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Congressional Subcommittee Rakes NIH For Lax Conflict of Interest Policies

By Paul Goldberg

At a contentious hearing May 12, a Congressional panel told NIH officials that their efforts to overhaul policies regulating conflicts of interest in the intramural program fall short of expectations of lawmakers from both parties.

In the first hearing in what appears to be a snowballing investigation, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, NIH officials were told that their efforts fell short of addressing several crucial issues and are yet to guarantee a sufficient (Continued to page 2)

In Brief:

U.S. Signs Tobacco Control Treaty; Mackey To Leave NYUCI For Job With Red Cross

HHS SECRETARY Tommy Thompson signed the Framework Convention on Tobacco Control May 10 at the United Nations. The World Health Assembly adopted the FCTC in May 2003. The U.S. is the 108th nation to sign the treaty. The FCTC is intended to provide for basic tobacco control measures to be implemented by all countries through domestic law. The objective of the FCTC is to protect "present and future generations from devastating health, social, environmental and economic consequences" of tobacco use and to reduce the prevalence of tobacco use and exposure to tobacco smoke. . . . ROSEMARY MACKEY has accepted the position of chief business and fund development officer at the American Red Cross of Greater New York. Mackey began her 40-year career in oncology as a pediatric oncology nurse working with Joe Burchenal at Memorial Sloan-Kettering Cancer Center, and moved on to hospital and cancer center management in Houston and New York. She has submitted her resignation as executive director of the New York University Cancer Institute, where she works with **Steven Burakoff**, director of NYUCI. The Institute will open a new clinical center in July and has implemented a strategic plan for cancer services at Bellevue Hospital Center. . . . RICHARD PAZDUR, director of the FDA Division of Oncology Drug Products in the Center for Drug Evaluation and Research, received the FDA Award of Merit for "outstanding leadership in cancer therapeutics development by developing and promoting interaction with national and international regulatory and scientific bodies and external stakeholders." . . . SUSAN G. KOMEN Breast Cancer Foundation gave Professor of Survivorship Awards to Noreen Aziz, program (Continued to page 8)

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Conflict of Interest Probe To Focus On NCI Next Week

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level of disclosure of consulting arrangements between government scientists and the industry.

While this week's hearing focused on NIH-wide problems, the next hearing, scheduled for May 18, is likely to zero in on NCI. Sources said Institute officials invited to testify at that hearing include Anna Barker, deputy director for advanced technologies and strategic partnerships; Carl Barrett, director of the Center for Cancer Research; Lance Liotta, chief of the Laboratory of Pathology; and Maureen Wilson, the NCI ethics officer. The subcommittee has not released the full list of witnesses.

The subcommittee's inquiry into ethics concerns at NIH began a year ago with a probe of travel arrangements, lectureship awards, and business connections of former NCI Director Richard Klausner (**The Cancer Letter**, July 4, 2003; Nov 14, 2003). In interviews, Klausner repeatedly denied impropriety.

Remarks by House members at the hearing earlier this week indicate that determination to pursue this investigation runs deep, and that Republicans are not reluctant to challenge the Administration.

NIH has evolved a novel form of ethical conflict, said Rep. James Greenwod (R-Penn.), chairman of the subcommittee. Employing a practice Greenwood describes as "swivel chair," an NIH scientist "can take outside consulting jobs with the drug industry as a



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scientific expert, yet still have the privilege of being on the inside at NIH, the crown jewel of the American biomedical research enterprise."

Though an advisory panel appointed by NIH Director Elias Zerhouni recently produced a series of 18 recommendations for regulating potential conflicts of interest, the system of safeguards against such conflicts at NIH remains insufficient, Greenwood and other legislators said.

Moreover, some apparent conflicts haven't been addressed, Greenwood said. The subcommittee is trying to force HHS to make additional disclosure of consulting arrangements by NIH scientists, and requesting that pharmaceutical companies also disclose such ties.

While this week's hearing avoided in-depth discussion of allegations, the May 18 hearing is expected to drill deeper and focus on specific instances of conflict, sources said. In earlier correspondence with NIH, the subcommittee explored the propriety of awards and lectures given to scientists by outside grantee institutions. The committee's questions focused on Klausner, but also involved other Institute officials.

