THE CANCER LETTER INTERACTIVE

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ODAC Recommends Iressa Approval As Third-Line Lung Cancer Treatment

AstraZeneca had a plan for developing its small molecule agent Iressa as a treatment for lung cancer:

The company was going to seek accelerated approval based on a phase II study of the agent as a third-line treatment for non-small cell lung cancer. The application was to be supported by data from randomized trials of the agent as a front-line treatment.

Soon after getting the drug on the market under accelerated approval, the company planned to return to FDA and seek approval for the more lucrative front-line indication.

Had things worked out as envisioned, the application for Iressa would

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In Brief:

Bush Nominates Health Policy Advisor Mark McClellan For FDA Commissioner

MARK McCLELLAN, a senior White House health policy advisor, was nominated Sept. 25 by **President Bush** for FDA Commissioner, ending a 20-month search to fill the position left vacant when Clinton appointee **Jane Henney** resigned.

McClellan, who earned his medical degree from Harvard Medical School and received an economics degree from the Massachusetts Institute of Technology, helped develop Bush's Medicare reform and prescription drug benefit proposals. McClellan is a native of Austin, Tex., and graduated from the University of Texas with degrees in English and biology. He practiced as a physician at Stanford University, where he also taught health care economics, before joining the Administration.

"We live in an era where sound public policy depends on informed analysis and scientific knowledge combined with strong, compassionate leadership. Dr. McClellan would bring all of those attributes to the FDA," HHS Secretary **Tommy Thompson** said. "Dr. McClellan has a strong background in medicine, science, public policy and economics. This experience would serve him well at the FDA as it continues its efforts to create a more responsive FDA, enabling it to better serve the needs of the American people with even greater efficiency and greater scope."

McClellan appears to have broad support in Congress. The Senate previously confirmed him for the President's Council of Economic Advisers. "Dr. McClellan has impressive credentials both as a physician

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ODAC: Some Patients Appear To Benefit, Side Effects Mild

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have been a no-brainer for FDA. The agency would have approved it the way it approved Gleevec, Eloxatin, and Tricenox, without consulting the Oncologic Drugs Advisory Committee.

Unfortunately, clinical trials are unpredictable business. Last month, the company announced that its two randomized trials of Iressa in two-drug regimens used in the front line treatment of lung cancer showed no advantage to adding Iressa.

"We were rolling along on our merry way here in our division," said Richard Pazdur, director of the FDA Division of Oncology Drug Products. "And then we were floored when the two large studies came into play."

Usually, drugs are first approved for later stages of cancer, then advanced toward the front line. In the case of Iressa, the chessboard looked different: the agent was check-mated twice in the front line.

Did it matter that the third-line trial tested Iressa as a single agent, while front-line trials tested it in combination with standard chemotherapy? If there has ever been a reason to convene ODAC, this was it.

On. Sept. 24, ODAC voted 11-3 that Iressa's response rate constituted sufficient grounds for accelerated approval. The debate that preceded the AstraZeneca victory was filled with sharply worded exchanges that sent chills down the spines of FDA-watchers.

The committee appeared to be influenced by the fact that some patients appeared to benefit from the therapy—the company claimed a 10-percent objective response rate—and that Iressa's side effects were mild. FDA's action in the Iressa application as likely to determine the future of other EGFR suppressors.

If Iressa is allowed on the market, competitors—Genentech Inc. and Abgenix—may find it more difficult to conduct clinical trials of their EGFR suppressors. If they, too, receive FDA approval, competitors would be vying for a cut of AstraZeneca's market.

FDA Pushes For Randomized Trials

The agency's questions about Iressa were consistent with its efforts to convince sponsors to conduct randomized trials as a basis of accelerated approval (**The Cancer Letter**, Sept. 6).

If the agency takes ODAC's advice, Iressa will become the 14th cancer indication to receive accelerated approval since the program began in 1995. All but one of these agents were approved on the basis of phase II studies.

In a nutshell, AstraZeneca found itself trying to convince ODAC and the agency that the results of its two well-designed phase III studies in the first-line treatment of non-small cell lung cancer were not germane to the application for third-line indication. This was a difficult argument to make, considering that a positive result would have likely been used to support the application.

