THE CANCER LETTER

Vol. 30 No. 24
June 11, 2004

Price $315 Per Year

Medicare To Seek Coverage Advice From NCI, Oncologists, McClellan Says

By Kirsten Boyd Goldberg

NEW ORLEANS--The Centers for Medicare & Medicaid Services and NCI said they are developing a Memorandum of Understanding to address how the agencies can work together to improve the process for making coverage decisions for cancer therapeutics and diagnostics.

Speaking at the annual meeting of the American Society of Clinical Oncology, CMS Administrator Mark McClellan said the collaboration would enlist oncologists in the evaluation of new interventions for reimbursement,

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In Brief:

The Cancer Letter Wins Journalism Awards For "Authoritative Examination" of NCI

THE CANCER LETTER editors **Kirsten Boyd Goldberg** and **Paul Goldberg** received the 2004 Robert D.G. Lewis Watchdog Award from the Society of Professional Journalists, Washington, D.C., Professional Chapter, for their "exhaustive, authoritative, and bold examination of the agenda of the National Cancer Institute director appointed by President Bush."

This is the third time and the second consecutive year **The Cancer Letter** has won the Lewis Award, given annually for "the best example of journalism aimed at protecting the public from abuses by those who would betray the public trust."

Last year, the newsletter received the award for publishing a story based on the FDA's "refusal to file" letter over Erbitux and subsequent coverage of ImClone Systems Inc. In 1999, **The Cancer Letter** won the Lewis Award for a series of stories on cancer treatment studies by Houston practitioner Stanislaw Burzynski.

The Cancer Letter's coverage of NCI Director **Andrew von Eschenbach** also received first place for Newsletter Washington Reporting from the SPJ Washington chapter. The award honors reporting from Washington "that contributes to a better understanding of the federal government."

The newsletter's reporting demonstrated that von Eschenbach's agenda has involved loosening regulations governing clinical research, lowering the bar for approval of cancer drugs, and privatizing tissue collection. The stories also uncovered the alliance between von Eschenbach's NCI and the National Dialogue on Cancer, and demonstrated that the Dialogue's public relations firm, Edelman, was involved in global marketing of tobacco and

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CMS Goal: Get Reimbursement Ready For New Treatments

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development of post-approval studies, and identification of opportunities to improve the quality of care for cancer patients.

"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 June 7 in a panel discussion at the ASCO meeting.

"We want to make sure that our procedures for paying for these treatments and getting the effective treatments to patients are effective and timely, and informed by the best science and clinical experience," he said. "We also are going to be working hard to increase the body of knowledge that clinicians and patients can use to guide decisions about how to use these new technologies effectively."

Cancer policy-watchers welcomed McClellan's approach of seeking expert advice, but said the agencies' plans were still vague. "It's an excellent idea. There needs to be a meeting of minds on the process for making clinical treatment decisions and the process for making coverage policy," said William McGivney, CEO of the National Comprehensive Cancer Network, an organization of cancer centers that develops clinical guidelines.

"Coverage has tended to be a yes-or-no decision, while clinical treatment is a risk-benefit decision," McGivney said. "Coverage needs to incorporate risk-benefit analysis."

Unlike FDA, CMS hasn't developed a formal mechanism for soliciting advice from cancer specialists. In recent years, the agency has confronted clinical questions that may be even more profound than those faced by FDA.

The agency is trying to develop policies that would determine whether FDA approval automatically entitles a sponsor to reimbursement for approved and off-label uses of drugs. Also, while FDA has the capacity to grant accelerated approvals based on surrogate endpoints, CMS has been deciding whether to demand more solid evidence of patient benefit.

At this writing, the agency says it's examining off-label uses of drugs, but it may also have to confront the question of cost of the new generation of cancer therapies, observers say. CMS first confronted these questions two years ago, launching a process called interchangeably "national coverage analysis" and "national coverage determination" of cancer therapies.

