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NIH To Ban Consulting By Top Officials, Limit Outside Work By Other Employees

By Paul Goldberg

NIH Director Elias Zerhouni said his measures for regulating conflicts of interest among intramural scientists would "completely change the system of ethics at NIH."

Though the measures Zerhouni seeks to adopt would be more strict than those proposed by a "blue ribbon panel" he convened earlier this year, they stop short of an outright ban on consulting by government scientists.

Zerhouni presented his plan at the June 22 hearing of the Oversight

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In Brief:

White House Names Five To NCAB; Chairman Niederhuber Reappointed For Two-Year Term

THE WHITE HOUSE last week appointed five individuals to the National Cancer Advisory Board for six-year terms that will expire March 9, 2010. The NCAB consists of 18 members appointed by the President. **John Niederhuber**, who will serve as chairman-designate for a two-year term, was reappointed to the board. He has served on the NCAB since 2002. Niederhuber is a professor of oncology and surgery at University of Wisconsin-Madison. The other appointees are:

Kathryn Giusti, president and co-founder of the Multiple Myeloma Research Foundation, founder of the Multiple Myeloma Research Consortium, and a survivor of multiple myeloma.

Diana Lopez, professor in the Department of Microbiology and Immunology at the University of Miami School of Medicine and a program leader in tumor immunology in the Sylvester Comprehensive Cancer Center. She was co-chairman of the Trans-HHS Cancer Health Disparities Progress Review Group.

Carolyn Runowicz, professor in the Department of Obstetrics and Gynecology and director of the Comprehensive Cancer Center at The University of Connecticut Health Center.

Daniel Von Hoff, director of the Arizona Health Science Center's Cancer Therapeutics Program, and a professor at the University Medical Center in Tucson.

* * *

PHILIP JUAN BROWNING, associate professor of medicine, cancer biology, and cell and developmental biology at the Vanderbilt

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Zerhouni And NCI Adopt "Mea Culpa" Strategy

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and Investigations Subcommittee of the House Committee on Energy and Commerce. At the hearing—the subcommittee's third, and, likely not last, on the matter—Zerhouni and NCI officials adopted the "mea culpa" strategy, admitting error in specific cases brought to their attention and promising to do better.

The ethics and disclosure rules adopted by NIH in 1995 were insufficient to guard against conflicts of interest, Zerhouni said.

"Further, I have reached the regrettable conclusion that some NIH employees may have violated these lenient rules, and the agency's ethics system didn't adequately guard against these violations," Zerhouni said. "It is very regrettable to me and painful to me that the actions of a few may have painted the good work of thousands of scientists who have not participated in any of these actions and who have worked daily at NIH to solve mysteries of disease and advance treatment and cures."

The probe initially focused on lectureship awards that former NCI Director Richard Klausner received from NCI grantee institutions, and expanded to include consulting arrangements between intramural scientists and pharmaceutical companies. Most recently, Congressional investigators presented a case where NCI and FDA scientists supervised a Cooperative Research and Development Agreement with one company while consulting for its competitor.

That case, which involved NCI scientist Lance Liotta and FDA scientist Emanuel Petricoin, was "the tipping point," Zerhouni said in testimony.

The Liotta and Petricoin situation became a major embarrassment for NIH as Congressional investigators produced evidence indicating that the two scientists were apparently inaccurate in their testimony before the subcommittee, and that Liotta continued to accept consulting fees even after Zerhouni ordered NIH employees to halt such arrangements.

"We need a complete scrubbing, complete reform," Zerhouni said, describing his reaction to the Liotta and Petricoin case. "That is not appropriate."

Though remarks by House members and other testimony suggest that Liotta's and Petricoin's testimony wasn't accurate, there were no indications that the two scientists are facing any specific penalties. *(See related story on page 5.)*

C-Change: NCI Gets Waivers To Participate

Zerhouni's testimony focused primarily on limitations on consulting and awards. However, one proposal that could have profound impact on oncopolitics involves the relationship between senior NIH officials and nonprofit groups.

Zerhouni's comments suggest that he plans to prohibit senior NIH employees from consulting with nonprofit institutions and serving on their boards of directors. "Consulting with nonprofits, non-grantee institutions is another issue," Zerhouni said. "There, you don't have the potential of conflict of interest in terms of disbursement of funds. In this case, we will prohibit it nonetheless for senior leadership, people who have grant-making or contract-making authority."

Zerhouni said the same principles apply to membership on boards of directors of nonprofits. "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," he said.

Responding to a question from **The Cancer Letter**, NIH officials said the hypothetical situation described by Zerhouni doesn't apply to the participation by NCI Director Andrew von Eschenbach and Deputy Director Anna Barker in C-Change, a nonprofit previously known as the National

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Dialogue on Cancer. Von Eschenbach is vice chairman of the C-Change board and Barker is a board member.

"Both Drs. von Eschenbach and Barker serve on the C-Change board in their official capacities," said NIH spokesman Don Ralbovsky. "Both employees have received the appropriate waivers for the conflicts of interest under Section 208. The proposed ban on consulting with nonprofits, non-grantees for senior leadership applies to outside activities only, and thus, would have no effect on Drs. von Eschenbach and Barker's official duty activities with C-Change."

