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# In Turnaround, HHS Says It Will Enforce Pediatric Rule, While Fine-Tuning Regs

In recent weeks, an observer risked becoming sea-sick by following the HHS stance on the "pediatric rule," a regulation that requires pharmaceutical companies to test drugs in children whenever children's diseases are the same as diseases in adults.

Last month, FDA attorneys said they would not to fight court challenges by three conservative groups who argue that the agency lacks legal authority to mandate pharmaceutical companies to conduct studies in children.

The agency's plan was to stop enforcement of the rule for two years,

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*In Brief:*

## Bunn To Succeed Norton As ASCO President; UCSF's Margaret Tempero Is President-Elect

**PAUL BUNN** will begin a one-year term as president of the American Society of Clinical Oncology at the society's annual meeting May 20 in Orlando, FL. He succeeds **Larry Norton**, of Memorial Sloan-Kettering Cancer Center. Bunn directs the University of Colorado Cancer Center and holds the Grohne/Stapp Chair in Cancer Research. **Margaret Tempero** will become president-elect of ASCO. She is deputy director of the University of California, San Francisco, Cancer Center and chief of the Division of Medical Oncology in the Department of Medicine. New board members will begin three-year terms. They are: **Gabriel Hortobagyi**, Nellie B. Connally Chair in Breast Cancer Research, director of the Multidisciplinary Breast Cancer Research Program and professor of medicine and chairman of the Department of Breast Medical Oncology at M.D. Anderson Cancer Center; **Richard Schilsky**, professor of medicine and associate dean for clinical research in the Biological Science Division at the University of Chicago and chairman of Cancer and Leukemia Group B; **Valerie Rusch**, William G. Cahan Chair and chief of Thoracic Surgery Division at Memorial Sloan-Kettering; **John Rainey**, clinical associate professor of medicine at Louisiana State University School of Medicine in New Orleans and president of Louisiana Oncology Associates. Elected members of the Nominating Committee are: **Charles Loprinzi**, professor of medical oncology and chairman of the Division of Medical Oncology at the Mayo Clinic and **Martine Piccart-Gebhart**, professor in the Department of Internal Medicine and head of the Chemotherapy Department at the Jules Bordet Institute in Brussels. . . . **ASCO** has awarded 10 institutions with three-year grants ranging from $150,000 to

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## After Protests, HHS Changes Stance On Pediatric Rule

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while deciding whether it was needed. However, after protests from Capitol Hill and from pediatric care groups, HHS changed its mind, and Secretary Tommy Thompson decided to continue to enforce the rule while fine-tuning it.

"Children need access to the same kinds of safe, effective treatments that are available to their parents, and that means conducting appropriate clinical trials," Thompson said in an April 19 statement that amounted to a cautious endorsement of the rule.

The conservative groups, some industry interests and the Administration say they prefer another approach, granting the sponsors six-month extensions of market exclusivity for conducting pediatric studies. This incentive, called the pediatric exclusivity extension, was first codified in the FDA Modernization Act of 1997, and last January was signed into law as a broader, stand-alone measure called Best Pharmaceuticals for Children Act.

"We will enforce and improve the FDA's pediatric rule, as we simultaneously take additional steps made possible when President Bush signed new legislation to promote the development of drugs that can save children's lives," Thompson said in a statement.

The new pediatric exclusivity extension has been expanded to apply to drugs that have lost market exclusivity, mandates that data from pediatric studies (even negative results) are made public, and sets up an NIH-administered fund that would finance studies of drugs that have lost market exclusivity.

Extensions can be granted even for negative trials.

While extension of exclusivity offers an incentive to pharmaceutical companies, the pediatric rule provides a clear mandate. Since pediatric cancer is rare, and since children are in many respects biologically different from adults, companies have not found it lucrative to develop cancer drugs for children.

Therefore, pediatric patient advocates as well as pediatricians argue that both the incentive and the requirement are needed to induce pharmaceutical companies to study cancer drugs in children.

Between April 1999 and February 2002, FDA invited the sponsors of 23 oncology products to apply for pediatric exclusivity extensions. Across all FDA divisions, the sponsors of 240 products have been invited to apply.

