PUBLIC-PRIVATE PARTNERSHIP PROGRAM

PPP ADVISOR

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MESSAGE FROM THE DIRECTOR

Dr. Barbara B. Mittleman

Spring is here and new activities are on the horizon. The stimulus package has brought with it an infusion of funds to the National Institutes of Health (NIH) - $10 billion over the next 2 years, and working toward sustainability of the new work to be conducted with these funds provides an opportunity for partnership development. In this spirit, the solicitation for the Challenge Grants included language regarding looking forward to public-private partnership (PPP) opportunities and offers the Public-Private Partnership Program staff as providers of advice in so doing. Dr. Wendy Smith is the PPP contact person for Challenge Grant applicants and we have already received many calls and e-mails from interested (and confused) applicants about how to initiate and implement PPPs.

Other spring news involves visits of PPP staff to a variety of conferences, meetings, organizations, and institutions. Highlights include a visit by Dr. Shawnmarie Mayrand-Chung and me to Deloitte, LLC, in New York, a consulting firm that works with many pharmaceutical and biotechnology companies. They have surveyed their clients regarding when and why they would consider partnerships generally, and partnerships with the government specifically. They will discuss their perspective and present the information they have collected at the April PPP Coordinating Committee (PPPCC) meeting.

Also included among the PPP Program staff field trips were the following: I visited the Sandia National Laboratories, a Federally Funded Research and Development Center (FFRDC) supported by the U.S. Department of Energy. Discussions there were broad and included how NIH and Sandia might partner in areas of shared interest such as nanotechnology and training of young scientists, as well as from the standpoint of mechanism, underlying agency authorities, and the difference of government-owned and -operated laboratories such as NIH vs. government-owned, but contractor-operated, facilities such as the National Laboratories. Partnerships with NIH were also a topic of conversation, and The Biomarkers Consortium (BC) was the example on which the conversation was focused at the Bioinformatics Meeting held at the Shady Grove campus of Johns Hopkins University in March at which I spoke and which was co-chaired and organized by Mojdeh Bahar of NIH's Office of Technology Transfer. I also visited the University of Illinois at Urbana-Champaign (UIUC), where the conversations and presentations were wide-ranging and included faculty, deans, the Provost, and students, and covered PPPs, the American Recovery and Reinvestment Act of 2009 funding, the UIUC campuswide initiative on health and wellness, and how labor economists can help us track the output of NIH-funded activities. Dr. Mayrand-Chung discussed the BC at a biomarker meeting, Global Discovery and Development Innovation Forum, in London and at the American Bar Association's 24th Annual Intellectual Property Law Conference in Washington on April 2.

We have also been on the receiving end of visits by GE Healthcare: Drs. Don Black, Head of Global Research and Development, Medical Diagnostics; Kim Gallagher, Head, External Scientific Affairs, R&D Medical Diagnostics; and Kevin Horgan, Head, Internal Medicine, R&D Medical Diagnostics, who continued an ongoing discussion of how NIH and GE might partner

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SPOTLIGHT

Transformation Report: The planned 3-day meeting, International Forum on the Science of Health, slated for June 2009, has changed its shape! In consultation with NIH and outside colleagues, and recognizing recent changes, NIH has an alternative plan: Several white papers will be developed via several planned workshops that will present in detail how changing focus from disease to health can be the basis for research and clinical and regulatory decision-making. We hope the big meeting will be rescheduled for the latter part of 2009.

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by presenting at the March PPPCC meeting. We have also been visited by several delegations from the Netherlands and the Russian FDA, and the Asia-Pacific Economic Consortium, rounding out our very busy schedules.

The outcomes of these many meetings, and others like them, are of several kinds: Some are simply informational while others lead to the development of relationships with NIH Institutes and Centers (ICs) members, and a subset of these lead to specific partnership or collaborative activities. Our approach in all meetings with outside parties, whether here on campus or away, is to listen very carefully, seeking areas of alignment of mission, scientific interests and opportunities, timeliness, and resources that may provide synergy in meeting the NIH mission. We then work to find the right interlocutors in the ICs: Who among the IC staff are the appropriate one(s) to engage with the potential partner about the activity and/or the science. We are always available to participate; to advise regarding partnership design structure and implementation; and to help in reviewing agreements and policies. When asked, we are also available to help in ongoing implementation of the partnership activity.

