THE CANCER LETTER

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A Letter On FDA Oncology Consolidation Reopens Debate Among Cancer Groups

By Paul Goldberg

For over a year, cancer advocacy groups and professional societies have been in agreement on what they wanted from FDA: consolidation of the agency's cancer programs into a single administrative unit run by oncology experts.

The question of goals has been settled since Feb. 24, 2003, when 19 groups that meet regularly as an informal policy forum called the Cancer Leadership Council sent a letter to the agency requesting the consolidation.

Moreover, as a consequence of the ImClone investigation, the House

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In Brief:

GM Foundation To Award Cancer Prizes To Kelly, Langer, Sherr, And Stillman

GENERAL MOTORS Cancer Research Foundation will honor four scientists next week for their seminal contributions to cancer research. The award recipients are **Thomas Kelly**, director, Sloan-Kettering Institute; **Robert Langer**, professor of chemical and biomedical engineering, Massachusetts Institute of Technology; **Charles Sherr**, Herrick Foundation Chair of Genetics and Tumor Cell Biology, St. Jude Children's Research Hospital; and **Bruce Stillman**, president and CEO, Cold Spring Harbor Laboratory. Kelly and Stillman will share the Alfred P. Sloan Jr. Prize for their major contributions to understanding of the biochemistry and regulation of DNA replication. Langer will receive the Charles F. Kettering Prize for pioneering the development of sustained-release drug delivery systems for the treatment of cancer. Sherr will receive the Charles S. Mott Prize for the discovery and characterization of key genes and proteins that control cell division and are frequently involved in the development of cancer. Langer and Sherr each will receive $250,000, while Kelly and Stillman will share the $250,000 prize. "Cancer research is crucial, because the effects of the disease are so far-reaching," said GMCRF Chairman **Harry Pearce**, a cancer survivor. "Over 10,600 GM employees, retirees, and their family members were treated for cancer in just the past year alone." The GMCRF Annual Scientific Conference will be held at NIH June 8-9, on "Genome Integrity and Cancer," and will include lectures by the award winners. GM will present the prizes at a ceremony at the U.S. Department of State in Washington, DC. . . . **NIH REAUTHORIZATION BILL** will be developed by the House Energy and Commerce Committee in time "to move in this committee

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FDA Asks Groups To Stop Letter-Writing, Invites Talks

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Committee on Energy and Commerce urged FDA to bring together its cancer programs, and agency officials promised to do just that.

In recent weeks, a Washington group called Friends of Cancer Research started circulating a letter that proposed an alternative, step-by-step approach. "We applaud the efforts already underway to improve the review of oncology products through programs like the NCI-FDA task force," said the letter dated May 28. The letter was circulated for signatures, but apparently hasn't been sent after triggering a rift among cancer groups.

In a disagreement over strategy, the American Society of Clinical Oncology prepared to submit a separate letter, and CLC prepared to circulate a document reaffirming its position. After learning about this flurry of writing, FDA officials asked the groups to hold off on mailing the letters and meet with the agency instead.

Though the letters have been stopped, the differences they uncovered are likely to affect the manner in which the cancer groups pursue change in FDA's handling of cancer applications. While the CLC letter laid out the goals of consolidation, the Friends letter suggested that the agency take a gradual approach.

"Even if some oncology products are not administratively consolidated into a dedicated oncology structure, comprehensive oversight authority that extends across centers and offices at FDA could better integrate the advancements in the molecular understanding of cancer that are dissolving the boundaries between preventatives, diagnostics, and therapeutics," the Friends letter said.

Sources said Ellen Sigal, chairman of Friends, urged that the letter be sent this week, apparently to coincide with an FDA announcement related to consolidation of its programs. Later, within three weeks, a rollout of the reorganization of the oncology divisions was going to take place, Sigal said on several occasions, sources said.

The timing of the Friends letter coincided with the ASCO annual meeting, where Friends is coordinating an inaugural meeting of a group called the "FDA Task Force."

Background materials circulated by Friends suggest that the effort was coordinated with FDA. "[We] understand that a substantive dialogue between the task force and the FDA would be welcome," wrote Alan Balch, director of policy and programs at Friends and son of ASCO Executive Vice President and CEO Charles Balch. "We have assurances that the specific individuals who sign on are going to be as important as the organizations they are representing."

In an interview, Sigal said to **The Cancer Letter** that she knew of no imminent announcements from the agency, and that she didn't know when the changes would take place. Sigal said FDA officials weren't involved in writing the letter or coordinating the Friends campaign. "There are a lot of falsehoods that are going on that are really, really, really, untrue, but the allegation that FDA helped us write the letter is just nonsense," she said. "It's just laughable. It's just absolutely, completely false."

Peter Pitts, FDA associate commissioner for external relations, said the agency had no changes to announce. "The rumors are untrue and unsubstantiated," said Pitts. "A lot of times these things take on their own momentum."

Separately, Pitts announced that he would be leaving the agency later this month.

Some of the signatures that appeared on the Friends letter had previously appeared on the CLC letter. Did these individuals—or their organizations—support vaguely specified, gradual change, as suggested by Friends, or more directed consolidation, as suggested by CLC?

Though ASCO declined to sign the Friends letter and drafted a separate document consistent with the CLC

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letter, several members of the ASCO leadership signed the Friends letter as individuals.

The task force includes three prominent members of ASCO leadership—President Margaret Tempero, President-elect David Johnson, and board member Richard Schilsky. It is unclear how the association would continue to work through Friends and CLC when the two groups are pursuing different strategies.

Several of those who signed the Friends letter said they never compared it with the CLC letter. "I looked at it and said, 'There is nothing offensive here,'" said one oncologist. "I didn't go over anything that was done previously." Another oncologist, who spoke on condition of not being identified by name, said that he agreed that a more accommodating strategy could produce better results. A third said he signed the letter largely because he believed that it was on the inside track at the agency.

