THE CANCER LETTER

Vol. 33 No. 38
Oct. 19, 2007

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

FDA Says Medicare Policy On ESAs "Consistent With The Available Data"

By Paul Goldberg

Plunging into the Congressional debate over proper use of erythropoiesis-stimulating agents in oncology, FDA officials said that the controversial new Medicare policy restricting coverage of these drugs is "generally consistent with the available data and the published scientific literature."

Responding in writing to questions from Reps. Pete Stark (D-Calif) and Henry Waxman (D-Calif.), the agency said that the CMS decision is also consistent with the current label. The FDA statement, dated Oct. 12, was released by the two House members on Oct. 16. Though signed by Stephen Mason, assistant commissioner for legislation, it was likely written with substantial collaboration from oncology officials.

FDA's statements illustrate the deep division over coverage for ESAs

(Continued to page 2)

Medicare:

CMS Abandons Proposal To Require Further Certification Of Clinical Trials For Coverage

By Paul Goldberg

The Centers for Medicare and Medicaid Services earlier this week abandoned its proposal for coverage of routine medical costs provided to patients enrolled in clinical trials.

In a departure from existing policy that deemed all trials sponsored by government agencies or reviewed by FDA to be eligible for coverage, the agency sought to require clinical investigators to certify that their trials were consistent with 13 criteria, which in the agency's estimation defined worthwhile trials (The Cancer Letter, Oct. 12).

The plan ran into opposition on Capitol Hill and was likely to trigger a legislative effort to vacate the coverage decision had it become final. The agency is facing similar resistance to its coverage decision on erythropoiesis-stimulating agents.

On Oct. 17, CMS announced that "after careful consideration" it decided that "no change… is appropriate at this time." In the decision memorandum, the agency said that greater monitoring of clinical trials is unnecessary, because recently passed FDA legislation "establishes significant requirements for clinical trials and additional authority for other agencies in the Department of Health and Human Services.

"CMS is continuing to review this new legislation and will work with

(Continued to page 4)

FDA Misinterprets ESA Label, ASCO Says In Statement

(Continued from page 1)

both in the oncology circles and on Capitol Hill. By supporting the Medicare policy, FDA places itself squarely in opposition to the American Society of Clinical Oncology, which is playing an increasingly significant role in the controversy.

Immediately after the FDA statement was released, ASCO issued a statement of its own, claiming that the regulatory agency is misinterpreting the label. FDA is in the process of revising the ESA label, and a recently passed law has enhanced its authority to respond to safety signals (The Cancer Letter, Sept. 21).

The FDA-CMS united front exposes the House and Senate leadership's disagreement on ESAs. In the House, the two agencies drew praise from Stark, chairman of the Subcommittee on Health of the House Ways and Means Committee, and Waxman, chairman of the House Committee on Oversight and Government Reform.

In the Senate, Max Baucus (D-Mont.), chairman of the Finance Committee, is a supporter and a likely sponsor of legislation that would seek to vacate the CMS action. The bill would likely be cosponsored by Sen. Mike Crapo (R-Idaho). In the House, Anna Eshoo (D-Calif.) and Mike Rogers (R-Mich.) introduced a similar bill (H.J. Res. 54) on Sept. 27.

"Facts are stubborn things," said Stark in a statement issued jointly with Waxman on Oct. 16. "The FDA letter confirms what Amgen and Johnson & Johnson are spending millions of dollars to deny. Medicare's new National Coverage Determination is consistent with the FDA's recommendations and scientific research. Excessive use of ESAs increases the risk of tumor progression in cancer patients. Medicare's action will prevent excessive use and protect patients' lives."

"Clearly the FDA letter confirms that the Medicare coverage decision is appropriately based on science," Waxman said in the press release.

In their letter to Stark and Waxman, FDA officials acknowledge that the safety signals on ESAs have been detected in off-label studies with high hemoglobin targets. However, "the risks of tumor promotion and shortened survival have not been excluded with lower target hemoglobin levels," the agency said.

