THE CANCER LETTER

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Group Chairs: Research in "Crisis"

ASCO Says NCTN Budgets Cut by 40 Percent, Warns of "Dangerous Disruption of Cancer Care"

By Paul Goldberg

The chairs of the adult clinical trials groups that make up the NCI National Clinical Trials Network said in a letter that recent budget cuts have triggered a "crisis" in clinical research.

Simultaneously, a statement by the president of the American Society of Clinical Oncology, Clifford Hudis, amplified the concerns of the group chairs, and pointed to a separate problem in NCI's transition to the new structure of clinical research: a three-month gap in funding for community oncology clinics engaged in institute-funded research.

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AACR, ASCO Publish Reports Criticizing The Current State of U.S. Cancer Care

By Conor Hale

Cancer research remains underfunded, and the U.S. cancer care system as a whole may be unprepared to handle an aging population, according to two separate reports from the American Association for Cancer Research and the American Society of Clinical Oncology.

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In Brief

AACR Academy Names 2014 Class of Fellows

THE AMERICAN ASSOCIATION FOR CANCER RESEARCH named its 2014 class of elected fellows of the AACR Academy. The fellows will be inducted at the association's annual meeting in San Diego, April 5-9.

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NCI Disputes Claim of 40% Cut, Pledges Continuity of Care

(Continued from page 1)

Open criticism of NCI on the part of the institute grantees and ASCO has not been seen in two decades. No such outcry against NCI has been observed since at least 1994, when NCI Director Samuel Broder fired Bernard Fisher from his job as chairman of the National Surgical Adjuvant Breast and Bowel Project (The Cancer Letter, May 13, 1994).

However, the Fisher firing was an isolated event, limited to questions over leadership of a single cooperative group. The controversy now on the table involves the fundamental structure of clinical cancer research in the U.S.

Even when former NCI Director Andrew von Eschenbach pursued his goal to "eliminate suffering and death due to cancer by 2015," his critics remained silent or worked behind the scenes.

Concern about the three-month funding gap, coupled with implications of patient harm—ASCO alludes to a "dangerous disruption of cancer care"—comes from people who usually keep their rhetoric in check. These protestations amount to a resounding invitation for congressional oversight.

In their April 1 letter to Varmus, the chairs of four newly-formed clinical trials groups said that the trials currently conducted by the groups will consume all available resources.

"We have determined that the execution of our current active trial portfolio alone will consume the proposed funding, and we will have to make decisions that substantially and adversely affect our cancer patients, possibly including, but not limited to closing dedicated disease committees, slowing patient accrual to or closing ongoing studies, and not opening new trials," the group chairs wrote.

Ending ongoing trials presents ethical problems, the group chairs wrote. "It is a serious ethical dilemma to consider stopping any of these critical trials in progress, to which our researchers have committed and our patients have consented," they wrote.

The statement by ASCO's Hudis amplified this message:

"The new National Clinical Trials Network, which replaced the nation's previous Cooperative Group clinical trials system, faces a 40 percent reduction in operating budgets," Hudis wrote. "This is forcing NCTN leaders to make an unreasonable choice: either halt critical research studies currently underway—and in the process renege on obligations to patients committed to these studies—or cancel planned and urgently needed new trials. Either choice spells the end, or a significant slowing, of research that could have delivered new treatments and more personalized and effective care to millions of Americans with cancer."

Hudis also focused on the three-month gap in funding for community-based research.

"National Cancer Institute has made the decision to end funding for federally-funded clinical trials in the community setting through the Community Clinical Oncology Program," Hudis said in a statement. "As of June 1, 2014, support for the CCOP program will end, jeopardizing care for thousands of patients in communities across the United States—unless and until these research programs receive new NCI research grant funding that is not available until at least September 2014. This will result in a dangerous disruption of cancer care for patients who rely on these trials."

This criticism comes at a time when NCI stands poised to launch a new generation of clinical trials, some with substantial industry support (The Cancer Letter, Feb. 21).

"We will respond to the group chairs directly," said Peter Garrett, acting director of the NCI Office of Communications and Public Liaison.

Garrett said the total amount NCI will spend on the groups in the 2014 fiscal year is expected to be roughly the same as it was in 2013: about $150 million. "This is not a 40 percent cut," he said.

Originally, the groups were expected to get a $25

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million increase, to make it possible to increase per-case reimbursement from $2,000 to $4,000 at qualifying sites. However, the money didn't come through, Garrett said.

Garrett said that operational concessions are required to provide higher reimbursement rates per patient to the academic sites that are developing and performing trials, as recommended by the 2010 IOM report.

He said that these higher rates will be approximately $4,000 per patient for about 50 percent of the patients accrued through the network accrual, compared with approximately $2,000 previously.