Under CMS rules, a negative outcome of such analysis becomes binding on the CMS contractors, and the agent in question becomes ineligible for reimbursement.

The agency first examined the radioimmunotherapy Zevalin, and, later, a separate analysis of the drug Eloxatin (**The Cancer Letter**, March 21, 2003, Vol. 29 No. 12). The scope of analysis expanded. The Zevalin question was broadened to include Bexxar after FDA approved that treatment for non-Hodgkins lymphoma. The Eloxatin analysis, too, was broadened to include Irinotecan, a previously approved drug.

Though the agency's questions have been framed differently at different times, observers expect that the newest generation of colorectal cancer therapies—Avastin and Erbitux—may also figure in the analysis. The reason for this is simple. According to industry figures, these newest therapies are expected to add as much as $4 billion to the cost of treating colorectal cancer in the U.S. (**The Cancer Letter**, March 5, 2004, Vol. 30 No. 10).

The agency hasn't set a due date for completing this review. The national coverage analysis tracking sheets posted on the agency's Web site state that "until CMS completes its review, coverage will continue to be determined by Medicare contractors in accordance with the Medicare statute."

The documents are available at www.cms.hhs.gov/ncdr/.

THE CANCER LETTER

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Subscription $315 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd.

McClellan: "We Want to Reach Out"

According to CMS, the memorandum of understanding would describe how the agencies plan to work together in five areas:

--"A joint process for identifying high-priority clinical questions about the optimal use of new cancer technologies and the creation of a process for conducting post-approval studies to address these priority questions.

--"Defining a systematic process for consultations between CMS and NCI experts in the evaluation of new diagnostic and therapeutic cancer technologies for the purposes of payment and coverage decisions.

--"Developing more efficient methods of collecting clinical evidence on new cancer technologies and strategies for making this information more widely available to patients, clinicians, and researchers. The two agencies will also explore the inclusion of CMS claims data on the NCI bioinformatics grid, CaBIG, to make this information more easily availability for research on outcomes, on comparative utilization of existing treatments, and other similar evaluations.

--"Developing a joint process for the prospective identification and evaluation of emerging technologies such as molecular imaging so that reimbursement policies will fully anticipate promising new cancer technologies and help expedite their adoption in the marketplace.

--"The two agencies will identify opportunities for sharing data and resources aimed at improving the quality of care for cancer patients and addressing additional concerns such as cancer health disparity issues, reducing unwarranted variation in treatment patterns, and improving palliative and end of life care.

The agencies also plan to "identify and initiate high-priority clinical trials in areas where clinicians and patients have said that they need more and better clinical information to guide their decision making about new or competing treatment regimens," CMS said. The "first step" will be to "develop a strategic approach for prioritizing these clinical questions and adopting joint processes that will allow for better clinical data collection after new treatments are approved" by FDA, CMS said.

As FDA commissioner, McClellan began a collaboration with NCI that included forming a task force that is looking at ways to streamline the development of therapeutics and harmonize requirements of the agencies.

CMS will consult experts at NCI in the evaluation of new cancer therapies and will include these experts in its process of national coverage determination, McClellan said at the ASCO meeting. "We also want to reach out to other experts as appropriate, including expert clinical oncologists," he said. "One of the things I saw at FDA is that getting perspectives from practicing oncologists is very helpful in allowing us to reach regulatory decisions. The same thing can happen for payment decisions as well."

Changes in the understanding of cancer biology are leading to a shift in diagnostic and therapeutic approaches, McClellan said. "The potential is there, and as I saw at FDA, there are more treatments in development than ever before, with sciences like proteomics, genomics, nanotechnology, that hold the potential for transforming cancer care," the former FDA commissioner said. "At the same time, there is a lot of worry out there about people seeing these technologies potentially coming along, but they may not be able to benefit, because they may not be able to afford the high cost.

