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White House Expected To Nominate Nobel Laureate Varmus As NCI Director

By Kirsten Boyd Goldberg and Paul Goldberg

Harold Varmus has emerged as the leading candidate for the top job at NCI, sources said.

Varmus, who is in the process of phasing out of his job as president of Memorial Sloan-Kettering Cancer Center, was expected to be named to head the institute later this week or by the middle of next week.

The expected appointment of 70-year-old Varmus represents two firsts: he would be the first Nobel laureate and the first former NIH director to head the cancer institute. He would be the second cancer center director to lead the institute, following the current director, John Niederhuber, who headed

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In the Cancer Centers:

Ian Thompson Named Director Of CTRC; Peter Vogt Wins Szent-Györgyi Prize

THE CANCER THERAPY & RESEARCH CENTER at The University of Texas Health Science Center at San Antonio named **Ian Thompson** to the permanent position of executive director. Thompson has served as interim executive director over the past five months.

In an email to CTRC faculty and staff, Thompson wrote that for now, he will continue to maintain his responsibility for leading the Department of Urology as chairman and directing the genitourinary cancer clinic at the Medical Arts & Research Center, the practice comprised of the Health Science Center's School of Medicine faculty.

Thompson said his first priority as executive director would be renewal of the NCI P30 grant next year. Other priorities include creating more integrated multidisciplinary clinics, continuing the integration of the CTRC's research and clinical expertise, and expanding community outreach to create opportunities for partnerships and philanthropic development.

PETER VOGT, professor in the Department of Molecular and Experimental Medicine at The Scripps Research Institute, is the recipient of the 5th Annual Szent-Györgyi Prize for Progress in Cancer Research, awarded by the National Foundation for Cancer Research.

Vogt's discovery of *src,* the first oncogene, launched a new era for cancer research and made seminal contributions to the understanding of the role of oncogenes, proto-oncogenes and many other critical molecular mechanisms

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Varmus Previously Described NCI Move As "Far-Fetched"

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the University of Wisconsin Comprehensive Cancer Center.

Varmus did not respond to an email from The Cancer Letter.

Last week, in an email to Science, he described reports of his heading to NCI as "far-fetched."

"I have no idea where you are getting such rumors but I can tell you that no one from the only reputable source, the White House, has contacted me!" he wrote in an email to the journal. "However, I've just renewed my R01 [NIH research grant] and am purchasing a new apartment on the West Side. Draw your own conclusions!" The article is posted at http://news.sciencemag.org/scienceinsider/2010/03/varmus-dispels-cancer-institute.html.

Nonetheless, multiple sources in the federal government and outside it confirmed that the announcement appears imminent.

It remains to be seen how Varmus's expected move would affect Memorial Sloan-Kettering. When he announced his decision to leave, Varmus said he would stay in his job until a replacement is found.

Varmus was part of the unstructured selection process, which was headed by NIH Director Francis Collins. The NCI directorship, a presidential appointment, has been offered to at least three scientists who apparently turned it down, sources said (The Cancer Letter, Feb. 12, 2010).

Varmus and Collins were among advisors to President Obama's 2008 campaign, and after the election, Varmus was named co-chairman of the President's Council of Advisors on Science and Technology.

In 1989, Varmus, then a professor at University of California, San Francisco, shared the Nobel Prize in Physiology or Medicine with J. Michael Bishop for their discovery of the cellular origin of retroviral oncogenes. A brief autobiography, written at the time, is posted at http://nobelprize.org/nobel_prizes/medicine/laureates/1989/varmus-autobio.html.

Varmus was appointed NIH director by President Clinton in 1993 and served through 1999. During his tenure, Congress nearly doubled the NIH budget. At NIH, Varmus pushed the institutes to apply more rigorous review by external advisors and loosen controls on hiring to enable recruitment of more accomplished scientists and administrators.

Toward the end of his tenure as NIH director, he began to advocate for streamlining what he called a "cumbersome" NIH structure of institutes and centers, and greater authority for the director's office (The Cancer Letter, Aug. 6, 1999). This set in motion the reorganization and authorities that Congress granted his successor, Elias Zerhouni.