The groups should see efficiencies, because many of the functions that were duplicated at cooperative groups have been centralized. Also, NCI has mandated a lower enrollment ceiling to make it possible to increase per-case reimbursement.

"NCORP is designed to become an integral component of the overall NCI NCTN," Garrett said. "It will provide access to studies of cancer control, prevention, screening, treatment, and cancer care delivery in the communities in which individuals live. NCORP will be comprised of some of the sites formerly funded through the CCOPs, MCCOPs, and NCCCP, as well new grantee institutions, in accord with advice received from many sectors during the planning process.

"During the transition to NCORP, we expect to announce most awards before the planned September 2014 date," Garrett said. "In accord with traditional NCI practice, no patients will be removed from a trial as a result of the reorganization, and accrual into existing studies will continue. The NCI's long-term goal remains the maintenance of a strong program for community-based clinical research."

Though the new NCTN officially started to function on March 1, the groups do not yet have their letters of award (The Cancer Letter, Feb. 28).

NCI is adding resources to its national laboratory in Frederick, Md. (The Cancer Letter, Feb. 28). The institute's spending on intramural research is above the NIH-wide average (The Cancer Letter, March 7).

Recently, NCI and NIH triggered Congressional oversight and appropriations mandates over the level of their spending on public relations activities (The Cancer Letter, Jan. 31).

Once again, the House Committee on Energy and Commerce appears to stand poised to enter the fray.

"The committee is aware of the NCI's decision to disrupt funding for clinical trials that may jeopardize treatment for thousands of cancer patients," a committee aide said to The Cancer Letter. "We are monitoring the situation."

Group Chairs Say Funding Insufficient

The text of the group chairs' letter to Varmus follows:

Dear Dr. Varmus,

As the Group Chairs of the new National Clinical Trials Network (NCTN) groups, we greatly appreciate your commitment to support efforts that meaningfully improve cancer outcomes. We recognize that the budget allocated to the NCTN by the NCI is relatively stable as compared with the 2012 budget of the legacy cooperative group system, and that this is a better scenario than seen in other NCI-supported research programs. However, the funding structure and allocations across all NCTN initiatives challenge our core network groups' ability to effectively conduct research, and they are certainly in opposition to many of the direct recommendations made in the 2010 Institute of Medicine report, which prompted the cooperative group restructuring. We are writing in response to the preliminary funding level notices received by our NCTN operations groups and statistical centers on March 1. These funding levels represent a significant reduction from the cooperative group core budgets in 2012 and come after several consecutive years of flat or decreased funding. The proposed funding levels are markedly insufficient to maintain the robust infrastructure necessary for success.

Successful cancer clinical research requires the maintenance of an infrastructure to support required core operations activities. These activities include protocol management, biostatistics and data management, biorepository operations, study auditing, regulatory affairs, institutional member management, training for study personnel, and publications. The creation of the NCTN through mergers of former cooperative groups achieved some efficiencies of scale; however a sufficient level of infrastructure and personnel must be maintained in each of the network groups to initiate, conduct, and complete high quality cancer clinical trials. We have determined that the execution of our current active trial portfolio alone will consume the proposed funding, and we will have to make decisions that substantially and adversely affect our cancer patients, possibly including, but not limited to closing dedicated disease committees, slowing patient accrual to or closing ongoing studies, and not opening new trials.

The NCI-approved portfolio of currently active NCTN trials includes molecularly-driven evaluations of targeted agents, new imaging modalities, and studies directed towards FDA registration being performed in partnership with the NCI and industry. It is a serious

ethical dilemma to consider stopping any of these critical trials in progress, to which our researchers have committed and our patients have consented. We also understand the vital importance of activating the new trials that we are developing in partnership with NCI and industry, trials which are vital to deepening our understanding of the relationship between the genomic profile of a given tumor and the likelihood of response and benefit from a defined therapy. Such trials include MATCH, ALCHEMIST, and a host of other exciting approaches previously unavailable to the patients and investigators we serve in academic and community settings.

It is increasingly apparent that the resources currently available to our core operations will not allow our network groups to conduct the type of clinical-translational research that has led to the approval of dozens of new antineoplastic agents. This research has improved the quantity or quality of life for hundreds of thousands of cancer patients, and most important, cannot and will not be carried out by any other academic or private groups. This realization is made following a full review of all the efficiencies that we can enforce in our system and with a full understanding of the serious consequences of choosing any of the options listed above. We are writing to inform you of this crisis and to engage you in this discussion so that together we can seek and identify solutions to this dilemma.

We greatly appreciate your consideration of these issues and would certainly appreciate any other ideas you may have. We will continue to work with our colleagues in CTEP to manage this budget crisis in the most constructive possible way.

