Report to the National Advisory Environmental Health Sciences Council Director, NIEHS

22–23 May 2012

Director's Message

The NIEHS Strategic Planning process is nearing completion. Earlier drafts of the Mission, Vision, and Strategic Plan were posted online for public comment in February and in April. NIEHS received many comments from interested individuals and organizations. NIEHS leadership carefully considered these comments and incorporated appropriate changes into the documents. The Strategic Plan, comprising a new articulated Mission and Vision, along with 6 broadly described Strategic Themes and 11 specific Strategic Goals, has now been finalized, and we are preparing for its release and dissemination. (A full copy of the Strategic Plan is included in the ECB). This strategic planning process has been one of discovery, introspection, openness, and inclusiveness, as we have strived to define anew at NIEHS who we are, what we do, and where we look to go in the future.

Mission Statement: The mission of the National Institute of Environmental Health Sciences is to discover how the environment affects people in order to promote healthier lives.

Vision Statement: The vision of the National Institute of Environmental Health Sciences is to provide global leadership for innovative research that improves public health by preventing disease and disability from our environment.

Strategic Themes: Fundamental Research, Exposure Research, Translational Science, Global Environmental Health and Health Disparities, Training and Education, Communications and Engagement. Crosscutting themes: Knowledge Management and Collaborative and Integrative Approaches.

Next Steps: With the formulation of a new Strategic Plan, the work has only just begun. Across NIEHS, divisions and offices have already begun the work of developing implementation plans that are responsive to the goals of the Strategic Plan. These plans include certain programs already in existence, as well as new and innovative ideas for the Institute. Cross-divisional working teams will also be formed to develop plans for specific topics that span the Institute's divisions and activities. Over the coming months, all of these plans will be thoroughly considered by NIEHS leadership, who will determine which components will be prioritized and implemented, and the necessary resources and timeline for this to occur. The goal is to have a final implementation plan for the Institute during the summer so that it can inform and align with the 2013 budget process.

Legislative Report

FY 2012 Appropriations

The House and Senate Appropriations Committees have released their 302b allocations (the amount of money given to a subcommittee for all programs under its jurisdiction). The Senate Subcommittee allocations are slightly above the amount of their FY 2012 appropriations; however, those for the House Subcommittees fall below their FY 2012 appropriation. The House Labor HHS allocation of \$150 billion is \$6 billion lower; the Interior Environment allocation of \$28 billion is \$1 billion lower. Both reductions mean painful cuts in some agency programs.

On 20 March 2012, the House Labor HHS Appropriations Subcommittee held a hearing on NIH funding for FY 2013 with a focus on NCATS. Francis Collins was accompanied by Tom Insel, NCATS Acting Director; Anthony Fauci, NIAID Director; and Harold Varmus, NCI Director. Representative Rehberg (Chairman, R-MT) opened with a strong statement on his expectation that NCATS follow the law. He stated his support for NCATS, but emphasized that it must not compete with industry or become a drug-developing organization. He added that he hopes that the FY 2013 request ensures that basic science is not negatively impacted by the recent focus on NCATS and translational science. In addition, he said that a transparent discussion is needed to ensure the proposed changes in the National Children's Study do not undermine its scientific value. Representatives Rehberg, Alexander (R-LA), Simpson (R-ID), and Lummis (R-WY) asked about the \$50 million cut for the IDeA program and the resulting increase for NCATS. Representative DeLauro asked a number of questions aimed at eliciting good news about NCATS. Representative Roybal-Allard asked when NIH would have a long-term research strategy for pancreatic cancer.

Witnesses on the second panel were Roy Vagelos, former chair and CEO of Merck; Scott Koenig, representing the Biotechnology Industry Organization; and Todd Sherer, CEO of the Michael J. Fox Foundation. They were asked to address obstacles in drug development that hinder translation science and how NIH or NCATS can coordinate activities to leverage basic science. Both Sherer and Koenig support NCATS. Dr. Vagelos, who does not support the creation of NCATS, stated "we have an enormous need for more basic research. We've succeeded up until now. We don't want to change that paradigm." The common ground among the panelists was NCATS' role in preclinical and early studies.

