THE CANCER LETTER

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FDA Authority To Regulate Off-Label Promotion Challenged In Federal Court

By Paul Goldberg

FDA's authority to regulate what companies can say about off-label uses of drugs is once again being tested in federal courts.

Allergan Inc., the sponsor of the neurotoxin Botox, has filed a suit that broadly challenges the regulatory agency's powers in the context of the First Amendment.

Though the issue of off-label promotion is important throughout medicine, it is particularly relevant to oncology, where such use of drugs is widespread. Allergan's court challenge, filed in the U.S. District Court for the District of Columbia, is taken seriously by legal observers and FDA-watchers familiar with what can happen when the courts apply the constitutional filter to the agency's regulatory practices:

—In 1998, the first time a federal court was asked to consider

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In the Cancer Centers:

Harold Varmus Plans To Leave Presidency Of MSKCC, Asks Board To Begin Search

By Kirsten Boyd Goldberg

Nobel Laureate Harold Varmus announced Jan. 12 that he plans to leave his job as president of Memorial Sloan-Kettering Cancer Center.

In a New Year's letter to staff, Varmus said he asked the center's Boards of Overseers and Managers to begin a search for a successor.

"I have greatly enjoyed this job, and I still do," Varmus wrote. "But I also believe that institutional leaders should ordinarily not stay in place for greatly extended periods, and that our institution would now benefit from a fresh approach to the issues it will face in the decade ahead."

Varmus came to MSKCC on Jan. 1, 2000, "with the intention of serving for about 10 years," he wrote. The job of MSKCC president is one of the top hospital jobs in the country, with annual compensation of $2.76 million, according to the center's 2008 IRS Form 990.

"Until a new president has been recruited, while recognizing that events are not completely predictable, I plan to continue to conduct the center's affairs with the same energy and enthusiasm that I have brought to the job for the past 10 years," Varmus wrote. "In other words, this is not a time for farewells or for valedictories about the past decade—there will be a time for that. Instead, I hope that all of you will help the Board's search committee

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Lawsuit Revives Decade-Old Debate Over FDA Authority

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constitutionality of off-label promotion regulations, a judge made the agency scrap its enforcement policies, declaring them unconstitutional (The Cancer Letter, Aug. 14, 1998).

—A year later, the same judge, Royce Lamberth of the U.S. District Court for the District of Columbia, ruled that the off-label promotion provisions of the FDA Modernization Act similarly violated constitutional free speech guarantees (The Cancer Letter, Aug. 13, 1999).

—Lamberth's decision on FDAMA was vacated by the appellate court, but only after FDA said that it would allow sponsors to distribute peer reviewed journal publications. The decision is posted on http://caselaw.lp.findlaw.com/cgi-bin/getcase.pl?court=DC&navby=case&no=995304A.

—Though off-label provisions of FDAMA have expired, FDA continues to allow companies to distribute unaltered materials from peer-reviewed publications (The Cancer Letter, Jan. 16, 2009).

In the past, the First Amendment challenges were mounted by the Washington Legal Foundation, a conservative public interest law firm. Though WLF is partially funded by the pharmaceutical industry, it mounted First Amendment court challenges on behalf of patients rather than drug companies.

Similarly, WLF represented the Abigail Alliance in an unsuccessful effort to allow terminal patients access to drugs that had gone through phase I testing. In that case—which was similarly framed as a constitutional right—a three-judge panel of an appellate court upheld WLF's constitutional argument. However, a decision by the entire D.C. appellate court ultimately reversed the ruling of a three-judge panel.

Together with Lamberth's First Amendment rulings, the Abigail Alliance case illustrates what can happen when FDA regulations are examined in light of the U.S. Constitution.

In the most recent challenge, Allergan is not hiding behind the back of WLF or its patient plaintiffs. The company's constitutional challenge begins with questioning appropriateness of the agency's definition of a drug label.

