

## Appeals Court Finds Terminal Patients Have Constitutional Right To Phase I Drugs

*By Paul Goldberg*

The Constitution guarantees terminally ill patients the right to access therapies that have completed phase I testing, the U.S. Court of Appeals for the District of Columbia ruled May 2.

A three-judge panel was split 2-1 in favor of the Abigail Alliance for Better Access to Developmental Drugs, a patient group that has sued FDA to get access to drugs that have gone through dose-escalation studies and are found to be suitable for further trials.

The ruling holds that the right to obtain phase I drugs is part of the Due Process Clause of the Fifth Amendment, which provides that “no person shall be... deprived of life, liberty, or property, without due process of law.”

A lower court was wrong to have dismissed the Abigail Alliance suit on technical grounds, for “failure to state a claim,” and must now proceed to

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## Von Eschenbach's NCI “Farewell Reception,” Gift Solicitation, Raises Legal And Ethical Issues

*By Kirsten Boyd Goldberg and Paul Goldberg*

A “farewell reception” planned in honor of NCI Director Andrew von Eschenbach raises legal and ethical concerns, lawyers say.

The invitation to the May 17 event, sent to top NCI and NIH officials, requires a payment of \$25 per person and states: “gift contributions also welcome.” The event is scheduled to be held on the NIH campus, and the R.S.V.P. contact listed in the invitation is an NCI contractor working in the Office of Communications.

“Dr. von Eschenbach’s gift has not yet been determined,” NCI spokesman Jen Thompson said in an email to The Cancer Letter. “There is no suggested contribution, and the gift will be paid for entirely by personal funds.”

Lawyers say that before the first hunk of cheese is cut into little pieces for the reception, NCI officials should consult a volume of Standards of Ethical Conduct for Employees of the Executive Branch, issued by the U.S. Office of Government Ethics, as well as Title 18 of the U.S. Code, covering Crimes and Criminal Procedure.

“To the extent that this invitation is actually soliciting contributions for gifts by stating that ‘gift contributions also welcome,’ it would appear to be in conflict with the prohibition on soliciting contributions from employees for

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## Court Finds Right To Drugs Part Of Due Process Clause

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consider the merits of the case, the ruling states. Now, the suit can go in one of three directions: to the lower court, to an "en banc" rehearing by all active D.C. appellate judges, or to the Supreme Court.

"If this ruling stands, and we expect it will, it will prevent FDA from interfering with a patient's access to a drug if the company agrees to provide it," said Steven Walker, an advisor to Abigail Alliance and the author of its drug development proposals.

Walker said the ruling adds urgency for the agency to redesign its approach to expanded access to drugs for terminal diseases. "This ruling is a major step forward in terms of instructing FDA that they have to put in place a procedure that is going to work not just for a few terminal patients, but for most terminal patients," he said to *The Cancer Letter*. "And that's going to require more than just tweaking the existing standard access. Whatever they build now will have to pass this test of Constitutional rights."

Scott Gottlieb, FDA deputy commissioner for medical and scientific affairs, said the agency is studying the opinion, and would consult with the Department of Justice regarding next steps.

"We remain sympathetic to the desire of terminally ill patients to gain access to experimental treatments when they have exhausted other therapeutic options, and

are exploring a number of new efforts to improve how we make investigational drugs available through expanded access programs," Gottlieb said in a statement.

Formed in 2001, the tiny Abigail Alliance has picked colossal targets: FDA, the methodology employed in development of cancer drugs, and the federal government's assertion that its drug regulations are based on science and evidence-based medicine.

Walker, an environmental scientist whose wife died of colon cancer, describes himself as a political moderate, as does Frank Burroughs, whose daughter, Abigail, died of head and neck cancer. However, from the outset, the alliance's cause has been championed primarily by the right.

The group's allies include free-marketeers on the editorial board of *The Wall Street Journal*, opponents of the FDA requirement that drugs demonstrate efficacy, and attorneys at the Washington Legal Foundation, a public-interest law firm that receives funding from the pharmaceutical industry (*The Cancer Letter*, Aug. 5, 2005).