According to FDA, the ESA label has caused confusion among doctors. "The current labeling advises that the hemoglobin not exceed 12 g/dL in cancer patients," the letter said. "FDA considers this to be an upper safety limit for ESA dosing, not a target for therapy. FDA is aware that there has been some confusion about the dosing recommendations in the current approved labeling and will work to clarify that confusion as we complete labeling changes that we are currently discussing with Amgen in follow-up to the May 2007 Oncologic Drugs Advisory Committee meeting."

ESAs have been approved as an alternative to blood transfusion and should be used in a similar manner, the agency said. According to the letter, "FDA's approved labeling recommends use of the lowest dose necessary to avoid the need for blood transfusions, and transfusions are not normally given to patients whose hemoglobin is 10 g/dL or higher."

Stark's and Waxman's letter to FDA is posted at http://www.house.gov/stark/news/110th/letters/20071002-waxman.pdf. The FDA response is posted at http://www.house.gov/stark/news/110th/letters/20071012-esa.pdf.

Under the new coverage decision, oncologists would have to wait till a patient's hemoglobin drops below 10 g/dL, and would not be allowed to use the drug until hemoglobin once again falls below that level. Critics, including ASCO, American Society of Hematology and US Oncology propose keeping hemoglobin between 10 and 12 g/dL following the first administration.

Last month, CMS declined the requests by ASCO to reconsider the coverage decision. The agency

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Subscriptions/Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
General Information/FAQ: www.cancerletter.com

Subscription $365 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.
Founded Dec. 21, 1973, by Jerry D. Boyd.

challenged critics to point to evidence demonstrating that cancer patients undergoing chemotherapy require hemoglobin levels of above 10 g/dL (The Cancer Letter, Sept. 28).

Since ESAs were approved based on their ability to reduce the risk of blood transfusions, their effects on survival and disease progression haven't been studied at labeled hemoglobin levels. Also, the relationship between the dose and response hasn't been rigorously studied.

Industry sources estimate that the CMS coverage decision would lower the use of ESAs by about two-thirds among Medicare patients.

ASCO Disagrees With FDA Interpretation

Responding to the FDA letter, ASCO disputed the agency's interpretation of the label.

"If CMS or FDA has access to data or information which is not publicly available, which raises serious safety concerns, or which supports the positions taken in its coverage decision, ASCO strongly urges immediate and specific release to assure the safety and quality of care for our patients," the professional society said in its response to FDA's letter to Stark and Waxman.

The statement presumably is based on the updated guidelines by ASCO and ASH, which are expected to be published Oct. 22 in the ASCO Journal of Clinical Oncology and the ASH journal Blood.

In a critique of the FDA position, ASCO claims the following inconsistencies between the CMS and FDA position and the label:

—"Of the trials which raised recent safety concerns, all were designed to either administer ESAs above a hemoglobin of 12 g/dL, or involved patients not receiving chemotherapy. Neither use is recommended by national guidelines, and neither use is included in the FDA-approved label.

"While these trials are very important in demonstrating that ESAs pose a significant safety risk when given above 12 g/dL, they do not support the CMS policy. The ASCO-ASH guideline already advises limiting administration of ESAs over 12 g/dL. This limitation is supported by most clinical studies and the FDA-approved label.

—"No studies conducted to date with ESAs have been designed to examine the safety and efficacy of maintaining hemoglobin levels below 10 g/dL, the level that CMS chose to restrict coverage. A hemoglobin of 10 g/dL is arbitrary and not supported by evidence. It is important to note that while CMS policy included a lengthy bibliography, it did not cite specific scientific studies to support the limitation of ESA administration at 10 g/dL.

—"There are a number of clinical circumstances in which the CMS restrictions are clearly at odds with the FDA-approved label. Given similar clinical circumstances, the FDA label and ASCO/ASH guideline would result in consistent clinical decisions about the use of ESAs. The CMS policy would not."

Advocacy Groups Cite Conflicts

Congressional efforts to vacate the CMS decision met with criticism from several patient and consumer groups.

In a letter to Stark and Waxman, the National Breast Cancer Coalition said that the "many individual physicians and physician organizations" who oppose the coverage decision have an economic stake in continued widespread use of these products.

"We ask that you consider the significant financial incentives that these physicians have to prescribe ESAs and the potential conflicts of interest these incentives might cause," NBCC President Fran Visco wrote in a letter dated Oct. 17. "NBCC believes that the FDA and CMS made their decisions regarding ESAs based on science and with the best interests of the patients in mind."