By law, FDA can regulate the content of drug labels. But what is a label? Is it a piece of paper that gets shipped with a vial, or does its definition extent to the totality of communications about safety and efficacy of a drug? Allergan's lawsuit argues for a more limited definition. Moreover, the company wants to be able to communicate risks and benefits related to Botox directly to physicians. This would exceed the agency's policy of limiting such communications to distribution of articles from peer-reviewed publications.

"It's huge across the board, every category, including oncology," Sidney Wolfe, director of the Public Citizen Health Research Group and a member of the FDA Drug Safety and Risk Management Committee, said of potential implications of the case.

"Companies want to sell drugs, and the best way of selling drugs is promoting them," Wolfe said in an interview. "The best way of promoting them is promoting for as many things as you can, whether it's an approved use or not. And if this decision goes the wrong way, companies will be able to promote for whatever comes to their mind without fear of being caught or getting in trouble."

Public Citizen has submitted a friend of the court brief in the Allergan case.

Alan Bennett, an attorney with the firm of Ropes and Gray, who specializes in pharmaceutical company issues, said the Allergan case could bring much-needed judicial scrutiny of FDA powers.

"Companies engage in a very broad range of informational activities, and it's really inappropriate to label them all 'promotion,' and therefore somehow worthy of stringent regulation," Bennett said in an email. "Indeed, in some cases where science has moved on from the label, the constraints on information

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sharing imposed by the regulatory scheme can result in suboptimal patient care.

"The question of whether that regulatory scheme is consistent with the Constitution has been written about and discussed for many years," Bennett said. "But, other than in the WLF case, which was vacated for reasons having nothing to do with the merits, it has never been litigated. Hopefully this case will provide guidance on how far the FDA can go in regulating speech without running afoul of the First Amendment."

The Allergan case is far removed from oncology. It is based on Botox, a purified botulinum toxin, which is approved for several conditions, including cervical dystonia, but is often used off-label. One category of such uses—various forms of spasticity—is covered by Medicare and Medicaid.

"As Botox's manufacturer, Allergan is uniquely positioned to inform physicians about steps they can take to achieve the benefits of treatment while minimizing risks, including risks of serious adverse events, and thereby improve the quality of patient care," the company's suit states.

However, when such communications concern an off-label use, the sponsor risks prosecution under criminal statutes.

The definition of a drug label, as covered in the Food, Drugs and Cosmetics Act, is central to the company's argument. The company wants the court to declare that the label is no more than the writing on a container, a wrapper, or other materials accompanying the drug. FDA's broader definition of the label—which extends to cover claims and communications between the drug's sponsor and the doctors—should be declared unconstitutional, the company argues.

"Lacking a clear statutory warrant, the FDA has read innocuous statutory provisions as giving it unprecedented and unconstitutional power over manufacturer expression," the suit states.

The existing system doesn't work, the complaint argues. "Off-label use is lawful, commonplace, and necessary to the provision of care—it is no exaggeration to say that the FDA's current regulatory regime could not function if it did not tolerate significant off-label use—but manufacturers' free speech rights are totally suppressed and the public interest in the free flow of information is totally disregarded."

Botulinum toxins are injected directly into muscles with the goal of temporarily reducing its activity. When the drug is used to treat spasticity—an off-label indication in the U.S.—large doses are used. This may increase the risk of distant spread of the toxin, which can be fatal.

Last year, FDA added a boxed warning to the drug's label and implemented a Risk Evaluation and Mitigation Strategy.

"Based on its review of available data, Allergan believes that the risk may be affected by several factors relating to the physician's treatment choices, including the dose used at a given injection site, the number and location of injection sites, the frequency of treatment, the injection technique used, as well as factors relating to patient selection," the complaint states. "Allergan seeks to proactively provide physicians with this important information."

However, communicating this information would require discussion of an off-label use and would expose the company to criminal liability, the complaint states.

According to the suit, another apparent contradiction in FDA laws stems from the definition of "intended use" of drugs:

"[If] a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put."

