THE CANCER LETTER

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NCI Advisors Approve $160-Million Network For Biomarker Discovery And Validation

By Kirsten Boyd Goldberg

An NCI advisory group approved the institute's plan to renew funding for the Early Detection Research Network, a $32-million per year program that supports biomarker research.

The NCI Board of Scientific Advisors voted 14-2 in favor of continuing the program, which began in 2000. The goal of the research network is to discover and validate biomarkers for assessment of cancer and cancer risk.

The board, at its March 2 meeting, also approved plans to renew funding for human specimen banking in NCI-supported cancer clinical trials cooperative groups and the Cancer Intervention and Surveillance Modeling Network, a consortium of investigators who use statistical modeling to

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White House:

Obama Lifts Ban On Federal Funding For Embryonic Stem Cell Research

President Obama March 9 signed an executive order lifting a ban on federal funding for embryonic stem cell research and issued a memorandum calling for guidelines for protecting government scientists from political pressure.

Obama's action revokes George Bush's 2001 executive order that prohibited the use of federal funds for stem cell research. The use of stem cells is not limited to surplus embryos generated by fertility clinics.

The President gives NIH 120 days to set ethical guidelines for such research.

The text of the executive order on stem cell research follows:

Section 1. Policy. Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem

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BSA Approves EDRN, CISNET And Group Specimen Banks

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understand cancer incidence and mortality trends. Both votes were unanimous.

(The board also approved several new concepts for grant programs, which will be covered in an upcoming issue of The Cancer Letter.)

Following are excerpts from the concept statements:

Early Detection Research Network. Concept for RFA, cooperative agreement, first year set aside $32 million, total cost $160 million over five years, estimated award date March 2010. Awards: up to 25 Biomarker Development Labs, up to 8 Clinical and Epidemiology Validation Centers, up to 4 Biomarkers Reference Labs, and up to 2 Data Management and Coordinating Centers. Program director: Sudhir Srivastava, Division of Cancer Prevention.

The Early Detection Research Network is a pioneering effort designed to discover and validate biomarkers for assessment of cancer and cancer risk. First launched in 2000, EDRN provides a vertically integrated network of academic and industry-based scientists collaborating to meet the challenge of developing new cancer screening and early detection products. The mission of EDRN is both to implement strategic and systematic, evidence-based discovery, development, and validation of biomarkers to identify cancer risk, cancer, and cancer prognoses, and to coordinate biomarker research and therapeutic strategies in order to reduce cancer morbidity and mortality.

Identifying biomarkers involves a rigorous process that begins with discovery and leads to development validation, and finally application. EDRN has fulfilled these expectations by establishing a process for biomarker development using a multidisciplinary and multi-institutional approach. The Network promotes collaboration among researchers by creating an investigator-driven environment of "cross-fertilization," that is, teamwork across disciplines and laboratories to achieve common goals. These objectives are:

—Discovery: Develop and test promising biomarkers or technologies in institutions with the scientific and clinical expertise to obtain preliminary information that will guide further testing;

—Validation: Efficiently validate promising, analytically proven biomarkers or technologies, including measures of diagnostic predictive accuracy, sensitivity, specificity, and, whenever possible, medical benefits as predictors of clinical outcome or surrogate endpoints for early detection and for prevention intervention clinical trials;

—Quality Assurance Programs Resource: Develop quality assurance programs and resources for bioinarker testijic, and evaluation, and

—Public-Private partnerships: Collaborate among academic and industrial leaders in molecular biology, molecular genetics, clinical oncology, computer science, public health, and other disciplines, for the development of high-throughput, sensitive assay methods for biomarkers for early detection and risk assessment.

The Network has four main components – Biomarker Developmental Laboratories (25), Biomarker Reference Laboratories (4 laboratories plus NIST), Clinical Epidemiology and Validation Centers (CEVC; 9 Centers), and one Data Management and Coordinating Center (DMCC). The BDL have responsibility for the development and characterization of new or the refinement of existing, biomarkers and assays. The BRL serve as a Network resource for clinical and laboratory validation of biomarkers, including, technological development and refinement. The CEVCs collaboratively conduct clinical and epidemiological research on the Network-wide clinical validation of biomarkers. The DMCC supports statistical and computational analysis, informatics infrastructure, and coordinates network-wide meetings and conferences.