George Blackledge, AstraZeneca's clinical vice president for oncology, said he was in no position to offer any hypothesis to explain the disappointing results of the two front-line studies. However, he offered two observations: Iressa is likely to work as a single agent, and not in combination with cytotoxic chemotherapy, and that no three-agent regimen has ever been proven to work in lung cancer.

At the same time, AstraZeneca officials argued that therapies like Iressa are markedly different from cytotoxic chemotherapy.

To support this claim, company officials spoke with Larry Norton, a breast cancer specialist at Memorial Sloan-Kettering Cancer Center. His opinion appeared on one of the slides:

"I think we are seeing a pattern emerge that is

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really (paradoxically) quite hopeful. We've said that these new therapies are dramatically unlike chemotherapy, but we've tried to develop them as if they were. Now we know they are not, and Iressa has to be used following different paradigms."

To qualify for an accelerated approval, drug companies have to show that tumor shrinkage is likely to be associated with a tangible benefit to patients. To support that claim, Zeneca presented the results of a survey that asked trial participants to assess their symptoms.

FDA staff found the survey unconvincing in the absence of a randomized trial. The agency also argued that the trial allowed the use of a variety of treatments to control symptoms of advanced lung cancer. These included painkillers, steroids, oxygen, antidepressants, antibiotics, and blood transfusions. Though these treatments may have had an effect, the data didn't track this.

"I think interpreting symptomatic response data in this type of a setting is treacherous," said Thomas Fleming, chairman of the Department of Biostatistics at the University of Washington, a consultant to ODAC. "It's long been recognized to be treacherous.

"It's an open-label trial. Pseudo-effects clearly exist. The fact that there are some immediate improvements may well be due in part to therapy. Response can simply be a marker for intrinsically better patients who would have had a better symptomatic outcome even without treatment," Fleming said.

"These data may well provide clues and encouragement for doing a properly controlled trial," Fleming said.

The committee agreed with Fleming, rejecting AstraZeneca's quality of life data. In a 9-5 vote, ODAC upheld FDA's view that "the relevance of the symptom improvement data…cannot be adequately evaluated without a randomized, blinded study with an adequate control arm."

However, clinicians on the committee noted that Iressa appeared to offer a clinical benefit.

"I don't know of anyone with non-small-cell carcinoma whose cancer went away by itself, or who had a partial response by itself," said Donna Przepiorka, an oncologist at the University of Tennessee and the new chairman of ODAC. "It's very clear that there is activity here, and, very clearly, 10 percent is pretty substantial as a third-line agent. I don't know that you could say 'for *all* non-small-cell lung cancer.' I think that's where some difficulty may lie. But, very clearly, there are patients who have derived clinical benefit from treatment with Iressa."

Iressa's low and manageable toxicity is a factor, too, said ODAC member David Kelsen, chief of gastrointestinal oncology at Memorial Sloan-Kettering Cancer Center. "Ten percent activity in third-line therapy in a variety of solid tumors is meaningful," Kelsen said. "Whether this is a surrogate for a higher level of benefit is difficult to say today, but it is a surrogate for activity. Risk-benefit profile for this agent is substantially better than the risk-benefit profile for irinotecan or oxaliplatin.

What Happened on the Front-Line?

The magnitude of the response rate was acceptable to FDA, Pazdur said.

"We are not asking about a 10 percent response rate," he said. "We have approved drugs on 12 percent response rates. If we didn't have these two [front-line] trials, we would have approved the drug and be on our merry way. We *have* this data here. We can't just ignore it.

"We have to take a look at the whole data package. The question here is not the 10 percent response rate; it's in the context of two other trials that are front-line trials. The observation that this drug doesn't work with chemotherapy is an *observation.* It is not an *explanation!*

"And I have not heard from the sponsor a viable explanation of why these trials have failed. If they would like to get up now and give it, I would like to hear it. George…"

BLACKLEDGE: I can hypothesize as well as anyone else. It's very clear that whatever effects you are seeing with doublet chemotherapy, you cannot, it appears, add to.

And that appears to be the case whether it's another chemotherapy agent, or whether it's a novel agent of this kind. I don't have an explanation yet, and I don't think anyone else does.