"This is a problem that I see from the patient standpoint, the co-pays and out-of-pocket payments for medicine," McClellan said. "It is a problem I see in the cost of insurance. For people who are covered by private insurance, if insurance picks it up, that's going to be translated back in terms of higher premiums. It's an issue for the doctor, who will spend more money on new kinds of cancer care and will have less money available to spend on other things that could potentially benefit society.

"So, our challenge today, more than ever, is to get innovation on the one hand, but keep health care affordable on the other.

"The most promising approach to dealing with this central challenge for our century [is] finding new ways of working together from the standpoint of developing new medical technologies, getting them into widespread and effective use, all along the discovery, development, and use continuum that Andy likes to talk about," said McClellan, referring to NCI Director Andrew von Eschenbach, who was sitting next to him in the panel discussion.

"If we don't find more effective ways to do each of those steps, we are going to face a challenge where we may have to make choices between innovation on the one hand and affordability on another," McClellan said. "The new technologies we have been discussing have not had an impact in a widespread way on patient care. The potential is there, but these technologies are still in development, and many of the new drugs that are coming along are taking a lot of years and a lot of

dollars to develop. The latest estimates are more than $1 billion for a new drug, and that's with at most a 20 percent chance of success after it makes it into actual clinical testing. Well, no wonder it's expensive to get these treatments to patients.

"Even after treatments become available, there are a lot of other questions we would like to know the answers to in order to provide effective treatment for our patients," McClellan said. "As you all have heard at meetings this week, some of the most important and most widely covered new developments are for treatments that have already been approved by FDA, where we find new evidence about when they work and when they don't, and particular types of patients. That's evidence that can lead us to use these treatments more effectively, but we don't have a good system in place for gathering evidence for treatments that have been approved and understand what really works best in particular patients, in particular settings, and we are going to lose out on those opportunities to direct our treatments, direct our resources, much more wisely.

"So, from the standpoint of making more accurate coverage decisions, more timely coverage decisions, for these new kinds of technologies, from the standpoint of developing better evidence on how we can use them effectively, we need new help. That is one reason we are looking at new ways of collaborating with NCI.

"We are also looking at new ways of collaborating with practicing oncologists. One of the things that is a real pleasure about being in this job, is that the Medicare and Medicaid programs right now, there is so much potential for bringing the perspective of practicing physicians to bear on using our dollars wisely, helping find better ways to conduct the clinical trials we were talking about, and helping find better ways to provide coverage.

"I'm looking forward to spending the time working with you all for how we can do a better job of getting both affordability and innovation when it comes to the potential for new treatments for cancer. The potential is there, but to deliver on that, we are going to have to find more effective ways to discover and develop and use these new treatments as they come along."

NCI: Collaboration Will Accelerate Progress

Collaborations with CMS and FDA will help NCI reach its goal to "eliminate suffering and death" due to cancer by 2015, von Eschenbach said.

"The President keeps giving [McClellan] these really critically important jobs, but ASCO and I keep benefiting from that because we get to come back and do another program together," von Eschenbach said. "It was great fun doing it last year with him as the commissioner of the FDA. We talked about how we might bring those two organizations together. This year, with him at CMS, NCI again has the privilege of working very closely with Mark and his staff at CMS."

The goal of those collaborations is to accelerate progress, von Eschenbach said. "If we can create optimal information technologies, the ability to process data, the ability to accelerate our opportunities in clinical trials, the ability to put in place systems and mechanisms that will allow for long-term monitoring and surveillance that contributes then to opportunities for early drug approval and device approval—all of these things will add up to a further increase in what is already almost a breathtaking pace of progress in cancer research and in cancer care," he said.

Cancer Policy:

Improve Mammogram Access, Personnel, IOM Report Says

While new technologies hold promise for increasing the accuracy of breast cancer detection, improving access to mammography and broadening the pool of medical personnel who can interpret mammograms offer the greatest potential for immediately reducing the number of lives lost to breast cancer in the U.S., according to a report from the Institute of Medicine and National Research Council of the National Academies.

