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Pediatric Rule Makes FDA Consider Defining Tumors By Molecular Target

FDA is holding a series of meetings to seek guidance from extramural scientists on the interpretation of the Pediatric Rule, a 1998 regulation that mandates drug sponsors to conduct clinical trials in children.

The rule applies only when pediatric diseases are the same as diseases in adults. Since many diseases are similar in adults and children, the rule has boosted the number of pediatric studies supported by the pharmaceutical industry.

Oncology is an exception. The interpretation of the rule and its
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In Brief:

UCSD Center Designated Comprehensive; Siteman Center In St. Louis Wins Core Grant

UNIVERSITY OF CALIFORNIA, SAN DIEGO CANCER CENTER was designated the 41st comprehensive cancer center by NCI, **Sen. Diane Feinstein** (D-CA) announced recently. The title signifies that the center covers a full range of cancer research activities, including basic and clinical science, population studies, community outreach programs and cancer-prevention activities. "Thirty years ago, the President and the U.S. Congress declared war on cancer and charged NCI with overseeing that effort," said Feinstein, chairman of the Senate Cancer Coalition and vice-chairman of the National Cancer Dialogue. "The designation further enhances our ability to make cancer-related discoveries, introduce more and better treatment options, recruit outstanding faculty and staff, and educate the public about cancer prevention and early detection," said **David Tarin**, director of UCSD Cancer Center and professor of pathology and associate dean for cancer affairs. The NCI cancer center grant for UCSD, which supports existing and new research programs and infrastructure, amounts to nearly \$19 million over five years and more than triples the previous level of NCI support. . . . **ALVIN J. SITEMAN CANCER CENTER** at Washington University School of Medicine and Barnes-Jewish Hospital has become an NCI-designated cancer center. The Siteman Cancer Center is the only institution to receive NCI designation in Missouri and within a 240-mile radius of St. Louis. The milestone recognizes the breadth, depth and balance of activities by researchers, clinicians and staff seeking to advance cancer knowledge, increase cancer screenings and ultimately to improve cancer care. Siteman Cancer Center comprises the combined
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In Requiring Pediatric Trials, FDA Mulls Switch To Targets

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applicability to childhood cancer are anything but straightforward, experts say. The regulation raises fundamental questions:

How does one determine when a cancer is the same in adults as in children? Should adult cancer and pediatric disease be compared on the basis of histology, tumor biology, or both?

“Unfortunately, the Pediatric Rule says that the condition has to be the same in the adult and pediatric population, and, generally, pediatric cancers are different from adult malignancies,” said Gregory Reaman, chairman of Children’s Oncology Group, professor of pediatrics at George Washington University, and chairman of hematology and oncology at Children’s National Medical Center

“What is now being considered and discussed is that if there are similar or identical molecular pathogenetic mechanisms, then there will be a mandate to study some of these new molecular-targeted drugs in pediatric populations,” Reaman said to **The Cancer Letter**.

At least in theory, a switch to defining tumors based on their biology rather than histology could broaden the horizons in pediatric oncology, experts say.

If the Pediatric Rule is taken literally and applied

only in cases where the disease is the same in children and adults, a drug labeled for breast or prostate cancer would be of little relevance in pediatrics.

“However, if a drug is targeting a pathway that also has relevance to pediatric cancers, then it may have a significant impact,” said Peter Adamson, chairman of the COG experimental therapeutics program and principal investigator at the Philadelphia Children’s Hospital’s Pediatric Pharmacology Unit. “There may be some shared mechanisms in signal transduction pathways.”

In pediatric oncology, nearly all drugs are administered off-label, and FDA has approved only one cancer drug for children in the past 20 years.

Richard Pazdur, director of the FDA Division of Oncology Drug Products, said change would probably come gradually.

“We must have a sound scientific understanding of the molecular target, the drug’s interaction with the target, and the relationship of this action to clinical benefit,” Pazdur said. “Since the Pediatric Rule is mandatory, we have to have the acceptance from the scientific community and the general oncology community.

“We are talking about a quantum shift in how we view tumors away from light microscopy, which has been there for over a hundred years, to molecular markers,” Pazdur said. “I think we are still going to have a combination of approaches of local and systemic therapies.”