So far, one cancer drug, Busulfex, sponsored by Orphan Medical Products, received the extension. Busulfex is part of a preparative regimen for bone marrow transplantation.

The agency doesn't disclose when the pediatric rule is invoked. The 1998 rule mandates that sponsors perform studies in children when pediatric and adult indications can be considered the same.

In oncology, the applicability of the pediatric turns on a fundamental question: Should the disease be defined based on the site of a primary tumor, the molecular characteristics, or other biological determinants?

Two years ago, the agency began to address this question by convening a series of meetings of a subcommittee of the Oncologic Drugs Advisory Committee (**The Cancer Letter**, Aug. 31, 2001).

However, the future of this ad hoc group, called the Pediatric ODAC, appears to be uncertain. The agency cancelled the March 12 meeting of the subcommittee, and the Federal Register notice offered no explanation for the cancellation.

The pediatric rule is vulnerable to a challenge because it's not codified by law. The rule was written on the basis of a 1997 Presidential executive order. Last year, an effort on Capitol Hill to incorporate the rule into the Best Pharmaceuticals for Children Act was thwarted by conservative members and the pharmaceutical lobby.

The industry's preference for the extension of exclusivity provision over the pediatric rule is

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understandable: the exclusivity provision is voluntary. Under the exclusivity provision, FDA has the authority to reward for the conduct of pediatric studies, but no power to mandate them.

The pediatric rule was challenged immediately after it was adopted. In 1998, three groups, the Association of American Physicians and Surgeons, the Competitive Enterprise Institute, and Consumer Alert filed a court challenge to the regulation.

The three groups were represented by Daniel Troy, a Washington attorney, who subsequently was named the FDA chief counsel by the Bush Administration. The agency says Troy has recused himself from the case, and therefore was not involved in the agency's decision to stop enforcing the rule and the subsequent decision by Thompson to continue enforcement.

Thompson's decision to stick with the rule followed a series of letters from advocates and legislators as well as editorials in The New York Times and USA Today. "What we have learned is that FDA is now planning to notify the court that it will suspend the pediatric rule for two years," three prominent House Democrats wrote in a March 18 letter to Thompson.

"During this period, FDA will evaluate whether to revoke the rule permanently," wrote Reps. Henry Waxman (D-CA), John Dingell (D-MI) and Sherrod Brown (D-OH). "This means that manufacturers seeking approvals for new drugs will no longer be required to conduct studies on pediatric safety and efficacy. It will also strip FDA of its ability to require pediatric testing of existing drugs.

"We urge you to direct FDA to reverse course and preserve access to vitally important safety and dosing information for children," the three House members wrote.

On March 22, six health care groups petitioned Thompson to keep the pediatric rule in force. "We are deeply distressed by the decision of the FDA to suspend the pediatric rule for two years," the group wrote. "This deals a tremendous blow in efforts to provide appropriate medications for infants, children and adolescents, and reverses several decades of effort to bring parity to children in the nation's drug supply."

The letter was signed by Ambulatory Pediatric Association, American Academy of Pediatrics, American Pediatric Society, Association of Medical School Pediatric Department Chairs, Elizabeth Glazer Pediatric AIDS Foundation, and Society for Pediatric Research.

"The Bush administration senselessly plans to abandon a farsighted regulation designed to ensure that all medicines used in children undergo proper testing for safety and efficacy," the Times said in an editorial April 7. The incentives alone will not do the job, the editorial said. "The voluntary approach will leave unstudied many medicines and age groups that the manufacturers see no profit in testing."

Meanwhile, Capitol Hill proponents of the pediatric rule are preparing to prop it up by making it a law. Later this week three Senate members will make an effort to introduce a bill codifying the rule. Sens. Hillary Clinton (D-NY), Mike DeWine (R-OH), and Christopher Dodd (D-CT) planned to introduce a bill that would codify the rule.

A corresponding House bill is also expected, sources said.

Meanwhile, HHS is working on integrating the provisions of the pediatric rule with the Best Pharmaceuticals for Children Act, which Bush Signed into law last January.