Varmus also has been a leading champion for open access to the results of publicly-funded research, arguing that scientists, not journal editors, should control the dissemination of their research. He advocated a system in which journals make their articles freely available on PubMed Central six months after publication. He is co-founder and chairman of the board of directors of the Public Library of Science, a not-for-profit open access publisher, and he is a member of the board of trustees of BioMed Central, the largest publisher of open-access journals.

Since January 2000, Varmus has served as president of Memorial Sloan-Kettering Cancer Center. His book, "The Art and Politics of Science," published by W. W. Norton in 2009, describes his decision to become a scientist, his cancer research, and his work as "a political scientist."

On Jan. 12, MSKCC announced that Varmus "asked the MSKCC Boards of Overseers and Managers to begin a search for his successor." The announcement also stated, "Varmus indicated that he plans to continue in his present position until a successor has been identified, and he will remain the head of his laboratory in the Cancer Biology and Genetics Program at the

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Sloan-Kettering Institute and an active member of the teaching faculty" (The Cancer Letter, Jan. 15, 2010).

Niederhuber, who was appointed by President Bush three years ago, is credited with stabilizing the institute after Bush's first appointee, Andrew von Eschenbach, a urologist and family friend, attempted to organize the institute around a blatantly absurd promise to "eliminate suffering and death due to cancer" by 2015.

Federal Agencies:

Biomarkers Consortium Starts I-SPY 2 Trial In Breast Cancer

The Biomarkers Consortium, a public-private partnership that includes FDA, NIH, and major pharmaceutical companies, led by the Foundation for the National Institutes of Health, announced the launch of a clinical trial to help screen promising new drugs being developed for women with high risk, fast-growing breast cancers.

The I-SPY 2 trial will employ a clinical trial model that uses genetic or biological markers from individual patient tumors to screen new treatments, identifying which treatments are most effective in specific types of patients. An adaptive trial design will enable researchers to use early data from one set of patients to guide decisions about which treatments might be more useful for patients later in the trial, and eliminate ineffective treatments more quickly.

"I-SPY 2 promises to leverage convergence of progress on a number of research fronts to speed the evaluation of promising new breast cancer drugs using molecular cancer biomarkers to identify those agents that are effective in specific subpopulations of breast cancer patients," said NCI Deputy Director Anna Barker and co-chairman of The Biomarkers Consortium Cancer Steering Committee. "This will allow us to finally design advanced, smaller and less expensive Phase III trials that test the right drugs in the right patients."

The large-scale trial involves a collaboration by scientists from NCI, FDA, and nearly 20 cancer research centers.

"The I-SPY 2 trial explores a whole new way to rapidly screen new cancer treatments and match the therapy to specific markers," said Janet Woodcock, director of the FDA Center for Drug Evaluation and Research. "Developing individualized medicines needs a solution bigger than any one group can generate. The Biomarkers Consortium is a public-private collaboration of scores of organizations working together to achieve this critical mission. It is a model for the future and FDA is proud to be a founding member."

The I-SPY 2 trial will focus on treatment in the neoadjuvant therapy setting, in which chemotherapy is given to patients to reduce tumor size before surgery. All patients will receive the current standard of care and most participants will receive one investigational drug. A distinctive feature of the trial is that it will screen multiple drugs from multiple companies—up to 12 different cancer drugs over the course of the trial. In order to do this, FNIH received a master Investigational New Drug approval from the FDA, which allows the team to graduate, drop, and add drugs throughout the course of the trial without having to stop the trial to write a whole new protocol. This will dramatically reduce the time it takes to move from one drug to another in the trial.

Five new investigational agents currently in development by three pharmaceutical companies have been selected for testing as part of the first phase of the trial, and will be donated by the companies with each agent representing a different drug class or type of chemical mechanism for attacking cancer. The first agents expected to be tested include:

• **ABT-888 (veliparib)**, a PARP inhibitor being developed by Abbott Laboratories.

• **AMG 655 (conatumumab)**, an APO/TRAIL inhibitor and **AMG 386**, an angiogenesis inhibitor, both under development at Amgen.