The purpose of the proposed RFA is to provide for the continuation of the EDRN infrastructure. Given that biomarker development must begin at the earliest

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stage of discovery, EDRN's signature accomplishment is having produced a developmental pipeline that provides standardized procedures and measurable milestones. EDRN has challenged the very culture of academic research by its emphasis both on team science as well as on close attention to milestones of biomarker development, a rigorous process not familiar to many academic environments.

EDRN supports the development, validation, and application of biologic biomarkers that can provide reliable detection, diagnostic and prognostic information on cancer and can serve as surrogate markers for assessing, the response to chemoprevention and treatment. Areas of particular interest include molecular assays to replace tissue based assays with biological fluids, improvements in body-imaging techniques, and development of a knowledge base for improving evidence-based screening of cancer. With the help of new technologies, candidate biomarkers are being identified; however, the translation of these new biomarkers is lagging behind due to the lack of reproducibility of biomarker assays and the need for improved study design in the discovery process. EDRN has begun addressing these issues by developing quality specimens, robust study designs, standard operating, procedures, and collaborations among technology developers.

Types of biomarkers of particular relevance to the EDRN's Strategic Goals include, genetic, genomic, epigenetic, gene expression, microRNA, proteomic, glycomic, metabolomic, and other as-yet uncharacterized novel categories. Further details on EDRN available at http://www.cancer.gov/edrn.

Support for Human Specimen Banking in NCI-Supported Cancer Clinical Trials. Concept for RFA reissue, cooperative agreement, first-year set aside $8.75 million, total cost $43.75 million over five years, anticipated award date April 2010, nine awards. Program director: Irina Lubensky, Division of Cancer Treatment and Diagnosis.

This initiative will provide continued funding to the Cooperative Group Banks for an additional five years. The CGBs were established to ensure collection, storage and utilization of well-annotated human specimens from patients entered into NCI-funded, phase III and large phase II clinical treatment trials. The CGB specimen collections are unique; there are no other U.S. biospecimen resources with large numbers of specimens with well-documented clinical and outcome date from patients uniformly treated in randomized trials. Access to CGB specimens with associated high quality clinical, treatment and outcome data is crucial to advancing our understanding of how to diagnose and treat a variety of cancers and is critical for developing personalized medical care and treatment in the future. Support of the CGBs is necessary to maintain a publicly available supply of high value biospecimens and to provide fair and open access to NCI Clinical Cooperative Group human specimens to the research community.

There was no dedicated funding for the Cooperative Group specimen banking activities until September 2005. The CGBs had been inconsistently and sporadically funded previously by the NCI Cancer Therapy Evaluation Program U10 cooperative agreements that provide the support for clinical trials. Available support depended on annual appropriations. The banking activities were also supported using a patchwork of NCI supplements, industry funds and funding from other sources. The patchwork approach has led to inconsistencies among groups and variations in support that made it difficult to operate and coordinate the banks.

The U24 Cooperative Agreement Group Banking Grants were awarded to PIs of nine Cooperative Groups to support the banks from 2005 to 2010. The nine supported CGBs include: American College of Surgeons Oncology Group, Cancer and Leukemia Group B, Children's Oncology Group, Eastern Cooperative Oncology Group, Gynecological Oncology Group, North Central Cancer Treatment Group, National Surgical Breast and Bowel Project, Radiation Therapy Oncology Group, and Southwest Oncology Group. The specimen bank of the National Cancer Institute Canada Clinical Trials Group participates in the work towards harmonization of operations and banking, but is not funded by NCI.

During 2006-2007, the CGBs had collected 807,767 solid tumor specimens, 143,047 serum specimens, and 49,491 leukemia specimens.