The Three Meetings

Grappling with the meaning of the rule, last year FDA formed a pediatric subcommittee of the Oncologic Drugs Advisory Committee.

The agency has convened three meetings to collect expert opinion on interpreting the law. “What we are examining is a systematic approach to describing tumor types, attempting to integrate a variety of validated scientific methods,” said Steven Hirschfeld, a pediatric oncologist in the FDA Division of Oncology Drug Products and the organizer of the initiative.

“By looking to establish some general principles as well as specific examples of ways to link adult and pediatric malignancies, we hope to be able to apply the Pediatric Rule in a way that is fair, consistent, and useful,” Hirschfeld said.

—At the first meeting, last September, the pediatric ODAC considered general approaches to tumor description.



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The advisors said that in cases where a molecular target is shown to be associated with a cancer and plays a critical role in the biology of that cancer, it would be appropriate for FDA to consider therapies aimed at tumors containing those targets.

According to a summary of the meeting by an FDA staff member, this recommendation may be the first step in changing the regulatory definition of an indication from a histologic tumor type to a molecular target.

“At this time, there isn’t any definitive recommendation,” said Susan Cohn, a member of the FDA subcommittee and associate professor of pediatrics at Northwestern University.

“A leukemia is not always a leukemia, and there are many different kinds of leukemia, and there are many different molecular abnormalities associated with leukemia, and before you make some kind of a global statement, you need to make sure that you look at specifics and you know what you are talking about,” Cohn said.

—At the second meeting, last April, the group focused on hematological malignancies.

The panel acknowledged that while the distribution of subtypes of acute leukemias and their response to current therapy varies according to age, all acute myeloid leukemias and all acute lymphocytic leukemias could be considered as classes of diseases and should be subject to the Pediatric Rule.

The chronic leukemias were less amenable to categorization, and should be considered on a case-by-case basis, the advisors said.

The panel recommended that Hodgkin’s disease and four subtypes of non-Hodgkin’s lymphoma be considered the same in adults and children.

—At the third meeting, in June, the committee considered solid tumors and CNS malignancies.

The committee recommended that any agent under development for adult sarcomas should also be studied in children, the agency staff summary states.

The committee also considered the potential ties among neuroendocrine tumors intriguing, but discussion centered on the need for more data before mandating pediatric studies, the summary states.

Ultimately, the committee endorsed triggering the Pediatric Rule on a case-by-case basis, depending on the mechanism of action of the drug and the available data.

Turning to CNS tumors, the committee recommended that the default condition should be that pediatric studies proceed, so as not to deny children

with brain tumors early access to potentially useful drugs.

“The advice we have received to date validates our initial approach to rethinking the regulatory definition of the term indication,” Hirschfeld said. “We now have a clearer idea of when to apply the Rule.”

The agency is planning another meeting later this year to solicit advice on how to implement the Pediatric Rule.

“We need to know what types of studies should be performed, what types of analyses are possible and preferred, and how any pre-existing data derived from adult studies could be applied or integrated into a development plan for children,” Hirschfeld said.

Pediatric Exclusivity: An Incentive

FDA also offers an incentive program for pharmaceutical companies to sponsor clinical trials of drugs in children.

The incentive, established under the FDA Modernization Act of 1997, prolongs the marketing exclusivity period for a drug if a sponsor performs pediatric studies formally requested by FDA.

In oncology, sponsors have to present phase I and phase II data in a number of common pediatric malignancies, no matter what adult indication is being developed. Sponsors can get additional six-month exclusivity regardless of the outcome of pediatric trials.

According to the agency, to date 20 requests have been issued for oncology drugs. Throughout FDA, the program has issued almost 200 formal requests and about 35 drugs have qualified for an exclusivity extension, agency officials said.

Pediatric oncologists say they are unable to get drugs early enough even for laboratory testing.

“One of the biggest challenges is not only getting the drugs into clinical trials, but having access to the drug for pediatric oncology laboratories,” Adamson said. “Industry is not willing to part with their drugs for preclinical investigations for intellectual property reasons.”

As a result, drugs aren’t studied in cell lines for pediatric uses until they are in late stages of clinical development for adults, pediatric oncologists say.

