

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

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

The meetings 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:* Center for Scientific Review Special Emphasis Panel PAR14-262: Weight and Sleep Outcomes After Bariatric Surgery.

*Date:* September 17, 2015.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Ellen K Schwartz, EDD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3144, MSC 7770, Bethesda, MD 20892, 301-828-6146, [schwarel@mail.nih.gov](mailto:schwarel@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel PAR Panel: Targeting Temporal Dynamics of the Brain Activity for the Treatment of Cognitive Deficits.

*Date:* September 29, 2015.

*Time:* 10:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181 MSC 7846, Bethesda, MD 20892-7846, 301-435-1236, [zhaow@csr.nih.gov](mailto:zhaow@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 21, 2015.

**Carolyn Baum,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-21153 Filed 8-25-15; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics**

**AGENCY:** National Institutes of Health, The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH) hereby announces the Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics for 2015. The Best Pharmaceuticals for Children Act (BPCA) seeks to improve the level of information on the safe and effective use of pharmaceuticals used to treat children. The BPCA requires that the NIH identify the drugs of highest priority for study in pediatric populations, and publish a list of drugs/needs in pediatric therapeutics. This notice fulfills the requirement to publish that list.

**ADDRESSES:** All nominations of pediatric therapeutics for future consideration by NICHD should be submitted to Dr. Perdita Taylor-Zapata at [taylorpe@mail.nih.gov](mailto:taylorpe@mail.nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Dr. Perdita Taylor-Zapata via email at [taylorpe@mail.nih.gov](mailto:taylorpe@mail.nih.gov); by phone at 301-496-9584; or by fax at 301-480-2897.

**SUPPLEMENTARY INFORMATION:** The pediatric medical community, the public health community, and government agencies have long recognized multiple gaps in knowledge regarding the use of therapeutics in children including the correct dosage, appropriate indications, side effects, and safety concerns of pharmaceuticals in the short- and long term. These gaps have frequently resulted in inadequate labeling for pediatric use and in widespread off-label use of prescription drugs in children. Off-label use of a drug substantially limits the ability to gain clinical information of the drug product such as appropriate dosing of a drug, changes in drug metabolism and response during growth and development, and important short- and long-term effects.

The NICHD, the Food and Drug Administration (FDA), other federal agencies, and various non-profit and commercial organizations are taking steps to fill knowledge gaps that exist in pediatric therapeutics and to promote

an increase in evidence-based data about medications used in children.

**Update on BPCA Prioritization**

The BPCA requires that the NIH, in consultation with the Food and Drug Administration and experts in pediatric research, identify the drugs and therapeutic areas of highest priority for study in pediatric populations. The NIH's authority and responsibility outlined in the BPCA legislation is to establish a program for pediatric drug testing and development and to publish a list of information needs regarding drugs used to treat children. The drug development program consists of a series of clinical trials in various therapeutic areas, which may be based on proposed pediatric study requests (PPSRs) submitted to FDA and/or from written requests (WR) received from the FDA. The BPCA Priority List consists of key therapeutic needs in the medical treatment of children and adolescents identified for further study; it is organized by therapeutic area, which can be a group of conditions, a subgroup of the population, or a setting of care. The first priority list of off-patent drugs needing further study under the 2002 BPCA legislation was published in January 2003 in the **Federal Register** (FR Vol. 68, No. 13; Tuesday, January 21, 2003: 2789-2790). The most recent priority list was published August 25, 2014; all **Federal Register** notices can be found on the BPCA Web site: <http://bpca.nichd.nih.gov/prioritization/status.cfm>. The BPCA legislation requires the NIH to update the priority list every three years. This publication serves as an update to the BPCA priority list of needs in pediatric therapeutics.