All I can say is, it does seem to be an emerging pattern for both chemotherapy agents added as a triplet, and also for novel agents. While I don't think we could ignore the data, I do think it looks like an extraordinary different situation from where we have clearly seen non-cytotoxic agents giving real benefit as monotherapy in various situations, when they haven't shown any additional benefit in combination. I think that once you must take these data into effect, used as a monotherapy, for clinical benefit and for response, it's a very, very different situation.

PAZDUR: One of the problems that I see with that answer, George, when you take a look at this drug, when it's favorable to your situation, you may look at it as a chemotherapy drug. When it is not favorable to your situation, you take a look at it as a special agent, which is somewhat perplexing to me. I am fully aware of the doublet/triplet information in lung cancer.

The question here, we have no other situation that I know of in medical oncology, and I am having a tremendously difficult time trying to figure out why, in a first-line setting, you would not have some effect.

Obviously, AstraZeneca has gone on an extensive development program, not only in lung cancer, but in a myriad of diseases, with chemotherapy and this agent. I assume, based on some pre-clinical rationale. We got the results of this trial, and it has thrown a tremendous monkey wrench. What's the explanation?

That's the essence of this question, and that's what needs to be discussed here. Not the 10-percent response rate. I don't know how low is low, and how low you can go… The first-line data is the crux of why we brought this drug to the committee.

ROBERT TEMPLE [director of the FDA Office of Drug Evaluation I]**:** Could I add just briefly to Dr. Pazdur's question for the sponsor? If the sponsor didn't anticipate that the two first-line studies would, in fact, provide a validation of the surrogate effects, justifying the accelerated approval, what was the strategy? Essentially, the accelerated approval strategy indicates that post-marketing studies would usually be under way, so if you prospectively—before you saw the results of the first-line trial—already knew that those results weren't going to be relevant to efficacy in third-line, what third-line, comparative, randomized studies were already underway as the basis for validating this accelerated approval in third-line?

BLACKLEDGE: We had no randomized third-line studies underway, and the reason for that is that when we planned study 39, we discussed extensively with our investigators about the possibilities of randomization, and they advised us that within the context of the U.S., that would be extremely difficult to carry out. In addition to that, the studies that we carried out in third line were validation of phase I data, where we unexpectedly saw responses. Now, we are clearly faced with a difficult situation. Obviously, none of us expected the results that we saw in the [first-line] studies. I don't believe that it [has impact on] the responses that we see and the strong, suggestive evidence of clinical benefits linked to those responses.

TEMPLE: Just in completing the response to this response, your approach in the [first-line] trials is remarkable. You did a remarkable effort to come forward with outstanding trials to establish whether there was effect on survival and other clinical endpoints in first line. As a result, it seems to be a paradox that you have mounted the accelerated approval in third line without any backup plan for how you are going to validate, as accelerated approval requires. It surely leads me to think that you actually were anticipating a favorable result in [front line] that would serve as a basis for validating. In which case, if we then took this logic to the limit, we would say, 'You did view that there would be relevance to what you see in first line to third-line indication.'

BLACKLEDGE: We have never linked the third-line submission with the first-line submission. Clearly, if there was a positive result, we would have been very pleased with that, and so would the patients. But this is not the only clinical trial program that we are carrying on. We are carrying on trials with monotherapy in adjuvant situations, we have maintenance studies going on, and we would be more than happy to attempt to validate the data that we have seen today in a randomized setting.

JOHN CARPENTER [ODAC member and professor of medicine at the University of Alabama at Birmingham]: It seems very clear that slow, indolent tumors are the ones that get better here. I think there is a whole flood of studies that can be done to elicit out the way you use this drug. You could study performance status 2 versus anything, since nothing else works very well. I think there is a study in older patients. We could use it in a short period, before front-line chemotherapy, with a crossover. You can use it as an adjuvant, with a placebo control after front-line chemotherapy to sort this out. All these things are easily doable studies. I am going to come out in favor of making this available, with the proviso that a bunch of studies of just how to use this drug need to be done and should be done.

