

## NCI's Future Depends On Recruiting Youth To Careers In Science, NCI Director Says

*By Kirsten Boyd Goldberg*

NCI's success in reducing the burden of cancer will depend on its ability to recruit young people to careers in science and medicine, and that recruitment will depend on the country's continued investment in science, NCI Director John Niederhuber said at his swearing-in ceremony Oct. 18.

Niederhuber's statement acknowledges the concerns recently expressed by prominent cancer researchers, who warned that NCI's declining budget would result in the loss of a generation of young scientists.

"We face very real challenges, which test our ability to persuade the very brightest, the most visionary of our young people, to see the opportunities and the rewards of a career in biomedical research and patient care," Niederhuber said to an audience of NIH, HHS, and Public Health Service officials gathered

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### Medicare:

## CMS Considering Regulatory Standards For Drug Company "Bundling" Of Products

*By Paul Goldberg*

The Medicare program is considering issuing regulatory standards for the practice of "bundling" multiple drugs administered in physicians' offices.

The Centers of Medicare and Medicaid Services could act early as Nov. 1, when the Medicare Part B Physician Free Schedule for 2007 goes into effect. However, considering complexity of the issue, it is more likely that CMS would act sometime next year, industry sources say.

The agency was asked to review the matter by Johnson & Johnson. In a letter to CMS and in separate court filings, the company alleges anticompetitive bundling practices by competitor Amgen Inc. In oncology, the bundling controversy involves two versions of erythropoietin: J&J's Procrit and Amgen's Aranesp.

Amgen bundles its EPO with white cell boosters Neupogen and Neulasta, offering deeper discounts to practices that switch from Procrit. J&J argues that practices that choose to use Procrit cannot effectively break even on administration of Neupogen and Neulasta.

In a report earlier this month, MedPac, an expert committee that advises Congress on Medicare, noted that physicians were concerned about the manner in which "discounts are allocated in the calculation of [Average Sales Price] when drugs produced by one manufacturer are sold in a bundle."

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## New NCI Director Promises To Be "Grounded In Facts"

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on the NIH campus.

"Our success—the ability to achieve our goals—depends on college students who see and who value the tremendous opportunities of a life immersed in scientific discovery: a life of service, of caring for those less fortunate," Niederhuber said. "These young citizens need to have confidence that this great country will continue its investment in science. They need to be confident that productive careers await them."

The former director of the University of Wisconsin Comprehensive Cancer Center, Niederhuber arrived in Bethesda late last summer to begin working under NCI Director Andrew von Eschenbach as deputy director for clinical and translational science. But Niederhuber unexpectedly found himself serving as the institute's "Chief Operating Officer"—a newly-created position—after President George W. Bush tapped von Eschenbach to serve as FDA commissioner.

Niederhuber led NCI as the COO for several months while von Eschenbach served in a dual role as NCI director-on-leave and acting FDA commissioner. Von Eschenbach stepped down as NCI director last June following his nomination for permanent status as FDA commissioner.

Bush appointed Niederhuber as NCI director on Aug. 15.

"Never, in all the years of sitting on the edge of my patients' beds during late-evening rounds; of making the walk from the operating room to the family waiting area; of working in the lab with my students and fellows... or coming to Washington all those times to serve on committees... did I picture myself standing at this podium at this time to accept the directorship of the National Cancer Institute," said Niederhuber, who served two years as chairman of the National Cancer Advisory board.

### Distanced Himself From 2015 Goal

In the past year, Niederhuber has distanced himself from his predecessor's emphasis on a goal to "eliminate the suffering and death due to cancer by 2015." Many scientists called that goal unachievable and irresponsible. After a meeting last fall with cancer center directors, which involved heated discussion of the goal, von Eschenbach, too, appears to have backed away from the 2015 target date.

Niederhuber indicated that his goals would be more reserved, and focused on the science:

"It is, after all, our responsibility to continually earn, and always merit, the public's trust," he said in the Oct. 18 speech. "We maintain that bond by being good financial stewards; by letting the best science be our guide; by clearly and plainly communicating what we learn about cancer; and by honestly saying what we have yet to learn.

