

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
153RD NATIONAL CANCER ADVISORY BOARD**

**Summary of Meeting
February 18, 2010**

**Bethesda Marriott (Pooks Hill)
Bethesda, Maryland**

NATIONAL CANCER ADVISORY BOARD
BETHESDA, MARYLAND
Summary of Meeting
February 18, 2010

The National Cancer Advisory Board (NCAB) convened for its 153rd regular meeting on 18 February 2010, at the Bethesda Marriott at Pooks Hill, Bethesda, MD. The meeting was closed to the public on Thursday, 18 February 2010, from 8:00 a.m. to 10:00 a.m. and open to the public on Thursday, 18 February 2010, from 10:00 a.m. until adjournment at 3:31 p.m. The NCAB Chair, Dr. Carolyn D. Runowicz, Director, The Carole and Ray Neag Comprehensive Cancer Center, Farmington, CT, presided during both the open and closed sessions.

NCAB Members

Dr. Carolyn D. Runowicz (Chair)
Dr. Anthony Atala (absent)
Dr. Bruce A. Chabner
Dr. Victoria L. Champion
Dr. Donald S. Coffey
Dr. Lloyd K. Everson
Ms. Kathryn E. Giusti (absent)
Mr. William H. Goodwin, Jr.
Dr. Waun Ki Hong (absent)
Mr. Robert A. Ingram
Dr. Judith S. Kaur (absent)
Mr. David H. Koch (absent)
Ms. Mary Vaughan Lester
Dr. Diana M. Lopez
Dr. H. Kim Lyerly (absent)
Dr. Karen M. Meneses
Dr. Jennifer A. Pietenpol
Dr. Daniel Von Hoff (absent)

President's Cancer Panel

Dr. LaSalle D. Leffall, Jr. (Chairperson)
Dr. Margaret L. Kripke (absent)

Alternate Ex Officio NCAB Members

Dr. Michael A. Babich, CPSC (absent)
Dr. Patricia Bray, OSHA/DOL (absent)
Dr. Steven Kleeberger, NIEHS (absent)
Dr. Michael Kelley, VA
Dr. Richard Pazdur, FDA
Dr. John F. Potter, DOD
Dr. R. Julian Preston, EPA (absent)
Dr. Michael Stebbins, OSTP
Dr. Marie Sweeney, NIOSH (absent)

Members, Executive Committee, National Cancer Institute, NIH

Dr. John Niederhuber, Director, National Cancer Institute
 Dr. Anna Barker, Deputy Director for Advanced Technology and Strategic Partnership
 Dr. Kenneth Buetow, Associate Director, Center for Bioinformatics and Information Technology
 Dr. Robert Croyle, Director, Division of Cancer Control and Population Sciences
 Mr. Jason Donaldson, Acting Director for Management and Executive Officer
 Dr. James Doroshow, Director, Division of Cancer Treatment and Diagnosis
 Dr. Joseph Fraumeni, Director, Division of Cancer Epidemiology and Genetics
 Dr. Paulette S. Gray, Director, Division of Extramural Activities
 Dr. Peter Greenwald, Director, Division of Cancer Prevention
 Dr. Lee Helman, Scientific Director for Clinical Research, Center for Cancer Research
 Ms. Kathy McBrien, Administrative Resource Center Manager
 Dr. Alan Rabson, Deputy Director, National Cancer Institute
 Dr. Craig Reynolds, Associate Director, NCI-Frederick
 Dr. Dinah Singer, Director, Division of Cancer Biology
 Dr. Sanya Springfield, Director, Center to Reduce Cancer Health Disparities
 Dr. Robert Wiltrout, Director, Center for Cancer Research
 Ms. Joy Wiszneauckas, Executive Secretary, Office of the Director

Liaison Representatives

Ms. Carolyn Aldige, Cancer Research and Prevention Foundation
 Ms. Paula Bowen, Kidney Cancer Association
 Mr. William Bro, Kidney Cancer Association
 Dr. Carol Brown, Society of Gynecologic Oncologists
 Ms. Pamela K. Brown, Intercultural Cancer Council
 Ms. Suanna Bruinooge, American Society of Clinical Oncology
 Mr. Adam Clarke, Lance Armstrong Foundation
 Dr. Yvette Colon, National Cancer Institute, Director's Consumer Liaison Group
 Mr. George Dahlman, Leukemia and Lymphoma Society
 Dr. Margaret Foti, American Association for Cancer Research
 Dr. Robert W. Frelick, Association of Community Cancer Centers
 Dr. Leo Giambarresi, American Urological Association
 Ms. Christy M.P. Gilmour, American Academy of Orthopaedic Surgeons
 Ms. Ruth Hoffman, Candlelighters Childhood Cancer Foundation
 Dr. Lovell A. Jones, Intercultural Cancer Council
 Ms. Rebecca A. Kirch, American Cancer Society
 Dr. Steven Klein, National Science Foundation
 Dr. Hal C. Lawrence, III, The American College of Obstetricians and Gynecologists
 Dr. W. Marston Linehan, Society of Urologic Oncology
 Mr. Richard Martin, American Society of Therapeutic Radiology and Oncology
 Ms. Margo Michaels, Education Network to Advance Cancer Clinical Trials
 Ms. Christy Schmidt, American Cancer Society
 Ms. Susan Silver, National Coalition for Cancer Survivorship
 Ms. Barbara Duffy Stewart, Association of American Cancer Institutes
 Dr. Robyn Lynn Watson, American Society of Therapeutic Radiology and Oncology
 COL (Ret.) James E. Williams, Jr., Intercultural Cancer Council