C-Change is funded primarily by NCI, the Centers for Disease Control and Prevention, pharmaceutical companies, and the organization's founder, the American Cancer Society.

NCI's contributions to C-Change are substantial, documents show. During a portion of fiscal 2001 through the end of fiscal 2002, the Institute's expenditures on C-Change were projected at $673,400 in staff time and other contributions. Insiders estimated NCI's subsequent contributions to C-Change at around $1 million a year.

Last year, NCI used C-Change to develop a controversial plan for centralized tissue banking. By using C-Change to develop the proposal, the Institute avoided requirements of the Federal Advisory Committee Act and the Freedom of Information Act.

Though the process wasn't open to public scrutiny, the Institute awarded a non-competitive grant to a contractor to conduct a survey of existing tissue banks, and supported another contractor's work in preparing the plan for the tissue bank, called the National Biospecimen Network.

The plan suggested that the multi-billion-dollar system should be created under the auspices of C-Change (**The Cancer Letter**, Aug. 8, Dec. 12, 2003).

The question of conflict of interest involving C-Change isn't new. HHS Secretary Tommy Thompson resigned from the organization, citing attorneys' advice three years ago, when he took the top post at the department (**The Cancer Letter**, June 1, 2003).

Barker also serves on the board of Friends of Cancer Research, that group's Web site indicates. Friends was involved in an unsuccessful Klausner-era effort to privatize NCI and, more recently, sought to play a role in changing the structure of FDA's handling of oncology products (**The Cancer Letter**, June 4).

"Dr. Barker has resigned from the Friends board," Ralbovsky said in response to a question from **The Cancer Letter**. "She has asked Friends to remove her name from their Web site." The site identified Barker by her pre-NIH affiliation.

Beyond the Blue Ribbon Panel

"It is absolutely important to build a firewall between the employees at NIH who have any authority whatsoever in grant-making, contract-making from any consulting with industry," Zerhouni said in his testimony. "That means that the entire senior leadership, including directors, deputy directors, scientific directors, clinical directors and all staff involved in making decisions be prohibited [from outside work]. And this is a total ban."

Scientists who have no authority over grants and extramural programs would have to operate under new restrictions, Zerhouni said.

These would include limits on the number of hours intramural scientists would be able to devote to moonlighting, a ban on acceptance of stock and stock options as compensation, restrictions on holding of stock, a ban on serving as corporate officers, and adoption of new rules that require centralized review and public disclosure of outside work.

"Because of concern about conflict of commitment—whom is the employee working for, the government or some other entity—I will go further than the blue ribbon panel proposed," Zerhouni said. "I will limit annual compensation from all outside activities with industry to 25 percent of the employee's salary, with no more than half of such income should come from one source, and limit the time spent to 400 hours annually."

Stock and stock options create an "indistinguishing conflict," Zerhouni said. "I do not wish to have that. I intend to prohibit any such relationships."

Also, NIH employees and their family members would be allowed to hold no more than $5,000 worth of stock of any biotechnology or pharmaceutical company, Zerhouni said. "And we will insist that divestiture occur," he said. "This will create a scrubbed environment for ethics at NIH."

NIH would disclose all outside activities of its employees. "We will have a database," Zerhouni said. "If you cannot disclose it publicly, it will not be allowed. Period. End."

Also going beyond the recommendations of the panel of experts he convened to guide him through the conflict of interest controversy, Zerhouni decided

that membership on corporate boards creates "a conflict of commitment and fiduciary responsibility."

"I want my employees to be responsible to NIH," Zerhouni said. "We will allow limited service on scientific advisory boards for ad hoc participation—and again—not for senior employees, only the ones in the laboratory. There is value there, and we need to make sure that it's reviewed centrally, but it be allowed."

Turning to lectureships and awards, an issue that surfaced in the subcommittee's investigation of Klausner, Zerhouni said NIH would stop short of a complete ban.

"I reviewed all the cases that came to my attention, he said. "I believe that there are awards that are very deserving. They are awards that relate to meritorious accomplishment of scientists sometime before they came to NIH. I think it would be unwise for us to prevent the recruitment of a director who may be a potential recipient of a Nobel Prize or a Lasker Award, or many other prizes that have a long-established life, that have a process that is independent from any grantee institution, in the sense of having a foundation and a clear, open process of nomination and an open process of awarding the award."

NIH would create a list of awards it deems legitimate, Zerhouni said. "We are going to submit that list and the criteria of that list to our independent Advisory Committee to the Director of NIH, and we will ask them, 'Is the Nobel Prize O.K.? Is the Lasker Award O.K.?' And then we will create a public, registered list of accessible awards to NIH scientists. If an award is received by an NIH employee, it will still be reviewed by our central advisory ethics committee."

The reviewers would be asked to decide whether the recipient of the award would be in a position to affect the conduct of the organization that offers the award, either directly or through a subordinate.