Public confidence in the regulatory process would be undermined if Congress yields to these financial interests and vacates the decision, Visco argued. "Patients and the broader public must be able to trust that scientists, doctors, FDA regulators, and CMS decisionmakers are looking after the public's best interests as they evaluate the benefits and harms of the drugs, tests and all interventions that become available to fight cancer," she wrote. "Consumers must be able to trust that decisions made by regulators are based on science and not politics or physician financial self-interest."

Visco noted that the quality of data on ESAs has been poor. "It is disconcerting that fourteen years after their approval as a supportive therapy in cancer, the risks of ESAs at the approved dose and schedule have not been characterized for cancer patients," she wrote. "It is unacceptable that primary data from studies has not been submitted to FDA or even to the manufacturers in some cases. We are also concerned about the persistent flaws in study design, which severely limit our ability to draw meaningful conclusions about the effects of ESAs on patient survival and tumor effects at the approved dose. Unfortunately, we know much more about the effects of ESAs at unapproved doses than at approved doses."

Also, Center for Medical Consumers, Center for Science in the Public Interest, Consumers Union, National Research Center for Women & Families, National Women's Health Network, TMJ Association, and US PIRG sent a joint letter urging legislators "not to interfere in the efforts of [CMS and FDA] to use the best available science to determine the proper dosing of erythropoietin stimulating agents.

"While it is true that [ASCO], which represents the nation's cancer physicians, protested the CMS decision, we cannot help but note that companies and physicians make enormous windfall profits from the sale and use of ESAs," states the letter dated Oct. 17. "Now they are trying to convince Congress that Medicare is denying a needed medical service."

Congressional efforts to set coverage for medical products "would set a terrible precedent," the letter states. "It would encourage companies making medical products as well as medical specialty organizations to constantly ask Members of Congress to override scientific evidence and spend taxpayer dollars needlessly on products whose sale would benefit those companies or specialties more than they benefit patients. In some cases, such overrides could promote the use of medical products in ways that are potentially dangerous to patients because they are unsafe or ineffective."

While the CMS coverage decision is on the books, the agency hasn't sent out new coverage instructions to local carriers.

Medicare:

CMS Retains Former Policy On Clinical Trials Coverage

(Continued from page 1)

other HHS components in order to avoid imposing duplicative or inconsistent obligations," the agency said.

This means that the policy that governed clinical trials coverage since 2000 remains basically intact. The only changes define routine costs and allow CMS to provide "coverage with evidence development." That category of coverage was first proposed in a reconsideration of the coverage policy that was completed on July 9.

The American Society of Clinical Oncology praised CMS for abandoning its proposal. "Because the majority of patients with cancer are over age 65, the proposed Medicare policy would have seriously impaired seniors' access to cutting-edge cancer therapies and our ability to advance cancer treatment," ASCO President Nancy Davidson, director of the breast cancer program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, said in a statement.

Before the final policy was announced, Sens. Benjamin Cardin (D-Md.) and Sam Brownback (R-Kan.), joined by 15 other Senate members, sent a letter to CMS urging the agency to refrain from making changes. In the House, Reps. Deborah Pryce (R-Ohio), Lois Capps (D-Calif.), Sue Myrick (R-N.C.), and Steve Israel (D-N.Y.), co-chairs of the House Cancer Caucus, sent a letter to CMS opposing proposed changes.

"The Oct. 17 decision is quite an abrupt retraction, but reasonable nonetheless," said Kirk Dobbins, an attorney with the Washington office of the firm King & Spalding, who specializes in CMS issues. "The final decision removes the many new complex and duplicative aspects of the Proposed National Coverage Decision."

The new FDA legislation gives HHS agencies greater authority to respond to safety concerns, mandate clinical trials, and change drug labels. Also, the new law expands the clinical trial registry database.

Cancer Statistics:

Cancer Death Rates Declined 2.1% A Year From 2002 To 2004

By Kirsten Boyd Goldberg

Cancer death rates declined on average 2.1 percent a year from 2002 through 2004, twice the annual decrease from 1993 through 2002, according to a report by federal health agencies and cancer organizations.