Remarks by Greenwood and others indicated that the Klausner investigation hasn't been concluded.

"Under current policies, an NIH Institute Director is permitted to accept a cash gift from a grantee or cooperative agreement holder with his institute, provided it is presented as a *bona fide* award, as long as there is adequate financial backing for such endeavors," Greenwood said. "If a university seeking NIH funds wants to attract, reward, or influence an NIH official... by paying cash to that official for a speech that is otherwise part of his taxpayer-supported official duties, it can do so without running afoul of criminal felony statutes and non-criminal ethics regulations by calling the event a 'lecture award."

The subcommittee initially focused on lecture awards, but was broadened last December, after Los Angeles Times published a story about consulting arrangements between NIH scientists and the pharmaceutical industry.

In response to the LA Times story, Zerhouni appointed a "blue ribbon panel" to recommend conflict of interest guidelines for intramural researchers.

The panel recommended that institute and center directors should be prohibited from consulting, and that others should be allowed to consult only if their consulting income is limited to half of their NIH salary. Also, consulting should be limited to one day a week, and no single consulting arrangement should add up to more than 25 percent of the salary.

The recommendations are posted at www.nih.gov/about/ethics COI panelreport.htm.

The panel steered away from specific allegations and didn't address the lecture awards.

Rep. Peter Deutsch (D-Fla.), the ranking minority member on the subcommittee, said NIH should immediately prohibit its researchers from "taking anything of value" from pharmaceutical or biotechnology companies and should suspend all ethics officials who have approved consulting arrangements between NIH scientists and the industry.

"The conflict is not defendable, short of NIH having supervisors review each and every task undertaken, work product produced, and each and every piece of advice provided the drug company, and comparing that against the current and future tasks likely to be undertaken on behalf of the government," Deutsch said at the hearing. "Even then, it is hard to imagine how the American taxpayer could possibly be assured that the employee on the payroll of a drug company was acting in their best interest."

Zerhouni acknowledged that the NIH policies have been insufficient.

"Much of the discussion about ethics policies and procedures at NIH has been unnecessarily negative," he said at the hearing. "NIH employees have great integrity. In retrospect, the policies and rules could have been even stricter, their implementation could have been more efficient and oversight could have been more rigorous. But for better or worse, this was the system NIH employees had to negotiate."

Zerhouni said a blanket prohibition on consulting would limit researchers' ability to collaborate, and would make NIH a less desirable place to work. "As we move forward, all of us will have to strike a careful balance between maintaining public trust in NIH and allowing appropriate interactions between NIH scientists, industry, academia and all elements of the research community," he said at the hearing.

"Collaborations with the non-governmental research community are vital, not only for understanding and advancing science, but for translating our knowledge into actual medical practice and treatment," Zerhouni said. "We should be more transparent, more vigilant about oversight, and we need to tighten the rules. But it would be a mistake to ban all compensated activities with outside organizations. Such an action would be bad for science, unfair to the employees, and ultimately hinder our efforts to improve the nation's health."

Zerhouni said he planned to take the following steps to enhance ethics at NIH:

--"I will seek to prohibit NIH senior management and NIH extramural employees who are responsible for program funding decisions and recommendations, and professional staff managing grants and contracts and publication review, from consulting with pharmaceutical or biotechnology companies or from paid consulting for academia, except in the case of the clinical practice of medicine.

--"I will reaffirm the prohibition against NIH scientists participating in research involving human subjects where the scientist has a personal or imputed financial interest in an organization whose interests would be directly and predictably affected by his research, except in those exceptional cases where the interest is not so substantial as to be deemed likely to affect the integrity of the employee's services to the Government or is otherwise subject to regulatory exemptions.

--"I will propose that employees engaged in compensated activities with outside organizations be, in future, prohibited from compensation in the form of stock or other forms of equity ownership in the companies for whom they are working.

--"I will set into place polices and procedures to fully consider the extent to which the recusals necessitated by an approved activities with outside organizations have an effect on the ability of senior scientific managers and decision makers to conduct their government work. NIH will clarify the use of recusals that are required because of financial relationships with outside organizations. We will require a uniform policy for informing relevant personnel of who is recused and establish a new process for monitoring recusals.