On April 24, the Administration published the following "notice of proposed rulemaking" in the Federal Register:

Given the present authorities contained in the Best Pharmaceuticals for Children Act, the FDA is issuing this advanced notice of proposed rulemaking to solicit comments on the most appropriate ways to update the 1998 "pediatric rule" so that it can most effectively address FDA's interest in timely pediatric studies of and adequate pediatric labeling for human drugs and biological products that are used or will be used in the treatment of children.

FDA is interested in what mechanisms, if any, may be necessary to augment the programs described in the BPCA and what present authorities, if any, have not proven effective, are now redundant, or need to be updated because of the BPCA…

On Jan. 4, the President signed into law the BPCA. This legislation both reauthorizes the exclusivity incentive program enacted originally in FDAMA and establishes an additional mechanism for obtaining information on the safe and effective use of drugs in pediatric patients.

The new BPCA mechanism consists primarily of authorizing several NIH funding mechanisms, including the [Foundation for the NIH], as vehicles for funding, using both public and private funds, studies of certain drugs under certain circumstances if the manufacturers of those drugs decline to conduct the requested pediatric studies. BPCA also provides a

mechanism for including information from such studies in the label of pediatric products.

Because it involves paying others to do the studies rather than having to litigate with a company to force it to conduct needed studies, some have argued that this new BPCA mechanism is a more cost- and time-efficient way of achieving the goal of adequate pediatric safety and efficacy labeling of these "gap" products than are some of the provisions of the pediatric rule.

Others point out that while these NIH funding mechanisms may be used to contract for pediatric studies of certain human drugs, the provision of BPCA for awarding study contracts does not extend to awarding contracts to study human biologics and certain antibiotics.

In addition, the public funding of these mechanisms is dependent on yearly congressional appropriations and the private donations are purely voluntary. Whether funds appropriated for such studies will be adequate to ensure that studies are performed and data submitted for all needed drug products remains uncertain. By statute, the BPCA is to sunset in 2007.

Because of these uncertainties in funding, limitations on the products covered, and the lack of required early planning regarding pediatrics in a drug's development process, some have argued that without the "requirement" provisions of the pediatric rule, FDA will not have the authority it needs to ensure that all medicines used in children of all ages are indeed safe and effective for that use.

Given the present authorities contained in the BPCA and the pediatric rule, this ANPRM is intended to solicit comments on the most appropriate ways to balance FDA's interest in timely pediatric studies of and adequate pediatric labeling for human drugs and biological products that are used or will be used in the treatment of children and FDA's interest in not imposing unnecessary human drug and biologic study requirements. FDA is particularly interested in what mechanisms, if any, may be necessary to augment the programs described in the BPCA and what present authorities, if any, are perhaps now redundant because of the BPCA.

The agency is particularly interested in the relationship between the approach to acquiring pediatric labeling information promulgated in the pediatric rule, and the approaches authorized in the BPCA. While FDA is interested in hearing any comments the public would like to submit on this issue, questions of specific interest to FDA include:

1. What changes to the pediatric rule, if any, would be necessary to integrate the BPCA and the pediatric rule more effectively?

2. How would the criteria used by NIH and FDA to request studies of already approved drugs relate to the standards promulgated in the pediatric rule for requiring pediatric labeling for certain drugs and biological products? Which criteria are more appropriate for determining when studies are conducted?

3. What provisions, if any, of the BPCA could apply to biological products?

4. How does the provision for a recommendation for a formulation change relate to the pediatric rule provision stating that in certain cases a sponsor may be required to develop a pediatric formulation? Should pediatric formulations be required in certain cases?

Resolution of these and other questions will be required before FDA can determine the optimum approach to ensuring that human drugs and biologics used in children have adequate information regarding the safe and effective use of these products in pediatric patients.

*NCI Programs:*

## USDA Expands Its Role In 5 A Day Partnership

The U.S. Department of Agriculture will expand its role in the National 5 A Day Partnership, the program that encourages consumers to eat five to nine servings of fruits and vegetables a day.

Under an agreement with the Department of Health and Human Services, USDA will increase consumer education opportunities related to 5 A Day, conduct research related to nutrient values in fruits and vegetables, and strengthen collaboration among federal, state, and industry organizations to promote fruit and vegetable consumption in addressing national health issues.

One specific goal is to provide additional information to consumers that encourages a balanced diet and includes physical activity that will help reduce the incidence of obesity in America.