Sincerely yours,

Monica Bertagnolli – Alliance

Robert Comis, Mitchell Schnall – ECOG-ACRIN Cancer Research Group

Norman Wolmark, Philip DiSaia, Walter Curran – NRG Oncology

Charles Blanke – SWOG

CC: James Doroshow, Jeffrey Abrams, Worta McCaskill-Stevens

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ASCO: Treatment Disruptions Will Occur

The text of a statement by ASCO President Hudis follows:

The nation's clinical trial network, which provides care to thousands of cancer patients across the United States, may have no choice but to abandon life-saving and life-extending research studies, including support for the patients participating in those studies, due to crippling proposed budget cuts. For decades, federally-supported clinical trials have produced critical advances in the fight against cancer, representing one of the greatest returns on research investment anywhere. But this progress could soon grind to a halt due to far-reaching—and largely unnoticed—budgeting decisions that are happening in plain sight.

In the face of its own inadequate budget, which Congress should address, the National Cancer Institute has made the decision to end funding for federally-funded clinical trials in the community setting through the Community Clinical Oncology Program (CCOP). As of June 1, 2014, support for the CCOP program will end, jeopardizing care for thousands of patients in communities across the United States—unless and until these research programs receive new NCI research grant funding that is not available until at least September 2014. This will result in a dangerous disruption of cancer care for patients who rely on these trials. The CCOPs are 60-plus community-based cancer research programs that make participation in clinical trials possible in nearly every community across America. To be very clear, they are being forced to choose between either ceasing research activities or self-funding it.

At the same time, the new National Clinical Trials Network, which replaced the nation's previous Cooperative Group clinical trials system, faces a 40 percent reduction in operating budgets. This is forcing NCTN leaders to make an unreasonable choice: either halt critical research studies currently underway—and in the process renege on obligations to patients committed to these studies—or cancel planned and urgently needed new trials. Either choice spells the end or a significant slowing of research that could have delivered new treatments and more personalized and effective care to millions of Americans with cancer.

These budget decisions mean that progress will slow. Life-saving therapies will be significantly delayed or not studied at all, local access to state-of-the-art treatments will be reduced, and patients currently receiving study treatments may no longer have expenses reimbursed or could even see their therapy interrupted.

At a time when there are enormous and

unprecedented opportunities to improve cancer care, America shouldn't be turning its back on cancer patients and science. Federally-funded trials have produced some of the biggest advances in cancer care, saving and improving countless lives over the last 50 years. We should not put cancer patients and our scientific leadership in jeopardy by interrupting funding for community-based cancer research.

We urge NCI to restore budgets to CCOPs to prevent the gap in funding to community-based centers and to NCTN operations to prevent this otherwise avoidable damage to our research infrastructure and progress while ensuring that patients with cancer receive critically important, life-extending care, regardless of where they live.

AACR, ASCO Publish Reports Criticising Current State Of U.S. Cancer Care

(Continued from page 1)

In the AACR annual Cancer Progress Report, the association highlighted advancements in cancer research, progress in survival rates, and new approvals of drugs and technologies in the past year, as well as examining the current levels of federal research funding for research and delivered a call to action to members of Congress.

ASCO's report, The State of Cancer Care in America, focused on the current problems facing the healthcare system as a whole, and trends that could lead to trouble in future treatment of cancer.

"By 2030, the number of new cancer cases in the United States will increase by 45 percent and cancer will become the nation's leading cause of death," the ASCO report said. "At the same time, the number of cancer survivors, now at 13.7 million, will continue to grow. Many of these individuals will require significant, ongoing care."

The report went on to say that access to quality cancer care remains uneven across the country, with rates of access disproportionately lower for African Americans and Latinos, and that overall costs have risen throughout the healthcare system.

In cancer care, "annual costs are projected to rise from $104 billion in 2006 to more than $173 billion in 2020," the report said, with demand for oncology services rising at least 42 percent by 2025. At the same time, the supply of trained oncologists will increase by only 28 percent, setting the potential for a shortage in the workforce.

"Shortfalls will be driven by tremendous growth in the number of Americans over the age of 65, along with the aging of the oncology workforce and large numbers of anticipated retirements," the report said. "Furthermore, ASCO's research indicates that these shortfalls may be further exacerbated by high levels of burnout, potentially leading to reduced clinical load or early retirement."

Data from ASCO's census of oncology practices was also presented, noting that the average size of practices increased from nine physicians to 15. Meanwhile in the same survey, 63 percent of small practices surveyed reported that they were likely to merge, sell or close within the next year.

The full report is available on the ASCO website and was published in the Journal of Oncology Practice.

The AACR Cancer Progress Report focused on making research count for patients, and included a special feature on immunotherapies. It also studied activities that carry a high risk of developing cancer, as well as the genetic basis of the disease. However, even with advancements in research, the AACR report remarked that cancer is soon to become the number one disease-related killer of Americans.