During 2000-2007, the CGBs distributed 720,172 solid tumor specimens and 28,728 leukemia specimens to about 2,000 investigators, including 313 researchers outside of the Cooperative Groups. The CGBs have supported an extensive variety of correlative studies. Over 1,350 peer-reviewed scientific publications and 36 patents have resulted from the use of CGB specimens and data from 2000-2008. Of these publications, 352 appeared in journals with an impact factor greater than 10 and report important scientific discoveries by the investigators who used CGB specimens.

Since the CGBs are in the process of harmonizing their standard operating procedures to provide open and

fair access to the researchers, NCI proposes recompeting the CGBs with a limited competition RFA. This is needed to ensure continuation of CGB activities to serve the needs of the scientific community. No other qualified groups exist outside the Cooperative Groups.

The average total cost for each of the nine CGBs is $972,200 per year.

Cancer Intervention and Surveillance Modeling Network. Concept for an RFA reissue, first year set aside $5.4 million, total cost $29.4 million over five years, six awards, anticipated award date Sept. 2010. Program director: Eric Feuer, Division of Cancer Control and Population Sciences.

CISNET is a consortium of NCI-sponsored investigators whose focus is to use modeling to improve our understanding of the impact of cancer control interventions on population trends in incidence and mortality. These models can be used to project future trends and aid in the development of optimal cancer control strategies. CISNET consists of four groups of grantees who focus on breast, prostate, colorectal, and lung cancers which utilize statistical simulation and other modeling approaches. The models incorporate data from randomized controlled trials, meta-analyses, observational studies, national surveys, and studies of practice patterns to evaluate the past and potential future impact of these interventions.

Information on CISNET accomplishments is available at http://cisnet.cancer.gov.

The purpose of the proposed RFA is to expand the work of CISNET in a systematic manner. Four commonly identified phases of the translation of medical research from initial discovery to population impact include: T1, discovery to health application; T2, health application to evidence-based practice guidelines; T3, practice guidelines to health practice; and T4, health practice to population health impact. CISNET models provide a platform for evaluating the potential downstream consequences of decisions and strategies that are made in earlier phases, and thus can be an effective tool for helping to optimize choices. Thus, the purpose of the reissuance of the CISNET RFA is to explore the following areas where modeling can assist in optimizing the flow of the translation of cancer research.

Multi-scale modeling: Bridging the gap between models developed at the molecular/cellular level and CISNET models which go from the tumor growth to the population level can help extrapolate the potential impact of basic science discoveries. Two pilot projects to integrate models developed in NCI's Integrative Cancer Biology Program with CISNET models are underway and a workshop is planned to bring the CISNET and ICBP communities together.

Incorporating genomic and family history risk profiles: Utilizing risk profiles that are based on family history and genomic information has the promise of more effectively targeting prevention, screening, and treatment efforts.

Upstream modeling: Most CISNET models start with risk factor trends, screening behavior, and diffusion of new treatment advances. Upstream modeling can add the social, political, cultural, economic, and individual determinants of risk factor changes, screening behavior, and treatment choices. These determinants can put the models a step closer to specific policies and programs that can help modify these factors in the future, and help evaluate specific programs.

Comparative Effectiveness and Downstream Modeling: In 2007, the Congressional Budget Office issued a report advocating research on the comparative effectiveness of medical treatments. Comparative effectiveness is a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. In 2005, AHRQ was authorized to conduct and support research on the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs). The idea is to focus on what is known now, ensuring that individual choices and programs benefit from past investments in research and what research gaps are critical to fill. Modeling can assist in extending current evidence from intermediate to long term outcomes, and helping to balance trade-offs (e.g., in prostate cancer treatment, radical prostatectomy has been shown to have a survival advantage over watchful waiting, but has tradeoffs in terms of greater urinary and sexual dysfunction). While most CISNET models include choices of first line treatment, few include anything beyond that in terms of post diagnostic sequelae. Modeling can include important issues with respect to choices and quality of care in post diagnostic surveillance, treatment choices at failure of first line therapy or recurrence, etc.