PRZEPIORKA: I have to weigh in with Dr. Carpenter. I think it's very clear that there is a clinical benefit in the single-arm study. I think the questions being asked in randomized studies are completely different questions. I am not sure we actually know that the inhibition of the kinase is actually the mechanism of action that this drug uses, because there

doesn't seem to be any correlation for EGFR expression. And I don't know that anybody right now could actually answer your question about why the combination does not work, because I don't think we have enough information available.

TEMPLE: We would ordinarily have been comfortable with the [10-percent] response rate. Should we not be comfortable anymore because of the [first-line] trials?

PRZEPIORKA: With all due respect to the statisticians, I think what we heard from the clinicians, from the sponsor, and the committee discussion, is we don't think the results of the randomized trials are that critically relevant to our opinion of the single-arm trial.

Philanthropy:

Avon Foundation Awards $30 Million In Grants

The Avon Foundation earlier this week said it will award $30 million in grants to 13 organizations.

Among the 13 grants is a $4.1 million gift to create the Avon-American College of Radiology Imaging Network "Partnership for Better Breast Imaging" to fund a two-year fellowship for a radiologist to train in breast imaging. Funds will also be used for a trial to evaluate breast ultrasound as a breast cancer screening tool in high-risk women.

Another grant recipient is the National Breast Cancer Coalition Fund, which will receive $2.4 million to expand the Project LEAD (Leadership, Education and Advocacy Training) program. Project LEAD provides training seminars for breast cancer advocates on scientific, medical, and legislative developments to enable them to better serve the breast cancer community.

"This new funding enables the National Breast Cancer Coalition to continue to educate advocates on the science of breast cancer and effective advocacy, leading to better breast care and medical research," said Fran Visco, NBCC president. "As a result of this generous gift from Avon, more women will directly benefit from better care and advanced research."

Cicatelli Associates/Avon Breast Care Fund was awarded a grant of $8 million to expand community-based programs that provide breast cancer education and access to low-cost or no-cost screening services to underserved women. The fund plans to increase its support to 115 programs.

Additional grants include:

—Avon-Centers for Disease Control and Prevention "Mobile Access Program." The grant of more than $4 million will fund at least four mammography vans for existing local and state screening programs for medically underserved women through the National Breast and Cervical Cancer Early Detection Program.

—American Association for Cancer Research Global Breast Cancer Education and Research Initiative. The $2.785 million grant will support the Avon Foundation-AACR Global Collaborative in breast cancer research and education among scientists and advocates in the U.S., Eastern Europe, Latin America and Asia, with particular focus on young scientists.

—Y-Me National Breast Cancer Organization: The $2.5 million grant expands the Y-Me support of Latina, Chinese, and Vietnamese women.

—Avon Breast Cancer Therapeutic Vaccine Initiative. A grant of $2.5 million will enable the Fred Hutchinson Comprehensive Cancer Center in Seattle and the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University in Baltimore to develop a comprehensive, clinically-oriented program in cell-based breast cancer vaccine therapy and other approaches to immunotherapy treatment.

—Cancer Research Institute, $250,000 to support research on antigens.

—Joan and Sanford I. Weill Medical College of Cornell University, Meditation and Healing Project, $250,000.

—Cancer Research Network, $150,000 to form a research agenda and pilot studies in complementary care for breast cancer patients.

—New York Presbyterian Hospital, Avon Women's Health Scholar, $150,000.

—The Children's Treehouse Foundation, $95,000.

—Howard University Cancer Center, $50,000.

The Kiss Goodbye to Breast Cancer Awards honored individuals and corporations who have led the fight against breast cancer. These included:

Medical Advancement: Craig Jordan, director of the Lynn Sage Breast Cancer Research Program at the Robert H. Lurie Comprehensive Cancer Center at Northwestern University.

Community Advocacy: Y-Me National Breast Cancer Organization, Margaret Kirk, CEO.

Media Leadership: The New York Times

Public Policy: Sen. Mary Landrieu

NIH News:

Study Seeks 50,000 Sisters Of Women With Breast Cancer

Researchers funded by the National Institute of Environmental Health Sciences have begun the Sister Study to gather information on the causes of breast cancer.

The study plans to enroll 50,000 women ages 35-74 whose sisters have been diagnosed with breast cancer. Sisters of women with breast cancer are known to have up to twice the risk of other women to develop breast cancer.