Essentially, this provision of the law holds that a sponsor who learns that a drug approved for breast cancer is being commonly used to treat colon cancer has the obligation to get the drug labeled for colon cancer. Failure to change the label would lead to the drug being misbranded.

"Any speech by a manufacturer about an off-label use thus places the manufacturer in a Catch 22," the Allergan suit states. Thus, the manufacturer violates one section of the law to change the labeling by adding directions for off-label use, but it also violates the "intended use" regulations by not changing labeling to add directions for that use.

"Given the prevalence of off-label use, this regulatory regime means that many pharmaceutical companies operate in ongoing violation of the law, and must self-censor in the hope that the government's prosecutorial discretion will save them," the suit states.

The company is seeking a permanent injunction barring the agency from enforcing its rules on off-label promotion.

In its response, FDA said the case should be dismissed.

"Broadly, the complaint is a sweeping assault on

the FDA authority established by Congress in 1962, to require manufacturers to show that a drug is both safe and effective for each of its uses before the manufacturer promotes the product for such use," the agency said in a court filing.

The filings are posted at http://cancerletter.com/special-reports.

According to a guidance to industry published in early 2009, companies are allowed to distribute reprints of papers covering off-label uses, provided they meet certain criteria.

Under the guidance, scientific articles should be:

—Published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles; and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;

—Peer-reviewed and published in accordance with the peer-review procedures of the organization; and

—Not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article. A scientific or medical reference publication that is distributed should not be:

—Primarily distributed by a drug or device manufacturer, but should be generally available in bookstores or other independent distribution channels (e.g. subscription, Internet) where medical textbooks or periodicals are sold;

—Written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or

—Edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

Letters to the editor, journal abstracts, and reports of phase I trials cannot be disseminated, the guidance states.

Reprints should be:

—Unabridged and not marked, summarized, or characterized by the manufacturer in any way;

—Accompanied by a comprehensive bibliography of previously published studies of the off-label use and, if applicable, by a copy of a representative publication that comes to a different or contrary conclusion regarding such use; and

—Distributed separately from information that is promotional in nature.

In a provision intended to curtail ghostwriting, the reprints have to disclose "any author known to the manufacturer as having a financial interest in the product or manufacturer or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer."

While the industry was relatively pleased with the guidance, Rep. Henry Waxman (D-Calif.) chairman of the House Committee on Energy and Commerce, described it as a "long-coveted parting gift" from the Bush Administration to the industry.

"Despite revelations that drug companies manipulate medical journal articles to exaggerate the benefits and downplay the risks of their drugs, the guidance gives companies a green light to promote unapproved uses of their products by handing out these journal articles," Waxman said in a statement at the time.

In the Cancer Centers:

MSKCC To Begin Search For Varmus Successor

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find the best possible new leader for the institution, while we continue to make progress against cancer as healers, scientists, and educators."

Among the challenges facing MSKCC over the next few years is the need to find more clinical space in Manhattan by 2012, when the center is projected to outgrow its current facilities, Varmus wrote. The letter to staff is posted at http://www.mskcc.org/mskcc/shared/graphics/Varmus/Message_from_Harold_Varmus.pdf.

Varmus received the 1989 Nobel Prize for Physiology or Medicine for work with J. Michael Bishop at University of California, San Francisco, demonstrating the cellular origins of the oncogene of a chicken retrovirus. This discovery led to the isolation of many cellular genes that normally control growth and development and are frequently mutated in human cancer.

In 1993, Varmus was named by President Clinton to serve as NIH director, a position he held until the end of 1999.

Douglas Warner III, chairman of the Boards of Overseers and Managers, said in a statement, "We are

looking strategically at the leadership needs of this great institution. The presidency of MSKCC is one of the most important biomedical positions in the world, and finding the right person is the boards' highest priority."