The Novartis drug Gleevec, recently approved for chronic myelogenous leukemia, has been an exception. The drug, which attacks a biological target, moved rapidly from adult to pediatric trials.

NCI officials worked with the company to make the drug available for pediatric trials, sources said. As a result, Novartis is likely to become eligible for an



additional six months of market exclusivity for the drug.

“Access to that agent has been very good,” Reaman said. “There is a phase I nearly completed in Philadelphia Chromosome-positive leukemia, there is a phase II study in newly-diagnosed high-risk Philadelphia chromosome positive ALL patients, there is a phase I study in solid tumors.

“I think it’s the beginning of what we have been hoping for,” Reaman said.

Ranking Scientific Questions

Several childhood cancer patient advocacy groups are working on a legislative proposal to create an HHS advisory group that would set priorities for childhood cancer trials and consider ethical considerations for testing new therapies.

“There has to be an open deliberation of priorities based on what’s best for the kids, rather than any other regulatory or economic consideration,” said Susan Weiner, president and founder of The Children’s Cause. “There has to be a proactive way to do this.”

The proposal, which is being developed by Sen. Hillary Clinton (D-NY), is expected to be introduced as an amendment to S.838, a bill that addresses the pediatric drug development aspect of the FDA Modernization Act.

Though the proposed advisory group would address the problem in the context of FDAMA, the committee may exercise influence throughout the government.

A more systematic approach would be needed to assess the many competing drug candidates, Weiner said.

“There are drugs that compete with each other within the same therapeutic class, and you have to have sufficient data to understand what’s going to be best bet for the kids,” she said.

NCI Programs: New Partnership To Guide National 5 A Day Program

The program that 10 years ago began exhorting consumers to eat five helpings of fruits and vegetables a day has bulked up its organizational structure and vows to muscle its way further into public consciousness.

The 5 A Day Program, co-sponsored for the past decade by NCI and the Produce for Better Health Foundation, now will be operated by the National 5 A

Day Partnership, an entity that includes representatives from NCI, the Centers for Disease Control and Prevention, the American Cancer Society, and other health organizations and produce industry groups.

Members of the partnership began to organize over the past year, following an evaluation of the 5 A Day Program by an expert advisory group to NCI. The report recommended that NCI continue to lead the program’s research and evaluation, and increase the communications budget of the program (**The Cancer Letter**, Vol. 27 No. 6, Feb. 6, 2001).

“NCI is primarily a research institute, so bringing in other partners will allow us to broaden the program and expand its reach,” Elizabeth Pivonka, president of the Produce for Better Health Foundation, said. “The idea behind the partnership is to integrate 5 A Day into the programmatic efforts of key groups interested in promoting fruit and vegetable consumption and also support the expansion of 5 A Day programs in each state.”

After the evaluation report, the program proposed forming a steering committee of those organizations “willing to put significant resources into the program,” Pivonka said. Last May, the organizations began to develop a strategic plan. The plan will be presented at the first National 5 A Day meeting, scheduled for Sept. 20-22, in Washington, DC.

Members of the National 5 A Day Steering Committee are: NCI, CDC, Produce for Better Health Foundation, United Fresh Fruit and Vegetable Association, Dole Food Company Inc., Produce Marketing Association, American Cancer Society, and the National Alliance for Nutrition and Activity. The U.S. Department of Agriculture and the American Heart Association have been invited to join the partnership.

The steering committee also will include a state health promotions director and a state coordinator.

“For the first couple of years, we will make sure we have all the right players at the level we want them involved,” Pivonka said.

The program’s annual budget is about \$3 million. In addition, NCI plans to spend a little over \$1 million for communications, but that figure does not include staff time, Pivonka said.

CDC has not made a financial commitment, because it lacks funding, Pivonka said. However, a coalition called the National Alliance for Nutrition and Activity is lobbying to increase CDC funding, she said.

The National 5 A Day meeting will include



discussion of the strategic plan as well as training for community organizers. The meeting is by invitation only, Pivonka said. However, representatives of any organization that is willing to take part may attend, depending on available space, she said. Interested persons may contact her at epivonka@5aday.com, or contact Barbara Berry at 302-235-2329, ext. 24, or bberry@5aday.com.