"We should convey hope, but always be grounded in facts."

Also, Niederhuber has abandoned von Eschenbach's management model that installed a level of deputies between the director's office and the NCI division directors. In an interview with The Cancer Letter last month, Niederhuber said he returned to NCI's traditional form of management in which the institute director works closely with the division directors.

Managing NCI with its current flat budget "will involve the careful stewardship of finite resources," Niederhuber said at the swearing-in ceremony.

"I will do my best to provide you with an open door and a listening ear, with strong leadership skills honed in the operating room and the laboratory, to captain this team in difficult times," he said. "It will be up to the leaders of NCI to find and allocate the resources necessary to maintain our scientific momentum."

The institute will have to consider partnerships, examine existing programs, and carefully consider new research programs, Niederhuber said. "Our responsibility is to continue conducting quality research,



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

offering solutions to our challenges,” he said.

The appointment of an NCI director “is a significant event for all of us,” NIH Director Elias Zerhouni said at the ceremony. “We need to recognize the historical importance of the National Cancer Institute anytime we can,” he said.

Zerhouni recalled his first impression of Niederhuber when they met while both were working at Johns Hopkins University:

“Those of you who know surgeons—and forgive me, if you are surgeons—when you meet a surgeon, he has about 30 milliseconds of listening time, and an hour of talking time, because they always know what to do, to take action,” Zerhouni said. “I was shocked that John was the opposite. I would talk for about three seconds, and stop to hear him talk about what to do next, and he would say, ‘Well, tell me more.’ Sounded like a psychiatrist to me.

“John was one of the most important colleagues that I have had in my career, and at Johns Hopkins, he made so many changes, because he combined basic science with the ability to understand what it meant in terms of the fight against cancer,” Zerhouni said. He brings to NIH and NCI an ideal set of skills and experiences.”

Describing the task ahead for the new NCI director, Phillip Sharp, of the MIT Center for Cancer Research, who shared the 1993 Nobel Prize in Physiology or Medicine and served as chairman of the NCAB from 2000 to 2002, said the institute faces “interesting and promising times” due to the aging of the U.S. population.

“Dr. Niederhuber is almost uniquely the right director for this period,” Sharp said. “Never before in its history has NCI been more important to the citizens of this country. The confluence of the demographics of the country—that is, the aging of the baby boomers—the emergence of new treatments for cancer based on specific targets that are more efficacious and with less toxic side effects, and the possibility of treating individuals based on the genetic constellation of their cancers, and, finally, the continuing advances in science related to cancer, make this the tremendous moment of opportunity and challenge for the new director.”

Niederhuber “has had significant experience and shown important leadership at every level of this challenge, from the lab bench to the patient, and from the health care delivery institutes to the administration of NCI,” Sharp said.

The U.S. is “about to experience an enormous increase in the demand for treatment of adult cancers,”

Sharp said. “The disease burden will pressure NCI to focus even harder on research to be able to provide the best quality care to patients across the country. Dr. Niederhuber has already stated that one of his priorities at NCI is to bring science to the patient.”

NCI’s work has made “a big impact” on the disease, Sharp said. The rate of age-adjusted deaths due to cancer began to decrease several years ago, and should accelerate in the future, he said. “Although we still have a long way to go, it is exciting to realize that death due to breast cancer has decreased by 20 to 25 percent over the past decade—a wonderful indication of future results in other cancers,” he said.

“The promise of the establishment of NCI—that it would generate better and more effective and less toxic treatments for cancer—has begun to be fulfilled,” Sharp said. “The targeted therapies for leukemias, myelomas, breast cancer, colon cancer, and lung cancer have awakened the country to a new horizon of possibilities. In contrast to the situation a short decade ago, every major pharmaceutical company has greatly expanded research and development to generate new therapies for cancer. The same is true for many biotechnology companies. The list of candidates in clinical trials is longer and stronger than it has ever been before.

“NCI has created this eruption in activity and has the challenge of developing new lines of research that ensures that these therapies will be tested and made available to patients in an optimal fashion,” Sharp said.