Parallel to court action, the alliance is promoting the "Tier 1" drug development schema, which would make give drug companies the option to start selling drugs after conclusion of phase I testing. The plan is included in a bill introduced by Sen. Sam Brownback (R-Kan.). The bill also seeks to place restrictions on the use of placebo in clinical trials (*The Cancer Letter*, Dec. 2, 2005).

Mainstream advocacy groups and professional societies haven't taken a position on Brownback's bill and are similarly refraining from commenting on the appellate ruling. Sources said the strategy is to let the bill and the alliance's court battles lose steam on their own. Though pharmaceutical companies would be affected by the Tier 1 proposal, industry groups have been silent on the matter.

Recently, the American Society of Clinical Oncology and the National Coalition for Cancer Survivorship filed a "citizen petition" urging FDA to come up with a systematic approach to expanded access to drugs (*The Cancer Letter*, April 14, 2006).

### A New Layer of Controversy: Judicial Philosophy

The appellate court ruling has added an overlay of judicial philosophy to this complex dispute.

The biggest surprise in the majority opinion is the methodology used to assert the constitutional right to phase I drugs. The ruling relied on "substantive due process analysis," an approach regularly condemned by conservatives as a justification for jurists to mine the



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Founded Dec. 21, 1973, by Jerry D. Boyd.

Constitution for new rights.

The majority opinion was filed by Judge Judith Rogers, a Clinton appointee, and joined by Chief Judge Douglas Ginsburg, a Reagan appointee and an unsuccessful nominee to the Supreme Court. (Ginsburg's nomination to the Supreme Court was withdrawn following disclosures that he smoked marijuana while teaching at Harvard Law School.)

Filing a dissenting opinion, Judge Thomas Griffith, a recent Bush appointee, lambasted the Rogers and Ginsburg opinion as an exercise in judicial activism. Observers say Griffith's views are closer to those of officials at the Department of Justice, which is defending the case on behalf of FDA.

Griffith was appointed to the bench last year, as a result of a deal that avoided the "nuclear option," an effort by Republicans to eliminate the Senate Democrats' right to filibuster judicial nominees. Democrats had blocked his nomination, citing concerns over Griffith's failure to maintain a legal license while he practiced law in Washington, D.C., and Utah, where he served as general counsel for Brigham Young University.

In the majority opinion, Rogers and Ginsburg argue that FDA is preventing terminally ill but mentally competent patients from accessing "potentially life-saving treatment."

"Barring a terminally ill patient from the use of a potentially life-saving treatment impinges on this right of self-preservation," the opinion states. "Such a bar also puts the FDA in the position of interfering with efforts that could save a terminally ill patient's life. Although the common law imposes no general duty to rescue or to preserve a life, it does create liability for interfering with such efforts."

While therapies that have gone through phase I trials are available to patients who enroll in phase II trials, access to such therapies is inequitably denied to patients outside these trials.

"The prerogative asserted by the FDA—to prevent a terminally ill patient from using potentially life-saving medication to which those in phase II clinical trials have access—thus impinges upon an individual liberty deeply rooted in our Nation's history and tradition of self-preservation," the opinion states.

Rogers and Ginsburg extrapolate the "right to live" from the "right to die" case, brought in 1990 on behalf of a comatose Missouri woman (*Cruzan v. Director of the Missouri Department of Health*). In that case, the Supreme Court ruled that individuals who are of sound mind have a right to decline medical treatment. However, the plaintiff, being in a coma, was unable to

exercise such rights.

"Like the right claimed in *Cruzan*, the right claimed by the alliance to be free of FDA imposition does not involve treatment by the government or a government subsidy," the majority opinion states.

"Rather, much as the guardians of the comatose patient in *Cruzan* did, the alliance seeks to have the government step aside by changing its policy so the individual right of self-determination is not violated.

"The alliance claims that there is a protected right of terminally ill patients to choose to use potentially life-saving investigational new drugs that have successfully cleared phase I. If there is a protected liberty interest in self-determination that includes a right to refuse life-sustaining treatment, even though this will hasten death, then the same liberty interest must include the complementary right of access to potentially life-sustaining medication, in light of the explicit protection accorded 'life.'"