• **CP-751,871 (figitumumab)**, an IGFR inhibitor and **HKI-272 (neratinib)**, a Pan ErbB inhibitor both under development at Pfizer, Inc.

I-SPY 2 will be coordinated by two principal investigators, Laura Esserman, professor and director, Carol Franc Buck Breast Care Center at the University of California, San Francisco; and Donald Berry, professor and chairman, Department of Biostatistics, Division Head, Division of Quantitative Sciences at University of Texas M.D. Anderson Cancer Center.

Clinical operations of the trial will be managed by Angie DeMichele, associate professor of medicine and epidemiology of the Abramson Cancer Center at the University of Pennsylvania Medical Center. Nola Hylton, professor of radiology and director of the Breast MRI Research Program at UCSF, developed new tools to use MRI as a quantitative measure of response to therapy developed in a previous research study, I-SPY 1. These tools will be an integral part of the I-SPY 2 trial and will help validate whether MRI tumor volume change, rather than surgery, can be used as a way of determining response to treatment.

"I-SPY 2 will provide a path to personalized

medicine," said Esserman, a breast cancer surgeon and researcher at UCSF. "The collaborative power behind this trial is truly transformational for breast cancer patients and for cancer research as a whole. We have set up a system where everyone can learn faster and, together, we can dramatically reduce the amount of time and the cost to bring those drugs to market that can make a difference in whether women live or die."

"A considerable advantage for trial participants in I-SPY 2 is that drugs and drug combinations can be given to more patients in the trial as soon as they are proven to be clearly beneficial," said Berry, who supervised development of the innovative Bayesian adaptive design for I-SPY 2. "By the same token, drugs that are ineffective in the trial can be dropped just as quickly, which increases the safety of the study."

I-SPY 2 is expected to cost approximately $26 million over five years. Funding will come from a variety of sources. Safeway Inc. will contribute a sizeable portion of proceeds from the Safeway Foundation's annual October Breast Cancer Awareness fundraising initiative to I-SPY 2. A major foundational investment has also been secured from Johnson & Johnson, and the project is being developed in part with funds from Genentech and Lilly. FNIH is working to raise the remaining funds from pharmaceutical and other companies, non-profit cancer organizations, and philanthropic foundations and individuals.

Breast cancer advocates have helped create brochures, a website, and DVD to inform patients about the trial and to ensure that the design of the trial is as convenient for patients as possible.

All results from the trial will be published by the investigators via articles in peer-reviewed scientific journals. The large amount of valuable data expected to be generated by the project will be stored in a database at UCSF and M.D. Anderson using tools developed as part of NCI's Cancer Bioinformatics Grid (caBIG) initiative.

FNIH will manage the trial as part of The Biomarkers Consortium, a public-private biomedical research partnership that endeavors to develop and qualify biomarkers to speed the development of medicines and therapies for detection, prevention, diagnosis, and treatment of disease and improve patient care. Members of the Consortium include over 50 partners including the NIH, FDA, the Pharmaceutical Research and Manufacturers of America, the Centers for Medicare & Medicaid Services, the Biotechnology Industry Organization, major pharmaceutical companies, and numerous non-profit medical research organizations.

Up to 20 cancer centers will recruit and treat patients as part of the trial. Currently selected centers include:

UCSF Helen Diller Family Comprehensive Cancer Center, Abramson Cancer Center, University of Minnesota Medical Center, Moores UC San Diego Cancer Center, University of Texas M.D. Anderson Cancer Center, University of Colorado Cancer Center, Mayo Clinic-Scottsdale, Mayo Clinic-Rochester, OHSU Knight Cancer Institute, Inova Health System of Falls Church, Va., University of Chicago Comprehensive Cancer Center, Harold C. Simmons Comprehensive Cancer Center at University of Texas Southwestern Medical Center-Dallas, USC Norris Comprehensive Cancer Center, Winship Cancer Institute of Emory University, University of Kansas Cancer Center, Cardinal Bernardin Cancer Center at Loyola University.

Technologies from Agendia, of Huntington Beach, Calif., and Sentinelle Medical Inc., of Toronto, Canada, will be used to measure biomarkers in the trial.