As an additional restriction, NIH would prohibit institute and center directors and others responsible for funding decisions that may affect entities giving the prize from receiving the cash component of the award.

Addressing a related problem, Zerhouni said consulting with nonprofit grantee institutions can be a conflict, too.

"I am going to propose that we prohibit this for all employees," he said. "You may ask, 'Why are you more strict for nonprofit grantee universities than you are for industry?' The difference is that grantee institutions come and ask for public money. Industry pays for the outside activity of the scientist."

Grantees would still be able to get guidance, Zerhouni said.

"In every case when we need to have science advice given to our grantees, we will do so after determination by supervisory review under the official duty scheme rather than the outside activity scheme, which will prevent personal rewards of any kind in that kind of a relationship," he said.

Though intramural clinicians would be allowed to moonlight, their income would be pegged to that of academic physicians in their market area. This would limit the "perverse incentive" of favoring the physicians' outside activities over their duties at NIH, Zerhouni said.

The limitation wouldn't affect purely academic pursuits, such as writing textbooks, editing journals, writing articles, or teaching courses on the university level. "Those are the core activities of our scientists," Zerhouni said. "I really don't wish to restrict this activity. "

All oversight would be centralized in the Office of the NIH Director, Zerhouni said.

Legislation or Rule-making?

Zerhouni said new legislation may not be needed, and changes may be instituted promptly.

HHS General Counsel Alex Azar said that in the past, ethics regulations at the department have gone to final rulemaking, bypassing the public comment procedure.

"I would advocate for that," Azar said at the hearing.

Several subcommittee members said they were considering introducing legislation. Subcommittee Chairman James Greenwood (R-Pa.) said he planned to introduce a bill to limit the use of Title 42 authority by NIH.

"I have already reached the conclusion that whatever final action is taken on outside consulting, it should take place in the context of legislative changes regarding the use of Title 42 authority," Greenwood said.

"The widespread use of 'special' compensation authorities intended for consultants in Title 42 to boost the pay of continuing, full-time NIH employees looks highly questionable on policy, if not legal, grounds," Greenwood said. "The data provided by HHS shows nearly $5 million in retention bonuses were paid to

444 Title 42 employees for the period of July 1, 1999, to May 1, 2004.

"The use of retention bonuses along with the questionable use of Title 42 is part of the gaming that has occurred with the salaries of NIH scientists. Recent data shows almost one-third of new NIH employees were hired under Title 42 authority in 2003.

"The gaming must end," Greenwood said.

Energy and Commerce Chairman Joe Barton (R-Tex.) said ethics problems at NIH lend urgency to reauthorization legislation. "The problems we are continuing to uncover… [are] further justification for why this committee needs to lead the way in restoring NIH's luster as the crown jewel of the federal government," Barton said.

Meanwhile, the subcommittee's investigation continues to turn up examples of apparent ethical lapses at NIH. At the June 22 hearing, Greenwood described the following findings:

—The subcommittee asked several drug companies to provide the financial details of their deals with NIH scientists. Information provided by the companies identified about 100 situations in which companies reported consulting agreements, but NIH didn't include those agreements in the data given to Congressional investigators.

The NIH list contained 264 deals.

"This is especially disturbing, given that the committee sent request letters only to the 20 companies that had the most agreements out of the hundreds of companies on the NIH lists," Greenwood said. "One hundred is a significant number from such a sub-sample of 264."

—According to information provided by Pfizer Inc., National Institute of Mental Health scientist Trey Sunderland was paid over $517,000 in fees, honoraria, and expense reimbursements over the past five years, Greenwood said.

"So far, however, NIH has reported to the committee that there are no outside activity request forms covering Dr. Sunderland's activities, nor are these financial details accounted for in his financial disclosure reports," Greenwood said. "These so-called outside activities appear related to [Sunderland's] government work."

—Another scientist, Alan Moshell, chief of the Skin Diseases Branch and program director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, has appeared as an expert witness, charging $600 per hour in product liability lawsuits involving the acne drug Accutane, Greenwood said.

"HHS and NIH have reported to the committee that Dr. Moshell didn't file outside activity request forms for these activities, even though HHS and NIH acknowledge that Dr. Moshell should have disclosed these activities to NIH and should have filed an outside activity request separately for each expert witness activity to obtain approval," Greenwood said.

—Congressional investigators compiled a list of the 77 scientists who had consulting agreements, while also acting as principal investigators on CRADAs.

—Turning to the Klausner inquiry, Greenwood said that as a Presidential appointee, Klausner had to have his award requests approved by the HHS Designated Agency Ethics Official.

"His award requests cannot be approved by an official at the NIH," Greenwood said. "The committee has identified two instances in 1997 in which the deputy director of NIH, not the HHS ethics official, approved Dr. Klausner's awards.

"In another case, an award to Dr. Klausner from the University of Arizona was approved by an HHS ethics attorney who didn't have a written delegation of approving authority for awards of Presidential appointees. In that same case, the first-class travel for Dr. Klausner was improperly approved as part of the award-approval process, because a first-class travel approval request must go through a separate approval procedure. This mistaken approval reportedly occurred because the HHS travel manual did not track all of the applicable requirements contained within the GSA regulations with regard to acceptance of first-class travel from a non-federal source."