Evaluation of diagnostic tests: CISNET methods developed in the context of screening could be adapted for use in the diagnostic context and produce methods for synthesizing available information from all sources in order to make credible projections about the potential impact of the use of diagnostic tests in clinical practice and to estimate their cost-benefit profile.

Optimizing biomarker development strategies: CISNET will explore how early in the development process reasonable models of potential cost effectiveness can be developed, assisting decisions of selecting the most promising biomarkers. Pilot projects will be developed with EDRN.

Suggesting optimal routes to reducing health disparities: Models can move beyond the standard racial/ethnic characterizations, and data sources can be linked to allow modeling as a function of disparities in income/education, insurance status, and geography.

Translation of trial results into clinical guidelines and public health policy: In the next several years this will likely increase as trial results for PSA screening for prostate cancer and CT screening for lung cancer in the U.S. and Europe become available. For both prostate and lung cancer screening, substantial overdiagnosis and mortality benefits may coexist, complicating population-level recommendations. CISNET will work to produce a more seamless link between trialists, modelers, and guideline-setting organizations.

Interactive policy-level decision-making tools: Development of interactive interfaces for models that will allow cancer control planners and policy makers to explore the impact of varying key parameters involved in their decision-making options.

The concept proposes funding up to six groups of linked applications averaging $900,000 total costs per year for five years. The program requests, in years 2-5, $600,000 per year for discretionary core collaborative study funds to facilitate collaborations.

Obituary:

Carl Baker, Led NCI 1969-72, Began Organ Sites Program

By Kirsten Boyd Goldberg

CARL BAKER, who served as director of the National Cancer Institute from 1969 to 1972, died Feb. 11 at a hospice in Rockville, Md. He was 88 and had myelodysplastic syndrome.

During his tenure, President Richard Nixon signed the National Cancer Act of 1971, which added $100 million to the institute's budget and gave it increased authorities. The NCI budget increased from $181 million to $378 million in the three years Baker led the institute.

"He was a wonderful leader of the institute and truly a great friend," NCI Deputy Director Alan Rabson said to The Cancer Letter. "He was a major force in bringing contracting to the research efforts."

Baker spent 23 years at NIH, starting in 1949 in the Laboratory of Biochemistry, led by Jesse Greenstein. He had to leave lab work due to severe allergies to animals, and move to administrative work, according to a 1997 NCI oral history interview.

Baker was a grants administrator before becoming assistant director of NCI in 1958. He became director of etiology in 1967. He also was a commissioned officer of the U.S. Public Health Service, reaching the rank of rear admiral.

In speeches and interviews, Baker often took great care to discuss the history of advances in cancer research. In a 1997 oral history interview for NCI, he emphasized that the institute's history didn't begin with the National Cancer Act. NCI's work in the 1950s and 1960s helped set the stage for many of the new programs that were created as a result of the act, he said.

"I just think that NIH by and large needs more history written, for two reasons: one, I think we ought to honor some of the great contributions that were made by NIH staff," Baker told an oral history interviewer. "And so one purpose of history, I think, is to do honor to people who made contributions.

"And secondly, it's pitiful, the lack of knowledge of previous activities," he said. "Such ignorance affects how you run an organization. And an organizational memory, I think, has more importance than a lot of people give it credit for."

Baker was involved in planning and hearings for the cancer act. He later said the planning efforts to look at NCI's entire research effort on a large scale were one of his most important accomplishments as NCI director.

Baker said his second major accomplishment as NCI director was the formation of the Organ Sites Program. At one point, he noticed that the institute funded only a few grants in large bowel cancer, and was told that no one knew what to do about bowel cancer. He went to library and found that there were animal models for the cancer.

"You give me an animal model, I can build a program around that," he said. He established special review groups for grant applications in bowel cancer, which were followed by bladder, prostate, and pancreatic cancers. Later, the program evolved into the Organ Systems Program, which eventually was phased out, but credited with providing the impetus for NCI's Specialized Programs of Research Excellence grants that focus on organ systems.

When the National Cancer Act took effect, the NIH and NCI directors became Presidential appointees, but

Nixon didn't pick Baker to continue as NCI director.