Trial information is available at http://www.ispy2.org.

NCI Programs:

Advisors Approve New SBIR Project In Molecular Analysis; Barrett's Esophagus Network

By Kirsten Boyd Goldberg

Advisors to NCI approved in concept the institute's plan to issue a Request for Applications under the Small Business Innovation Research Program to support the development of molecular analysis technologies.

The NCI Board of Scientific Advisors voted unanimously in favor of the project, which would use $4 million in Congressionally-mandated SBIR set-aside funding over three years. Five to seven awards would be supported.

The concept proposes to target "those technologies whose development has already been supported, or would have been supported, with NCI divisional funding" through the NCI Innovative Molecular Analysis Technologies program, according to the concept statement.

The BSA also voted 16-3, with two abstentions, in favor of a new grants program that would create a translational research network to study the increase in incidence of esophageal adenocarcinoma and its precursor lesions, Barrett's esophagus.

The Barrett's Esophagus Translational Research

Network would support five awards for a total of $35 million over five years.

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

In the Cancer Centers:

Vogt Honored For Discovery Of *src*, The First Oncogene

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of cancer, the foundation said.

"Dr. Vogt's fundamental basic science discovery of cancer-causing genes in retroviruses shed the first light on the genetic paradigm that now dominates our understanding of cancer development in humans," said **Ronald DePinho**, chair of the Szent-Györgyi Prize Selection Committee and last year's recipient. "His groundbreaking work has yielded several of the most important targets in cancer therapy. We are honored to present this coveted award to an individual of iconic stature."

UC SAN DIEGO MEDICAL CENTER and the Moores UCSD Cancer Center named **Bob Carter** chief of the division of neurosurgery. Carter, a neurosurgeon and scientist, will lead the effort to form a multidisciplinary Brain Tumor Treatment Center that will serve as a destination for patients and referring physicians seeking integrated care from multiple specialists in one location.

He joined UCSD from Massachusetts General Hospital and Harvard Medical School where he specialized in surgical treatment of brain and skull base tumors, brain aneurysms, and other intracranial neurologic diseases. Carter was one of the first researchers to identify a genetic signature for brain tumors in blood samples of cancer patients.

At UCSD, his goals include developing a specialized ICU for neurological patients, offering rapid assessment and treatment of complex neurological illnesses including stroke, brain hemorrhage, traumatic brain injury, coma, and neurological infections.

FRED HUTCHINSON CANCER RESEARCH CENTER evolutionary biologist **Harmit Singh Malik** received the 2010 Vilcek Prize for Creative Promise in Biomedical Science for his research on the co-evolution of humans and diseases.

The award also went to the California Institute of Technology biochemist Alexander Varshavsky. The Vilcek Foundation awards $25,000 cash prizes to celebrate "immigrant achievement in biomedical science and arts."

STANFORD SCHOOL OF MEDICINE professor of oncology **Branimir Sikic** received the Croatian Presidential Medal for Science and Medicine.

The award recognizes Sikic's achievements in cancer research and his contributions to medical education and cancer care and prevention in Croatia. Sikic is an associate director of the Stanford Cancer Center and is an expert in the pharmacology of cancer drugs. His lab studies mechanisms of drug resistance and predictive therapeutic biomarkers; his clinical research team develops new cancer therapies.

Sikic's family emigrated to the U.S. when he was eight years old. His work in Croatia began in the mid-1990s, when the country was economically devastated. Croatian physicians lacked the resources to attend medical meetings, so Sikic organized and led the Central European Oncology Congress, a continuing medical education meeting there.

In 2007, Sikic joined a delegation of medical experts, including then NIH Director **Elias Zerhouni**, to advise Croatian officials on strategic planning in clinical oncology. In addition to spawning projects between the NCI and Croatian investigators, a key outcome of the meeting was a 2008 law that banned cigarette smoking in public places in Croatia.

UNIVERSITY OF FLORIDA named **David Nelson** to the position of director of the Clinical and Translational Science Institute. Nelson is a professor of medicine and a leader in liver transplantation and hepatology at the UF College of Medicine.