Several other spring events bear mentioning: In May the 2009 BIO International Convention (BIO) will be held in Atlanta. This is the annual meeting of the biotechnology industry trade association and is broadly attended by industry and others from all over the world. Taking advantage of the Atlanta location, the Centers for Disease Control and Prevention (CDC) is sponsoring a day, May 18, during which the Federal agencies (NIH, CDC, and U.S. Food and Drug Administration [FDA]) will discuss their activities, present booths, provide tours of the CDC campus, and interact more closely with some 400 participants at the meeting. The BC is planning workshops in subject areas needing biomarker development: beta cell function symposium this month, and sarcopenia in the elderly and markers for depression as subjects for two focused discussions not yet scheduled.

Ongoing activities continue across the seasons, including meetings with IC Directors to seek input about how the PPP Program can meet IC needs most effectively; continuing work with the Foundation for the National Institutes of Health and FDA on projects in the BC; newly launching projects and projects in development; and thinking about how we can continue to improve the utility of the monthly PPPCC meetings. New activities under development include the Science of Health, now morphed into a series of workshops and white papers to define the needs and opportunities before convening a large working conference meeting. We are also developing a proposal centered on the development of a think tank about general principles and practices relevant to partnerships and an associated casebook. And, as always, we are available to advise ICs regarding all aspects of PPPs and to review agreements and partnership documents. Last but not least, this is the first semester of a new Foundation for Advanced Education in the Sciences (FAES) course on Public-Private Partnerships - FAES 392. We will see how the reviews look, but the students seem very engaged and a number of outside speakers have described a variety of perspectives on PPPs. The students are currently designing PPPs of their own as the culmination of what they have learned.

Happy spring; we look forward to partnering with all of you. ❖

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2009 BIO International Convention: Update

Dr. Shawnmarie Mayrand-Chung and Marjorie A. Bonorden

The 2009 BIO International Convention, the annual meeting of the trade organization of the biotechnology industry, will be held in Atlanta, Georgia, May 18 to 21. The official program has been finalized and includes over 150 breakout sessions covering important areas in biotechnology, marketing, partnering, and business development as well as networking events. This is a chance for the National Institutes of Health (NIH) staff, from both technology transfer and program areas, to engage with our counterparts in the

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2009 BIO International Convention: *Update*

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biotechnology industry in order to exchange information, seek licensing opportunities, and identify areas of mutual interest and potential collaborators for partnerships.

To see the complete breakout sessions and speakers agenda, please go to http://convention.bio.org/attendees/sessions_speakers/.

A half-day program devoted to "Federal Programs" has been finalized* and includes:

1. Biomedical Advanced Research and Development Authority (BARDA): Nuts and bolts for the urgent development, expedited approval, and distribution of countermeasures. This session would review Emergency Use Authorization (EUA).
2. Biomedical High-Performance Computing: The high-volume and complex data generated from advances in biotechnology exceed current capabilities (e.g., genomic sequences, proteomics, cell biology). Furthermore, untapped potential exists to forge interfaces between these data and existing data collection systems that contain clinical information (e.g., EMRs, surveillance systems, large-scale surveys). Leveraging the significant Federal funding for computing (>$3 billion in FY08) will promote the development of shared approaches and maximize the value of both new and existing data.
3. Hot Federal Biotechnologies for Licensure Survey: Including all aspects of Federal government (e.g., U.S. Department of Health and Human Services [HHS], National Aeronautics and Space Administration [NASA], U.S. Department of Defense [DoD]) to showcase technologies that need partners to commercialize.
4. How To Partner With Government:
   - Funding opportunities: Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR), grants, contracts
   - Tech Transfer: Cooperative Research and Development Agreement (CRADA), Material Transfer Agreement (MTA), licensing/patents
   - Collaborations: Public-private partnership through Federal foundations (e.g., FDA, CDC, NIH)
5. Federal Laboratory Consortium: The Federal Laboratory Consortium for Technology Transfer (FLC) is the nationwide network of Federal laboratories that provides the forum to develop strategies and opportunities for linking laboratory mission technologies and expertise with the marketplace.

