THE CANCER LETTER

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FDA To Elevate Oncology To Office Level, Consolidate Most Cancer Programs

By Paul Goldberg

FDA last week announced a plan to consolidate the organizational structure for review of cancer products.

The plan requires little immediate action and is, for the most part, timed to kick in next April.

Agency officials said the implementation is pegged to the move of oncology medical reviewers from the FDA buildings in Rockville to the new campus in White Oak, Md., but observers noted that the timetable would allow the agency to make adjustments if Republicans lose the White

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In Brief:

NCI Advisors Complete Service On Board; Appelbaum Ends Term As BSA Chairman

NINE MEMBERS of the NCI Board of Scientific Advisors have completed their terms: **Mary Daly**, director of the Cancer Control Science Program at Fox Chase Cancer Center; **Herbert Kressel**, professor and chairman of radiology, Beth Israel Deaconess Medical Center; **Gilles McKenna**, professor and chairman of radiation oncology, Hospital of the University of Pennsylvania; **Enrico Mihich**, executive director for sponsored programs, Roswell Park Cancer Institute; **John Minna**, director of the Hamon Center for Therapeutic Oncology Research, University of Texas Southwestern Medical Center; **Nancy Meuller**, professor of epidemiology and associate director for population sciences, Dana-Farber/Harvard Cancer Center; **Ellen Sigal**, chairman, Friends of Cancer Research; **William Wood**, professor and chairman of surgery, Emory University School of Medicine; and **Robert Young**, president of Fox Chase Cancer Center. . . . **FREDERICK APPELBAUM**, chairman of the NCI Board of Scientific Advisors since 1999 and a board member since the board's inception in 1996, also completed his extended service. Appelbaum is director of the Clinical Research Division, Fred Hutchinson Cancer Research Center. . . . **UNIVERSITY OF PITTSBURGH Medical Center** has established the Hereditary Colorectal Tumor Program for high risk individual and their families. The program provides risk assessment, genetic counseling, prevention programs, clinical trials, and a full range of treatment options. "People who have a family history of colorectal cancer have about twice the risk of developing the disease compared to the general population," said **Linda Farkas**, clinical director,

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FDA To Hire Clinical Oncologist To Head New Cancer Office

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House in November.

Though changes contemplated by FDA could have profound impact on development of cancer drugs, the world outside oncology was not clamoring to hear the news. Attendance at the July 16 press conference was sparse, and the majority of questions to HHS Secretary Tommy Thompson, acting FDA Commissioner Lester Crawford, and NCI Director Andrew von Eschenbach focused on the unrelated, but apparently sexier, decision by HHS to allow Medicare coverage for treatments of obesity.

The FDA plan has the following features:

—The majority of the agency's cancer programs would be consolidated in a new office within the Center for Drug Evaluation and Research. The director of this office, a clinical oncologist, would have signatory authority over cancer drugs, but would report to a higher-ranking administrator.

—The office would include an "oncology program," which would address scientific questions, such as endpoints for approval of therapies, and interact with other units of FDA, NCI, as well as other agencies, professional societies, and advocacy and trade groups.

—The review of cell, gene, and tissue therapies will remain at the agency's Center for Biologics Evaluation and Research. Similarly, devices used in the treatment of cancer would remain in the agency's Center for Devices. Several groups, including the patient-run Cancer Leadership Council and the American Society of Clinical Oncology have asked the agency to wrap these units into the new oncology office. Devices haven't emerged as a political issue.

—FDA officials said agents for cancer prevention would fall into the purview of the new office. Today, applications that involve testing a therapy in healthy people end up in various areas of the agency, sometimes based on the organs of the primary tumor.

—FDA officials said that by the end of the summer, they would begin a search for the director of the new office.