"There is a suite of new devices under evaluation--such as ultrasound and computer-aided detection--that should make early detection even more effective in the future, although improvements in the next few years are likely to be incremental rather than revolutionary," said committee chair Edward Penhoet, director of science and higher education programs, Gordon and Betty Moore Foundation, San Francisco, and former dean, School of Public Health, University of California, Berkeley.

New technologies based on protein or gene profiling hold promise for providing more personalized screenings and identifying women at greatest risk for breast cancer. However, it remains to be shown whether these technologies will yield results that are reliable enough to be useful in the early detection of breast cancer, said the committee that wrote the report. "In the meantime, because current mammography technology is good but imperfect, and because there are many barriers hindering access to mammography, too many women will die from breast cancer this year," Penhoet said. "Improving and increasing the use of current

mammography technology is the most effective strategy we have right now for further reducing the toll of breast cancer."

The report was written by the Committee on New Approaches to Early Detection and Diagnosis of Breast Cancer, under the National Cancer Policy Board and the Division on Policy and Global Affairs, Board on Science, Technology, and Economic Policy.

Access to breast cancer screening is endangered due to a shortage of breast imaging specialists, the report says. Each year, more than 1.2 million American women turn 40, the age when most are recommended to get their first mammogram, but there are not enough breast imaging specialists to keep up with the demand. Fewer radiologists are going into breast imaging because of heavy regulation, fear of lawsuits, and low reimbursement for long hours. At the same time, mammography facilities are closing faster than new ones are opening. Between 2000 and 2003, the number of mammography facilities operating in the United States has dropped from 9,400 to 8,600--an 8.5 percent decrease. As a result, women are being made to wait up to five months for mammograms in some areas, the report notes.

Studies in the U.K. show that trained nonphysician health care professionals can interpret results with the same accuracy and speed as radiologists. Given the failure of the U.S. health care system to keep pace with the growing demand for mammography, the committee recommended that mammography facilities should enlist specially trained nonphysician personnel to pre-screen or double-read mammograms to expand screening facilities' capacity. Nonphysician personnel would not make diagnoses, and every mammogram would be independently viewed by a breast imaging specialist.

To improve the quality of cancer screening, the U.S. should adopt elements of screening programs that have proved successful in Sweden, the Netherlands, and the U.K., which have lower rates of false-positive results, the committee said. It estimated that reducing the number of false positives could cut the costs related to additional testing by $100 million a year because approximately 200,000 fewer women would be called back for follow-up work. The U.S. also should consider such practices as requiring double readings of mammograms, interpretation of mammograms in high-volume centers, and screening services that also integrate treatment, counseling, and other support services.

Tests are under way to assess the clinical value of ways to refine screening strategies for high-risk women and to improve the accuracy of mammographic interpretations. These methods include digital mammography, CAD, ultrasound, and magnetic resonance imaging. The committee encourages the validation and integration of new technologies into breast cancer screening because current mammography is imperfect and does not work equally well in all women. Mammography correctly flags undetected cancers 83 percent to 95 percent of the time, but this means that up to 17 percent of tumors go undetected. Moreover, the chance of a false-positive result from a traditional mammogram is about 1 in 10.

The report notes that research and discovery phases of new technology development are proceeding well. The weak link in development is the phase in which technologies are shown to improve health outcomes and that they can be used effectively in routine clinical practice. Many cancer detection technologies that have been proposed and developed over the years have proved to be of no value to patients or medical practice, the committee noted. It urged that more attention be paid to validating technologies and building a more robust system for assessing whether they will be useful in clinical practice. Organizations that fund breast cancer research, such as NIH, the Department of Defense, and private foundations, should support research on how best to evaluate and apply new screening and detection technologies.