NCI and the foundation are promoting the ninth annual National 5 A Day Week, Sept. 9-15. The foundation offers suggestions and solutions for encouraging consumption of fruit and vegetables to retailers, health educators, teachers, children, and families on its Web site at <http://www.5aday.com>.

NCI's findings from its 5 A Day Focus Group Executive Summary is available in the news section of the foundation Web site. The 12 focus groups in the study looked at trends, barriers, and common themes to fruit and vegetable consumption.

"Consumption is going up," Pivonka said. "If we want to move this along faster, we need to broaden our partners. We have some ambitious plans and huge possibilities."

Americans are consuming more fruits and vegetables since the 5 A Day program began, according to NCI. On average, adults consume 4.4 daily servings and children consume 3.9 daily servings.

A serving is defined as: one medium piece of fruit; 1/2 cup of fruit or vegetables; one cup of leafy salad greens; 1/4 cup of dried fruit; 3/4 cup or six ounces 100% fruit juice; 1/2 cup cooked or canned dried peas or beans.

Funding Opportunities: **Career Development Awards**

Application Deadline: Nov. 1

American Association for Cancer Research and the California Department of Health Services, Cancer Research Section, invite applications from cancer research scientists affiliated with institutions in California for the AAC-California Department of Health Services Career Development Awards in Gender-Related Cancer Research. The awards will be given in 2002 for translational, clinical or prevention research: one focusing on prostate cancer and the other on ovarian cancer. The two-year awards of \$50,000 per year will support non-tenured, tenure-track scientists at the level of assistant professor. At the time of application, candidates must be in the first or second year of a full-time, tenure-tracked faculty appointment.

Inquiries: AACR Web site <http://www.aacr.org>.

NCI RFPs Available

RFP N01-CP-21001-38: Cancer Incidence and Mortality in Blood Donors and Recipients: A Population Based Record Linkage Study

Proposals Due Date: March 20

Duration of Master Agreement Pool: July

Division of Cancer Epidemiology and Genetics and the Division of Cancer Control and Population Sciences, NCI, through the record linkage master agreement pool, will award a master agreement order contract to describe cancer risk in blood donors and recipients, and in assessing if risk in recipients is associated with cancer in donors after adjustment for donors HIV status. Those firms currently in the Master Agreement Pool have already submitted proposals which have determined them to be prequalified to propose for work issued under this mechanism. The purpose of the RFP is to quantify cancer incidence and mortality in cohorts of blood donors and transfusion recipients whose records are linked to large population-based cancer and vital status registries. The main hypotheses that will be tested are: 1) site-specific cancer risk (including risk of second primary tumors) and mortality patterns in blood donors do not exceed that of the general population; 2) site-specific cancer risk and mortality patterns in blood transfusion recipients do not parallel patterns observed in blood donors; and 3) after accounting for transmission of oncogenic viruses through blood transfusion, excess cancer risk in recipients is not associated with cancer history in the donors whose blood products they received.

The North American Industry Classification System project code is 541710. Proposals will only be considered from offerors in the master agreement pool. Those wanting inclusion in the pool should consult the Research Contracts Branch Web site at <http://amb.nci.nih.gov> under current requests for proposals and refer to RFP NO1-CP-01003-13.

Inquiries: Kim Hall, contract specialist, Epidemiology and Support Section, NCI, Executive Plaza South, Rm 620, Bethesda, MD 20892-7224; phone 301-435-3781; fax 301-480-0241; e-mail kh175r@nih.gov or Sharon Miller, contracting officer, phone 301-435-3783; fax 301-480-0241; e-mail sm103r@nih.gov.

RFP N02-CP-21004-38: Multidisciplinary Investigations of Nutrition and Cancer

Response Due Date: Sept. 14, 2001

The Nutritional Epidemiology Branch, Epidemiology and Biostatistics Program, NCI, will award a contract to conduct investigations and projects on the role of nutrition in the etiology of human cancer. The contract serves several purposes: 1) study oversight on projects in locales where additional oversight is needed (e.g., India); 2) rapid, flexible development of full nutrition-and-cancer studies of small to moderate size, without the need to develop separate procurements for