HHS Secretary Tommy Thompson and Agriculture Secretary Ann Veneman made the announcement at a meeting of National 5 A Day partners on April 25.

NCI serves as the lead agency for 5 A Day, in a partnership that includes the Produce for Better Health

Foundation, the Centers for Disease Control and Prevention, the American Cancer Society, the National Alliance for Nutrition and Activity, the Produce Marketing Association, and the United Fresh Fruit and Vegetable Association.

Through programs such as the National School Lunch Program and the Women, Infants and Children Program, the USDA has the ability to reach millions of Americans with healthy eating tips.

"Fruits and vegetables are the original fast food," Thompson said. "The simple action of eating five to nine servings of fruits and vegetables a day reduces the risk for cancer, heart disease, diabetes, obesity, hypertension and other chronic diseases."

"USDA is proud to expand our role in this important partnership and will commit the necessary resources to help Americans meet these goals," said Veneman. "By helping Americans consume a balanced diet and incorporate exercise into their lifestyles, we can address the growing obesity problem in the U.S., especially among children."

The Memorandum of Understanding between the agencies supports the advancement of comprehensive planning at the federal, state and local level, expanded channels for the delivery of evidence-based interventions and improved availability of high quality data related to fruit and vegetable consumption.

"Approximately 70 percent of all adults and children in the U.S. do not eat the recommended five to nine servings of fruits and vegetables a day for good health," said Lorelei DiSogra, director of the 5 A Day at NCI. "And over 60 percent of Americans are still not aware of the need to eat five to nine servings of fruits and vegetables a day. This partnership is an excellent model of how diverse groups can come together to improve the public's health."

## Bethesda Guidelines Revised For Reporting Pap Results

A revised system for reporting the results of Pap tests, published in the April 24 issue of the Journal of the American Medical Association, will change the way laboratories communicate with physicians about the 50 million cervical cancer screening tests performed each year in the U.S.

Known as the 2001 Bethesda System, the reporting system conveys laboratory findings that help physicians and their patients decide what to do about the abnormalities found on Pap tests.

The 2001 Bethesda System does not itself include guidelines for managing these abnormalities. However, it serves as the basis for new management guidelines that appear in a companion article in JAMA. The guidelines were developed under the sponsorship of the American Society for Colposcopy and Cervical Pathology in tandem with the 2001 Bethesda System.

Publication of the two papers is considered a milestone in efforts to improve cervical cancer screening. "Together, Bethesda 2001 and the ASCCP guidelines should provide more uniform, evidence-based care of women with cervical abnormalities," said Diane Solomon, who has coordinated development of The Bethesda System at NCI.

Bethesda 2001 updates the earlier Bethesda System, first published in 1989 and revised in 1991. The 2001 version reflects the most current knowledge about the biology of Pap test abnormalities and addresses new screening technologies that appeared in the past decade.

Key changes include:

—Sample adequacy: The Bethesda System has always required laboratories to evaluate the adequacy of cervical cell samples based on a standard set of criteria. The 2001 Bethesda System incorporates criteria that are specific to the new thin-layer, or liquid-based, cell collection method now used by many doctors.

—New term (ASC-H) to denote atypical cells at higher risk of association with precancer: The older Bethesda System grouped all cells considered equivocal—atypical but not clearly precancerous— into one category known as atypical squamous cells of undetermined significance or ASCUS. Bethesda 2001 adds a new category for atypical cells at higher risk of association with precancer: "atypical squamous cells—cannot exclude a high-grade lesion" or "ASC-H." By highlighting such cases, the new system should help physicians detect and treat precancerous lesions more rapidly. In addition, the term "atypical squamous cells favor reactive" has been eliminated in order to focus attention on women at higher risk of having an abnormality.

—Benign cellular changes identified as "negative": The previous version of Bethesda included a category of "benign cellular changes" to communicate findings due to a variety of factors (e.g. inflammation). However, this approach caused confusion at times for clinicians who questioned whether this term indicated negative results or the need for follow-up. Now such benign changes are

more clearly identified as "negative."

In other changes, Bethesda 2001 recommends that laboratories report the use of computerized scanning of Pap test slides and the results of molecular testing (such as tests for the human papillomavirus).

