

## As Legacy Foundation Seeks New Money, Critics Fear Symbiosis With Big Tobacco

By Kirsten Boyd Goldberg

Cheryl Healton, president and chief executive officer of the American Legacy Foundation, has a problem:

Her foundation needs money to run public health campaigns to discourage youth from using tobacco and help adults quit. Unfortunately, Legacy's windfall from the 1998 legal settlement with tobacco companies has ended, and new funds haven't materialized.

In April 2003, Legacy received its final \$300 million payment as part of the Master Settlement Agreement between American tobacco companies and the attorneys general of 46 states. As Legacy's programs erode its \$878.9  
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### In Brief:

### David Schwartz Named Director, NIEHS, National Toxicology Program

**DAVID SCHWARTZ** was named director of the National Institute of Environmental Health Sciences and the National Toxicology Program at NIH. Schwartz is director of the Pulmonary, Allergy, and Critical Care Division and vice chairman for research in the Department of Medicine at Duke University, where he developed three interdisciplinary centers in Environmental Health Sciences, Environmental Genomics, and Environmental Asthma. Schwartz will replace **Kenneth Olden**, who served as NIEHS director since 1991, and stepped down last year. Olden will remain at NIEHS as a researcher in the intramural program. Schwartz will join NIH on April 4. NIEHS, based in Research Triangle Park, NC, has a research budget of \$711 million and supports 850 grants. His research, supported by NIEHS since 1990, focuses on the genetic and biological determinants of environmental lung disease and host defense. . . . **JOHNS HOPKINS KIMMEL CANCER CENTER** has received a five-year, \$10 million grant from the Department of Defense to study breast cancer metastasis. **Saraswati Sukumar**, the Barbara B. Rubenstein professor of oncology, is principal investigator of the grant. Sukumar will screen metastatic tumors for key molecular signatures that distinguish them from non-metastatic tumor cells. The award will establish a Center of Excellence based at Hopkins with collaborators **Steve Madden**, of Genzyme Biotechnologies; **Renata Pasqualini**, professor of cancer biology and medicine at M. D. Anderson Cancer Center; **Angela Brodie**, professor of pharmacology and experimental therapeutics at the University of Maryland School of Medicine and the Greenebaum Cancer Center; and  
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## Healton Describes Legacy's "Parochial" View: Survival

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million reserve, Healton is looking for ways to return to the old well: tobacco companies.

"Some people are so adamant that any use of tobacco funds is by definition immoral, that they don't care," Healton said to **The Cancer Letter**. "I've got a very parochial view. I'm CEO of an organization that has made a major dent in youth smoking, and if I can't get that money to continue, that will stop. So I'm a little bit more flexible."

Healton's quest to extract money from the industry it seeks to combat has powerful allies. These include several members of Congress, tobacco control advocates and researchers—and the National Cancer Institute. Last year, NCI, Legacy, and two other groups financed a meeting to resolve the "ethical, legal and policy issues" of accepting money from tobacco companies.

Legacy's stance is one of the peculiarities of tobacco control in the 21<sup>st</sup> century. In debates that preceded the passage of the corporate tax relief bill last month, antismoking advocates lobbied for government buyouts of tobacco farmers, and tobacco industry executives testified in favor of FDA regulation of their products. These realignments have caused rifts among activists and researchers, many of whom fear that tobacco control groups like Legacy are maneuvering into a permanent symbiotic relationship with tobacco

companies.

"Many of us tried to convince Legacy that this was not a good idea, and is inconsistent with the goal of ending tobacco use entirely," said Michael Siegel, a tobacco control researcher and an assistant professor at Boston University School of Public Health. "Legacy's own existence has become more important than principles."

Healton's efforts have added a new level of complexity to today's oncopolitics. In October 2002, about six months before receiving the last big settlement check, Legacy gave \$3 million to C-Change, a non-profit group comprised of cancer organizations, officials of several government agencies, and pharmaceutical industry executives. Healton said the donation was intended to "elevate the tobacco issue" at C-Change.

Only the American Cancer Society, the founder of C-Change, has made a greater commitment: \$5 million, C-Change documents show. At the time, Legacy's contribution was twice as large as those of AstraZeneca, Aventis Oncology, Bristol-Myers Squibb, GlaxoSmithKline, and Pharmacia, which pledged \$1.5 million each (**The Cancer Letter**, Dec. 12, 2003).

C-Change, formerly known as the National Dialogue on Cancer, is governed by a board that includes NCI Director Andrew von Eschenbach, who serves as the vice chairman, and Deputy Director Anna Barker. With these officials wearing two hats, the Institute's efforts to aid Healton, regardless of their merits, can create an appearance of a conflict of interest, legal experts say.

"There are often concerns when government officials serve as officers of private groups, especially when those groups, or their members, are regulated by or are overseen by the agency they work for," said Jeffrey Lubbers, an administrative law expert at the American University Washington College of Law. "Such arrangements can certainly create an appearance of conflict and ethical problems."

The relationship between Legacy, C-Change, and NCI could harm the government's cancer research and public health policies, said Charles Tiefer, professor of law at the University of Baltimore and former solicitor and acting general counsel of the House of Representatives. "This has the appearance of an effort to open the door for tobacco companies to influence official cancer research and public health policies," Tiefer said. "For tobacco companies to acquire influence in this way over official cancer research policies and funding creates the appearance of conflict."

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

## **Campaign to Protect the Truth**

In 2002, the most recent year for which Legacy's tax filings are available, the foundation received \$308 million and spent \$138.1 million.

