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Senate Resolution Urges CMS To Reopen Coverage Policy On ESAs In Oncology

By Paul Goldberg

The U.S. Senate last week came to the defense of the shrinking franchise for erythropoiesis stimulating agents.

In a “sense of the Senate” resolution passed by unanimous consent on Sept. 4, the legislators urged the Centers for Medicare and Medicaid Services to change its recent National Coverage Determination that severely restricts the use of ESAs in oncology.

The nonbinding resolution cites the language that appears in a series of three letters that the American Society for Clinical Oncology sent to CMS after the NCD was first announced July 30.

“[The] American Society of Clinical Oncology... is specifically concerned about a provision in [the NCD] that restricts coverage whenever
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In the Cancer Centers:

Winship Cancer Institute Receives SPORE For Head And Neck Cancer Research

WINSHIP CANCER INSTITUTE at Emory University received a five-year, \$12.5 million Specialized Program of Research Excellence grant from NCI for head and neck cancer research—the first SPORE grant ever received in the state of Georgia. Southeastern states rank among the highest in the nation in head and neck cancer incidence, according to NCI statistics. “Because of the large number of aging smokers and ex-smokers in the U.S. population, the incidence of aerodigestive cancers, including lung cancer and head and neck cancers, will remain high for the next two to three decades, despite the overall decline in smoking,” said **Dong Moon Shin**, professor of hematology and oncology at Emory Winship, Georgia Cancer Coalition Distinguished Cancer Scholar, and principal investigator of the grant. The grant will fund four translational research projects to test hypotheses about biology, prevention, and novel therapies driven by molecular science and nanotechnology, said Shin. The four main projects are: Chemoprevention with Green Tea Polyphenon; Targeting Death Receptors-Mediated Apoptosis for Head and Neck Cancers; Development of Novel Curcumin Analogs for the Treatment of Head and Neck Cancer; and Biodegradable Nanoparticle Formulated Taxol for Targeted Therapy of Head and Neck Cancer. “We earned this grant thanks to the exceptional science that will be conducted here; however, it’s important to note that the NCI places great value on the strong commitment of support, including space, recruitment, shared resources, and
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ASCO Letters To CMS Cited In Senate Resolution On ESAs

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a patient's hemoglobin goes above 10 g/dL," states the resolution co-sponsored by Sens. Arlen Specter (R-Penn.), and Frank Lautenberg (D-N.J.). Sen. Tom Harkin (D-Iowa), was among original sponsors, but withdrew sponsorship before the resolution went to the floor.

Quoting ASCO's statement that this "restriction is inconsistent with both the FDA-approved labeling and national guidelines," the Senate resolution states that CMS "should begin an immediate reconsideration" of the NCD, and "should consult with members of the clinical oncology community to determine appropriate revisions." Finally, the resolution urges CMS to "provide a briefing to Congress in advance of announcing such changes."

For sponsors of the ESAs, the Medicare cuts represent an imminent threat. According to widely used Wall Street projections, the CMS action would cut the government's purchases of the agents by about two-thirds.

The threat is so ominous that the sponsors of these products—Amgen Inc. and Johnson & Johnson—set aside their long-running bitter rivalry in order to lobby Congress and CMS on ESA coverage.

In this endeavor, they were joined by professional societies, care providers, and patient groups. In July, this campaign produced a barrage of sign-on letters from Capitol Hill. One letter included signatures of 224

House members. Another was signed by 46 Senators (The Cancer Letter, July 20). "By issuing this NCD, CMS has caused such an uproar, that they've managed to accomplish something no one has done before: they brought this community together," noted one lobbyist.

In the past, the Senate has resorted to resolutions on its forays into controversies in oncology.

This happened during the 1997 debate over mammography screening for women under the age of 50, when the Senate pressured NCI to reconsider its screening recommendation. Similarly, Congressional efforts to double the NIH budget began as a non-binding Senate resolution.

In the current debate, ASCO has emerged as the central player in the effort to reverse the CMS coverage policy.

The professional society's most recent letter to CMS, dated Aug. 30, urges the agency to allow higher targets for ESA use in some patients at initiation of therapy, and to increase the allowable maintenance level to just below 12 g/dL.

Though numerous studies are cited by both sides, the ESA controversy is extraordinary because of what FDA and critics in academia have described as the paucity of data on safety and efficacy of these drugs, even in the labeled indications (The Cancer Letter, June 15).