TABLE OF CONTENTS**THURSDAY, FEBRUARY 18, 2010**

| | | |
|-------|--|----|
| I. | Call to Order, Opening Remarks, and Consideration of 1–2 December 2009 Minutes— Dr. Carolyn D. Runowicz | 1 |
| II. | Future Board Meeting Dates—Dr. Carolyn D. Runowicz | 1 |
| III. | NCI Director’s Report—Dr. John Niederhuber | 1 |
| | Questions and Answers | 2 |
| IV. | President’s Cancer Panel Report—Dr. LaSalle D. Leffall, Jr. | 2 |
| | Questions and Answers | 3 |
| V. | Legislative Update—Ms. Susan Erickson | 3 |
| VI. | NCI Federally Funded Research and Development Center (FFRDC)—Dr. Craig Reynolds..... | 3 |
| | Questions and Answers | 4 |
| VII. | Advanced Technology Research Facility—Dr. Craig Reynolds | 5 |
| | Questions and Answers | 5 |
| VIII. | Annual Delegations of Authority—Dr. Paulette S. Gray..... | 6 |
| IX. | NCI Cancer Human Biobank (caHUB)—Drs. Carolyn C. Compton and Ken Buetow..... | 7 |
| | Questions and Answers | 8 |
| X. | Opportunities To Collaborate and Develop Joint Clinical Programs With Walter Reed and Suburban Hospital—Drs. Lee Helman and John Niederhuber..... | 8 |
| | Questions and Answers | 9 |
| XI. | SEER: Annual Report to the Nation—Drs. Robert Croyle and Brenda Edwards | 9 |
| | Questions and Answers | 10 |
| XII. | Update: NCI Community Cancer Centers Program (NCCCP)—Dr. Steven Clauser..... | 10 |
| | Questions and Answers | 11 |
| XIII. | NCAB Ongoing and New Business—Dr. Carolyn D. Runowicz | 12 |
| XIV. | Closed Session—Dr. Carolyn D. Runowicz | 13 |
| XV. | Adjournment—Dr. Carolyn D. Runowicz | 13 |

THURSDAY, FEBRUARY 18, 2010**I. CALL TO ORDER, OPENING REMARKS, AND CONSIDERATION OF 1–2 DECEMBER 2009 MINUTES—DR. CAROLYN D. RUNOWICZ**

Dr. Runowicz called to order the 153rd NCAB meeting. She welcomed members of the Board, the President's Cancer Panel (PCP), *ex officio* members of the Board, liaison representatives, staff, and guests. Members of the public were welcomed and invited to submit to Dr. Paulette S. Gray, Director, Division of Extramural Activities (DEA), National Cancer Institute (NCI), in writing and within 10 days, any comments regarding items discussed during the meeting. Dr. Runowicz reviewed the confidentiality and conflict-of-interest practices required of Board members in their deliberations.

Motion. A motion was made to approve the minutes of the 1–2 December 2009 NCAB meeting. The motion was seconded, and the Board unanimously approved the minutes.

II. FUTURE BOARD MEETING DATES—DR. CAROLYN D. RUNOWICZ

Dr. Runowicz called Board members' attention to future meeting dates, which have been confirmed through 2011. She noted that the September 2010 NCAB meeting dates have been changed to 7–9 September 2010.

Motion. A motion was made to accept the NCAB meeting dates for 2012. The motion was seconded and approved unanimously.

III. NCI DIRECTOR'S REPORT—DR. JOHN NIEDERHUBER

Dr. John Niederhuber, Director, welcomed members and provided information about NCI's fiscal year (FY) 2010 and 2011 budgets, efforts to facilitate target discovery and new agent development, and the NCI Executive Committee (EC) Scientific Retreat.

Budget. Dr. Niederhuber informed members that the FY 2010 appropriation is \$5.103 B, which is \$136 M higher (+2.7 percent) than the FY 2009 operating budget of \$4.966 B. Accounting for infrastructure and science programs, such as AIDS research and the Latin America breast cancer pilot program, as well as additional wish list requests from Divisions, Offices, and Centers, the fiscal appetite could push the FY 2010 budget subtotal to close to -\$300 M. Budget allocations for FY 2010 include: research project grants (RPGs) (44%); research centers (11%); other research (8%); research training (1%); research and development contracts (12%); intramural research (16%); research management and support (8%); and buildings and facilities (0%).

The President's Budget proposal for FY 2011 includes \$6.036 B to support a range of bold and innovative cancer efforts, including new drug trials, doubling of the number of novel compounds in clinical trials, and a catalog of cancer mutations for the 20 most common malignancies. The allocation to the NCI totals \$5.260 B. Dr. Niederhuber referred members to the copy of the NCI bypass proposal for the FY 2011 budget, which relates NCI's progress against cancer to help the House and Senate Appropriations Committees advise Congress regarding the President's Budget and also provides a resource for the cancer community. The trend in NCI budget appropriations has increased from a flat budget in 2004 to 2008, followed by a steady increase in 2009 and 2010. Competing RPG levels have remained consistent between 2008 and 2009, with unsolicited applications far outnumbering solicited RPGs.

Facilitating Target Discovery and New Agent Development. Dr. Niederhuber said that the NCI is harnessing the power of genomics and technology to dissect the complexity of cancer. The Cancer Genome Atlas (TCGA) pilot project provides an excellent example of the NCI's ability to facilitate

collaboration in sequencing and tumor characterization among centers in the academic research community across the country; the Institute is committed to ensuring that the information will be accessible to other researchers, which is important in this data-generating era of science. The NCI's target discovery and development process focuses on the bioinformatic mining of cancer genomic data beginning with samples from a patient's cancer that are characterized, yielding data that will drive science to understand biology systems and potential targets. Improved knowledge about biologic pathways will help stimulate research at the cellular and genomic levels, abetting the search for novel compounds to inform drug discovery. The NCI Experimental Therapeutics (NExT) program supports this transition from data discovery to small molecules to bring improved therapies to cancer patients by facilitating the progression of new anticancer drugs and imaging agents. The NExT pipeline involves many large NCI programs, including Cancer Centers, Specialized Programs of Research Excellence (SPoREs), RPG investigators (P01, R01), as well as biotechnology and pharmaceutical companies. NCI's investment in sequencing projects, such as TCGA and genome-wide association studies, is creating a catalog of germline and somatic mutations in the same patient and in larger populations of patients that can inform cancer etiology, progression, and outcome. The cancer Human Biobank (caHUB), bioanalytics, and functional and chemical biology consortia support research on high-risk and other tumors through patient characterization centers. This effort promotes nimbleness in scientific investigations across the academic community and facilitates the movement of promising agents to the private sector for further development.