Written testimony and a recording of the hearing are posted at http://energycommerce.house.gov/108/Hearings/06222004hearing1312/hearing.htm.

Executives Contradict Scientists' Claim That Firms Didn't Appear To Compete

By Paul Goldberg

At a hearing last month, NCI scientist Lance Liotta and his FDA colleague Emanuel Petricoin argued that the two proteomics companies with which they were connected differed fundamentally from each other.

According to the scientists' testimony before a Congressional panel May 18, Correlogic Systems Inc. of Bethesda, the firm whose Cooperative Research

and Development Agreement they supervised, was not a competitor of Predicant Biosciences Inc. of South San Francisco, the firm that employed them as consultants.

These accounts by Liotta and Petricoin were scrutinized at the June 22 hearing of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce.

To examine these claims, the lawmakers played three audio clips from Liotta's and Petricoin's earlier testimony, and asked executives of Correlogic and Predicant, a company formerly called Biospect, to comment on their accuracy.

In all three cases, the executives disagreed with Liotta's and Petricoin's statements, and said that the companies are, in fact, competitors in the business of designing systems for proteomic analysis. Also, the investigation turned up copies of cancelled checks that were apparently transferred to Liotta's bank account after February, when Zerhouni declared a moratorium on outside consulting by NIH employees. The last check, for $3,125, was dated May 1.

After establishing the discrepancies, the lawmakers asked NCI officials to justify their decision to allow Liotta to consult for Predicant while supervising the Correlogic CRADA.

The two scientists were not invited to explain their earlier statements.

"NIH is looking into all the allegations of misconduct raised by the committee," said NIH spokesman Don Ralbovsky. "If any misconduct is found, action will be taken."

Attorneys for Liotta and Petricoin say their clients obtained all required approvals and acted appropriately.

"We believe the record of the May 18 hearing speaks for itself," said Charles Morton, an attorney with Venable LLP, a firm that represents both Liotta and Petricoin. "Drs. Liotta and Petricoin did everything they were supposed to do. Our fundamental view is that the agreement was approved not once, but twice."

Morton said Liotta complied with Zerhouni's directive and refrained from accepting new assignments from Predicant, "but he continued to wrap up the things he was working on." The last job Liotta accepted was in April, and payment came through on May 1, Morton said to **The Cancer Letter**.

At the hearing, Subcommittee Chairman James Greenwood (R-Pa.) cited internal NCI e-mail in which Liotta stated that he had not been paid by Biospect since February.

"At the May 18 hearing, Dr. Liotta testified under oath that his work at Biospect had been 'placed on hold' since February 2004, pursuant to Dr. Zerhouni's directive that all existing consulting relationships with pharmaceutical or biotechnology firms be stopped and resubmitted to the newly-created NIH Ethics Advisory Committee for review and input, before such activities could be reapproved, if appropriate," Greenwood said in his opening statement.

"Further, Dr. Liotta confirmed his activities with Biospect were on hold in response to the following e-mail from the NIH Ethics Director, Holli Beckerman Jaffe, dated May 5, 2004: 'Please also confirm with him that while he has not received any payments since February (in other words, he was last paid in February), he has not consulted with Biospect since February—the arrangement has been put on hold until he receives approval from Dr. Kington. I know I'm beating a dead horse, but I want to be very clear on the facts. It's in the best interest that we have all the facts and no uncertainty.' "

Greenwood said that records obtained from Predicant show that Liotta received and cashed checks dated March 1, April 1, and May 1.

"These transactions all occurred during the period that Dr. Liotta claimed that the Biospect agreement was 'on hold,' " Greenwood said.

The Liotta-Petricoin situation may not be unique, Greenwood said. Altogether, the committee found that 77 NIH scientists who did outside consulting were also principal investigators on CRADAs.

Sound Clip No. 1: A Different Business

At the May 18 hearing, Liotta described Correlogic as "a software company," and Biospect as "an instrument company."

"From what I know about Correlogic, Correlogic is a software company, and they are applying their specific type of pattern recognition algorithm listed within the CRADA to data that we generate, and Biospect—to the best of my knowledge then and now—is an instrument company, and they are developing a new proprietary platform for chemistry separation," Liotta testified. "So, an instrument company; software company. They seem completely different."

After playing the clip, Greenwood turned to Jonathan Heller, vice president for information and

project planning at Predicant. "Dr. Heller, do you consider yourself a medical device company?" he asked.

HELLER: "I don't know what a medical device company is, Mr. Chairman. I would say that we are trying to provide a complete solution, which contains an instrument, contains software, contains an application, and we plan on delivering that entire system to the market for diagnosis."

Next, Greenwood turned to Peter Levine, president and CEO of Correlogic. "Do you agree that Dr. Liotta's assertion, which you've just heard, that what Correlogic was doing seems 'completely different' from what Biospect was doing?" he asked.