Pressure To Consolidate

Over the past two years, the agency has been under considerable pressure to consolidate its oncology divisions. During Congressional hearings on the development of the ImClone Systems Inc. agent Erbitux, several members of the House Committee on Energy & Commerce directed FDA to harmonize its criteria for approval of biologics with those used for approval of drugs (**The Cancer Letter**, Oct. 18, 2002).

In an apparent response to that mandate, the agency transferred the cancer biologics division to CDER. However, cell, gene, and tissue therapies remained in CBER (**The Cancer Letter**, Oct. 10, 2003). Cancer groups, particularly the patient-run Cancer Leadership Council, asked for a complete consolidation, but agency officials have said consistently that such changes would not be feasible.

Separately, over the past year, NCI and FDA officials have been meeting regularly to explore potential areas of collaboration. These discussions appear to have produced several features of the plan announced by the agency.

Some groups, including Friends of Cancer Research, the American Cancer Society, and the American Association for Cancer Research, were willing to accept partial change offered by FDA. Others—including the American Society for Clinical Oncology—were determined to stick to the original position taken by CLC and seek complete consolidation of cancer programs.

Two weeks ago, ASCO President David Johnson wrote a letter to Crawford reiterating the society's view that all oncology programs—including cell, gene,

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and tissue therapy—should be wrapped into the new office (**The Cancer Letter**, July 9).

"Overall, we are pleased with what has happened," Johnson said to **The Cancer Letter.** "Sure, we would have liked to see it done somewhat differently, as outlined in our letter to the Commissioner. However, we think the plan is a good initial step. We think over time, this will evolve.

"We wrote our letter for a very specific purpose," Johnson said. "While I am sure not everybody in the cancer community would agree with what our letter said, we nonetheless felt it was important to clearly state ASCO's long-held views regarding FDA's proposed reorganization. We felt it was important to restate our thoughts on this prior to a public announcement of the plan. Had we not done so, it would have been difficult for us to dissent or to continue to be a valid, constructive adviser had the announced FDA plan been something less than what we felt was needed to improve the process of oncology product review."

Ellen Stovall, president of the National Coalition for Cancer Survivorship and one of the leaders of CLC, agreed.

"We believe that this announcement is a step in the right direction," Stovall said in a statement. "NCCS has worked for many years to achieve comprehensive FDA reform that would improve the process for review of all oncology products," Stovall added, "but to the extent that some oncology products remain in other parts of the agency, the job is not finished."

Other groups expressed unqualified support for the FDA move.

"We applaud this great news," Margaret Foti, CEO of AACR, said in a statement. "The AACR feels confident that this office will increase the clarity, consistency, and predictability of the clinical development pathway so that products could be brought to the patient in the most efficient manner."

Foti said the change is the result of collaboration between NCI and FDA.

Friends of Cancer Research, the Washington group that spearheaded an effort to garner support for the agency's plan, was similarly complimentary. "We feel that this FDA announcement is a vital first step that promises new hope and new science to patients in desperate need," the group said in a statement. "Moreover, we are encouraged by the FDA's plans to provide an evaluation mechanism that will gauge the effectiveness of these initial reforms for improving the FDA's approach to oncology products."

The Oncology Office

In a July 16 conference call with "stakeholders," John Jenkins, director of the CDER Office of New Drugs, said the new office would assemble "a critical mass of oncology experts in one office to coordinate and facilitate review to hopefully improve consistency, and also improve efficiency, with the overall goal of making it faster than ever to get products through the development cycle and through the approval process and out to patients."

Jenkins said the agency has decided that the office would contain three divisions, but offered no other details about the organization's structure.

"We have not finalized all the details about how the oncology office will be organized as far as the assignment of products and staff in that office," he said during the half-hour call with patient groups, professional societies, and pharmaceutical companies. "We expect to be making these decisions over the next couple of months."

The plan to divide the office into three units is typical for the Office of New Drugs, Jenkins said.

"We are planning to consolidate the review of drugs and biologics that are in the Center for Drugs for the prevention of cancer into the oncology office," he said.

