

*Minutes from the June 2005 Meeting of the NTP Board of Scientific Counselors
Nanotechnology Working Group (NWG)*

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I. ATTENDEES

The National Toxicology Program (NTP) Board of Scientific Counselors Nanotechnology Working Group (NWG) met on June 24, 2005, at Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences, 111 T. W. Alexander Drive Research Triangle Park, North Carolina. The following individuals attended this meeting.

NWG Members

John Balbus, M.D., M.P.H.

Mark Lafranconi, Ph.D.

Martin Philbert, Ph.D.

James Platner, Ph.D.

Steven Roberts, Ph.D.

Mary Vore, Ph.D.

*Kristen Kulinowski, Ph.D., joined by phone to represent Vicki Colvin, Ph.D.

NIEHS Staff

David Balshaw, Ph.D.

Amy Brix, Ph.D.

John Bucher, Ph.D.

Raj Chhabra, Ph.D.

Dori Germolec, Ph.D.

Chris Portier, Ph.D.

Kris Thayer, Ph.D.

Cynthia Smith, Ph.D.

Molly Vallant, Ph.D.

Allison Veit

Nigel Walker, Ph.D.

Mary Wolfe, Ph.D.

Other Federal Staff

Norris Alderson, Ph.D. (FDA)

Clayton Teague, Ph.D. (National Nanotechnology Initiative)

Mary Lynn Woebkenberg, Ph.D. (NIOSH/CDC)

Steve Stern, Ph.D. (National Cancer Institute-Frederick, Inc.)

Public

Mohammad Ali

Piotr Grodzinski, Ph.D.

Rodney Miller, Ph.D.

Morando Soffritti, M.D.

Background materials and presentations for NWG meetings are available on the NTP web site (<http://ntp.niehs.nih.gov/> see "Advisory Boards & Committees"). The meeting was broadcast through the Internet and the public was provided opportunity to comment in person. The meeting was taped for preparation of summary minutes.

II. STRUCTURE AND GOALS OF THE WORKING GROUP

Dr. John Bucher briefly reviewed the charge and function of the NWG (see Attachment 1). Dr. John Balbus asked for background on the extent to which the NTP Board of Scientific Counselors ("the Board") has discussed nanotechnology. Dr. Steven Roberts, Chair of the NWG, said the Board strongly supports the NTP testing program on nanomaterials and recognizes the challenges of this research. In fact, the Board's discussions on research challenges provided an impetus for organizing the "Developing Experimental Approaches for Evaluation of Toxicological Interactions of Nanoscale Materials" workshop. This workshop was co-sponsored by the University of Florida in conjunction with multiple federal agencies including NIEHS/NTP and held November 3-4, 2004, at the University of Florida Hotel and Conference Center, Gainesville, Florida. The purpose of the workshop was to discuss experimental challenges in nanomaterial research. The workshop report and recommendations are available at <http://ntp.niehs.nih.gov/> (see "Meetings & Workshops"). One recommendation is to urge journal editors to require proper physical and chemical characterization of nanoscale materials in submitted manuscripts that investigate biological/toxicological interactions or effects of nanotechnology-derived products.

In response to this recommendation, Dr. Bucher sent a letter outlining this issue to editors of journals that publish articles on the biological effects of nanotechnology (a sample letter and list of relevant journals was included as background materials for the NWG meeting). Dr. Clayton Teague asked how keywords to identify the journals were selected. Dr. Bucher was not aware of the complete list of specific terms used as the search was conducted by staff in the NIEHS library. Dr. Bucher said he would send the search strategy to Dr. Teague.

Dr. Kristen Kulinowski discussed activities of the International Council for Nanotechnology (ICON) relevant to the NWG. ICON is developing “standards of care” that will include guidance on nanotechnology toxicology test methods. In addition, ICON is maintaining a database of nanotechnology literature expected to be publicly available by Fall 2005. The database was established at Oak Ridge National Laboratory and now has over 1300 records dating back to the 1980s.

Dr. Balbus asked for additional detail on the NWG charge. He interpreted the charge to include (1) providing general input on nanotechnology research needs, (2) advising on NTP research activities in light of federal agency needs, and (3) reviewing NTP research agendas and protocols. Dr. Bucher said reviewing specific research protocols is beyond the scope of the NWG, but discussing the NTP research agenda for nanotechnology is appropriate.

