THE CANCER LETTER

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Von Eschenbach Endorses Rep. Clay Shaw In Tour of Florida Congressman's District

By Kirsten Boyd Goldberg

NCI Director and Acting FDA Commissioner Andrew von Eschenbach has taken a partisan role in a Congressional campaign by endorsing a key Republican ally who is running for re-election this year in what political observers expect to be a tightly contested race.

Speaking at a press conference at Broward General Hospital in Fort Lauderdale, von Eschenbach praised Rep. E. Clay Shaw Jr. (R-Fla.) for his "leadership" in supporting increased funding for cancer research and for endorsing NCI's goal to "eliminate suffering and death due to cancer" by 2015.

Shaw, who had surgery on Jan. 4 to remove a recurrence of lung cancer originally diagnosed in 2003, invited Bush appointee von Eschenbach on a two-day "cancer awareness tour" of Florida's 22nd Congressional district. On the tour, Jan. 20-21, von Eschenbach and Shaw made joint appearances at hospitals, were interviewed for a television news program, and addressed the South Florida Komen Race for the Cure.

Shaw, who has served in Congress since 1981, is defending his seat in

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Rep. Shaw's Disease Exemplifies Elusiveness Of 2015 Goal He Shares With Von Eschenbach

By Paul Goldberg

Bronchoalveolar carcinoma, the disease that afflicted Rep. E. Clay Shaw Jr. (R-Fla.), making him into a political ally of NCI Director and FDA Acting Commissioner Andrew von Eschenbach, doesn't readily lend itself to politicization.

Scientific questions posed by BAC are so nuanced that strategies for controlling it are unlikely to emerge by 2015, the year when Shaw and von Eschenbach pledge to eliminate "suffering and death due to cancer."

BAC usually grows slower than other forms of non-small cell lung cancer. It accounts for 2 to 4 percent of lung cancer diagnosed in the U.S., but its true incidence is unknown and classifications of the tumor are debated. Since BAC is often asymptomatic, patients tend to be diagnosed by accident, through screening, or after they present with bronchitis or pneumonia.

Though the disease can be lethal, oncologists who treat it say that some patients survive for many years, even decades—long enough to die of other causes, without ever getting lung cancer diagnosis or treatment.

"It may be that patients with BAC live longer regardless of the treatment administered," said David Johnson, director of the division of hematology

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Democrats Say Rep. Shaw Vulnerable In Must-Win Race

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the mid-term elections against Democratic state Sen. Ron Klein. Shaw is chairman of the Subcommittee on Trade of the House Committee on Ways and Means. In 2003, he formed the 2015 Caucus with Rep. Collin Peterson (D-Minn.) for House members who are cancer survivors.

In remarks at the Jan. 20 press conference, von Eschenbach said cancer research provides "a powerful new story of hope" that will replace "the fear that exists in everyone's mind" about cancer. But, he said, research requires "commitment."

"None of that will happen without the kind of leadership that we've experienced from Congressman Shaw," von Eschenbach said. "He's not only understood the importance of the goal and what it can mean to cancer patients and to those who are threatened by cancer, he has also understood that in order to do that, we need a national commitment. We need resources, but even more importantly, we need the will—the will to come together and use those resources the way they are being used here, in Florida, in a coordinated, collaborative way."

Von Eschenbach continued: "With his leadership in Congress, helping to guide and shape and develop our national policies, and with opportunities that I'm aware of—having the privilege to be the director of the National Cancer Institute—and coming to an institution like this today and actually seeing it being realized—we are not talking about a disease that will inflict fear, but a disease for which we have great hope."

Answering questions from the press, von Eschenbach again endorsed Shaw's leadership:

"There's much yet to do. That's why the Congressman has led the 2015 initiative on Capitol Hill, so that we could lay out a comprehensive strategy and plan, much like we did with previous challenges that this nation faced by putting a man on the moon, and we could then be able to bring all the parts and pieces together in a coordinated and effective way. It's that kind of leadership, combined with this kind of expertise, that I believe will get us to a point where, tomorrow, the story that we'll be telling will be different than the one that we are telling today."

Administration appointees regularly make campaign appearances for members of their political party, and von Eschenbach's remarks wouldn't be considered unusual if he held posts other than those in science and medicine. But traditionally, NIH and NCI directors, FDA commissioners, and other top NIH and FDA scientists have maintained at least an appearance of neutrality, on the assumption that any political party could support advances in science and medicine.

In 2000, then-NCI Director Richard Klausner, a Clinton administration appointee, spent two days touring hospitals and research centers in the Kansas City area with Sen. Sam Brownback (R-Kan.), at Brownback's invitation. According to an article at the time in the Kansas City Star, Brownback said he hoped the effort to expand the area's life sciences capabilities would be bipartisan.

Von Eschenbach's remarks about Shaw were anything but bipartisan, said Charles Tiefer, professor at the University of Baltimore School of Law and former solicitor and deputy general counsel of the House of Representatives.

"If that's not an endorsement of the partisan candidate his administration prefers for partisan reasons, I don't know what is," Tiefer said to The Cancer Letter. "Since there are precious few open races in this mid-term election, it is noteworthy that an administration official went down to that one."

Shaw and his Democratic opponent Klein reported raising over $1 million each last year for their campaigns. Democrats consider the race key to regaining control of the House.

