THE CANCER LETTER

Vol. 34 No. 45
Dec. 12, 2008

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

Trials Could Start Earlier If Model Contract Language Adopted, NCI, CEO Group Say

By Kirsten Boyd Goldberg

NCI and the CEO Roundtable on Cancer have developed model clinical trial agreement language to help shorten the time it takes companies and research institutions to finalize the contracts necessary to begin trials of experimental therapies.

Contract negotiations between pharmaceutical and biotechnology companies and academic medical centers often can take up to a year. Clinical trialists complain that these negotiations often begin de novo, each time an agreement is required. Yet, the final agreements usually contain quite similar language.

The standardized contract language could "reduce contract negotiation

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White House Transition:

NCI Director Among Bush Appointees Asked To Submit Letters Of Resignation By Jan. 20

By Paul Goldberg

NCI Director John Niederhuber is among government officials who have been instructed by the White House to submit letters of resignation by noon on Jan. 20, 2009.

At least until Niederhuber's immediate predecessor, Andrew von Eschenbach, the NCI director's position hasn't been blatantly political, and in recent memory, institute directors stayed on for some time following the changes of administrations.

Most recently, Richard Klausner, a Bill Clinton appointee, announced his resignation on Sept. 11, 2001, nine months after George W. Bush moved into the White House.

FDA Commissioners, too, have been known to stay on. David Kessler, a George H.W. Bush appointee, stayed on for three-and-a-half years into Clinton's presidency.

Most observers agree that von Eschenbach shouldn't procrastinate with his order of book boxes and packing tape.

On Dec. 11, Obama formally nominated Tom Daschle to the positions of HHS secretary and director of what will be a new White House Office on Health Reform, paving the way for announcing appointments for lower positions at the department.

The NIH transition team includes former NIH Director Harold Varmus

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NCI Urges Companies, Centers To Use Model Contract Clauses

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time from as many as 300 days to as few as 30 days," said James Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis, who led the institute's involvement in the project.

In a presentation Dec. 8 to NCI's Clinical Trials Advisory Committee, Doroshow urged cancer center directors, clinical trialists, and industry executives to inform their organizations about the model language. "The only way this will get used is if people insist," he said.

NCI Director John Niederhuber said the institute cannot mandate the use of the model language. "It's voluntary," he said. "We can't enforce it and we can't incentivize it. We hope that simply because it's there, it will be so obvious to everyone that this is the way to go, that they will utilize it. If our cancer center directors don't work hard to get this done, it won't."

Two years ago, the NCI Clinical Trials Working Group recommended that industry and academic medical centers work together to develop a model clinical trial agreement.

The CEO Roundable on Cancer, a nonprofit organization primarily of pharmaceutical companies, made this effort the priority for its Life Sciences Consortium, a working group that includes participants from companies, cancer centers, and cooperative groups.

The consortium obtained copies of 78 clinical trial agreements from the participating organizations, including 49 redacted copies of final negotiated agreements and 29 agreement templates.

The project identified seven key clauses: intellectual property, study data, publication rights, subject injury, confidentiality, indemnification, and biological samples. An analysis identified 45 key concepts in these categories, captured exact language, and analyzed similarities and differences.

The analysis found that final negotiated agreements showed greater than 67 percent convergence on the majority of concepts analyzed. The project then drafted proposed clauses based on the common concepts analyzed, obtained comment on the clauses from legal and company representatives, and refined the proposed clauses.

"About two-thirds of the time, negotiated agreements showed an enormous degree of convergence," Dorshow said. "People ended up in the same place, over and over again."

Based on an analysis of the agreements, the group developed some proposed language. "Perhaps the hardest part of this was to meet by phone in an enormous number of conference calls, with technology transfer staffs and business staffs, of the cancer centers and pharma companies, and get input from the participants and refine the clauses," Doroshow said.

CTAC member Gabriel Leung, executive vice president of OSI Pharmaceuticals, said the consortium plans to work through the Pharmaceutical Research Manufacturers Association and Biotechnology Industry Organization to send information on the model language to companies. He discussed a proposed certification process for companies using the templates.

"This has been a system that has been owned by the people invested in the process, not by the people invested in the outcome, and that's why this think has not worked for so long," said CTAC member David Parkinson, president and CEO of Nodality Inc.