This money paid for programs which include the "truth" and "Streethery" media campaigns aimed at youth, and "Great Start," "Circle of Friends," and "Mary Quits" campaigns for adult smokers.

At the end of 2002, the foundation had \$948.1 million in assets, tax documents show. As of June 30, this reserve has been drawn down by \$69.2 million, Legacy officials said.

The 1998 Master Settlement Agreement established a National Public Education Fund, which Legacy operates. Unfortunately for Legacy, the settlement agreement had a catch: after 2003, the cigarette makers were able to stop contributing to the fund if their combined share of the total U.S. market dropped by 0.95 of a percentage point.

The NPEF payments represented 80 percent of contributions to Legacy. The foundation will continue to receive \$25 million a year through 2008 from another MSA pot, called the Base Fund. Also, a Smokeless Fund provides Legacy \$96 million over 10 years through a separate settlement agreement with smokeless tobacco companies.

Legacy isn't trying to get money directly from tobacco companies, Heaton said. Instead, the foundation would like the companies and the attorneys general to reopen the MSA and amend it to reestablish NPEF payments.

After receiving the final NPEF payment last spring, Legacy gave \$1.5 million to the National Association of Attorneys General to fund The Citizens' Commission to Protect the Truth, which began a campaign to gather a million signatures on a petition to urge tobacco companies to continue supporting the public education fund.

Joseph Califano Jr., Secretary of Health, Education and Welfare from 1977 to 1979 and chairman and president of the National Center on Addiction and Substance Abuse at Columbia University, is head of the commission, which is comprised of all living former U.S. Secretaries of Health, former U.S. Surgeons General, and former directors of the Centers for Disease Control and Prevention.

The Califano commission is filing "friend of the court" briefs in several ongoing lawsuits against the industry, proposing that payments to the public education fund be considered as one of the remedies for industry misconduct.

Last month, 16 members of Congress signed a letter circulated by Sen. Richard Durbin (D-Ill.) urging the tobacco companies and the attorneys general to renew support for the foundation.

Tobacco control researcher Stanton Glantz, who is a Legacy grantee, agrees with the foundation's approach.

"When [Washington State Attorney General] Christine Gregoir and the other attorneys general negotiated the Master Settlement Agreement, they included this ridiculous clause that said if the big manufacturers' aggregate market share dropped below 99.05 percent, they wouldn't have to make payments into the National Public Education Fund anymore," said Glantz, professor of medicine and director of the Center for Tobacco Control Research and Education at University of California, San Francisco.

"Any idiot would have known this was going to happen," Glantz said. "Effectively, what Gregoir did was put a sunset clause in the Legacy Foundation. It think it was an unbelievably stupid move.

"I think the Legacy Foundation is behaving responsibly in trying to keep the public education fund going and trying to create a situation where the tobacco companies are forced to agree to fix the MSA," said Glantz.

"We know the 'truth' campaign works," Glantz said. "We know a lot of the things Legacy is doing work, and if you don't have any money to do them, they will stop. We know from the state programs that have been compromised and shut down that when that happens, smoking goes up."

Boston University researcher Siegel argues that there are no grounds for convincing a judge to reopen the MSA. "The only other approach is for the companies to voluntarily donate, and that's taking tobacco industry money," he said.

## **A New Role in Tobacco Research?**

Heaton would like to expand the foundation's role in research by filling a special niche: funding academic studies of "potential reduced-exposure products," or PREPs.

"This research has to be funded by the industry—through a completely hands-off mechanism where they do not control the process at all—or through the federal government," Heaton said. "What would bring the tobacco industry to the table to put some money into this is that they want to have some mechanism for making determinations about their claims. On the other side, the attorneys general want some mechanism of

enforcement. I think it's conceivable that they might enter into a new MSA."

Healton said she had broached this subject with the attorneys general.

"My discussions with the attorneys general have been very informal, but at one point, I told a couple of the AGs that if the MSA seemed like the appropriate mechanism, and if Legacy made sense, then as long as there was agreement in the tobacco control community, we could either set up a separate 501-C-3 to [fund product research], or do it within Legacy," she said.

PREPs are the new "light" forms of tobacco products that claim to preserve tobacco flavor while potentially reducing its toxic effects. "The public health impact of PREPs is unknown," a 2001 Institute of Medicine report concluded. "They are potentially beneficial, but the net impact on population health could, in fact, be negative.... Regulation cannot assure that the availability of risk-reducing PREPs will lead to reduced tobacco-related harm in the population as a whole. However, a regulatory agency can assure that data are gathered that would permit the population effects to be monitored."

The IOM report, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction," called for regulation of all tobacco products as "a necessary precondition for assuring a scientific basis for judging the effects of using PREPs and for assuring that the health of the public is protected."

Had Congress given FDA the authority to regulate tobacco products, the agency would have been authorized to receive \$750 million a year from the industry to fund harm reduction research. However, the proposal to give FDA this new authority was removed from the corporate tax relief bill that passed last month.

John Hughes, a professor of psychiatry at the University of Vermont and a spokesman for the Society for Research on Nicotine and Tobacco, said tobacco companies, not the taxpayer, should pay for testing PREPs.

"When the pharmaceutical industry has products that are going to be tested, they pay for research to test those to see if they do what they say they are going to do," Hughes said. "If the tobacco industry has products that make claims, why should the taxpayer pay to assess that, which is what's happening now?"