--"NIH, working with HHS and OGE, has already increased the number of senior managers who must publicly disclose their compensated activities with outside organizations and the amounts received. These are interim steps. I will aggressively seek additional authorities to require more employees to disclose their activities with outside organizations, where appropriate, including disclosure of relevant relationships and financial holdings in connection with research publications, speeches, inventions, and clinical research. As I have said previously, public disclosure and transparency will be the cornerstone of the NIH ethics program.

--"I will ask NIH employees to voluntarily disclose all relevant relationships with outside organizations and financial holdings in their work products, such as publications, speeches, and invention disclosures. And I will seek changes to regulations to make such disclosures a requirement.

--"I will propose that regulations allow NIH scientists to receive compensation for teaching, speaking or writing about their research, but only if the information is shared in a public forum and has already appeared in published literature.

--"NIH will continue to allow certain types of consulting arrangements, teaching and lecturing opportunities, receipt of bona fide awards, and collaborations with the private sector, but only under clear, rigorous rules meant to eliminate real and appearances of conflict of interest. Consulting, collaborating and teaching must continue in order to expedite the translation of research advances, but only under clear guidelines.

--"I will seek to limit the amount of time spent on consulting and the amount of compensation received annually. The limits proposed by the Blue Ribbon Panel will be considered as the draft regulation is developed.

--"NIH will improve its ability to manage and track approved activities with outside organizations by increasing the accountability of managers, creating a centralized data base, centralizing review of senior managers and scientists, conducting random audits of files pertaining to activities with outside organizations, and continuing the rigorous peer review conducted by the NEAC.

--"NIH will develop and implement a new, more understandable method of training employees on ethics rules, and we will establish a web site that displays rules in plain language, updates employees on regulatory trends and changes and discusses—anonymously—ongoing cases as examples of best practices or unacceptable practices."

In the Media:

Intel Chairman Grove Criticizes Von Eschenbach On Talk Show

By Kirsten Boyd Goldberg

Intel Corp. Chairman Andrew Grove unleashed a scorching verbal attack on NCI Director Andrew von Eschenbach and the direction of federally funded cancer research on a national television talk show.

Grove, a prostate cancer survivor, called von Eschenbach's discussion of NCI's plans "a wishful dream," characterized his statements as "chemo speeches...describing how wonderful it's going to be," and recommended a moratorium on cancer research funding "until the cancer research establishment reforms

itself," in remarks on the Charlie Rose Show April 29.

Grove's attack is significant, because von Eschenbach claims to model his CEO-like management of NCI on the Intel chairman's example, often citing Grove's books, and comparing the development of cancer research with that of the computer industry. Both men appear frequently at Michael Milken's Prostate Cancer Foundation events.

One of von Eschenbach's signature statements, that cancer research is "in the midst of a strategic inflection," is borrowed from Grove's book, "Only the Paranoid Survive." Grove defined "strategic inflection point" as "a time in the life of a business when its fundamentals are about to change."

Von Eschenbach, who also is a prostate cancer survivor, didn't fight back. He jumped into the discussion only six times and seemed unable to succinctly deliver the points he often makes in his stump speech.

In contrast, Harold Varmus, president and CEO of Memorial Sloan-Kettering Cancer Center, spoke up 16 times in the discussion. He appeared at ease with the format, having been on the program 10 times since 1999.

Also appearing on the show was Clifton Leaf, a Hodgkin's disease survivor and executive editor of Fortune, who found progress stagnant in the war on cancer in a recent issue of the magazine (**The Cancer Letter**, April 9). Leaf aimed his criticism at what he considers excessive emphasis on basic research.

However, the show was entirely Grove's, as host Rose repeatedly turned to him for reaction. At one point, von Eschenbach said NCI is "looking at the entire clinical trials process and how that might be able to be reformatted and changed so that it's adapted to our new way of approaching patients." The Institute and FDA are "engaged in a relationship" to work on streamlining trials, he said.

This exchange followed:

ROSE: Andy, you have an incredulous look on your face.