"Because more than 75 percent of cancer diagnoses occur in those aged 55 and older and this segment of the population is increasing in size, we face a future where the number of cancer-related deaths will increase dramatically," said the AACR report. "This trend is being mirrored globally, and it is estimated that in 2030, more than 13 million people worldwide will lose their lives to cancer."

"Yet, more than 50 percent of the 580,350 cancer deaths expected to occur in the United States in 2013 will be related to preventable causes," the report continued.

"Modifying personal behaviors to adopt a healthier lifestyle that eliminates or reduces these risks, where possible, could therefore have a remarkable impact on our nation's burden of cancer. However, a great deal more research and resources are needed to understand how to best help individuals to change their lifestyle."

The progress report applauded 11 FDA approvals of anticancer drugs from September 2012 to July

2013, as well as three new uses for previously approved drugs and three imaging technologies. The report also noted two drugs approved in conjunction with genomic diagnostics.

AACR called on members of Congress to make cancer research and biomedical science a national funding priority: "A new level of commitment by Congress to increase funding for the NIH will be required if we are to accelerate the pace of progress against cancer and meet the challenges described earlier in this report."

"Sequestration dealt a 5.1 percent cut to the agency, slashing its budget by $1.6 billion," the report said. "At the reduced fiscal year 2013 funding level of $29 billion, the NIH is now funding the lowest number of research projects since FY 2001."

"The impact of sequestration on the NCI was a commensurate cut of $293 million," it said. "These cuts have ramifications across the research spectrum—reducing the number of promising grant proposals that can be funded, potentially leaving the next cancer therapy or cure on the cutting room floor."

AACR urged Congress to reinstate the cuts made by sequestration, and called upon the association's members to encourage policymakers to provide sustainable funding increases to the NIH.

"If we are to ultimately transform scientific discoveries into therapies that improve and save the lives of cancer patients, it is going to require an unwavering commitment of Congress and the administration to invest in our country's remarkably productive cancer research and biomedical research enterprise led by the NIH and NCI."

Oncologists Tell Congress Community Cancer Practices Are Not Adequately Reimbursed

Current Medicare policies do not adequately reimburse cancer care provided in the community setting, the Community Oncology Alliance and the U.S. Oncology Network said in a joint, open letter to members of Congress.

The two organizations cited closures of community cancer clinics, mergers with large hospitals, and increasing barriers to accessing care in rural areas as results of current Medicare policy, which, according to the two organizations, incentivizes care provided in more expensive hospital outpatient departments while also increasing costs for the program and for seniors with cancer.

"We are truly in crisis mode," said Mark Thompson, president of COA. "Coupled with sequestration cuts that reduce reimbursement for costly cancer-fighting drugs, we're at a breaking point, and seniors with cancer will suffer most."

Over the past six years, 288 treatment facilities have closed and 469 practices, typically having multiple treatment facilities, have been forced to merge or affiliate with hospitals, according to data collected by COA. In 2005, 87 percent of chemotherapy was administered in community cancer clinics, but by the end of 2011, that number declined to 67 percent.

COA says that cancer care delivered in hospital outpatient departments costs Medicare $6,500 more per beneficiary on an annualized basis compared to care provided in physician-run community cancer clinics.

Hospital-based care also costs seniors $650 more in out-of-pocket copayments compared to community-based care.

"Congress must act immediately to stabilize the community cancer care delivery system in any Medicare legislation before the shift of cancer care to the more expensive hospital setting becomes irreversible," the letter reads. "Members of Congress on both sides of the aisle recognize this threat and have sponsored legislation to stop [Centers for Medicare & Medicaid Services] application of the sequester cut to cancer drugs (H.R. 1416), to fix the prompt pay problem that artificially lowers cancer drug payments (H.R. 800 and S. 806), and to adopt site-neutral payments for outpatient cancer care services (H.R. 2869)."

Community providers are asking Congress to create payment parity across sites of service, as recommended by the Medicare Payment Advisory Commission. Providers are also asking Congress to address the reimbursement mechanism for cancer drugs, which does not cover the full cost of acquiring, handing, storing and disposing of medications and has been further impacted by sequestration.

The full letter is available on The Cancer Letter website.

In Brief

AACR Academy Inducts 2014 Class of Fellows

(Continued from page 1)

The academy recognizes individuals who have made exceptional contributions to cancer research and cancer-related biomedical science.

Members of the AACR Academy 2014 class of fellows are:

• **Jerry Adams**, joint head of the Molecular Genetics of Cancer Division and director of the Leukemia and Lymphoma Society Specialized Center of Research, Walter and Eliza Hall Institute of Medical Research, in Melbourne, Australia.