The long-term declines in cancer death rates continued through 2004 for both sexes, the report found. While men had overall higher death rates, the declines from 2002 through 2004 were 2.6 percent per year among men and 1.8 percent per year among women. Death rates decreased for the majority of the top 15 cancers in men and women.

Important declines were noted for the three leading causes of cancer deaths in men: lung, prostate and colorectal cancers. In women, deaths rates from colorectal cancer and breast cancer decreased, while the rate of increase for lung cancer deaths slowed substantially.

"The significant decline in cancer death rates demonstrates important progress in the fight against cancer that has been achieved through effective tobacco control, screening, early detection, and appropriate treatment," said Centers for Disease Control and

Prevention Director Julie Gerberding. "As a nation, we must commit to continuing and enhancing these important public health efforts."

The annual report is a joint project of the American Cancer Society, the Centers for Disease Control and Prevention, NCI, and the North American Association of Central Cancer Registries. It was published online Oct. 15 at www.interscience.wiley.com/cancer/report2007 and will be appear in the Nov. 15 issue of Cancer.

"These exciting new data demonstrate what many of us in the cancer research and practice community have known for some time. The long-term federal investment in cancer research is paying off," said Nancy Davidson, president of the American Society of Clinical Oncology.

"But this impressive pace of progress will slow if we don't recommit to funding cancer research," Davidson said. "Adjusted for inflation, cancer research funding has actually declined 12 percent since 2004—this has never happened in our nation's history. Without additional funding, the chance to build on the extraordinary progress to date, and provide new treatments for 1.4 million Americans diagnosed with cancer every year, will be delayed or lost."

ASCO has called for a nearly 7 percent increase in the NIH budget to help reverse the effects of flat funding, keep pace with inflation, and maintain the research infrastructure. Congress is currently considering much smaller increases in NIH funding for the current fiscal year.

Cancer Incidence Rates Decline Slightly

Overall cancer incidence rates—the rates at which new cancers are diagnosed—for both sexes and all races combined declined slightly from 1992 through 2004. Incidence rates for female breast cancer dropped substantially from 2001 through 2004. This drop is possibly related to declining use of hormone replacement therapy as well as the recently reported decline in use of screening mammography.

Also, lung cancer incidence rates in women stabilized from 1998 through 2004 after long term increases, and in men the rate declined 1.8 percent per year from the period 1991 through 2004. Colorectal cancer incidence rates decreased by more than 2.0 percent per year for men and women, likely due to prevention through the removal of precancerous polyps.

"The evidence is unmistakable: we are truly turning the tide in the cancer battle," said John Seffrin, chief executive officer of the American Cancer Society. "The gains could be even greater if everyone in the U.S. had access to essential healthcare, including primary care and prevention services."

American Indians And Alaska Natives

This year's report includes a special section that provides the most comprehensive cancer data to date for American Indians and Alaska Natives (AI/AN) across the U.S. While this population generally has lower overall cancer incidence rates than the non-Hispanic white population, a large regional variation in rates pointed to the need to increase cancer prevention and control efforts, particularly tobacco control and cancer screening, the report said.

From 1999 through 2004, AI/AN men from the Northern Plains region and AI/AN women from Alaska and the Northern and Southern Plains regions had higher cancer incidence rates than non-Hispanic white (NHW) men and women in the same areas, the report found.

"The key is that there are very distinct regional patterns in this population that varies by cancer site," said David Espey, lead author of the report and a cancer epidemiologist from the U.S. Centers for Disease Control and Prevention in Atlanta who was assigned to the Indian Health Service Division of Epidemiology and Disease Control, in Albuquerque, N.M.

"Certain cancers are much higher in some regions, especially the plains regions, and lower elsewhere, in the Southwest," Espey said.

Lung and colorectal cancer incidence rates were highest in the Northern Plains and Alaska and were significantly elevated in comparison with NHW rates. "It underscores the need to look further, to take these descriptive statistics and find out why these rates are different," Espey said.

In the case of lung cancer, the elevated rates in Alaska and the Northern Plains can be explained by decades of high prevalence of cigarette smoking among the AI/AN population of those regions, evidence that is further strengthened by the very low rates in the Southwest where AI/AN smoking has historically been very low, the report said.