"The goals expressed in the Friends letter are potentially of great benefit to oncology patients," Schilsky said to **The Cancer Letter**. "That's certainly why I signed on to it, and why I expect that much of the oncology community signed on to it. I think the only problem with it is that the specifics of how to accomplish the goal are not expressed in the letter, but that would be the subject for continuing discussion with the agency and the other stakeholders."

A Consensus?

"There is complete consensus on what everybody thinks needs to happen," Sigal said. "The only issue is how you get there, and whether you can have major change overnight, or whether it has to be incremental. But everybody wants the same thing. There is no difference at all. Clearly, everyone who knows anything about it feels there is an opportunity for change."

Sigal said she was willing to accept gradual change. "The only issues are going to be how quickly you get there, and how you get there, and timing, not to create disruption, and to do it right," she said. "It's really hard in a structure that's regulatory to make Draconian changes overnight."

Leadership of the cancer program is more important than its structure, Sigal said. "The biggest issue in my opinion is really the leadership," she said. "It's not exactly the structure. If you get the right leadership that's really, really trained and clinically driven in oncology, I think we'll get to where we need to get to."

Though FDA official Pitts contends that no announcement was imminent, it is apparent that the agency has been working on a consolidation of its oncology programs. The communications touched off by the Friends letter have yielded a description of the oncology unit FDA was apparently considering. The plan is likely to provide a benchmark for assessing proposals that may emerge later.

Sources said the agency planned to create an "oncology office" headed by an oncologist who would have the authority to sign off on cancer approvals. The oncologist would be appointed following a national search.

The office would have control over biologics, drugs and imaging technologies. In addition to processing applications, it would coordinate cancer-related activities at other FDA divisions and centers.

Though the head of the oncology office would have signatory authority, this official would report to an administrator on the office level at FDA. Several sources who were told about the plan said the oncologist running the office could end up being dependent on this administrator, which could render the signatory authority meaningless.

Currently, Robert Temple, director of the Office of Drug Evaluation I, has the signatory authority for new molecular entities in oncology at the FDA Center for Drugs Evaluation and Research. Temple is not an oncologist.

The CLC letter was the result of several years of discussions among advocacy groups, professional societies and FDA.

The Friends letter comes from a different milieu, a series of meetings that FDA and NCI have been holding regularly over the past year.

"The FDA-NCI task force started it," Sigal said to **The Cancer Letter**. "Without that, I don't think we could have gotten to where we are today. That opened the opportunity to make some changes. I think the fact that people are sitting around the table, even if you don't agree, you start to get some information, you start to get some consensus."

Letter-writing alone can't bring about change, Sigal said.

"Letters don't get anything done," she said. "Anybody who thinks that a letter gets something done is sadly informed. The FDA gets 1,000 letters a day. The way you get things done is by getting consensus in the community, and working with people. Letters don't get anything done. It's laughable to think that you are going to write a letter to FDA, and all of a sudden they are going to change."

As they sought to preempt letters, FDA officials assured ASCO and CLC that the agency has no firm

plans for change, and is open to hearing advice, sources said.

Ellen Stovall, president and CEO of the National Coalition for Cancer Survivorship and a founder of CLC, confirmed that she received a call from FDA. "We are delighted to learn that FDA is considering our letter of Feb. 24, 2003, as a basis for discussion about what this potential consolidation would look like," Stovall said to **The Cancer Letter.** "The groups involved with CLC have engaged the agency in discussion on this consolidation, and our ideas have been well received.

"In addition to developing consensus on consolidation, over the past three years, representatives from ASCO and CLC have had ongoing discussion with FDA officials and Congressional staff on this matter," Stovall said. "The CLC organizations are looking forward to working with FDA to assure that patients who need these drugs receive them in a timely manner, and with quality review by trained professionals who understand the complexity of cancer care today."

The organization of the FDA oncology programs attracted Congressional attention two years ago, as the House Committee of Energy and Commerce investigated the problems in development of the monoclonal antibody Erbitux by ImClone Systems Inc.

At the time, critics said that the agency's procedures for reviewing biologics differed from its procedures for reviewing drugs. Remedies suggested by lawmakers included formation of a single center that would review all oncology products.

In testimony and correspondence, agency officials at the time said that they planned to combine all cancer activities within CDER (**The Cancer Letter**, Oct. 18, 2002).

FDA has been taking incremental steps toward consolidation. Last fall, the agency's unit that reviewed Erbitux was moved from the Center for Biologics Evaluation and Research to CDER. The two cancer units ultimately report to John Jenkins, director of the Office of New Drugs.

Also last fall, the agency formed a third unit, which reviews gene, cell, and tissue therapies. That unit is part of CBER (**The Cancer Letter**, Oct. 10, 2003).

The Friends Letter

A copy of the Friends letter obtained by **The Cancer Letter** was dated May 28 and addressed to Lester Crawford, acting FDA Commissioner. Sigal said the letter was later modified, but declined to provide the updated version for publication. The text of the letter follows:

"I wish to join my fellow members of the cancer community in voicing support for an accelerated strategy of consolidation and coordination of the FDA's oncology activities that will facilitate the scientific evolution towards molecular diagnosis, preventative agents, and individualized treatment. Rapid scientific advancements in proteomics and tumor genomics, in addition to the increasing need to combine small molecule drugs with biologics for cancer therapy, call for the immediate integration of scientific expertise in these and other areas through an oncology program led by recognized cancer experts.

"We applaud the efforts already underway to improve the review of oncology products through programs like the NCI- FDA task force. It is in that same spirit of constructive collaboration that members of patient advocacy groups, professional societies, and the scientific community are speaking out on this important issue. It is our common hope that numerous stakeholders can work together toward a collective vision for a cancer program that will enhance the clinical development of safe and effective cancer products and facilitate their efficient delivery to the American public.