"I don't think you need to certify anybody," Parkinson said. "You just have companies announce that they will preferentially work with institutions that use it. You have institutions announce that they will preferentially work with companies using this language.

"Darwinian selection will take care of the rest."

CTAC member Richard Schilsky, chairman of Cancer and Leukemia Group B, said his group found the language acceptable. "I think it will work well for most if not all of the cooperative groups," he said. "We find that

THE CANCER LETTER

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PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

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

Subscription $375 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.
Founded Dec. 21, 1973, by Jerry D. Boyd.

every negotiation with a company is a new negotiation. It doesn't matter if it's a company we've been working with for years, or a drug we've been working on with multiple studies, or a contract that has had several life cycles. Every time a new employee in the company touches it, it starts over. So this is absolutely critical that the CEOs really push this."

The model clauses for clinical trials agreements are available at http://www.ceoroundtableoncancer.org/.

Industry participants in the Life Sciences Consortium include AstraZeneca, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Novartis, OSI Pharmaceuticals, Pfizer, Quintiles, Sanofi-Aventis, Schering Plough, and Wyeth.

NCI-designated cancer centers that participated included University of Arizona, City of Hope, University of Chicago, University of Colorado, Dana-Farber, Fox Chase, Johns Hopkins, Mayo Clinic, Moffitt, M.D. Anderson, University of Pittsburgh, Roswell Park, UNC Lineberger, and UCSF.

Cooperative groups that participated included: Eastern Cooperative Oncology Group, Southwest Oncology Group, Cancer and Leukemia Group B, Gynecologic Oncology Group, and Children's Oncology Group.

Funding Model for Complex Trials

An NCI working group has developed criteria for selection of phase III trials to receive an additional $1,000 per patient reimbursement based on the complexity of the trial.

The criteria were developed at the recommendation of the Clinical Trials Working Group, which suggested that complex trials receive a higher capitation rate than the $2,000-per-patient amount for most NCI-funded trials.

The "complexity model for phase III trials" developed by the Complexity Model Working Group, identified the key elements of studies thought to require additional work at participating sites and categorized these elements into three main tiers.

The elements are: number of study arms, informed consent process, registration or randomization steps, complexity of investigational treatment, length of investigational treatment, feasibility and personnel impact, data collection complexity, follow-up requirements, ancillary studies, and participant feasibility and enrollment.

The model was tested by cooperative groups, which were allowed to recommend up to five trials for additional funding.

NCI's Cancer Therapy Evaluation Program reviewed the recommendations and selected 14 trials. FY08 funds were distributed beginning June 1.

The working group continues to refine the model and monitor the impact of the program, NCI staff said.

Industry News:

PhRMA Tightens Restrictions On Direct-To-Consumer Ads

By Paul Goldberg

Responding to pressure from Capitol Hill, the Pharmaceutical Research Manufacturers Association has tightened restrictions on direct-to-consumer advertising by its member companies.

DTC has been a symbol of America's special relationship with the pharmaceutical industry. Only one other country—New Zealand—permits the practice. PhRMA's move appears to be a direct response to an investigation by the Democratic side of the House Committee on Energy and Commerce (The Cancer Letter, May 9).

The committee's hearing seven months ago focused on DTC advertising of several drugs, including the Johnson & Johnson erythropoiesis-stimulating agent Procrit (epoietin-alpha). Documents released by the committee demonstrated that FDA staff attempted to stop those ads as misleading, but their efforts were thwarted by the industry-friendly FDA Office of Chief Counsel.

The agency clamped down on the use of ESAs after emergence of data that showed increases in toxicities and suggested promotion of disease progression.

PhRMA's voluntary guidelines now state that companies shouldn't "promote medicines for off-label uses, including in DTC advertisements." The Procrit ads, which ran for seven years, between 1998 and 2005, went beyond the label, claiming to relieve "fatigue" and give patients "strength for living."

The association's rules also include the following changes:

—"DTC product advertisements featuring actors in the roles of healthcare professionals should identify that actors are being used. If actual healthcare professionals are featured and are compensated for their appearance, the advertisement should acknowledge the compensation.

—"Television or print advertisements featuring a celebrity endorser should accurately reflect the opinions, findings, beliefs or experience of the endorser.

Companies should maintain verification of the basis of any actual or implied endorsement, including whether the endorser is or has been a user of the product.