Dr. Mary Vore asked whether the NTP research program will address interactions between nanoparticles and other environmental exposures or compromised health status. Dr. Bucher said there is no specific program addressing combined exposure at this time although this is an important issue. Dr. Nigel Walker added that the NWG should feel free to comment on general research gaps including those that may be better addressed by non-NTP mechanisms such as extramural funding. Also, the scope of what NTP considers to be a nanomaterial is very broad and can include particles and devices, although less complex agents will be evaluated initially.

Dr. Roberts noted that a written public comment from Dr. Sherry Ward was received.

III. OVERVIEW OF THE NATIONAL NANOTECHNOLOGY INITIATIVE (NNI)

Dr. Clayton Teague, Director, National Nanotechnology Coordination Office (NNCO), discussed the NNI, a federal research and development program established to coordinate the multiagency efforts in nanoscale science, engineering, and technology. Major topics covered by Dr. Teague included:

- Nanotechnology development, applications, and target industries
- U.S. nanotechnology research and development spending (1997 – 2005)
- Interagency management of the NNI within the framework of the National Science and Technology Council (NSTC) Committee on Technology
 - The NSTC is a Cabinet-level body and the principal means by which the President coordinates science and technology programs across the federal government
- Roles of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee and the Nanotechnology Environmental and Health Implications (NEHI) Working Group
- The 21st Century Nanotechnology Research and Development Act of 2003
- NNI vision and goals and the “NNI Strategic Plan” document released December 2004
- Roles, research and development priorities, and fiscal year 2006 budget request for NNI participating agencies

- Application of existing regulations to nanotechnology

A NWG member asked how the NNCO is funded. Dr. Teague replied that the NNCO is funded through a tax on agencies that participate in the NSET subcommittee and the current budget is approximately two million dollars. Most of the funding for the NNCO is used to support the triennial review of the NNI conducted by the National Research Council of the National Academies. A considerable portion of funding is also used to support coordination of workshops and publication preparation.

Dr. Balbus asked whether it is possible to get a breakdown of funded projects included in the \$38.5 million directed towards Environment, Health, and Safety (EHS) research for fiscal year 2006. Dr. Teague said yes for the National Science Foundation (NSF), but not necessarily for other agencies. Dr. Vore asked whether the NSF money would address human health issues. Dr. Teague replied that most of the funding is likely focused on environmental research with some directed to research on basic cellular mechanisms. Dr. Martin Philbert asked what proportion of the EHS money is directed towards understanding potential impacts of nanomaterials in workers. Dr. Teague replied that the \$3.1 million slated for NIOSH would represent the majority of this work. Although NIOSH has ongoing activities to address nanomaterials in the context of ultrafine particles generated from mining and other processes, the \$3.1 million represents new money to address engineered nanomaterials.

IV. U.S. FEDERAL AGENCY EFFORTS IN NANOTECHNOLOGY¹

A. Food and Drug Administration (FDA)

Dr. Norris Alderson, Associate Commissioner for Science at the FDA, provided an overview of FDA considerations for nanotechnology in public health. In brief, Dr. Alderson discussed:

- The types of products FDA regulates, regulatory issues specific to nanomaterials, and nanotechnology approvals
- The FDA risk management approach for nanomaterials
- FDA research on nanotechnology
 - FDA does not conduct research in support of any product except under the orphan products program
 - The FDA National Center for Toxicological Research (NCTR) is conducting skin absorption and phototoxicity studies of titanium dioxide (TiO₂), zinc oxide (ZnO), and quantum dots
- FDA nanotechnology policy coordination

Dr. Philbert said one of the most challenging issues for understanding distribution of nanomaterials in the body is that the labeling of nanomaterials can fundamentally change their chemistry. Dr. Alderson agreed this is an important issue and said the imaging capabilities of nanomaterials could be a valuable tool in this respect. Dr. Philbert agreed but radionucleotides may exert biological effects also and it will be difficult to discern effects due to the nanomaterial, its components, or the radionucleotide.

Dr. Balbus asked for clarification on the two nanotechnology devices approved by FDA (Synthetic bone made from calcium phosphate nanocrystals produced by Angstrom Medica, Inc and Supreme Universal Restorative based on nanomers and nanoclusters manufactured by 3M).