"Like our colleagues at the NIH, NCI, and the FDA, we believe that the unprecedented rate of scientific and technological discovery brings new hope for the prevention, treatment, and cure of serious illness such as cancer. From the 'Road Map' to the '2015 Initiative' to the 'Critical Path,' there is great consensus about the urgent need to develop more efficient and productive pathways for advancements in medical research and drug development. There also exists a mutual concern that the pace of translation from the laboratory bench to clinical trials and, ultimately, clinical practice remains too slow. We join the FDA in acknowledging that the 'current medical product development path is becomingly increasingly challenging, inefficient, and costly.'

"We must begin addressing these problems now because innovations in biomedical science are revolutionizing the approach to research on diagnostic, therapeutic and preventive agents applicable to cancer. Cancers defined by molecular profile rather than histology will be treated by targeted small molecules, proteins, vaccines, radiation, or, more likely, some combination of these (often along with conventional cytotoxics). The hundreds of innovative oncology products currently in the development pipeline will be critical to our nation's efforts to try and eliminate the suffering and death due to cancer in the near future. Unfortunately, the FDA's current fragmentation of oncology based on disease site or therapeutic class is not optimally suited for many of these cutting edge cancer products.

"It is our common belief that the FDA has a unique opportunity to help increase the efficiency, predictability, and consistency of the clinical development path for state of the art cancer research by working towards a cancer program with oversight and jurisdiction over oncology products (such as small molecules, biologics, cellular therapies, vaccines, hormonal agents, and supportive care products). Even if some oncology products are not administratively consolidated into

a dedicated oncology structure, comprehensive oversight authority that extends across centers and offices at FDA could better integrate the advancements in the molecular understanding of cancer that are dissolving the boundaries between preventatives, diagnostics, and therapeutics.

"Given the medical and scientific challenges, the leadership of a cancer program should consist of trained oncologists with broadly recognized credentials and credibility in cancer research, trial design, and patient care. The staff involved in the design and review process for a product with an oncology indication should possess a robust understanding of cancer as well.

"The combination of empowered leadership and a consolidated cancer program should be coupled with the jurisdiction necessary for the development of a more efficient capacity to review preventative agents, theranostics, and molecularly targeted therapies. In addition, a strong cancer program should better enable cancer experts to coordinate the broad expertise necessary across FDA to reach rigorous and timely conclusions regarding the clinical development and review of oncology products.

"Although these overarching principles are comprehensive and will require additional resources, we are pleased to provide the input and support necessary to start the process now. We want to work with you to help bring safe and effective cancer products to the patients who desperately need them in the most efficient manner possible."

According to an accompanying note from Friends official Alan Balch, the following individuals signed the letter at that time:

James Armitage, of the University of Nebraska Medical Center; Richard Atkins, of the National Prostate Cancer Coalition; Edward Benz, of Dana-Farber Cancer Institute; Steven Burakoff, of NYU Cancer Institute; Robert Comis, of the Coalition of National Cancer Cooperative Groups; William Dalton, of H. Lee Moffitt Cancer Center & Research Institute; Harmon Eyre, of the American Cancer Society; Margaret Foti, of the American Association for Cancer Research; William Hait, of AACR; Ronald Herberman, of the University of Pittsburgh Cancer Institute; Waun Ki Hong, of M.D. Anderson Cancer Center; David Johnson, of Vanderbilt-Ingram Cancer Center; Paula Kim, of the Pancreatic Cancer Action Network; H. Kim Lyerly, of Duke Comprehensive Cancer Center; Richard Schilsky, of the University of Chicago; Ellen Sigal, of Friends of Cancer Research; Barbara Duffy Stewart, of the Association of American Cancer Institutes; George Vande Woude, of AACR and Van Andel Cancer Research Institute; Jerome Yates, of ACS.

The CLC Letter

The CLC letter, dated Feb. 24, 2003, was addressed to then FDA Commissioner Mark McClellan. The text of the letter follows.

"As you know, the oncology community has an abiding interest in steps that might be taken to improve the process of reviewing new products for the prevention, diagnosis and treatment of cancer. We have had recent discussions with officials of the Food and Drug Administration that we believe may serve to advance that interest in a manner that not only enhances the efficiency of FDA but also measurably increases the likelihood that cancer patients can access potentially life-extending therapies at an earlier date.

"We have advocated the creation of an 'Oncology Center' at FDA, but, following our discussions with Dr. Janet Woodcock and her colleagues from the Center for Drug Evaluation and Research, we now appreciate that the term 'Center' has a special meaning within the FDA structure. Clearly, we do not intend to press changes in that structure that would be disruptive to the agency's overall mission.

"However, we do insist that review of products for cancer patients be exclusively in the hands of trained cancer specialists. To that end, we were encouraged to hear that a model for such consolidated review already exists at FDA for review of infectious disease products, which are uniformly reviewed in an 'Office' dedicated to that therapeutic area. We would be pleased to see the agency move in that direction for purposes of oncology product review, and, with the announced move of many biologics to CDER from the Center for Biologics Evaluation and Research (CBER), there would appear to be a sufficient critical mass of cancer-related products within CBER to justify a dedicated Office for those products.

"We urge that the agency initiate planning to achieve a smooth transition to an Office specifically assigned to the review and approval of all regulated products for people with cancer or at risk for cancer and led by trained cancer specialists. Among those products should be included drugs, biologics and devices (including diagnostic tests) currently reviewed by divisions other than the CDER Oncology Products Division if those products are indicated for cancer. This may eventually involve either coordination or shifting of resources among parts of FDA that historically have not been under the guidance of oncology experts. But, in the new era of molecular medicine and multidisciplinary approaches to cancer treatment, cancer-specific expertise is essential, and modern oncology principles should govern the review of a wide array of new products.