The existing structure at FDA has no clear schema for review of applications for agents for cancer prevention. The need for standard procedure for development of agents for cancer prevention was one of the subjects that came up frequently during closed-door discussions with NCI, sources said.

"NCI has been very much in favor of that, since they currently hold many of the INDs for looking at drugs for chemoprevention," Jenkins said.

Jenkins didn't explain the rationale for leaving cancer cell, gene, and tissue therapies at CBER. Agency sources and outside observers say the move of these therapies would be challenging, in part because many scientists and reviewers combine cancer work with work on other diseases. In an earlier reorganization, last year, cancer biologics had been moved to CDER, and the loss of another component would leave the center only with the blood division, prophylactic vaccines, and the general medicine unit.

Jenkins said the agency's first step in the reorganization was to start a search for the office director.

"We expect to have that announcement out later this summer, and that will be both an external and an internal search to find what we expect to be an oncology-trained individual, but also and individual with impeccable credentials in clinical trials design and analysis, drug development and the regulatory aspects of bringing products to market for cancer," Jenkins said.

Jenkins said agency officials are yet to determine the criteria for selection of this official. "We have not sat down yet and actually defined the interview and selection process," he said. "We'll be working on that over the next several weeks."

The search would be both internal and external.

The move to White Oak "will allow all the new drug review staff to be in one place for the first time in many years, and we think that will bring a lot of excitement and synergy to our program," Jenkins said. "We hope by the time we are ready to move into that facility, we will have identified a new director for the oncology office and, hopefully, have that person on board."

Jenkins acknowledged that this timetable was optimistic. "We recognize that an external recruitment effort in the federal government can take some time, and, also, if we do select someone from outside the agency—say, someone from an academic position—they may need some time to close up their affairs at their current position before they come," he said.

The Oncology Program

The proposed oncology program would be housed in the oncology office and would coordinate cancer activities of other centers, Jenkins said.

Though it is unclear how this unit would be structured and what its authority would be, it has the potential to influence drug development, definition of endpoints for approval, and even Medicare reimbursement.

"This oncology program would be housed in the oncology office at the Center for Drugs, and will have cross-cutting agency responsibility to facilitate communication of the experts across the agency, provide a forum and an opportunity to discuss and develop regulatory policy and standards for approval of oncology products, and also serve as a primary focal point for our interaction and collaboration with outside stakeholders such as NCI and professional societies in the oncology arena," Jenkins said.

Jenkins said the agency's interaction with NCI is expanding.

"There has been a lot of work ongoing to streamline the communication and the handoff of information from NCI to FDA as we go from the discovery to the regulatory process," Jenkins said. "There are also initiatives underway that will be starting this fall for cross-training NCI staff in FDA procedures and FDA staff in some of the NCI scientific aspects. We think the collaboration is strong, and there are plans to make it stronger."

An earlier version of the reorganization plan that FDA floated in discussion with advocacy groups and professional societies called for creation of an oncology program that would have been independent from the oncology office, sources said.

Several outside groups objected to this split (**The Cancer Letter**, July 8). "[The policy role] should not be segregated from the product review and oversight function lodged in one person as the Director of either a Center or Office dedicated to cancer products," ASCO president Johnson wrote in a letter to acting FDA Commissioner Crawford. "[We] are convinced that the most efficient approach to the all-important policy function is to assign it to the same official who is charged with ongoing regulation of products."

It appears that this plan to separate policy from review and oversight has been abandoned by the agency.

Observers said the oncology program would be a logical point of interaction between FDA, NCI and CMS.

After FDA's approval of a generation of new, extraordinarily expensive cancer therapies, CMS has to decide how these agents should be reimbursed.

The agency recently initiated a "national coverage decision" on therapies for colorectal cancer, but has suspended that project indefinitely.

The coverage decision, which could have the effect of banning reimbursement for therapies in question, was initiated following approval of Camptosar and Eloxatin for colorectal cancer.