Dr. Alderson said these two devices met a standard that already existed for these types of products and size was not considered in the approvals. Within the device law, high risk products require pre-clearance evaluation of safety and low risk devices, such as the ones presented, are approved based on a standard that has been approved for those types of products. New products meeting these standards are approved without any evaluation. The concern is whether FDA has the appropriate tools for evaluation. Dr. Balbus asked about nanomaterials used in cosmetics. With respect to nanomaterials in cosmetics, the FDA does not approve cosmetics and it is up to the manufacturer to assure safety. The FDA may regulate cosmetics if adverse events are reported once a cosmetic is in use. The burden of proof to demonstrate harm lies with the FDA. It would be helpful in the area of cosmetics to have validated protocols for assessing the toxicity of nanoparticles for use by the cosmetic industry. Dr. Mark Lafranconi said it is important to be able to follow the physical state of the nanomaterial (i.e., solid state or solution) in addition to the chemical signal. He believes this sort of fundamental analytical work is best conducted by the government and industry has the responsibility to apply the work to specific applications.

B. National Institute for Occupational Safety and Health (NIOSH)

Dr. Mary Lynn Wuebkenberg, Director of the NIOSH Division of Applied Research and Technology (DART), reviewed NIOSH activities related to nanotechnology. Dr. Wuebkenberg's presentation described:

- The newly established NIOSH Nanotechnology Research Center
- Critical occupational health and safety issues related to nanotechnology
 - Exposure and dose, communication and education, epidemiology and surveillance, recommendations and regulations, sampling, toxicity, controls, risk assessment, and safety
- NIOSH intramural and extramural research projects related to nanotechnology

Dr. James Platner said one of his concerns with nanotechnology is the safety of production operations. He believes NIOSH should address hazards in the work process (importance of engineering controls, waste streams, etc.) and not just the product. Dr. Wuebkenberg said NIOSH does not have the resources to evaluate total life cycle, but NIOSH is looking at different jobs within certain production processes.

C. National Institute of Environmental Health Sciences (NIEHS)

Dr. Sally Tinkle, Program Administrator, Division of Extramural Research and Training (DERT) at NIEHS, discussed:

- NIEHS coordination with other federal agencies on nanotechnology
- How NIEHS efforts fit into the NNI Strategic Plan
- The NIEHS Nanoscale Science Initiative which will involve a request for applications (RFA – R01/R21), program announcement(s), and an interagency agreement
 - to address dose; response; determinants of biological compatibility or toxicity; technologies to support exposure or risk assessment, biologic mechanism or therapeutic intervention; exposure and risk assessment; and interagency activities on societal impact, education, and training
- NIEHS's participation in an interagency RFA on environmental and human health effects of manufactured nanomaterials with the Environmental Protection Agency (EPA), NSF, and NIOSH

- to support research on the toxicology of manufactured nanomaterials; environmental and biological fate, transport and transformation; and exposure and bioavailability of nanomaterials

Dr. Philbert asked whether any of this research will address the ability of nanoparticles to sequester and concentrate other chemicals in the environment. Dr. Tinkle said this is an important area and NIEHS has already fielded an inquiry about interactions between nanoparticles and air pollution. Dr. Alderson asked about the funding levels of the agencies in the interagency RFA. Dr. Tinkle believed the total would be \$8 million (\$7 million from EPA, NSF, and NIOSH and \$1 million from NIEHS).

D. National Toxicology Program (NTP)

Dr. Nigel Walker, Project Leader for the NTP Nanotechnology Safety Initiative, discussed NTP's efforts in nanotechnology research. He reviewed:

- The testing nomination from Dr. Vicki Colvin, Director Center for Biological & Environmental Nanotechnology at Rice University, and rationales for need to assess safety
- Research needs and questions (e.g., exposure, pharmacokinetics, toxicity evaluations)
- Current and future challenges NTP faces in addressing nanotechnology (e.g., selecting specific nanomaterials for study, procurement and characterization of nanomaterials, strategy for evaluation, and communication)
- Initial NTP focus areas: single and multi-walled nanotubes, fullerene C60, titanium dioxide/metal oxides, and quantum dots
- Ongoing and planned skin absorption and phototoxicity studies of nanomaterials at the NTP Center for Phototoxicity (directed by Dr. Paul Howard and housed at the NCTR)
- NIOHS activities on single walled carbon nanotubes