NCI Executive Committee Scientific Retreat. Dr. Niederhuber informed members that themes covered during the NCI's EC Scientific Retreat in January 2010 included biospecimens, patient data, and patient-reported outcomes needed for evaluation to inform health care reform, as well as that the research reward culture needs to fully recognize the contributions of participants in team science. He reported that participants agreed that single-agent interventions will not work, and that the Cancer Centers, SPoREs, and other programs should be used to test new modalities. Dr. Niederhuber said that consensus at the retreat was that the continuum of patient care begins before diagnosis, and effective translational science requires active coordination throughout the process. Cancer treatment going forward will not be single-agent interventions but recipes addressing specific genetic mutations and signaling pathways.

Questions and Answers

Dr. Bruce Allan Chabner, Clinical Director, Massachusetts General Hospital Cancer Center, and Chief of Hematology/Oncology, Massachusetts General Hospital, asked about NCI's plan to assist NCI-designated Cancer Centers with transitioning into testing of therapeutics that are aimed at very specific molecular targets and communication of information across multiple centers with multiple laboratories involved. He noted that this approach is not easily incorporated into core activities of Cancer Centers and challenges will exist in how to prepare grant applications for this topic and in educating the peer review board. Dr. Niederhuber said that the NCI is establishing a way to coordinate and set the standard for information sharing and consistency in this new era of translational research. Dr. James Doroshow, Director, Division of Cancer Treatment and Diagnosis (DCTD), added that this effort also will set the stage for developing a network of institutions to accomplish this. Dr. Anna Barker, Deputy Director for Advanced Technology and Strategic Partnership, described the rapid acceleration in cancer research using an analogy of the acceptance of information terminology, which in general takes up to 8 years for widespread adoption in a specific field, but has occurred in approximately 5 years in the cancer research field.

IV. PRESIDENT'S CANCER PANEL REPORT—DR. LASALLE D. LEFFALL, JR.

Dr. LaSalle D. Leffall, Jr., Chair, President's Cancer Panel (PCP, the Panel) and Charles R. Drew Professor of Surgery, Howard University Hospital, thanked the NCAB and the NCI staff, in particular Dr. Abby Sandler, PCP Executive Secretary for the Panel, for assisting the PCP at this meeting. The Panel currently consists of Dr. Leffall and Dr. Margaret L. Kripke, and they are awaiting White House

appointment of a third Panel member. Dr. Leffall reminded members that the mission of the Panel is to monitor the development and execution of the activities of the National Cancer Program and to report directly to the President. Any delays or blockages in rapid execution of the Program are brought immediately to the President's attention.

The 2008–2009 Panel report *Reducing Environmental Cancer Risk: What We Can Do Now* has been completed and will be released in March 2010. The 2009–2010 meeting series covered the topic “America's Demographic and Cultural Transformation: Implications for the Cancer Enterprise.” Meetings were held in Seattle, WA; Los Angeles, CA; Wilmington, DE; and Miami, FL. Dr. Leffall said that the following important points were made at the Wilmington, DE, meeting: racial categories are socio-political constructs and often do not reflect genetic ancestry; cancer disparities experienced by minorities are largely a result of preventable environmental factors and decreased access to care; cultural and logistic barriers, particularly language barriers, often impede prompt, accurate treatment and adherence; and each individual has a unique complement of cultural, environmental, biological, and genetic risk factors that coalesce to determine cancer risk. Key points made at the meeting in Miami, FL, include: health care access is limited in many population groups, especially American Indians; cultural factors, such as use of complementary and alternative medicine, influence health behaviors and outcomes; significant behavioral and genetic heterogeneity exists within racial and ethnic groups; and implicit bias may exist within cross-cultural provider-patient relationships, adversely affecting patient satisfaction and health outcomes. Dr. Leffall informed members that the Panel has begun preparing the 2009–2010 report.

Dr. Leffall said that the 2010–2011 meeting series is inspired by the 40th anniversary of the 1971 National Cancer Act and will reflect on past progress and consider the best direction for the future of cancer research, care, and policy. The series also will consider how the cancer community can utilize a broad array of scientific, computational, and emerging disciplines to advance the cancer enterprise.

Questions and Answers

Dr. Runowicz encouraged efforts to improve the access to care in the “Black Belt”, in Appalachia, and other parts of the United States where populations focus on maintaining subsistence living. She also offered the Board's assistance in filling the vacant position on the Panel through a Board letter to the President. Dr. Leffall expressed appreciation for the assistance.

Dr. Chabner observed the similarity between the PCP agenda and the NCAB's strategic planning effort and suggested that the Panel might contribute to it. Dr. Leffall agreed this might be a beneficial activity for both groups.

Motion. A motion was made to prepare a letter expressing the NCAB's strong support in filling the vacant position on the President's Cancer Panel (PCP). The motion was seconded and approved unanimously.

V. LEGISLATIVE UPDATE—MS. SUSAN ERICKSON

In the interest of time, Ms. Susan Erickson, Director, Office of Government and Congressional Relations (OGCR), deferred the legislative update. Members were referred to the materials in their meeting books for legislative items of interest.

VI. NCI FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTER (FFRDC)—DR. CRAIG REYNOLDS

Dr. Craig Reynolds, Associate Director, NCI-Frederick, said that the mission of the NCI-Frederick Federally Funded Research and Development Center (FFRDC) is to provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for

the prevention, diagnosis, and treatment of cancer and AIDS. The facility, which was established in 1971 by President Nixon and in 1975 was designated as an FFRDC, is a government-owned and contractor-operated facility with 2,800 employees working onsite. The FFRDC recently was cited by *The Scientist* as one of the best places to work among U.S. research institutions and for postdoctoral fellows.