"Most immediately, we would like to express our view that the transfer of products from CBER to CDER should include cancer vaccine products. We understand and agree that traditional vaccines, designed primarily to prevent bacterial or viral infections, belong in CBER. Cancer vaccines, in contrast, are therapeutic rather than preventative and are designed to treat cancer through manipulation of the immune system. It does not appear that cancer vaccines are the same as traditional vaccines in their biology, their uses or the criteria that should be employed in their review and approval. The manner in

which cancer vaccines have been studied by investigators and ultimately by CBER has, from time to time, been a source of concern among both physicians and patient advocates, and we believe that review of these products would benefit from their transfer to a consolidated oncology review authority within CDER. While we appreciate that any transition must be orderly and mindful of resource needs, current planning should envision that cancer vaccines would be part of an oncology Office within CDER.

"We are pleased with our discussions with both CDER officials, ranging from CDER Director Woodcock to the current head of CDER's Oncology Products Division Dr. Richard Pazdur, and are confident that this much-needed consolidation of oncology review at FDA will succeed.

"Thank you again for your interest in our perspective about the role FDA plays in bringing safe and effective cancer agents and devices to market. We look forward to working with you and your staff to ensure that products for cancer patients and those at risk for cancer are in the hands of trained oncology experts."

The letter was signed by ASCO, Alliance for Lung Cancer, American Society for Therapeutic Radiology & Oncology, Cancer Care, Cancer Research and Prevention Foundation, Coalition of National Cancer Cooperative Groups, Colorectal Cancer Network, Kidney Cancer Association, the Leukemia & Lymphoma Society, Lymphoma Research Foundation, Multiple Myeloma Research Foundation, National Childhood Cancer Foundation, National Coalition for Cancer Survivorship, National Patient Advocate Foundation, National Prostate Cancer Coalition, North American Brain Tumor Coalition, Pancreatic Cancer Action Network, Us Too! International, and Y-ME National Breast Cancer Organization.

Annual Report to the Nation:
Age-Adjusted Cancer Deaths, Incidence, Decrease Slightly

By Kirsten Boyd Goldberg

The age-adjusted cancer incidence rate decreased by 0.5 percent per year from 1991 to 2001, but stabilized from 1995 through 2001, according to the annual report on U.S. cancer incidence and mortality, released June 3.

Age-adjusted death rates from all cancers combined fell 1.1 percent per year from 1993 to 2001, said the report by NCI, the Centers for Disease Control and Prevention, the American Cancer Society, and the North American Association of Central Cancer Registries.

Death rates decreased for 11 of the top 15 cancers in men, and eight of the top 15 cancers in women, the report said. This year's annual report contained a new section on cancer survival, concluding that five-year relative survival rates have improved overall, but the risk of dying from cancer is higher in most minority populations compared with whites.

Officials of the organizations that prepared the report said the data confirm that progress is being made against cancer. Officials also pointed to a leveling off of lung cancer deaths rates among women between 1995 and 2001 as evidence that smoking cessation efforts are working.

"This new report clearly shows we've made considerable gains in reducing the burden of cancer in the U.S.," ACS CEO John Seffrin said in a June 3 press release. "The first ever drop in lung cancer incidence rates in women is remarkable proof that we are making a difference in the number one cancer killer, and is powerful evidence that our successful efforts must continue."

"Cancer is a devastating disease that impacts so many people. But the good news is there is hope and these data show we are winning the battle as people with cancer are living longer and more healthier lives than ever before," CDC Director Julie Gerberding said in a statement. "But we can't become complacent. We must renew our efforts to make sure people make healthy choices to prevent cancer, that they are properly screened for cancer, and that they receive the appropriate treatment when they have cancer."

"These survival statistics are a reason for optimism, as they show us that we are on the right track to reaching the NCI Challenge Goal to eliminate the suffering and death due to cancer," NCI Director Andrew von Eschenbach said in a press release.

Previously, von Eschenbach set a target date to reach that goal: 2015. Assessments by other groups have found that date wildly optimistic. Cancer death rates would have to decline rapidly over the next 10 years to reach von Eschenbach's ambitious target. NCI has not proposed specifically how to measure progress against "suffering" due to cancer.

The annual report uses rates age-adjusted to the 2000 U.S. standard used by the Census Bureau. The actual number of cancer cases is increasing as the population grows and ages.

Worldwide, cancer cases are projected to increase from 10 million new cases in 2000 to 15 million in 2020, due to steadily aging populations and current trends in smoking prevalence, according to the World Cancer Report, published last year by the International Agency for Research on Cancer (**The Cancer Letter**, April 18,

2003, Vol. 29 No. 16).

"The actual numbers in general are going up in the U.S. as well," Brenda Edwards, associate director for the NCI Surveillance Research Program, said to **The Cancer Letter**. "But adjusted for growth in population and age, that's where we are seeing a decline over time in death rates. For incidence rates, that is variable, because incidence is subject to screening.

"What we are saying in this report is that overall, it looks as if there is a decline in incidence, but that is a simple summary," Edwards said. "If we adjust the rates for the fact that we know some cases [are reported] late, it looks as if the incidence rate is stable. It's stable for men, but increasing for women. Then, if you look at different cancer sites, you see that some are coming down, while some are going up."

Previous annual reports included data on only the top four cancer sites, while the new report provides data on the top 15 cancers.

"The continued measurable declines for overall cancer death rates and for many of the top 15 cancers, along with improved survival rates, reflect progress in the prevention, early detection, and treatment of cancer," the report concluded. "However, racial and ethnic disparities in survival and the risk of death from cancer, and geographic variation in stage distributions suggest that not all segments of the U.S. population have benefited equally from such advances."

Following are highlights of the report:

--Among men, cancer incidence rates have recently declined for seven of the top 15 cancer sites: lung, colon, oral cavity, leukemia, stomach, pancreas, and larynx. Incidence rates increased only for melanoma and cancers of the prostate, kidney, and esophagus.