Business Forum

A coordinated NIH presence in the BIO business forum provides NIH Institutes and Centers (ICs) an opportunity to arrange meetings at BIO 2009 with other BIO participants. Several ICs participated in the BIO business forum at BIO 2008 and found it very useful.

Registration for 2009

Online registration will be open up to the last day of the convention, Thursday, May 21, 2009.

Centers for Disease Control and Prevention (CDC) Campus Event

The CDC Campus Day Program will be held on May 18, 2009, at the CDC campus, 1660 Clifton Road, Atlanta, Georgia. Full Convention Access or Session Only Registrants can register for this half-day free optional program (limited to first 350 registrants) at www.bio2009.org.

The PPP Program is participating at the CDC Program Day in a workshop entitled Creative Public-Private Partnerships: Working With the CDC Foundation and the Foundation for the NIH. This interactive and informative session will highlight the entrepreneurial approaches to building public-private partnerships utilized by both the CDC Foundation and the Foundation for the NIH. Both foundations work to build bridges from the private and philanthropic sectors to the government to help these sectors achieve together what neither could achieve alone. NIH will participate in the CDC Program Day and the agenda* for this program is as follows:

10:30 a.m. - 11:10 a.m.: Buses depart from the Georgia World Congress Center every 10 minutes from 10:30 a.m. to 11:00 a.m.

11:15 a.m.: Registration at CDC Tom Harkin Global Communications Center.

11:30 a.m. - 12:30 p.m.: CDC Director's Emergency Operations Center guided tours to demonstrate how CDC leads domestic and international public health response efforts (limited to the first 150 registrants).

2:00 p.m. - 4:00 p.m.: CDC Global Health Odyssey Museum features the history of CDC and a visiting Smithsonian exhibition, Design for the Other 90%, which

*Please note: Agenda and contents are subject to change.

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showcases ancient and innovative technologies that impact global health.

12 noon - 1:45 p.m.: Presentations and Luncheon hosted by the CDC Foundation

Welcome: Tanja Popovic, M.D., Ph.D., Chief Science Officer, CDC.

Keynote Address: Bradley Perkins, M.D., M.B.A., Chief Strategy and Innovation Officer, CDC, and Charles Stokes, President and Chief Executive Officer, CDC Foundation.

2:00 p.m. - 3:00 p.m. and 3:15 p.m. - 4:15 p.m.: Concurrent Workshops; select two workshops from the following:

1. *Leveraging Federal Opportunities To Build Commercial Success*
   Speakers: Andrew Watkins, J.D., Ph.D., Director, Technology Transfer Office, CDC, and Anna Amar, Lead, Technology Development, Office of Technology Development, National Institute of Allergy and Infectious Diseases, and Juliana Cyril, Ph.D., M.P.H., Associate Director, Office of Public Health Research, CDC
2. *Personalized Health Care and the FDA*
   Moderator: Federico Goodsaid, Ph.D., Associate Director for Operations in Genomics, Office of Clinical Pharmacology, FDA, with Distinguished Panelists
3. *Creative Public-Private Partnerships: Working With the CDC Foundation and the Foundation for the NIH*
   Speakers: Charles Stokes, M.S., President and Chief Executive Officer, CDC Foundation, and Barbara B. Mittleman, M.D., Director, Public-Private Partnership Program, NIH, and Ann Ashby, M.B.A., Deputy Executive Director, Foundation for the NIH

Poster Session and Networking

2:00 p.m. - 4:30 p.m.: NIH will have the chance to set up booths and distribute materials during the booth and poster session.

2:00 p.m. - 4:30 p.m.: Buses depart every 30 minutes for the Georgia World Congress Center. ❖

The Biomarkers Consortium: *Updates and Developments*

Dr. Shawnmarie Mayrand-Chung

The first quarter of 2009 has been a very active time for The Biomarkers Consortium (BC), with developments at both the project concept and project plan levels. Since my last update on the BC, several new biomarkers project concepts and project plans have been approved. More specifically, at the level of the BC Executive Committee, the following projects were approved and launched:

- **Comparison of Two PET Radioligands Labeled With 11C or 18F to Quantify the Peripheral Benzodiazepine Receptor, A Potential Biomarker of Inflammation.** The goal of this project will be to assess the utility of two newly developed PET radioligands to image and quantify inflammation in periphery and brain. These newly developed PET radioligands will be tested in Alzheimer's disease and atherosclerosis, which were selected because both result in significant disability and often death. Also, these two diseases are representative of inflammation in the brain or periphery, respectively. An ultimate application of the results of this study might extend to neurodegenerative and psychiatric diseases and serve as a tool for developing new drug delivery systems and brain cancer treatment regimens. (Neuroscience Steering Committee)
- **Plasma-Based Biomarkers in Alzheimer's Disease.** This study is an extension of a large 5-year longitudinal natural history study known as the Alzheimer's Disease Neuroimaging Initiative (ADNI), which was conducted as a partnership among the National Institute on Aging and private and pharmaceutical companies in an effort to identify imaging and biochemical biomarkers for disease state and disease progression. The goal of the add-on biomarker project is designed to use targeted approaches and whole proteome profiling approaches to identify

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The Biomarkers Consortium: Updates and Developments (continued from page 4)

and validate plasma-based biomarkers of Alzheimer's disease. Results from this study aid in the identification of biomarker candidates to study disease state and/or disease progression in Alzheimer's disease and serve as tools for clinical drug development and assessment of disease in Alzheimer's patients. (Neuroscience Steering Committee)

Additionally, the following two projects have been approved for implementation by the BC Executive Committee, and the Foundation for the NIH (FNIH) is actively seeking the necessary funding to allow the official launch of these projects.

- **Evaluation and Validation of Circulating Tumor Cells (CTC) as Biomarkers of Castration-Resistant Metastatic Prostate Cancer.** This project is aimed at predicting response and survival to an investigational agent to treat men afflicted with progressive castration-resistant prostate cancer. The goal of this research is to validate the CTC number as a biomarker for survival, which could ultimately guide treatment and accelerate drug development. The project proposes to conduct CTC analyses on blood samples from men already participating in a Phase III randomized registration trial in order to evaluate the association between posttreatment change in the CTC number and survival. (Cancer Steering Committee)
- **DCE-MRI Technique Optimization Study Using Prostate Cancer as a Model System.** DCE-MRI has been proposed as a means of predicting and monitoring response to cancer therapeutics. Part of its appeal is that it measures tumor blood flow. This has significant implications for the prediction and monitoring of response to treatments that target the tumor vasculature including the VEGF pathway. The use of DCE-MRI has been limited by lack of standardization. This project is aimed at establishing a rational, standardized approach to DCE-MRI so that it may be employed more broadly in the development and clinical deployment of therapies targeting tumor blood flow. This initial effort, if successful, would lead to a second phase that would validate the practical approach developed in a more generalized application such as a clinical trial in renal cell carcinoma. This project concept has been approved by the Cancer Steering Committee (CSC) for further development. (Cancer Steering Committee)

There has also been much activity at the level of the Steering Committees, including several project concept approvals and the development of workshops to identify the next important biomarker questions to be addressed by the BC.

- **Cancer SC (CSC).** Several project concepts have been approved by the CSC over the last 4 months, and project teams are working hard to develop these concepts into detailed project plans for approval by the BC Executive Committee. The projects in development include:
  - I-SPY TRIAL-2 (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging and Molecular Analysis): An Adaptive Breast Cancer Trial Design in the Setting of Neoadjuvant Chemotherapy
  - Detection and Characterization of Circulating Tumor Cells in Prospective Cancer Treatment Trials – Neoadjuvant Breast Cancer
  - Detection and Characterization of Circulating Tumor Cells in Prospective Cancer Treatment Trials – Metastatic Breast Cancer
- **Metabolic Disease SC.** A proposal to convene a Sarcopenia Summit to better define the diagnosis of sarcopenia was approved at the February meeting of the BC Executive Committee. Specifically, this summit is designed to Establish Guidelines for Initial Diagnostic Criteria for "Sarcopenia Clinically Important Weakness" and Associated Evidence for Treatment Benefit. The summit will focus on the physical functional changes associated with mobility disability and what constitutes an improvement in function, and identify a biomarker or set of biomarkers that can predict who is at risk of falling. One performance-based assessment with widespread use in clinical practice is the Short Physical Performance Battery (SPPB), which includes chair stands, balance tests, and a timed walk over a set distance. This project will collect information and evaluate (1) the correlation between SPPB results and metabolic biomarkers, (2) how changes in muscle quantity and quality are associated with changes in the SPPB score, and (3) the sensitivity and specificity of this measure as an endpoint in clinical trials.