On 28 March 2012, the Senate Labor HHS Subcommittee held its hearing on NIH. Dr. Collins was accompanied by the directors of NCI, NIAID, NIDDK, NIA, and NIMH, and the acting director of NCATS. Senator Harkin (Chairman, D-IA), a longtime champion for NIH, expressed his concern about the effect of the mandatory cuts (7.8 % for NIH) that will take place next January if Congress does not enact a budget in line with the debt ceiling agreement or if Representative Ryan's budget, that would cut the NIH budget up to 5 % the first year and 19 % the next, is enacted. He added that NIH funding creates 430,000 jobs in the United States. Senator Shelby (Ranking Member, R-AL) expressed his concern about the flat request for NIH, and noted that the tap for HHS evaluation activities could

reduce the NIH budget by \$215,000,000. He also expressed concerned with the proposed changes in awarding grants, especially in capping the amount that a PI can receive. Dr. Collins spoke NIH's proposal to reduce budgets for non-competing Research Program Grants by 1 % and to restrain growth in the average size of new awards. He provided powerful statistics on employment: every grant creates 7 high-quality jobs; NIH services the foundation for the U.S. medical innovation sector that employs 1,420,000 people directly, and supports an additional 6,600,000 jobs. Senator Harkin asked about the effect of the across-the-board cuts. He also asked Dr. Varmus how he had managed NCI with smaller or no increases. Later in the hearing, Harkin made it very clear that no money would be taken from the Prevention and Public Health Trust Fund for Alzheimer's research. Senator Shelby asked about obesity especially in minority communities and the IDeA program. Senator Brown (R-MA) wanted to know why NIH is changing its plan for the National Children's Study and what NIH is doing to prevent and treat TB. Senator Moran (R-KS) focused on the role of NCATS in improving the research community's ability for turning medical discoveries into lifesaving treatments. Senator Pryor (D-AR) asked if the breast cancer research program might be a good model for tackling pancreatic cancer. Senator Cochran (R-MS) expressed his concern about the cut in funding for the IDeA program. Senator Mikulski (D-MD) was interested in how NIH sets priorities and how it accelerates research from basic to therapeutics. Senator Harkin closed the hearing by expressing his concern about the tension between more grants for less money and fewer grants for more money.

The Senate and House subcommittees have started marking up their bills with the least controversial first and the most difficult to be last. The House Energy & Water Subcommittee Report made no reference to the NIEHS/DOE Worker Training Program. The Senate Subcommittee Report included language directing DOE to fund the Hazardous Waste Worker Training Program, but did not state the amount of funding to be transferred.

Congressional Meetings

On 25 April 2012, Dr. Birnbaum met with Paul Cunningham, Chief of Staff, and Debbie Jessup, Legislative Assistant for Health, for Congresswoman Lucille Roybal-Allard (D-CA). The Congresswoman is a member of the Labor HHS Appropriation Subcommittee and a strong supporter of environmental health research with a special interest in NIEHS research related to breast cancer. Later that day, Dr. Birnbaum met with Rita Culp, a detailee from the EPA Budget Office to the Senate Interior Environment majority staff. The purpose of the briefing was to provide information on the NIEHS Superfund Research and Worker Training Programs activities in 2012 and plans for 2013. Ms. Culp noted that Senator Jack Reed, Subcommittee Chairman, had been to Brown University to meet with NIEHS grantee Dr. Kim Boekelheide and other members of the Brown Superfund team, as well as NIEHS DERT Director Dr. Gwen Collman.