NCI-Frederick, one of 37 government research centers that share the FFRDC designation, is the only FFRDC in the Department of Health and Human Services (HHS) and the only one solely dedicated to biomedical research. Key FFRDC characteristics include a long-term government/contractor relationship that helps to safeguard expertise, flexibility, increased efficiency, accountability, and rapid response. Dr. Reynolds offered the Nanotechnology Characterization Laboratory as an example of how the FFRDC meets an urgent need for product development through close collaboration among the NCI, Food and Drug Administration (FDA), and National Institute of Standards and Technology (NIST). The FFRDC operates a number of programs, including the Biopharmaceutical Development Program (BDP), Vaccine Clinical Materials Program (VCMP), National Community Cancer Centers Program (NCCCCP), NCI/National Institute of General Medical Sciences (NIGMS) Beamline Project, NCI Biospecimen Resources Network (BRN), Mouse Models of Human Cancer Consortium (MMHCC), and Cancer Bioinformatics Grid (caBIG™). The Center also assists with TCGA and the Therapeutically Applicable Research to Generate Effective Treatments (TARGET) project. More recent projects supported by NCI's American Recovery and Reinvestment Act (ARRA) funds are the caBIG™ electronic health records, caBIG™ Cancer Cloud, Chemical Biology Consortium (CBC), cancer Human Biobank (caHUB), Patient Characterization Center (PCC), and Clinical Assay Development Center (CADC). In addition to the NCI and HHS, the FFRDC has provided advanced technology support to the Department of Defense (DoD), FDA, and U.S. Department of Agriculture. The facility also has filed more than 50 percent of NCI's invention reports, produced more than 60 novel biopharmaceutical products and vaccines, and supported more than 350 NCI- and National Institute of Allergy and Infectious Diseases (NIAID)-sponsored clinical trials to test innovative cancer and AIDS treatments.

Dr. Reynolds said that the NCI-Frederick FFRDC meets the most urgent biomedical research needs of the Nation, including NCI, other NIH Institutes and Centers, other government agencies, extramural investigators, and NCI corporate partners. It could serve the needs of the academic, industry, and small business communities even more effectively by improving access to advanced technologies and clinical trial resources; developing a national training program in advanced technologies, biopharmaceuticals, and clinical assays; providing a more robust beta-test program for the development of new technologies; facilitating the use of public-private partnerships to expedite the development of novel agents; and effectively developing a wider range of public-private partnership opportunities.

Questions and Answers

Dr. Donald S. Coffey, The Catherine Iola and J. Smith Michael Distinguished Professor of Urology, and Professor of Urology/Oncology/Pathology/Pharmacology and Molecular Science, Johns Hopkins University School of Medicine, asked about budget increases necessary for the next 10 years to address the Center's efforts and whether training could be conducted at another location. He encouraged the NCI to focus on the most important issues rather than supporting all activities at every institute. Dr. Reynolds responded that the FFRDC's role should be to facilitate those activities, and that much of the work would be done through the extramural program, cooperative agreements, and the small business program. He added that the idea is to train postdoctoral fellows who will bring their knowledge to other institutions during their careers. Dr. Niederhuber commented that the training will be project and technology specific; training could be conducted elsewhere but the extramural community may not be able to support it. He also clarified that the VCMP's role is to produce vaccines for rare hemorrhagic infectious diseases, which does not include cancer vaccines. Dr. Barker stated that the development of vaccines for rare viruses could not be conducted elsewhere, and that the Nanocharacterization Laboratory is a unique resource in the United States.

Dr. Chabner encouraged future presentations about the Center to include detailed, specific examples, with a focus on the facility's accomplishments during the past 10 years and its potential major role during the next 10 years. He observed that the facility's AIDS effort in the 1990s provides a good example of a response to a national emergency situation. Dr. Jennifer A. Pietenpol, Director, Vanderbilt-Ingram Cancer Center, B.F. Byrd, Jr. Professor of Oncology, and Professor of Biochemistry, Vanderbilt University Medical Center, agreed and recommended that future overviews of the Center should provide key examples of achievements that could not have been realized without the facility. Dr. Niederhuber confirmed that unique achievements exist but these are difficult to present because of their complexity. He mentioned that it would be necessary to receive special authorities from Congress for the FFRDC to work more effectively with the private sector.

VII. ADVANCED TECHNOLOGY RESEARCH FACILITY—DR. CRAIG REYNOLDS

Dr. Reynolds informed members that the Advanced Technology Partnership Initiative (ATPI) aims to accelerate the delivery of new products to cancer patients through the strategic application of advanced technologies and effective translational research collaborations between the public and private sectors. The justification for the ATPI is based on the recommendations of a 2004 NCI Roundtable and FDA Report; a 2006 Government Accounting Office (GAO) Report and NCI Strategic Plan; and a 2007 NCI Translational Research Working Group Report. The ATPI concept was initiated in 2005 and presented in 2007 to the NIH Director, the HHS Assistant Secretary, and the NCAB; discussions with industry leaders, the Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) community, and academic investigators followed. Dr. Elias Zerhouni, NIH Director at the time, supported the ATPI concept because the initiative is "modest in scope" and "reasonable in cost." Dr. Zerhouni said that NCI-Frederick resources are unique and of high quality and that the NCI should proceed with the initiative by further engaging industry to define partnerships, and by evaluating potential expansion sites to facilitate the ATPI. The industry response included that: the NCI is the logical organization to facilitate the collaborations; the ATPI would enhance both therapeutic and diagnostic agent development; pre-competitive technology development will foster initiatives that a single company cannot answer; the ATPI offers the ideal mechanism for solving problems; and the NCI easily can provide the means to test combination therapies from competing firms.

Dr. Reynolds said that the majority of ATPI support activities will be located in a research park, and NCI-Frederick special authorities and resources will be leveraged to facilitate partnerships. NCI technology programs that currently are scattered among 34 buildings will be consolidated into the Advanced Technology Research Facility (ATRF), thereby promoting efficiency, synergism, and collaboration among the programs. The facility will be sited in a 330,000-square-foot office building with laboratory space and encompass nearly 600 current and future staff, with an estimated operating budget of \$222 M. The existing campus at NCI-Frederick will be maintained. Construction of the principal building at the Riverside Research Park in Frederick, MD, is underway and scheduled for completion in September 2010, with occupancy planned for 2011–2012.

Questions and Answers

Dr. Niederhuber said that the NCI would welcome biotechnology and pharmaceutical companies that establish facilities on the same campus. He noted that a local college and developers are considering an educational facility and a hotel and conference facility, respectively. Dr. Niederhuber explained that the NCI successfully negotiated with the NIH a new lease term that decreased the costs for the NCI and potentially other NIH Institutes. Dr. Reynolds further described the educational center and said that the University of Maryland, Hood College, Mount St. Mary's University, and The Johns Hopkins University (JHU) have expressed interest in participating.