By contrast to the ancient right of self-preservation, the government's right to regulate the safety and efficacy of drugs is of recent vintage, the opinion states.

"For over half of our Nation's history, then, until the enactment of the 1906 [Food, Drug, and Cosmetic Act], a person could obtain access to any new drug without any government interference whatsoever," the opinion states.

"Even after enactment of the FDCA, in 1938, Congress imposed no limitation on the commercial marketing of new drugs based upon the drugs' effectiveness. Rather, at that time, the FDA could only interrupt the sale of new drugs based on its determination that a new drug was unsafe.

"Government regulation of drugs premised on concern over a new drug's efficacy, as opposed to its safety, is of recent origin. And even today, a patient may use a drug for unapproved purposes even where the drug may be unsafe or ineffective for the off-label purpose.

"Despite the FDA's claims to the contrary, therefore, it cannot be said that government control of access to potentially life-saving medication 'is now firmly ingrained in our understanding of the appropriate role of government,' so as to overturn the long-standing tradition of the right of self-preservation."

### **Drug Regulation: New Role For Courts?**

In his dissenting opinion, Griffith wrote that the majority would force the courts to assume the role of drug regulators.

"Before today, scientists and physicians at the FDA, in consultation with the greater scientific and

medical communities through scientific advisory panels, applied limited and often disputed scientific knowledge about an experimental drug in determining what level of access should be given to terminally ill patients and what medical circumstances warrant such access,” Griffith wrote.

“Under the majority’s approach, the U.S. District Court for the District of Columbia must now evaluate limited scientific knowledge about a phase I drug and determine whether that drug is potentially life-saving enough to require constitutional protection.

“Because the alliance has failed to present objective evidence establishing a deeply rooted right to procure and use experimental drugs, I would apply rational basis review to its due process challenge...

“Although terminally ill patients desperately need curative treatments, their death can certainly be hastened by the use of a toxic drug. Prior to distribution of a drug outside of controlled studies, the government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of such a drug.”

The opinions are posted at <http://www.cadc.uscourts.gov/bin/opinions/allopinions.asp>.

### ***Troubled Farewell:*** **Lawyers Urge Review Of Ethics Before Von Eschenbach “Roast”**

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a gift to the employees’ superior,” said John Engel, an attorney with the Washington firm of Engel & Novitt.

“In particular, to the extent that this solicitation has been sent to current NCI employees and/or current FDA employees, it would appear that there is an issue under the ethics regulations codified in Title 5 CFR 2635.302a,” Engel said.

The regulation cited by Engel states that “an employee may not: (1) Directly or indirectly, give a gift to or make a donation toward a gift for an official superior; or (2) Solicit a contribution from another employee for a gift to either his own or the other employee’s official superior.”

The same principles that bar federal officials from soliciting political contributions could apply to seeking gift contributions, said Charles Tiefer, professor of law at the University of Baltimore School of Law and former solicitor and deputy general counsel of the U.S. House of Representatives.

“It has been a felony for a federal officer like Dr. von Eschenbach to solicit contributions of a political

nature from his subordinate employees as long as there has been a federal civil service,” Tiefer said. “Before he put the squeeze on the people who work for him, he should have read 18 USC, Section 602, which says, ‘it shall be unlawful for an officer of any department to knowingly solicit any [political] contribution from any other such officer, employee, or person.’ This is punishable by up to three years in prison.

“That Dr. von Eschenbach shakes down his vulnerable government workers for his personal pocket rather than his political pocket may keep him out of prison, but does nothing to improve his tarnished ethics,” Tiefer said.

The appearances are troubling, too, said Michael Clark, a health care lawyer with the Houston firm of Hamel Bowers & Clark and a former federal prosecutor.

“It’s just an unseemly scenario,” Clark said. “The idea of saying, ‘and we strongly suggest that you bring gifts,’ bothers me. Because the negative pregnant there is... ‘and if you don’t...’ Are they going to be keeping the list and checking it twice, to find out who is naughty and nice?”