"I had a grant from NCI to test these products," Hughes said. "So the taxpayers had to pay me to evaluate tobacco industry products. But the pharmaceutical industry funds its own. I think the tobacco industry should have to fund its own product evaluation, and it

should have to do it through a neutral third party. That's in principle. We need to have discussion about whether that's feasible."

"The argument has been that the tobacco industry has been qualitatively different than everybody else," Hughes said. "In my view, you can make an argument that a lot of organizations mislead the public. The question is, is the industry's misleading qualitatively different?"

The tobacco industry is indeed different, Siegel said.

"The pharmaceutical industry is producing products that when used properly, help people," he said. "The other is producing products that kill people. To me, it's night and day."

### **The Ethics Workshop**

In February 2003, NCI, Legacy, SRNT, and the California Tobacco-Related Disease Research Program held a workshop on "the ethics of tobacco industry funding of research," Institute officials said in a "Congressional Justification," a document federal officials generally use to report their progress in implementing the mandates of the appropriation committees.

"This conference included independent scientists, tobacco control advocates, ethicists, lawyers, and even several tobacco company representatives," the document continued. "A goal was to assess whether there is a mechanism whereby tobacco companies could provide funds for research in a way that would be considered acceptable to the scientific and tobacco control advocacy groups.

"The general perspective is that it may be possible to accomplish that goal."

NCI received no Congressional mandate to open the door for the tobacco industry to fund cancer research.

Interviews with officials who ran the meeting and researchers who attended it indicate that no consensus was sought and none was established. The "possibility" described in the Congressional Justification is remote at best, participants said.

"That's probably wishful thinking," said Scott Leischow, chief of the Tobacco Control Research Branch in the Division of Cancer Control and Population Sciences, who was the moderator at the meeting. "It's not for NCI to say this is what we want to happen. It was just to explore the issues. At the end of the meeting, there was no consensus at all, but my perception was that the tobacco companies that were there and the tobacco

control advocates who where there were not providing major objections to having a continued dialogue on how that might happen.

“There was a positive tone to it,” Leischow reflected. “The potential was there. It could have turned into a shouting match. From that perspective, it was a positive outcome.”

The meeting, titled “Tobacco Funding and Scientific Research Workshop: Ethical, Legal and Policy Issues,” was held following the SRNT annual conference. Documents show that NCI provided \$35,000 to Pyramid Communications Inc., a contractor selected by Legacy to organize the workshop.

NCI tobacco control expert Mark Parascandola, who was assigned to organize the meeting, said development of consensus wasn't a goal. “Basically, our goal was just to promote a dialogue on this issue,” Parascandola said. “It’s an issue of concern to researchers and institutions. The goal was not to develop a policy or to reach any consensus, but just to understand the concerns.”

Healton acknowledged that the workshop didn’t move the discussion forward. “There was a very generally tense atmosphere between the industry representatives and the others at the meeting,” she said. “I don’t think a lot of progress was made in that regard.

“There is definitely an interest in trying to figure out how important harm reduction research can go on,” she said. “The hope was that if the FDA [tobacco regulation] bill passed, it would go on with a very large budget out of FDA.

“I think the energy behind the meeting [was lacking], because people felt fairly confident that the FDA bill was going to pass,” she said. “I think people were just waiting to see what was going to happen.”

Phillip Gardiner, research administrator for social and behavioral sciences in the California TRDRP, also said the meeting produced no consensus.

“What was discussed was how could you set up a situation where money could be given by tobacco to a third party, and administered for research,” Gardiner said. “No conclusion was reached.”

University of Vermont professor Hughes praised Legacy and NCI for sponsoring the meeting. “I have been pushing Scott [Leischow] in doing something about this,” said Hughes, who attended the meeting. “Is there a way to do this through a third organization, a quasi-public organization that would accept money from the tobacco industry and then distribute it? I am interested in seeing if that is feasible, and I would like

NCI to push that.”

Hughes said the workshop didn’t take up that question. “The discussion was: Should you do it; yes or no?” he said. “It wasn’t: If you were going to do it, how would you do it? They never resolved that first question.”

NCI’s official summary of the workshop concluded that “there continues to be widespread disagreement on the primary question of: Can a scientist receive funding from the tobacco industry without compromising the integrity of their research and their research institution?”

The summary claims that the workshop produced a “middle-ground idea” to establish an “independent funding institution that would distribute tobacco industry funds to scientists and institutions based upon funding priorities, needs, and scientific legitimacy.” The institution would be “staffed by independent policy experts and scientists” and would “help protect against industry influence on research conduct,” the summary said.

“Prior to funding occurring via this process and institution, there would need to be a better understanding of the downstream consequences of taking research dollars from the industry as well as discussion about what the exact funding model for research would look like,” the summary said.

The summary concluded:

“Given that tobacco companies in the United States continue to conduct scientific research using either internal or external researchers, research funding practices will continue to generate debate. Simultaneously, there is a lack of funding for many scientists and research institutions, especially in areas such as harm reduction and potentially reduced exposure products. The tobacco industry money could provide needed resources, especially for younger up-and-coming scientists, to conduct important research. Yet further work is needed to identify procedures and mechanisms that may help protect against past abuses of research conduct.”

NCI’s summary appears to be consistent with Healton’s view that industry money could be funneled through a third party to researchers.

“What are the ethics of collaborating in any way, even through a third party that insulates or double-insulates, in the case of, say, a NAAG-Legacy solution, versus taking a stronger stance and saying any of their money, no matter how it’s gotten, is dirty money and we’re not going to take it?” Healton said. “I would say that probably 10 percent of the tobacco control

community still holds [the latter] view.