Dr. Chabner noted that the creation of partnerships is a key element of this venture, asked how many partners could be fit into the remaining space, and inquired about the vision of working together and sharing intellectual property (IP). Dr. Reynolds responded that 200 people will participate through partnerships and will occupy the space, which is distributed across the facility to encourage collaborations among various groups. If partners enter in a training mode, IP will not be an issue; other situations will be handled similar to current collaborations. The goal is to encourage, and not to stifle, new technologies. Dr. Michael Stebbins, Assistant Director, Biotechnology, Office of Science and Technology Policy (OSTP), Executive Office of the President, asked whether this will be synergized with the SBIR program. Dr. Reynolds acknowledged efforts to synergize with the small business community and mentioned plans for bioincubators to start up new technologies.

Dr. Pietenpol asked about incentives to recruit partners. Dr. Reynolds responded that intellectual value is the current incentive and said that additional incentives might be needed for companies to occupy other buildings at the research park. Dr. Niederhuber said that the NCI has been working with the local and state governments, and that the Governor of Maryland considers biotechnology development a significant priority.

VIII. ANNUAL DELEGATIONS OF AUTHORITY—DR. PAULETTE S. GRAY

Dr. Gray requested concurrence by the NCAB on two Delegations of Authority to the Director of the NCI. She described the delegations and the provisions in the Statement of Understanding. Delegation A allows the Director to obtain the services of not more than 151 special experts or consultants who have scientific or professional qualifications. Delegation B specifies that the NCI Director can appoint advisory committees composed of private citizens and officials of Federal, state, and local governments.

The Statement of Understanding with NCI Staff on Operating Principles in Extramural Grants also falls within the Delegations of Authority to the Director, NCI. The NCAB operations are conducted in accordance with management and review procedures described in the NIH Manual Issuance 4513. Concurrence of the NCAB with recommendations of initial review groups will be required except for the following: 1) Training grants and fellowships and other non-research grant applications are not subject to NCAB review and approval, and without other concerns may be awarded without presentation to the NCAB for concurrence with the exception of Ruth L. Kirschstein National Research Service Awards. 2) Applications over the 50th percentile will not have summary statements presented to the NCAB. 3) For applications assigned raw scores that are not percentiled, the cutoff will be a priority score of 250 for all mechanisms except R41, 42, 43, and 44 awards; for the latter, all scored applications will be included. Expedited Concurrence: 1) for R01 and R21 applications with percentiled or raw scores that fall within the NCI paylines for that mechanism, a process of expedited concurrence will be used; and 2) the Executive Secretary will alert Board members with responsibility for expedited concurrence when review outcomes for eligible applications are available on the Electronic Expedited Concurrence portion of the Electronic Council Book. Administrative Adjustments: 1) Permission is delegated to the Director, NCI, to allow staff to negotiate appropriate adjustments in dollars or other terms and conditions of grant and cooperative agreement awards. 2) Administrative requests for increases in direct costs that are the result of marked expansion or significant change in scientific content of a program after formal peer review will be referred to the Board for advice and recommendation. 3) Actions not requiring Board review or advice, such as change of institution, change of principal investigator (PI), phase-out or interim support, or additional support need not be reported to the Board. 4) NCI staff may restore requested time and support that were deleted by the initial review group when justified by the PI in an appeal letter or restoration is in the best interest of the NCI and the project is of high NCI programmatic relevance.

Motion. A motion to approve the NCI's Annual Delegations of Authority was seconded and approved unanimously.

IX. NCI CANCER HUMAN BIOBANK (caHUB)—DRS. CAROLYN C. COMPTON AND KEN BUETOW

Dr. Carolyn C. Compton, Director, Office of Biorepositories and Biospecimen Research (OBBR), provided an update on the NCI's caHUB initiative. Dr. Compton told members that the absence of high-quality, clinically annotated human specimens has become the limiting factor for translational cancer research. The NCI has established the caHUB to address the needs for specimens and services and in 2009 allotted \$60 M of ARRA funds to the initiative. caHUB is intended to be a unique, centralized, nonprofit public resource. Its primary mission is to ensure an adequate and continuous supply of high-quality, highly annotated human biospecimens and high-quality biospecimen services to the research community. The Biobank will serve the NCI and NIH, other government agencies such as FDA and NIST, patient advocacy organizations, and all industrial sectors involved in medical science research, medical product development, and technology development.

The need for caHUB has been clearly expressed from all sources: a survey of NCI investigators; market research using focus group sessions with academia and industry decision-makers; interviews with commercial tissue providers and industry users; a caHUB Users Workshop; mining of request data from the NCI Tissue Locator during the last 7 years; and input from potential users such as the Cancer Therapy Evaluation Program (CTEP), NCI PCC, and numerous biomarkers programs. The importance of a national biospecimen resource has been cited on many levels, including the HHS 2007 Personalized Health Care Report, the President's Cancer Panel 2008 Report, and the NCI Bypass Budget for FY 2010.

Development of caHUB involves planning committees that operate for 1 year to advance topics in administration; strategic planning; normal tissue and biospecimen acquisition; ethical, legal, and social issues; facilities requirements and design; informatics; and partnerships and business models. Planning will be aided by 210 expert contributors to the process and products. The delivery of white papers, standard operating procedures (SOPs), and other manuscripts representing the products of the planning committees is scheduled for April 2010. Dr. Compton explained details about specimen collection (prioritization, strategies, SOPs, design informed by user need) and data management (functionalities, principles, procedures, and systems), and provided an overview of the caHUB Comprehensive Data Resource.

The caHUB Business Model is a Commodities and Services Model with a focus on cost recovery for specimen and data collection and revenue generation through service provision. Factors that influence the business model include accrual and inventory maturation rates, commodities price points, demands for customized processing services and managed collections, and education and training offerings within caHUB's center-of-excellence. An example demonstrated the collection for a special purpose and showcased caHUB as a service provider for CTEP. Cost recovery modeling based on highly conservative assumptions showed that caHUB could recover 70 percent of the costs by Year 5. Considering market price data for samples, a full cost recovery from the sale of commodities could occur by Year 3.