One of the meeting participants asked how the 100 g quantity of nanomaterial required for subchronic testing was derived. Dr. Walker said it was based on number of animals being tested and a top estimated dose of 400 mg/kg for a proposed low toxicity material. Dr. Christopher Portier added that the required amounts change dramatically depending on toxicity (more toxic agents require less) and NTP has conducted studies requiring kg amounts for relatively non-hazardous materials. Dr. Tinkle commented that the nanomaterials for which this type of quantity would be a problem in procuring may also be those for which there is limited human exposure and thus less need to conduct animal studies. Dr. Philbert asked about species selection. Dr. Walker replied that NTP animal studies are generally conducted in rodents, although non-rodent species are used on occasion. Dr. Vore asked for clarification on the issue of expressing dose on a mass basis (e.g., mg/kg) rather another metric. Dr. Walker said expressing dose on a mass basis rather than a surface area per unit exposure basis may dramatically change the dose. Also, different aspects of surface area can be expressed, such as total or functional surface area. Dr. Tinkle commented that the smaller materials are not necessarily more toxic and that a recent study shows toxicity is material and composition specific.

Dr. Portier said development of physiologically based pharmacokinetic (PBPK) models will not wait until the pharmacokinetic studies have been started and this effort will have an intramural component. Dr. Balbus asked for more information on PBPK efforts. Dr. Portier said the advantage of doing PBPK studies early is it allows the model to evaluate "what if" scenarios to anticipate what experimental concerns might arise so that these issues can be addressed experimentally to get answers to shape the model. Dr. Lafranconi asked if the NTP research program would have both *in vitro* and *in vivo* components to allow screening level predictions.

Dr. Walker replied that *in vivo* studies are the initial focus and they would be followed by *in vitro* studies that target effects observed *in vivo*. Dr. Platner asked how NTP tracks which nanomaterials are being produced and thus most relevant for testing. Dr. Walker said it's a real challenge to find the information and then identify nanomaterials with near market applications. He uses interactions within the NEHI to help identify relevant companies and then he reads the company websites and other trade literature to see what is being produced. Dr. Teague added that there is a study underway to estimate total international production of single and double walled nanotubes. He was concerned that although C60 is one of the more characterized nanomaterials, it is not likely to enter the marketplace in the same quantities as other nanomaterials such as quantum dots. Dr. Walker replied that from his background research he has learned C60 is likely to have a bigger market than other nanomaterials such as nanotubes.

V. CONCLUDING REMARKS

Dr. Bucher said the intent of the current meeting was mostly to provide information on federal activities in nanotechnology and future NWG meetings will be more evenly balanced between discussion time and presentations. He proposed that appropriate topics for the next meeting are characterization and measurement to include presentations from the National Institute of Standards and Technology (NIST) and the National Characterization Laboratory located at the National Cancer Institute in Frederick, MD. In addition, he anticipates a presentation by EPA on their nanotechnology activities.

Dr. Bucher said advice provided at the next meeting will be useful since it is taking some time to develop the research program. Dr. Bucher asked if there were suggestions for other topics. Dr. Balbus asked for a more detailed discussion on the *in vitro* methods for novel mechanisms mentioned in Dr. Walker's talk.

Dr. Portier thanked everyone for attending and the meeting adjourned at 4:45 PM.

NTP BOARD OF SCIENTIFIC COUNCELORS (BSC) NANOTECHNOLOGY WORKING GROUP

Purpose

In recent years, nanotechnology has become an increasing focus of U.S. and global research and development efforts. As with many technological advances, novel materials are created, and as a result, the potential exists for new and unanticipated human exposures for which the impact on human health is unknown. The National Toxicology Program (NTP) is developing a broad-based research program to address potential human health hazards associated with the manufacture and use of nanoscale materials. This research program will include studies of nanoscale materials that apply existing and novel toxicological methods to assess potential health effects associated with exposure to these materials.

In order to enhance public and stakeholder input into the nanotechnology research program, the NTP intends to establish the Nanotechnology Working Group of the NTP Board of Scientific Counselors (“the NWG”). The NWG is a technical advisory body established to provide a structured and formal mechanism for bringing stakeholders together to learn about NTP nanotechnology research related to public health, address issues related to that research, and promote dissemination of those discussions to other federal agencies, nanotechnology stakeholders, and the public. Specifically, the NWG will provide advice to the NTP Board of Scientific Counselors (“the Board”) on NTP nanotechnology research. The Board is a federally chartered advisory committee whose members are appointed by the Secretary, Health and Human Services. The Board provides primary scientific oversight to the Director of the NTP and evaluates the merit of the NTP’s intramural and collaborative programs.