each study; 3) initiation of smaller-scale research efforts ancillary to existing projects; 4) initiation and conduct of pilot studies; 5) development of methodologic studies relevant to the problem areas cited above (e.g., dietary assessment instrument evaluation); 6) support for biospecimen handling; 7) provision of opportunities for new training fellows to become involved quickly in study design and management under mentorship of senior investigators. The scientific direction and overall supervision for all projects are the responsibility of the professional staff of NEB. Support services provided by the contract include developing liaisons with organizations and individuals whose cooperation is needed for the conduct of the studies; design and development of forms required for field investigations (interview forms, record-abstracting forms, interviewer manuals, biologic specimen collection manuals, etc.); hiring, training, and supervision of technical personnel (interviewers, record abstractors, persons for collecting and transporting biospecimens); collection of the required data; tracing of individuals; and data processing activities (e.g., coding, keying, and editing). The contractor must also provide field supervision and develop quality control mechanisms for all aspects of a study. It is anticipated that an incrementally-funded, cost-reimbursement, term type contract will be awarded for a five-year period of performance. The estimated level of effort for this contract is 50,000 hours.

Inquiries: See preceding RFP.

RFA Available

RFA-TW-02-008: International Bioethics Education and Career Development Award

Letter of Intent Receipt Date: Sept. 7, 2001

Application Receipt Date: Jan. 11, 2002

Fogarty International Center, in partnership with the National Institute of General Medical Sciences, the National Institute of Environmental Sciences, the National Center for Complementary and Alternative Medicine and the National Institute of Dental and Craniofacial Research, invites applications from nonprofit, private or public, domestic or international, educational and research institutions to develop or expand current graduate curricula and training opportunities in international bioethics related to performing research on acute and chronic diseases in low- and middle-income nations. Applicant institutions can request up to four years support to create full curriculum development and training programs, or up to two years support for curriculum development alone in preparation to apply for full training program support in the future. The proposed curricula should provide a core set of advanced study courses that focus on the internationally relevant aspects of the ethical, legal and social principles guiding the responsible conduct of research in developing countries, particularly on scientific integrity and the protection of

the interests of research participants. Support will be provided for multi-disciplinary training for developing country health professionals working at institutions conducting biomedical, behavioral or public health research involving human subjects, and for ethicists or philosophers from developing countries with an interest in biomedical/clinical research. Appropriate training may include advanced degree and non-degree associated course work and practicums. Support may also be included for the development and implementation of intensive short courses designed specifically for individuals directly involved in human subjects research ethical review and in conducting clinical trials in developing countries. The RFA will use the NIH education project grant R25 award mechanism that limits facilities and administrative (F & A) costs to eight percent. The RFA is available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-02-008.html>.

FIC will hold a workshop associated with the Global Forum on Bioethics in Research in the Gambia Nov. 8-10, 2001. All documents distributed at this workshop and a summary of questions and answers regarding this RFA raised at the workshop will be posted on the FIC Web site (<http://www.nih.gov/fic/programs/bioethics.html>) subsequent to the workshop.

Inquiries: Barbara Sina, Division of International Training and Research, Fogarty International Center, 31 Center Dr., Rm B2C39, MSC 2220, Bethesda, MD 20892-2220, phone 301-402-9467; fax 301-402-0779; e-mail barbara_sina@nih.gov.

Program Announcements

PA-01-127: Pilot and Feasibility Program Related to the Kidney

The Division of Kidney, Urologic and Hematologic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases, the Biology of Aging Program of the National Institute on Aging and the Cancer Cell Biology Branch of NCI invites applications through the exploratory/developmental R21 grant mechanism from investigators with research interests related to the kidney and fall within the purview the NIH mission. The initiative would promote development of high-risk pilot and feasibility research by newly independent or established investigators, to develop new ideas sufficiently to allow for subsequent submission of R01 applications focusing on research problems relevant to the study of both acute and chronic kidney diseases, and their complications, in both the adult and pediatric populations. The program will be supported through the exploratory/developmental grant R21 mechanism. The PA is available at <http://grants.nih.gov/grants/guide/pa-files/PA-01-127.html>.