“Post-MSA, there is much more appreciation for taking their money and laughing all the way to the bank,” she said. “I think there is a way to do it, because it’s already been done through the MSA. I think the key issue is that they [tobacco companies] not have any control.”

Siegel, who didn’t attend the meeting, said he finds this approach repugnant. “In other words, we would set up a money-laundering foundation that would launder money from the tobacco companies to researchers and institutions, so that the connection between the industry and the scientists would not be so apparent,” he said.

It is unclear why NCI seems to have allowed “wishful thinking” to color its Congressional Justification and its summary of the workshop. Was someone at the Institute trying to create a paper trail and an illusion of support for a controversial policy?

“This is how politically attuned officials justify controversial policies,” said University of Baltimore professor Tiefer. “They drop them into CJs, and ultimately, when the matter comes to light, they can point to the CJ and say, ‘But Congressman, it says so right here...’ And in retrospect, who is to say that the truth has been stretched?” Tiefer’s book, “Veering Right: How the Bush Administration Subverts the Law for Conservative Causes,” was recently published by the University of California Press.

Submitting a misleading CJ is a bad idea, but not a crime, lawyers say.

“It’s not under oath, so it’s not within the perjury statute, and I don’t believe it’s within the federal false statement statute, which punishes knowing and willful false statements to government agencies, including the Congress,” said Stanley Brand, an attorney with the Washington firm of Brand, Lowell & Ryan and former general counsel to the House of Representatives.

The False Statement Act relates only to administrative matters, including claims for payment or procurement of property or services, or investigations by Congressional committees.

Congress can punish untruthful statements as part of its role of supervising government agencies. “Congress can deny them the money, or condition the money, or put a rider on, or narrow their discretion,” Brand said. “They can call them up in the committee and dragoon them, they can try to impeach officers of the government. There are a lot of remedies, but they are generally not adjudicative remedies. They are legislative or political remedies.”

### **Socratic Dialogue With Tobacco Executives**

The workshop included a “Socratic Dialogue,” which was moderated by Harvard law professor Charles Nesson.

According to the NCI summary, the session “brought together a diverse group of individuals with divergent viewpoints on tobacco funding issues to discuss what ethical decisions they would make in a variety of hypothetical situations.”

The group was diverse enough to include Richard Solana, vice president for worldwide scientific affairs at Philip Morris, and Christopher Proctor, head of science and regulation of British American Tobacco.

Documents released through recent lawsuits demonstrate that Proctor’s work was emblematic of the industry’s reliance on sponsored research to cast doubt on potentially adverse findings.

Proctor took part in disputing second-hand smoke findings in Japan and Central and South America. Philip Morris documents describe him as a “behind the scenes study director” of an industry-sponsored study designed to refute an influential 1981 paper that found that women non-smokers married to heavy smokers were up to twice as likely to get lung cancer as wives of non-smokers.

To challenge these findings, the industry used a front group to organize a “Japanese spousal study” that ultimately found no link between exposure to second-hand smoke and lung cancer. The results were published under the name of an industry consultant, and Proctor’s contribution was never acknowledged. Industry documents describing the study were examined by Lisa Bero, professor of clinical pharmacy at UCSF, and published in the British Medical Journal, Dec. 14, 2002.

Proctor also appears to have acted as a behind-the-scenes manager of BAT’s “Latin Project,” which sponsored scientists to broaden the agenda beyond tobacco smoke, speak to the media, and lobby governments to preempt efforts to limit second-hand smoke.

According to an industry document, the project “aims to generate high quality scientific data, literature and commentary that can be used to respond persuasively to what is expected to be an increasing number of exaggerated media claims of adverse health effects from ETS exposure as well as to oppose government initiatives to ban or restrict smoking in public places... [and develop] solid scientific data not only with respect to ETS specifically but also with respect to the full range of potential indoor and outdoor contaminants.”

The project is described in a paper by Glantz in the

November 2002 issue of the journal Tobacco Control.

Glantz said he didn't fault the workshop organizers for inviting Proctor and Solana. "Legacy is required to meet with the industry a few times a year," he said.

Siegel isn't as tolerant. "This kind of action does tangible public health damage," he said. "It helps to legitimize the tobacco companies as legitimate players in the scientific and public health communities, and as legitimate participants in discussions over the ethics of tobacco corporate behavior and tobacco marketing practices.

"What kind of absurdity is this?" Siegel said. "We already know what kind of ethical decisions the tobacco companies have made in a variety of real situations. We know what Christopher Proctor has done in at least two major efforts to secretly help undermine established scientific and medical conclusions."

The industry's effort to manipulate research is at the heart of the Department of Justice racketeering case that has been on trial for the past seven weeks in the courtroom of U.S. District Judge Gladys Kessler, of the U.S. District Court for the District of Columbia. The trial began Sept. 21, and is expected to continue for a year, unless a settlement is reached.

"Substantial evidence establishes that Defendants have engaged and executed--and continue to engage in and execute--a massive 50-year scheme to defraud the public," according to the lawsuit.

Two organizations funded by the industry, the Council for Tobacco Research and the Center for Indoor Air Research, were disbanded for reasons of antitrust issues, as a result of the 1998 litigation.

Tobacco companies are back in the business of sponsoring research. In 2000, Philip Morris established an External Research Program to fund research grants and post-doctoral fellowships.

Dennis Eckhart, California senior assistant attorney general who is involved in tobacco litigation by the National Association of Attorneys General, said the companies should be able to conduct research on their products, as long as they don't direct the research or dictate the results.