Two things might have hurt Baker's chances of being appointed to the post. First, when Sen. Edward Kennedy (D-Mass.) asked Baker during a Senate hearing whether he had an overall plan for the cancer program, he replied that he didn't.

In fact, Baker said in the oral history interview, he did have a plan, which had been submitted but not yet approved by the Department of Health, Education and Welfare. "I was being a good executive branch member by saying, since it wasn't approved, that we didn't have it. I think that was a mistake, probably," Baker said.

Second, he opposed the plan advocated by philanthropist Mary Lasker and others to move NCI out from under NIH and run it as separate agency. "When I told Mary Lasker directly that I was opposed to pulling NCI out of NIH, her relations with me cooled quite a bit," he said.

In 1972, Baker was named president and scientific director of Hazelton Laboratories, of Vienna, Va. From there, he became a senior official with the Health Resources Administration. In 1976, he moved to Zurich to serve as medical director of the Ludwig Institute for Cancer Research. He retired in 1982 and lived in Olney, Md. He taught organizational behavior at Columbia Union College in Takoma Park and science courses at the University of Maryland.

Baker was born Nov. 27, 1920, in Louisville, Ky. He earned an A.B. in zoology from the University of Louisville in 1942 and entered its medical school, graduating in 1944. He served in the Navy as a medical officer in the Pacific in 1945. In 1949, he received a master's degree in biochemistry from the University of California, Berkeley.

Baker received the Public Health Service's Meritorious Service Medal and was a director of the American Association for Cancer Research, director-at-large of the American Cancer Society and a secretary of the American Chemical Society's Division of Biological Chemistry.

His marriage to Lois Oxsen Baker ended in divorce.

Survivors include his wife of 34 years, Catherine Smith Baker of Olney; two daughters from his first marriage, Cathryn Schafer of Fawn Grove, Pa., and Jeannette Jefferies of Woodbine, Md.; a stepson from his first marriage, David Moquin of Ocean Pines, Md.; three stepchildren from his second marriage, Robert Kibler of Burlington, N.D., Bruce Kibler of Superior, Wis., and Kathleen Mahoney of North Potomac; 12 grandchildren; and 10 great-grandchildren.

HHS News:

New HHS Recovery Act Office Distributes More Than $3 Billion

The Department of Health and Human Services said it has formed the Office of Recovery Act Coordination to distribute an estimated $137 billion in American Recovery and Reinvestment Act funds managed by the department.

Dennis Williams will lead the new office and serve as HHS Deputy Assistant Secretary for Recovery Act Coordination.

Williams has served in the department for more than 20 years in offices including the Health Resources Services Administration and the Office of the Assistant Secretary for Management and Budget.

HHS distributed $3 billion in recovery funds as of March 11, to support a variety of policies and programs including Community Health Centers and Medicaid.

To track the progress of HHS activities funded through the ARRA, see www.hhs.gov/recovery. To track all federal recovery funds, see www.recovery.gov.

NCI has created a Web site, http://www.cancer.gov/recovery, in recognition of the cancer community's interest in the recovery act.

NCI officials said the site would be updated regularly with the institute's implementation plans and related announcements, including links to detailed information about the NIH Challenge Grants in Health and Science Research, and recently posted funding opportunities. Also, the site includes an email address for submitting questions or comments to the institute.

NIH APPLICATIONS for a total of $1.5 billion in grants funded by the American Recovery and Reinvestment Act became available earlier this week.

"NIH is extremely grateful to President Obama and the Congress for recognizing both the economic and health impacts of biomedical and behavioral research," said Acting NIH Director Raynard Kington. "The science funded by the Recovery Act will stimulate the national economy, and have a profound impact on people's health for many years to come."

The NIH will allocate the Recovery Act funds as follows:

—At least $200 million in Challenge Grants to support research on topics that address specific scientific and health research challenges in biomedical and behavioral research that would benefit from significant 2-year jumpstart funds;

—$1 billion in construction grants to help build new or improve existing research facilities and help grow the economy;

—$300 million in shared instrumentation grants to facilitate the purchase of research equipment that will enable scientists and researchers to complete their critical work.