Inquiries: For NCI—Judy Mietz, Cancer Cell Biology Branch, NCI, 6130 Executive Blvd., Executive



Plaza North, Rm 5032, Rockville, MD, 20852, phone 301-496-7028; fax 301-402-1037; e-mail mietzj@nih.gov

PA: Economic Studies in Cancer Prevention, Screening, and Care (Reissued)

The PA solicits research in methodological research to improve techniques for the collection and analysis of economic data related to cancer control, descriptive studies of the economic burden of cancer to individual and society, and cost-effectiveness studies of cancer control interventions and policies. The PA is so intended to foster collaborative activities between researchers from these disciplines and more traditional cancer oriented researchers.

Examples of research supported by this PA are: 1) The economic burden to the individual cancer patient, family and society resulting from cancer and cancer treatment. Economic factors at the individual, community and health system level that effect access to and outcomes following the use of cancer-related prevention, screening, diagnostic and treatment services. 2) The cost and organizational structure of delivering cancer prevention, screening and treatment services. 3) Cost-utility, cost-effectiveness or cost-benefit analysis. 4) The economics of decision making processes. 5) The role of economic factors and financial incentives in clinical trials. 6. The identification, development and validation of data resources. 6) Methodological studies. The PA is available at <http://deainfo.nci.nih.gov/concepts/TPA-01-131.htm>.

Inquiries: Martin Brown, Applied Research Program, phone 301-496-5716; e-mail: mb530@nih.gov.

Other Funding Notices

NOT-CA-01-016: Policy of NCI for Allowable Requested Budget Levels of Competing Continuation Type 2 R01 and U01 Applications

Beginning with the Nov. 1, 2001, receipt date, budget requests for direct costs for NCI support competing continuation (type 2) R01 and U01 applications cannot exceed an increase of 20 percent over the direct cost award level in the last non-competing (type 5) year. Awardees in their last year of current support will be notified by NCI of the maximum permissible budget for a competing continuation. The notice is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-CA-01-016.html>.

Inquiries: associate director for referral, Review and Program Coordination, Division of Extramural Activities, NCI, 6116 Executive Blvd., Rm 8051, Bethesda, MD 20892-8328, phone 301-435-5655; fax 301-402-0742; e-mail db85g@nih.gov

In Brief:

Siteman Wins Core Grant; Other Cancer Center News

(Continued from page 1)

cancer-related programs of Barnes-Jewish Hospital and Washington University School of Medicine. Washington University School of Medicine received an NCI cancer center support grant for basic and clinical cancer research and cancer prevention programs. "We are deeply honored to achieve this distinction for the extraordinary work of the researchers, clinicians and staff affiliated with Siteman Cancer Center," said **Timothy Eberlein**, center director. "Receiving NCI designation is a tremendous acknowledgement of our ability to make a difference in the fight against cancer in the St. Louis community and beyond." The services at Siteman soon will expand as part of new facilities expected to open in fall 2001 in the Center for Advanced Medicine, being built by Barnes-Jewish Hospital and Washington University. The center will have a distinct entrance, lobby and elevators within the larger Center for Advanced Medicine. The substantial majority of the nearly 5,000 newly diagnosed cancer patients treated annually by Washington University physicians and Barnes-Jewish Hospital will receive their outpatient care within the new facility. "The achievement of an NCI-designated cancer center is a victory for the people of St. Louis as well as for the entire region," says **Ronald Evens**, president of Barnes-Jewish Hospital. "Cancer patients at the Siteman Cancer Center can be assured of the latest treatments and care including all the clinical and psychological components in a patient-friendly environment." The effort to gain NCI designation accelerated in 1995, when the university won an NCI Cancer Center Planning Grant. An additional critical step in the growth of cancer programs at Washington University and Barnes-Jewish Hospital occurred in 1996, when the board of Barnard Free Skin and Cancer Hospital decided to have the university—later joined by Barnes-Jewish Hospital as well—coordinate Barnard's indigent cancer care, cancer research, and community education programs, thus bringing more resources to bear in the effort to create a broad-based and cohesive cancer program for St. Louis. Eberlein, the Spencer T. and Ann W. Olin Distinguished Professor at Washington University and Surgeon-in-Chief at Barnes-Jewish Hospital, became the director of the growing cancer center in November 1999. That same