Contracted components for caHUB Phase 1 (pilot phase) are tissue procurement, caHUB central functions, the caHUB comprehensive data base, and biospecimen research and development. The functional organization during the ARRA period is administration, communication and outreach, services/tools, comprehensive data resource, pathology reference center, ethical/legal/policy, and research and development. Phase 1 will begin in the second half of 2010; Phase 2 (post-pilot phase), consisting of the ramp-up and maturation of the project, will commence at the end of 2012.

Dr. Compton said that caHUB is a transformation initiative that will result in more efficient research and use of resources, ensured implementation of best practices, stronger clinical correlation, more efficient product and technology development, and added clinical value. Most importantly, it will generate improved outcomes for cancer patients with more lives saved, improvements in quality of life, a positive impact on personal and national economics, and overall savings to the health care system.

Questions and Answers

Dr. Runowicz asked how researchers are encouraged to send samples and about the NCI's plan to ensure the high quality of samples and sample processing. Dr. Compton explained that maintaining quality is a matter of compliance with contractual requirements that include detailed SOPs, monitoring every step, and tracking and recording all critical parameters. Dr. Pietenpol queried how participants will be motivated. Dr. Compton responded that there will be monitored contracts with tissue-donating sources, sources will receive money for specific performances, and sites will be inspected. In addition, caHUB will rely on a participant's professional willingness and dedication.

Dr. Chabner asked whether specimens will be fresh, fixed, or frozen. Dr. Compton replied that all three types of specimen will be collected and that specimen-processing SOPs will address users' concerns. Dr. Pietenpol inquired about plans to prioritize the collection and access to samples. Dr. Compton said that monetary constraints will impact acquisition goals as well as processing and storage of samples. Access policies still have to be developed. Dr. Barker noted that other countries have set up national biobanks, and that China is moving ahead quickly. It is apparent that access to samples, legal considerations, and the protection of sample quality will become major issues regarding grantees and at the national level. Dr. Pietenpol asked what lessons have been learned from the Cooperative Human Tissue Network (CHTN). Dr. Barker responded that many protocols and opinions exist. During the past several years, caHUB has tried to develop evidence-based SOPs. Available evidence is limited, however, because evidence for the quality of specimens has been collected only since 2008. Dr. Compton remarked that CHTN's infrastructure represents a demand-and-supply system, not a biobank, and that CHTN does not collect clinical data to the extent that is planned for caHUB. Dr. Coffey congratulated Dr. Compton on the coordination effort and also expressed caution regarding the quality of pathology sample interpretations. Dr. Compton replied that digital pathology by morphometric image analysis will be implemented in combination with transparent SOPs for interpretation, showing how an interpretation was derived, and this information will be integrated into the dataset for caHUB samples.

Dr. Chabner raised concerns about the feasibility of covering costs with a low charge for services, considering the comprehensive plan for the collection of specimens and data as well as analysis of data. Dr. Compton clarified that the charge will be \$250 per aliquot and a standard data set associated with it; part of the business plan is a scaled pricing system that accommodates additional services.

X. OPPORTUNITIES TO COLLABORATE AND DEVELOP JOINT CLINICAL PROGRAMS WITH WALTER REED AND SUBURBAN HOSPITAL—DRS. LEE HELMAN AND JOHN NIEDERHUBER

Dr. Lee Helman, Scientific Director for Clinical Research, Center for Cancer Research, described the vision for NCI Clinical Center collaboration in clinical initiatives with Walter Reed National Medical Center (Walter Reed) and JHU Suburban Hospital. The three institutions are located in close proximity to each other. The opportunity for this collaboration evolved from the military Base Realignment and Closure (BRAC) process, resulting in the relocation of tertiary medical services to Walter Reed. The Walter Reed facility will include 345 inpatient beds and cover more than 1.5 million square feet that include: vision centers; centers of excellence, including a National Intrepid Center of Excellence; a comprehensive Warrior Transition Support Service; a joint pathology service; and a proposed Walter Reed/NCI Cancer Center. Further collaboration will be enhanced by the existing Uniformed Services University of the Health Sciences (USUHS) at Walter Reed.

Dr. Helman told members that the NCI has a substantive working relationship with the military, particularly regarding clinical research and training as well as patient referral through collaboration. The NCI has worked with the National Naval Medical Center in Bethesda, MD, since 1981, and the cross-

training activities between the institutions strengthen their respective programs in medical oncology, radiation oncology, and gynecologic oncology. Future opportunities for collaborative activities include radiation oncology and centers of excellence, particularly in lung cancer, breast cancer, and gynecologic oncology. An implementation team has been established to build the vision for partnership between the NCI and Walter Reed for world-class medical care, and discussions are underway regarding the JHU Suburban Hospital partnership.

Questions and Answers

Dr. Niederhuber acknowledged the efforts of Drs. Helman and Sue Bailey, former Assistant Secretary of Defense for Health Affairs, in the collaborative process with Walter Reed. He added that the NCI had been in long-term discussions with Suburban Hospital, and he welcomed the presence of JHU in the partnership. These collaborations provide an opportunity for the NCI to attract the best scientists to work across the cancer spectrum, particularly clinical research and care. Dr. Coffey observed that Dr. William Nelson, Director of Johns Hopkins Kimmel Cancer Center, strongly supports the NCI and will abet the collaborative process with the NCI.

Dr. John F. Potter, Director, United States Military Cancer Institute, Walter Reed Army Medical Center, expressed that Institute's enthusiasm for this collaboration, noting that cancer is a major problem in military health, with approximately 355,000 patients treated for cancer or followed up annually at a cost of \$1.2 B. He added that the Institute feels that the synergy with the NCI offers spectacular opportunities for patient care and research. Dr. Chabner commented that specimens available from the military and Suburban might ease pathology concerns faced by caHUB. Dr. Potter noted the existence of a tissue bank in the military, in which quality control is a major factor; education of the medical team, particularly the circulating nurse, also is important. Dr. Runowicz cautioned that because circulating nurses often have multiple tasks, the specimen might not be processed in the operating room as quickly as desirable.