• **James Allison,** professor and chair of the Department of Immunology, director of the Immunology Platform, and deputy director of the David H. Koch Center for Applied Research in Genitourinary Cancers, Department of Genitourinary Research at MD Anderson Cancer Center.

• **Mariano Barbacid,** professor of molecular oncology of the Centro Nacional de Investigaciones Oncológicas, in Madrid, Spain.

• **José Baselga,** physician-in-chief of Memorial Sloan Kettering Cancer Center.

• **Stephen Baylin,** deputy director and associate director for research, Sidney Kimmel Comprehensive Cancer Center; Virginia and D.K. Ludwig professor for cancer research and medicine and chief of the Cancer Biology Division at Johns Hopkins University School of Medicine.

• **Günter Blobel,** John D. Rockefeller Jr. professor in the Laboratory of Cell Biology of The Rockefeller University and an investigator for the Howard Hughes Medical Institute.

• **David Botstein,** Anthony B. Evnin professor of genomics at Princeton University; chief scientific officer of Calico.

• **Joan Brugge,** Louise Foote Pfeiffer professor of cell biology and chair of the Department of Cell Biology at Harvard Medical School.

• **Lewis Cantley,** Margaret and Herman Sokol professor and director of the Meyer Cancer Center at Weill Cornell Medical College.

• **Pierre Chambon,** honorary professor of the Collège-de-France; professor of molecular biology and genetics at the University of Strasbourg Institute for Advanced Study; group leader of the Institut de Génétique et de Biologie Moléculaire et Cellulaire.

• **Hans Clevers,** professor in medical genetics at the University of Utrecht; president of the Royal Netherlands Academy of Arts and Sciences.

• **James Darnell Jr.,** Vincent Astor professor emeritus and head of the Laboratory of Molecular Cell Biology at The Rockefeller University.

• **Titia de Lange,** Leon Hess professor, American Cancer Society research professor, and director of the Anderson Center for Cancer Research at The Rockefeller University.

• **Vincent DeVita Jr.,** Amy and Joseph Perella professor of medicine at Yale Cancer Center; and professor of epidemiology and public health at Yale Medical School.

• **Lawrence Einhorn,** distinguished professor of medicine and Lance Armstrong Foundation professor of medicine at the Indiana University School of Medicine.

• **Stephen Elledge,** Gregor Mendel professor of genetics and medicine at Harvard Medical School and Brigham and Women's Hospital.

• **Ronald Evans,** professor and director of the Gene Expression Laboratory and March of Dimes chair in molecular and developmental biology at The Salk Institute for Biological Studies and an investigator for the Howard Hughes Medical Institute.

• **Andrew Fire,** George D. Smith professor in

molecular and genetic medicine at Stanford University School of Medicine.

• **Emil Freireich,** Ruth Harriet Ainsworth chair, distinguished teaching professor, director of the Adult Leukemia Research Program, and director of the Special Medical Education Programs at MD Anderson Cancer Center.

• **Robert Gallo,** Homer and Martha Gudelsky distinguished professor of medicine, professor of medicine and of microbiology and immunology, and director of the Institute of Human Virology at the University of Maryland School of Medicine.

• **Douglas Hanahan,** director of the Swiss Institute for Experimental Cancer Research.

• **Richard Hynes,** Daniel Ludwig professor for cancer research at the Massachusetts Institute of Technology and an investigator for the Howard Hughes Medical Institute.

• **William Kaelin Jr.,** professor of medicine at Dana-Farber Cancer Institute and Harvard Medical School and an investigator for the Howard Hughes Medical Institute.

• **Kenneth Kinzler,** professor of oncology and director of the Ludwig Center at Johns Hopkins University Kimmel Cancer Center.

• **Richard Kolodner,** member and head of the Laboratory of Cancer Genetics of the Ludwig Institute for Cancer Research and distinguished professor in the Departments of Medicine and Cellular and Molecular Medicine at University of California, San Diego School of Medicine.

• **Ronald Levy,** Robert K. and Helen K. Summy professor of medicine at the Stanford University School of Medicine.

• **Frederick Li,** professor of clinical cancer epidemiology emeritus at the Harvard School of Public Health and professor of medicine emeritus at Dana-Farber Cancer Institute.

• **David Livingston,** deputy director of the Dana-Farber Cancer Institute, chief of the Charles A. Dana Division of Human Cancer Genetics, and Emil Frei professor of genetics and medicine at Harvard Medical School.

• **Paul Marks,** president emeritus of Memorial Sloan Kettering Cancer Center.

• **Peter Nowell,** Gaylord P. and Mary Louise Harnwell professor emeritus in the Department of Pathology and Laboratory Medicine at the University of Pennsylvania Perelman School of Medicine.