Report on Carcinogens

On 25 April 2012, the House Committee on Science, Space, and Technology's Subcommittee on Investigations and Oversight and the House Committee on Small

Business's Subcommittee on Healthcare and Technology held a hearing on "How the Report on Carcinogens Uses Science to Meet Its Statutory Obligations and Its Impact on Small Business Jobs." The Chairman and Chairwoman of the Subcommittees expressed their concerns with the Report on Carcinogens process and its impact on small businesses. The ranking members of the subcommittees expressed their concerns with the selection of the second panel by the majority. Congressman Richmond (D-LA) discussed the importance of the Report on Carcinogens to the public, but also expressed concerns about how the report could impact businesses and industry. The first panel of the hearing included Dr. Linda Birnbaum and Charles Maresca, Director of Interagency Affairs at the U.S. Small Business Administration's Office of Advocacy. Dr. Birnbaum opened the panel with her testimony describing the *Report on Carcinogens*, and the process used by the National Toxicology Program (NTP) to determine if a substance is "known to be a carcinogen" or "reasonably anticipated to be a carcinogen." She discussed how NTP has changed the process for the 13th *Report* to be more transparent and efficient. She also clarified that the *Report on Carcinogens* is neither a risk assessment nor a regulatory document, but rather a science-based public health document that provides information about the relationship between the environment and cancer. Mr. Maresca testified about small business concerns with the Report on Carcinogens including the contention that substances have been listed in the Report based upon potentially inaccurate scientific information, and that the peer review and public comment processes should be improved. He explained how accurate and credible scientific assessments were vital for small businesses, and the potential for adverse economic impacts for small businesses that use certain substances if that substance is were listed inaccurately.

The second panel included Dr. James Bus, Director of External Technology, Toxicology, and Environment Research and Consulting from Dow Chemical Company; Ms. Ally LaTourelle, Vice-President of Government Affairs from BioAmber, Inc.; Dr. Richard Belzer, President of the Regulatory Checkbook; Dr. Linda Grimsley, certified industrial hygienist and Associate Professor from Tulane University School of Public Health and Tropical Medicine; Bonnie Webster, Vice-President of Monroe Industries; and John Barker, Corporate Manager of Environmental Affairs, Safety and Loss Prevention for Strongwell Corporation.

Oversight of Federal Funding and Conferences

The House has passed a bill (HR 2146) to increase oversight of all federal funding including grants, contracts, and loans by requiring federal agencies and recipients of grants and contracts to report all expenditures on a quarterly basis. In addition, it includes provisions to cap spending per conference at \$500,000; to limit travel to international conferences to 50 employees per agency unless the DOS Secretary determines that more attendees is in the Nation's best interest; to limit until 2016 total agency travel expenses to 80 % of expenses for FY 2010; and to require agencies to post quarterly reports on conferences on the internet. The Senate has passed a bill (S 1789) with identical provisions.

Pancreatic Cancer

Companion bills HR 733 and S 362 have been introduced in the House and Senate by Representative Eshoo (D-CA) and Senator White house (D-RI) that call for increased research on the prevention, diagnosis, and treatment of pancreatic cancer. The bills would establish a committee to prepare a research plan, evaluate and make recommendations for funding grants to advance the understanding of the biology of pancreatic cancer, its natural history, and the genetic and environmental factors that contribute to its development; to improve diagnostic methods, and to advance clinical trials. With 233 cosponsors in the House and 46 in the Senate, passage before 6 November 2012 is likely.