"Under the current legal framework, the attorneys general are concerned about false and deceptive claims for tobacco products," Eckhart said. "The master settlement forbids companies from making material misrepresentations of facts of health consequences of using tobacco. That's there because of the history of the Council. The industry's campaign for decades fostered this idea that there was no real causal connection between smoking and diseases."

Gardiner, of California's TRDRP, is skeptical of the industry's current programs to support research.

"If the tobacco industry was so interested in public health, why don't they stop making their products?" he said.

Policies on accepting tobacco industry funding are far from uniform:

—Legacy declines to fund researchers within university schools or departments where other researchers accept money from tobacco companies. Over the past five years, Legacy has awarded about \$25 million in research grants.

—The American Cancer Society last year adopted a policy barring investigators who take tobacco industry research funds from receiving grants from the society. The policy will take effect for grants made after July 1, 2005.

—Robert Wood Johnson Foundation doesn't have overall restrictions, and its policy varies depending on the goals of specific programs, said spokesman Joe Marks. In a call for proposals released last summer for a Tobacco Policy Change Program, the foundation said institutions would be ineligible if they accept tobacco industry funding.

—The Society for Research on Nicotine and Tobacco doesn't have an official policy on such conflicts, but advises researchers not to accept funds from tobacco companies.

—NCI has no policy on grantees accepting funds from tobacco companies. However, an NCI book designed to help local health organizations establish communications efforts discourages commercial partnerships with firms owned by tobacco companies. The Institute's words of advice appear in "Making Health Communications Work," also known as NCI's "pink book."

In 1994, the National Cancer Advisory Board, in a report to Congress titled, "Cancer at a Crossroads," recommended that the federal government establish a policy of refusing funding to researchers who receive tobacco industry support.

### **Legacy's Seven-Point Plan for C-Change**

When Legacy joined the National Dialogue on Cancer, the group that would be renamed C-Change, it established seven "milestones" for its participation:

"1. Tobacco Ties: NDC [Foundation] includes prohibition on tobacco industry ties in by-laws. NDC distributes model policies to Partners.

"2. Raising Awareness of Partners: NDC distributes the Opinion Leader Knowledge and Attitude Survey.

“3. Policy Issues: NDC distributes and promotes internally and externally awareness of the 2003 Report Card on Tobacco Settlement Spending.

“4. Access to Tobacco Prevention and Cessation Services: NDC distributes model language to State Cancer Planning Leaders.

“5. National Media Initiative: Tobacco control (i.e., key information about the impact of tobacco use on cancer and how to reduce tobacco dependency) features prominently on the NDC website which will be used as fulfillment for all NDC communication programs.

“6. Research: NDC Team on Research appoints, funds, and staffs sub-group on Tobacco Control and Prevention Research.

“7. Joint Announcement: NDC and Legacy jointly announce their collaborative effort.”

Since that time, C-Change has prohibited industry ties, surveyed its members (“Partners”) about their knowledge and attitudes about tobacco, and created a tobacco committee, Heaton said. “They have tobacco now very prominently on their agenda.”

The first meeting of the C-Change Tobacco Control Team was held last August, led by co-chairmen Jerold Mande, associate director for policy at the Yale Cancer Center, and Matthew Myers, president of the Campaign for Tobacco-Free Kids.

Last year, C-Change hosted a “National Summit on the Primary Prevention and Early Detection of Cancer” to “develop a coordinated national strategy for cancer prevention and early detection,” according to a C-Change press release. Legacy provided support for the summit.

“This was an organization that hasn’t focused on tobacco and that seems to have changed radically,” Heaton said. “They are going to be terrific in reinventing the organization to take on the product that causes one-third of all cancers, which was essentially getting zero attention. If they don’t meet the plan, they won’t get the second year [of funding].”

When Legacy made its contribution to C-Change, NCI was using that non-profit to develop a national tissue bank intended to operate outside the government. By paying appropriated funds to consultants who technically reported to C-Change, NCI was able to shield development of the tissue bank from openness requirements of the Federal Advisory Committees Act and the Freedom of Information Act. It would have been difficult to describe C-Change as a disinterested party. It was, in fact, openly vying to run the tissue bank (**The Cancer Letter**, Aug. 8, Dec. 12, 2003).

Legacy’s commitment to C-Change was tested in

August 2003, when **The Cancer Letter** reported that Edelman, the public relations firm hired by C-Change, continued to represent tobacco companies despite the pledge by its top officials that it would drop all such clients. Edelman dropped one offending account, and continues to work for C-Change.

By remaining with C-Change, Legacy had in effect accepted Edelman’s claim that it had no control over its foreign subsidiaries who continue to accept tobacco business, and that Edelman client companies like Kraft Foods aren’t tobacco companies, despite ownership by Altria Group Inc., which also owns Philip Morris (**The Cancer Letter**, July 25).

Concerns about conflicts of interest posed by membership in C-Change aren’t new. After taking the job as HHS Secretary in 2001, Tommy Thompson resigned from C-Change, which at the time was called the National Dialogue on Cancer, citing attorney’s advice (**The Cancer Letter**, June 1, 2003). In the midst of recent controversy over conflicts of interest inherent in outside activities of intramural scientists, NIH Director Elias Zerhouni said he would prohibit senior bureaucrats from serving on boards of non-profits.

“We will prohibit [such arrangements] for senior leadership,” Zerhouni said in Congressional testimony June 22. “Even though you may be director of Institute X, if you are to serve on a nonprofit, disease-related group, we will prohibit that for senior leadership, but we will allow it for non-senior, non-authority-type leaders.”