The first phase of recruiting began in Tampa at the Sept. 21 Race for the Cure. A similar effort will kick off recruitment in Phoenix, at its Oct. 13 Race for the Cure, then St. Louis, and Providence, RI. The initial recruiting goal for the four cities together is 2,000 participants over the next six to nine months.

Dale Sandler, acting chief of the NIEHS Epidemiology Branch, and Clarice Weinberg, chief of the NIEHS Biostatistics Branch, are the principal investigators in this study.

Besides collecting biological and environmental samples from participants, the study will use questionnaires to gather information about health histories, environmental exposures, and lifestyles.

For further information: www.sisterstudy.org.

UC Davis To Coordinate Asian American Network

University of California, Davis, School of Medicine is the new national headquarters for the Asian American Network for Cancer Awareness, Research and Treatment, a five-year, $7.6 million project funded by NCI to develop awareness and prevention programs for segments of this population.

The UC Davis Department of Epidemiology and Preventive Medicine and UC Davis Cancer Center will coordinate the efforts of researchers at six other cancer centers, including Dana-Farber Cancer Institute, Herbert Irving Comprehensive Cancer Center, Solove Cancer Research Center, Fred Hutchinson Cancer Research Center, UCSF Comprehensive Cancer Center, and Jonsson Comprehensive Cancer Center at UCLA.

While Asian Americans have a relatively low risk of cancer overall, they suffer disproportionately from several forms of the disease. Asian Americans and Pacific Islanders are three times more likely than whites to die of liver cancer, and twice as likely to die of stomach cancer. Moon Chen Jr., associate director for cancer prevention and control at UC Davis Cancer Center, is the principal investigator for AANCART nationally.

Letter to the Editor:

SEER Expects To Lower Black Cancer Incidence Rates By 3%

I am writing to correct a few statements that could be misinterpreted or misconstrued in an otherwise thorough and detailed article on cancer rates in the Sept. 20, 2002 issue (Vol. 28, No. 34) of **The Cancer Letter**.

SEER's overall cancer rates are usually based on 10% to 14% of the U.S. population and not just the metropolitan Atlanta region. Therefore, the SEER rates are much more stable and reliable. This point was lost by the focus on a population problem in just one geographic area.

Death rates we report are based on 100% of the U.S. population. Consequently, upon receiving final Census counts, we expect U.S. SEER cancer incidence rates for the 1995-1999 period to decrease about 3% for blacks and about 1% for whites. We expect cancer death rates for the entire U.S. to decrease even less. This is markedly less than the 18% adjustment for blacks in metropolitan Atlanta, and less of a problem nationwide than might be inferred by parts of the article.

We want to point out one factual inaccuracy: the projected estimates of the white population in Atlanta made by the U.S. Census. For the late 1990s, these overestimates are approximately 3% rather than the substantially larger figure of 10% you reported.

Also, readers glancing at the headline could construe that NCI estimates were "faulty" or broken. They may better be described as estimates based on a system that has inherent limitations. NCI continuously adjusts its rates to reflect the best information available each year, including the latest Census estimates. You accurately reported why it is so difficult to calculate an exact rate based on changing Census estimates, but this view was not reflected in the title of the article.

Brenda Edwards
Associate Director, Surveillance Research Program, NCI Division of Cancer Control & Population Sciences

Funding Opportunities:

Program Announcement

PA-02-169: Integrating Aging and Cancer Research

National Institute on Aging and NCI invite R01 applications for studies across the scientific spectrum of cancer control for early detection, diagnosis, prevention, treatment, prognosis and survivorship in older persons. Clinical studies and the biology interface of aging and cancer research are included in this initiative. Studies are needed on the assessment of the effectiveness of different prevention and treatment relative to the type of malignancy, the stage of disease, and significant features and characteristics of old age and the aging process.

The PA is directed to researchers in the extramural scientific community at large. The NIA and NCI intention, in issuing this particular PA, is to appeal to a broad-based community of investigators in cancer, aging, and other disciplines and professions throughout the nation, thereby underscoring the value of the creative ideas stemming from the cancer centers workshop and the urgent need to advance the knowledge base on cancer in older persons.