GROVE: I'm suffering. I'm suffering when I hear this is a tough problem about an organizational issue, and I'm suffering when I hear "we are looking at" and "we are engaging in." The problems we are talking about are not new. They are not science problems. They are problems very similar to the Apollo program, organizational and engineering problems. They are completely within our capabilities to fix, and there is a very simple issue that Cliff's article highlights. Cancer is easiest to deal with in an early stage, before tumors are aggregating. Clinical trials are aimed at late stage

patients and predominantly track effectiveness by measuring already formed tumors, or life expectancy.

It is too late. It is cumbersome. And about a year ago, there was a very profound article in Lancet, where a medical doctor turned into a cancer patient calls the clinical trial methods that are employed today in cancer "unethical." Not my word, it is the doctor's word.

ROSE: Unethical because it was focusing on people who have later stages of cancer rather than earlier stages, where it could be more effectively treated, is that the idea?

GROVE: That is absolutely the idea. And as Dr. Varmus points out, we need biomarkers, something that tracks the molecular progression of the disease before the tumors are formed.

Grove to von Eschenbach: "Wishful Dream"

After von Eschenbach outlined his strategy of viewing cancer as a disease process which researchers can attack at multiple points, Grove again went on the attack.

GROVE: Andy Von Eschenbach, can I address you directly here?

VON ESCHENBACH: Please.

GROVE: You sound like I did and my colleagues did when we gave chemo speeches at industry conventions, describing how wonderful it's going to be when every computer is going to talk to every other computer, dot, dot, dot, dot, even do our wash for us. It's not reality, and that's not what we are doing. We are struggling with viruses and we're struggling with crashing computers, and we're struggling with busy networks. And the reality of what you are spending your money on and your efforts on in the NCI and what the other half or two-thirds of the cancer spending goes on has almost no bearing on the, excuse me, wishful dream that you describe. Given that--let me ask you a question. If somehow or other the existing cancer strategies, NCI and extramural, outside of the NCI, were erased, and you and Dr. Varmus were to be locked into a room, you can't come out of there until you tell us how to put the pieces that we just erased back together again, would you come up with the existing structure or would you come up with something different?

VON ESCHENBACH: Well, let me answer your question, but first let me just say that I don't believe this is just simply wishful thinking. The examples I talked about--prevention, detection, and elimination, and treatment and modulation--in each one of those categories, there are real world, proof of principle examples today of where those strategies are

successful.

Now, do we need to refine--finalize and finish the job? Of course not. But we have a basis upon which we can continue to build, Andy, and I don't believe it's any more wishful thinking. I think the pathway to progress is now much clearer than it has been before. Now we must pursue it.

Do we have the right system in place? I think the system has to continually improve. Points that were raised about the importance of integration and coordination, points about using other technologies that would facilitate our ability to accelerate the pace of progress, there no question we have to find ways to incorporate that.

ROSE: OK, he put both you and Andy in the room...

VARMUS: Yeah, I'm in the room too. We probably have some agreement on these issues. I think if we were asked to take the NCI apart and put it back together, we would have something that's actually pretty similar to what we have now.

It's important to remember, we have to train people, good people. This is a problem that requires attracting outstanding scientists to work on these problems. We have to have some individual initiatives. We need some team efforts, building of infrastructure, of the kind we have through the Cancer Center program. We should have an intramural cancer program that focuses on things with quick turnabout time. We need resources in building--in building tumor banks and other kinds of infrastructure support for certain kinds of programs.

I don't think it would be that different. I think it's important to distinguish the kinds of problems we're trying to deal with. In some cases, let's take metastasism, an issue that Cliff's article appropriately focuses on. I take a somewhat different position from Cliff on why we've made so little progress in this area. It's not that scientists like me have been unaware of the importance of metastasis, we've known that for a long time.

The issue is having the right tools, and here one of the important tools is having good animal models where you can begin to study these problems. In the last two or three years, some very palpable changes have occurred in this area.

But you can't do that by saying, we're going to centralize a bunch of engineers and tell them to go fix the metastasis problem. Sure, metastasis kill, we know that. But we need ideas, and we need great people thinking about these ideas, and a lot of that has to be supported by individual grants. Competitive people, working hard, competing with each other, trying to figure out what's

the answer to this incredibly perplexing problem.