*Following is the text of Niederhuber’s speech:*

Mr. Secretary, Dr. Zerhouni, fellow directors of the Institutes and Centers of the National Institutes of Health, honored guests, NCI colleagues, and my many friends: I am deeply indebted to all of you for being here today, and for sharing with me this very special occasion in my life.

I want to express my gratitude to President Bush and to Secretary Leavitt for the privilege and distinct honor of serving as the Director of the National Cancer Institute. I am profoundly humbled by your confidence in me and by the fact that you are willing to entrust me with the leadership and the distinguished history of this proud institution.

Never, in all the years of sitting on the edge of my patients’ beds during late-evening rounds; of making the walk from the operating room to the family waiting area; of working in the lab with my students and fellows (some of whom are here today) or coming to Washington all those times to serve on committees for Vince, Sam,

Rick, and, most recently, Andy—never did I picture myself standing at this podium at this time to accept the directorship of the National Cancer Institute.

And while I have been doing this job now for a year, I think it has only been in the past couple of weeks, since my official appointment, that the enormity of the responsibility of this position—the responsibility to our patients suffering with cancer—has really struck home.

On the day he formally proposed the National Cancer Act of 1971, President Nixon said: “The time has now come for us to put our money where our hopes are.” But he also made it eminently clear that dollars weren’t enough. “Money,” Mr. Nixon continued, “can help set the stage for faster progress, but in the end it is our brainpower alone which can lead us to our goals.”

President Nixon’s words are even more fitting today. The momentum of our progress against cancer, and of biomedical research as a whole for all diseases, is occurring at a pace none of us could have predicted. For the very first time in more than 70 years that our country has kept statistics on cancer incidence and mortality, we have seen an actual, real decline in cancer deaths.

For every one of us here today, that is the hope—the promise—we have so desperately needed. This progress, this pace of discovery, and our nation’s leadership position in biomedical research must not to be taken for granted.

Today, even more so than in 1971, we face very real challenges, which test our ability to persuade the very brightest, the most visionary of our young people, to see the opportunities and the rewards of a career in biomedical research and patient care.

Our success—the ability to achieve our goals—depends on college students who see and who value the tremendous opportunities of a life immersed in scientific discovery: a life of service, of caring for those less fortunate. These young citizens need to have confidence that this great country will continue its investment in science. They need to be confident that productive careers await them.

The National Institutes of Health has long been the mechanism through which this great Nation supports the world’s premier biomedical research engine. Through its outstanding intramural laboratories and the support of an unmatched cadre of extramural scientists, we have been blessed with success after success.

There is no other NIH. There is no other place like NCI anywhere in the world. It is imperative that we tell our story, and that we work with the leaders of our country to ensure that the United States continues to lead

the world, that we continue to serve the world.

Elias, my friend, I could not be more proud, nor can I think of any greater honor, than to be asked to join my colleagues on the NIH team. To my fellow Institute and Center directors, I extend a hand of friendship, of collegiality, and—perhaps most important—of collaboration.

While we at NCI are dedicated to lessening the burden of cancer, we also recognize that cancer has been, and will continue to be, a research model for many diseases. An article in the *Journal of the National Cancer Institute* provides a timely reminder of our importance as a community of scientists. “Progress,” the author wrote, “has been most rapid in scientific research when imaginative, talented, technically curious, and, above all, sincerely interested investigators are encouraged to search for new facts, beyond the curtains that limit our knowledge and to pool their specialized resources and skills on a basis of mutual interest and respect.”

That’s a message we can—and do—embrace. But it is even more profound when you consider that the quote I just read comes from an article written nearly half a century ago, in 1957, by G. Burroughs Mider, the NCI’s associate director in charge of research. His words remind us that the need for scientific collaboration across disciplines is not a new idea.

It is my great hope that through my leadership at NCI and through the talented NCI scientific community, we can continue, and even fortify, the tradition Dr. Mider so eloquently described.

To the staff of NCI: I am honored and proud to work in your service. Institutions—university or government, private or public—that do great work and make a true difference in this world are always infused with people of enormous talent, commitment, and drive.