Full text of the PA is available at http://grants1.nih.gov/grants/guide/pa-files/PA-02-169.html.

Inquiries: Patricia McCormick, Cancer Centers Branch , NCI, 6116 Executive Blvd., Suite 700, MSC 8345, Bethesda, MD 20892-8345, phone 301-496-8531; fax 301-402-0181; e-mail pm60y@nih.gov

NCI Funding Notices

PAS-02-009, Cohort Studies in Cancer Epidemiology: NCI Division of Cancer Control and Population Sciences announces an additional receipt date for revised R01 grant applications originally submitted under PAS-02-009, Cohort Studies in Cancer Epidemiology (NIH Guide October 11, 2001).

Revisions to applications originally submitted on either Feb. 21, 2002, or Feb. 21, 2003, will be accepted Nov. 1, 2003, in addition to the usual annual receipt date.

Inquiries: Sandra Melnick, DCCPS, NCI, Executive Plaza North, Rm 5100, MSC 7374, Bethesda, MD 20892-7324, phone 301-435-4914; 301-402-4279; e-mail sm33k@nih.gov

Notice of Limited Competition Integrating Cancer and Aging Research in NCI-Designated Cancer Centers: NIA and NCI announce a limited competition for planning grants (P20s) for developing aging/cancer programs (or equivalently effective models) that will become incorporated as stable components of Cancer Center Support Grants.

Inquiries: Patricia McCormick, program director, Cancer Centers Branch, NCI, phone 301-496-8531; fax 301-402-0181; e-mail pm60y@nih.gov or Rosemary Yancik, National Institute on Agin, phone 301-496-5278; fax 301-402-1784; e-mail yancikr@nia.nih.gov.

In Brief:

Lasker Honors Cell Scientists, Inventors Of Kidney Dialysis

(Continued from page 1)

and as an economist, and I look forward to learning more about his views on issues critical to the FDA," said **Sen. Edward Kennedy** (D-Mass), chairman of the Senate Health, Education, Labor and Pensions Committee, which would consider the nomination.

* * *

ALBERT LASKER Medical Research Awards were scheduled to be presented Sept. 27 to two scientists who pioneered the use of kidney dialysis, and to the discoverers of cellular membrane trafficking. The 2002 Lasker Award for Basic Medical Research will be shared by **James Rothman**, of the Sloan-Kettering Institute, and **Randy Schekman**, of the University of California, Berkeley, for the discovery of the universal molecular machinery that orchestrates the budding and fusion of membrane vesicles. This advance has transformed the study of molecular trafficking from a descriptive field into one of detailed molecular clarity. The 2002 Lasker Award for Clinical Medical Research will be presented to **Willem Kolff**, of the University of Utah School of Medicine, and **Belding Scribner**, of the University of Washington School of Medicine, for the development of renal hemodialysis, a technological advance that has revolutionized the treatment of acute and chronic kidney failure. The 2002 Lasker Award for Special Achievement in Medical Science will honor **James Darnell**, of the Rockefeller University, for leading breakthroughs in understanding of gene regulation and for fostering the careers of more than 125 young scientists. . . . **MICHAEL SPORN, of** Dartmouth Medical School, was selected as the inaugural recipient of the American Association for Cancer Research-Cancer Research Foundation of America Award for Excellence in Cancer Prevention Research. Sporn will present a lecture during the first AACR Frontiers in Cancer Prevention Research meeting Oct. 14-18, in Boston. . . . **AMERICAN CANCER SOCIETY** volunteers gathered in Washington, DC, on Sept. 19 to urge Congress to make cancer a national priority. About 3,000 "Relay Community Ambassadors" celebrated cancer survivorship while telling Congress more needs to be done to promote research, education and prevention, and to call for expanded access to early detection and treatment to help people fight cancer. The group