At least for now, the FDA package insert uses 12 g/dL as the target for ESA use, but the agency is widely believed to be re-evaluating the label in oncology and nephrology in light of recently reported adverse outcomes in both indications.

Earlier this year, FDA eliminated all quality of life claims in oncology from the ESA labels, reaffirming that ESAs were approved as an alternative to blood transfusions, which are rarely administered unless a patient's hemoglobin drops well below 10 g/dL.

A "black box" warning placed on the ESA labels in March urges doctors to "use the lowest dose... that will gradually increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion."

FDA has consulted the Oncologic Drugs Advisory Committee, but hasn't announced any changes in the label (The Cancer Letter, May 11, May 18).

On Sept. 11, the agency's Cardiorenal Drugs Advisory Committee and the Drug Safety and Risk management Advisory Committee will review the ESA label in nephrology, potentially reducing hemoglobin targets and thereby limiting the use of ESAs in that market.



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

If FDA revises the ESA label to lower the hemoglobin target in oncology, the Senate resolution, the ASCO position, and the uproar in the community would likely become moot, observers say.

The CMS coverage policy in oncology has caused Amgen to take cost-cutting measures. Last month, the company announced that it would cut \$600 to \$700 million in costs, eliminating 12 percent of its workforce and, likely, reducing expenditures on research and development.

In a slide presented at a conference call with analysts Aug. 15, Amgen said that Medicare represents 40 percent of Aranesp's \$2.1-billion sales in oncology.

Company officials said that they believed that "private payers will take a more considered approach to reimbursement changes" for Aranesp. In the past, private insurers have usually followed Medicare's lead.

ASCO Proposes Alternative Language For NCD

In the most recent round of letters, ASCO urged CMS to go back to the target of 12 g/dL, and suggested the language that would make the NCD more acceptable.

In the Aug. 30 formal request for reconsideration of the NCD, Joseph Bailes, chairman of the ASCO government relations council, wrote that CMS "materially misinterpreted the existing evidence" at the time it published the NCD.

In an accompanying document, ASCO requested CMS to increase the levels of hemoglobin that would be allowed under the NCD. The regulation requires that the patients' hemoglobin levels drop below 10 g/dL before therapy can begin.

ASCO suggested that this be replaced with the following language:

"The hemoglobin level immediately prior to initiation of ESA treatment is < 10 g/dL... or between 10 g/dL and 12 g/dL when accompanied by moderate to severe anemia symptoms (e.g., shortness of breath or impaired exercise capacity), or certain clinical circumstances (e.g., limited cardiopulmonary reserve or underlying coronary artery disease)."

In the past, most Medicare carriers paid for ESA treatment as soon as a patient's hemoglobin dropped below 12 g/dL.

The society suggests modifications in the maintenance therapy, too. The existing language of the NCD states:

"Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10 g/dL... 4 weeks after initiation of therapy and the rise in hemoglobin is

> 1g/dL (hematocrit > 3%)."

ASCO suggests bumping this up to 12 g/dL:

"Maintenance of epoetin therapy is the starting dose if the hemoglobin is not approaching 12 g/dL 4-6 weeks after initiation of epoetin therapy, and the rise in hemoglobin is > 1g/dL... If the hemoglobin level approaches 12 g/dL... at any point during epoetin therapy, decrease epoetin dose by 25%. Maintenance of darbepoetin therapy is the starting dose if the hemoglobin is not above 11 g/dL... 4-6 weeks after initiation of darbepoetin therapy, and the rise in hemoglobin is > 1g/dL... If the hemoglobin level goes above 11 g/dL (hematocrit 33%) at any point during darbepoetin therapy, decrease darbepoetin dose by 40%."

According to ASCO:

—"The clinical studies supporting FDA approval of ESAs did not involve stopping administration of the ESAs when the patient's hemoglobin exceeded 10 g/dL. There are no clinical studies demonstrating that the NCD's rules for administering ESAs result in their safe and effective use. CMS's implicit conclusion that the NCD provides for safe and effective therapy is based on a material misinterpretation of the clinical evidence.

—"The NCD assumed that additional blood transfusions will not be required, since it misinterpreted the existing evidence and based a definitive policy on a body of evidence that is unclear and therefore does not allow for the definitive policy adopted. In addition, the NCD did not properly interpret evidence concerning patients with conditions that put them at increased risk.