"If Democrats want to take control of the House, we consider [Florida's 22nd district] a must-win," wrote Larry Sabato, director of the Center for Politics at the University of Virginia, where he is the Robert Kent

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"Rep. Clay Shaw is a perennial Democratic target, even though his seat was made more Republican by the 2001 redistricting process," wrote Washington Post political columnist Chris Cillizza (http://blogs.washingtonpost.com/thefix). "Democrats are (again) touting a candidate to knock off Shaw—state Sen. Ron Klein…. Klein has proved a formidable fundraiser so far in 2005, so it appears Shaw is in for a nail-biter."

Shaw has been criticized by Democrats for receiving $30,020 from ARMPAC, the political action committee run by Rep. Tom DeLay (R-Texas), and for donating $5,000 to DeLay's legal defense fund. DeLay is being prosecuted on money laundering charges. Shaw hasn't offered to return the money.

The von Eschenbach-Shaw "cancer awareness tour" made Klein supporters wonder whether the incumbent was trying to use his cancer experience to appeal to seniors or to get a sympathy vote as he seeks a 14th term (see related story, page 1).

Shaw's district, which includes parts of Palm Beach and Broward Counties, has the largest population of persons over 65 than any Congressional district.

The Klein campaign hasn't raised questions about Shaw's health, a spokesman said.

"Sen. Klein has told Mr. Shaw that his cancer is not an issue in this campaign," Klein campaign manager Brian Smoot said to The Cancer Letter. "So we hope that nobody in this race makes cancer an issue in this campaign."

Klein supports "any effort we can make, whether it be funding or change of priorities, to truly provide a climate by which we can deal with this disease," Smoot said.

"Sen. Klein has fought for funding to prevent children from smoking in the state of Florida," Smoot continued. "This is one of his highest priorities."

At the press conference Jan. 20, von Eschenbach and Shaw didn't discuss tobacco or smoking.

Shaw, 66, has said he quit smoking in the mid-1960s. His oncologist, Gerold Bepler, program leader, Thoracic Oncology Division at H. Lee Moffitt Comprehensive Cancer Center, said it's not clear what causes the type of lung cancer Shaw has, bronchoalveolar carcinoma.

"More and more people are being diagnosed who quit smoking 35 years ago, like Congressman Shaw," Bepler said at the press conference. "He quit in his 30s, and still gets lung cancer. So, I think in his case, smoking probably hasn't played a role at all, and there are other factors out there that we haven't fully figured out that play a role in the development of lung cancer." Other experts agree that BAC may not be related to smoking.

Shaw received $27,500 in contributions from tobacco companies from 1993 to 2002, according to data at www.opensecrets.org, the Web site of the Center for Responsive Politics. These included Brown & Williamson, Cigar Association of American, Swisher International, US Smokeless Tobacco, Philip Morris, and RJR Nabisco.

According to data compiled by Common Cause, Shaw received $31,300 from tobacco industry political action committees from 1986 to 1995, placing him at 13th among all House members.

Florida ranks 43rd among the states in spending on tobacco prevention, according to a 2005 report by the Campaign for Tobacco Free Kids. The state established a tobacco control program in 1998 with $70 million, but the program's budget was cut to $37.5 million in FY 2003, and reduced further to $1 million in FY 2006. The program "was once considered a national model" that made significant progress in reducing youth smoking rates in the state, the report said.

Health activists are trying to garner support for a ballot initiative in November that would reinstate funding for the Florida tobacco control program.

Tour Was "Previously Scheduled"

Although von Eschenbach took a leave of absence from administrative duties at NCI last fall in order to serve as acting FDA commissioner, he continues to make appearances and speeches as NCI director.

"Where appropriate, and his FDA schedule has allowed, Dr. von Eschenbach has kept a limited number of previously scheduled speaking engagements," NCI spokesman Michael Miller said in an email to The Cancer Letter. "This was one such event, given Dr. von Eschenbach's long-standing commitment to the 2015 goal, and the focus of the tour."

NCI continues to pay von Eschenbach's salary, Miller said. The NCI director is a "Title 42" employee, a designation that refers to Title 42 of U.S. Code Section 209(f), which allows the Public Health Service to hire scientists at higher salaries than possible under the civil service. The program was intended for hiring scientists as short-term consultants, but HHS extended it to cover NIH institute directors and many other scientists. Title 42 salaries can reach a total annual pay of $275,000 without approval of the HHS Secretary, while the civil service salary tops out at about $175,000 a year.

NCI declined to release von Eschenbach's salary. In 2004, von Eschenbach's salary was reported as $200,000 by The Washington Post.

The federal Hatch Act prohibits certain federal employees, including members of the Senior Executive Service, from campaigning for candidates in a partisan elections and making campaign speeches. Penalties for violating the law could include removal from office or suspension without pay.

However, most federal employees can give speeches supporting a candidate, as long as the employee doesn't directly solicit political contributions.

"Cancer Is Not For Sissies"

Shaw and von Eschenbach's cancer awareness tour won the Congressman significant television and newspaper exposure. Shaw was able to address questions about his health without going into detail, and get headlines for his "crusade" for funding for cancer research.