The 2001 Bethesda System is the product of a workshop, sponsored by NCI and numerous professional societies, which took place April 30-May 2, 2001, in Bethesda. The workshop included more than 400 participants.

Even broader participation in the revision process was made possible through a dedicated Web site http://bethesda2001.cancer.gov, where more than 1,000 individual comments were received on the draft recommendations.

More than 90 percent of laboratories in the U.S. use The Bethesda System, as do laboratories in many other countries. To date, more than 20 national and international societies have endorsed Bethesda 2001.

*Funding Opportunities:*

## DOD Breast Cancer Program Innovator Award Recipients

The Department of Defense Congressionally Directed Medical Research Programs has funded five Breast Cancer Research Program Innovator Awards for fiscal year 2001.

The award was designed to recognize talented individuals, rather than projects, from any field of study by providing funding and freedom to pursue creative, potentially breakthrough research that could ultimately accelerate the eradication of breast cancer. The Innovator Awards will fund individuals up to $3 million for a period of up to four years.

The 2001 recipients of the Innovator Awards are:

**Mina Bissell**, director, Life Sciences Division, and senior staff scientist, Lawrence Berkeley National Laboratory. Bissell plans to investigate how aggressive breast cancer cell lines could be brought under control using signaling inhibitors.

**Gerald Diebold**, professor of physical chemistry, Brown University. Diebold seeks to develop a new method of breast tissue imaging based on an electroacoustic effect known as ultrasonic vibration potential. This is a new and unique approach to imaging that differs completely from the normal reflection phenomenon of ultrasound currently in use.

**Gregory Hannon**, associate professor, Cold Spring Harbor Laboratory. Capitalizing on his studies of the mechanisms of double stranded RNA-induced gene silencing, Hannon plans to search the human genome for proteins that are selectively required for the survival of breast cancer cells. The ultimate goal is the identification of novel targets for breast cancer treatment.

**Erkki Ruoslahti**, distinguished professor, The Burnham Institute. The focus of Ruoslahti's Innovator Award will be to devise strategies targeting the vasculature of breast cancer.

**Junying Yuan**, professor, Department of Cell Biology, Harvard Medical School. Yuan will identify molecules that allow human cells to undergo aging and eventual death. Identification of such molecules will play a major role in future therapies for breast cancer.

The CDMRP offers the BCRP Innovator Award again for FY02. The program is looking for individuals with proven abilities in any field that wish to redirect their careers in ways that would aggressively accelerate the eradication of breast cancer.

The Innovator Award mechanism provides up to $3 million over a four-year period. The primary criteria for making these awards will be the record and potential for accomplishment of the applicant, not the merits of a specific research project. Applications require an essay rather than a traditional research proposal.

A required electronic Letter of Intent is due by May 30, and submission of the electronic application is due by June 13. Full details on eligibility, requirements, and instructions for applications are available on the CDMRP web site: http://cdmrp.army.mil/funding/archive/02bcrp2.pdf.

For further information on other current CDMRP research funding opportunities in breast, prostate, and ovarian cancer; neurofibromatosis; tuberous sclerosis; and chronic myelogenous leukemia, see http://cdmrp.army.mil.

## Foundation Seeks Applicants In Mesothelioma Research

Mesothelioma Applied Research Foundation Inc. invites applications for the third round of its developmental projects that relate to either benchwork research or clinical research that are not presently funded or pending review.

The projects may be conducted through any not-for-profit academic, medical or research institution,

in the U.S. or abroad. Over the previous two rounds, four grants of approximately $100,000 each were awarded out of 17 applications received. The award for any project will be for a period of 12 months, renewable for 12 more months with a funding of up to $50,000 per year (maximum total per project, $100,000). MARF does not pay institutional indirect costs.

Encouraged projects include, but are not limited to, benchwork/clinical investigations of: Strategies for early detection of new or progressive disease; Definition of targetable differences between normal and transformed mesothelium and development of novel strategies for treatment taking advantage of these targets; Therapeutic intervention, including a. Gene therapy, b. Immunotherapy, c. Novel chemotherapeutic compounds, d. Novel radiation techniques, e. Novel mechanisms which inhibit angiogenesis metalloproteinases; Determination of clinical/molecular determinants for prognosis; Pain management.