—"The NCD's policies on dose escalation and timing of a dose increase are inconsistent with the FDA-approved labeling and therefore with the underlying clinical studies. CMS has misinterpreted the clinical data in assuming that the NCD's rules on dose escalation and timing of a dose increase have been shown to be safe and effective."

US Oncology Claims "Misinterpreted" Data

Another critic of the NCD, US Oncology, argues that CMS should reconsider the coverage policy because it's based on "substantively misinterpreted" clinical evidence.

The letter, dated Sept. 4 and signed by Fred Eckery, chairman of US Oncology National Policy Board and Michael Kolodziej, chairman of the company's physicians network, states:

—"The scope of the coverage policy should explicitly include oral and biologic agents known to induce anemia. While CMS has verbally indicated that

such coverage is intended, explicit language in the NCD will assure that contractors will uniformly offer it.

—“The NCD needs to make specific provision for cases where anemia, even at hemoglobin levels exceeding 10 g/dL, pose a substantial risk to patients due to comorbid conditions, such as cardiopulmonary disease, or other impairments of oxygen transport.

—“The policy should accommodate “off the shelf” dosing increments, as is the current practice, to avoid subjecting patients to multiple subcutaneous injections, to avoid drug wastage, and to avoid the need to compound ESAs in physician offices in the course of routine care.

—“The policy should allow for a hemoglobin target range of 10-12 g/dL for ESA use in Chemotherapy Induced Anemia (CIA), consistent with the safety record established in over 40 clinical trials. Providing a target hemoglobin range will allow physicians to titrate ESA dosing in a manner consistent with the evidence-based standard of care and permit more predictable, uniform use.

—“The policy needs clear language that states that physicians may ignore the transient effect of transfusions on hemoglobin values in making decisions to administer ESAs, thus allowing their rational use in CIA.

—“The policy would benefit from the inclusion of parameters (including timeframe) for dose escalations that are consistent with trial data.

—“The policy should either incorporate parameters for evaluating clinical response that are broader than a 1g/dL rise in hemoglobin by 8 weeks, or discard the 8 week standard entirely. Management of anemia using ESAs or transfusions or both is more complicated than simply reacting to hemoglobin values. Maintenance (as opposed to increases) of hemoglobin levels in patients undergoing myelosuppressive chemotherapy is a valid clinical objective. Moreover, the mixed use of ESA’s and transfusions simultaneously is a reasonable strategy in a patient who has symptomatic anemia – but the follow-up hemoglobin is not a valid measure of the ESA response.

—“It is a mistake not to explicitly cover ESA use in Myelodysplasia (MDS) within the NCD. ESAs are shown to prolong survival in patients with MDS, because they act as a therapeutic intervention, obviating the need for multiple transfusions and eliminating the risk of iron overload. There is also emerging evidence that ESA’s may delay transformation to acute leukemia. Reconsideration based on CMS’ misinterpretation of the evidence submitted by multiple oncology groups in previous letters regarding this NCD is appropriate.”

The ASCO and US Oncology documents are posted at www.cancerletter.com. The Senate resolution is posted at <http://thomas.loc.gov/cgi-bin/bdquery/z?d110:SE00305:@@P>.

In the Cancer Centers: **Avon Awards \$1M To Winship For Breast Cancer Center**

(Continued from page 1)

matching funds from Emory University School of Medicine, Emory Woodruff Health Sciences Center, Georgia Cancer Coalition and Georgia Research Alliance,” said **Fadlo Khuri**, deputy director for clinical and translational research at Emory Winship and co-principal investigator of the grant. . . . **WINSHIP** also received a \$1 million grant from the Avon Foundation for the Avon Foundation Comprehensive Breast Cancer Center at Grady Memorial Hospital. The grant will be used for early detection education and for the expansion of breast health care for medically underserved women in metropolitan Atlanta. “Research developments that have been funded by Avon have enabled the AFCBC to build on its work to address health care disparities among minority women and the underserved population in Georgia,” said **Otis Brawley**, director of the Georgia Cancer Center of Excellence at Grady. The AFCBC is comprised of a multidisciplinary team of medical and surgical oncologists, epidemiologists, pathologists, radiation oncologists, surgeons, psychiatrists, scientists, and statisticians. Avon Foundation funding has helped with access-to-care issues through creation of a Mammography Task Force, which established appointment timelines for services. Screening mammograms are now scheduled within 30 days, and diagnostic mammography appointments and biopsy procedures are scheduled within two weeks. . . . **EMORY** and **GEORGIA STATE** University researchers were awarded a four-year, \$850,000 grant from the American Cancer Society to study risk factors for long-term social and cognitive problems in adult survivors of pediatric brain tumors. The study will examine 100 adults in their 20s who have survived at least 10 years beyond initial diagnosis. The research team will use neuroimaging technology and neuropsychological evaluations to look for neurological, cognitive and psychosocial predictors of adaptive functioning, said **Hui Mao**, assistant professor of radiology in the Emory University School of Medicine and lead investigator. The study would look into brain structural and functional changes caused by the tumor and their links to those