The tour began at 10 a.m. Jan. 20, at the ABC affiliate WPLG Local 10 in Miami for the taping of an interview with Michael Putney, senior political reporter and host of "This Week In South Florida." Putney, a lung cancer survivor, also writes a semimonthly column on politics for The Miami Herald.

The interview, which aired Jan. 22, couldn't have been more friendly.

PUTNEY: "Congressman, first, just to get this out of the way, and I mean it, since you and I have know each other a long time, how are you feeling?"

SHAW: "I'm feeling great. I tell you, the wonders of medicine today are really just unbelievable. I was operated on on a Wednesday, I was out of the hospital on a Friday, I was back in my office on Monday. We had the operation over at Moffitt in Tampa. They did just an unbelievably good job, and I feel good. I'm back, I'd say, 85-90 percent right now, and I have a regular schedule."

PUTNEY: "And the prognosis for your health long-term is?"

SHAW: "The margins are clear, and the tumors were removed, and right now it's good. I got a letter from Larry Robinson, the surgeon, and he said the outlook was very, very encouraging. So, you know, for lung cancer, I can tell you, and you know, Michael, you're a survivor yourself—"

PUTNEY: "I am."

SHAW: "—Cancer is not for sissies, I can tell you that. It's a scary thing to go through, but if you have a positive attitude and try to bring something good out of it, that helps you so, so much, and that's why I'm so delighted to be here with my friend, Andy von Eschenbach, who's been watching me through this whole process."

PUTNEY: "You know, Dr. von Eschenbach, that brings up an obvious point, and that is… every family I think I know has been touched by cancer. You yourself, I know, are a cancer survivor. There was a time when even saying that word to somebody was tantamount to a death sentence. But that's not the case anymore, is it?"

VON ESCHENBACH: "No, it's not, Michael. And you're absolutely correct, cancer strikes fear into our hearts because of the fact that we've seen so many people suffer and die from this disease, but today, we're at a point where we can really change that. We're beginning to understand cancer, and understand it for the first time at its genetic and molecular level, and as we understand cancer and the mechanisms that are associated with this process that we call cancer, we're now able to detect the disease and control the disease in ways that even 10 years ago were not possible."

PUTNEY: "There have been, obviously, some huge strides because of research, but more money is needed for research, and Congressman, you are on a crusade now, and you've enlisted Dr. von Eschenbach, who certainly is a great ally in this cause, to try to, if not eliminate, reduce the suffering of this disease by 2015. Let me just ask you, is that an achievable goal?"

SHAW: "Well, you've got the expert sitting next to me. He certainly believes so. I didn't pick that date. Andy told me that he thought that was achievable. You know, I liken it to a race. You're in a marathon. When you get close to the finish line, you don't jog. And we are close to the finish line. You sprint. And that's what we have to do. I'm trying to get the administration right now to make a commitment—and perhaps even in the State of the Union address—just as Kennedy said we were going to go to the moon and bring them back safely, I would like for our national commitment to say that we are going to cure cancer, or at least have it as a manageable disease, by 2015. It should be a national commitment."

PUTNEY: "And you are close to President Bush. Any indication that he might mention that in the State of the Union, later this month?"

SHAW: "Even being close to the President, he plays his cards very close to the chest, and I don't think he's going to really let it out, what's in the State of the Union address, until the speech is written and he's on the floor of the House of Representatives delivering it."

PUTNEY: "Well, we'll all find out at the same

time. You know, Dr. von Eschenbach, today, the Journal of Clinical Oncology, I have read, is publishing a report that says black patients with treatable lung cancer—and, thankfully, Congressman Shaw had a treatable lung cancer—that black patients are less likely to be thoroughly examined and less likely to undergo surgery than white patients with the same severity of the illness. What can be done to reduce or eliminate the disparity in treatment according to race and ethnicity?"

VON ESCHENBACH: "We are taking a very comprehensive approach to the problem, Michael, in terms of looking for a solution to cancer. It's not just the fact that we have to do more research and more discovery. We also have to develop interventions based on that new knowledge, and then, even more important, be sure that those interventions are being delivered to everyone who is in need. So, our delivery end of the continuum, and making certain that patients have access to the most modern interventions, and have the ability to have the fruits of discovery and development delivered to them, is really a very important part of our national agenda. The elimination of cancer health disparities is one of the areas that the National Cancer Institute focused on over the past three years, and prepared a blueprint for our opportunity for our nation to do just that."

PUTNEY: "Dr. von Eschenbach, how much money, in your heart of hearts, would you like to get from Congress to seriously do more research, research that is not done now, because you can't afford it?"

VON ESCHENBACH: "We continue to lay out an agenda for how we could preempt the process of cancer in a way that, by 2015—not eliminate all cancer, but eliminate the outcome, making certain that patients not suffer and die as a result of cancer. We know that people don't die because they get cancer. If that was the case, I would be dead three times. They die, because the cancer goes undetected and uncontrolled. We, now, have multiple opportunities with which we can preempt that process, and making strategic investments across that continuum is an agenda that we are presenting and attempting to help people understand, so that whatever resources can be obtained, we will apply rationally and effectively."

SHAW: "Michael, I'm going to be, when we get back to Washington, I'm preparing a bill right now that we will be filing that will make screening under Medicare part of the Medicare package. Early screening—if it weren't for my being screened early and detected early, almost by mistake, I would not be sitting here talking to you today, because cancer, lung cancer, is a very, very deadly form of cancer."