--In addition to the decrease in lung cancer, incidence rates decreased for five other cancers out of the top 15 in women: colon, cervix, pancreas, ovary, and oral cavity. Breast, thyroid, bladder, and kidney cancer and melanoma rates are rising among women.

--This year's report highlights trends in cancer survival by comparing five-year survival rates of cancer patients diagnosed in two time periods: 1975-1979 and 1995-2000. Between those time periods, survival substantially improved for most of the top 15 cancers in both men and women, and the top 10 sites in children.

--For men, large gains in cancer survival rates (more than 10 percent) were seen in cancers of the prostate, colon and kidney, and non-Hodgkin lymphoma, melanoma, and leukemia. Modest gains (5 percent to 10 percent) were found for cancers of the bladder, stomach, liver, brain, and esophagus.

--For women, large gains in cancer survival rates were seen for colon, kidney, and breast cancers and non-Hodgkin lymphoma. Modest gains were found for bladder, oral cavity, stomach, brain, esophageal, and ovarian cancers and melanoma and leukemia.

--Limited survival improvement was noted for the most fatal forms of cancer in adults including cancers of the lung, pancreas, and liver, which are characterized by late stage at diagnosis and relatively poor survival rates even when these cancers are diagnosed at a localized stage. There was also little or no gain in several cancers that already have high survival rates, including larynx, thyroid, and uterine cancers.

--Childhood cancers showed some of the largest improvements in cancer survival during the past 20 years, with an absolute survival rate increase of 20 percent in boys and 13 percent in girls. The current five-year survival rate of over 75 percent confirms substantial progress made since the early 1960s, when childhood cancers were nearly always fatal.

--The report identifies wide variations in survival associated with race and ethnicity. In every racial and ethnic population, with the exception of Asian/Pacific Islander women, the risk of cancer death from all cancer sites combined was higher than the risk of death for non-Hispanic white patients. Black men were at higher risk of dying of 12 cancers compared to white men, with the increased risk ranging from 9 percent (lung cancer) to a high of 67 percent (oral cavity). Black women experienced higher risks of death from 12 cancers, with the increase ranging from 7 percent (lung cancer) to 82 percent (corpus uterus and melanoma). Non-Hispanic white and Asian/Pacific Islander patients tended to have higher survival rates than other racial and ethnic groups except for patients with brain cancer and leukemia.

The "Annual Report to the Nation on the Status of Cancer 1975-2001, with a Special Feature on Survival," was published June 3 in Cancer: http://interscience.wiley.com/cancer/report2004. Further information also is available www.seer.cancer.gov.

Capitol Hill:

Bill Would Give FDA Authority To Oversee Tobacco Industry

House and Senate members last week introduced a bill that would give FDA the authority to oversee the tobacco industry.

The bill, called the Family Smoking Prevention and Tobacco Control Act, is supported by the unlikely mix of public health groups and Philip Morris USA.

The House bill--H.R.4433--was introduced by Government Reform Committee Chairman Tom Davis (R-Va.) ranking member, Henry Waxman (D-Ca.) The Senate bill--S.2461--was introduced by Mike DeWine (R-Ohio) and Edward Kennedy (D-Mass.).

"This bill will help keep our children away from tobacco products and protect them from being targeted by the tobacco industry," said Davis. "It also seeks to help adult smokers by empowering FDA to develop programs to help them quit, regulate the way that manufacturers talk about their products, and work on ways to reduce the toxicity of tobacco products so that they ultimately will cause less and less disease over time."

The bill allows FDA to remove harmful substances from tobacco products, whether or not they are already on the market. The marketing and access restrictions found in the 1996 FDA regulation are to be issued as an interim final rule. These restrictions will go into effect shortly after enactment of the bill, and will be subject to federal enforcement.

The bill would permit the FDA to prohibit the use of descriptors, such as "light" and "ultralight," and it contains provisions designed to reduce the trade in counterfeit and other illicit tobacco products.

Davis said that ultimately the legislation should be combined with a tobacco quota buyout. "Tobacco growers in Virginia have waited far too long for relief from a Depression-era anachronism that has placed them in dire financial straits," Davis said. "The government created quota system needs to be bought out and eliminated."

In a joint statement, the American Cancer Society, American Heart Association, American Lung Association and Campaign for Tobacco-Free Kids said they supported the legislation:

"We urge both the Senate and the House to quickly enact this legislation into law and to resist all efforts to weaken it.

"This legislation meets the standards long established by the public health community for a strong FDA tobacco regulation bill that protects the public health. It would give the FDA the necessary tools and resources to effectively regulate the manufacturing, marketing, labeling, distribution and sale of tobacco products. The FDA would have the authority to:

--"Restrict advertising and promotions that appeal to children.

--"Stop illegal sales of tobacco products to children.

--"Require changes in tobacco products, such as the reduction or elimination of harmful chemicals, to make them less harmful or less addictive.

--"Prohibit unsubstantiated health claims about so-called 'reduced risk' tobacco products that would have the effect of discouraging current tobacco users from quitting or encouraging new users to start.

--"Require the disclosure of the contents of tobacco products and tobacco industry research about the health effects of their products.

--"Require larger and more informative health warnings on tobacco products.

"While this legislation represents an important step forward, we remain concerned that opponents of effective FDA tobacco regulation will seek to weaken or kill the bill at every opportunity. The public health community has already made significant compromises to achieve bipartisan FDA legislation that both protects the public health and can pass in this Congress.

"For example, while protecting the FDA's authority to require changes to reduce the harm caused by tobacco products, this legislation reserves to Congress the authority to ban a whole class of tobacco products, such as cigarettes or smokeless tobacco products, or to reduce nicotine levels to zero. This bill represents the bottom line of the public health community and any weakening would lose our support. Our organizations are committed to doing everything we can to pass this strong FDA legislation that protects the public health, but we are equally committed to defeating any weak legislation that falls short of this goal."