—"Print advertisements should include FDA's MedWatch number for reporting of potential adverse events and DTC television advertisements should include the company's toll-free number or refer patients to a print advertisement that contains the MedWatch number.

—"An existing principle regarding education of health professionals prior to a DTC campaign for a new medicine or indication is expanded to add that companies should consider individually setting specific periods of time for education before launching a branded DTC campaign."

—"A revised principle includes language strengthening guidance related to the content and placement of DTC advertisements with adult-oriented content. Specifically, the new version states that DTC television or print advertisements 'containing content that may be inappropriate for children' should be placed in programs or publications 'reasonably expected to draw an audience of approximately 90 percent adults (18 years or older).'

—"An existing requirement addressing risk-benefit balance in DTC advertising is strengthened to specify that risks and safety information, including the substance of relevant boxed warnings, should be 'presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content.'

Reps. John D. Dingell (D-Mich.), Chairman of the Committee on Energy and Commerce, and Bart Stupak (D-Minch.), Chairman of the Subcommittee on Oversight and Investigations, said the new restrictions are a step in the right direction, but are insufficient.

The restriction stop short of mandating a two-year prohibition on DTC ads for newly approved drugs, as recommended by the Institute of Medicine, doesn't propose the completion of valid clinical outcomes studies on a drug prior to its being advertised to the general public, and doesn't call for inclusion of the FDA's toll-free MedWatch number in all DTC television ads.

"I commend PhRMA on taking our investigation seriously," Dingell said in a statement. "Although this revision is the first step toward protecting American consumers, there is much more that can be done. We look forward to working with PhRMA to add further consumer protections into their policies."

"On one hand, PhRMA has taken our Committee's concerns seriously by revising parts of their DTC code; on the other hand, some of these changes are merely a rewording of prior policy that does nothing to increase consumer protection," said Stupak. "Our investigation will continue, and we will be keeping a watchful eye on how well the industry follows these guidelines."

At the May 8 hearing, the Oversight & Investigations subcommittee framed the DTC issues by focusing on three DTC campaigns: the J&J Procrit cancer fatigue ads, the Pfizer ads for Lipitor featuring Robert Jarvik, and the Merck/Schering-Plough "food & family" ads for Vytorin.

The Procrit ads ended after that drug's market share was eclipsed by Amgen's Aranesp (darbepoetin), which wasn't marketed through DTC ads. (Instead, Amgen marketed the white blood cell factor Neulasta directly to consumers and relied on a system of rebates to induce physicians to pitch Aranesp to their patients).

The controversial Lipitor and Vytorin ads were voluntarily withdrawn shortly after the investigation began.

Though Dingell recently lost committee chairmanship to Rep. Henry Waxman (D-Calif.), the committee's emphasis on drug safety and aggressive marketing is expected to continue.

NCI Programs:

Board OKs $100M For Teams Linking Physics And Biology

Advisors to NCI approved the institute's plan to set aside $75 million to $100 million over the next five years to form research teams of experts from the fields of physics, mathematics, chemistry, engineering, and cancer biology.

The NCI Board of Scientific Advisors voted 22-4 in favor of the concept for a new grant program that would fund four to six teams that would form "Physical Sciences-Oncology Centers." The program would cost about $15 million to $21 million a year.

At three workshops that NCI sponsored over the past year, "we were surprised that these cultures are starting to get together already," said NCI Deputy Director Anna Barker. "Both sets of people argued that the cultures are ready to do this."

Excerpted text of the concept statement follows:

Physical Sciences-Oncology Centers. Concept for a new RFA, first-year set-aside $15 million to $21 million, four to six awards, five years, estimated total $75 million to $105 million. Program director: Larry Nagahara, NCI Office of the Director.

The purpose of this RFA [concept] is to drive the

formation of a network composed of new generation of Physical Sciences-Oncology Centers that will bring together experts from the fields of physics, mathematics, chemistry, engineering, and cancer biology to assemble and develop the infrastructure, capabilities, research programs and teams required to catalyze a fundamental level of understanding of the physical and chemical forces that shape and govern the emergence and behavior of cancer at all levels. These coordinated trans-disciplinary teams will develop and test innovative cancer-focused frameworks and create new fields of study based on the physical laws and principles that operate in the biological spaces that are critical to understanding and controlling cancer.