UNIVERSITY OF NEW MEXICO CANCER CENTER has been awarded $3,254,682 from the American Recovery and Reinvestment Act for new research, equipment, positions and supplemental programs, including: $1,264,145 supplemental funding for recruitment of new faculty; $278,627 administrative supplement for investigator-initiated clinical trials and equipment; $50,168 for participation in the Adoption of New Technologies for Remote Data Capture and Protocol Authoring (ADOPT) initiative to reduce clinical cancer trial costs; $168,000 to **Robert Hromas** for research in the decatenation ability of metnase that is down regulated by auto-methylation and another $617,174 for Hromas for research in etoposide resistance; $147,045 for **Marianne Berwick** to support an existing program and case-control melanoma study; $100,000 to Melanie Royce for an NCI Clinical Team Leadership Award; $317,201 for **Claire Verschraegen** to hire a researcher who will recruit minority patients to cancer clinical trials; and $312,322 for **Angela Wandinger-Ness** for a confocal stereology microscope for UNM's Fluorescence Microscopy Core.

UNIVERSITY OF ARKANSAS for Medical Sciences was awarded a nearly $10.5 million grant from NIH to support construction of the 12-story expansion tower to the UAMS Winthrop P. Rockefeller Cancer Institute. The grant will fund completion of two research laboratory floors in the building, which is scheduled to open its first phase this summer. Funding for the grant comes from the American Recovery and Reinvestment Act of 2009 stimulus monies allocated to NIH for construction grants. The $10,458,675 grant will fund completion of the ninth and 11th floors in the institute's second tower, resulting in an additional 33,660 net square feet of research space. The project is expected to create 123 construction-related jobs and 87 research-related positions. Expected completion of the floors is mid-2011.

VANDERBILT-INGRAM CANCER CENTER said **Wendell Yarbrough**, associate professor of Otolaryngology and Cancer Biology, was awarded two NIH Challenge Grants for the study of head and neck cancer, totaling more than $1.4 million. The first grant, funded by NCI, will support human-in-mouse modeling of head and neck squamous cell cancer to predict response to therapy. The second grant, funded by the National Institute of Dental and Craniofacial Research, supports the development of a mouse model in salivary cancer.

CITY OF HOPE received a $2.5 million gift by longtime supporters **Morgan and Helen Chu** to establish an endowed chair in the Beckman Research Institute. **Richard Jove**, the institute's director and professor in the Department of Molecular Medicine, will be the first holder of the Morgan and Helen Chu Director's Chair. Morgan Chu is a partner at the Los Angeles-based law firm of Irell & Manella.

FOX CHASE CANCER CENTER said **Hormoz Ehya**, chief of cytopathology, was inducted as president of the American Society of Cytopathology in November during the organization's annual scientific meeting in Denver. Also, **Michelle Rodoletz** has joined Fox Chase as a clinical psychologist in the department of psychiatry. She comes to Fox Chase from HealthForumOnline.com and was previously associate director of the psychosocial and behavioral medicine program at Fox Chase.

N.C. CANCER HOSPITAL said Sanofi-Aventis committed $2 million toward the hospital endowment, which helps support the institution's clinical research and patient programs. In recognition of the donation, the hospital named the facility's conference center "The Sanofi-Aventis Conference Center." The hospital, which opened last August, is the clinical home of the UNC Lineberger Comprehensive Cancer Center.

OHIO STATE UNIVERSITY Comprehensive Cancer Center-Arthur G. James Cancer Hospital and Richard J. Solove Research Institute said **Michael Lairmore**, a veterinarian in the College of Veterinary Medicine at Ohio State, has been elected president of the American College of Veterinary Pathologists. At Ohio State, Lairmore chairs the department of veterinary biosciences and is associate director for basic sciences at the Ohio State Comprehensive Cancer Center. He holds a joint appointment in microbiology and immunology.