"I was amazed at that comment, because at that time, going back as early as April 2002, it's very clear from the license agreement that we have with the Public Health Service and from what has now been a two-year negotiation, that the very central issue was the creation of a turn-key system," Levine said. "That was the content of a good two-thirds of our CRADA meetings. It was the sticking point of our negotiations with PHS, the selection of components.

"Dr. Liotta was involved in all those negotiations."

Sound Clip No 2: Pattern Analysis

At the May 18 hearing, Petricoin said he didn't know that Biospect was involved in pattern analysis.

"The first time I heard that Biospect was working with pattern analysis was when my center director, [Director of the FDA Center for Biologics Evaluation and Research] Jesse Goodman, brought me into his office and informed me that upon recent re-review the FDA determined that Biospect had become a 'significantly regulated entity,' " Petricoin said. "He used the terms 'pattern analysis,' that they had found. And that was the first time that I had heard a reference to that."

Rep. Cliff Stearns (R-Fla.) asked Predicant vice president Heller to respond to this assertion. "Based on Biospect's relationship with Dr. Petricoin, do you believe it is likely that this encounter with Dr. Goodman was the first time that Dr. Petricoin understood that Biospect did [pattern] analysis?" Stearns asked

HELLER: "With all due respect, I cannot really say what Drs. Petricoin and Liotta remember about what we told them. I have the utmost respect for Drs. Liotta and Petricoin, and, therefore, it's actually hard for me to understand the clip that we just heard. I believe that we had past discussions with them, starting with the beginning of their consulting relationship with us, which made them aware that the company was doing pattern recognition, pattern analysis, and subsequent to that, we signed a confidentiality agreement with NCI to acquire new data that was publicly available, but not yet published, from Drs. Liotta and Petricoin. And I believe they were aware that we had signed that consulting agreement and downloaded their data."

STEARNS: "Can I summarize by saying you don't think that is believable, what you just heard?"

HELLER: "I can't say under oath what they were thinking when they answered that…"

STEARNS: "Let me ask you, yes or no, what you heard, do you think that is believable?"

HELLER**:** "Not to my knowledge."

Sound Clip No. 3: The Confrontation

Levine told the story of his slow realization that Liotta and Petricoin were working for a competitor.

Correlogic concluded its research CRADA with NCI in August 2002.

Levine first became aware of Biospect in May 2003, when another executive sent him a Web address of a company he described as "competition."

Without reviewing this e-mail carefully, Levine sent it over to Petricoin and Liotta. "I forwarded that information as just an FYI," Levine said at the hearing. "I had no idea that they were consulting for Biospect."

In the four or five weeks that followed this e-mail, Levine learned from other biotech insiders that they had heard that Petricoin and Liotta were consulting for Biospect.

Over the July 4 weekend, Levine went to the Biospect Web site, only to learn that former NCI Director Richard Klausner was listed as a founder and that several former Institute officials had joined the firm as employees.

"I went to the Web site for the first time myself, and all the pieces came together," Levine said. "I realized that Biospect was located on the same floor in our building in Bethesda, and that I had indeed seen Drs. Petricoin and Liotta there, which struck me as being rather odd, from time to time. At that point, I called Dr. Petricoin, whom I consider to be a friend, and I confronted him. My concern was not that there were all these former NCI folks. My concern was very specifically that Biospect was a competitor, and that they were consulting with the competitor."

At the May 18 hearing, Petricoin gave the following account of the confrontation:

"The recollection I have of that conversation is that Mr. Levine was unhappy with the fact that there seemed to be a lot of former NCI employees at Predicant," Petricoin said. "I thought he was unhappy that Dr. Liotta and I had an outside activity that would perhaps take away our time. My recollection of that conversation was that he expressed some question about why there are so many NCI employees there."

Approval and "Reapproval" by NCI

NCI officials said they didn't have access to all information on Biospect's business activities when they approved Liotta's consulting for the company in 2002.

"[We] didn't have access to the Web site in 2002," said NCI ethics officer Maureen Wilson, who reviewed the case. "Biospect's Web site in 2002 was not available to us. So, we relied on the description of the company, on the documents provided by the company, as to what he was going to do."

Wilson said J. Carl Barrett, director of the NCI Center for Cancer Research, was asked to review the scientific issues. "Given that it was limited by the provisions that were put into the contract, it was determined that those things were matters of general applicability," Wilson said.

Joe Barton (R-Tex.), chairman of the Committee on Energy and Commerce, said the conflict should have been obvious to Institute officials.

"If I interpret this colloquially, Babe Ruth was a great pitcher for the Boston Red Sox," Barton said. "He turned out to be a great hitter for the New York Yankees. And, according to this ruling, he could continue to do both. He could play right field for the Yankees, hit home runs, and when he wasn't playing for the Yankees, he could go up to Boston and pitch for the Red Sox."

WILSON: "But in the same instance, would you have stopped him from coaching his children?"

BARTON: "I think if you had told the owner of the Yankees that he still wanted to go pitch for the Red Sox, both ownerships would have had a problem with that."

WILSON: "I do not disagree with that."