outcomes. Other Emory researchers include **Nicolas Krawiecki**, associate professor of pediatrics, and **Anna Janns**, associate professor of pediatrics, a Georgia Cancer Coalition Scholar and a member of the Emory Winship Cancer Institute and the Aflac Cancer Center and Blood Disorders Service of Children's Healthcare of Atlanta; and **Chad Holder**, assistant professor of radiology. Researchers from Georgia State University include **Tricia King**, assistant professor of psychology and principal investigator; and Robin Morris, professor of psychology and vice president for research. . . .

UNIVERSITY OF NEW MEXICO Health Sciences Center has received a grant of \$285,000 from NCI to study uterine cancer and the effects of a G-protein known as GPR-30. **Eric Prossnitz**, professor of cell biology and physiology at UNM, and colleagues at the UNM Cancer Center and the Department of Chemistry and Biochemistry at New Mexico State University who are members of the UNM Cancer Center's Women's Cancers Research Program, discovered that GPR30 binds the female hormone estrogen. . . .

UNIVERSITY OF KANSAS Hospital Cancer Center and Medical Pavilion opened its \$25 million outpatient facility on Westwood campus. The new facility was needed due to the growth of the cancer program at UK Hospital. The new space provides a single location for services from early cancer detection through survivorship and supports the hospital goal of achieving NCI designation, the hospital said. . . .

CANCER THERAPY AND RESEARCH CENTER Institute for Drug Development announced the addition of three scientists. **Jennifer Carew** and **Stephen Nawrocki**, both of St. Jude Children's Research Hospital, are co-directors of the IDD Preclinical Research Department. Their research initiatives and collaborations include small animal imaging and specialized animal models that focus on the mechanisms of action by anti-cancer agents.

Swaminathan Padmanabhan, of Roswell Park Cancer Institute, was named clinical investigator and director of hematologic malignancies for the phase I program. In his newly created position, Padmanabhan's research includes malignancies such as leukemia, lymphoma, and myeloma. Padmanabhan completed a fellowship in hematology/oncology at Sylvester Comprehensive Cancer Center of University of Miami. Carew completed a postdoctoral fellowship at St. Jude Children's Research Hospital. Nawrocki was a postdoctoral fellow at St. Jude. . . .

LESLIE BERNSTEIN was appointed director of the new Department of Cancer Etiology, Division of Population Sciences at City of Hope. An epidemiologist known for establishing the connection between exercise

and reduced breast cancer risk, Bernstein will lead a research program on the genetic and environmental causes of cancer to identify cancer prevention strategies. She also was appointed professor and dean for faculty development in Beckman Research Institute. She is professor of preventive medicine, the AFLAC Inc. Chair in Cancer Research, and program leader of the Women's Cancers Program at the USC/Norris Comprehensive Cancer Center. She is co-director of the USC Center on Transdisciplinary Research on Energetics and Cancer, a \$54 million NCI initiative on how increasing physical activity and reducing obesity can prevent cancer. Her appointment at City of Hope begins Sept. 15. . . .

ELIZABETH DUNNE was appointed executive officer of the medical center at City of Hope. Dunne was senior vice president and chief operating officer of Anaheim Memorial Medical Center. She begins her appointment in late August, said **Alexandra Levine**, chief medical officer, City of Hope. . . .

SAI YENDAMURI was appointed staff physician in the Thoracic Division of the Department of Surgery at Roswell Park Cancer Institute. He will treat lung and esophageal cancers using treatments such as endobronchial ultrasound and advanced airway interventions. Yendamuri completed a residency in cardiothoracic surgery at MD Anderson Cancer Center. He also is clinical assistant professor of surgery at the University at Buffalo. . . .