"The overwhelming influence in cancer is tobacco, and that's a problem—how to address tobacco control in this population that has a higher prevalence of smoking," Espey said. "It's very hard to address. If we want to be serious about cancer prevention and control in these areas, we have to start with tobacco control."

The cause of differences in AI/AN regional colorectal cancer rates is less clear and is likely due to multiple factors that may include diet, genetic

makeup, tobacco use, diabetes, environmental factors and others.

CDC is looking at ways of providing colorectal cancer screening in remote areas of Alaska, Espey said.

Espey said federal health agencies have made progress in helping control cervical cancer in the AI/AN population. While the rates are still higher than the NHW population, the gap is narrowing.

"We invested a lot in controlling cervical cancer in 1970s and '80s, and we are seeing the benefits of that. Colorectal cancer, in this population and the general population, is still in that phase of public and provider education."

A bill introduced in the House would create a colorectal cancer screening program similar to CDC's Breast and Cervical Cancer Screening Program, which has helped provide screening in tribal populations as well as other underserved areas.

"That would be a tremendous boost for the under- and un-served population," Espey said. "When you invest in these screening programs, you actually get results."

The report found other differences for cancer incidence by region and type of cancer, including:

—For all cancers combined, AI/AN incidence rates were lower in the Southwest and higher in the Plains and Alaska.

—The incidence rates for cancers of the kidney, stomach, liver, cervix and gallbladder were higher in AI/AN than in NHW populations in all regions combined.

—With the exception of Alaska, AI/AN persons were less likely than NHW persons to be diagnosed with early stages of colorectal cancer, with the difference being larger in the Southwest, Northern Plains, and Southern Plains than other regions.

—AI/AN women in all regions of the U.S. were less likely than NHW women to be diagnosed with localized breast cancer.

"We are firmly committed to addressing cancer health disparities so that the benefits of decades of research can reach all Americans," NCI Director John Niederhuber said. "The fact that lung and colorectal cancers rates were higher in some American Indian and Alaska Native populations points to the work we still have to do."

Many types of cancer with higher incidence rates in AI/AN populations are associated with infections: human papilloma virus in cervical cancer; Helicobacter pylori bacteria in stomach cancer; and hepatitis B virus and hepatitis C virus in liver cancer.

Poverty among the AI/AN population was three times that of the NHW population, with the Southwest AI/AN population having the highest regional prevalence of poverty. AI/AN adults were less likely to graduate from high school and were more likely to have less than a ninth grade education than NHW adults, with Alaska and Southwest AI/AN populations having the lowest formal education attained.

The percentage of AI/AN persons under age 65 years with no health coverage was twice that of NHW adults. The proportion of persons ages 18 to 64 years with no usual source of care was higher among the AI/AN population overall and in all regions.

For NHW and AI/AN populations in all regions, men were more likely than women to have no usual source of medical care. AI/AN persons in Alaska aged 65 years reported the highest prevalence of no healthcare coverage; a 10-fold higher prevalence than NHW persons over 65 years old, the report said.

Also, in all regions, more AI/AN than NHW persons reported being obese. Screening rates for breast, colorectal, prostate, and cervical cancers were lower among AI/AN than NHW persons.

AI/AN populations are among the fastest growing populations in the U.S. According to the 2000 U.S. Census, 1.1 percent of the population stated they have AI/AN ancestry.

The Indian Health Service provides primary health care to about 1.8 million enrolled members of federally-recognized tribes, out of the estimated 3.3 million AI/AN persons in the U.S.

The 150 IHS hospitals and clinics are primarily located on reservation lands and in a few cities with relatively large AI/AN populations. Half of these health care facilities are managed by tribal governments under negotiated agreements with the U.S. federal government, and half are operated directly by the federal government.

An additional 34 urban health centers receive some federal funding to provide health care to urban AI/AN individuals.

Eligible AI/AN persons can receive free health care at any IHS facility, but a complex set of rules governs and restricts delivery of contract health services for specialty medical care, such as cancer treatment, which is generally not available in IHS facilities.

Geographic, financial, and bureaucratic barriers to receiving appropriate cancer treatment, as well as cultural beliefs, may also contribute to poor survival rates among AI/AN persons.