UNIVERSITY OF CALIFORNIA, San Diego School of Medicine, said **Santosh Kesari** has been named chief of the Division of Neuro-Oncology in the Department of Neurosciences and associate professor of neurosciences. Kesari, who is also the director of

neuro-oncology at the Moores UCSD Cancer Center, specializes in the treatment of brain tumors and has special interests in drug development, biomarkers for cancer detection, and the behavior and potential therapeutic use of both normal and cancer stem cells.

Kesari comes to UC San Diego from the Dana-Farber Cancer Institute and Brigham and Women's Hospital, where he was assistant professor of neurology at Harvard Medical School.

Professional Societies:

Link Elected ASCO President; Gene Testing Statement Issued

MICHAEL LINK was elected president of the American Society of Clinical Oncology for a one-year term beginning in June 2011. He will take office as president-elect during ASCO's annual meeting in Chicago in June.

Link is the Lydia J. Lee Professor of Pediatric Hematology/Oncology at Stanford University School of Medicine and director of the Bass Center for Cancer and Blood Diseases at the Lucile Salter Packard Children's Hospital at Stanford. His research interests include the biology and management of non-Hodgkin's lymphoma and Hodgkin's disease in children and the treatment of sarcomas of bone and soft tissue.

Link is a member of the FDA Oncologic Drugs Advisory Committee and recently completed a term as a member of the NCI Board of Scientific Advisors.

ASCO also elected five members to the Board of Directors and two members to the Nominating Committee. The new board members are:

Julie Vose, elected to the Undesignated Specialty seat, is the Neumann M. and Mildred E. Harris Professorial Chair and chief of the Oncology/Hematology Section in the Department of Internal Medicine at University of Nebraska Medical Center.

James Abbruzzese, elected to the Medical Oncologist seat, is chair of the Department of Gastrointestinal Medical Oncology at the University of Texas M. D. Anderson Cancer Center, and holds the Annie Laurie Howard Research Distinguished Professorship.

Robin Zon, elected to the Community Oncologist seat, is vice president/partner, Medical Oncology for Michiana Hematology-Oncology, P.C. She also serves as medical director for oncology research, Memorial Hospital of South Bend in Indiana, and lead investigator for the Northern Indiana Cancer Research Consortium.

Lori Pierce, elected to the radiation oncologist seat, is professor of Radiation Oncology at the University of Michigan School of Medicine.

Frances Shepherd, elected to the Non-US Oncologist seat, is professor of medicine at the University of Toronto.

The new Nominating Committee members are:

Howard Burris, chief medical officer and director of drug development for the Sarah Cannon Research Institute. Having received the highest number of votes, Burris will serve as the committee chairman.

Roy Herbst, chief of the Section of Thoracic Medical Oncology in the Department of Thoracic/Head and Neck Medical Oncology and holds the Barnhart Family Distinguished Professor in Targeted Therapies at M. D. Anderson Cancer Center.

Genetic Testing

ASCO issued its latest recommendations for genetic testing for cancer susceptibility. The updated statement addresses new developments over the past seven years, including the availability of genetic tests of unproven clinical benefit and direct-to-consumer genetic testing.

The updated statement advises that when determining the role of genetic testing in cancer care, it is useful to consider whether tests are professionally mediated and have clinical utility. To date, most genetic testing for cancer susceptibility can be categorized as professionally mediated and of accepted clinical utility. However, the emergence of DTC testing and tests with unproven clinical utility are beginning to require health care providers, patients, and other consumers of genetic information to think in new ways about genetic testing in oncology and preventive care.

The statement update recommends that oncologists and other health care providers who offer genetic tests continue to be guided by ASCO's 2003 statement, which says that testing should be offered when the following criteria are met:

—The individual being tested has a personal or family history suggestive of genetic cancer susceptibility;

—The genetic test can be adequately interpreted;

—The test results have accepted clinical utility.