ANGELA BRADBURY was named director of the Margaret Dyson Family Risk Assessment Program at Fox Chase Cancer Center, a prevention and early-detection program for women with a hereditary or genetic risk of breast or ovarian cancer. Bradbury succeeds **Mary Daly**, who is now senior vice president of the population science division. Bradbury has clinical expertise in general oncology, breast oncology, clinical cancer genetics and clinical medical ethics. She is a collaborative investigator with the Cooperative Family Registry for Breast Cancer Studies and her primary research goal is to study ethical dilemmas that arise in cancer prevention and predictive genetic testing. Before joining Fox Chase, Bradbury was an instructor in the section of hematology-oncology at the University of Chicago, Department of Medicine. She was also an associate faculty member at the MacLean Center for Clinical Medical Ethics. . . .

THOMAS O'HALLORAN was named associate director for basic sciences at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. He is currently the Charles E. and Emma H. Morrison Professor in the Department of Chemistry and in the Department of Biochemistry, Molecular Biology and Cell Biology at Northwestern and serves as director

of the new Chemistry of Life Processes Institute at Northwestern. O'Halloran replaces **Teresa Woodruff**, the Thomas J. Watkins Professor of Obstetrics and Gynecology and a groundbreaking leader in fertility research, who steps down to focus on her roles as executive director of the Institute for Women's Health Research and chief of the newly created Division of Fertility Preservation. Woodruff is professor of biochemistry, molecular biology and cell biology, Weinberg School of Arts and Sciences. She serves as director of the Center for Reproductive Research and principal investigator of the newly funded Oncofertility Consortium grant. O'Halloran's research interests center on the regulatory biology and chemistry of transition metal receptors involved homeostasis and oxidative stress pathways. His work focuses on the intracellular chemistry of elements essential for growth and proliferation, nanoscale drug delivery mechanisms and on the mechanisms of clinically important anticancer agents that are based on arsenic, molybdenum and platinum chemistry. His discoveries have established the function and structures two new classes of soluble receptors: metalloregulatory proteins which govern metal responsive gene expression and metallochaperone proteins which control intracellular trafficking pathways. He is currently a PI on two R01 NIH grants from the National Institute for General Medical Sciences and a project in the Cancer Center for Nanotechnology Excellence grant from NCI.

In the Cooperative Groups: **SWOG Appoints Meyskens To Lead Cancer Prevention**

SOUTHWEST ONCOLOGY GROUP has appointed **Frank Meyskens Jr.** as associate chairman of cancer control and prevention. Meyskens will head all cancer control and prevention efforts for the NCI-sponsored clinical trials network. Meyskens is director of the Chao Family Comprehensive Cancer Center at the University of California Irvine Medical Center, where he is also associate vice chancellor of health sciences.

Meyskens was the founding chairman of the Committee on Control and Prevention for SWOG. In his new position, Meyskens will shape forward-looking initiatives that build on the lessons of past chemoprevention and cancer control studies and push for answers to some of the field's puzzling questions.

"After more than 20 years of SWOG leadership in this field, we are appointing someone who can build upon our extraordinary foundation, but take us in

new directions," said **Laurence Baker**, chairman of the group and a professor of internal medicine at the University of Michigan, where the Southwest Oncology Group is headquartered.

As associate chairman, Meyskens will build on the group's past track record in initiating important cancer control and prevention trials, working with NCI's Community Clinical Oncology Program network.

"I have tremendous respect for Frank Meyskens. We look forward to working with him as the SWOG leader in cancer prevention and control," said **Peter Greenwald**, director of the NCI Division of Cancer Prevention. "As we look to the future, we hope to see more clinical trials in prevention and control that have solid basic studies imbedded within them."

Meyskens will succeed **Charles Coltman Jr.**, who has served as associate chairman for cancer control and prevention since 2005. Coltman was chairman of SWOG from 1981 to 2005.

Under Meyskens, a reorganization of cancer control and related activities within the group will occur, group officials said. Cancer control hasn't been adequately addressed at the cooperative group level, Meyskens said.

"The term 'cancer control' is frequently used to include prevention, but to me it includes the initial end of the cancer spectrum, which includes genetic and environmental factors and special populations," Meyskens said. "At the other end of the spectrum, it includes quality of life and symptom control in the treatment setting. SWOG is in a great position to address these areas, to further enhance our ability to produce positive outcomes related to cancer for patients and for our society."

Meyskens earned his M.D. at the University of California San Francisco in 1972. After receiving his medical oncology training at the National Institutes of Health, he spent 12 years at the Arizona Cancer Center at the University of Arizona, where he established a highly successful cancer prevention research program. In 1989, University of California Irvine recruited him to develop its cancer center; which is now an NCI-designated comprehensive cancer center.