Science Policy:

Report Urges Development Of Toxicogenomics Initiative

NIH's environmental health institute should begin to explore the feasibility of a human toxicogenomics initiative approaching the scale of the Human Genome Project, according to a report from the National Research Council.

The project would incorporate genomic data into risk assessments of chemicals and medicines. Chemicals and drugs often cause health problems by altering gene expression and other cell activity. Research on these processes, called toxicogenomic research, could eventually lead to more sensitive toxicity tests that can supplement current tests, the report said.

"We have just begun to tap the potential for toxicogenomic technologies to improve risk assessment," said David Christiani, chairman of the committee that wrote the report, and professor of occupational medicine and epidemiology at the Harvard School of Public Health. "To harvest public health benefits requires both greater investment in research and coordinated leadership."

The National Institute of Environmental Health Sciences should work with scientists and other agencies to develop a human toxicogenomics initiative (HTGI) that would support the collection of toxicogenomic data and coordinate the creation and management of a large-scale database that would use systems biology approaches and tools to integrate the results of toxicogenomic analyses with conventional toxicity testing data, the report said.

According to the report, elements of the HTGI should include the following:

1. Creation and management of a large, public database for storing and integrating the results of toxicogenomic analyses with conventional toxicity-testing data.

2. Assembly of toxicogenomic and conventional toxicologic data on a large number (hundreds) of compounds into the single database. This includes the generation of new toxicogenomic data from humans and animals for a number of compounds for which other types of data already exist as well as the consolidation of existing data. Every effort should be made to leverage existing research studies and infrastructure (such as those of the National Toxicology Program) to collect samples and data that can be used for toxicogenomic analyses.

3. Creation of a centralized national biorepository for human clinical and epidemiologic samples, building on existing efforts.

4. Further development of bioinformatic tools, such as software, analysis, and statistical tools.

5. Consideration of the ethical, legal, and social implications of collecting and using toxicogenomic data and samples.

6. Coordinated subinitiatives to evaluate the application of toxicogenomic technologies to the assessment of risks associated with chemical exposures.

The generation of data from such studies, and toxicogenomic research in general, raises a host of social, legal, and ethical questions that the new initiative needs to address—including protecting the privacy of genetic and health data, the report said.

Individuals might decide against genetic testing if there is a danger that health insurers or employers could access their information and use it to deny them insurance or work. Safeguarding the privacy of this data will be increasingly challenging as the use of electronic medical records grows.

Improved legislation is needed to protect the privacy, confidentiality, and security of health information anywhere it is collected, stored, and transmitted—not just at organizations already subject to privacy rules under the Health Insurance Portability and Accountability Act.

The decision to learn about one's genetic vulnerabilities should rest with the individual, the report said. Except in rare circumstances, people who choose to get tested to learn about their particular genetic susceptibilities to a workplace chemical should be allowed to decide for themselves whether to accept the risks involved in employment.

The study was sponsored by NIEHS. The report, "Applications of Toxicogenomic Technologies to Predictive Toxicology and Risk Assessment" is available at http://www.nap.edu.

Funding Opportunities:

NCI RFA Available

RFA-CA-08-002: Network for Translational Research: Optical Imaging in Multimodal Platforms. U54. Letters of Intent Receipt Date: Dec. 24. Application Receipt Date: Jan. 24. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-002.html. Inquiries: Houston Baker, 301-594-9117; bakerhou@mail.nih.gov.

In the Cancer Centers:

Weiner Named Director, Lombardi Cancer Center

LOUIS WEINER was appointed director of Lombardi Comprehensive Cancer Center at Georgetown University Medical Center and Georgetown University Hospital. A medical oncologist specializing in gastrointestinal cancers, Weiner is chairman of the Department of Medical Oncology at Fox Chase Cancer Center, where he holds the G. Morris Dorrance Jr. Endowed Chair in Medical Science. He joined Fox Chase in 1984. Weiner is also professor in the Department of Medicine at Temple University School of Medicine. He serves as chairman of the Immunology Task Force of the American Association for Cancer Research, and is a member of the steering committee of the NCI Translational Research Working Group and the Cancer Immunopathology and Immunotherapy Study Section of NIH. Weiner succeeds **Anatoly Dritschilo**, who has served as interim director since 2005.