The NTP anticipates meetings of the working group will generally include presentations intended to educate the NWG and the public about nanotechnology research efforts related to environmental health within the federal government. The NWG may use this information as it evaluates the adequacy of the NTP testing program.

Function

The NWG shall advise the NTP Board of Scientific Counselors on matters of scientific content of the nanotechnology research program. The NWG shall conduct periodic reviews of this program advising on the overall merit and quality of the activities and whether they address areas of public health concern, needs of U.S. regulatory agencies, or issues of product development as they relate to public health.

Structure

The NWG’s membership shall be sufficiently broad to promote input and exchange of ideas and information. NWG shall consist of up to twelve members, including the Chair. Voting members may include representatives from industry, non-profit public health and environmental organizations, the International Council on Nanotechnology (ICON), Federal agencies represented on the NTP Executive Committee and the Nanotechnology Environmental Health (NEHI) Working Group of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee¹, and others with relevant experience. The Director shall appoint the Chair from

¹ The Nanoscale Science Engineering and Technology (NSET) Subcommittee of the NSTC coordinates planning, budgeting, program implementation and review of the National Nanotechnology Initiative (NNI). The NNI is a federal R&D program established to coordinate the multiagency efforts in nanoscale science, engineering, and technology. Eighteen agencies participate, 10 of which have R&D budgets. The NNI is

among the members of the NTP Board of Scientific Counselors represented on the NWG. A quorum of business shall consist of a majority of currently appointed members. The NWG shall report its activities to the Board on an annual basis or as deemed necessary.

Management and support services will be provided by the NTP Liaison and Scientific Review Office within the Office of the Director of the Environmental Toxicology Program.

Meetings

The working group is expected to meet annually or at the call of the Chair as need dictates. A government official shall be present at all meetings. The NTP will make the NWG meetings as accessible as possible to the public and follow appropriate National Institutes of Health (NIH) guidelines for the management, oversight, and conduct of working groups.

Compensation

NWG members shall be paid at a daily rate equivalent to that of Board members, plus per diem and travel expenses. Members who are officers or employees of the U.S. government shall not receive compensation for service.

Termination

The NWG shall continue until deemed by the Board as no longer necessary with approval by the Government official.

managed within the framework of the National Science and Technology Council (NSTC). Additional information about the NNI is available at <http://www.nano.gov/>.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Hua-Chuan Sim, MD, Scientific Review Administrator, National Library of Medicine, Extramural Programs, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: May 25, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-11080 Filed 6-2-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel, R03/R21 Review.

Date: July 15, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Hua-Chuan Sim, MD, Health Science Administrator, National Library of Medicine, Extramural Programs, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: May 25, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-11081 Filed 6-2-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Library of Medicine Special Emphasis Panel, Translational Informatics.

Date: July 26, 2005.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Hua-Chuan Sim, MD, Health Science Administrator, National Library of Medicine, Extramural Programs, Bethesda, MD 20892-796.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: May 25, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-11082 Filed 6-2-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Meeting of the NTP Board of Scientific Counselors Nanotechnology Working Group

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Meeting announcement.

SUMMARY: The National Toxicology Program (NTP) has established the Nanotechnology Working Group ("the NWG") to the NTP Board of Scientific Counselors in order to enhance public and stakeholder input into the NTP nanotechnology research program. The NWG is a technical advisory body established to provide a structured and formal mechanism for bringing stakeholders together to learn about NTP nanotechnology research related to public health, address issues related to that research, and promote dissemination of those discussions to other Federal agencies, nanotechnology stakeholders, and the public. The first meeting of the NWG is scheduled for June 24, 2005, at the NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

DATES: The working group meeting will be held June 24, 2005. The meeting will begin at 12:30 p.m. and end at approximately 4:30 p.m. Individuals who plan to attend are encouraged to register by June 17, 2005, in order to ensure access to the NIEHS campus (*see FOR FURTHER INFORMATION CONTACT* below). Persons needing special assistance, such as sign language interpretation or other reasonable accommodation, in order to attend are asked to notify the NTP at least 7 business days in advance of the meeting.