ROSE: What is it's budget ought to look like? What ought a new NCI look like? What is your strategy, because clearly on this issue, you are personal, angry, and demanding.

GROVE: I'm a cancer survivor.

ROSE: I understand.

GROVE: I go in for a PSA test every six months. I have for eight years, and I dread the result indicating that I might have a recurrence. I know what horrible choices I have if I have a recurrence and how little they have changed over the eight years that I've been watching it. So yes, I'm impatient, yes, I'm angry, and I represent a whole lot of other angry survivors. And I'm not satisfied with feasibility proofs and existent proofs and experiments run on the margin. I am looking for a transformation that takes all the fantastic science that has been developed in the last decades and puts it into practice.

And yes, Dr. Varmus, a lot of that is an engineering practice--an engineering problem. I am an engineer, I'm proud to be an engineer. Engineers create a whole lot of good things. And engineers should be put in charge of revamping, for example, the clinical trial process, revamping the whole field of biomarkers away from imaging solid tumors to looking at markers on a molecular level, revamping that, and on that basis revamping the clinical trial system using those biomarkers.

Win, Lose or Draw?

Is the war on cancer being lost? Rose's guests offered these replies:

- --"Well, I would say that we are not anywhere near winning the war, and I think that we're in danger of having the wrong strategy to the point where we're losing," Leaf said. "I think some of that is changing. I think some of the work that's being done actually at the NCI now, changing directions with the road map is helpful."
- --"I think we are losing it," Grove said. "The population is aging, and cancer rates are naturally want to go up, because it tends to be a disease of older people. And we are swimming against the tide, and we are losing ground. And it's kind of hard to blame it on resources."
- --"We are making progress against cancer," Varmus said. "It's not as fast as I would like. We make a lot of discoveries. I think Cliff's article does bring to the public's attention the inability we've had to convert all that information into clinically effective treatments.

On the other hand, we have had some remarkable successes.... The overall numbers are not good, and they could be better, I think, but I don't see anyone who has a simple plan for getting us there. It's all well and good to say, 'We haven't cured cancer.' But I think it's important to have a reasonable view of what the difficulty is in solving this enormously difficult problem.

"Only in the last couple of years have we begun to understand the nature of the genetic changes that lead to a cancer, and began to use new drugs, new diagnostic procedures, new classification procedures, that are based on a fundamental understanding of cancer," Varmus said. "I would say we're not losing the war on cancer, we're not winning it as quickly as we would like."

--"What's occurring as we look back at the past, is we are beginning to be able to change fundamentally how we approach cancer," von Eschenbach said. "And we're beginning to do that based on our knowledge of these fundamental mechanisms, and it's impacting on clinical trials today."

Grove: Moratorium on Funding

Rose closed the program by asking Grove for his final thought.

GROVE: Last thought is first, an observation, I don't think I got a satisfactory answer from the two doctors as to whether they would or would not come out with the same distribution of resources when they came out of that room.

And I think that is where the problem is. I think science moves much faster in this field than the organization adapts to the new knowledge, adapts to the new knowledge to put it into practice, to put it through engineering into deployment, to clinical trials and to patient population.

I think tinkering at the margins is not sufficient. The scientific establishment is extremely set in its ways, has all kinds of reinforcing mechanisms to do similar things that we have done in the past, and a revolutionary change is needed.

And if you allow me to make a simple proposal, I would say the following. If I was running for some kind of an office, I would adopt a platform that says, I'm going to declare a moratorium on additional spending on cancer research until the cancer research establishment reforms itself. And since it will not reform itself, I will use a model that has been used recently in another change-resistant organization, which is the military, the model provided by the base closing commission. I would have an independent body re-examine the budget priorities, project priorities, come up--resetting on the

basis of the existing knowledge how it should be, and provide that package to Congress and the administration for approval, thumbs up or thumbs down. That will bring revolutionary change.

The Charlie Rose Show for April 29 can be purchased on videotape at www.charlierose.com.

Capitol Hill:

Senators Support Increase For Health Outcomes Research

In a letter to the Senate Labor, HHS, and Education Appropriations Subcommittee, a bipartisan group of senators urged an increase in funding for research on health outcomes and clinical effectiveness of healthcare services, including prescription drugs.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 authorized \$50 million for the Agency for Healthcare Research and Quality to conduct outcomes research. Last March, the Senate approved a non-binding Sense of the Senate Amendment supporting \$75 million for outcomes research for FY2003.