The importance of what we do at NCI, on behalf of every man, woman, or child who knows or fears cancer, cannot be underestimated. And, as a cancer research community, we are certainly not exempt from the disease we dedicate our careers to fight. Indeed, for a great many of our colleagues at the National Cancer Institute, cancer is a personal, as well as a professional, issue, because they—or perhaps I should say we—are survivors, patients, caregivers, or loved ones of cancer patients.

Sometimes, in the course of our lives, we talk about being in the right place at the right time. Sometimes we may speak of destiny or fate or direction. However we choose to interpret them, I believe that these important crossroads in life are about recognizing and grasping

opportunities, and making all you can of them.

As I said earlier, the rapidity with which we are gaining new knowledge, coupled with the emergence of constantly advancing technologies, is creating greater opportunity to accelerate progress against cancer than any of us dared to dream at the time I began my career. Cancer, we know today, is a disease of alterations in genes, which accumulate over a lifetime. Each day, it seems, our insights grow deeper. We come to a greater understanding of the genetic changes that render a cell malignant. We learn more about the complex interactions of the cancer cell with its microenvironment and host. We learn more about the drivers of metastasis.

In today's post-genomic scientific environment, we are rapidly entering an entirely new era of risk determination, disease prevention, diagnosis, and highly targeted therapies. It is the era of genomically and proteomically characterized disease. As we move into this new era of personalized medicine, ideas, tactics and techniques are coming from many sectors of science. The physical sciences and engineering are being applied to optimize the discovery, development, and, ultimately, the delivery of interventions to the patient. The once-futuristic tool of nanotechnology is being used to perform molecular classification of tumors, to enable high-throughput screening and to predict therapeutic efficacy. Imaging is becoming a tool to ascertain just how much of a small molecule is reaching a targeted receptor and whether the therapeutic molecule changes cellular function. Computational biology—systems biology, if you will—is addressing issues such as information scale, modeling, simulations, and data interpretation.

For certain, new technologies will continue to blossom and multiply.

I know that our time together at NCI will hold moments of great success. I look forward to every exciting advance and discovery.

I also know our time together will bring many challenges. We are in a fiscal period in which management of the National Cancer Institute will involve the careful stewardship of finite resources.

I will do my best to provide you with an open door and a listening ear, with strong leadership skills honed in the operating room and the laboratory, to captain this team in difficult times. It will be up to the leaders of NCI to find and allocate the resources necessary to maintain our scientific momentum.

To this end, NCI will need to consider new partnerships, in order to leverage resources and knowledge. We will need to carefully consider each new

research program and scientific proposal. We will need to examine all existing programs, to search for ways to be leaner, but at the same time even better, in achieving our mission. Our responsibility is to continue conducting quality research, offering solutions to our challenges. As Albert Einstein said: "In the middle of every difficulty lies opportunity."

It is critical in these times that we communicate effectively across our various constituencies. As a cancer community, we must strive to speak with a more unified voice, in order to call others to action on behalf of cancer research.

I believe we must work to find the best ways to bring the latest science to patients in the communities where they live—through our NCI-supported cancer centers, which are always referred to as the "crown jewels" of NCI—and by the building of a new rim of community-based cancer care.

We must make our science, our medical advances, available to all of our citizens, especially those who may lack the financial means, the language capacity, the education, or simply the physical strength to seek out the best care. We must bring our science—our technology—to the patients where they live.

I share the view of my friend and colleague John Seffrin, chief executive officer of the American Cancer Society, who so effectively states his belief that, in the next decade, patient access to our accomplishments—our science—will become a greater determinant of cancer mortality than any currently recognized cause.

In one of the most-quoted lines of American politics, the late Vice President Hubert Humphrey said the moral test of government is how it treats "those who are in the dawn of life, the children; those who are in the twilight of life, the elderly; and those who are in the shadows of life, the sick, the needy and the handicapped."