ELLEN GRITZ, chairman of the Department of Behavioral Science and Olla S. Stribling Distinguished Chair for Cancer Research at M.D. Anderson Cancer Center, was elected to the Institute of Medicine. Gritz was previously a member of the IOM National Cancer Policy Board and the Board on Population Health and Public Health Practice. She is known for her work on cigarette smoking behavior, including prevention, cessation, pharmacologic mechanisms, effects on weight and special issues of concern to women and high-risk groups, including ethnic minorities, youth, cancer patients and people living with HIV/AIDS. Gritz is one of 65 new members and four foreign associates.

In Brief:

AACR Awards $2.7 Million For Colon Cancer Research

AMERICAN ASSOCIATION FOR CANCER RESEARCH announced the four recipients of the 2007 Jeannik M. Littlefield-AACR Grants for Metastatic Colon Cancer Research, totaling $2.7 million. In its second year, the grant program, which is funded by the Littlefield 2000 Trust, supports research for metastatic colon cancer treatments. Special emphasis is placed on research that brings therapeutics to patients within a one- to two-year period. The grantees are: **Michael Kahn**, University of Southern California; **Michael Karin**, University of California, San Diego; **Louis Weiner**, Fox Chase Cancer Center; and **Makoto Taketo**, Kyoto University. Individual grants range from $500,000 to $1 million.

ASSOCIATION OF AMERICAN CANCER INSTITUTES will present its 2007 Public Service Awards to Senate Majority Leader **Harry Reid** of Nevada and Reps. **Michael Castle** of Delaware and **Edward Markey** of Massachusetts. The award is given to public officials displaying dedication to advancing cancer research and who support of programs that ease the burden of cancer on Americans. Reid will be recognized for his work and support of the Breast Cancer and Environmental Research Act, the Coordinated Environmental Public Health Network Act that addresses the correlations between environmental exposures and diseases, and the Stem Cell Research Enhancement Act, and other efforts. Castle will be honored for his co-sponsorship of the Stem Cell Research Enhancement Act of 2007 and in securing Congressional funding increases for NIH and NCI. Markey will be honored for his commitment to the federal investment in biomedical and cancer research. The presentations will be made during the AACI annual meeting, Oct. 28–30 in Washington, D.C.

Distribution Policy for The Cancer Letter

Thank you for your purchase of this issue of The Cancer Letter! Because issue and subscription sales are our major source of revenue, we wouldn't be able to provide you with the information contained in this newsletter without your support. If you have any questions or comments about the articles, please contact the editors (see page 2 of your issue for contact information).

We welcome your use of the newsletter and encourage you to send articles once in a while to colleagues. But please don't engage in routine distribution of The Cancer Letter to the same people week after week, unless your organization has purchased a site license or group subscription. If you aren't sure, ask the person who is paying for this subscription. If you are sending the newsletter to an unauthorized list, please stop; your actions are against Federal law. If you received this newsletter under an unauthorized arrangement, know that you are in receipt of stolen goods. Please do the right thing and purchase your own subscription.

If you would like to report illegal distribution within your company or institution, please collect specific evidence from emails or photocopies and contact us. Your identity will be protected. Our goal would be to seek a fair arrangement with your organization to prevent future illegal distribution.

Please review the following guidelines on distribution of the material in The Cancer Letter to remain in compliance with the U.S. Copyright Act:

What you can do:

- Route a print subscription of the newsletter (original only) or one printout of the PDF version around the office.
- Copy, on an occasional basis, a single article and send it to a colleague.
- Consider purchasing multiple subscriptions. We offer group rates on email subscriptions for two to 20 people.
- For institution-wide distribution or for groups larger than 20, consider purchasing a site license. Contact your librarian or information specialist who can work with us to establish a site license agreement.

What you can't do without prior permission from us:

- Routinely copy and distribute the entire newsletter or even a few pages.
- Republish or repackage the contents of the newsletter in any form.

If you have any questions regarding distribution, please contact us. We welcome the opportunity to speak with you regarding your information needs.

The Cancer Letter
PO Box 9905
Washington DC 20016
Tel: 202-362-1809
www.cancerletter.com