rallied at a makeshift track around the Capitol Reflecting Pool and part of the National Mall, with individuals from every state delegation walking the track at all times to symbolize the fight against cancer. HHS Secretary Tommy Thompson addressed the group in the afternoon. ACS asked legislators to complete doubling of the NIH budget this year, fully fund the NCI, commit resources to the new National Cancer Center for Minority Health and Health Disparities at NIH, and increase funding for cancer-related programs at the Centers for Disease Control and Prevention. Also, ACS asked Congress to support and pass the Eliminate Colorectal Cancer Act (S.710/ H.R.1520) this year. The Act would give patients access to the full range of colorectal cancer screenings, the same access Congress has already given Medicare patients. Celebration on the Hill is organized by Relay For Life, the society's signature activity, which this year raised $245 million, the society said. . . . **AMIT SACHDEV** was appointed FDA senior associate commissioner for legislative affairs, FDA Deputy Commissioner **Lester Crawford** said. Sachdev served for the past four years as the majority counsel for the House Committee on Energy and Commerce. Prior to that, he worked at the Washington, DC, offices of Ropes and Gray, and the Office of General Counsel at the Chemical Manufacturers Association. . . . **UNIVERSITY OF CHICAGO CANCER RESEARCH CENTER** announced personnel changes in its programs, core facilities, and administration. **Marcy List,** associate director for administration, was named scientific director for the Protocol and Data Management Office. **Gini Fleming**, former scientific director, resumed her position as director of the Medical Oncology Breast and Gynecologic Oncology Programs in the Hematology/Oncology section. **Jay Lewis** was appointed assistant director for informatics and technology. **Harinder Singh,** professor, Department of Molecular Genetics & Cell Biology, Committees on Developmental Biology, Immunology, Cancer Biology and Genetics, and Howard Hughes Medical Institute, replaced **Elaine Fuchs** as program leader of Molecular Biology of Cell Growth and Differentiation. **Fred Wondisford**, professor and section chief, Endocrinology Section, Department of Medicine, chair, Committee on Human Nutrition and Nutritional Biology, was named scientific director of the Transgenic Mouse/Embryonic Stem Cell Facility, also previously lead by Fuchs. Following the departure of **Yair Argon**, the Immunology & Cancer Program and Immunology Applications Facility is being lead by **Tom Gajewski**, assistant professor, Department of Pathology and Department of Medicine, Section of Hematology/Oncology, and **Anne Sperling**, assistant professor of Pulmonary & Critical Care Section, Department of Medicine. **Edwin Cook**, professor, Departments of Psychiatry, Pediatrics & Human Genetics will lead the DNA Sequencing Facility. **Robert Haselkorn**, professor, Departments of Molecular Genetics & Cell Biology, Biochemistry & Molecular Biology and Chemistry, Committees on Genetics, Developmental Biology and Virology, and the College has stepped down. . . . **NATIONAL COMPREHENSIVE CANCER NETWORK** and the American Cancer Society have released the "Ovarian Cancer Treatment Guidelines for Patients." Information is available at www.nccn.org. . . . **HOWARD KATZENSTEIN** and **LOUIS RAPKIN** have joined the AFLAC Cancer Center and Blood Disorders Service of Children's Healthcare of Atlanta. Katzenstein will serve as clinical associate professor of pediatrics at Emory University School of Medicine and will direct the new Clinical Experimental Therapy Program for the AFLAC Cancer Center. Katzenstein was assistant professor of pediatrics at Northwestern University Medical School and served in the hematology/oncology division of Children's Memorial Hospital in Chicago. Rapkin, who will serve as a clinical assistant professor of pediatrics, was with the Department of Hematology/Oncology at St. Jude Children Research Hospital. . . . **STATE-OF-THE-SCIENCE** meeting sponsored by NCI on adult sarcomas held July 17 produced recommendations for further research in pathology, molecular pathogenesis and classification, targeted therapeutics development, epidemiology, prognostic assessment, imaging, and clinical management. Recurrent themes were the need for enhanced bioinformatics, addressing the critical shortage of an appropriate tissue resource to better define the biologic and molecular characteristics of these tumors, and the importance of applying lessons learned from the GIST/ imatinib experience to guide the continued development of targeted systemic therapeutics in sarcomas as well as other solid tumors. Overarching recommendations included the need for more interdisciplinary collaboration and infrastructure development for concerted molecular studies. Details can be viewed at www.webtie.org/SOTS/html/Sarcoma%20Home.htm.

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