UF won a competitive Clinical and Translational Science Award last year from NIH. The $26 million award over five years will help lay a framework for accelerating the progress of translational research and medical advances at the university. The institute, a partnership of several colleges and entities within the university and in the wider community, also is supported by $23 million from the UF Office of Research and $70 million in commitments from the College of Medicine. Nelson oversees more than 15 clinical trials and his NIH and industry-sponsored research grants top $8 million.

OHIO STATE COMPREHENSIVE CANCER CENTER and Richard J. Solove Research Institute

received a $1.25 million NCI grant to study how genetic interactions affect risk for colorectal cancer. **Amanda Toland**, an assistant professor of Molecular Virology, Immunology and Medical Genetics at the OSUCCC, is the principal investigator on the study. Other OSUCCC-James team members involved in the study include **Heather Hampel**, **Umit Catalyurek**, **Soledad Fernandez** and **Lai Wei**.

UNIVERSITY OF NEBRASKA Medical Center said **Vimla Band** has been named chairman of the Department of Genetics, Cell Biology and Anatomy. Band joined UNMC in 2007 as professor in genetics, cell biology and anatomy and as vice chairwoman for research.

She and her husband, **Hamid Band**, were recruited to UNMC from Northwestern University. Hamid Band is a professor in the Eppley Institute for Research in Cancer and associate director for translational research at the UNMC Eppley Cancer Center.

Professional Societies:

Connie Yarbro To Receive ONS Lifetime Achievement Award

THE ONCOLOGY NURSING SOCIETY announced its annual awards to be presented at the society's 35th Annual Congress, scheduled for May 13–16 in San Diego:

• **Connie Henke Yarbro**, of Destin, Fla., is the recipient of the Lifetime Achievement Award. Yarbro is the editor of Seminars in Oncology Nursing and an adjunct clinical associate professor at the University of Missouri-Columbia Sinclair School of Nursing.

In 1975, Yarbro co-founded ONS and has served in leadership roles within ONS since then to help continue to advance the mission and vision of the Society. She served as president and treasurer of ONS. In 1981, she helped found the ONS Foundation and became the Foundation's first president. Yarbro also is active in the International Society of Nurses in Cancer Care and has served as their president.

• **Kathleen Mooney** was named the Distinguished Researcher. She is a professor and Peery Presidential Endowed Chair in Nursing at the University of Utah College of Nursing in Salt Lake City. Mooney's research has focused on improving unrelieved symptoms related to cancer and its treatment. Unique in relation to traditional approaches to symptom care, this research focuses on a mechanism to improve communication about unrelieved symptoms and uses innovative technology to provide added support and surveillance that efficiently keeps the oncology team informed. The ultimate goal is to develop the program for translation and adoption in everyday ambulatory clinical practice.

• **Cynthia Cantril** received the Distinguished Service Award. Cantril is the coordinator of cancer support services and nurse navigator at Martin-O'Neil Cancer Center at St. Helena Hospital in California. The award recognizes her contributions in assisting ONS to fulfill its mission at the national and local levels in the study, research, and exchange of information, experiences, and ideas leading to improved oncology nursing. Cantril is a co-founder of ONS and served as vice president of ONS's first board of directors. The award reflects on her role as a dedicated nurse navigator for her patients.

• **Darcy Burbage** received the Pearl Moore Making a Difference Award. Burbage is a clinical nurse specialist in the Breast Center at the Helen F. Graham Cancer Center at Christiana Care Health System in Newark, Del. The award recognizes her contributions to the oncology nursing profession at the local and regional levels.

• **Sultan Kav** received the International Award for Contributions to Cancer Care. Kav is an associate professor at Baskent University in Ankara, Turkey. The award recognizes her impact on cancer care and her work to improve patient teaching throughout the world by educating nurses who can then better educate their patients.

• **Lois Trench-Hines** has been awarded honorary membership to the Oncology Nursing Society. Trench-Hines is the president and founder of Meniscus Limited, a healthcare communications company located in West Conshohocken, Penn. In 1982, she founded Meniscus Limited as a vehicle to fill the need for keeping oncology nurses up to date with changing cancer treatments. Through ONS, Trench-Hines established a $3,000 Multidisciplinary Education and Practice Career Development Award to promote lifelong learning and enhanced multidisciplinary collaboration in the care of patients with cancer. The grant has been awarded annually since 1989.