It is, after all, our responsibility to continually earn, and always merit, the public's trust. We maintain that bond by being good financial stewards; by letting the best science be our guide; by clearly and plainly communicating what we learn about cancer; and by honestly saying what we have yet to learn. We should convey hope, but always be grounded in facts.

And so it is with an unshakable commitment—to every cancer patient, every survivor, advocate, friend, father, mother, son, daughter, and caregiver—that I sincerely thank you for the opportunity to serve this great institution and this great country, and solemnly pledge to do my very best. May God bless America and give us the knowledge and wisdom to serve our patients.

## Medicare:

# Drug Bundling Battle Lands At CMS, Far From Resolved

(Continued from page 1)

MedPac said it would study this issue and urged the HHS Secretary to do the same.

In its comments to CMS earlier this year, J&J asked Medicare to develop a reallocation formula that would reflect actual prices physicians pay for Aranesp, Neupogen, and Neulasta.

“Absent action by the agency, Medicare will continue to incur an Aranesp dose premium as oncology clinics are coerced to purchase Aranesp in lieu of Procrit,” J&J said in a Sept. 28 letter to CMS. This use of the ASP calculation to reapportion the prices “would alleviate the coercive nature of the bundle, allowing oncologists to purchase Procrit and thereby generating savings to patients and Medicare,” J&J said in its letter.

Amgen disputes J&J’s allegations of coercive and anticompetitive behavior. The discounts give the best price to its best customers, the company said.

“Johnson & Johnson has made many allegations, which Amgen has disputed both in court and to CMS, and once the facts are put on the table and all the facts are told, the J&J story isn’t really that compelling,” said Josh Ofman, Amgen’s vice president for global coverage and reimbursement.

“A lot of stakeholders are telling CMS that it would be risky for them to undermine ASP just to solve a competitive dispute and a problem that J&J has in the marketplace,” Ofman said to The Cancer Letter. “That would be a risk, and in order to take such a risk, they would want to really determine that there is a problem. This needs to be evaluated before anything is done, and if anything were done, it should be open to public comment and there should be a specific proposal put out there.”

In August, when CMS issued a proposed rule on Medicare Plan B reimbursement for physicians, the agency invited public comment on bundling arrangements where “a purchaser’s price for one or more drugs is contingent upon the purchase of other drugs or items.”

At the time, the agency said that its goal was “to ensure that the ASP is an accurate reflection of market prices for Part B drugs and that the treatment of bundled price concessions in the ASP calculation does not create inappropriate financial incentives.”

The agency is yet to put forth a specific proposal

for ASP calculations in such instances.

“Our litigation against Amgen is about addressing, under the antitrust laws, what we believe is improper conduct in the marketplace,” said Mark Wolfe, a J&J spokesman. “Quite separately, our comments to CMS are focused on the need for a uniform, explicit methodology for appropriately allocating discounts to accurately reflect a product’s ASP, to address the manipulative tactics currently being employed by Amgen and to allow physicians and payers the freedom to choose treatments best suited to the needs of individual cancer patients.

“Let’s be clear, Amgen has implemented a sophisticated scheme to reduce competition by leveraging a monopoly, life-saving product and gaming the federal payment system,” Wolfe said.

The Pharmaceutical Research and Manufacturers of America asked CMS to develop a specific method for potential recalculation of prices of bundled products and make it available for public comment.

“PhRMA is concerned that any methodology adopted may be inelastic and fail to foster beneficial arrangements,” the association said. “To help ensure that any additional guidance that CMS ultimately issues on the treatment of bundled price concessions in ASP calculations provides clarity, elasticity, and the predictability needed and results in improved accuracy, therefore, CMS should publish a specific proposal in draft form and give stakeholders a meaningful opportunity to comment.”

The Biotechnology Industry Organization made a nearly identical comment.

Earlier this week, Newt Gingrich, a former Speaker of the House, took J&J’s side in the dispute.

“We should not permit a company to use one drug to drive utilization of another drug when the result is limited physician choice, the potential for inferior patient care, higher co-payments for Medicare beneficiaries suffering from cancer, and higher cost to the federal government,” Gingrich wrote on the web site of his Center for Health Transformation. “CMS should act in the 2007 Proposed Physician Fee Schedule to ensure that life-saving drugs without clinical alternatives are not bundled in order to drive the utilization of drugs that face competition.”