The price of treating colorectal cancer has increased by billions of dollars following approval of Avastin and Erbitux (**The Cancer Letter**, March 5). Similar increases are occurring in the cost of treating lung cancer, another big-ticket item for Medicare.

A troika of federal bureaucracies—CMS, NCI and FDA—would likely be needed to generate the data that could support limits on the use of these new drugs, and the agencies appear to be moving toward this common goal, observers say.

Recently, NCI expressed an unusual level of interest in health care delivery, and has made formal collaboration agreements with both CMS and FDA.

CMS, too, has been reaching out for help. At ASCO's annual meeting last month, CMS Administrator and former FDA Commissioner Mark McClellan said his agency needed guidance from oncologists in assessing new cancer-treatments.

"One of the goals is to make sure that we are developing reimbursement frameworks that are appropriate for the new kinds of treatments that are coming along for cancer care," McClellan said at the time (**The Cancer Letter**, June 11).

NCI Programs:

Cancer Genetics Network Ends, Contractor To Maintain Data

By Kirsten Boyd Goldberg

The NCI Board of Scientific Advisors approved the Institute's plan to provide $11.7 million over five years to fund a "streamlined" version of the Cancer Genetics Network, established in 1998 as a national network of centers specializing in the study of inherited predisposition to cancer.

NCI plans to issue a Request for Proposals to seek a contractor to maintain support for the CGN's database of 24,000 individuals with cancer or a family history of cancer. The contract also will maintain biospecimens and enrollee follow-up.

The grants to the eight centers funded six years ago under the CGN will not be recompeted. The NCI Executive Committee decided not to reissue the RFA last December, and the BSA concurred with the recommendation last March. A BSA subcommittee said the network's productivity was "modest" and its use by outside investigators was "inadequate" considering the cost, which was about $6 million a year for the centers and $1.3 million a year for informatics.

The network failed for organizational reasons, NCI officials said. "This wasn't well and appropriately staffed," said Robert Croyle, director of the NCI Division of Cancer Control and Population Sciences, who was a CGN investigator at University of Utah when the program began. "It is now, but it's too late."

Also, there wasn't clear communication between the investigators and NCI, Croyle said to the BSA at its June 24 meeting. "The PIs felt like the mission of the CGN changed."

The CGN was the Institute's first large network initiative begun under the tenure of former director Richard Klausner. "Other ones, the Director's Challenge, the Cancer Genome Anatomy Project, were quite successful," Croyle said. "We didn't hit 100 percent. This could have been done better."

BSA member Nancy Mueller, professor of epidemiology and associate director for population sciences at the Dana-Farber/Harvard Cancer Center, said NCI's action was an appropriate response to the board's review of the CGN. "This has been a painful cut," she said. "It's important for NCI to look at why this didn't work."

In a report last year, the National Cancer Policy Board recommended that when NIH funds large projects, it "should strive to avoid trying to figure out how to organize" the project during the funding period, but plan ahead so that grantees "can get on the field and get going," Mueller said.

The RFP concept "really is a streamlining," Mueller said. "It's anorexic."

NCI plans to do a better job of promoting the availability of the database to researchers, said program director Carol Kasten.

The original network centers and principal investigators were:

—Duke University Medical Center, J. Dirk Iglehart, in collaboration with the University of North Carolina, Chapel Hill, and Emory University.

—Fred Hutchinson Cancer Research Center, John Potter, in collaboration with the University of Washington School of Medicine.

—Georgetown University Lombardi Cancer Center, Caryn Lerman.

—Johns Hopkins University, Gloria Petersen, in collaboration with the Greater Baltimore Medical Center.

—University of California, Irvine, Hoda Anton-Culver, in collaboration with the University of California, San Diego.

—University of Pennsylvania, Barbara Weber.

—University of Texas M.D. Anderson Cancer Center, Louise Strong, in collaboration with the University of Texas Health Science Center, San Antonio, University of Texas Southwestern Medical Center, Dallas, and Baylor College.