Application Receipt Date: Aug. 1. Applications are limited to 10 pages. It is anticipated that review will be completed by Oct. 15 and any award(s) activated by Nov. 30, 2002. For a copy of the application, see http://www.marf.org/marfFrames/ApplicationFrame.htm.

Inquiries: Submit an original application and 10 copies to: MARF Inc., 1609 Garden St., Santa Barbara, CA 93101; phone 805-560-8942; fax 805-560-8962; email: c-hahn@marf.org.

## Program Announcements

**PAR-02-037: Small Grants Program for Behavioral Research in Cancer Control**

Application Receipt Dates: April 22, Aug 20, Dec. 20, 2002; April 21, Aug. 20, and Dec. 22, 2003.

NCI Division of Cancer Control and Population Sciences invites behavioral research applications in cancer control from new investigators or established scientists refocusing their research interests to behavioral research in cancer. The Small Grants Program is designed to aid and facilitate the growth of a nationwide cohort of scientists with a high level of research expertise in behavioral cancer control research. Small grants are short-term awards to provide support for pilot projects, development and testing of new methodologies, secondary data analyses, or innovative studies that provide a basis for more extended research. The following program areas focused on behavior and cancer are appropriate for small research grant applications:

Screening and early detection: preliminary studies to improve compliance with and utilization of proven screening technologies; research regarding patient and provider decision making when screening guidelines are controversial or uncertain (e.g., PSA testing). The development and design of new approaches to increase screening in diverse populations as well as the refinement of behavioral measures are encouraged. In the area of breast screening and detection, studies of breast self-examination as a single modality will not be accepted. Other examples can be found at: http://dccps.nci.nih.gov/ACSRB/type.html.

Health promotion research: studies to change current behaviors and/or institute new behaviors, such as diet, physical activity, energy balance, virus exposure, sun exposure and other behavioral risk factors relevant to reducing incidence, morbidity or mortality from cancer. Other examples may be found at: http://healthpromotionresearch.cancer.gov.

Tobacco control research: tobacco use etiology, prevention and cessation including, but not limited to, pilot studies that test strategies for improving utilization of current technologies in high risk individuals and populations; studies assessing the effect of various policies on tobacco initiation and use; secondary data analyses of existing datasets. Additional examples may be found at: http://tobaccocontrol.cancer.gov.

Support of this program announcement will be through individual research project grants RO3. The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PAR-02-037.html.

Inquiries: Veronica Chollette, Division of Cancer Control and Population Sciences, NCI, 6130 Executive Blvd, Suite 4100, MSC 7331, Executive Plaza North, Rockville, MD 20892, phone 301-435-2837; e-mail vc24a@nih.gov

**PAR-02-042: Colorectal Cancer Screening in Primary Care Practice**

Letter of Intent Date: May 16, Sept. 18, 2002; Jan. 16, May 16, 2003.

Application Receipt Date: June 20, Oct. 23, 2002; Feb. 20, June 20, 2003.

NCI and Agency for Health Care Research and Quality are interested in promoting research to enhance understanding of colorectal cancer screening delivery, utilization, and outcomes in primary care practice. The objective is to encourage applications for exploratory/developmental grants R21 designed to improve the delivery and uptake and evaluate the short-term outcomes of colorectal cancer screening in primary care practice. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-02-042.html.

Inquiries: Carrie Klabunde, Applied Research Program, NCI, , DCCPS, EPN 4005; 6130 Executive Blvd., Bethesda, MD 20892-7344, phone 301-402-3362; fax 301-435-3710; e-mail Ck97b@nih.gov

*In Brief:*

## ASCO Awards $1.9 Million In Geriatric Oncology

(Continued from page 1)