For more information and grant applications, see http://grants.nih.gov/recovery.

NIH Funding Announcements

Recovery Act of 2009: NIH Review Criteria, Scoring System, and Suspension of Appeals Process. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-054.html

Announcement of Participation of NCI on PA-09-100, Energy Efficiency and Renewable Energy System Technology Research and Development (SBIR [R43/R44]). http://grants.nih.gov/grants/guide/notice-files/NOT-CA-09-018.html

Addition of Recovery Funds to the Shared Instrumentation Grant Program. http://grants.nih.gov/grants/guide/notice-files/NOT-RR-09-008.html

Recovery Act Limited Competition: Core Facility Renovation, Repair, and Improvement. http://grants.nih.gov/grants/guide/rfa-files/RFA-RR-09-007.html

Recovery Act Limited Competition: Extramural Research Facilities Improvement Program. http://grants.nih.gov/grants/guide/rfa-files/RFA-RR-09-008.html

Recovery Act Limited Competition: High-End Instrumentation Grant Program. http://grants.nih.gov/grants/guide/pa-files/PAR-09-118.html

White House:

Obama: "Science Must Inform Decisions of My Administration"

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cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.

Sec. 2. Research. The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

Sec. 3. Guidance. Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

Sec. 4. General Provisions.

(a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 5. Revocations.

(a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.

(b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.

Memorandum on Scientific Integrity

The text of the memorandum on scientific integrity follows:

Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health, protection of the environment, increased efficiency in the use of energy and other resources, mitigation of the threat of climate change, and protection of national security.

The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.

By this memorandum, I assign to the Director

of the Office of Science and Technology Policy (Director) the responsibility for ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes. The Director shall confer, as appropriate, with the heads of executive departments and agencies, including the Office of Management and Budget and offices and agencies within the Executive Office of the President (collectively, the "agencies"), and recommend a plan to achieve that goal throughout the executive branch.

Specifically, I direct the following:

1. Within 120 days from the date of this memorandum, the Director shall develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch, based on the following principles:

(a) The selection and retention of candidates for science and technology positions in the executive branch should be based on the candidate's knowledge, credentials, experience, and integrity;

(b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;

(c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;

(d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;

(e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and

(f) Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decisionmaking or otherwise uses or prepares.

2. Each agency shall make available any and all information deemed by the Director to be necessary to inform the Director in making recommendations to the President as requested by this memorandum. Each agency shall coordinate with the Director in the development of any interim procedures deemed necessary to ensure the integrity of scientific decisionmaking pending the Director's recommendations called for by this memorandum.

3. (a) Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Washington In Brief:

Obama Signs Government Spending Bill For FY 2009

FY 2009 APPROPRIATIONS: The Senate March 10 passed a $410 billion omnibus spending bill for fiscal 2009 that will give NIH $30.3 billion, a $938 million increase over last year.

President Obama signed the bill March 11.

NCI will receive $4.97 billion. The 2008 budget was $4.83 billion. The bill states that up to $8 million may be used for facilities repairs and improvements at the NCI-Frederick research and development center.

FDA CANDIDATES? The Administration appears to be ready to name two public health experts to the top jobs at FDA, sources said. Though no formal announcements have been made and the White House is making no comment, the Commissioner's job is expected to go to **Margaret Hamburg**, former New York City health commissioner, The Wall Street Journal reported. Hamburg, 54, also served as assistant HHS commissioner in the Clinton administration.

The No. 2 job at the agency is expected to go to **Joshua Sharfstein**, the Baltimore health commissioner who served on the Obama transition team for the agency. Before taking the Baltimore job, Sharfstein, 39, was an investigator for **Rep. Henry Waxman** (D-Calif.).

The nominations to NIH and FDA jobs have been held up because of the aborted candidacy of **Tom Daschle** to the top job at NIH. The administration's current pick for that job—Kansas Gov. **Kathleen Sebelius**—is yet to clear confirmation hearings.

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