Surgeon General:
Report Links Smoking To More Cancers, Other Diseases

Smoking causes disease in nearly every organ of the body, according to a new report by the U.S. Surgeon General, Richard Carmona.

The new report, published 40 years after the surgeon general's first report on smoking, finds that cigarette smoking is conclusively linked to leukemia, cataracts, pneumonia, and cancers of the cervix, kidney, pancreas, and stomach.

"We've known for decades that smoking is bad for your health, but this

report shows that it's even worse," Carmona said in a statement last week. "The toxins from cigarette smoke go everywhere the blood flows. I'm hoping this new information will help motivate people to quit smoking and convince young people not to start in the first place."

According to the report, smoking kills an estimated 440,000 Americans each year. On average, men who smoke cut their lives short by 13.2 years, and female smokers lose 14.5 years. The economic toll exceeds $157 billion each year in the U.S.--$75 billion in direct medical costs and $82 billion in lost productivity.

"We need to cut smoking in this country and around the world," HHS Secretary Tommy Thompson said. "Smoking is the leading preventable cause of death and disease, costing us too many lives, too many dollars and too many tears. If we are going to be serious about improving health and preventing disease we must continue to drive down tobacco use. And we must prevent our youth from taking up this dangerous habit."

In 1964, the Surgeon General's report announced medical research showing that smoking was a definite cause of cancers of the lung and larynx in men and chronic bronchitis in both men and women. Later reports concluded that smoking causes a number of other diseases such as cancers of the bladder, esophagus, mouth and throat; cardiovascular diseases; and reproductive effects.

The new report expands the list of illness and conditions linked to smoking to include cataracts, pneumonia, acute myeloid leukemia, abdominal aortic aneurysm, stomach cancer, pancreatic cancer, cervical cancer, kidney cancer, and periodontitis.

The report concludes that smoking reduces the overall health of smokers, contributing to such conditions as hip fractures, complications from diabetes, increased wound infections following surgery, and a wide range of reproductive complications.

Another major conclusion, consistent with recent findings of other scientific studies, is that smoking so-called low-tar or low-nicotine cigarettes does not offer a heath benefit over smoking regular cigarettes.

"There is no safe cigarette, whether it is called 'light,' 'ultra-light,' or any other name," Carmona said. "The science is clear: the only way to avoid the health hazards of smoking is to quit completely or to never start smoking."

The report found that for a number of diseases and conditions associated with smoking, the evidence is not yet conclusive to establish a causal link. For these illnesses, which include colorectal cancer, liver cancer, prostate cancer, and erectile dysfunction in men, additional studies are needed to reach the threshold of evidence required by the Surgeon General's causal criteria to declare that they are causally related to smoking. These criteria were introduced in the 1964 report and have been updated in the 2004 report using new uniform standards.

For breast cancer, the evidence suggests that there is no causal relationship overall to smoking. However, the report notes that on a genetic basis, some women may be at increased risk if they smoke. More research is required to clarify the role of smoking in the cause and progression of breast cancer.

The 960-page printed report, "The Health Consequences of Smoking," is available at www.surgeongeneral.gov.

Professional Societies:

ASCO To Honor Clinicians For Participation In Trials

American Society of Clinical Oncology will honor 10 community oncologist practices June 5 for their commitment to cancer research through the incorporation of clinical trials into their practices. The Clinical Trials Participation Awards will be presented during the ASCO annual meeting in New Orleans.

"This award was established last year to build awareness in the practice community about the value of increased trials participation," said ASCO President Margaret Tempero. "ASCO hopes that the Clinical Trials Participation Award Program will encourage community practices to participate in clinical trials and to increase their accrual efforts."

The recipients were selected by the NCI cooperative groups and the ASCO Clinical Practice Committee, which identified those practices that enrolled the highest number of patients to phase III trials over a three-year period. This year, the cooperative groups nominated practices from among its Community Clinical Oncology Program affiliates. The awards are supported by a grant from the Coalition of National Cancer Cooperative Groups and provides travel grants to attend the annual meeting. The honorees include:

Pediatric Hematology-Oncology Associates, All Children's Hospital, St. Petersburg, Fla., Jerry Barbosa. Nominated by Children's Oncology Group.

Helen F. Graham Cancer Center, Newark, Del., Michael Deeda. Nominated by Radiation Therapy Oncology Group.

Metro-Minnesota Community Clinical Oncology Program, Minneapolis, Patrick Flynn. Nominated by Eastern Cooperative Oncology Group.

Missouri Valley Cancer Consortium CCOP, Omaha, Neb., James Mailliard. Nominated by North Central Cancer Treatment Group.

Southeast Cancer Control Consortium Inc. CCOP, Winston Salem, NC, Larry Wickerham on behalf of James Atkins. Nominated by National Surgical Adjuvant Breast and Bowel Project.

St. Elizabeth's Hospital Radiology Department, Youngstown, Ohio, Richard Barr. Nominated by American College of Radiology Imaging Network.

St. Thomas Hospital, Nashville, Tenn., John Nesbitt. Nominated by American College of Surgeons Oncology Group.

Tyler Cancer Center, Tyler, Tex., Donald Richards. Nominated by ASCO Clinical Practice Committee.

Upstate Carolina Community Clinical Oncology Program, Spartanburg, SC, James Bearden III. Nominated by Southwest Oncology Group.

Virginia Oncology Associates, Norfolk, Va., Paul Conkling. Nominated by Cancer and Leukemia Group B.

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ASCO said it is forming a Government Relations Council to enhance the society's public policy activities. The council will serve as the society's primary resource for coordinating issue advocacy in Congress and the Administration. **Joseph Bailes** will serve as co-chairman, with the ASCO president. Members will be selected who have special knowledge or skill in political action and advocacy or who have strategic relationships with national policymakers, the society said.