Science Advances (NIEHS authors in bold)

Division of Extramural Research

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Aschengrau A, Weinberg JM, Janulewicz PA, Romano ME, Gallagher LG, Winter MR, Martin BR, Vieira VM, Webster TF, White RF, Ozonoff DM. 2012. Occurrence of mental illness following prenatal and early childhood exposure to tetrachloroethylene (PCE)contaminated drinking water: a retrospective cohort study. Environ Health 11(1):2. <u>http://www.ncbi.nlm.nih.gov/pubmed/22264316</u>

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Division of Intramural Research

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Cupul-Uicab LA, Skjaerven R, Haug K, Melve KK, Engel SM, Longnecker MP. 2011. In utero exposure to maternal tobacco smoke and subsequent obesity, hypertension, and gestational diabetes among women in the MoBa cohort. Environ Health Perspect; doi:10.1289/ehp.1103789 [Online 29 November 2011]. http://www.ncbi.nlm.nih.gov/pubmed/22128036

Galliher-Beckley AJ, Williams JG, Cidlowski JA. 2011. Ligand-independent phosphorylation of the glucocorticoid receptor integrates cellular stress pathways with nuclear receptor signaling. Mol Cell Biol 31(23):4663-4675. http://www.ncbi.nlm.nih.gov/pubmed/21930780

Freudenberg JM, Ghosh S, Lackford BL, Yellaboina S, Zheng X, Li R, Cuddapah S, Wade PA, Hu G, Jothi R. 2011. Acute depletion of Tet1-dependent 5-hydroxymethylcytosine levels impairs LIF/Stat3 signaling and results in loss of embryonic stem cell identity. Nucleic Acids Res; doi:10.1093/nar/gkr1253 [Online 30 December 2011]. http://www.ncbi.nlm.nih.gov/pubmed/22210859

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Division of the National Toxicology Program

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NIEHS News and Highlights

Data Sharing and Integration

The Institute has led and participated in a number of important activities lately to improve the understanding and capacity in the areas of data sharing and integration, which are critical for solving environmental health problems. A "Data Sharing Strategies for Environmental Health Science Research Workshop" was held in February in to discuss responses to a solicitation for input and recommendations from the scientific community. Issues that emerged include protection of privacy and confidentiality, Institutional Review Board issues, legal and regulatory issues, NIH programmatic and logistical considerations, and computational challenges. Follow up meetings are envisioned with a goal of eventually shaping best practices and guidelines.

In a related activity, NIEHS co-sponsored an event of the South Atlantic National Research Conference along with EPA, the Office for Human Research Protections, and multiple regional universities on "Engaging the Community for Research Success: What Scientists and IRBs Need to Know." The purpose of the meeting was to develop a better understanding of ethical, regulatory, and policy issues involved in conducting community-engaged research in national and international settings, including data sharing issues; and to provide a forum for researchers, regulators, and community representatives to network and form partnerships.

On May 8, Dr. Birnbaum participated in a panel providing the federal perspective at "Building for Better Decisions: Multi-Scale Integration of Human Health and Environmental Data," a workshop sponsored by the EPA and Society of Toxicology.

In April, U.S. Chief Technology Officer Todd Park, who served as HHS chief technology officer from 2009-2012, spoke at NIEHS on the HHS Health Data Initiative. The initiative maintains a constantly evolving, centralized Health.Data.gov platform for delivering new datasets and tools, along with supporting a community of data users and providers through social networking, as part of the HHS and Institute of Medicine commitment to open government.

National Toxicology Program

In a surprising finding arrived at using the Tox21 robotic high-throughput screening system, a group of NIH researchers have demonstrated that some anti-oxidants damage DNA and kill cells instead of protecting them as they are commonly thought to do. The finding was made inadvertently through research to screen potential drug candidates for treating cancer. The results were published in the March 19 *Proceedings of the National Academy of Sciences*.

Scientific review panels have peer-reviewed and approved the conclusions of seven draft technical reports. The substances studied include N,N-Dimethyl-*p*-toluidine (DMPT), a high-production chemical used in dental materials and bone cements; *Gingko biloba* herbal extract; two AIDS therapeutics (3'-azido-3'-deoxythymidine (AZT) and its combined mixtures with lamivudine or nevirapine); trimethylolpropane triacrylate; and

pyrogallol, a byproduct of plant tannins used to make consumer products, such as some hair dyes.