month, St. Louisans Alvin and Ruth Siteman committed \$35 million to Barnes-Jewish Hospital and Washington University to support cancer-related efforts, thus expanding and providing a cohesive identity for the medical school and hospital's combined cancer programs, which were then renamed the Alvin J. Siteman Cancer Center. Washington University submitted a grant application to NCI in October 2000 to request federal designation as an NCI Cancer Center. As part of the NCI designation, the center will receive a \$4 million grant to facilitate multidisciplinary research. This new NCI grant is in addition to the more than \$80 million in cancer research and related training grants currently held by the school's more than 240 researchers and physician-scientists affiliated with the Siteman Cancer Center. . . . **UCLA JONSSON CANCER CENTER** received a five-year, \$6.9 million grant from NIH to examine the impact of urologic diseases on the American public, an endeavor that may influence insurance coverage, access to care, the allocation of research dollars and the availability of treatments and services. The effort represents the first coordinated attempt to detail the significant burden of a variety of urologic diseases, said **Mark Litwin**, researcher at the UCLA Jonsson Cancer Center, associate professor in the departments of Urology and Health Services and study leader. The study will focus on urologic cancers, such as prostate cancer, bladder cancer, testicular cancer and kidney cancer, but also will examine high-profile disorders such as male sexual dysfunction and urinary incontinence, Litwin said. The study will be led and coordinated by Litwin at UCLA, while data analysis will be done at RAND. Researchers from the VA Greater Los Angeles HSR&D Center of Excellence, a consortium of investigators from Veterans Affairs campuses at UCLA, the University of California, San Diego, and RAND, will provide epidemiological consultation and conduct the epidemiological and health services research analyses of VA data. At the conclusion of the study, researchers will provide a report in written and electronic formats for use by legislators, health care professionals and policy makers and the public. "We know of no comparable work in progress anywhere in the United States," Litwin said. . . . **TWO CANCER CENTERS** were awarded \$2.5 million each for breast cancer biomedical research and clinical care by Avon Products Foundation: University of Colorado Cancer Center and Fred Hutchinson Cancer Research Center. Colorado will use the award to recruit new faculty, purchase scientific equipment

and to establish and endowed chair. At the Hutchinson Center, the gift will be used to support pilot projects and initiatives for detection, treatment and diagnosis and to fund a program of direct clinical care and research for a racially and ethnically diverse population of low-income women in King County, WA. . . . **SUSAN LINDQUIST** was named director of the MIT Whitehead Institute. Lindquist, a molecular biologist at the University of Chicago and a member of the National Academy of Sciences, works with heat shock proteins and fruit flies. She will take over as director when **Gerald Fink** steps down in October. . . . **ALBERT DEISSEROTH**, hematologist/oncologist specializing in biological therapy and genetics, was appointed president and CEO of the Sidney Kimmel Cancer Center in La Jolla, CA. Deisseroth was director of the Genetic Therapy Program, chief of the Section of Medical Oncology and associate director for clinical research of the Yale Cancer Center, Yale University School of Medicine. His emphasis at SKCC will be molecular biology, genetics and vascular therapy to target tumor cells. As part of his strategic five-year plan, Deisseroth will recruit faculty and expand prostate, breast and ovarian cancer research programs and move SKCC closer to non-toxic therapies and cures. Clinical trial programs directed by Deisseroth will take treatment developed at SKCC to cancer patients through an affiliation with Sharp HealthCare. "These are cutting-edge experimental therapies that are unavailable anywhere else in the world," said **Ira Lechner**, chairman, SKCC. . . . **FRANK TORTI**, director of the Comprehensive Cancer Center of Wake Forest University, was awarded MERIT status for his NIH funded research. The recognition is given to less than 3 percent of NIH grantees for consistent excellence in advancing scientific knowledge. Torti investigates the molecular basis of iron homeostasis in health and disease. . . . **JOHN RUCKDESCHEL**, director and CEO of the H. Lee Moffitt Cancer Center & Research Institute, was named the 2001 Distinguished Oncologist by the Southern Association for Oncology. The award is given to an individual who has made contributions in education, research and patient care in oncology, said **Kelly Drake**, SAO president. . . . **BENJAMIN MOVSAS**, director of clinical research and thoracic radiotherapy at Fox Chase Cancer Center, was appointed vice chairman of the Department of Radiation Oncology. Movsas is chairman of the Radiation Therapy Oncology Group quality of life committee and patterns of care lung committee.



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