Because there is so much individual variation in susceptibility to breast cancer, more refined screening strategies should be developed, the report says. Screening based on individualized genetic risk profiles for women will substantially improve early detection efforts, the report says. However, more research is needed on genetic risk factors before these biologically based technologies can be used fully to tailor detection strategies.

In addition, the actual risks of developing breast cancer need to be better communicated to women so that they can make informed decisions about screening and their lifestyle. Surveys show that older women are more likely to underestimate their risk than younger women, and that younger women tend to overestimate their risk. NCI, private foundations, and others should develop better tools for communicating risk to help health care providers discuss breast cancer risk more effectively with patients and the media.

The report, "Saving Women's Lives: Strategies for Improving the Early Detection and Diagnosis of Breast Cancer," expands on the work of a previous IOM and NRC committee that a few years ago examined the array

of promising detection and diagnostic technologies under development. That committee's report, "Mammography and Beyond: Developing Technologies for Early Detection of Breast Cancer," published in 2001, concluded that mammography, despite its problems, was still the best choice for screening the general population to detect breast cancer at early and treatable stages.

The new report was sponsored by the Breast Cancer Research Foundation, NCI, Apex Foundation, Josiah H. Macy Jr. Kansas Health Foundation, Carl J. Herzog Foundation, Corbin Gwaltney, and John Castle.

Copies of the report are available at www.nap.edu.

NCI Programs:

President's Cancer Panel, NCAB, Honor Calabresi

The National Cancer Advisory Board and the the President's Cancer Panel presented a resolution last week in honor of the late Paul Calabresi, a former NCAB chairman and cancer panel member, last week.

Calabresi, of Brown University School of Medicine and Rhode Island Hospital, served on nearly two dozen committees of NCI. He died last October at age 73 (**The Cancer Letter,** Oct. 31, 2003, Vol. 29 No. 40).

"Dr. Calabresi exemplified through his own extraordinary dedication, capabilities, and achievements that the call to public service is a noble one," said the resolution, presented to Calabresi's widow Celia Calabresi.

NCI has established a Program Announcement for the Paul Calabresi award for Clinical Oncology (**The Cancer Letter**, May 7). The award will provide career development grants to M.D.s who conduct clinical oncology therapeutic research. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-04-096.html. The application receipt date is July 1.

Funding Opportunities:

Program Announcements

PA-04-108: Innovative and Exploratory Research in Digestive Diseases and Nutrition

Division of Digestive Diseases and Nutrition at the National Institute of Diabetes and Digestive and Kidney Diseases and the NCI Division of Cancer Prevention invite applications through the exploratory/developmental R21 grant mechanism for research in gastroenterology, hepatology, obesity, and nutrition for novel approaches to digestive diseases (including associated cancers) and nutrition research. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-108.html.

Inquiries: For NCI--Sharon Ross, NCI, Nutritional Science Research Group, Division of Cancer Prevention, phone 301-594-7547; fax 301-480-3925; e-mail sr75k@nih.gov.

PA-04-107: Midcareer Investigator Award in Patient-Oriented Research

The award provides investigators support for patient-oriented research and to act as research mentors for clinical residents, clinical fellows and/or junior clinical faculty. The award is for clinician investigators at the associate professor level or are functioning at that rank in an academic setting or equivalent non-academic setting, and who have an established record of independent, peer-reviewed Federal or private research grant funding in POR. It is expected, for example, that investigators will obtain new or additional independent peer-reviewed funding as the PI for POR and establish and assume leadership roles in collaborative POR programs; and that there will be an increased effort and commitment to mentor beginning clinician investigators in POR to enhance the research productivity of the investigator and increase the pool of well-trained clinical researchers of the future. For the purposes of the PA, patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena)for which an investigator directly interacts with human subjects. This area of research includes 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials, and; 4) the development of new technologies. The PA will use the NIH K24 award mechanism. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-107.html.

Inquiries: For NCI--Lester Gorelic , phone 301-496-8580; e-mail lg2h@nih.gov.