The paper is posted at <http://www.healthtransformation.net/home/>. J&J Healthcare Systems, a unit of J&J, figures on the list of 73 businesses and non-profits that have contributed funds to the center.

The Community Oncology Alliance took Amgen’s side in the debate, arguing that efforts to undo bundling

arrangements would decrease the quality of patient care. "If our ability to negotiate with the manufacturer is removed or substantially limited due to an apportioning methodology, many patients may be left without the potentially life-saving drugs that they require," the organization said in its comments to CMS.

The American Society of Clinical Oncology said bundling results in inaccurate reporting of prices paid for drugs.

"ASCO's primary concern is that the ASP reported to CMS for Part B drugs should be an accurate reflection of the prices paid by physicians," the society said in its comments.

"For example, if a Part B drug is sometimes bundled in a sale with an item other than a Part B drug, attributing any discount on the non-Part B drug to the ASP of the Part B drug would lower the Medicare payment amount and would be especially unfair to physicians who did not purchase the Part B drug in the bundled arrangement," ASCO said.

"ASCO urges CMS to adopt rules on including bundled sales in ASP calculations that result in accurate payment amounts for each Part B drug involved and that do not adversely affect physicians who purchase the drugs involved, but not through the bundled sale arrangements.

"These rules should be subject to public comment before they become final," ASCO said.

### FDA News:

## **Former FDA Head Crawford Pleads Guilty In Stock Case**

*By Paul Goldberg*

Former FDA Commissioner Lester Crawford pleaded guilty Oct. 17 to two misdemeanor charges stemming from his failure to disclose ownership of stocks of companies regulated by the agency.

Crawford, who resigned from FDA in September 2005, filed incomplete disclosures to HHS as well as to a committee of the U.S. Senate. He is charged with one count of filing false reports and one count of conflict of interest.

Under a plea agreement, Crawford is likely to face a fine of up to \$50,000, as well as probation, home detention, or up to six months in jail. Each of the misdemeanor charges carries penalties of up to a year of prison.

Magistrate Judge Deborah Robinson of the U.S. District Court for the District of Columbia has scheduled a sentencing hearing for Jan. 22, 2007.

Crawford's lawyer, Barbara Van Gelder, said that Crawford had made "errors," but that stock holdings didn't influence his conduct at the agency.

According to court documents, Crawford owned shares in Kimberly-Clark, Pepsico, and Sysco Corp., and his wife also owned undisclosed stock in Wal-Mart.

The stocks were managed by a broker, who engaged in trades throughout Crawford's stay at FDA, sending notices of transactions to the Crawfords' home address. Crawford's Pepsico holdings were valued at \$53,000 to \$76,000. His Sysco stock was valued at \$48,000 to \$99,000, his Kimberly-Clark shares were worth \$56,000 to \$90,000, and the Wal-Mart holdings were worth \$31,000 to \$74,000.

During his tenure at FDA, the Crawfords earned \$2,000 in dividends from Pepsico, \$4,000 from Sysco, \$6,000 from Kimberly-Clark, and \$1,000 from Wal-Mart.

Also, Crawford owned stock options in Embrex Corp., an agricultural biotechnology company where he had served as a member of the board before coming to the agency.

The company's products include an automated injection system that eliminates the need for manual vaccination of newly hatched broiler chicks.

In 2003, while serving as FDA Deputy Commissioner, he exercised an option to buy 2,000 shares of Embrex stock, earning \$8,150. While serving as Deputy Commissioner, he exercised another option, and after reselling the stock earned \$20,627. He reported these earnings correctly as ordinary income on the IRS forms, documents state.

The conflict of interest charges stem from Crawford's participation in drafting FDA nutritional policies while holding stock in manufacturers of food products, snacks and soft drinks.