To generate new knowledge and fields of study that effectively integrate the physical science and cancer research, PS-OCs will be expected to create a center organization that focuses its efforts on one of the themes outlined [below] as the organizing framework for the Center, but may also incorporate other themes in support. Themes other than those listed can be proposed if they are adequately defended scientifically for their role in cancer. It should be noted that the organizing framework that define the overall research directions and projects for the PS-OCs will be expected to address major barriers and questions in cancer vs. narrow questions that may be focused on a specific disease or model. A complete description can be found in the meeting report, but briefly, the four specific focus themes for the RFA include:

1. Understanding the Physics (Physical Laws and Principles) of Cancer (e.g., thermodynamics, fluid dynamics).

This theme relates directly to some of the major problems we continue to face in controlling metastatic cancer. During metastasis, cancer cells encounter several obstacles such as negotiating extracellular matrices, invading surrounding cells and tissues, and traversing in/out of vasculature and lymphatics. To overcome these barriers, cancer cells undergo transitions that perturb cell processes such as surface receptors expression, cytoskeleton reorganization, and directional polarity, which ultimately contribute to enhanced cell migration/motility. These barriers can not be well understood using the tools of cancer research today, but are areas of major study and strength in the physical sciences. Physicists and engineers represent major resources for sophisticated investigation of cell migration/motility—and can define the magnitude of the extreme compressive (pressure) and tangential (shear) forces that these cells encounter. For example, being able to detect and understand certain types of mechanical changes could provide entirely new directions for the development of novel intervention approaches. The following represents a few examples of areas/questions that could represent potential focus for center frameworks and projects to facilitate broader cross-network collaborations:

—Can physical sciences/engineering principles be used to examine rare cell types present in tumors (i.e., study weak signal (cancer stem cells) amongst the background noise (overt tumor cells).

—What role does energy/physical forces play in cancer development and metastasis? Can these be 'biomarkers'/signatures that can be used to describe a metabolic state or be an (early) indicator of the disease?

—Can the tools of physics be leveraged to study the role of time dimensions in the development of cancer to determine whether the stages in cancer are reversible or reprogrammable?

2. Exploring and Understanding Evolution and Evolutionary Theory in Cancer from a Physics Perspective.

An interesting theme area that emerged as critically important in the view of physicists, engineers and mathematician and cancer biologists was the critical importance of evolution and evolutionary theory in understanding all aspects of the origin and behavior of cancer cells at multiple scales. Cancer, as viewed by the physical sciences, should be considered a complex adaptive system that is most appropriately studied in the context of evolution and evolutionary theory. A major foundational aspect of this focus area will be experimentation and theoretical models that support the development of an evolutionary construct to understand, predict and control the cancer process. Such a construct would need to include the accommodation of "omics" data for evaluating and testing robust theoretical constructs and ways to measure physical science parameters. The following represents a few examples of areas/questions that could represent potential focus for center frameworks and projects to facilitate broader cross-network collaborations:

Are the statistical mechanics of somatic evolution definable and measurable? How do we measure the reality and function of molecular clocks in terms of understanding the evolutionary process in cancer?

—What emergent properties will be critical to measure and understand in understanding the role of evolution and cancer?

—Which approaches to non-linear system dynamics will be critical to understand/predict evolutionary changes - and behavior of cancer cells at all scales?

—What technologies and models can be used to assess/model chemical gradients in metastasis?

—Can we define the differential equations needed to model evolutionary dynamics?

—If we accept that cancer evolves through stochastic processes - can a framework be developed?

3. Understanding the Coding, Decoding, Transfer, and Translation of Information in Cancer

This theme evolved as a critical focus area since current thinking in information coding and decoding in biological systems generally implies a (one-way) information flow from DNA—transcribed to RNA—translated to proteins. Recent studies in developmental biology and epigenetics show that this information flow can be influenced by external physical forces while leaving the underlying DNA sequence unaltered. Increasingly it is becoming clear that this complex information system is not only two-way communication but feed-back loops present another level of complexity, especially related

to external environmental forces. The following represents a few examples of areas/questions that could represent potential focus for center frameworks and projects to facilitate broader cross-network collaborations:

—How do cells communicate; overall, how do information transfer and management occur within and among cancer cells? Is it different from normal? What drives the enormous degree of heterogeneity in cancer in terms of sub-molecular information management?

—Are there overarching information flow processes/ principles that span across the various length scales in cancer (i.e., subcellular to tumor environment)?