Meyskens is currently engaged in studies testing chemoprevention agents in patients at risk for colon and prostate cancer, as well as studies of cellular mechanisms in the development of melanoma. Among numerous honors, Meyskens is a past president of the International Society for Cancer Prevention, the founding chair of Cancer Control and Prevention Committees at the American Society of Clinical Oncology and at SWOG,

and has served in several posts for the American Association of Cancer Research. He chaired the Board of Scientific Counselors of the NCI Division of Cancer Prevention and Control from 1991-1992 and served on the Oversight Committee of CCOP from 1989-1992.

Professional Societies:

Michael Caligiuri Elected AACI Vice President, President-Elect

MICHAEL CALIGIURI, director of the Ohio State University Comprehensive Cancer Center, has been elected to serve a two-year term as vice president and president-elect of the Association of American Cancer Institutes. Following his term as vice president and president-elect, in October 2009, Caligiuri will begin serving an additional two-year term as the AACI's president.

AACI represents 89 academic and free-standing cancer research centers. Caligiuri will succeed **Edward Benz**, of the Dana-Farber Cancer Institute, as vice president of AACI.

"I am honored that my peers have asked me to serve as one of the principle ambassadors for the cancer research community," Caligiuri said. "At Ohio State, I have worked with researchers, patients, advocates and government officials to bring cancer research to the forefront of discussion. As the president of AACI, I will continue to address these issues on a national stage."

Also, four new members have been elected to AACI's Board of Directors for three-year terms: **Timothy Eberlein**, director of the Siteman Cancer Center at Barnes-Jewish Hospital and Washington University Medical Center; **Craig Thompson**, director of the Abramson Cancer Center of the University of Pennsylvania and associate vice president for cancer services for the University of Pennsylvania Health System; **Donald Trump**, president and chief executive officer of Roswell Park Cancer Institute; and **Cheryl Willman**, director and chief executive officer of the University of New Mexico Cancer Center.

Heading Ohio State's Comprehensive Cancer Center since July 2003, Caligiuri has been instrumental in recruiting more than 170 clinicians and researchers and quadrupling cancer research funding from the NCI and NIH.

Ohio State is one of two cancer centers that have successfully competed for NCI Phase I and Phase II contracts for drug development. Ohio State also heads one of the AACI-NCI partnership initiatives on Cancer Imaging.

Caligiuri received both graduate and medical degrees at Stanford University School of Medicine. He trained in internal medicine, oncology, bone marrow transplantation and immunology at Harvard before joining the Harvard Medical School faculty.

In 1997, Caligiuri left his position as a tenured professor at Roswell Park Cancer Institute to join Ohio State's Comprehensive Cancer Center as associate director for clinical research. He holds the John L. Marakas Nationwide Insurance Enterprise Foundation Chair in Cancer Research and served as the director of the division of hematology/oncology at Ohio State from 2000-2007.

* * *

AL BENSON III, associate director for clinical investigations at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University and professor of medicine at the Northwestern Feinberg School of Medicine, was elected president of the International Society of Gastrointestinal Oncology. He succeeds **Richard Goldberg**.

Funding Opportunities:

RFA-TW-08-003: International Cooperative Biodiversity Groups. U01. Letters of Intent Receipt Date: Nov. 6; Application Receipt Date: Dec. 4. Full text: <http://www.grants.nih.gov/grants/guide/rfa-files/RFA-TW-08-003.html>. Inquiries: Yali Fu, 301-496-8783; fuyali@mail.nih.gov.

RFP N02-RC-71010-74: Radiation Support and Related Services. Response Due Date: Sept. 9. Full text: <http://www.fbodaily.com/archive/2007/08-August/25-Aug-2007/FBO-01383650.htm>. Inquiries: Juana Diaz, 301-496-8613; e-mail: diazj@mail.nih.gov.

RFP N02-CO-82402-92: Computer and Statistical Support Services at the NCI-Frederick. Full text: <http://www.fbodaily.com/archive/2007/08-August/19-Aug-2007/FBO-01376211.htm>. Inquiries: <http://rcb.cancer.gov/rcb-internet/index.html>. (click on current RFPs to access).