Court documents state that at the time Crawford owned stocks in these companies while serving as chairman of the FDA Obesity Working Group, which made recommendations on the labeling of the carbohydrate content of food and urged the restaurant industry to institute a voluntary nutritional information campaign.

The case was prosecuted by the U.S. Attorney's office for the District of Columbia.

### Funding Opportunities:

## **NIEHS Offers \$74M In Grants**

As part of the new Exposure Biology Program, NIEHS is making available \$74 million in grant opportunities for technologies that will measure environmental exposures



that contribute to disease. The three grant opportunities will support research to develop portable sensing devices to measure personal exposure to chemical and biological agents. The grants will also support development of biomarkers.

—**Environmental Sensors for Personal Exposure Assessment.** The grant supports the development of field-deployable or wearable sensing devices that provide direct measurements of exposure to ozone, fine particles, diesel exhaust, heavy metals, volatile organic compounds, pesticides, microbial toxins, and other environmental agents that have been linked with common illnesses.

—**Biological Response Indicators of Environmental Stress.** The grant focuses on the development of sensitive biomarkers that reflect subtle changes in inflammation, oxidative damage and other pathways that can lead to disease. By measuring the cellular and molecular responses that are involved in disease development, researchers will be better able to define the relationships between the genetic and environmental components of human illness.

—**Biological Response Indicators of Environmental Stress Centers.** The grant focuses on the development of sensitive biomarkers that reflect subtle changes in inflammation, oxidative damage and other pathways that can lead to disease, and the incorporation of these markers into field- and laboratory-based sensing devices.

The Program also includes two other grant opportunities: Improved Measures of Diet and physical Activity for the Genes and Environment Initiative, led by NCI and National

Heart, Lung and Blood Institute, and Field-Deployable Tools for Quantifying Exposures to Psychosocial Stress and to Addictive Substances for Studies of Health and Disease, led by the National Institute on Drug Abuse.

For information: <http://www.gei.nih.gov/exposurebiology/index.asp>.

## RFAs And PAs Available

**RFA-CA-07-501: TNCI Limited Competition Supplements for Pilot Projects for Community Networks Program to Reduce Cancer Health Disparities.** U01. Letters of Intent Receipt Date: Nov. 20; May 29. Application Receipt Date: Dec. 18; June 27. Full text: <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-501.html>. Inquiries: Kenneth Chu, 301-496-8589; [kc10d@nih.gov](mailto:kc10d@nih.gov).

**RFA-CA-07-503: Advanced Technology Radiation Therapy Clinical Trials Support.** U24. Full text: <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-503.html>. Inquiries: James Deye, 301-496-6111; [deyex@mail.nih.gov](mailto:deyex@mail.nih.gov).

**PA-07-009: Symptom Clusters in Cancer and Immune Disorders.** R21. Full text: <http://grants.nih.gov/grants/guide/pa-files/PA-07-009.html>. Inquiries: Ann O'Mara, 301-496-8541; [omaraa@mail.nih.gov](mailto:omaraa@mail.nih.gov).

**PA-07-008: Biobehavioral Methods to Improve Outcomes Research.** R21. Full text: <http://grants.nih.gov/grants/guide/pa-files/PA-07-008.html>. Inquiries: Paige McDonald, 301-435-5037; [mcdonalp@mail.nih.gov](mailto:mcdonalp@mail.nih.gov).

**Have you, or has someone you love, been previously treated for metastatic colorectal cancer?**

If so, you or your loved one may be eligible to participate in a nationwide research study of an investigational drug called panitumumab given along with chemotherapy for the treatment of metastatic colorectal cancer. This study is designed to test if an intervention on the skin rash often seen with panitumumab, and similar drugs, affects its course. This study is called STEPP (Skin Toxicity Evaluation Protocol with Panitumumab) and is being sponsored by Amgen.

Participants in the study will:

- Gain access to a research treatment that may or may not be as effective as standard therapy
- Help other patients by advancing knowledge of the treatment of colorectal cancer

To learn if you may be eligible to enroll, **CALL 1-866-57AMGEN (1-866-572-6436) TODAY AND ASK ABOUT THE STEPP TRIAL.**  
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