PUTNEY: "Yes, it's a virulent form of cancer, and, in fact, if I hadn't been diagnosed very early and somewhat luckily, I wouldn't be sitting here talking with you, as we have been. I want to thank you both. E. Clay Shaw, good to see you healthy and in good shape, and Dr. von Eschenbach, a pleasure to speak with you as well."

No language reflecting Shaw's and von Eschenbach's 2015 goal appeared in the President's State of the Union address Jan. 31.

Press Event At Broward General

After the interview, the tour headed to Fort Lauderdale for an 11:30 a.m. "press event" at Broward General.

Shaw and von Eschenbach sat at a table next to Bepler, Shaw's oncologist. "I'm tremendously comforted by being seated next to my good friend Andy von Eschenbach," Shaw said.

Shaw expressed surprise at seeing Bepler. "I don't know whether that was contrived or whether that's a coincidence, but I was delighted to see him this morning when I came into the hospital."

Shaw spoke informally about his disease.

"Having cancer is one of the scariest things that you can possibly have. It was in this very building that I was diagnosed with lung cancer, and I'll never forget it. It was like seeing the jury coming in with a guilty verdict. My doctor did not want to look me in the eye. It was a tough, tough time, and it's a very scary procedure.

"The first thing I did was to get on the phone with Andy von Eschenbach, who Emilie and I had made friends with in Washington, but never thought that we would be talking to him on a professional basis in order to get his recommendations for where I should go. I will tell you, he gave me several places, and Moffitt was one of them, and I was very, very pleased to have gone there, and I complement all the people here at Broward General for that affiliation. I think the combination is really going to bring tremendous health care right here to Broward County.

"My father was the only urologist in South Florida, living in Miami. Back during World War II… he would come up here as the only urologist in order to see patients at Broward General.

"There's nothing scarier than hearing you have cancer. You always think of that as a death sentence. My wife Emilie, she lost her mother, her father, and her sister to cancer. In my case, I think I'm a first-generation

cancer survivor on my side of the family. I want to underscore the word survivor, because surviving is what it's all about, and that is the direction we can go.

"Andy von Eschenbach told me some years ago, he said, 'By 2015, if we do this thing right, we will make cancer a manageable disease, or perhaps even a cure.' And that is the goal we have set.

"When I left Moffitt, I told Larry Robinson, who was the surgeon who did the first surgery on me for lung cancer, I told him, I said, 'I'm going back to Washington, and I'm going to do everything I can to put you out of business.' And he laughed and he said, 'I hope you do.'

"We've been working on that, and we're trying to get the funding that's necessary in order to make that a reality. Twenty-five percent of the deaths in this country are due to cancer. That's entirely too high. John F. Kennedy made the proposal many, many years ago that we would take a man to the moon and bring him back safely by a certain date. It's time that we make that a national commitment to find a cure for this dreadful disease.

"In my case, I'm lucky—very, very fortunate—because of the early detection that I had. And again, that was done in this building with a biopsy. I can say that I'm a cancer survivor. I had a recurrence, but I went right over, and two weeks ago last Wednesday, I had the other one, a wedge taken out, and I feel good. As a matter of fact, I was operated on Wednesday, left Moffitt on Friday—Dr. Bepler says I snuck out before he could come see me again—and I was back in my office on Monday. So that's the type of care that is available, and the type of recovery that is out there.

"Cancer should not be and will not be, in the near future, a death sentence. We can live with cancer, but so much more needs to be done. And I'm just delighted to be here, in this building, with these gentlemen who are going to make it happen."

Von Eschenbach's Story of Hope

Next, von Eschenbach said he would relate "a story" for the assembled press.

"It's so important that the press is here this morning, because you are critical and essential to telling a story, the story that began in 1971 when this nation committed, by the National Cancer Act, to conquer cancer," von Eschenbach said. "Over the past 35 years, we have been frustrated that we have not made as much progress in finding a cure for this disease, but what we did do over that 35 years, was invest in an effort to begin to understand cancer.

"In 1971, cancer was a complete mystery," the NCI director said. "Today, because of the investment of this nation, we are beginning to understand cancer as a disease process and understand the genetic and molecular mechanisms that are responsible for why we develop cancer, how it progresses, and why it kills.

"Based on that knowledge, we have a new story to tell: the story that says it is now within our grasp to be able to preempt this process. By understanding it and developing new and more sophisticated interventions, we will be able to prevent many cancers from ever developing in the first place. We will be able to detect other cancers very early when we can safely and easily eliminate them. There may be others that we will be able to control, much like we control diabetes or high blood pressure, such that patients live with, and never die from, cancer.

"It's a powerful new story of hope," von Eschenbach said. "Hope to replace the fear that exists in everyone's mind, that one of two men and one of three women in their lifetime will hear the words, 'You have cancer.'"

Broward's affiliation with Moffitt, an NCI-designated cancer center, creates "synergy" that "will enable us to develop new interventions and deliver those to patients," he said.

"Tomorrow, The Story Will Be Different"

Answering questions, Shaw and others focused on the Congressman's surgery, rather than his disease and prognosis.

"I slept through the whole thing," Shaw said. "The surgery took a couple of hours. I have no follow-up therapy." Shaw said he didn't even need to take Tylenol once he got home.