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AMERICAN SOCIETY for Therapeutic Radiology and Oncology announced its 2004 Gold Medal winners. **Eli Glatstein**, **Luka Milas**, and **Paul Wallner** will receive their awards Oct. 4, during the annual meeting of the society in Atlanta, said **Joel Tepper**, chairman of ASTRO.

Glatstein, professor and vice chairman in the Department of Radiation Oncology at the University of Pennsylvania Medical Center in Philadelphia, is known for his work on improving how physicians stage cancer, particularly Hodgkin's disease. As chief of the NCI Radiation Oncology Branch in the early 1970s, he combined radiation oncology with medical oncology, thereby changing the standing of radiation oncology in the cancer community. Milas, an experimental radiation oncologist, professor of experimental radiation oncology, deputy head for translational research in the Division of Radiation Oncology at M.D. Anderson Cancer Center, holds the United Energy Resources Inc. endowed professorship in cancer research. He is recognized for his work in the basic biology of tumors and clinical applications. Wallner, chief of the NCI Clinical Radiation Oncology Branch, is known for his service in the sociopolitical and economic arenas, forging relationships with policymakers in the private sector and government.

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ONCOLOGY NURSING SOCIETY has announced its nominating committee. New members are **Catherine Glennon,** health center administrator of oncology services at Duke University Medical Center, and **Susan Sturgeon-Walker**, vice president of professional development at Indiana Community Cancer Care Inc. in Indianapolis**. Liesel Wabnig**, of New Orleans, is chairman. Other members include: **Mary Roll**, of Cheektowaga, NY; **Mary Gullatte**, of Marietta, GA; **Linda Krebs** of Lakewood, CO; and **Judy Lundgren**, of Fort Worth.

In The Cancer Centers:

UC Davis Wins $1.1 Million For Prostate Cancer Research

Two molecular geneticists at the UC Davis Cancer Center won $1.1 million to turn biodefense technology into potential methods of prostate cancer treatment and diagnosis. The grants were awarded by the U.S. Department of Defense Prostate Cancer Research Program.

Paul Gumerlock, professor of hematology/oncology, received a three-year, $557,000 grant to test a new gene-silencing method, developed last summer at Lawrence Livermore National Laboratory. Gumerlock will use the new method to silence certain DNA repair genes in prostate cancer cells to make the cancer cells more vulnerable to radiation therapy.

Philip Mack, a research geneticist, received a three-year, $334,000 grant to test the same gene-silencing method, known as siHybrid technology, against certain mutations of the p53 tumor suppressor gene. Mack will test whether silencing the mutations can help to prevent androgen independence, a poorly understood process that renders prostate cancer untreatable.

Gumerlock also received a second, 18-month grant for $111,000 to exploit two other biodefense technologies from Lawrence Livermore. One is a method of affixing cell-free DNA fragments to chips of glass, so the fragile fragments can be examined without being damaged. The other is a technique, in situ rolling circle amplification, which allows minute DNA fragments to be detected in the bloodstream with much greater sensitivity than previous methods. Gumerlock intends to develop a blood test that can detect methylated, or deactivated, gene sequences common in prostate cancers.

The Lawrence Livermore technologies were developed by Allen Christian for use in combating bioterrorist attacks.

UC Davis Cancer Center and Lawrence Livermore National Laboratory forged a formal cancer research partnership in November 2000.

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FOX CHASE CANCER CENTER and **Geisinger Health System** of Danville, Pa., are exploring a partnership for comprehensive, state-of-the-art cancer services and programs at the Frank M. and Dorothea Henry Cancer Center at Geisinger Wyoming Valley Medical Center near Wilkes-Barre, Pa..

Each member of the partnership would retain its independent status. The organizations are recruiting a medical director for the venture.

The partnership would build on a relationship formed in 2001 between Fox Chase and Geisinger Cancer Institute to expand cancer research programs and make more clinical trials available to Geisinger patients, said **Robert Young**, president of Fox Chase.

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CENTER FOR ADVANCED Diagnostic Imaging is in the planning stages as a collaboration among M.D. Anderson Cancer Center, UT Health Science Center at Houston, UT System, Texas Enterprise Fund, and GE Healthcare.

The groups have committed $55 million for a research incubator to develop technologies that detect heart disease, cancer, and other illnesses at early stages. The project would be located at the UT Research Park.

The Texas Enterprise Fund committed $25 million to the project. M. D. Anderson and the UT Health Science Center at Houston provided $25 million together. UT System committed $5 million and GE Healthcare is providing equipment, technology, and expertise. M. D. Anderson and the UT Health Science Center will raise additional funds as needed in the coming months, the groups said.

Juri Gelovani, chairman of the Department of Experimental Diagnostic Imaging at M. D. Anderson, is director of the Center for Advanced Diagnostic Imaging.

Gelovani and **Bruce Butler**, director of the Office of Technology Development of the UT Health Science Center, will coordinate the research activities in collaboration with the GE Healthcare team, said **John Mendelsohn,** president of M. D. Anderson Cancer Center. The groundbreaking will take place later this year.

President's Cancer Panel:
Report Urges Greater Coverage For Cancer-Related Services

The federal government should implement comprehensive health care reform that includes coverage for psychosocial services during and after cancer treatment, and other provisions for cancer patients and survivors, the President's Cancer Panel said in a June 4 report.

The report, "Living Beyond Cancer: Finding a New Balance," is based on the panels' series of meetings over the past year taking testimony from nearly 200 cancer survivors, caregivers, health care providers, and insurers. The panel also released a supplemental report on survivorship in Europe.

The report examines the late effects of cancer treatment both across the life span and among four age groups: children ages 15 and younger; adolescents and young adults ages 16 to 29; adults ages 30 to 59; and older adults ages 60 and above.