Additionally, a Beta Cell Function Symposium is scheduled for April 14-15, 2009, at the Capital Hilton in Washington, DC. The first day of the symposium will be dedicated to presentations by experts in the field, and the second day to discussion and a focus on generating a consensus statement regarding future research directives,

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The Biomarkers Consortium: *Updates and Developments* (continued from page 5)

listing which tests should be used to address particular questions, and the clinical utility or research application. A specific issue to be discussed is the need for a database (what should be included in it, how the information should be structured, and the funding needs to develop, launch, and maintain such a database). Also, an Atherosclerosis Workshop was held on February 12, 2009, to explore biomarker research opportunities in the areas of imaging and circulating and pharmacogenomics biomarkers.

As we reported earlier, the base-line results of the completed adiponectin project entitled "Evaluating the Utility of Adiponectin as Biomarker of Glycemic Efficacy" were presented by Dr. Maria Vassileva at the annual meeting of the American Society for Clinical Pharmacology and Therapeutics. Dr. Vassileva will present a poster with the complete study results at the American Diabetes Association annual meeting in June 2009. Additionally, a manuscript has been submitted by the Metabolic Disorders Steering Committee to the Journal of Clinical Pharmacology and Therapeutics.

- **Inflammation and Immunity SC (IISC).** At the April 2 IISC meeting, a project concept entitled "PET Imaging of Inflammation in Arthritis" was approved for further development. This project concept was submitted by Dr. Bob Innis from the National Institute of Mental Health and involves using a positron emission tomographic (PET) radioligand (developed in Dr. Innis' laboratory) that is a marker for macrophages to examine whether they can identify active inflammation in patients with rheumatoid arthritis. Additionally, a project concept entitled "Biomarker Identification in COPD: Profiling of the ECLIPSE Cohort" is under consideration for further development, and project concepts are under development in the area of osteoarthritis.
- **Neuroscience SC (NSC).** On March 31 the NSC held its biannual face-to-face meeting at the Pooks Hill Bethesda Marriott. This meeting was a fruitful exchange of ideas, and several new project concepts were presented and discussed. Notably, a project concept entitled "Metabolomics Signatures and Biomarkers for Depression" was approved by the SC for further development and a project team will be established to draft a detailed project plan. Additionally, there is a project concept under development for "Use of Targeted Multiplex Proteomic Strategies to Identify CSF-Based Biomarkers in Alzheimer's Disease."

In addition to promoting the advancement of several scientific projects, the BC team has continued to review, evaluate, and explore ways to promote the BC. In February, I gave a talk entitled "Intellectual Property Issues for Biomarkers and Biomarker Panels: A Government Perspective" at the AUTM 2009 Annual Meeting, and in March, I had the opportunity to speak at the Global Discovery and Development Innovation Forum (London, United Kingdom). I spoke about public-private partnerships involving the NIH and, in particular, the BC, with which the NIH is a funding partner. This was a great opportunity to interact with the industry, and my talk was well received by the entire conference and generated much discussion. The opportunity to have strategic discussion with the leaders in global health development was invaluable and I established connections with the heads of R&D at Novartis, Pfizer, and other leading pharmaceutical and biotechnology companies. ❖

News From Clinical Research Partnerships

Dr. Wendy B. Smith

Clinical research partnership activities in the last few months have included working on the Science of Health initiative, speaking to applicants for American Recovery and Reinvestment Act of 2009 Challenge Grants, working with the Patient-Reported Outcomes Measurement Information System (PROMIS) Work Group to help design a potential public-private partnership (PPP) to afford long-term sustainability to that effort, meeting with various Institutes and Centers (ICs) staff seeking advice and help in fashioning PPPs, and more.