Shaw said his lung cancer is "not as aggressive as some forms of cancer."

The questions turned to von Eschenbach's promise: What specific new options will there be in 10 years? What advances can be made in early detection, when PSA, CA-125, and mammography aren't entirely reliable?

"I think we have to view this in terms of a vision for the future, rather than making a decision that we've actually solved the problem today," von Eschenbach said. "There's much yet to do. That's why the Congressman has led the 2015 initiative on Capitol Hill, so that we could lay out a comprehensive strategy and plan, much like we did with previous challenges that this nation faced by putting a man on the moon, and we could then be able to bring all the parts and pieces together in a coordinated and effective way.

"It's that kind of leadership, combined with this kind of expertise, that I believe will get us to a point where, tomorrow, the story that we'll be telling will be different than the one that we are telling today," von Eschenbach said.

In the evening of Jan. 20, Shaw and von Eschenbach continued further north to Palm Beach County, where they met with hospital administrators, healthcare providers, researchers, and cancer advocates from several local hospitals and the American Cancer Society.

The next morning, the two addressed Jupiter Medical Center's Cancer Symposium on lung cancer.

The tour wrapped up around noon in West Palm Beach, with speeches to participants in the South Florida Race for the Cure.

"Cancer is not for sissies," Shaw said from the stage, the Palm Beach Daily News reported. "We're a tough group up here. We are going to conquer cancer. It's not going to bring us down."

Little Known About Incidence, Treatment, Prognosis Of BAC

(Continued from page 1)

and oncology at Vanderbilt-Ingram Cancer Center, an expert on BAC.

Another BAC expert, Howard West, estimates that one in three newly diagnosed patients he sees would be alive five years later. "My guesstimate would be that as many as a third of patients with BAC can have a remarkably slow progression no matter what you do," West, director of medical therapeutics for thoracic oncology at Swedish Cancer Institute in Seattle, said to The Cancer Letter.

"I have a handful of patients with evidence of BAC on CT, but they are doing so well that they don't need any treatment, and it remains to be seen whether they ever will," said West. "I have Tarceva ready for them, or chemo, or other options, but they may need none of that if they are 70 years old, and the BAC grows imperceptibly from one year to the next. I see as much BAC as anybody, but the majority is probably under the radar of any clinician, just asymptomatic and maybe never destined to harm the patient who dies of heart failure at 75. The BAC may have caused them shortness of breath and death at 90 or 100."

Shaw, 66, said his experience has made him a believer in early detection. "One of the things that saved me was not only good treatment and good friends, but also early detection," he said at a press conference Jan. 20. "And without that early detection, I would not be here today."

This may be true for Shaw's disease, but as a public health measure, early detection of BAC may not be beneficial, and may, in fact, be harmful to some patients.

"BAC can be like very low-grade prostate cancer, the kind we think of as likely to die 'with, but not of,'" said West.

These patients face a lower risk of dying from the disease, but sometimes receive the same treatment as other NSCLC patients, whose risks are high. "Unfortunately, patients with this disease are all too often lumped in with other forms of NSCLC and get 'standard' treatment," Johnson said. "This can be the right thing to do, but not always."

Shaw's BAC Experience

The Cancer Letter asked three lung cancer experts to review the information Shaw has released about his disease.

To eliminate potential bias, experts were told only that they were reviewing information released by a public figure, but the patient's name and the name of the institution where he was treated were withheld.

Throughout his disease, Shaw was treated at the H. Lee Moffitt Comprehensive Cancer Center.

Few standards exist for treatment of BAC. However, experts said Shaw's treatment appeared to be state-of-the-art, and curing the patient still appears to be the goal.

According to information he made public, Shaw was initially diagnosed with BAC "almost by accident" in January 2003. The disease was confined to the upper section of his left lung.

"Almost by accident" is textbook presentation of BAC, experts say. "I presume it was an accidental finding—during cardiac evaluation or after an episode of bronchitis," said Mark Green, an oncologist in Charleston, S.C., and medical director at Network for Medical Communication.

Shaw underwent surgery—the preferred aggressive treatment approach when disease isn't disseminated and the patient is able to withstand it. No chemotherapy or radiation was performed.

This suggests that the disease was localized, either stage I or stage II, which means that the disease hadn't spread to the lymph nodes.

"If it was stage IA, I would have recommended no [follow-up] therapy," said Paul Bunn, director of the University of Colorado Cancer Center. "If it was stage II or IIIa, I would recommend adjuvant chemotherapy."

Bunn said that he would have told a patient with early stage disease that the standard of care would be to offer no therapy, but that there was some evidence of an increase in cure rate with chemotherapy, which could be available in a clinical trial.

West said he would probably recommend surgery, even if the disease were more advanced.

"The idea of resecting any BAC contained within the same lobe, even if there is more than one focus there, is not a textbook answer for general lung cancer, but most who are very familiar with the natural history and options for BAC would consider this a very appropriate and arguably optimal strategy, especially if there is no evidence of disease outside of that lung lobe."

About 28 months after surgery—in May 2005—another BAC lesion was found in the lower lobe of Shaw's left lung. In a press release at the time, Shaw described the second tumor as "small" and a "recurrence."