XI. SEER: ANNUAL REPORT TO THE NATION—DRS. ROBERT CROYLE AND BRENDA EDWARDS

Dr. Robert T. Croyle, Director, Division of Cancer Control and Population Sciences (DCCPS), informed members that the Surveillance, Epidemiology and End Results' (SEER) Program initiatives are an interagency and global effort and that the NCI serves as a technical resource within the United States and to other nations in their surveillance efforts. The DCCPS would be pleased to provide the NCAB with additional information about statistics and SEER's efforts to more effectively communicate evidence and data to the public, if desired. Dr. Croyle introduced Dr. Brenda K. Edwards, Associate Director, Surveillance Research Program, DCCPS, who described the results of the 2009 *Annual Report to the Nation*.

Dr. Edwards noted that SEER monitors the impact of cancer and the progress to reduce cancer. This includes all cancer sites and all population groups, and the identification of unusual patterns. Since the mid-1990s, the United States has significantly improved published data for population-based cancer incidence to more than 85 percent. The *Annual Report to the Nation* has been published since 1998 and is coordinated by the NCI, Centers of Disease Control and Prevention (CDC), American Cancer Society (ACS), and North American Association of Central Cancer Registries (NAACCR). Its focus is on the latest cancer incidence and mortality data, and each annual report features a specific topic, which for the 2009 report is colorectal cancer. Members were referred to the journal *Cancer* (1 February 2010) for a commentary on this subject. Overall, rates of new diagnoses and rates of death from all cancers combined declined significantly in the most recent time period for men and women and for most racial and ethnic U.S. populations. Concerning the top 15 cancer sites for men and for women, death rates generally have declined with few exceptions. A reduction in mortality has occurred in most groups, but mortality stayed constant in American Indians and Alaska Natives. Specifically, U.S. death rates have declined

considerably for lung and bronchus cancer in all men; in most women, however, the trend is usually flat, although a definitive increase still can be observed in American Indian and Alaska Native women. The second leading cause of cancer death in men is prostate cancer, with incidence and mortality rates declining in most population groups. The incidence and mortality rates of liver and intrahepatic bile duct cancer are increasing in most groups. For women, incidence and mortality for cervical cancer have declined. The third leading cause of cancer death in both sexes is colorectal cancer; incidence and mortality have declined for all population groups.

The Report also describes micro-simulation modeling (MISCAN-Colon model). This tool was used to analyze the impact of changes in risk factors, screening, and treatment practices on past cancer trends, and to project future mortality rates. Modeling results showed that declines in future colorectal cancer death rates could be accelerated with more favorable trends in risk factors (e.g., quitting smoking, improved dietary and physical activity practices), higher utilization of screening (e.g., colonoscopy), and optimal treatment (e.g., more patients receiving effective chemotherapy). Such actions could result in a 50 percent reduction by 2020 in the 2000 colorectal cancer death rates. A *Cancer Trends Progress Report* 2009/2010 update will be issued in April 2010.

Future challenges include increasing demands on SEER for more data regarding comorbidity; recurrence; prognostic factors and clinically relevant tumor characteristics; biospecimens; diagnosis, treatment, and medical management; and delivery of care. A greater reliance on electronic health records, automated data collection and processing, database linkage, better understanding of population differences, and coordination and integration among surveillance partners also are needed.

Questions and Answers

Dr. Victoria L. Champion, Associate Dean for Research, Mary Margaret Walther Distinguished Professor of Nursing, Center for Research & Scholarship, Indiana University School of Nursing, remarked on the effect of lifestyle factors on cancer mortality and asked whether the modeling predictions for 2020 considered obesity, smoking, and other factors equally. She commented that the decrease in smoking might have reached a plateau and little impact has been made on decreasing obesity. Dr. Edwards replied that the model inputs for past and future data on smoking, obesity, and physical inactivity were dynamic and changed differentially over time. These parameters are available as a supplemental table and were based on a Cancer Intervention and Surveillance Modeling Network (CISNET) study published in 2006.

Dr. Runowicz asked whether cancer incidence in women has changed because of the decrease in estrogen replacement therapy. Dr. Edwards confirmed a decline in the last ten years and noted that there have been drops and increases observed at other times, such as in 1985 when President Reagan was diagnosed with colorectal cancer, which increased the Nation's awareness of the disease. Another positive impact factor may have been the preventive use of folate; its effect still is discussed because a parallel increased screening effort also could have had an impact. Dr. Chabner asked about the effects of using drugs such as oxaliplatin and pointed out that the treatment is used for adjuvant therapy and for cancers with grades 2 and 3, not for metastatic disease. Dr. Edwards responded that all four chemotherapy regimens have been considered in the model based on current standards.

XII. UPDATE: NCI COMMUNITY CANCER CENTERS PROGRAM (NCCCP)— DR. STEVEN CLAUSER

Dr. Steven Clauser, Chief, Outcomes Research Branch, Applied Research Program, DCCPS, provided an update of the NCCCP, which works to reach cancer patients in local communities outside of NCI designated cancer centers where approximately 85 percent of cancer patients receive cancer care. Practice patterns and quality of care in community settings currently are not always optimal. Additionally, disparities remain a national challenge, only limited research occurs within community settings, and

expanding science will require new approaches, infrastructure, and connections. The NCCCP's goal is to enhance access, improve quality of care, and expand research, with the community hospital at the center of these activities. In 2007, 10 subcontracts with 16 sites were awarded across the United States. The program has unique attributes such as public-private and physician-management partnerships, networking among sites, leveraging of NCI scientific resources, and rigorous program evaluation procedures.

The NCCCP has achieved progress in several areas. Concerning health care disparities, a vision, work plan, and dashboard with metrics have been developed, resulting in improvements to understand and address disparities, capacity building, and race and ethnicity tracking. To address quality of care, site-assessment tools for multidisciplinary care, and genetic counseling and testing have been created and implemented. The NCCCP also assess adherence to evidence-based practice by participating in national quality measurement and improvement initiatives with the American College of Surgeon's Commission on Cancer and the American Society of Clinical Oncology. To overcome the absence of a comprehensive approach for survivorship and palliative care, best practices were shared about the implementation of treatment summary and care plan documents. Program matrix assessment tools were developed for comprehensive palliative and psychosocial care delivery. Model educational/intervention programs for survivors and their families were showcased.