Richard Brenner, principal of Chaco Canyon Consulting, a business teamwork consultant, said events of this sort are bad for morale. “When it comes to ethics, appearance is paramount,” Brenner said. “The goal should always be to meet either the spirit of the regulation’s constraints, or the regulation’s actual constraints, whichever you think is more constraining.

“It’s all about conflict of interest,” Brenner said. “If the outgoing director can in any way affect the career status of anyone attending the ‘roast’—either positively or negatively—then gifts of real value, and even the decision to attend, are in my view problematic.”

It doesn’t help that von Eschenbach isn’t retiring to Texas, but assuming the top position at FDA, an agency that regulates NCI, lawyers say. “Dr. von Eschenbach is an official who will continue serving as the superior of solicited government employees either at NCI or at FDA, and, in the latter position, he will continue to have responsibility for regulating NCI-sponsored clinical trials,” Engel said.

Since von Eschenbach continues to run both NCI and FDA, he finds himself in an ethical bind. As FDA commissioner, he has to treat his NCI employees as a “prohibited source” of gifts, lawyers say. This conflict wouldn’t disappear after he formally resigns from NCI.

Von Eschenbach has said he would leave NCI, but is yet to announce the date of his departure. President

Bush has nominated him for FDA commissioner, but two Senators placed a hold on his candidacy until the agency makes a decision on approval for over-the-counter sale of the emergency contraceptive Plan B.

No acting NCI director has been named.

“Dr. von Eschenbach has said that he plans to resign; at this time, we do not have a specific date for his official resignation,” Thompson, a spokesman for the institute, wrote in an email to *The Cancer Letter*. “The announcement of an acting or official NCI director will come from the White House. We do not have additional information at this time.”

Thompson confirmed that an event for von Eschenbach is being planned. “The reception invitation is being sent to NIH and NCI leadership, as well as to NCI management,” she wrote in the email. “The reception is a way to thank Dr. von Eschenbach for his service and work at NCI.”

The reception is scheduled to be held at NIH Building 60, known as the Cloister, because it was built in 1923 to house an order of nuns, the Sisters of the Visitation of Washington. The banquet space holds up to 150 people. NIH permission is required to use the space.

The invitations specified “R.S.V.P. to Ms. Beverly Goodwine,” an NCI contractor in the Office of Communications. An NCI phone number and an email address were specified.

One invited guest said attendance wasn’t treated as optional. “I thought it was expected, so I sent in my \$25 and a gift contribution,” the official said.

It was unclear whether the “roast” part of the reception would actually take place, as guests and planners encountered reluctance on the part of staff to lampoon von Eschenbach, sources said.

Von Eschenbach’s gift-giving has embarrassed the institute in the past, raising the same legal and ethical concerns as the parting gift contemplated by his NCI staff.

In 2004, von Eschenbach publicly presented what he described as a “token of . . . appreciation and respect” to then-FDA Commissioner Mark McClellan, for his participation in the NCI Director’s Lecture Series.

The token, a trophy called Ovation, stood almost a foot tall and consisted of a glass block topped with an antler-like form and a cobalt-blue sphere. Engraved, the Ovation was generally sold for \$287, well above the government limit on token gifts (*The Cancer Letter*, Feb. 6, 2004).

After lawyers told *The Cancer Letter* that NCI would be considered a prohibited source of gifts for

an FDA official, McClellan returned the gift to von Eschenbach.

One NCI insider suggested that the Ovation, if it’s still intact, would make an appropriate parting gift for von Eschenbach. “But I guess it wouldn’t be legal for him to accept it, either,” the official added.

## Professional Societies: **ASCO Recognizes Leaders For Outstanding Achievement**

The American Society of Clinical Oncology announced the recipients of its 2006 Special Awards, which recognize individuals who have made significant contributions to both ASCO and the practice of clinical oncology. The awards will be presented during the ASCO annual meeting in Atlanta June 2-6.