With respect to the planned International Science of Health Forum, changing times and much discussion have yielded an alternative plan. Several focused workshops to develop further background materials/consensus and develop a set of white

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News From Clinical Research Partnerships

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papers will precede a larger conference. The first white paper under development will lay out the background for why a Science of Health is needed, and will include a discussion of how changing focus from disease to health can be the basis for research and clinical and regulatory decision-making, as well as be useful in the broader policy arenas regarding healthy food, urban planning, labor, information technology, etc. This paper is on a fast track and we hope a draft will be ready for sharing with IC partners and outside partners very soon. A series of workshops this summer will lead to additional white papers that we expect will explore the issues relevant to the ecological model of health represented in the Forum agenda: the individual; the individual in relationships; and the individual and the environment.

This activity is timely, and several recent programs and events have focused on the potential for a health promotion perspective and integrative medicine to contribute to the health care reform process. These complement as well as help inform the development of the Science of Health projects. One such event was sponsored by the Institute of Medicine and The Bravewell Collaborative (a philanthropic collaborative whose mission is to bring about optimal health and healing for individuals and society), which partnered to convene a summit that explored the science and practice of integrative medicine as an approach to improve patient-centered care. The meeting focused on the potential for integrative medicine and its underlying principles of including the mental, emotional, and physical aspects of health, for contributing to a new health care system. Aspects of prevention, research, education, and clinical care were presented and discussed by health care leaders, and the summit convened a broad and extensive array of participants. The meeting also emphasized the contribution of the context of care, that is, how the personal, community, and larger environments impact on patients' ability to engage actively in their own health care.

These topics were the focus of several recent Senate hearings of the full Health, Education, Labor and Pensions Senate Committee in February (Principles of Integrative Health: A Path to Health Care Reform (2/23; Senator Mikulski, Chair); and Integrative Care: A Pathway to a Healthier Nation (2/26; Senator Harkin, Chair). Both hearings concerned integrative health and the administration's upcoming health reform process (see http://help.senate.gov/./Hearings.html for a complete list of witnesses and video links for the testimony). Witnesses included Drs. Mehmet Oz, Dean Ornish, Andrew Weil, Jim Gordon, and Brian Berman, each of whom described his own work, experience, and projects relevant to integrative health (including clinical, education, research, and national service). Witnesses agreed on the importance of including health, health promotion, and wellness aspects in the health care reform process. In addition, several of the witnesses called for an Office of Health (and Health Promotion or Wellness) to be created at the White House level. This office would be responsible for coordination of activities across government agencies.

The American Recovery and Reinvestment Act of 2009 was signed into law by President Obama on February 17, 2009. The Act provides a total of $10.4 billion, available until September 2010 to support several types of scientific activities including grants, supplements, and other activities designed to fit the goals of the Act, including support for the new NIH Challenge Grants program. This program is designed to focus on health and science problems for which progress can be expected in 2 years. New language was added to the Challenge Grants program that encourages applicants to consider partnership development as a way to address longevity of projects and sustainability past the initial 2-year term of awards. I am the PPP Program contact for applicants for Challenge Grants.

On March 19, the Fogarty International Center hosted a delegation from the Netherlands Organization for Scientific Research (NWO). The NWO is the Dutch counterpart to the National Science Foundation and, through its organization ZonMw, is also responsible for programming of medical research. The goal of the visit was to strengthen relationships with similar organizations in the United States and engage in discussions to help inform their new NWO-wide strategy for the future. We discussed topics including commercialization and application of research and knowledge; interaction with universities, industry, and government; international exchange of scientific researchers and science policy; and exploration of developing more formal ties between Dutch and U.S. scientists. The delegation included Dr. Cees de Visser, General Director of the NWO, directors of science policy, engineering and applied sciences, humanities, communication, and external affairs, and the Director and Deputy Director of Science Policy from the Ministry of Education, Culture, and Science. ❖

Visit us at **http://ppp.od.nih.gov**

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Calendar

Date	Meeting	Time	Location	Speaker	Subject
4.16.09	PPP Coordinating Committee	1 - 3 pm	NIH Campus Bldg 1/ Wilson Hall	Raphael Marcello Terri Cooper Jacques Mulder	TBA
5.21.09	PPP Coordinating Committee	Meeting cancelled. PPP program will be at the BIO 2009 Conference.			
6.18.09	PPP Coordinating Committee	1 - 3 pm	NIH Campus Bldg 1/ Wilson Hall	TBA	TBA

Please check the PPP Web site for updates and additions.

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