Limited participation in clinical trials, including by minority and other underrepresented populations, has been observed. The achieved progress in this area includes a high accrual to the Wake Forest Chronic Lymphocytic Leukemia (CLL) Trial, with 63 entered patients in a trial with 293 participants. The clinical trial log workgroup created a permanent IT application that allows for dynamic data entry, site-directed management and accountability, and real-time queries and outcomes. A collaborative effort with the Community Clinical Oncology Program (CCOP) leadership also has been established.

Dr. Clauser said that the shortage of high-quality biospecimens for research purposes remains a challenge. To address this problem, 100 percent of sites currently use best-practice protocols for breast cancer testing; model protocols have been developed for non-routine biospecimen disposal in collaboration with the Disparities Subcommittee to integrate special religious and cultural considerations. Three sites are participating in TCGA and five sites in the Moffitt Total Cancer Care (TCC) program. Notable accomplishments in the field of information technology include implementation of caBIG™ tools at 11 of 16 NCCCP sites that have implemented caBIG™ tools; 9 of 16 sites have operational electronic health records.

The NCCCP network is expanding as a result of \$80 M from the ARRA investment, which includes 2 years of funding. Approximately \$40 M will support 18 projects at the current sites, with the remaining \$40 M funding a projected 14 additional community cancer centers. The procurement process is ongoing, and awards are anticipated in April 2010.

Questions and Answers

Dr. Runowicz asked if the biorepository group had reflected on the success of the Moffitt-Merck academic-private partnership. Dr. Barker responded affirmatively and said that the TCGA model was used to start the NCCCP biospecimen collection activity. Efforts have been successful in adopting best practices and creating a center of excellence.

Dr. Chabner requested data about patient accrual to clinical trials and the number of patients who have completed participation in the therapeutic trial since program inception. He also asked about the research that is expected to originate from this effort. Dr. Clauser mentioned that most of our data available on clinical trials come from specific trials of focus in the NCCCP; total counts are not currently available. He also described evaluation studies related to clinical quality improvement of and how our research of the

Commission on Cancer network collaborative may add research value. Dr. Runowicz asked for confirmation that one objective of the program's mission is to help communities obtain access to the most up-to-date cancer care. Dr. Niederhuber explained that the program's overall goal is to use input from all of NCI's divisions to improve access to cancer care in communities. He mentioned examples such as improving care for minority populations and achieving better collaboration across specialties of private-practice physicians. Dr. Chabner remarked that all of the centers have encountered problems with reaching out to communities and improving practice. Efforts have to be designed carefully to make an impact. Dr. Coffey suggested incorporating into a business model the cost savings that could be achieved by a percentage drop in cancer rates.

Dr. Coffey encouraged NCI program staff to review the organ systems program that was created by SPORE investigator Dr. Andrew Chiarodo in Dade County, FL, in the 1980s. Although the program likely has been discontinued, that program's procedures of biospecimen collection, fixation, and storage may provide an appropriate model for current research and biospecimen collection activities.

XIII. NCAB ONGOING AND NEW BUSINESS—DR. CAROLYN D. RUNOWICZ

NCAB *Ad Hoc* Biomedical Technology Subcommittee. Dr. Runowicz said that NCI staff requested that the Board establish a working group to help address the issues confronting TCGA and its myriad of activities. Dr. Jennifer Pietenpol will serve as the Chair.

Motion. A motion was made to approve the creation of the NCAB *Ad Hoc* Biomedical Technology Subcommittee. The motion was seconded and approved unanimously.

Creating a Strategic Vision for the National Cancer Program Working Group. Dr. Runowicz reminded members of several discussions by the Board in 2009 concerning the effectiveness of NCAB's role in advising the NCI Director, the HHS Secretary, and the President regarding the National Cancer Program and the importance of the NCI in leading this agenda. The NCAB Subcommittee on Activities and Agendas discussed at the NCAB retreat in January 2010 the possibility of the Board convening an *ad hoc* NCAB working group to create a strategic plan for the National Cancer Program, broadly review the NCI, and review the authorities, structure, and governance of the NCAB. The working group should evaluate the NCI's evolution during the 40 years since the passage of the National Cancer Act in 1971 as well as project where the NCI should be in the next decade. This will assist in the development of a strategic plan and help determine the required structure to enhance organizational effectiveness to facilitate progress and understanding in diagnosing, preventing, and treating cancer. The Board indicated at the retreat that it supported the Subcommittee's recommendation. Dr. Chabner added that the focus would center on the last 10 years and weigh future directions and changes. The co-Chairs are NCAB members Mr. Bill Goodwin, Mr. Bob Ingram, and Dr. Chabner, and former NCAB member Dr. Phil Sharp. Dr. Gray will serve as the Executive Secretary.

Motion. A motion was made to approve the creation of the NCAB Working Group to create a strategic plan, broadly review NCI's portfolio, and review NCAB's role and authorities. The motion was seconded and approved unanimously.

Motion. A motion was made to name the group "Creating a Strategic Vision for the National Cancer Program Working Group." The motion was seconded and approved unanimously with the agreement that the name would be modified to encompass the notion that NCAB's authorities include an annual review and strategic planning effort.

XIV. CLOSED SESSION—DR. CAROLYN D. RUNOWICZ

This portion of the meeting was closed to the public in accordance with the provisions set forth in Sections 552b(c)(4), 552b(c)(6), Title 5 U.S. code and 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2).

Members were instructed to exit the room if they deemed that their participation in the deliberation of any matter before the Board would be a real conflict or that it would represent the appearance of a conflict. Members were asked to sign a conflict-of-interest/confidentiality certification to this effect.

The *en bloc* vote for concurrence with IRG recommendation was affirmed by all serving Board members present. During the closed session of the meeting, a total of 2,259 applications were reviewed requesting support of \$804,366,196.

XV. ADJOURNMENT—DR. CAROLYN D. RUNOWICZ

Dr. Runowicz thanked all of the Board members, as well as all of the visitors and observers, for attending.

There being no further business, the 153rd regular meeting of the NCAB was adjourned at 3:31 p.m. on Thursday, 18 February 2010.

Date

Carolyn D. Runowicz, M.D., Chair

Date

Paulette S. Gray, Ph.D., Executive Secretary