—Can a nonlinear feedback systems approach be applied to cancer such that it is possible to use multispectral analysis techniques to understand information flow in cancer, among different cells, and within individual cells?

4. "De-convoluting" the Complexity of Cancer

This integrative theme represents a major focus area that will benefit greatly when viewed through the lens of the physical sciences. Knowledge in areas such as thermodynamics, fluid and classical mechanics in combination with multi-core computer graphics/computational physics based visualization and robust constructs that could begin to support the development of information needed to design the virtual cancer cell. Complex systems represent major areas of study for physical scientists. This is an area that holds great promise for developing tools that will clearly speed up a wide range of cancer research studies—allowing PS-OC teams to explore processes which are not easily observed and/or are too expensive to achieve. Developing the experimental approaches needed to define cancer as a complex system across all length scales will provide an essential construct for performing theoretical cancer biology. The following represents a few examples of areas/questions that could represent potential focus for center frameworks and projects to facilitate broader cross-network collaborations:

—Can a molecular ecology construct be developed that incorporates non-equilibrium statistical mechanics in the same way that physicists use such methods to explain the behavior of Internet networks and swar-ming/flocking behaviors? Such an approach could produce a general theory of evolutionary cancer dynamics that includes stochastic events.

—Can theoretical constructs (e.g., game and evolutionary information exchange theories) be applicable to the problem of cancer as a complex system?

—How can PS-OCs best integrate the physicists approach to complexity (i.e., reducing it to simplicity in a way that is useful and testable) to understand the physics of cancer and its progression?

Center Structure and Governance: Centers will consist of one to three institutions that work on two to four projects targeted to the four focus areas defined in the RFA. The RFA will require that the lead principal investigator be a trained physical scientist along with a co-principal investigator who is a recognized and trained cancer researcher.

Each center will be expected to participate in collaborative activities and challenge projects across the network. A steering committee (SC) will be established which will consist of the PIs (physical scientist and cancer researcher) from each center and NCI program staff. The SC's responsibilities will include 1) reviewing overall progress of the research activities with the PS-OCS, 2) provide a forum to exchange emerging scientific and resource opportunities, and 3) develop collaborative strategies. The SC will convene three times a year. Each PS-OC team will be required to submit semi-annual reports of research progress to NCI program staff. In addition, an annual PI meeting will provide a venue to exchange research recent finding between PS-OC scientists and promote further collaborations between centers. A science focus group (SFG) will also be established consisting of external experts from relevant areas of physical sciences and cancer biology. The SFG will provide input to PS-OC teams and NCI program staff.

Synergistic Interactions with Current NCI Programs: PS-OCs will be multi-scale, inter-disciplinary, and will operate based on the approach that physical scientists employ to address a problem with unknown parameters. These new centers will focus on building entirely new knowledge based in answering the key questions related to the physics of cancer processes. The PS-OC network will synergistically leverage and engage with all of the NCI programs that study and frame cancer through the generation, analysis and modeling of large-scale datasets, such as TCGA, CPTC, TMEN, EDRN, and ICBP. It should be emphasized that the PS-OC network will focus on the development of solutions to key cancer problems through the leverage of physics and engineering in collaboration with cancer biologists—in some respects one of the most basic approaches, but potentially of highest value in terms of new directions for therapy and diagnosis, to understanding cancer at the fundamental sub-molecular and sub-atomic levels. Over time the PS-OCs will provide new directions, data and theoretical constructs to inform and support the ICBP and new opportunities for technology development by the members of the NCI Alliance for Nanotechnology. Collaborations with caBIG will be needed to help determine and weigh variables in a wide range of anticipated studies.

In the Cancer Centers:

Louisville Receives Gift Of $20 Million For Center

UNIVERSITY OF LOUISVILLE will receive a gift of $20 million over the next five years from the James Graham Brown Foundation to benefit the cancer center that bears its name. "Thanks to this partnership, we are putting Louisville, Ky., on the map through groundbreaking discoveries and cancer treatment that is as good as any available in any city in the U.S.," said **Donald Miller**, director of the James Graham Brown Cancer Center. . . . **INDIANA UNIVERSITY** School of