Initially, surgery was considered, but not performed, and the drug Tarceva was prescribed instead.

Bunn said there is more than a 50-percent chance that a BAC patient who recurs following surgery has systemic disease.

West didn't estimate the odds. BAC has a unique tendency to stay within the lungs and progress slowly, he said.

"BAC has a natural history that often includes multiple isolated recurrences many months or years after resection of all visible disease, potentially because of spread within the lungs that can't be detected and is growing very slowly, or possibly because the lung tissue has a precancerous condition that predisposes development of multiple BAC lesions that didn't spread from one to another," he said.

"A resection, to me, would have been the obvious standard approach" if the disease was indeed localized and if the patient could withstand surgery, Green said.

"In the investigational setting, it would be OK to give him a short trial of Tarceva to see if his tumor is responsive," Green said. "That would not be instead of resection, but rather, perhaps, to decide that his physicians might want to give him prolonged Tarceva in the post-op or adjuvant setting. There are no data to support adjuvant Tarceva in such a setting, but VIPs often get nonstandard therapy, and so he and his physicians might have been thinking ahead about post-operative therapy options."

According to Shaw, Tarceva kept the disease stable and isolated, but had not eliminated it. "Tarceva… worked for a while, and it actually shrunk my tumor, but then after a while it quit working, and I frankly didn't want to mess with it anymore, and I decided, let's just get it cut out," Shaw said at the press conference Jan. 20.

Since the pathology of his tumor wasn't released, it's unknown whether he has true BAC or an adenocarcinoma, another less aggressive lung cancer that can have some BAC characteristics and is sometimes classified as BAC. Published data suggests that adenocarcinoma that at times has BAC features can be strongly associated with response to Tarceva.

West said he would prefer to use Tarceva when patients have multiple BAC lesions, but would consider starting it for solitary lesions as well, if the disease appears to be progressing at a pace that suggests that it may be clinically significant,

As he opted for surgery, Shaw said in a press release that he had ruled out "the option of taking a new prescription drug" as treatment for his "one small remaining tumor." Experts say that the "new prescription drug" was likely Avastin, which is given with chemotherapy.

Green said he would need to know whether the patient had an entire lobe of the left lung removed after initial diagnosis in 2003. He described three scenarios:

—"If this is locally recurrent disease after less than a standard cancer operation and at surgery there was modest bulk of intraparenchymal disease at the prior resection site with no nodal involvement or other evidence of spread, this individual may have long term disease control," Green said.

—"However, if in 2003, he had a standard cancer operation and now has recurred in one of the remaining lobes of the left lung, that is a far less favorable circumstance and would likely portent other sites of metastatic disease appearing over the next several months.

—"An intermediate risk circumstance would be if this new disease is, in fact, a second primary. In that case, the prognosis of the second cancer would again be based on its stage. If it were another primary with no involved nodes, the outlook would again be rather favorable—though there would then be two competing risks for relapse and death from lung cancer: one from a late relapse of the first cancer and the other from the relapse of this second primary lesion."

West said he saw reasons for an optimistic prognosis. "Certainly within the confines of what I have available, I can see where [the doctors] and the patient were coming from, and there's reason to be hopeful about his prognosis," he said.

Bunn said the treatment appears to be aimed at curing the patient, and said he would recommend follow-up monthly or every six weeks.

The Cancer Letter asked Shaw's office to allow the Congressman's oncologist Gerold Bepler of Moffitt to discuss the case, but an interview couldn't be arranged by deadline.

At the Jan. 20 press conference with his patient and von Eschenbach, Bepler focused his remarks on recent advances in cancer surgery and the promise and convenience of Tarceva.

"The important thing to note is that nowadays, when surgery is being done, even if surgery is being done on the chest, anesthesia is considerably better than it used to be 10-20 years ago, so patients come out of the anesthesia much faster, and without many problems," Bepler said. "We have much better ways of controlling blood pressure during surgery. The incisions in the chest that are made are much smaller, because the instruments available are more sophisticated. So, overall, a surgery that was 100 years ago totally unthinkable, now can be done within a short period of time, and as in this case, with Congressman Shaw, he can literally go home two days after a very major surgery."

Local reporters asked no detailed questions about Shaw's disease, his treatment, or his prognosis. Earlier that day, in a television interview, Shaw described his surgery.

"The margins are clear and the tumors were removed," he said.

Shaw's previous statements referred to a single tumor. It could not be determined whether he misspoke.

NCI Programs:

New Grants To See 29% Cut, R01 Funding At 11th Percentile

New competing (Type 1) grants funded this fiscal year will be cut by 29 percent from the level approved by peer review, NCI said in a budget policy statement.

The reductions are required because NIH established a funding policy to pay the same number of competing grants in FY 2006 as were paid in FY 2005, and at the same average cost per grant, the NCI statement said.

NCI said it will cut larger grants more than smaller grants (those with seven modules or fewer). Competing renewal (Type 2) grants will cut by about 2 percent below their current budgets. "This is intended to achieve equity with the non-competing grants that will be cut 2.35% from committed levels," the statement said.

For non-competing (Type 5) continuations excluding small business grants, NCI will pay at 97.65 percent of the committed levels on their regular anniversary dates. Non-competing grants awarded earlier this fiscal year under the continuing resolution will be restored to match the new funding policy.