However, Zerhouni has stopped short of extending this ban to von Eschenbach and Barker’s positions on the C-Change board. According to NIH officials, the two officials serve on the C-Change board in their official capacity, which, at least technically, means that they are exempt from the NIH ban on such outside activities (**The Cancer Letter**, June 25).

The prohibition of use of appropriated funds for lobbying can be a problem, too. The Congressional General Accounting Office addressed that issue in a 1979 case, where top officials of the Maritime Administration also served on a non-profit group called the Maritime Council, which lobbied the government (**The Cancer Letter**, Sept. 24).

“The precedent regarding the Maritime Administration applies when appropriated monies are used to fund a lobbying operation relating to the funding agency itself,” said Tiefer.

#### “Mini-War in Tobacco Control”

Capitol Hill sources say it’s likely that a bill to give

FDA jurisdiction over tobacco will be reintroduced in the next session of Congress.

“Right now, there is a mini-war going on in the tobacco control community about the legislation, with about 90 percent in favor of it and a very vocal 10 percent opposed,” Heaton said.

While industry executives have testified in Congress in favor of FDA regulation, some tobacco control advocates charged that the provision dropped from this year’s bill included too many loopholes favorable to the industry.

Much will depend on who is elected President on Nov. 2.

Democratic challenger, Sen. John Kerry, supports FDA regulation of tobacco products. “It is unconscionable that the FDA can’t really regulate tobacco,” Kerry campaign policy director Sarah Bianchi said to the American Public Health Association Sept. 14. “There is no question that it is an addictive drug, it’s been proven. If we’re going to improve the public health of this country we’ve got to address that problem point-blank.”

The tobacco buyout does “nothing to address the public health problem of smoking in this country that is one of the largest drivers of healthcare costs and one of the most tragic public health epidemics, essentially, that we face in this country,” Bianchi said.

President George W. Bush doesn’t favor FDA regulation of tobacco products, Colin Roskey, of the Bush campaign, said at the APHA session. “That shouldn’t surprise a lot of people at this point,” Roskey said.

The remarks of the campaign officials are available at <http://www.kaisernetwork.org/healthcast/apha/14sep04>.

*Paul Goldberg contributed to this report.*

### NCI Programs: **Integrative Biology Centers Funded For \$14.9 Million**

NCI said it has funded nine centers under a new Integrative Cancer Biology Program, for \$14.9 million.

The ICBP is designed to gain new insights into the development and progression of cancer through a systems-wide approach. An integrative and multi-disciplinary effort among all fields of cancer research will be applied, incorporating a spectrum of technologies such as genomics, proteomics, and molecular imaging, to generate computer and mathematical models that

could predict the cancer process.

The centers will provide the nucleus for the design and validation of computational and mathematical cancer models. The models will simulate complex cancer processes, and will be used to address all stages of cancer, from the basic cellular processes through tumor growth and metastasis.

“The key aspect that sets the ICBP effort apart from others is the focus on building predictive cancer models, and not just analyzing data,” said Daniel Gallahan, associate director of the NCI Division of Cancer Biology.

The ICBP centers also will serve as training and outreach programs.

The centers and the principal investigators are:

—Thomas Deisboeck, Massachusetts General Hospital.

—Todd Golub, Dana-Farber Cancer Institute.

—Joe Gray, Lawrence Berkeley National Laboratory.

—Tim H-M Huang, Ohio State University.

—Richard Hynes, Massachusetts Institute of Technology.

—Timothy Kinsella, University Hospital of Cleveland.

—Joseph Nevins, Duke University.

—Sylvia Plevritis, Stanford University School of Medicine.

—Vito Quaranta, Vanderbilt University Medical Center.

NCI’s Cancer Biomedical Information Grid program will coordinate all the bioinformatics software needed by the ICBP as part of caBIG’s effort to simplify and integrate the sharing and usage of data by providing access to NCI’s cancer research communities.

### Funding Opportunities: **NIH Awards 1,400 Student Loan Repayment Contracts**

NIH has awarded student loan repayment contracts to more than 1,400 health researchers in fiscal 2004, the Institutes said.

This brings the total number of awards to over 3,200 since FY 2002, the first year NIH implemented the loan repayment programs nationwide. The 1,407 new contracts for FY 2004 totaled nearly \$68 million, averaging \$48,300 each.

Loan repayment is competitively awarded to health professionals who commit to engage in

research careers. Over half of the awards were to researchers who completed their doctoral degrees within the past five years. In addition, more than 40% of the awardees hold M.D. degrees, 34%, Ph.D degrees, 9% M.D./Ph.D. degrees, and 7%, other doctoral degrees.

The NIH Loan Repayment Programs can repay up to \$35,000 of qualified educational debt for health professionals pursuing careers in clinical, pediatric, contraception and infertility, or health disparities research. The programs also provide coverage for Federal and state tax liabilities.

Applications are currently being accepted online at <http://www.lrp.nih.gov>.

Eligible applicants must possess a doctoral-level degree, devote 50% or more of their time to research funded by a non-profit organization or government entity (federal, state, or local), and have educational loan debt equal to or exceeding 20% of their institutional base salary. U.S. citizens, permanent residents, or U.S. nationals may apply. The online application closes on Dec. 15.

“The NIH Loan Repayment Programs is one of our nation’s most significant efforts to ensure a solid foundation of clinical, pediatric, contraception and infertility, and health disparities research professionals for the next generation,” said Ruth Kirschstein, senior advisor to the NIH Director. “These programs provide a means for health professionals to launch their research careers unfettered by the burden of student loan debt.”