—University of Utah, Raymond White, in collaboration with the University of Colorado, and University of New Mexico.

The Informatics Technology Group, which handled the CGN information exchange and data

management and statistical needs, has been based at University of California, Irvine, Massachusetts General Hospital, and Yale University.

The BSA approved the concept for a streamlined CGN on a vote of 16-0, with five members abstaining due to involvement in the program. The excerpted text of the concept statement follows:

Streamlined Cancer Genetics Network. Concept for a new RFP, one award with 17 subcontracts, first-year set-aside $2.2 million, total $11.7 million over five years. Program director: Carol Kasten, Division of Cancer Control and Population Sciences.

The objective of this RFP concept is to maintain the CGN for future research, while reducing its costs. The most valuable and critical CGN functions will be maintained. Some of these functions include: (a) the database of over 24,000 enrollees and biospecimens accumulated over CGN's six years. These resources must be well curated in order that they are available for investigators to use in future research projects; (b) annual follow-up on enrollees; (c) involvement of the current PIs for maintaining IRB approvals, making contact with study participants, directing the annual follow-up, access to enrollees, writing IRB applications for collaborations and other required functions.

Some of the current CGN functions will be dropped for efficiency. These include (a) new enrollments that are not paid by funded, peer-reviewed grants; (b) infrastructure resources that were utilized for multiple studies and core enrollment; and (c) the pilot studies research mechanism.

A marketing plan will be developed by NCI and the contractor to increase visibility of the CGN and knowledge throughout the research community of how its data may be used and its ability to make available study participants for a wide range of research studies. The objective will be to increase the number of research projects that use the CGN. Proposed projects that will utilize the research must go through peer-review and be funded. The requested length of the RFP, five years with the option of an additional two, is needed to accommodate the grant cycle.

The proposed contract also will accommodate the needs of several ongoing or proposed studies including the Sibling Study of Inheritance of Colon Cancer, which is a CGN pilot study. The investigators plan to submit an R01 application this October. The Ovarian Cancer Screening Study in High Risk Women is also a CGN pilot. It is the only screening study in the U.S. or Europe that will provide data on high-risk women. An R01 from this pilot will be reviewed this summer. A new collaborative study, the Identification of the Susceptibility Genes for Renal Cell Carcinoma Study has IRB approval, funding, and awaits finalization of contracts with the CGN centers. The collaborators include Bert Zbar, Joan Bailey-Wilson, and Marston Linehan.

The budget proposed for the streamlined CGN represents 26.4 percent of the five-year total costs of the current CGN grants ($44.4 million).

The RFP will mandate a change in management structure. The current CGN structure consists of eight participating centers funded under and U24 mechanism with an additional seven sites subcontracting to three of the centers. There are three ITG centers funded using a U01 mechanism. One ITG center manages the core database. Another ITG center, the statistical coordinating center, manages all aspects of the CGN pilot studies. The third ITG center, the software center, developed the TrialDB software for CGN. It is used for all CGN databases and pilot projects. This center develops new software for new research studies as needed. TrialDB, developed with CGN funding, will be a part of NCI's CaBIG products.

The streamlined CGN will have one Statistical Coordinating Center, which will serve as the hub for all streamlined CGN functions. The new SCC will subcontract to the participating centers, their sites, and the software ITG center. One of the ITG centers will be dropped. In the RFP, the new SCC will be the only center where the CGN core database and data from the CGN pilot studies will be curated. The future CGN will include only the current CGN centers and sites. The new SCC must be one of the two data centers in the original CGN. The reason is the CGN database and access to its enrollees cannot be transferred to the NCI. Enrollees from each of the participating centers can be contacted for any future study only by the PI from the center where they were consented and enrolled.