THE ASCO CANCER FOUNDATION has awarded $2.7 million in two grants.

One of the projects focuses on the challenges facing young women with breast cancer, and the other seeks to bring high-tech cancer care to rural settings.

The grants are the first to be awarded through the new Improving Cancer Care Grants program, funded

by Komen for the Cure. At $1.35 million each, they represent the largest awards in the history of the ASCO foundation.

The recipients of these grants submitted proposals to develop and implement new solutions to existing challenges in cancer care, the foundations said. The awards were made to:

• Dana-Farber Cancer Institute. The institute will address the concerns facing young women who are receiving breast cancer treatment, particularly concerns about fertility. Researchers will implement a program in community care settings to provide additional care, support and education for young women with breast cancer, and education and clinical tools to assist providers. The program will be evaluated in comparison to another intervention through a randomized controlled trial involving oncology practices. The project is led by **Ann Hart Partridge**. Other team members include **Karen Emmons**, **Mary Greany**, **Kathryn Ruddy** and **Julie Najita**.

• **Shaw Regional Cancer Center**. To help bridge the gap between small radiation oncology rural practices and rapidly advancing technology in larger group practices, Shaw Regional Cancer Center in Edwards, Co., will develop a program which uses the internet for a web based radiation oncology treatment planning review program. Radiation oncologists will virtually collaborate with experts in breast radiation oncology, mimicking traditional patient chart reviews. Rural oncology practices will be able to consult with some of the top radiation oncologists in the world. **Patricia Harrigan Hardenbergh** will serve as the principal investigator for the program and lead the team from the Shaw Regional Cancer Center. **Carol Hahn** of Duke University will be a co-investigator on the project.

RADIATION ONCOLOGY INSTITUTE has issued a request for proposals to conduct a national research needs assessment for radiation oncology.

The results will be the main tool ROI will use to set the national research needs agenda and frame its research priorities. These priorities will then be used by ROI to determine its research projects. ROI plan to use the RFP process to identify a vendor who would perform a needs assessment through a variety of methods including interviews, focus groups and surveys of thought leaders in radiation oncology.

The RFP can be found online at www.roinstitute.org. Applications deadline: April 16.

AMERICAN SOCIETY FOR RADIATION ONCOLOGY named **Sheila Madhani** assistant director of health policy and **Anushree Vichare** as a research health analyst at the Research and Health Policy departments. Madhani is the former senior public affairs adviser at Holland and Knight LLC. Vichare worked at the Virginia Department of Health as an HIV/AIDS quality assurance epidemiologist.

FDA News:

FDA Seeks Public Comment On Industry Transparency

FDA is seeking public comment on the proposal to form a Task Force on Increasing Transparency With Regulated Industry.

The agency formed the internal task force in response to the Obama administration's commitment to achieve "an unprecedented level of openness in government."

The group is developing recommendations for making information about FDA activities and decisions more useful, understandable, and readily available, while appropriately protecting confidential information.

The group has held public meetings last June and last November and, based on input, has divided its work into three phases:

• The first phase, creating a web-based resource called "FDA Basics" to provide information on commonly misunderstood aspects of the agency, has been completed.

• The second phase, improving FDA's disclosure of information to the public, is underway and the agency intends to issue draft proposals for public comment soon.

• The request for comment for the third phase follows a series of January sessions with members of regulated industry. Transcripts and summaries of those listening sessions are available at http://www.fda.gov/transparency and at http://www.regulations.gov.

For this final phase, FDA is seeking comment on how it can make improvements in the following areas:

• Training and education for regulated industry about the FDA regulatory process in general and/or about specific new requirements.

• The guidance development process.

• Maintaining open channels of communication with industry routinely and during crises.

• Providing useful and timely answers to industry questions about specific regulatory issues,

Electronic comments may be submitted to http://www.regulations.gov. Deadline is April 12.