Medicine-South Bend and the University of Notre Dame broke ground Nov. 21 for the Mike and Josie Harper Cancer Research Institute, an expanded medical and cancer research facility. The building will connect on three levels with the existing Raclin-Carmichael and will include laboratories and offices for IUSM-SB and Notre Dame cancer research. Scientists from both institutions will collaborate on research in cancer biology, with an emphasis on genomics and proteomics, as well as breast, prostate, and colon cancers. **Rudolph Navari**, assistant dean at the Indiana University School of Medicine and director of IUSM-SB, also directs the Harper institute. Charles "Mike" Harper is the retired chairman and CEO of ConAgra Foods and RJR Nabisco. His $10 million gift to Notre Dame to support the construction of Harper Hall was matched with $10 million appropriated by the state of Indiana to the university. . . . **CITY OF HOPE** Department of Supportive Care Medicine received a $2.5 million gift from **Arthur Coppola**, chairman and CEO of the Macerich Co., to establish the Arthur M. Coppola Family Chair in Supportive Care Medicine. **Jay Thomas**, chairman of the department, was named the first holder. The gift will help fund supportive care research, including quality-of-life studies. . . . **BENHAM BADIE**, director of the Brain Tumor Program at City of Hope, received a three-year, $450,000 21st Century Science Initiative in Brain Cancer Research Award from the James S. McDonnell Foundation. The grant supports his collaborative study with **Rama Natarajan**, professor in the Division of Diabetes, Endocrinology and Metabolism, on the role of a gene receptor in suppressing the immune response. . . . **MAURA GILLISON**, associate professor and a member of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University School of Medicine, was named professor of medicine in the Division of Hematology and Oncology and member of the Cancer Control and Viral Oncology Programs in the Ohio State Comprehensive Cancer Center. She will hold the Jeg Coughlin Chair in Cancer Research. Gillison plans to build a program identifying associations between infections and cancers with the goal of prevention treatment of the disease. "With Dr. Gillison's groundbreaking research, she will advance the standard of care for HPV-associated head and neck cancers," said **Michael Caligiuri**, cancer center director. . . . **ROSWELL PARK** Cancer Institute received a five-year $100,000 Grand Challenges Explorations Grant from the Bill & Melinda Gates Foundation. The award will support a project conducted by **Yasmin Thanavala**, professor of immunology at RPCI. Her project would eliminate the need for multiple vaccines in young children by developing a single-dose vaccine that would protect against several diseases. . . . **WILLIE UNDERWOOD** was named to the faculty of the Department of Urologic Oncology at Roswell Park Cancer Institute. In the Office of Cancer Health Disparities Research, his academic efforts will focus on improving the early detection and treatment of prostate cancer in medically underserved New Yorkers. Underwood was assistant professor in the Department of Urology at Wayne State University and Karmanos Cancer Institute. . . . **CARLO CROCE**, member of the Ohio State University Comprehensive Cancer Center-James Cancer Hospital and Solove Research Institute, received the Leopold Griffuel Prize from the French Association for Cancer Research. He was recognized for discovering that chromosome translocations activate oncogenes and initiate the process of malignant transformation. . . . **DOUGLAS YEE**, director of the Masonic Cancer Center at the University of Minnesota, was appointed to the John H. Kersey Chair in Cancer Research. The chair honors the founding director. Yee joined the University of Minnesota in 1999 and was named director in 2007, succeeding Kersey. Yee also is co-leader of the Women's Cancer Research Program and a professor in the Department of Medicine. . . . **MICHAEL LAIRMORE** was elected vice president/president-elect of the American College of Veterinary Pathologists. Lairmore, veterinarian in the College of Veterinary Medicine at Ohio State, is associate director for basic sciences at the cancer center and holds a joint appointment in microbiology and immunology. . . . **HAROLD MOSES**, the Hortense B. Ingram Professor of Molecular Oncology, was named a Vanderbilt School of Medicine Distinguished Alumni Award winner for 2008. Moses, professor of cancer biology, director emeritus of Vanderbilt-Ingram Cancer Center, and a 1962 medical school graduate, was honored during the Vanderbilt Medical School Reunion Oct. 24. He now runs the Frances Williams Preston Laboratories at Vanderbilt-Ingram. . . . **VANDERBILT** Medical Center named **Debra Friedman** the E. Bronson Ingram Chair in Pediatric Oncology in the Department of Pediatrics. She also is leader of the Vanderbilt-Ingram Cancer Center's Prevention and Control Program and will serve as director of the REACH (Resources, Research, Education, Clinical Care and Health Promotion) for Survivorship Program. She was director of the LiveStrong Survivorship Center of Excellence at the Fred Hutchinson Cancer Research Center, and director of the Cancer Survivorship Program at Children's Hospital and Regional Medical Center, Seattle.