Effective with the September 2005 National Cancer Advisory Board round (the first funding cycle of FY 2006), Type 1 and Type 2 R01 applications up to the 11th percentile will be paid, the statement said. Non-percentiled R01s will be paid on a case by case basis.

R01s designated as new MERIT Awards will be permitted a 5 percent increase, while MERIT extension requests will be paid at current levels.

For the first and second funding cycles of FY 2006, the payline for large percentiled R01 ($700,000 or more direct cost requested in any year) is the 11th percentile.

NCI said it will provide an "extended percentile payline," yet to be determined, for new competing R01 applications from first-time investigators.

Program project (P01) applications will continue to be paid on a case by case basis, NCI said. New P01s also will be cut by 29 percent, and competing renewals will be cut by 2 percent.

NCI said it is "committed to the review and funding of all RFAs that have been previously announced and solicited for competition and award in FY 2006." Success rates for RFAs depend on the number and scientific merit of the applications received.

"To achieve the budget policy objectives, competing RFAs will comply with the budget policies established for R01 and P01 grants," NCI said.

The statement is available at http://deainfo.nci.nih.gov/grantspolicies/FinalFundLtr.htm.

In the Cancer Centers:

Simons Resigns As Director, Winship Cancer Institute

JONATHAN SIMONS announced his resignation as director of the Winship Cancer Institute, effective Sept. 1, or when a new director is appointed. He will continue at Emory University as professor of hematology/oncology in the WCI and will continue his prostate cancer clinic. "In reaching this decision, Dr. Simons stated that he has accomplished what he set out to do: He and his faculty have positioned the Winship Cancer Institute to move to the next level in achieving NCI Comprehensive Cancer Center status," **Thomas Lawley**, dean of the School of Medicine, in

an announcement to the center staff. Simons plans to work on the newly-awarded National Center of Cancer Nanotechnology Excellence grant from NCI to support the Emory-Georgia Tech Nanotechnology Center for Personalized and Predictive Oncology. Simons and Shuming Nie in the Emory School of Medicine Department of Biomedical Engineering are co-investigators of the grant. He also plans to reactivate his prostate cancer translational research laboratory and return to clinical care. Simons has been the WCI director since 1999. During his term, the center completed a new building, recruited several division directors and faculty, established a cancer center at Grady Hospital, received a P-20 cancer center planning grant from NCI, and raised its cancer-related research grant base to more than $50 million. . . . **CITY OF HOPE Comprehensive Cancer Center** announced three senior internal staff appointments. **Smita Bhatia** was named professor and chairman of a new Division of Population Sciences and associate director of the cancer center. Under her direction, the new division will bring together cancer prevention and control research with the outreach activities of the institution in a comprehensive program supporting interventions to reduce cancer-related morbidity. She will also lead the Cancer Prevention and Control Program and will retain an appointment as a staff physician in the Division of Pediatrics. She was director, Epidemiology and Outcomes Research, Division of Pediatrics at City of Hope. **Yun Yen** was named director of the Department of Clinical & Molecular Pharmacology, Division of Medical Oncology & Therapeutics Research. Yen, a professor of medical oncology, also was named associate director for translational research and co-director of the Experimental Therapeutics Program. **Ravi Bhatia,** director of Stem Cell Biology Program in the Division of Hematology and HCT, was named director of the new Department of Hematopoietic Stem Cell & Leukemia Research, as well as co-director of the Hematological Malignancies Program. The new department will focus on basic and translational hematopoietic stem cell and leukemia biology. He continues as professor and staff physician in the Division of Hematology & Hematopoietic Cell Transplantation. . . . **UNIVERSITY OF ALABAMA** at Birmingham received a $5 million gift to build the Hazelrig-Salter Radiation Oncology Facility at UAB Comprehensive Cancer Center. The donation was given by W. Cobb Hazelrig, a Mountain Brook businessman. Groundbreaking will take place in the spring with completion in 2007. . . . **VANDERBILT-INGRAM Cancer Center** Clinical Trials Mentor Program has opened for patient enrollment. The program offers training to cancer survivors or family members in the basics of clinical trials and the opportunity to talk with other clinical trial participants. The program has five trained mentors. "Patients have said this is what they want and need," said **Karen Stroup**, manager of patient advocacy at Vanderbilt-Ingram. "You get all the information you need about clinical trials from a doctor or nurse, but what you don't get is anything from another patient who has been where you are." . . . **STEVEN DEVINE**, of Washington University School of Medicine in St. Louis, was appointed director of the Blood and Transplant Program at Ohio State University Comprehensive Cancer Center-Arthur G. James Cancer Hospital and Richard J. Solove Research Institute. Known for his work in allogeneic blood cell transplantation for advanced acute myeloid leukemia and myelodysplastic syndrome adult stem cell transplants, he is chairman or co-chairman of two multi-center clinical transplantation trials in AML supported by NIH. . . . **J. ROBERT BECK,** professor of pathology and professor of family and community medicine, was named deputy director of the population science division at Fox Chase Cancer Center. He will be academic advisor for faculty, assist with the administrative activities of the division and continue his work in biomedical informatics. He also will continue as vice president and chief information officer, said **Mary Daly**, senior vice president of the population science division. Prior to his new role, Beck directed the evaluative sciences program in the division. He holds grants from the National Library of Medicine, the Pennsylvania Department of Health and from the NCI Cancer Biomedical Informatics Grid. . . . **ELIZABETH WILLIAMS** was named associate director for minority affairs at Vanderbilt-Ingram Cancer Center. She was director of disparity elimination for the Tennessee Department of Health. At Vanderbilt-Ingram, she will focus on health promotion, education, access to care, clinical trials and behavioral interventions for minority populations. Williams also will work to strengthen the Vanderbilt-Ingram partnership with Meharry Medical College through joint recruitment of faculty and further strengthening of the clinical trials infrastructure of the partnership, said **Raymond DuBois**, director of the Vanderbilt-Ingram Cancer Center. Williams succeeds the late **Philip Browning**. . . . **JOAN MASSAGUE**, program chairman, Cancer Biology and Genetics Program, Memorial Sloan-Kettering Cancer Center, will received the inaugural Vilcek Prize in Biomedical Research from the Vilcek Foundation March 21 in New York. The award honors the contributions of foreign-