RFP N02-CP-71005-53: Mutli-Disciplinary Investigations of Nutrition and Cancer. Full text: <http://www.fbodaily.com/archive/2007/09-September/01-Sep-2007/FBO-01391614.htm>. Inquiries: Sharon Miller, 301-435-3783; sm103r@nih.gov. and Kenya Crawford, 301-435-3787, crawfordke@mail.nih.gov.

NOT-CA-07-021: Announcement by NCI of Intent to Release a Request for Applications for Network for Translational Research in Optical Imaging. Full text: <http://www.grants.nih.gov/grants/guide/notice-files/NOT-CA-07-021.html>.



The National Comprehensive Cancer Network (NCCN), a not-for-profit alliance of 21 of the world's leading cancer centers, is dedicated to improving the quality and effectiveness of care provided to patients with cancer. The NCCN is currently offering several exciting and challenging opportunities in our suburban Philadelphia office for individuals seeking to impact the practice of oncology.

Medical Director, Information and Informatics

For a medical oncologist seeking to impact oncology nationally and internationally, this position provides clinical guidance and informatics expertise to NCCN information programs, including NCCN Clinical Practice Guidelines in Oncology™ and CE programs. This staff physician works collaboratively with NCCN physicians and non-physician staff to ensure production of accurate, clinically relevant, and multi-functional information products. Opportunity also exists to work on the Oncology Outcomes Database Project and Oncology Research Program.

Requirements:

- An MD or DO with recent clinical experience and board certification or eligibility in medical oncology, hematology, or other oncology-related specialty
- A current and broad understanding of the issues and literature in managing cancer patients
- Expertise in medical informatics, including EMR and clinical decision-assist systems
- Excellent writing skills, strong interpersonal skills, the ability to interact effectively with personnel at various levels, and the organizational proficiency to manage multiple projects and meet deadlines
- Experience in outcomes research and/or health services research a plus.

Oncology Scientist – Compendium

This position develops and maintains the NCCN Drugs and Biologics Compendium™ and the NCCN Standard Chemotherapy Order Templates, working collaboratively with physician and non-physician staff to ensure prompt and accurate incorporation of new drug indications into the Compendium. This individual will work with NCCN clinical pharmacist representatives and others to develop and maintain the Order Templates, develop and maintain a Not-Indicated List for each disease site, and review FDA indications to update Compendium to reflect changes.

Requirements:

- A PhD in pharmacology or PharmD with ability to evaluate clinical research
- Extensive expertise in and experience with cancer treatment modalities
- Ability to evaluate medical and drug use recommendations and translate them into different formats
- Proficiency in MS Office products
- Strong interpersonal communication skills and the ability to interact effectively with internal and external personnel at various levels

- Excellent writing skills and the ability to formulate medical information in a clear and concise manner
- Experience in scientific/medical writing preferred, and understanding of implications of compendium and order set products for utilization and coverage policy is a plus.

Oncology Scientist/Medical Writer

This position will work with NCCN expert panels to develop content for the NCCN Clinical Practice Guidelines in Oncology™, NCCN Drugs and Biologics Compendium™, and other projects as required.

Requirements:

- An MD, PhD, or PharmD and experience in oncology
- Excellent writing skills and the ability to formulate medical information in a clear and concise manner
- Ability to understand and evaluate medical literature, to abstract information concisely, and to work to deadlines
- Proficiency in MS Office products
- Strong interpersonal communication skills and the ability to interact effectively with internal and external personnel at various levels

Policy Fellow

The NCCN Policy Fellowship offers the opportunity for a clinical professional or individual with related training to gain understanding of the coverage and reimbursement policies that influence access to and availability of diagnostics and therapeutics in cancer care. The fellow will learn directly about policy development and also research, evaluate, and track coverage policies of public and private payors. The fellow will compare coverage policies to the NCCN Clinical Practice Guidelines in Oncology™, the NCCN Drugs and Biologics Compendium™ and other clinically relevant recommendations and follow-up with payors to attempt to reconcile differences. This position is funded for a 1-year term, but additional funding may extend its duration.

Requirements:

- An MD, Pharmacist, Nurse Practitioner, or PhD in health policy, public health or related discipline
- Understanding of clinical aspects in oncology
- Ability to self start, strong critical appraisal and analytic skills
- Strong interpersonal communication skills, the ability to work effectively in teams and independently, and the ability to interact effectively with internal and external staff at various levels
- Proven organizational skills and absolute attention to detail
- Proficiency in MS Office products

C-N-0571-0907

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