Public Health Leadership

NIEHS strives to guide the field of environmental public health through a variety of activities that identify critical areas of research and research questions, and that engage with a spectrum of stakeholders. The NIEHS Partnerships for Environmental Public Health (PEPH) grantees assembled at the National Institutes of Health (NIH) in March for their annual meeting, titled "Strengthening a Dynamic Environmental Public Health Network for Tomorrow: Advancing Science through Critical Reflection." The two-day meeting was built around three "tracks": research translation, capacity building, and communication. A variety of activities were designed to promote grantee interactions, foster group learning, and create dialogue particularly around these three issues. Grantees came from as far away as Alaska to participate in scientific and poster sessions, as well as featured training sessions on PEPH evaluation metrics and innovative public health outreach tools.

A January meeting co-hosted by NIEHS and The Collaborative on Health and the Environment (CHE), a 450-member Fertility and Reproductive Health working group, laid the foundation for a consortium focused on advancing research in the role of the environment in women's reproductive health.

A topic of enormous national economic, environmental, and health significance, shale gas extraction or "fracking," was the focus of discussion at the recent Institute of Medicine (IOM) Roundtable on Environmental Health Sciences, Research, and Medicine. Presentations explored using health impact assessments to understand the potential health impacts as these new energy technologies are deployed, particularly in rural and vulnerable communities.

The Gulf Long-term Follow-up (GuLF) STUDY has reached a recruitment milestone. Nearly two years after the Deepwater Horizon oil spill in the Gulf of Mexico, more than 20,000 cleanup workers and volunteers have enrolled in the study. These enrollments were achieved through outreach to people who took the cleanup worker safety training and participated in cleanup in the region following the spill. Approaches to invite people to join include billboards, radio and TV, Facebook and Twitter, community meetings, and a recruitment video filmed by the U.S. Surgeon General.

Meetings and Events

More than 150 scientists, experts, and stakeholders convened in March at the Centers for Children's Environmental Health and Disease Prevention Research annual meeting, held at NIH. The meeting was co-sponsored by NIEHS and EPA to allow center researchers to share scientific strategies, discuss new research approaches, and highlight late-breaking science in the field, as well as to engage with their advocacy and community partners.

Nearly 250 trainers from the NIEHS Worker Education and Training Program (WETP) met in March 28-29 in Fort Lauderdale to improve training methods and exchange ideas on effective health and safety training for emergency response workers. The sixth annual National Trainers' Exchange, titled "Training Today for a Safer Tomorrow," gave trainers an opportunity to discuss new technologies and best practices, as well as identify challenges to effective training.

The NIEHS Environmental Health Sciences Core Centers met March 27-29 in Boston. Following the meeting, Dr. Birnbaum, accompanied by NIEHS and Core Center staff, toured area neighborhoods to see both environmental concerns and a number of successful urban revitalization projects that have advanced environmental sustainability, fostered historical preservation, improved infrastructure, and expanded affordable housing opportunities in area communities. That evening, the group joined local government officials and public health advocates for a community forum at the Dorchester House Multi-Service Center.

The NIEHS-led National Academies' Committee on Emerging Science for Environmental Health Decisions held an April workshop, "Biological Factors that Underlie Individual Susceptibility to Environmental Stressors, and Their Implications for Decision-Making." The meeting focused on the endogenous and biological factors that influence individual variability in response to environmental exposures, such as genetics and epigenetics, physiology, life stage, and other biological differences. Presenters explored innovative approaches for characterizing individual variability.

May brought the directors of the NIEHS-funded Centers for Neurodegenerative Diseases to the institute's campus for a meeting to share updates and highlights of the work of each of these centers, as well as to discuss NIEHS interests in the field and future research needs.

Also in May, the Superfund Research Program hosted a meeting in Providence, Rhode Island to explore the "Social, Psychological, and Economic Impacts of Superfund and Other Contaminated Sites." The workshop was designed to provide a small forum for scientific and related communities to discuss the full spectrum of issues surrounding the economic and societal costs of site contamination. Participants worked to identify how the social sciences can provide a more holistic understanding of the effects that hazardous waste sites have on society.