ADDRESSES: The meeting will be held in the Rodbell Auditorium, Rall Building at the NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. A copy of the agenda, working group roster, and any additional information, when available, will be posted on the NTP Web site (<http://ntp.niehs.nih.gov/> select "Advisory Board & Committees") or may be requested in hardcopy from the NWG Executive Secretary (*see FOR FURTHER INFORMATION CONTACT*).

FOR FURTHER INFORMATION CONTACT: Correspondence should be submitted to Dr. Kristina Thayer (NIEHS, P.O. Box 12233, MD A3-01, Research Triangle

Park, NC 27709; telephone: 919-541-5021, fax 919-541-0295; or e-mail: thayer@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

In recent years, nanotechnology has become an increasing focus of U.S. and global research and development efforts. As with many technological advances, novel materials are created, and as a result, the potential exists for new and unanticipated human exposures for which the impact on human health is unknown. The NTP is developing a broad-based research program to address potential human health hazards associated with the manufacture and use of nanoscale materials. This research program will include studies of nanoscale materials that apply existing and novel toxicological methods to assess potential health effects associated with exposure to these materials. In order to enhance public and stakeholder input into this program, the NTP has established the Nanotechnology Working Group to provide advice to the NTP Board of Scientific Counselors on NTP nanotechnology research. Additional information on the NWG, including charge and roster, is available at the NTP Web site ([http://ntp.niehs.nih.gov/select/AdvisoryBoard & Committees](http://ntp.niehs.nih.gov/select/AdvisoryBoard&Committees)”).

Preliminary Agenda

NTP Board of Scientific Counselors Nanotechnology Working Group (NWG); National Institute of Environmental Health Sciences, Rodbell Auditorium B, Rall Building, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709. (A photo ID is required to access the NIEHS campus.)

12:30 p.m.:

- Call to Order and Introductions.
- Welcome and Remarks from the National Toxicology Program (NTP).
- Structure and Goals of the NWG.
- Overview of the National Nanotechnology Initiative (NNI).
- U.S Federal Agency Efforts in Nanotechnology.
 - National Toxicology Program.
 - National Institute of Environmental Health Sciences.
 - National Institute for Occupational Safety and Health.
 - Food and Drug Administration.
 - Environmental Protection Agency.
- Public Comment.
- General Discussion.

Attendance and Registration

The meeting is scheduled for June 24, 2005, from 12:30 p.m. to adjournment (approximately 4:30 p.m.) and is open to

the public with attendance limited only by the space available. Please note that a photo ID is required to access the NIEHS campus. The NTP is making plans to videocast the meeting through the Internet at <http://www.niehs.nih.gov/external/video.htm>.

Request for Comments

Public input at this meeting is invited. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to send a copy of their statement to the NWG Executive Secretary (*see FOR FURTHER INFORMATION CONTACT* above) by June 17, 2005, to enable review by the NTP Board and NIEHS/NTP staff prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the NWG and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site. Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document.

Dated: May 23, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05-11111 Filed 6-2-05; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, June 23, 2005, 12:00 p.m. to June 23, 2005, 1:00 p.m., The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037 which was published in the **Federal Register** on May 18, 2005, 70 FR 28549-23552.

The meeting is cancelled due to the reassignment of the applications.

Dated: May 25, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-11077 Filed 6-2-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Enabling Bioanalytical and Biophysical Technologies Study Section, June 23, 2005, 8:30 a.m. to June 24, 2005, 6 p.m., Wyndham City Center Hotel, 1143 New Hampshire Ave., NW., Washington, DC, 20037 which was published in the **Federal Register** on May 18, 2005, 70 FR 28549-28552.

The starting time of the meeting on June 23, 2005 has been changed to 8 a.m. until adjournment. The meeting dates and location remain the same. The meeting is closed to the public.

Dated: May 25, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-11078 Filed 6-2-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 12, 2005, 7:30 a.m. to June 14, 2005, 3 p.m., Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD, 20814 which was published in the **Federal Register** on May 6, 2005, 70 FR 24099-24102.

The starting time of the meeting on June 12, 2005 has been changed to 7:30 p.m. until adjournment. The meeting dates and location remain the same. The meeting is closed to the public.