"Our ability to detect cancers early and treat them successfully has improved dramatically over the past 30 years," said LaSalle Leffall Jr., panel chairman. "Today there are nearly 10 million Americans who are cancer survivors. Now we're recognizing that their challenges often continue long after their treatment concludes, and some of these challenges vary depending on the survivor's age at diagnosis."

The panel concluded that as a patient ends treatment, the healthcare provider should give the patient a detailed record of his or her disease and treatment. This could be helpful in later years if the patient has a recurrence, residual effects, or other illness related to the cancer treatment. Also, the patient should receive a plan for follow-up care that includes a schedule of periodic cancer screenings and examinations for known late effects of the therapy.

The Panel noted that as America's "baby boomers" reach their 60s, the age when cancer occurs most frequently, there will be a significant increase in the number of older people with cancer, making their treatment, follow-up care, and support needs of increasing importance.

The President's Cancer Panel, established by the National Cancer Act of 1971, consists of three presidential appointees. Besides Leffall, they are Lance Armstrong, of the Lance Armstrong Foundation, and Margaret Kripke, chief academic officer of the University of Texas M.D. Anderson Cancer Center.

The report is available at http://pcp.cancer.gov.

Funding Opportunities:

Program Announcement

PA Exfoliated Cells, Bioactive Food Components and Cancer Prevention

NCI invites applications for R01, R21, and R03 applications to evaluate exfoliated cells for dietary exposures to bioactive food components in cancer prevention. The objectives are to evaluate the ability of exfoliated cells to reflect absorption and retention of bioactive food components and genomic and epigenetic events that occur in intact cells following exposure to a bioactive food component. Interdisciplinary collaborations are encouraged.

Although serum and blood cells have been used to evaluate exposure and physiological response to bioactive food components, they may not always predict responses in target tissues. Surrogate samples, such as exfoliated cells may offer a noninvasive opportunity to evaluate not only exposure but also physiological response in target tissues. Evidence already exists that exfoliated colonocytes may provide information for evaluating the physiological effects of some food components. The hypothesis of this concept is that the analysis of biomarkers in exfoliated cells is preferable to the analysis of serum or blood cells and thus may represent an underutilized approach to evaluate the effect of bioactive food components in target tissues. The PA is available at http://deainfo.nci.nih.gov/concepts/exfoliatedcells_PA.htm.

Inquiries: Cindy Davis, NCI Division of Cancer Prevention, phone 301-594-9692; fax 301-480-3925; e-mail davisci@mail.nih.gov

In Brief:

Barton Seeks Change To NIH In Reauthorization Legislation

(Continued from page 1)

in this Congress," Chairman **Joe Barton** (R-Tex.), said at a hearing June 2. The bill is likely to contain some changes for NIH, Barton said. NIH funding was doubled to about $27 billion in 2004, but NIH Director **Elias Zerhouni** has little control over the 27 individual institutes, Barton said. "We are not just going to turn a blind eye and say business as usual is OK, because the dollars are too big and the consequences are too big," Barton said at a subcommittee hearing attended by Zerhouni. "Quite frankly, the assets at the disposal of NIH are significant. If we can channel them in a more comprehensive and coordinated fashion, we're going to do great deeds in the years ahead." . . . **JOSEPH TOMASZEWSKI** was appointed acting associate director for the Developmental Therapeutics Program in the NCI Division of Cancer Treatment and Diagnosis. He has been chief of the DTP Toxicology and Pharmacology Branch for the past 13 years, where he oversaw preclinical testing of more than 130 clinical candidates, leading to 77 new drug applications and four FDA approved drugs. He succeeds **Edward Sausville**, now of the Greenebaum Cancer Center, University of Maryland. . . . **ANNA DIEHL**, professor of medicine at Johns Hopkins University, was named chief of the Division of Gastroenterology at Duke University Medical Center. Diehl also directs the Duke Liver Center. She succeeds **Rodger Liddle**, who continues as professor of medicine in the Division of Gastroenterology and clinician at Veterans Affairs Medical Center. . . . **DAVID SCHULLER**, executive director of Ohio State University Arthur G. James Cancer Hospital and Richard J. Solove Research Institute and deputy director of the OSU Comprehensive Cancer Center, was named the first John W. Wolfe Chair in Cancer Research. . . . **DAVID WARD,** member of the National Academy of Sciences, was named deputy director of the Nevada Cancer Institute. He will coordinate scientific investigation efforts in basic research and population science. Ward was a member of the Yale faculty for more than 30 years, most recently as a professor in the Department of Genetics, Molecular Biophysics and Biochemistry. . . . **CHRISTOPHER AMOS**, professor in the Department of Epidemiology at M.D. Anderson Cancer Center, was awarded the Leadership Award from the International Genetics Epidemiology Society for his research and for his service as past president of the society. Amos holds an Ashbel Smith Professorship from The University of Texas Board of Regents. . . . **MARY HENDRIX** has joined the Robert H. Lurie Comprehensive Cancer Center of Northwestern University as president and scientific director of Children's Memorial research institute and professor of pediatrics at the Northwestern University Feinberg School of Medicine, said **Steven Rosen**, director of RHLCCC. She was head of the Department of Anatomy and Cell Biology at the University of Iowa, where she was also deputy director of the Holden Comprehensive Cancer Center in the medical school. . . . **SCOTT GOLDSTEIN**, assistant professor of surgery at Jefferson Medical College of Thomas Jefferson University, was named director of colon and rectal surgery in the Department of Surgery at Thomas Jefferson University Hospital. Goldstein, who has been at Jefferson for a decade, had served as director of colon and rectal surgery at Pennsylvania Hospital. . . . **CORRECTION:** In the May 28 issue of **The Cancer Letter**, in a story on American Society of Clinical Oncology award winners, Robert Young was inaccurately credited with developing the paclitaxel+carboplatin regimen for ovarian cancer. He was instrumental in its development.

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