• **Christiane Nüsslein-Volhard,** director of the Department of Genetics at the Max Planck Institute for Developmental Biology, in Tübingen, Germany.

• **Sir Richard Peto,** professor of medical statistics and epidemiology at the University of Oxford.

• **Charles Sawyers,** chair of the Human Oncology and Pathogenesis Program and member at Memorial Sloan Kettering Cancer Center; professor at the Weill Cornell Graduate School of Medical Sciences; and an investigator for the Howard Hughes Medical Institute.

• **Sir Michael Stratton,** director of the Wellcome Trust Sanger Institute in Cambridge, U.K.

• **Axel Ullrich,** director of the Department of Molecular Biology of the Max Planck Institute of Biochemistry, in Munich, Germany.

• **Inder Verma,** Irwin and Joan Jacobs chair in exemplary life science and American Cancer Society professor of molecular biology at The Salk Institute for Biological Sciences.

• **Irving Weissman,** director of the Institute for Stem Cell Biology and Regenerative Medicine, director of the Stanford Ludwig Center for Cancer Stem Cell Research and Medicine, and professor of pathology and developmental biology at the Stanford University School of Medicine.

• **Owen Witte,** director of the Broad Stem Cell Research Center and distinguished professor of microbiology, immunology, and molecular genetics at University of California, Los Angeles. and an investigator for the Howard Hughes Medical Institute.

In Brief

PCORI Names Members to Clinical Trial Advisory Board

THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE appointed 10 members to a new **Advisory Panel on Clinical Trials**. The panel will convene for its first meeting May 1 in Washington, D.C.

Members of the panel will provide expertise on the design and implementation of randomized controlled trials. Topics include selection of appropriate patient-centered outcomes, informed consent of study participants, periodic evaluations of the institute's clinical trial portfolio, and the readiness of trial results for dissemination.

The panelists and four alternates were selected from 231 applicants. More than half are biostatisticians, epidemiologists, or others with technical expertise in conducting clinical trials. Two others represent patients, patient advocates, or family caregivers and another is an expert in the ethical aspects of such studies.

The 10 panelists are:

• **Jason Connor**, director and senior statistical sat Berry Consultants.

Connor is a biostatistician specializing in Bayesian and adaptive trial design. He currently holds academic appointments as a visiting professor at The Johns Hopkins University Bloomberg School of Public Health and assistant professor at the University of Central Florida College of Medicine.

• **Sanford Jeames**, adjunct professor at Huston-Tillotson University and coordinator of Health Sciences Program, at Eastside Memorial High School.

Jeames is a community health educator and patient advocate. His interests include health education, cancer prevention, and healthier lifestyle interventions, with a focus on under-served populations. On behalf of NCI, he has served as a protocol reviewer with the Special Emphasis Panel and as a clinical trials reviewer for the Adult Central Institutional Review Board.

• **John Lantos**, professor of pediatrics at Children's Mercy Hospital

After 20 years on the faculty of The University of Chicago's Pritzker School of Medicine, Lantos moved to Kansas City to create and direct a pediatric bioethics center at Children's Mercy Hospital. His research focuses on the ethics of clinical trials and he has analyzed the ethical issues in neonatology, cancer chemotherapy, renal dialysis, cardiac assist devices, and primary care pediatrics.

• **Anne McTiernan**, professor at Fred Hutchinson Cancer Research Center and the Schools of Public Health and Medicine at the University of Washington

McTiernan's research focuses on disease prevention through weight control, physical activity, and chemoprevention. She has led multiple randomized controlled trials testing weight loss, exercise, medications, and supplements, and was the principal investigator of the NCI-funded Seattle Translational Research on Energetics and Cancer.

• **Margo Michaels**, executive director and founder of the Education Network to Advance Cancer Clinical Trials.

Michaels has developed numerous programs to educate cancer advocates, community leaders, and healthcare professionals about policy and science issues related to cancer. Previously, she served as branch chief at the NCI's Public and Survivor Education Branch; as the lead consultant to the Clinical Research: Affiliates Funding Trials program at the Susan G. Komen Breast Cancer Foundation; and as the director of the National Breast Cancer Coalition's Project LEAD.

• **Craig Nichols**, co-director of the Virginia Mason Medical Center Testicular Cancer Clinic and executive officer of Cancer Prevention and Control.

Nichols's research focuses on rare malignant diseases and the development of clinical trials focused on cancer. He serves on the boards of several cancer non-profits and has extensive service with the NCI, national and international cancer research organizations, and cancer nonprofit organizations.

• **Frank Rockhold**, senior vice president of Global Clinical Safety and Pharmacovigilance at GlaxoSmithKline.