Dated: May 25, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-11083 Filed 6-2-05; 8:45 am]

BILLING CODE 4140-01-M

NTP BOARD OF SCIENTIFIC COUNCELORS NANOTECHNOLOGY WORKING GROUP (NWG)

FRIDAY, JUNE 24, 2005

AGENDA

**National Institute of Environmental Health Sciences
Rodbell Auditorium B, Rall Building
111 T. W. Alexander Drive,
Research Triangle Park, NC 27709**

Friday, June 24, 2005

- | | | |
|----------|--|--|
| 12:30 PM | Call to Order and Introductions | Dr. Steve Roberts (Chair), U. of Florida |
| 12:40 PM | Welcome and Remarks from the Associate Director, National Toxicology Program (NTP) | Dr. Christopher Portier, NIH/NIEHS |
| 12:45 PM | Structure and Goals of the Working Group <ul style="list-style-type: none">• General Discussion• Public Comment | Dr. John Bucher, NIH/NIEHS and
Dr. Kristina Thayer, NIH/NIEHS |
| 1:15 PM | Overview of the National Nanotechnology Initiative (NNI) from the Director, National Nanotechnology Coordination Office (NNCO) | Dr. Clayton Teague, NNCO |

U.S Federal Agency Efforts in Nanotechnology

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|---------|---|---|
| 1:45 PM | Food and Drug Administration (FDA) | Dr. Norris Alderson, FDA |
| 2:05 PM | National Institute for Occupational Safety and Health (NIOSH) | Dr. Mary Lynn Woebkenberg,
CDC/NIOSH |
| 2:25 PM | Break | |
| 2:40 PM | National Institute of Environmental Health Sciences (NIEHS) | Dr. Sally Tinkle, NIH/NIEHS |
| 3:00 PM | National Toxicology Program (NTP) | Dr. Nigel Walker, NIH/NIEHS |
| 3:30 PM | Open Discussion | |
| 4:30 PM | Adjourn | |

NTP Board of Scientific Counselors Nanotechnology Working Group (NWG)

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Public Comment

Re: NTP's Nanotechnology Working Group

**Sherry L. Ward, PhD, MBA
Physicians Committee for Responsible
Medicine (PCRM)**

June 24, 2005

PCRM

The Physicians Committee for Responsible Medicine (PCRM) is a nonprofit organization of physicians, scientists, and laypersons working together for compassionate and effective medical practice, research, and public health.

For both ethical and scientific reasons, we advocate for the replacement of animals in research, product development and testing, and education.

Our Concerns

- **That the types of information that would be collected using current regulatory test schemes may not be useful in assessing the safety of nanoscale materials in humans or in the environment**
- **That many thousands of animals will be subjected to inadequate and inaccurate tests before a more rational approach is adopted for evaluating nanoparticle toxicity**

Purpose of the Nanotechnology Working Group (NWG)

**The NTP has established the
NWG...“to enhance public and
stakeholder input into the NTP
nanotechnology research
program.”**

Interested Stakeholders

The animal protection community is an interested stakeholder in Federal programs that require, recommend, or encourage the use of animals in research or testing

Recommendations on Structure of the NWG

- Animal protection groups must be included as interested stakeholders in NWG activities**
- Scientists from animal protection organizations should have one or more representatives appointed to the NWG**

Recommendations on Goals of the NWG

- Evaluating the toxicities of nanoscale materials is a complex and emerging science that must be better understood before a sound and meaningful regulatory testing paradigm can be developed and imposed**
- Due to the novel nature of the nanoparticle test materials and their biological effects, both animal and nonanimal tests recommended for evaluation of nanoparticle toxicity by a regulatory agency must be considered as new or revised test methods and therefore must be validated according to the ICCVAM Authorization Act**

Recommendations on Goals of the NWG (con't)

- The NTP nanotechnology research program can provide valuable information on new methods to assess nanoparticle toxicities such as: the mining of existing data (human exposure and hazard data) on nanoparticles to develop predictive databases and computer models for toxicity assessment; the development of *in vitro* and high throughput technologies to develop faster and more predictive methods for evaluating nanoparticle safety to humans and the environment; etc.

Recommendations on Goals of the NWG (con't)

- **The NWG has the opportunity to play an important role in providing advice to the NTP on the types of research and approaches that will be useful in developing nonanimal approaches for assessing nanoparticle toxicity, which we anticipate will provide more predictive and cost-effective data than could be obtained by defaulting automatically to the existing regulatory framework**