The new SCC will perform many of the functions that the current CGN SCC now undertakes. It will maintain both a public and private website. It will monitor annual follow-up and develop semi-annual CGN newsletters to provide feedback to the enrollees. These newsletters will be mailed out by the centers and sites. It will complete a web-based central database that permits form entry via scannable forms

from all CGN centers and sites. All documents will be stored on the CGN private website. It will track all biospecimens using TrialDB. The SCC will respond to queries from outside investigators using the new, unified CGN database and maintain enrollee anonymity. It will coordinate statistical support and protocol development for funded, peer-reviewed outside investigators.

The new SCC will also work with NCI in implementing the marketing plan for the streamlined CGN. It is essential that this research resource be utilized to the fullest extent possible. Therefore, implementation of the required aspects of the marketing plan by the SCC will be written into the RFP.

Funding Opportunities:

Leukemia/Lymphoma Scholar In Clinical Research

Preliminary Application Due Date (submitted via Web site): Sept. 15

Complete Application Due Date: Oct. 1

Leukemia & Lymphoma Society, as part of its Career Development Program, has instituted an addition to its Scholar Program. The Scholar in Clinical Research award will be given to individuals who have demonstrated, over a period of not less than three years, their ability to design and conduct original clinical research on leukemia, lymphoma, and myeloma.

Applicants should hold the position of assistant or very early associate professor or its equivalent. Applicants should have primary involvement in the development and implementation of clinical research concerning prevention, diagnosis or treatment of the lymphohematopoietic malignancies. Applicants should propose early-stage clinical studies that test new hypotheses regarding the management of these malignancies. The proposed studies should translate new concepts and basic science discoveries into clinical practice. The investigative approaches can be based on molecular, cellular, epidemiologic or integrated systems findings.

The Award will provide $110,000 annually ($105,000 for salary and benefits and $5,000 for institutional costs), renewable for five years (total award $550,000), based on annual review of progress.Application form and instructions are available at www.LLS.org.

Inquiries: director of research administration, Leukemia & Lymphoma Society, 1311Mamaroneck Ave., White Plains, NY 10605; phone 914-821-8859; e-mail researchprograms@TLLS.org.

Program Announcement

PA-04-126: Supplements to Promote Reentry into Biomedical and Behavioral Research

NIH announces a continuing program for administrative supplements to research grants to support individuals reentering an active research career after taking time off to care for children or attend to other family responsibilities. It is anticipated that at the completion of the supplement, the reentry scientist will be in a position to apply for a career development K award, a research award, or some other form of independent research support. In all cases, the proposed research must be directly related to the funded approved ongoing research of the parent grant or cooperative agreement. The individual supported under this supplemental award must be afforded the opportunity to act as a full participant in the research project and must be given an opportunity to update and enhance her or his research capabilities. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-126.html.

Inquiries: For NCI—Bobby Rosenfeld, senior program analyst, Comprehensive Minority Biomedical Branch, phone 301-496- 7344; fax 301-402-4551; e-mail roberta.rosenfeld@nih.hhs.gov.

RFP Available

RFP PHS-2005-1: A Solicitation of the Public Health Service for Small Business Innovation Research Contract Proposals

Response Due Date: Nov. 5, 2004

NIH and Centers for Disease Control and Prevention are soliciting proposals from small business concerns that possess the research and development expertise to conduct research that will contribute to the program objectives of the agencies. The SBIR Phase I Contract Solicitation will only be available via electronic means at the NIH Small Business Funding Opportunities home page at http://grants.nih.gov/grants/funding/sbir.htm.