Rockhold previously led the GSK Cardiovascular Development and Clinical Safety and Pharmacovigilance Departments. He has held leadership positions focusing on clinical trials, data standards, benefit to risk, clinical research, epidemiology, and most recently, pharmacovigilance.

• **Elizabeth Stuart**, associate professor of mental health and biostatistics at The Johns Hopkins Bloomberg School of Public Health.

Stuart previously worked on a number of large-scale randomized trials of social interventions as a Researcher at Mathematica Policy Research. Her research interests include statistical issues associated with randomized trials, including handling complexities such as missing data, clustering, mediation analysis, and noncompliance.

• **Robert Temple**, deputy center director for clinical science at the FDA Center for Drug Evaluation and Research

Temple began his career at FDA in 1972, serving as a reviewer in the endocrine and metabolic division. Since then, he has served as assistant to the center director, with responsibility for final sign-off on Drug Efficacy Study Implementation conclusions, as director of the Cardiorenal Division, as director of the Office of Drug Evaluation, and as director of the Office of Medical Policy.

• **Merrick Zwarenstein**, director of the Centre for Studies in Family Medicine, Department of Family Medicine, Western University in Ontario, Canada.

Zwarenstein's research focuses on health care program development and evaluation in Canada and internationally, especially in South Africa, where he holds professorships at Stellenbosch University and the University of Cape Town. His interest focuses on optimizing health care delivery through research on effectiveness.

MARION COUCH was named the Richard T. Miyamoto Professor and chair of the **Indiana University School of Medicine Department of Otolaryngology-Head and Neck Surgery**. Couch will assume her duties June 1, pending approval by the trustees of Indiana University.

A head and neck surgical oncologist, she is professor and interim chair of the Department of Surgery at the University of Vermont College of Medicine and surgeon-in-chief of Fletcher Allen Health Care.

She joined the University of Vermont faculty in 2010 as division chief of otolaryngology-head and neck surgery and was appointed interim chair and physician leader of surgery in 2011. She also served as interim chief of ophthalmology and associate vice president of finance for the UVM Medical Group.

Couch will succeed Richard Miyamoto, chair and Arilla Spence DeVault Professor of Otolaryngology-Head and Neck Surgery and medical director of audiology and speech language pathology.

Miyamoto performed Indiana's first cochlear implant in 1979. In 1995, he and his team at Riley Hospital for Children implanted a device in a 16-month-old boy, the youngest ever to receive a cochlear implant at that time.

JOHN POWDERLY II was named the recipient of the David King Community Clinical Scientist Award by the **Association of Community Cancer Centers**. Award winners become lifetime members of the ACCC National Academy of Community Oncology Scientists.

Powderly is president and founder of Carolina BioOncology Institute, the only oncologist Certified Physician Investigator in the Charlotte, N.C., region, and is an adjunct clinical assistant professor of medicine at Duke University and the University of North Carolina, Chapel Hill.

The association's award is named after David King, who died after a brief battle with cancer. King served the association in many capacities—as president, chair of the Annual Presidents Retreat, and co-chair of ACCC's Reimbursement Committee.

SAMUEL BRODER was named executive vice president of scientific and public affairs at the **Intrexon Corporation**. The former director of NCI was most recently chairman of Intrexon's health sector.

Broder will lead the company's communications programs with media, academia, government, and non-profit organizations, spanning health, food, energy, environment, and consumer sectors.

THE RARE CANCER RESEARCH FOUNDATION and **Caring for Carcinoid Foundation** announced up to $300,000 in globally available awards to develop cell lines for intestinal carcinoid and pancreatic neuroendocrine cancer.

These rare cancers have few FDA-approved treatment options. The lack of widely available, validated neuroendocrine cancer cell lines is a major obstacle to neuroendocrine cancer research. The program will feature intestinal carcinoid and pancreatic neuroendocrine cancer as the first awards.

Investigators who create one or more immortal cell lines from intestinal carcinoid and/or pancreatic neuroendocrine tumors are invited to submit the cell line(s) for prompt validation, to establish eligibility, and to initiate the process for repository deposit. Investigators whom the CFCF has funded after 2011 to create cell lines are ineligible for the prize.

Complete submission criteria are available at: https://www.innocentive.com/ar/challenge/9933510.

THIRTEEN GRADUATE STUDENTS received the **2014 Harold M. Weintraub Graduate Student Award** sponsored by the Basic Sciences Division of **Fred Hutchinson Cancer Research Center**.

The recipients, all advanced students at or near the completion of their studies in the biological sciences, will participate in a scientific symposium May 2 at Fred Hutch consisting of scientific presentations by the awardees.

The award recipients will receive a certificate, travel expenses and an honorarium from the Weintraub and Groudine Fund, established to foster intellectual exchange through the promotion of programs for graduate students, fellows and visiting scholars.