In Brief:

NATIONAL CANCER POLICY FORUM at the Institute of Medicine has scheduled a workshop Feb. 9-10, titled "Assessing and Improving Value in Cancer Care." With recent rapid advances in the field of oncology, concerns over rising treatment costs and uncertain clinical benefit have sparked new discussion of value in cancer care, and greater consensus is needed on how to measure and increase value in oncology as rising costs continue to place unsustainable burdens on health insurers, employers, and patients alike. To register, email Adam Schickedanz at aschickedanz@nas.edu or click on the registration link at the workshop's website, http://www.iom.edu/cancercarevalue. Seating is limited and registration is on a first-come-first-serve basis. . . . **AMERICAN SOCIETY OF HEMATOLOGY** announced the election of five officers to its executive committee. **J. Evan Sadler**, co-director of the Hematology-Oncology Fellowship Program at the Washington University School of Medicine, will serve a one-year term as vice president, followed by successive terms as president-elect and president. **Charles Abrams**, associate professor at the University of Pennsylvania School of Medicine, will serve as secretary. **David Bodine**, **Elaine Muchmore**, and **David Williams** will serve four-year terms as councilors. Bodine is chief of the Genetics and Molecular Biology Branch at the National Institute for Human Genome Research. Muchmore is professor of medicine, University of California San Diego. Williams is chief of hematology/oncology and director of translational research, Children's Hospital Boston. . . . **STEVEN YOUNG** was appointed president of the Addario Lung Cancer Medical Institute. **Tony Addario**, former president of ALCMI, assumed the role of CEO. Young was executive director of the Multiple Myeloma Research Consortium. . . . **AMERICAN SOCIETY** for Therapeutic Radiology and Oncology and the **AMERICAN COLLEGE** of Radiology announced a joint radiation oncology practice accreditation program. Under the collaboration, radiation oncology programs will have access to self-assessment and independent external expert audit, based on nationally recognized guidelines, including ACR and ASTRO guidelines and technical standards. . . . **LINDA BIRNBAUM** was named director of the National Institute of Environmental Health Sciences. She is senior advisor at the Environmental Protection Agency, where she has been director of the Experimental Toxicology Division for 16 years. She also is an adjunct professor at University of North Carolina, Chapel Hill, and in the Integrated Toxicology Program at Duke University.

White House Transition:

Stupak: Don't Entrust FDA To Current Senior Leadership

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and former director of the National Human Genome Research Institute Francis Collins. The FDA transition team is led by Joshua Sharfstein, the Baltimore health commissioner and former staff member of Rep. Henry Waxman (D-Calif.).

Also, Collins is viewed as a candidate for the job as NIH director, and Sharfstein as a candidate for the top job at FDA.

The list of members of the teams is posted on the Obama transition website, http://change.gov/learn/obama_biden_transition_agency_review_teams.

Rep. Bart Stupak (D-Mich.), chairman of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, urged the Obama administration not to entrust temporary control of FDA to any of its current senior employees. The most likely person to vie for the interim job is Janet Woodcock, head of the agency's Center for Drug Evaluation and Research.

In the letter dated Dec. 3, Stupak said that his subcommittee's investigations "revealed how the current FDA senior management blocked clinical trials, drove dedicated medical professionals out of the agency, and lined their pockets with outrageous bonuses.

"Current senior FDA employees are too close with the industries they regulate, creating a question of who they are working for. A new commissioner or interim commissioner must bring the agency back to the forefront of science, integrity, and transparency. The American people deserve an FDA that will vigorously protect the American people from unsafe food and drugs."

Funding Opportunities:

RFA-RM-09-005: New Methodologies for Natural Products Chemistry. NIH Roadmap initiative. R01. Letters of Intent Receipt Date: April 17. Application Due Date: May 14. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-09-005.html. Inquiries: John Schwab, 301-594-3827; schwabj@nigms.nih.gov.

RFA-CA-09-009: Physical Science-Oncology Centers. U54. Letters of Intent Receipt Date: Feb. 13. Application Receipt Date: March 13. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-09-009.html.

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