NOT-CA-04-019: Rapid Access to Intervention Development

Request for Support Receipt Dates: Feb. 1, Aug. 1. Current requests must be received by Aug. 1.

NCI is requesting applications for the RAID initiative, which will make available to academic investigators, on a competitive basis, the preclinical development contract resources of the NCI Developmental Therapeutics Program. RAID is not a grant program. Because the goal is to move molecules and concepts from the laboratory to the clinic for proof-of-principle clinical trials, RAID will provide any (or all) of the preclinical development steps that may be obstacles to clinical translation. Possible tasks may include production, bulk supply, good manufacturing process manufacturing, formulation, and toxicology. Suitable agents for RAID will include small molecules, biologics, or vaccines. The Notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-04-019.html.

Inquiries: RAID, NCI, Office of associate director, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, phone 301-496-8720; fax 301-402-0831; e-mail raid@dtpax2.ncifcrf.gov.

In Brief:

Journalism Awards Recognize Work By The Cancer Letter

(Continued from page 1)

spinning the food industry's message on obesity. The Dialogue has since changed its name to C-Change.

The stories that won the award included:

--"NCI Director Sets A Goal: Eliminate Suffering, Death From Cancer By 2015," Feb. 14, 2003.

--"Von Eschenbach Presents His 2015 Goal As Logical Progression of Cancer Program" (interview), May 16, 2003.

--"NCI Deputy Barker Hits FDA, Calls for New Incentives for Pharmaceutical Industry," May 30, 2003.

--"NCI Director Defends Goal to Eliminate Suffering, Death from Cancer by 2015," June 13, 2003.

--"NCI Chips In $2 Million for AACR Meeting; Advisors, Senior Staff Not Consulted," June 20, 2003.

--"Cancer Clinical Trials System Needs Comprehensive Review, NCI Director Says," July 11, 2003.

--"AACR Thanks NCI For Funds, Provides Platform For Von Eschenbach's 2015 Goal," July 18, 2003.

--"PR Firm Worked For Tobacco Company And The National Dialogue on Cancer," July 25, 2003.

--"A Tissue Bank To Break The Bank? NCI, Dialogue Plan Expensive Resource," Aug. 8, 2003.

--"Advisors Tell NCI To Rethink Contracts For Cooperative Group Tissue Banks," Nov. 21, 2003.

--"NCI's Use Of Dialogue For NBN Blueprint Raises Legal, Procedural Questions," Dec. 12, 2003.