—Lance Armstrong, testicular cancer survivor and founder of the Lance Armstrong Foundation, will receive the Special Recognition Award. Armstrong and his foundation have significantly increased public awareness of the role clinical trials play in the fight against cancer, and of the issues facing cancer survivors. LAF has awarded more than \$14.4 million in support of survivorship and testicular cancer clinical research and more than \$3.7 million to non-profit cancer organizations across the country. Armstrong’s foundation has improved cancer survivor care through the creation of LIVESTRONG SurvivorCare and, in collaboration with Centers for Disease Control, the National Action Plan, which both serve to address survivors’ specific challenges and specialized health care needs.

—Clara Bloomfield, Distinguished Service Award for Scientific Achievement. For more than three decades, Bloomfield has worked to discover new treatments and cytogenetic and molecular markers. Her pioneering clinical research in adult leukemia and lymphoma found that acute leukemia, previously believed to be fatal, could be cured with the use of chemotherapy.

—Alan Coates, Distinguished Service Award for Scientific Leadership. Coates’ leadership as CEO of The Cancer Council Australia contributed to the creation of the first national government cancer agency, Cancer Australia, in his native country. He also is co-chairman of the International Breast Cancer Study Group and formerly served as chairman of the Australia New Zealand Breast Cancer Trials Group. He was the first internationally-based oncologist elected to the ASCO board.

—Francis Collins, Science of Oncology Award and

Lecture. In his 13-year tenure as director of the National Human Genome Research Institute, Collins led a team of scientists in successfully completing the Human Genome Project. Collins has developed and advanced the idea of “positional cloning,” a means of finding the gene involved for a specific disease by determining its position in the genome, rather than isolating genes based on a biochemical or physiologic measure of disease.

—Kathy Giusti, Partners in Progress Award. Giusti, founder and CEO of the Multiple Myeloma Research Foundation and CEO of the Multiple Myeloma Research Consortium, has raised more than \$56 million for myeloma research and clinical trials. A 10-year multiple myeloma survivor, Giusti became a dedicated full-time spokesperson for people living with this rare form of cancer shortly after her diagnosis at age 37.

—V. Craig Jordan, American Cancer Society Award and Lecture. Jordan, of Fox Chase Cancer Center, will be honored for his translational research with tamoxifen and raloxifene in the prevention of breast cancer. He was one of the first researchers to analyze tamoxifen’s anticancer properties, which led to his extensive research, and one of the first to study raloxifene. He is scientific chair for the Study of Tamoxifen and Raloxifene trial.

—Anna Meadows, Pediatric Oncology Award and Lecture. Meadows, of the Children’s Hospital of Philadelphia, is receiving this award for her dedication to the development of successful programs for the care of long-term survivors of childhood cancer. She has carried out research that has resulted in effective interventions with survivors to lessen many long-term complications.

—Joseph Simone, Public Service Award. Simone will receive this award in recognition of his work, including the founding of ASCO’s Quality Oncology Practice Initiative, which provides measurement, feedback, and improvement resources for medical oncology practices. He has also chaired the National Cancer Policy Board of the Institute of Medicine, which issued influential reports on the quality of cancer care. Through his earlier work at St. Jude Children’s Research Hospital, Simone helped develop therapies for childhood leukemia, which resulted in substantial cure rates.

—Dennis Slamon, David A. Karnofsky Memorial Award and Lecture. Named for one of the true pioneers in oncology, this award is bestowed on individuals who, through their clinical research, have changed the way oncologists think about the general practice of oncology. Slamon, of the University of California, Los Angeles, Jonsson Cancer Center, is a leader in the field of breast

cancer genetics and in the emerging wave of targeted therapy. He and his colleagues conducted the basic and applied research that laid the groundwork for the development of trastuzumab, the first targeted therapy for patients with HER-2-positive breast cancer.

### **ASCO Honors Community Oncologists**

ASCO also will honor 12 community oncology practices for their commitment to improving the care of people with cancer through increased participation in clinical trials. The Clinical Trial Participation Awards will be presented June 3 during the annual meeting.