Barrett's response could be described as a mea culpa with an explanation. "We reviewed this carefully, but as we admitted last time, knowing what we know today, we would not have made the same decisions."

BARTON: "But what do you know today that you didn't know then?"

BARRETT: "At the time, we knew that Biospect was a new company that had a very general description of their activities. It was not clear that they were involved in pattern recognition. What was also known was that in the CRADA with Correlogic, Correlogic's contribution was the computational analysis. We put very clear exclusionary language in the consulting agreement to make it very clear that if there was any overlap, that would be excluded."

BARTON: "Dr. Heller, when he was before us, basically said that you can't blame his company, because they complied with all the rules, and you are the people that are applying the rules, and you are saying you didn't know… I am not a biological scientist, but it sure looks to me like they are doing the same thing… I don't see that any effort was made to check what was really going to on."

BARRETT: "What we did do was to look at the scope of the CRADA, and the scope of the CRADA was much more narrow than the scope of the overall mission of the company."

BARTON: "Do you feel that it would have been appropriate for somebody in the government position to let the first company know that Dr. Liotta was acquired for his ability to be a consultant for what appears to be a competitor?"

BARRETT: "We fully agree with Dr. Zerhouni's conclusion that these things should be transparent."

BARTON: "You agree with it today, but you didn't at the time. Did anybody bring that up? Did anybody sit around the table and say, 'You know, we really ought to let those saps at Correlogic know?' "

Levine said he brought his concerns about Liotta's dual role to NCI Deputy Director Barker sometime early last year. Barker then asked Wilson and Barrett to review the case again.

Though the Biospect Web site described the company's business, Wilson said that her office had reviewed that information, but didn't forward it to Barrett.

"It appears to have been an oversight, and may very well have been my office's fault that it was not provided to Dr. Barrett, so he may very well have been unaware."

GREENWOOD: "Here is what's troubling us: Mr. Levine comes in and says, 'I am upset. I am working with these guys on my CRADA, and I find out that they've never told me they work for Biospect. I view Biospect as a competitor.' So you have the

information that the guy at Correlogic thinks that his company's secrets are at risk. So you have pretty good red flags in the person of Mr. Levine. So then you re-review, and the thing that worries us is that out there at Biospect you got on the board the old boss of the NCI, the Big Man, the Big Dude, Klausner… out there, making money at Biospect. And we worry that that would have clouded your judgment…"

BARRETT: "It didn't enter into my decision at all. I was told that Dr. Klausner was part of the venture capital group that had funded this. I reviewed the statement of work in the consulting agreement. I used my knowledge of the CRADA, and those didn't seem to overlap, and that was the sole basis for the decision."

Cancer Statistics:

Number of Cancer Survivors Reaches 9.8 Million In U.S.

There are 9.8 million cancer survivors in the U.S., according to a report released June 24 by the Centers for Disease Control and Prevention and NCI.

The agencies define a cancer survivor as anyone who has been diagnosed with cancer, from the time of diagnosis through the balance of his or her life. The findings are published in the June 25 issue of CDC's Morbidity and Mortality Weekly Report, "Cancer Survivorship—United States, 1971—2001."

"We expect the number of survivors to increase as improvements are made in cancer detection, treatment and care and as the population ages," said HHS Secretary Tommy Thompson.

The authors of the report used incidence and follow-up data from NCI's Surveillance, Epidemiology and End Results program to estimate annual cancer prevalence—the number of people living following a diagnosis of cancer—and trends in cancer survivorship.

According to the report:

—64 percent of adults whose cancer is diagnosed today can expect to be living in five years.

—Breast cancer survivors make up the largest group of cancer survivors (22 percent) followed by prostate cancer survivors (17 percent) and colorectal cancer survivors (11 percent).

—The majority (61 percent) of cancer survivors are aged 65 and older.

—An estimated one of every six people over age 65 is a cancer survivor.

—Seventy-nine percent of childhood cancer survivors will be living five years after diagnosis and nearly 75 percent will be living 10 years following diagnosis.

The MMWR is available at www.cdc.gov/mmwr.

"The findings in this report have important implications for both the public and health practitioners," said Loria Pollack, CDC medical officer. "There is a growing need to promote health and ensure the social, psychological, and economic well-being of cancer survivors and their families. In the past, public health programs concentrated on early detection and prevention of cancer. However, the focus has now expanded to include cancer survivorship, transforming survivorship research into practice, and developing clinical guidelines to provide attentive follow-up and health promotion to survivors."

CDC's Division of Cancer Prevention and Control is supporting states, tribes, and tribal organizations to develop and incorporate survivorship priorities into their comprehensive cancer control plans. CDC and the Lance Armstrong Foundation released a report, "National Plan for Cancer Survivorship: Advancing Public Health Strategies," available at www.cdc.gov/cancer/survivorship/index.htm#plan.

The President's Cancer Panel released a report, "Living Beyond Cancer: Finding a New Balance," available at http://deainfo.nci.nih.gov/ADVISORY/pcp/pcp03-04rpt/Survivorship.pdf.