$225,000, a total of $1.9 million, to develop combined training programs in medical oncology and geriatric medicine. The society received a grant from the John A. Hartford Foundation Inc., of New York, for the initiative. **Charles Balch**, executive vice president and CEO of ASCO and **John Bennett**, professor of medicine, Laboratory Medicine and Pathology at the University of Rochester Medical Center, will serve as co-principal investigators. Recipients include: **Sharon Levine**, Boston Medical Center; **Keith Sullivan**, Duke University Medical Center; **Ross Donehower**, Johns Hopkins University; **William Gradishar**, Northwestern University; **Dennis Slamon**, UC-Los Angeles; **Miriam Rodin**, University of Chicago; **Catherine Klein**, University of Colorado Health Sciences Center; **Scott Gitlin**, University of Michigan at Ann Arbor; **Deepak Sahasrabudhe**, University of Rochester and **Toni Miles**, University of Texas, San Antonio. . . . **AMERICAN ASSOCIATION FOR CANCER RESEARCH** provided 70 early career minority scientists with Minority Scholar Awards, and 28 faculty from historically black colleges and universities with Faculty Scholar Awards, to enable the scientists and faculty to travel to the AACR meeting in San Francisco earlier this month. The awards are supported by a grant from the NCI Comprehensive Minority Biomedical Program. The AACR-Women in Cancer Research Council awarded 10 Brigid G. Leventhal Scholars in Cancer Research Awards to promising early-career women scientists. . . . **ARIZONA CANCER CENTER** at the University of Arizona and the National Foundation for Cancer Research are collaborating on the NFCR Center for New Therapies Development at the Arizona Cancer Center. **Daniel Von Hoff**, director of the Arizona Cancer Center, and **Laurence Hurley**, Howard Schaeffer Chairman in Pharmaceutical Sciences at the University of Arizona College of Pharmacy, will co-direct the center. The center will conduct research on pancreatic cancer. . . . **BAYLOR HEALTH CARE SYSTEM** received a $5 million gift from the W.W. Caruth Jr. Foundation Fund to establish the W.W. Caruth Jr. Program in Transplantation Immunology and the W.W. Caruth Jr. Chair in Organ Transplantation Immunology at Baylor Research Institute. Baylor has begun a search for a transplant immunologist. The grant, matched by Baylor Health Care System Foundation, will create a $10 million endowment. . . . **LEONARD HERZENBERG,** professor of genetics, Emeritus at Stanford University, received the 2002 Edwin F. Ullman Award, sponsored by Dade Behring Inc., at the American Association for Clinical Chemistry Annual Oakridge conference in La Jolla, CA. Herzenberg was recognized for the development of monoclonal antibodies and the Fluorescence Activated Cell Sorter as tools for biomedical studies. . . . **PEDIATRIC AIDS** Clinical Trials Group will receive $36 million in renewed funding from the National Institute of Allergy and Infectious Diseases. The five-year awards will support 18 university-based clinical trials sites, a statistical and data management center, and a coordinating and operations center. A new emphasis will be reducing the AIDS epidemic among U.S. adolescents. The PACTG also will support clinical research at four international sites, two in South Africa and two in Thailand. The PACTG was established in 1997 and to date, has begun 113 clinical trials and, as of December 2001, enrolled about 27,432 women and children. The sites and principal investigators are: University of Alabama at Birmingham, Robert Pass; University of California, Los Angeles, School of Medicine, Yvonne Bryson; University of California, San Diego, Stephen Spector; University of California, San Francisco, Moffit Hospital, Diane Wara; University of Miami School of Medicine, Gwendolyn Scott; Children's Memorial Hospital/Chicago, Ram Yogev; Tulane University Medical School/New Orleans, Russell Van Dyke; Johns Hopkins University School of Public Health and Hygiene/Baltimore, Andrea Ruff; Children's Hospital/Boston, Kenneth McIntosh; University of Massachusetts Medical School/Worchester, Katherine Luzuriaga; UMDNJ-New Jersey Medical School/Newark, Paul Palumbo; Bronx-Lebanon Hospital Center, Saroj Bakshi; Columbia University College of Physicians and Surgeons Columbia Presbyterian Medical Center/New York City, Anne Gershon; Duke University Medical Center/Durham, Ross McKinney Jr.; Children's Hospital of Philadelphia, Stuart Starr; University of Puerto Rico Pediatric Hospital, Irma Febo; St. Jude Children's Research Hospital/Memphis, Patricia Flynn; Texas Children's Hospital/Houston, William Shearer. Statistical and data management center: Harvard School of Public Health, Boston, Michael Hughes. Coordinating and research operations center: Social & Scientific Systems Inc., Bethesda, Steven Spector.

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