at the Feinberg School of Medicine.

In Brief:

Nobel Prize For Medicine Recognizes Gene Targeting

2007 NOBEL PRIZE in physiology or medicine was awarded to three scientists for developing the powerful technology known as "gene targeting."

The prize is shared by Mario Capecchi, of the University of Utah School of Medicine, Oliver Smithies, of the University of North Carolina at Chapel Hill, and Sir Martin Evans, of Cardiff University.

Mice developed with this technology are used for a wide range of medical research, from basic studies of biological processes to investigations of cancer, heart disease, cystic fibrosis, and other conditions. The technique enables scientists to breed mice with specific diseases and use them to test new treatments.

Capecchi's work uncovered the roles of genes involved in organ development in mammals, while Evans developed strains of gene-altered mice to study cystic fibrosis, the prize committee said.

Smithies created strains to study high blood pressure and heart disease.

NIH's National Institute of General Medical Sciences began supporting the work of Capecchi in 1968 and Smithies in 1973, providing nearly $20 million to support the two scientists.

The National Heart, Lung, and Blood Institute provided more than $19 million to support Smithies' research. He also received support from the National Institute of Diabetes and Digestive and Kidney Diseases and NCI.

The National Institute of Child Health and Health Development has provided more than $5 million to support the research of Capecchi's work.

* * *

FOOD AND DRUG ADMINISTRATION is seeking nominations from patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations to serve on the board of directors of the newly created Reagan-Udall Foundation.

The mission of the private, independent, nonprofit entity foundation is to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

The makeup of the 14-member board would be: four representatives from general pharmaceutical, device, food, cosmetic and biotechnology industries; three representatives from academic research organizations; two representatives from patient or consumer advocacy groups; one member representing health care providers; and, four at-large representatives with expertise or experience relevant to the purpose of the Reagan-Udall Foundation.

FDA, NIH, Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality have 30 days to appoint the board of directors. FDA will handle the submission process. Nine members are to be appointed from a list of candidates provided by the National Academy of Sciences, while five are to be appointed from lists of candidates submitted by the other organizations.

Nominations may be made to Lisa Rovin or Nancy Stanisic by fax to 301-443-9718, or e-mail Reagan-Udall-Board@fda.hhs.gov. The deadline is Oct. 15.

Federal Register notice: http://www.fda.gov/OHRMS/DOCKETS/98fr/oc07233-n000001.pdf.

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New SEER Monograph: NCI released "SEER Survival Monograph: Cancer Survival Among Adults: U.S. SEER Program, 1988–2001, Patient and Tumor Characteristics," which examines cancer survival by patient and tumor characteristics for more than 1.6 million adult cancers diagnosed during 1988–2001.

Survival data are from NCI's Surveillance, Epidemiology, and End Results Program and represent cancer in about one-fourth of the U.S. population. The tumor characteristics may include subsite, size of tumor, extension of the tumor, positive lymph nodes, distant metastases, and histologic type. The patient characteristics are age, race, and sex.

The monograph is available at http://www.seer.cancer.gov/publications/survival/.

Funding Opportunities

RFA-RR-07-003: Research on Research Integrity. R21. Letters of Intent Receipt Date: Oct. 20. Application Submission/Receipt Date: Nov. 20. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RR-07-003.html. Inquiries: Ann O'Mara, 301-496-8541; omaraa@mail.nih.gov.

RFA-RR-07-004: Research on Research Integrity. R03. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RR-07-004.html.

NOT-CA-07-022: NCI Will Participate in PAR-07-420, Lymphatic Biology in Health and Disease. R01. Full text: http://www.grants.nih.gov/grants/guide/notice-files/NOT-CA-07-022.html. Inquiries: Suresh Mohla, 301-435-1878 mohlas@mail.nih.gov.

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