"Issues faced by cancer survivors include maintaining optimal physical and mental health, preventing disability and late-effects related to cancer and its treatment, and ensuring social and economic well-being for themselves and their family," said Julia Rowland, director of the NCI Office of Cancer Survivorship. "NCI takes these factors into consideration when conducting research to identify, examine and prevent or control adverse effects associated with cancer."

Cigarette Use Declining Among High School Students

Cigarette use among high school students is on a decline, according to a report by the Centers for Disease Control and Prevention. The report, "Trends in Cigarette Use Among High School Students-United States, 1991-2003," was published in the June

18 issue of the Morbidity and Mortality Weekly Report.

The study found that although the prevalence of lifetime cigarette use was stable among high school students in the 1990s and the prevalence of both current and current frequent cigarette use increased into the late 1990s, all three behaviors declined significantly by 2003. Some of the report's highlights:

—During 2003, 21.9 percent of high school students currently smoke cigarettes, down from 36.4 percent in 1997. Current smoking is defined as having smoked on one or more days of the 30 days preceding the survey.

—Lifetime cigarette use among high school students is 58.4 percent, down from 70.4 percent in 1999.

—Current frequent smoking, defined as smoking on at least 20 of the 30 days preceding the survey, increased from 12.7 percent in 1991 to 16.7 percent in 1997 and 16.8 percent in 1999, then declined significantly to 9.7 percent in 2003.

Current, frequent, and lifetime smoking rates in 2003 are at the lowest level since the national Youth Risk Behavior Survey was begun in 1991.

White students were significantly more likely than black and Hispanic students to report current smoking. More white female students than black and Hispanic female students and more Hispanic female than black female students reported current smoking.

Smoking prevalence wasn't significantly different among white, black, and Hispanic male students.

NIH News:

University of Wisconsin Wins $7 Million Construction Grant

NIH has awarded a $7 million grant to the University of Wisconsin to help construct a cancer research facility, which will enable basic researchers and clinical investigators to work together to address the causes, prevention, and treatment of breast cancer, HHS Secretary Tommy Thompson said.

Last year, NIH awarded a similar grant to the University of Wisconsin for research on prostate cancer.

"Breast cancer is the second leading cause of death from cancer in American women," Thompson said. "In 2004, there will be an estimated 215,000 new cases of breast cancer in women. While researchers have made great strides in unraveling the mysteries of this disease, the new research facility at the University of Wisconsin presents a unique opportunity to marshal our resources to accelerate treatments and cures for our nation's citizens."

Both this year's award and the one made last year are for the construction of different floors in the University of Wisconsin Comprehensive Cancer Center/Interdisciplinary Research Complex. The center is an NCI-designated comprehensive cancer center.

The grant funding will provide state-of-the-art laboratories, address an overall shortage of research space, and allow investigators, who now are spread out over multiple floors and buildings on the campus, to work in close proximity in order to collaborate on their research findings. The grant is supported by the National Center for Research Resources, a component of NIH.

"Scientific discovery requires approaches that bring together—both physically and intellectually—scientists and clinicians with a broad range of expertise and skills," said NIH Director Elias Zerhouni. "By removing physical barriers, researchers at this facility can work as interdisciplinary teams—taking research gained from cellular and molecular discoveries in the laboratories and translating them into treatments and cures for patients suffering from breast cancer."

The new facility will permit researchers to share resources, including microimaging instrumentation, an animal vivarium, a molecular screen facility, a flow cytometry laboratory, and a molecular pathology/tissue bank facility.

The grant was awarded under NCRR's Research Facilities Improvement Program, which provides funding to public and nonprofit private institutions to expand, remodel, and renovate existing research facilities or construct new research facilities. The facilities must support basic or clinical biomedical and behavioral research.

Funding Opportunities:

Program Announcements

PAR-04-116: Understanding and Promoting Health Literacy

Letter of Intent Receipt Date: Sept. 13, 2004; Sept. 13, 2005; Sept. 13, 2006

Application Receipt Date: Oct. 13, 2004; Oct. 13, 2005; Oct. 13, 2006

Participating Institutes, Centers and Offices of

NIH and the Agency for Healthcare Research and Quality invite investigators to submit R03 research grant applications to increase scientific understanding of the nature of health literacy and its relationship to healthy behaviors, illness prevention and treatment, chronic disease management, health disparities, risk assessment of environmental factors, and health outcomes including mental and oral health.

Increased scientific knowledge of interventions that can strengthen health literacy and improve the positive health impacts of communications between healthcare and public health professionals (including dentists, healthcare delivery organizations, and public health entities), and consumer or patient audiences that vary in health literacy, is needed. Such knowledge will help enable healthcare and public health systems serve individuals and populations more effectively and employ strategies that reduce health disparities in the population.

The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-04-116.html.

Inquiries: For NCI—Sabra Woolley, NCI, Health Promotion Research Branch, Division of Cancer Control and Population Sciences, phone: 301-435-4589; e-mail woolleys@mail.nih.gov.