## LLS Translational Research Programs Seek Applicants

Preliminary Application Due Date: March 1

Full Application Due Date: March 15

Proposal should be based on epidemiological, molecular, cellular or integrated systems findings and be conceptually innovative. The application should have a clear plan for the clinical exploitation of the studies proposed. This feature of the proposal will be an important consideration of the review process.

Principal investigators may request that society be a part for an application to the NCI. Academic Public/Private Partnership Program. The application must indicate the applicant will apply for a Translational Research Program grant through the Society’s standard procedure, which, if awarded, may be used for the A4 program’s matching requirements.

Awards will be limited to a maximum of \$200,000, which include direct costs and a maximum overhead of \$20,000 or 11.1 percent of direct cost per year for three years. Budget requests should be carefully justified and commensurate with the needs of the project. Renewal of funding for two additional years may be available from the Society. Requests for renewal of support require a competitive renewal application and must include an IRB-approved clinical trial as the centerpiece of the research plan.

Inquiries: Director of research administration, The Leukemia & Lymphoma Society, 1311 Mamaroneck Ave., White Plains, NY 10605, phone 914-821-8859; e-mail [researchprograms@tlls.org](mailto:researchprograms@tlls.org).

## Program Announcement

### PA-05-009: Research on the Economics of Diet, Activity, and Energy Balance

Letter of Intent Receipt Dates: not applicable

Application Receipt Dates: <http://grants.nih.gov/grants/funding/submissionschedule.htm>

The PA solicits projects that enhance the state-of-the-science on the causes of obesity and to inform federal decision making on effective public health interventions for reducing the rate of obesity in the U.S. Research strategies that nest economic analysis within a broader interdisciplinary context of other social and behavioral sciences as well as the epidemiological, bio-statistical, medical, and biological disciplines relevant to public health policy are especially encouraged.

Research areas include: consumer economics, industrial organization, community structure, policy, cost-effectiveness/cost benefit studies. A multidisciplinary research approach that integrates economics research in one or more of these areas with knowledge and methodologies from other social and behavioral sciences, and/or with epidemiological and clinical research is strongly encouraged. The PA will use the NIH exploratory/development R21 award mechanism and the NIH investigator-initiated research project grants R01 award mechanism. The PA will use the NIH exploratory/development R21 award mechanism and the NIH investigator-initiated research project grants R01 award mechanism. The PA is available at <http://grants.nih.gov/grants/guide/pa-files/PA-05-009.html>.

Inquiries: For NCI--Martin Brown, Applied Research Program, Division of Cancer Control and Population Sciences, phone 301-496-5716; fax 301-435-3710; e-mail [mb53o@nih.gov](mailto:mb53o@nih.gov).

## RFAs Available

### RFA-TW-04-004: International Cooperative Biodiversity Groups

NIH, National Science Foundation, and the U.S. Department of Agriculture invite applications to establish ICBGs that address the interdependent issues of biodiversity conservation, economic capacity, and human health through

discovery and development of therapeutic agents for diseases in developing countries, as well as for developed countries. Eligibility is limited to groups that are funded by ICBG R21 planning grant awards issued in 2003. Particularly relevant disease areas and health needs include HIV-AIDS and its opportunistic infections and associated malignancies, tuberculosis, malaria, other emerging diseases, mental disorders of adults and children, cancer, drug abuse and cardiovascular and pulmonary diseases. Applicants are encouraged to consider marine coral reef organisms as well as new sources of previously unexplored or under explored microorganisms, including but not limited to those arising from symbiosis, extreme environments such as thermovents, and deep sea microbes. Applications that propose to work primarily with plants for pharmaceutical drug discovery are encouraged to propose research and training related to phytomedicine analysis. Research and capacity building toward the development of agricultural agents is permissible as a secondary activity where it complements work on human health agents. The RFA will use the NIH U01 award mechanism and will support awards of up to \$600,000 per year in direct costs for up to four years. The RFA is available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html>.

Inquiries: Joshua Rosenthal, deputy director, Division of International Training and Research, Fogarty International Center, NIH, phone 301-496-1653; fax 301-402-0779; e-mail [rosenthj@mail.nih.gov](mailto:rosenthj@mail.nih.gov).

#### **RFA-DK-04-013: Site Specific Approaches to Prevention or Management of Pediatric Obesity**

Letters of Intent Receipt Date: Dec. 23

Application Receipt Date: Jan.

The RFA encourages the development and empirical testing of intervention approaches to prevent or manage overweight in children and adolescents: capitalizing on the strengths of various sites in which such, interventions can be delivered. It is anticipated that responsive applications will generally be in the form of clinical trials, that is, prospective studies involving a behavioral or biomedical intervention in one or more groups of human subjects, with appropriate control or comparison groups. This RFA targets interventions that focus on behavioral or environmental modifications either individually or, where appropriate, in combination. Recognizing that previous studies done in isolation within various sites have shown limited efficacy, applications that examine approaches across two or more sites are encouraged. Research applications that include the home/family as a site are especially encouraged, emphasizing the influence of parents as role models, gatekeepers for food and beverage access, screen time, and physical activity opportunities. In addition to efficacy trials, effectiveness studies for prevention or management of overweight that can be delivered in or across specific sites and that have compelling preliminary data also would be responsive to this announcement. Priority studies include: 1) child care centers, pre-schools, and other

sites for youth age 2 to 5 years; 2) community recreational centers and community organizations frequented by youth, which can create social systems that support behavioral action and maintenance; and 3) home/family. The funding opportunity will use the NIH Research Project Grant R01 and Exploratory/Developmental Grant R21 award mechanisms. The RFA is available at <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-04-013.html>.