The award winners were selected based on many factors including patient accrual to clinical trials over a three-year period. Special consideration was given to practices that increased clinical trial participation among underrepresented populations, as well as practices that used innovative techniques to overcome barriers to the enrollment of cancer patients onto clinical trials.

“The knowledge gained through clinical trials has helped scientists and doctors develop new ways to slow, halt, and even prevent the development of cancer,” said Joseph Bailes, interim executive vice president and CEO of ASCO. “However, less than 5 percent of adult patients with cancer are enrolled in clinical trials, and this lack of participation is slowing progress in the development of new therapies.

“With the Clinical Trial Participation Awards, we are honoring practices for their exceptional dedication to improving the quality of cancer care by increasing awareness in the community about the value of clinical trials participation,” Bailes said.

Nominations for the award were made by several NCI cooperative groups, the ASCO Clinical Practice Committee, the CCOP Program, and the following community-based oncology research networks: US Oncology, Minnie Pearl Cancer Research Network, and Hoosier Oncology Group.

Applications were peer-reviewed by a subcommittee of ASCO’s Cancer Research Committee. The top 12 were selected.

This awards program is supported by a grant from the Coalition of National Cancer Cooperative Groups that enables ASCO to provide award recipients with a travel grant to attend ASCO’s annual meeting.

To date, 31 community-based practices have received ASCO’s Clinical Trial Participation Award.

The 2006 honorees are:

Carle Cancer Center CCOP, Urbana, Ill.

Florida Hospital Cancer Institute, Orlando, Fla.

Green Bay Oncology Ltd., Green Bay, Wisc.  
Marshfield Clinic, Marshfield, Wisc.  
Michiana Hematology-Oncology, P.C., South Bend, Ind.  
New York Oncology Hematology, Albany, New York.  
Rocky Mountain Cancer Centers, Denver, Co.  
St. Joseph Mercy Hospital Cancer Program, Ann Arbor, Mich.  
St. Luke's Mountain States Tumor Institute, Boise, Idaho.  
Tennessee Oncology PLLC, Nashville, Tenn.  
Warren Cancer Research Foundation, Tulsa, Okla.  
Wichita CCOP, Wichita, Kan.

*In Brief:*

## **Horwitz Wins BMS Award For Work On Paclitaxel**

**SUSAN BAND HORWITZ** is the winner of the 29<sup>th</sup> annual Bristol-Myers Squibb Freedom to Discover Award for Distinguished Achievement in Cancer Research for her discovery of the mechanism of action of paclitaxel. Horwitz is the Falkenstein Professor of Cancer Research and the co-chair of the Department of Molecular Pharmacology at the Albert Einstein College of Medicine of Yeshiva University. Horwitz discovered that paclitaxel works by binding to microtubules, impeding uncontrolled cancer cell growth. "Dr. Horwitz's pioneering research and critical insights into the mechanisms of action of paclitaxel more than two decades ago propelled it into clinical development by the National Cancer Institute, where it was ultimately shown to be a highly effective cancer drug that has had a profound effect on enhancing and extending the lives of thousands of cancer patients around the world," said **Robert Kramer**, vice president, Oncology and Immunology Discovery Biology, Bristol-Myers Squibb. "That achievement alone should have been sufficient to grant this award. Yet Dr. Horwitz has gone well beyond that research in the years since. The emergence of drug resistant cancer cells that develop after treatment with effective therapies such as paclitaxel have plagued patients and physicians, spurring researchers to study the mechanisms of cancer drug resistance in order to seek methods or agents to restore a tumor's ability to respond to chemotherapy. As one of the world's leading molecular pharmacologists, Dr. Horwitz has been in the forefront of that effort. By so doing, she is continuing to extend