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R. SUZANNE SWANN was named senior director of statistics for the American College of Radiology. Swann will serve as statistics director for two of the major grants from NCI, the Radiation Therapy Oncology Group and the Patterns of Care Study. Swann joined ACR in 2002. As acting director of statistics, Swann helped reorganize the RTOG headquarters staff into disease site-based teams, said RTOG Chairman **Walter Curran**. Previously, Swann was a research analyst for the South Carolina Rural Health Research Center. She replaces **Charles Scott**, who resigned in July 2003. . . . **GABRIEL HORTOBAGYI**, professor of medicine and chairman of Department of Breast Medical Oncology at M. D. Anderson Cancer Center, received the Miami Breast Cancer Award of Excellence and two research grants from the Evelyn Lauder Breast Cancer Research Foundation. The annual award is given for contributions to breast cancer management. Hortobagyi and his colleagues also received two grants totaling $375,000 from The Evelyn Lauder Breast Cancer Research Foundation. Hortobagyi and **Mien-Chie Hung**, professor and chairman of the Department of Molecular and Cellular Oncology, were awarded $250,000 for their work in gene therapy research. BCRF awarded Hortobagyi and **Lajos Pusztai**, assistant professor in the Department of Breast Medical Oncology, $125,000. Hortobagyi, who holds the Nellie B. Connally Chair in Breast Cancer, has been a member of M. D. Anderson faculty since 1976. . . . **DEBORAH WALTER** was named senior director for policy and government affairs of the Association of Community Cancer Centers. She was with the Pharmaceutical Research and Manufacturers of America, where she worked on the policy and legislative agenda for the association. Walter replaces **Saira Sultan**, who is director of federal affairs at Sanofi-Synthelabo. . . . **BART BARLOGIE** received the 2004 Robert A. Kyle Lifetime Achievement Award in recognition of his 20-year career in multiple myeloma treatment by the International Myeloma Foundation. . . . **LAURENCE COOPER** was named Young Investigator of the Year by the American Society of Gene Therapy for his work in genetically manipulating human T cells of the immune system to fight cancer. Cooper is a physician in the Department of Pediatric Hematology/ Oncology and an assistant professor the Division of Molecular Medicine at City of Hope Cancer Center. . . . **ROSWELL PARK Cancer Institute** appointed **Susan Nowell** to the Division of Cancer Prevention and Population Sciences and **Sergio Onate** to the Departments of Urologic Oncology and Pharmacology & Therapeutics. Nowell completed her training in 2003 at the National Center for Toxicological Research. Onate was assistant professor in the Department of Cell Biology & Physiology at University of Pittsburgh. . . **CANCERCARE** honored two individuals at its annual Human Services Awards Dinner in New York. **David Brennan**, president and CEO of AstraZeneca, and **Joseph Aboud**, chairman emeritus and director of JA Apparel, were singled out for their leadership in the cancer community, said **Diane Blum,** executive director of CancerCare. The organization raised $600,000 during the May 12 event. . . . **CEDARS-SINAI Medical Center** has established the Samuel Oschin Comprehensive Cancer Institute. The institute will serve as an umbrella for cancer research and care conducted at Cedars-Sinai, with a focus on clinical care, clinical trials, genetic

research, and drug development. . . . **COMMISSION for Scientific Medicine and Mental Health** has asked FDA to require warning labels for nutritional supplements and is seeking to have the 1994 Dietary Supplement Health Education Act repealed. Makers of herbal remedies and dietary supplements are unregulated and only carry caveats inadequate for remedies linked to serious illness or death, the commission said. . . . **COLD SPRING Harbor** and the **European Molecular Biology Laboratory's European Bioinformatics Institute** have formed an NIH-funded collaboration to launch Reactome, a free, open-source curated database of biological processes in humans. The database, www.reactome.org, can be used by general biologists as an online textbook of biology, or by bioinformaticians for biological pathways research. Reactome also includes individual biochemical reactions from non-human systems such as rat, mouse, pufferfish, and zebrafish. Also new in Reactome are cross-references to the online databases PubMed, UniProt, LocusLink, Ensembl and the Gene Ontology**.** Reactome is supported by the National Human Genome Research Institute and the Cell Migration Consortium, a European Union Project Grant and funding from the EBI Industry Programme. . . .. **HEALTH and Human Services** has created an internal task force to promote medical technologies, such as drug and biological products and medical devices. Participating agencies will include Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, FDA, and NIH, said HHS Secretary **Tommy Thompson.** Electronic public comments will be accepted until Aug. 23 at www.fda.gov/dockets/ecomments. Participants in the task force will include **Julie Gerberding**, director of CDC; **Mark McClellan**, administrator of CMS; **Lester Crawford**, acting commissioner of FDA; and **Elias Zerhouni**, director of NIH. Crawford will serve as chairman of the task force. . . . **FDA SEEKS COMMENT** on its "Critical Path Initiative," a report on reducing hurdles in medical product design and development. The agency invites public comment at www.fda.gov/OHRMS/DOCKETS/98fr/04-9147.htm. Further information about the FDA Critical Path Initiative is available at www.fda.gov/oc/initiatives/criticalpath/. . . . **FDA REVIEW** of more than 1,800 outside activities of employees found "no other activities of concern," the agency said last week. The review was conducted in response to an investigation by the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce (**The Cancer Letter**, May 21).

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