However, the statement also acknowledges that emerging technologies like genomic profiling for low penetrance genetic variants (markers of very low disease risk) may be appropriate for patients who do not have a personal or family history suggestive of cancer risk. Patients may undergo genetic testing outside of the

traditional patient-health care provider setting through the use of DTC tests, but may ask their health care providers for assistance in interpreting the test results and obtaining follow-up care. For any genetic test, the statement urges health care providers to recommend follow-up care that is based on established cancer risk factors such as family history, behavioral factors, environmental exposures, and scientifically-validated tests for cancer risks.

ASCO also reaffirms its position that all genetic testing should be conducted with pre- and post-test counseling and recommends that DTC testing companies provide this counseling or refer people to independent providers of these services.

The statement was published in the Jan. 11 issue of the Journal of Clinical Oncology.

Research Funding:

Women Less Likely Than Men To Win Research Funding

Women were less likely than men to receive major funding for scientific research, according to a study from the University of Michigan Health System.

The study also found that only a quarter of all researchers, both men and women, who received a major early career award went on to get further federal funding within five years.

The study looked at 2,783 researchers who received the highly competitive early career awards called K08 or K23. These awards provide funding that protects a researcher's time and include a mentoring component to help nurture a young clinician-scientist's career. The funding is typically for three to five years.

The researchers then matched the K award recipients to those who were awarded an R01, a prestigious federal grant that is a milestone in a researcher's career.

They found that within five years of a K08 or K23 award, only 23 percent of all researchers had attained an R01. But while 25 percent of men had been awarded an R01, only 19 percent of women had. After 10 years, fewer than half of all K awardees had an R01: 36 percent of women and 46 percent of men.

Results appeared in the Dec. 1 issue of Annals of Internal Medicine.

"It's concerning that the whole group is not succeeding at a higher rate, and it is especially concerning that the women are doing even worse than the men," said lead study author Reshma Jagsi, assistant professor of radiation oncology at the U-M Medical School.

"The K08 and K23 grants are highly competitive, prestigious awards that are supposed to help young scientists become independent investigators," Jagsi said. "People who get these awards are expected to be the best and the brightest, and they are expected to succeed. They not only have the aptitude for and commitment to research, but the grant is supposed to give them the resources they need—protected time and mentorship."

The authors suggest that family demands, including childbirth, could pull some women scientists from their careers. Women may also be more likely to feel pressures to contribute to the clinical workload and be less successful at negotiating with their department chairs for adequate time to devote to research.

The authors also say some of the fall-off between a K award and an R01 may occur as researchers choose other career paths, such as leadership or administrative roles. They believe further research is necessary to understand how to retain promising young physicians in research careers.

"We in academic medicine need to work harder to help promising young researchers succeed," said senior study author Peter Ubel, professor of internal medicine and director of the Center for Behavioral and Decision Sciences in Medicine at the U-M Medical School.

"Research takes time and energy, and when young researchers are trying to balance work and family, the major breakthroughs might have to wait a few extra years. New researchers not only need time, they need mentorship. And they need department chairs who understand that scientific success does not require researchers committing every aspect of their lives to their science," Ubel adds.

The study authors urge strengthening the mentoring component of the K awards and considering an increase to the award amounts.

"We as a society have invested critical resources in these individuals. Our findings suggest dysfunction in the pipeline of physician-scientists," Jagsi says. "This is not an easy career path for anyone, and it may be particularly hard for women. We need to figure out how to make this a more tenable career path, and right now both men and women seem to need additional support."

Philanthropy:

Stand Up To Cancer Awards 13 Grants To Young Scientists

Stand Up To Cancer said it has awarded $9.68 million to support high-risk/high-reward cancer research conducted by 13 young scientists.

Over a three-year period, each investigator will receive a total of up to $750,000 as part of SU2C's Innovative Research Grants program.

These grants represent the second major funding commitment made by Stand Up To Cancer. Earlier this year, SU2C awarded $73.6 million to five interdisciplinary, multi-institutional Dream Teams with more than 300 members from 20 institutions. Since its launch in May 2008, SU2C has raised more than $100 million.