Inquiries: For NCI--Amy Yaroch, Health Promotion Research Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences, phone 301-402-8425; fax 301-480-2087; e-mail [yarocha@mail.nih.gov](mailto:yarocha@mail.nih.gov).

## **NCI RAID Seeks Applicants For Contract Resources**

### **NOT-CA-05-003: Rapid Access to Intervention Development**

Receipt Dates, Feb. 1 and Aug. 1, 2005

NCI is requesting applications for the preclinical development contract resources of the NCI Developmental Therapeutics Program. RAID is not a grant program. Approved applications to RAID instead gain access to the drug development contract resources of the Developmental Therapeutics Program. The goal of RAID is the rapid movement of novel molecules and concepts from the laboratory to the clinic for proof-of-principle clinical trials. RAID will assist investigators who submit successful applications by providing any (or all) of the preclinical development steps that may be obstacles to clinical translation. Possible tasks may include production, bulk supply, good manufacturing process manufacturing, formulation, and toxicology. Suitable agents for RAID will include small molecules, biologics, or vaccines.

Inquiries: RAID, NCI, Office of Associate Director, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, phone 301-496-8720; fax 301-402-0831; e-mail Email: [raid@dtpx2.ncicrf.gov](mailto:raid@dtpx2.ncicrf.gov).

### ***In Brief:***

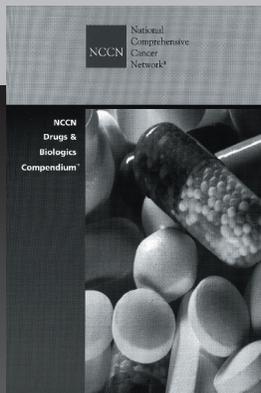
## **Fox Chase Cancer Center Appoints Eight Staff Members**

(Continued from page 1)

**Zaver Bhujwalla**, professor of radiology and oncology at Hopkins. . . **FOX CHASE CANCER CENTER** has appointed eight staff members. **Hossein Borghaei**, chief fellow at Fox Chase, joined the department of medical oncology, specializing in leukemias, lymphomas and lung cancer. **David Chen** joined the department of surgical oncology, specializing in urologic oncology. He was Ferdinand C. Valentine Fellow in the laboratory of urological oncology, Department of Urology at New York-Presbyterian Hospital-Weill Cornell Medical. **Douglas Flieder**, assistant professor of pathology at

the Weill Medical College of Cornell University and assistant attending pathologist at New York-Presbyterian Hospital, was named chief of surgical pathology. **Veda Giri**, of the University of Michigan Medical Center, has joined Fox Chase with dual appointments in the division of population science and the Department of Medical Oncology. **Jon Glass**, part of the Fox Chase associate medical staff since 2000, has accepted a full-time position in the department of medical oncology as director of the Division of Neuro-Oncology. He also is associate professor of neurology at Temple University School of Medicine and holds a hospital appointment at Jeanes Hospital. **Miriam Lango**, an ear, nose and throat specialist and a resident at the Hospital of the University of Pennsylvania, joined the Department of Surgical Oncology. Breast cancer specialist, **Ramona Swaby**, joined the Department of Medical Oncology. She was assistant professor in the comprehensive breast program at the H.L. Moffitt Cancer Center and Research Institute. **Jeffrey Tokar**, a gastroenterologist, has joined the medical oncology department. He was a clinical instructor at the University of Virginia Health System. . . . **VIRGINIA COMMONWEALTH UNIVERSITY** Massey Cancer Center received a \$600,000 grant from

the V Foundation for Cancer Research for translational research into whether chemotherapies can be customized based on tumor genetics. The collaboration between the VCU Massey Cancer Center and the Baylor College of Medicine will examine tumor-to-tumor differences in gene expression and how these genetic differences affect response to different chemotherapy drugs. **Peter O'Connell**, chairman of the VCU human genetics department, is the principle investigator. The research team includes **Harry Bear**, chief of surgical oncology; **Carleton Garrett**, division chairman, pathology; **Kelly Archer**, assistant professor, biostatistics; **Steven Townson**, assistant professor, human genetics; **Catherine Dumur**, molecular diagnostic technician, pathology; and **Jim Kruse**, surgical oncology research fellow. Collaborators from Baylor include **Jenny Chang**, clinical oncologist; and **Craig Allred**, anatomic pathologist. . . . **JULIA STEPENSKE** was selected by the Oncology Nursing Certification Corp. as the 2004 Certified Pediatric Oncology Nurse of the Year. She is an expert nurse in the Ambulatory Stem Cell Unit at Children's Memorial Hospital in Chicago. She is a research assistant for an NCI study on teen survivorship.



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## ANNOUNCING

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The National Comprehensive Cancer Network announces the authoritative source for determinations about the appropriate use of drugs and biologics in the care of cancer patients — *The NCCN Drugs & Biologics Compendium™*. The Compendium defines appropriate uses as recommended in the *NCCN Clinical Practice Guidelines in Oncology™* — the standard for clinical policy in cancer care. These uses include FDA-approved disease indications and additional uses deemed appropriate based upon sound scientific evidence and the expertise of the multidisciplinary NCCN Guidelines Panels. The Compendium is designed for easy reference by decision-makers in health care and continues the tradition of the NCCN Guidelines as the most up-to-date source of treatment recommendations in the field of Oncology. The Compendium includes:

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