NCI is specifically interested in: Virtual Microscopy for the Early Detection of Cancer; Development of a Database and Candidate Gene,

Protein, and Biochemical Pathway Nomination Software for Tobacco-Related Disease and Tobacco Addiction Investigations; Plant Genomic Models for Establishing Physiological Relevance of Bioactive Components as Cancer Protectants; Metabolomics for Early Cancer Detection; Methods for Innovative Pharmaceutical Manufacturing and Quality Assurance; Synthesis Modules for Radiopharmaceutical Production; Targetry Systems for Production of Research Radionuclides; Establishment of Benchmark Data Sets for Radiotherapy Quality Assurance; Using Social Marketing to Disseminate Evidence-based Energy Balance Intervention Approaches to Worksites; Developing Item Response Theory Software for Outcomes and Behavioral Measurement; Integrating Patient-Reported Outcomes in Clinical Oncology Practice; Portable - Technology Tools For Real-Time Energy Balance Research; Systems to Enhance Data Collection and Medication Compliance in Clinical Trials.

The RFP is available at www.fbodaily.com/archive/2004/07-July/14-Jul-2004/FBO-00618969.htm.

Inquiries: NIH Office of Extramural Programs Office of Extramural Research, phone 301-435-2688.

In Brief:

UPMC Forms Hereditary Colorectal Tumor Program

(Continued from page 1)

Hereditary Colorectal Tumor Program, and assistant professor of surgery, Division of Surgical Oncology. "By identifying individuals and families at high risk for colorectal cancer, we can start their screening earlier, follow them more closely and treat them as soon as they show evidence of disease. Early treatment, in turn, may translate to a lower mortality rate in this group." The program will serve individuals with a personal or family history of colorectal or endometrial cancer diagnosed before the age of 50, families with multiple generations affected by colorectal cancer, persons of Ashkenazi Jewish decent with colorectal cancer, individuals with multiple cancers (colon and ovarian, or more than one colon cancer); persons with a personal or family history of HNPCC; and first-degree relatives of those who may be a genetic carrier of colorectal cancer. Besides Farkas, the staff includes **Joseph Kelley**, a specialist in gynecologic oncology, and two genetic counselors, **Darcy Thull**, and **Dana Farengo-Clark**. Other program staff includes a pathologist and three basic science researchers. Clinical program staff members coordinate contact among family members and their physicians as well as provide information about cancer risk, screening and genetic testing. . . . **CANINE GENOME** sequence has been assembled and deposited into free public databases by the National Human Genome Research Institute. **Kerstin Lindblad-Toh**, of the Broad Institute, Massachusetts Institute of Technology, and Agencourt Bioscience Corp., Beverly, Mass., led the team which assembled the genome of the domestic dog (Canis familiaris). The team chose the boxer to sequence, because the breed had the least amount of variation and would provide the most reliable reference genome sequence. The data is available at GenBank, www.ncbi.nih.gov/Genbank, and other public databases. . . . **FOGARTY INTERNATIONAL CENTER**, NIH, said 21 fellows from 16 U.S. medical schools and one school of public health are the recipients of its Fogarty-Ellison Fellowship in Global Health and Clinical Research. In the new program, U.S. and developing country graduate students in the health professions participate in one year of mentored clinical research at an NIH-funded research center in a developing country, said **Sharon Hrynkow**, acting director of FIC. Research scholar partnerships are created by pairing the U.S. students with students from the host country. The 14 institutions selected for the initial fellowship year are located in Botswana, Brazil, Haiti, India, Kenya, Mali, Peru, South Africa, Thailand, Uganda, and Zambia. FIC, The Ellison Medical Foundation and the NIH National Center on Minority Health and Health Disparities support the fellowship program. The Association of American Medical Colleges and the Association of Schools of Public Health provide support for recruitment, review, and matching. . . . **MICHAEL STEINBERG** was appointed to a two-year term as a voting member on the Center for Medicare and Medicaid Services Medicare Coverage Advisory Committee. Steinberg practices at the Santa Monica Cancer Treatment Center, Santa Monica, Calif. He is an elected member of Board of Directors of the American Society of Therapeutic Radiology and Oncology. The committee conducts reviews of medical literature, execute technical assessments and evaluate data sets on topics regarding effective and appropriate medical services, and items covered or eligible under Medicare.

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