The 13 Innovative Research Grant recipients for 2009 are: **Fernando Camargo,** Children's Hospital Boston; **Elizabeth Lawlor,** Childrens Hospital Los Angeles; **Matthew Levy,** Albert Einstein College of Medicine of Yeshiva University; **Markus Müschen,** Childrens Hospital Los Angeles; **William Pao,** Vanderbilt-Ingram Cancer Center; **Charles Roberts,** Dana-Farber Cancer Institute; **Rajat Rohatgi,** Stanford University; **José Silva,** Columbia University Medical Center; **Kimberly Stegmaier,** Dana-Farber Cancer Institute; **Muneesh Tewari,** Fred Hutchinson Cancer Research Center; **Loren Walensky,** Dana-Farber Cancer Institute; **David Weinstock,** Dana-Farber Cancer Institute; and **Hang Yin,** University of Colorado at Boulder.

"We asked our best and brightest young researchers to step outside their comfort zones and strive to make big differences with bold initiatives," said Richard Kolodner, professor of medicine at the University of California, San Diego, senior researcher at the Ludwig Institute for Cancer Research and chairman of the review committee for the grants. "If these projects come to fruition, some of the ideas could be game-changers in cancer research."

American Association for Cancer Research assembled the SU2C Scientific Advisory Committee and the Innovative Research Grants Review Committee, which administered the scientific review process and will provide ongoing scientific oversight of the grants.

American Cancer Society®

MEN2 Thyroid Cancer Research Scholar, Mentored Research Scholar, and Postdoctoral Fellows:

A Request for Applications

Research Scholar Grant Eligibility Expanded to Include Independent Investigators at any Career Stage

Next Receipt Deadline: April 1, 2010

The American Cancer Society announces this revised Request for Applications for the American Cancer Society MEN2 Thyroid Cancer Consortium. Funds remain available for up to seven (7) Research Scholar and/or Mentored Research Scholar grants and up to five (5) Postdoctoral Fellow grants will be awarded. The Consortium will be led by a single renowned senior scientist who will be awarded the American Cancer Society MEN2 Thyroid Cancer Professorship and act as leader for the overall program (details at links below). Appropriate areas of investigation include, but are not limited to: understanding consequences of RET mutations, molecular events underlying the development of MEN2-related tumors, improved animal models of MEN2, new screening and monitoring tools, new imaging approaches, and new pharmacologic and other strategies to blunt the effects of mutations in RET and other genes associated with medullary thyroid cancer.

Individuals applying for a Research Scholar Grant must have an independent research or faculty position and can be at any stage of their career. These grants will be awarded for up to $200,000 a year, direct costs, for 5 years. Mentored Research Scholar Grants will be awarded to junior faculty members with a doctoral degree in a clinical or cancer control research discipline (e.g., M.D., and/or Ph.D.) that are within the first four years of a full time faculty appointment or equivalent, and have no more than 4 years of postdoctoral research experience immediately prior to their faculty appointment. The successful applicant is expected to transition into a career as an independent investigator. Awards are for up to five years and for up to $135,000 per year direct costs.

Applicants for Postdoctoral Fellowships must have obtained their doctoral degree prior to activation of the fellowship. Awards are for three years with progressive stipends of $44,000, $46,000, and $48,000 per year, plus a $4,000 per year institutional allowance. Individuals who have held a PhD or MD and have been doing research for more than 4 years at the time of application are not eligible.

Deadline: Complete applications are due by April 1, 2010. Funding will begin January 1, 2011. For information regarding funding policies or to obtain an application, go to https://proposalcentral.altum.com or refer to the ACS website at www.cancer.org/research: select Funding Opportunities followed by Index of Grants, scroll down to Special Initiatives and select the appropriate RFA for MEN2 Thyroid Cancer.

For inquiries, contact Charles Saxe, PhD at (404) 929-6919 (charles.saxe@cancer.org).