The 2014 Harold M. Weintraub Graduate Student Award Recipients follow:

• **Andrew Adey**, of the University of Washington, Ph.D. in molecular and cellular biology

• **Colin Conine**, of the University of Massachusetts, Ph.D. candidate in molecular biology and genetics

• **Daniel Hochbaum**, of Harvard University, Ph.D. candidate in engineering/applied sciences/applied physics

• **Hidehiko Inagaki**, of the California Institute of Technology, Ph.D. candidate in biology

• **Liron Bar-Peled**, of the Massachusetts Institute of Technology, Ph.D. in biology

• **Nora Pencheva**, of The Rockefeller University,

Ph.D. candidate in molecular biology

• **Alistair Russell**, of the University of Washington, Ph.D. candidate in microbiology

• **Andrew Stergachis**, of the University of Washington, Ph.D. candidate in genome sciences

• **Emma Watson**, of the University of Massachusetts, Ph.D. candidate in systems biology

• **Kipp Weiskopf**, of Stanford University, Ph.D. candidate in stem cell biology/regenerative medicine/ cancer biology

• **Sarah Wilson**, of the University of California, Berkeley, Ph.D. candidate in molecular and cell biology

• **Jiaxi Wu**, of the UT Southwestern Medical Center, Ph.D. candidate in genetics and development

• **Swathi Yadlapalli**, of the University of Michigan, Ph.D. candidate in cell and developmental biology

THE COMMUNITY ONCOLOGY ALLIANCE released the results of its **IV Fluid Shortage Survey**. Sixty-six practices from across the country were surveyed. The results showed that:

• 85 percent of the practices surveyed have received warnings from multiple manufacturers and/ or have been impacted by the shortage of IV fluids

• 44 percent of the practices surveyed have adjusted how and when fluids are used, are pursuing additional distributors to meet their patients' needs, and/or are attempting to create excess inventory against further shortages

• Less than 15% of the practices surveyed have made no changes in light of the current or future shortages

The complete survey results, including comments from participants, are available on the COA website.

THE NATIONAL COMPREHENSIVE CANCER NETWORK updated its clinical practice guidelines in oncology for **Genetic/Familial High-Risk Assessment: Colorectal**.

• *For colon cancer*, the colonoscopy screening recommendations were changed to "Colonoscopy at age 25-30 y or 2-5 y prior to the earliest colon cancer if it is diagnosed before age 30 y and repeat every 1-2 y" from "Colonoscopy at age 30-35 y (may need to be earlier in some families, depending on ages of cancers observed) every 2-3 y, and then after age 40 y every 1-2 y."

For extra colonic, 1st sub-bullet was changed to "For endometrial and ovarian cancer, see surveillance for MLH1, MSH2 and EPCAM carriers (See LS-3)" from "Consider prophylactic hysterectomy and BSO in women who have completed childbearing."

• *A new clinical testing criteria was added for Lynch Syndrome* based on personal and family history: "Consider testing individuals with ≥5% risk of LS on any mutation prediction model (eg, MMRpro, PREMM[1,2,6], MMRpredict)."

• *In Juvenile Polyposis Syndrome*, a new heading title was added called, "Genetic Testing."

The following bullet was added and revised: "Clinical genetic testing is recommended with approximately 50% of JPS cases occurring due to mutations in the BMPR1A and SMAD4 genes. If known SMAD4 mutation in family, genetic testing should be performed within the first 6 months of life due to hereditary hemorrhagic telangiectasia (HHT) risk."

"Hemorrhagic Telangiectasia (HHT)" was added to the table with a recommendation, "In individuals with SMAD4 mutations, screen for vascular lesions associated with HHT." The initiation age was added: "Within first 6 mo of life."

• *In Colonic Adenomatous Polyposis of Unknown Etiology:*

Personal history of >10-<100 adenomas: Small adenoma burden manageable by colonoscopy and polypectomy, the sub-bullet for management/ surveillance was revised: "Clearing of all polyps is recommended preferable but not always possible. Repeat at short interval if residual polyps are present."

Personal history of >10- <100 adenomas: Dense polyposis or large polyps not manageable by polypectomy, the management/surveillance was revised: "Subtotal colectomy or proctocolectomy depending on adenoma density and distribution," and a new bullet was added: "Consider proctocolectomy if there is dense rectal polyposis not manageable by polypectomy."

For each family history phenotype, "consider" was added to each of the management/surveillance recommendations and a corresponding footnote "b" was added: "There are limited data to suggest definitive recommendations for when to initiate screening or the interval of screening."

• *In Peutz-Jeghers Syndrome*, MRI was added as a screening procedure option of the small intestine, and age to initiate screening for pancreatic cancer was changed from "25-30 y" to "30-35 y."

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