PAR-04-117: Understanding and Promoting Health Literacy

Letter of Intent Receipt Date: Sept. 13, 2004; Sept. 13, 2005; Sept. 13, 2006

Application Receipt Date: Oct. 13, 2004; Oct. 13, 2005; Oct. 13, 2006

The PA will use the NIH R01 award mechanism. The PA will use the NIH R03 award mechanism.

The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-04-117.html.

Inquiries: See preceding PAR.

PA-04-109:Cross-Disciplinary Translational Research at NIH

The purpose of this PA is to promote research that will have a practical impact on the treatment and prevention of drug abuse through the development of new research technologies that are based on existing basic and/or clinical research knowledge, and technology transfer knowledge.

The PA will use the NIH research project grant R01, small grant R03: NIH small research grant program R03, and exploratory/developmental R21; NIH exploratory/developmental Research grant award R21 award mechanisms.

The PA is available at http://grants2.nih.gov/grants/guide/pa-files/PA-04-109.html.

Inquiries: For NCI—Jacqueline Stoddard, Tobacco Control Research Branch, phone 301-496-0274; fax 301-496-8675; email stoddaja@mail.nih.gov.

In Brief:

Philip Browning, 51, Expert In Viruses And Cancer, Dead

(Continued from page 1)

University School of Medicine and a former NCI fellow recognized for his work in viruses and cancer, died June 22 at his home in Brentwood, Tenn., of colon cancer. He was 51 and served as associate director for diversity and minority clinical affairs at the Vanderbilt-Ingram Cancer Center. Browning was one of the first faculty recruits to the center in 1994, said center director **Harold Moses**. "Philip was truly loved by his colleagues and especially by the post-docs and students he worked with, not only in his own lab but throughout the cancer center," Moses said. "Philip constantly challenged himself and those around him to do and to be better." Browning was born in East Chicago, Ind., one of six children. He initially dropped out of Fisk University to live in a commune, but returned to study pre-med. He was a graduate of Tufts University School of Medicine. He completed an internal medicine residency at Brigham and Women's Hospital and fellowships at Harvard Medical School, the Dana-Farber Cancer Institute, and NCI. He became interested in HIV-related Kaposi's sarcoma while working in the NCI laboratory of **Robert Gallo**. At Vanderbilt, his work focused on how the Kaposi's sarcoma herpes virus regulates gene transcription. "Philip has been more than a colleague, he's been a true friend," said **David Johnson**, the Cornelius Abernathy Craig Professor of Oncology at Vanderbilt. "He was someone who truly relished life and was the kind of person you want to be. He truly was a remarkable individual." After his diagnosis with colon cancer four years ago, Browning saw his experience as an opportunity to reach out to others. "Life is a temporary assignment, and we only have a little bit of time to make a difference," he said. His wife of 24 years, **Renee Upchurch-Browning**, is a member of the VICC Clinical Trials Office. In addition to his wife, Browning is survived by two sons, Philip and Andrew; and three brothers and two sisters. The Philip J. Browning M.D. Minority Medical/Cancer Research Fund is being

established at the Vanderbilt-Ingram Cancer Center. Gifts can be made "in memory of Philip Browning" to the Vanderbilt-Ingram Cancer Center, VU Gift Processing, VU Station B 357727, Nashville, TN 37235-7727. . . . **MARK CLANTON**, NCI deputy director for cancer care delivery systems, will oversee the Office of Science Planning and Assessment, the Institute announced earlier this week. The office, headed by **Cherie Nichols**, produces the NCI Annual Plan and Bypass Budget and implements the recommendations of Progress Review Groups. It is also the home of the NCI Office of Women's Health. "Dr. Clanton's leadership will strengthen the planning and implementation of trans-NCI strategic initiatives," the Institute said. . . . **FDA** has revised its "FDA Breast Implant Consumer Handbook—2004" for women considering breast implants. The handbook, available at www.fda.gov/cdrh/breastimplants/indexbip.html, covers types of implants, complications, issues to consider such as mammography and breastfeeding, and other information resources. . . . **BRADLEY AGLE**, director of the David Berg Center for Ethics and Leadership and associate professor, Katz Graduate School of Business, University of Pittsburgh, was appointed to fill the non-member seat on the Oncology Nursing Society Board of Directors. The ONS president appoints one person to the board from outside of ONS membership, in an effort to broaden and strengthen the board's perspective. "Dr. Agle's leadership in the field of business ethics and leadership will enable ONS to continue its work on developing comprehensive conflict of interest policies," said **Karen Stanley**, ONS president. . . . **ONCOLOGY NURSING CERTIFICATION CORP.** Board of Directors said it will reduce the number of test items on the Oncology Certified Nurse and Certified Pediatric Oncology Nurse Examinations. Beginning in January 2005, OCN and CPON exams will have 165 test items, rather than 225 items. Candidates will have two hours and 45 minutes to complete the shorter exams. Candidates will also have 15 minutes to complete a computer-based testing tutorial and an exit survey, for a total session time of three hours. "Our research indicates that the body of knowledge tested by each examination can be accurately measured in the shorter format," said **Julie Ponto**, ONCC president. "The psychometric properties of each examination ensure that the abbreviated tests are as reliable and valid as longer examinations."

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