"Consumers and other healthcare purchasers should have reliable information that compares different treatment options," the letter sent to subcommittee chairman Arlen Specter (R-Penn.) and ranking member Tom Harkin (D-Iowa) said. "There are numerous clinical areas where the synthesis and evaluation of existing research--as well as better, more definitive research-could improve the quality of care and help to reduce costs."

The signatories included Max Baucus (D-Mont.), Hillary Rodham Clinton (D-N.Y.), Senate Majority Leader Bill Frist (R-Tenn.), Charles Grassley (R-Iowa), Orrin Hatch (R-Utah), and Tim Johnson (D-S.D.).

Funding Opportunities:

Program Announcements

PA-04-099: Diet Epigenetic Events, and Cancer Prevention

NCI invites applications for new R01, R21, and R03 grants for collaborative research between nutrition and epigenetic to determine how diet and dietary factors impact DNA methylation and other epigenetic processes involved in cancer prevention. The objective is to continue to address the following issues: how bioactive food components regulate DNA methylation or other epigenetic events for cancer prevention, how bioactive food components might alter DNA methylation or other aberrant epigenetic events and restore gene function, and how these components might circumvent or compensate for genes and pathways that are altered by

epigenetic events. The PA will use the NIH Investigator-initiated Research Project Grant R01, the NIH Exploratory/Developmental grant R21, and the NIH Small Grants Program R03 as award mechanisms. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-099.html.

Inquiries: Sharon Ross, NCI Division of Cancer Prevention, hone 301-594-7547, e-mail rosssha@mail.nih.gov.

PA-04-094: Novel Technologies for In Vivo Imaging

NCI and other NIH institutes invite applications for the development and delivery of novel in vivo image acquisition or enhancement technologies and methods for biomedical imaging and image-guided interventions and therapy.

The interests of NCI focus on imaging in vivo for cancer pre-conditions, cancer screening, diagnosis, progression, treatment monitoring, recurrence, and image-based surrogate end points. NCI's interests include development and delivery of imaging technologies that are cancer specific, and optimization and validation of imaging technologies for cancer applications. The scope includes system integration, contrast agents, pre- and post-processing algorithms and software for imaging, image understanding, and related informatics that are cancer specific. The PA uses the SBIR and STTR mechanisms, which are set-aside programs. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-094.html.

Inquiries: For NCI--Guoying Liu, Keyvan Farahani, James Deye, or Houston Baker, phone 301-496-9531 for GL, KF, or HB; phone 301-496-6111 for JD; e-mail guoyingl@mail.nih.gov, farahank@mail.nih.gov, deyej@mail.nih.gov; bakerhou@mail.nih.gov.

PA-04-101: Characterization, Behavior and Plasticity of Pluripotent Stem Cells

Several NIH Institutes invite applications for studies on the characterization, behavior and plasticity of human and non-human stem cells, regulation of their replication, differentiation, integration and function in the nervous system, and the identification and characterization of normal and tumor stem cells. The R21 and the R01 mechanisms will be used to support projects. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-101.html.

Inquiries: For NCI--Neeraja Sathyamoorthy, program director, Tumor Biology & Metastasis Branch, Division of Cancer Biology, phone 301-435-1878; fax 301-480-0864; e-mail ns61r@nih.gov.

PA-04-103: Testing Tobacco Products Promoted to Reduce Harm

The PA would stimulate multidisciplinary research on reduced-exposure tobacco products, both smoked and smokeless, through the interplay of basic, biological, and behavioral research, surveillance, and epidemiology. The tobacco industry is promoting products with claims that they are less harmful or less addictive because these products purportedly deliver lower amounts of toxic, carcinogenic, and/ or addictive agents to the user compared with conventional products. However, to date, the scientific evidence is insufficient to evaluate whether these new products actually reduce the users' exposure or risk for tobacco-related diseases. The key research question of this PA is: Do potential reduced-exposure tobacco products provide a truly, less-harmful alternative to conventional tobacco products, both on the individual and population level? The PA will use the R01 and R21 award mechanisms. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-04-103.html.