born scientists and carries a $50,000 cash award. Massague also has been chairman of the Cell Biology Program at MSKCC for the past 15 years.

Professional Societies:

ASCO, NCCS To Honor President Sandra Horning

SANDRA HORNING will be honored by the American Society of Clinical Oncology and the National Coalition for Cancer Survivorship during the ASCO annual meeting in Atlanta, June 3. Horning, an oncologist and a cancer survivor, is being recognized by both organizations for her work as ASCO president over the past year, particularly in the area of cancer survivorship, said **Ellen Stovall,** president and CEO of NCCS, and **Joseph Bailes**, interim executive vice president and CEO of ASCO. The funds raised during the tribute to horning will benefit NCCS and The ASCO Foundation. . . . **ASTRO** announced two staff appointments. **Emily Wilson** was named government relations representative with management responsibility for the ASTRO political action committee, ASTRO PAC. Wilson, who has healthcare and lobbying experience, was senior associate at an association management organization. **Amanda Sarata** was named senior policy analyst. Sarata, who was a program analyst at NIH, will work on federal legislative and regulatory issues affecting radiation oncology including cancer quality care and nuclear regulatory concerns. She also will be the liaison to federal healthcare agencies.

Funding Opportunities:

RFP Available

RFP N02-CP-61005-50: Clinical Genetics Branch Support Services Contract

Response Date: Mar 21

NCI Clinical Genetics Branch, Division of Cancer Epidemiology and Genetics is re-competing a contract for interdisciplinary studies in clinical cancer genetics. The contract requires conducting domestic and international family studies and field--case-control and cohort studies. Although the scientific design and oversight of the contract-supported activities are the responsibility of the CGB professional staff, the resources the contract provides include: 1) nursing, project management, and genetic counseling support 2) maintain a locked medical record room to which CGB investigators have access within 60 seconds—a mandatory qualification requirememt 3) support the development and conduct of chemoprevention trials conducted at the NIH Clinical Center 4) develop coordination and liaison at a local or international level with collaborating investigators or institutions 5) assist in the design and pilot testing of forms required for field investigations 6) project direction and hiring, training, and supervision of field personnel. The RFP is available at NCI Office of Acquisition Web site http://rcb.cancer.gov/rcb-internet/.

Inquiries: Karen McFarlane, 301-435-3782, km63k@nih.gov; Sharon Miller, 301-435-3783, sm103r@nih.gov.

RFA Available

RFA-06-008: Interdisciplinary Research Consortium. Application Receipt Date: Dec. 19.

The program would support interdisciplinary approaches to solving significant and complex biomedical problems, particularly those that have been resistant to traditional approaches. Interdisciplinary consortia are expected to identify an important biomedically relevant problem, evaluate why previous approaches have not worked, justify why the proposed interdisciplinary approach will work, identify the methods that will keep the interdisciplinary team focused and coordinated, and propose a timeline. The funding opportunity will use the U54, R01, R21, competitive supplements, T90/R90, K01, R25, and P30 award mechanisms. The RFA is available at http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3320.

Inquiries: Greg Farber farberg@mail.nih.gov; Michael F. Huerta mhuert1@mail.nih.gov.

Program Announcements

PA-06-121: PHS 2006-2 Omnibus Solicitation of the NIH for Small Business Technology Transfer Grant Applications

The funding opportunity will use the R41 and R42 award mechanisms. The PA is available at http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3323.

PA-06-122: Preapplication for Interdisciplinary Research Consortium

Letter of Intent Receipt Date: Mar. 21

Application Receipt Date: Apr. 18

As part of the NIH Roadmap, a program to support exploratory centers for interdisciplinary research was initiated in FY2004 and 21 planning awards were funded. This announcement is the beginning of the program for creating full interdisciplinary research consortia. Rather than limit participation in this second program to the funded exploratory centers, any research team will be allowed to apply for an interdisciplinary consortium. The application process has two parts: submitting a pre-application and then submitting the full interdisciplinary research consortium. The announcement details the first part of the process, submitting a pre-application of the full consortium application. The funding opportunity will use the X02 award mechanism. The PA is available at http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3324.

Inquiries: Greg Farber - farberg@mail.nih.gov; Michael Huerta mhuert1@mail.nih.gov.

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