her research and the reach of her contributions to new frontiers and discoveries that will benefit humankind." Horwitz is a past-president of the American Association for Cancer Research. . . . **ARTHUR RIGGS**, director of Beckman Research Institute at City of Hope, was elected to membership in the National Academy of Sciences. Riggs was selected for his work in founding the field of epigenetics. His work also led to the founding of the biotechnology industry through research that led to recombinant DNA technology that was used by Genentech to produce the first FDA-approved biotechnology product, the synthetic insulin Humulin for diabetes. Through his work with the production and engineering of monoclonal antibodies, Riggs has contributed to the development of cancer therapies, including Herceptin, Avastin, and Rituxan. . . . **JOHN EDWARD PORTER** will receive the 2006 Association of American Cancer Institutes Public Service Award in recognition of his efforts to advance cancer research and to support programs for patients, caregivers, and communities. A 21-year U.S. Congressman from Illinois, Porter served on the Appropriations Committee, and was chairman of the Subcommittee on Labor, Health and Human Services, and Education. Porter is chairman of the board of Research! America and vice chairman of the Foundation for NIH. Porter also is partner in the Washington law firm Hogan & Hartson. "Because of Mr. Porter's consistent and effective leadership in the Congress and in particular his support for the doubling of the National Institutes of Health budget, clinicians, scientists, and educators at cancer research centers have the resources to develop programs that ease the burden of cancer in their communities," said Steven Rosen, director of the Robert H. Lurie Comprehensive Cancer Center at Northwestern University and a member of the AACI annual meeting program committee. The award will be presented at the AACI annual meeting in October. . . . **PAUL SELIGMAN** was appointed to the new position of associate center director for safety policy and communication in the FDA Center for Drug Evaluation and Research. "This step will provide a more standardized and predictable approach to ensuring drug safety and enhance the effectiveness and timeliness of the information we provide to the healthcare community and the public," said CDER Director **Steven Galson**. Seligman will have oversight of the Drug Safety Board staff and the MedWatch program and will have a role in implementing recommendations from external organizations, such as the Institute of Medicine and the Government Accountability Office. Seligman joined FDA in 2001 as director of the CDER Office

of Pharmacoepidemiology and Statistical Science. . . . **JOYCE NILAND** was named as the first holder of the newly endowed Edward and Estelle Alexander Chair in Information Sciences, and appointed as associate director of City of Hope. The chair was established through a bequest from the estate of Edward and Estelle Alexander, said **Theodore Krontiris**, executive vice president, medical and scientific affairs, and director of City of Hope. Niland joined City of Hope in 1988. She is a professor in the Beckman Research Institute and holds a joint appointment within the Keck School of Medicine at University of Southern California. She also heads the City of Hope Division of Information Sciences. "City of Hope is a key participant within the NCI clinical trials informatics initiative," said Niland. "This endowment will enable us to continue our collaborations with other cancer centers in creating a global information model to speed future biomedical research." . . . **UNIVERSITY OF ARKANSAS** Medical Sciences Cancer Research Center scientists received a \$2.9 million grant from the Department of Defense breast cancer research program. **Thomas Kieber-Emmons**, the Josetta Wilkins Chair of Breast Cancer Research and lead investigator, and **Laura Hutchins**, director of the Division of Hematology and Oncology, were awarded the grant to study a carbohydrate-targeting vaccine that kills tumor cells. The UAMS proposal was the only one of 46 submissions recommended for funding. The grant will fund all safety testing required by FDA, as well as a three-year clinical trial of about 50 high-risk breast cancer patients. . . . **AMERICAN SOCIETY OF CLINICAL ONCOLOGY** will publish its first clinical practice guideline on fertility preservation options for people living with cancer in the June 20 issue of the *Journal of Clinical Oncology*. "This is the first in a series of clinical practice guidelines that ASCO is developing for the long-term care of cancer patients," said **Kutluk Oktay**, senior author of the guideline and director of the Fertility Preservation Program at Weill Medical College at Cornell University. The guideline is available at [www.plwc.org/portal/site/PLWC](http://www.plwc.org/portal/site/PLWC).