Upcoming Meetings and Events

- NIH/Office of Dietary Supplements and NIH/NIEHS/DNationl Toxicology Program will co-sponsor an "Excess Folic Acid Workshop," June 12-13 in Washington, DC
- NAS Committee on Emerging Science for Environmental Health Decisions will hold a workshop on Systems Biology on June 14-15, Washington, DC

Awards and Recognition

NIEHS Director Linda Birnbaum, PhD, has received several prestigious awards and honors in recent months, including:

- The 2012 Health Policy Hero Award from the National Research Center for Women & Families recognizing her leadership at the NIEHS
- The 2012 Science Leadership Hero Award from the Breast Cancer Fund

• An invitation from the American Association for the Advancement of Science to present the 12th Robert C. Barnard Environmental Lecture

Other NIEHS awardees:

- Mr. Liam O'Fallon, Mr. Joseph "Chip" Hughes, and Ms. Sharon Beard received the HHS Green Champions Good Neighbor Award for their work in environmental justice for workers
- Robert Sills, PhD, DVM, chief of NIEHS and NTP pathology and the Cellular and Molecular Pathology Branch, was elected President of the Society of Toxicologic Pathology
- Senior Researcher Kenneth Korach, PhD, received the Dale Medal, the highest accolade awarded by the Society for Endocrinology
- Dale Sandler, PhD, Chief of the Epidemiology Branch, was elected into the Alpha Chapter of the Delta Omega honor society at Johns Hopkins Bloomberg School of Public Health
- Epidemiologist Walter Rogan, MD, was named an honorary fellow by the American Academy of Pediatrics for his exemplary service with the organization's Council on Environmental Health
- Karen Adelman, PhD, was awarded tenure at NIH for her work in the Laboratory of Molecular Carcinogenesis
- The NIEHS Office of Communications and Public Liaison (OCPL) received a Pegasus Award of Distinction for its video about the 2011 NIH Summer Internship program at NIEHS
- Deputy Associate for Management Chris Long was recognized by NIH for his leadership of the Combined Federal Campaign (for charity donations) in North Carolina

NIEHS-related Awardees:

- Biochemist Keith Yamamoto, PhD, from the University of Southern California, presented the 2012 Rodbell Lecture, "Cell-, Gene-, and Physiology-Specific Regulation by the Glucocorticoid Receptor"
- Grantee Kirk Smith, PhD, of the University of California at Berkeley won a 2012 Tyler Prize for Environmental Achievement for his work on global indoor air pollution
- Grantee Gail Prins, PhD, director of the Andrology Laboratory at the University of Illinois at Chicago, was named a 2011 Researcher of the Year at her institution
- Gail Martin, PhD, from the University of California at San Francisco, delivered the 2012 NIEHS Spirit Lecture, which recognizes outstanding women in science

News from Building 1

New FCOI Rule

The U.S. Department of Health and Human Services (HHS) has issued a final rule in the <u>Federal Register</u> that amends the Public Health Service (PHS) regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which PHS*

Funding is Sought (42 C.F.R. Part 50, Subpart F) (commonly known as the Financial Conflict of Interest, or FCOI, regulations) to address the increasing complexities of the financial interests held by biomedical and behavioral researchers and the resulting interactions among Government, research Institutions, and the private sector. These regulations establish new standards and clarify previously established standards to be followed by Institutions that apply for or receive research funding from PHS Awarding Components, including the National Institutes of Health (NIH), for grants, cooperative agreements, and research contracts. The 2011 revised regulations were written to increase accountability, add transparency, enhance regulatory compliance and effective Institutional management of Investigators' financial conflicts of interest, and strengthen NIH's compliance oversight. The primary goal is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.