Inquiries: For NCI--Mirjana Djordjevic, Division for Cancer Control and Population Sciences, phone 301-496-8584; fax 301-496-8675; e-mail djordjev@mail.nih.gov.

RFP Available

N02-CM-47030-45: Manufacture of Oral and Topical Dosage Forms

NCI Division of Cancer Treatment and Diagnosis is soliciting proposals to provide the NCI with oral and topical dosage forms for NCI-sponsored clinical trials. The contractor will be responsible for formulation studies, process optimization, manufacture of the clinical dosage forms, release testing, quality control, and quality assurance. Preformulation data may be provided to the contractor by NCI, but the contractor may be requested to conduct preformulation studies. Data obtained from this contract(s) may be used to support INDs submitted to FDA. The government anticipates that a single, cost-reimbursement, incrementally funded contract will be awarded on or before Nov. 30, for a base period of five years. The RFP may be accessed at http://rcb.nci.nih.gov/.

Inquiries: Kathleen Giuliano, phone 301-435-3821, e-mail giuliank@mail.nih.gov.

In Brief:

Aziz, Albain Win Awards; AFLAC Center Opens

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director of the NCI Office of Survivorship, and Kathy Albain, clinical director of the Breast Cancer Research Program, co-director of the multidisciplinary Breast Oncology Center and director of the Thoracic Oncology Program at Loyola's Cardinal Bernardin Cancer Center. Aziz was recognized for promoting cancer survivorship and follow-up care as research priorities for NIH. Albain is known for research and advisory activities in breast cancer, survivorship, and special populations. As chairman of the Committee on Special Populations for the Southwest Oncology Group, she formed a lay advocate program. . . . AFLAC CANCER CENTER and Blood Disorders Service of Children 's Healthcare

of Atlanta opened an outpatient center at Children's at Scottish Rite. The center was funded in part by a \$2.5 million gift from AFLAC Inc. . . . GABRIEL HORTOBAGYI received the Award of Excellence during the Miami Breast Cancer Conference, on Feb. 26. Hortobagyi is professor of medicine, chairman of Breast Medical Oncology, and director of the Breast Cancer Research Program at M. D. Anderson Cancer Center. . . . NATIONAL COALITION for Cancer Survivorship created new content for its free audio program, Cancer Survival Toolbox, adding 100 minutes on issues specific to life beyond diagnosis and initial treatment. The program is designed to help cancer patients, survivors, and caregivers understand the medical, financial, emotional, and social aspects of having cancer. The National Association of Social Workers helped NCCS, the Oncology Nursing Society, and the Association of Oncology Social Work to develop the new module, which is available at www.cancersurvivaltoolbox. org. . . . HOLDEN COMPREHENSIVE CANCER **CENTER** announced three University of Iowa faculty appointments. Larry Oberley, professor of radiation oncology, will serve as deputy director of the cancer center. Oberley also directs the Free Radical and Radiation Biology Graduate Program. Gail Bishop, Distinguished Professor of Microbiology and Internal Medicine, was appointed associate director for basic research. John Lowe, professor and head of the Department of Community and Behavioral Health in the College of Public Health, was named associate director for population science. . . . ANN HAGAN was named associate director for extramural activities at the National Institute of General Medical Sciences at NIH. She will oversee the fiscal management of the \$1.9 billion research and research training grant program in the basic biomedical sciences. . . . A. DOUGLAS **KINGHORN** was named the first Jack L. Beal Chair in Natural Products Chemistry and Pharmacognosy in the College of Pharmacy at The Ohio State University. He was assistant head of the Department of Medicinal Chemistry and Pharmacognosy and associate director of the program for collaborative research in the pharmaceutical sciences at the University of Illinois at Chicago. He will be working with members of the OSU Comprehensive Cancer Center's Experimental Therapeutics and Molecular Carcinogenesis and Chemoprevention Programs. Kinghorn will also be working on an NCI National Cooperative Drug Discovery Group grant. Kinghorn, who has been editorin-chief of the Journal of Natural Products since 1994, will move the editorial offices to Ohio State.

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