### Funding Opportunities:

## RFP Available

**RFP: S06-241 Cancer Array Informatics Project.** Response due date: May 15. NCI Center for Bioinformatics Cancer Array Informatics Project is seeking a subcontractor for database support, domain knowledge in microarray, technical leadership, and program management services. The service professionals will work with the NCICB appointed caArray project manager. The caArray project provides NCI

intramural and extramural researchers with technologies to store, retrieve, and analyze cancer gene expression data. The project supports NCI-funded programs, including caBIG, SPOREs, MMHCC, and the NCI Directors Challenge. Full text: <http://www.fbodaily.com/archive/2006/04-April/26-Apr-2006/FBO-01033742.htm>.

Inquiries: Melayne Cromwell-Richards, 301-228-4021 or Shannon Jackson, 301-846-1520, [mrichards@ncifcrf.gov](mailto:mrichards@ncifcrf.gov), [sjackson@mail.ncifcrf.gov](mailto:sjackson@mail.ncifcrf.gov).

## RFA Available

**RFA-CA-07-014: Cancer Genome Characterization Centers.** U24. Full text: <http://grants1.nih.gov/grants/guide/rfa-files/RFA-CA-07-014.html>. Inquiries: Daniela Gerhard, 301-451-8027; [gerhardd@mail.nih.gov](mailto:gerhardd@mail.nih.gov).

## Program Announcements

**PAR-06-372: CAM at Minority or Health Disparities Research Centers.** R21. Full text: <http://grants.nih.gov/grants/guide/pa-files/PAR-06-372.html>. Inquiries: Sharon Ross, 301-594-7547; [rosssha@mail.nih.gov](mailto:rosssha@mail.nih.gov).

**PA-06-373: Ruth L. Kirschstein National Research Service Awards for Individual Postdoctoral Fellows.** F32. Full text: <http://grants.nih.gov/grants/guide/pa-files/PA-06-373.html>. Inquiries: Nancy Lohrey, 301-496-8580; [lohreyn@mail.nih.gov](mailto:lohreyn@mail.nih.gov).

**PA-06-371: In vivo Cancer Imaging Exploratory/Developmental Grants.** R21. Full text: <http://grants.nih.gov/grants/guide/pa-files/PA-06-371.html>. Inquiries: Anne Menkens, 301-496-9531; [menkensa@mail.nih.gov](mailto:menkensa@mail.nih.gov).

**PA-06-367: Research On Ethical Issues In Human Subjects Research.** R03. Full text: <http://grants.nih.gov/grants/guide/pa-files/PA-06-367.html>. Inquiries: Kim Witherspoon, 301-496-8866; [withersk@ctep.nci.nih.gov](mailto:withersk@ctep.nci.nih.gov).

**PA-06-368: Research On Ethical Issues In Human Subjects Research.** R21. Full text: <http://grants.nih.gov/grants/guide/pa-files/PA-06-368.html>. Inquiries: Kim Witherspoon, 301-496-8866; [withersk@ctep.nci.nih.gov](mailto:withersk@ctep.nci.nih.gov).

**PA-06-369: Research On Ethical Issues In Human Subjects Research.** R01. Full text: <http://grants.nih.gov/grants/guide/pa-files/PA-06-369.html>. Inquiries: Kim Witherspoon, 301-496-8866; [withersk@ctep.nci.nih.gov](mailto:withersk@ctep.nci.nih.gov).

**PA: 06-306: The Effect of Racial And Ethnic Discrimination/Bias On Health Care Delivery.** R21. Full text: <http://grants1.nih.gov/grants/guide/pa-files/PA-06-306.html>. Inquiries: Vicki Shavers, 301-594-1725; [shaversv@mail.nih.gov](mailto:shaversv@mail.nih.gov).

**PA-06-305: Decision Making in Cancer: Single-Event Decisions.** R21. Full text: <http://grants1.nih.gov/grants/guide/pa-files/PA-06-305.html>. Inquiries: Wendy Nelson, 301-435-4590; [nelsonw@mail.nih.gov](mailto:nelsonw@mail.nih.gov).

**PA-06-304: Studies of the Economics of Cancer Prevention, Screening, and Care.** R21. Full text: <http://grants1.nih.gov/grants/guide/pa-files/PA-06-304.html>. Inquiries: Martin Brown, 301-435-3710; [mb53o@nih.gov](mailto:mb53o@nih.gov).



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