The Obstetric and Pediatric Pharmacology and Therapeutics Branch of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), NIH, has developed a prioritization process for the determination of the needs in pediatric therapeutics. There are two main phases: Phase I of the prioritization process entails identifying therapeutic areas, which are general categories of conditions, diseases, settings of care, or populations with multiple therapeutic needs. The NICHD solicits input from experts in pediatric research, general pediatric and subspecialty care, organizations focused on specific conditions, and professional societies to determine these therapeutic areas that need further study. Each year, the NICHD revisits the current list of needs in pediatric therapeutics, prioritizes three therapeutic areas of interests for that calendar year, and develops working groups in the

prioritized areas. Recommendations from these working groups are then presented to the NICHD and the FDA at the annual BPCA meeting. Previous meeting minutes can be found on the BPCA Web site: [http://bpca.nichd.nih.gov/prioritization/meeting\\_summary.cfm](http://bpca.nichd.nih.gov/prioritization/meeting_summary.cfm). Phase II of the prioritization process includes an extensive review and ranking of all stakeholder nominations received based on key criteria for prioritization, such as relevance, gaps in labeling information, affected populations and feasibility. Please visit the BPCA Web site for more details ([http://bpca.nichd.nih.gov/prioritization/priority\\_list.cfm](http://bpca.nichd.nih.gov/prioritization/priority_list.cfm)).

Below is an updated list of therapeutic areas and drugs that have been prioritized for study since the inception of the BPCA and a summary of the NICHD's plans and progress in all of these areas to date. The NICHD welcomes input from the pediatric medical community on additional gaps in pediatric therapeutics for future consideration. All nominations should be submitted to Dr. Perdita Taylor-Zapata at the address in the **ADDRESSES** section of this notice.

#### Priority List of Needs in Pediatric Therapeutics 2015

In accordance with the BPCA legislation, the list outlines priority needs in pediatric therapeutics for multiple therapeutic areas listed below. The complete list can be found on the BPCA Web site at the following address: <http://bpca.nichd.nih.gov>.

- *Table 1: Infectious Disease Priorities*
- *Table 2: Cardiovascular Disease Priorities*
- *Table 3: Respiratory Disease Priorities*
- *Table 4: Intensive Care Priorities*
- *Table 5: Bio-defense Research Priorities*
- *Table 6: Pediatric Cancer Priorities*
- *Table 7: Psychiatric Disorder Priorities*
- *Table 8: Neurological Disease Priorities*
- *Table 9: Neonatal Research Priorities*
- *Table 10: Adolescent Research Priorities*
- *Table 11: Hematologic Disease Priorities*
- *Table 12: Endocrine Disease Priorities and Diseases with Limited Alternative Therapies*
- *Table 13: Dermatologic Disease Priorities*
- *Table 14: Gastrointestinal Disease Priorities*
- *Table 15: Renal Disease Priorities*
- *Table 16: Rheumatologic Disease Priorities*

#### Table 17: Special Considerations.

Dated: August 19, 2015.

**Francis S. Collins, M.D.,**

*Director, National Institutes of Health.*

[FR Doc. 2015–21155 Filed 8–25–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2015–0042]

### National Infrastructure Advisory Council

**AGENCY:** National Protection and Programs Directorate, DHS.

**ACTION:** Committee Management; Notice of an Open Federal Advisory Committee Meeting.

**SUMMARY:** The National Infrastructure Advisory Council will meet Friday, September 11, 2015, at the Navy League Building, 2300 Wilson Blvd. Arlington, VA 22201. This meeting will be open to the public.

**DATES:** The National Infrastructure Advisory Council will meet on September 11, 2015 from 1:30 p.m.–4:30 p.m. EDT. The meeting may close early if the committee has completed its business. For additional information, please consult the National Infrastructure Advisory Council Web site, [www.dhs.gov/NIAC](http://www.dhs.gov/NIAC), or contact the National Infrastructure Advisory Council Secretariat by phone at (703) 235–2888 or by email at [NIAC@hq.dhs.gov](mailto:NIAC@hq.dhs.gov).

**ADDRESSES:** Navy League Building, 2300 Wilson Blvd. Arlington, VA 22201. Members of the public will register at the table at the door to the meeting room. For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Council as listed in the “Summary” section below. Comments must be submitted in writing no later than 12:00 p.m. on September 9, 2015, in order to be considered by the council in its meeting. The comments must be identified by “DHS–2015–0042,” and may be submitted by any one of the following methods:

- *Federal eRulemaking Portal:* [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting written comments.

- *Email:* [NIAC@hq.dhs.gov](mailto:NIAC@hq.dhs.gov). Include the docket number in the subject line of the message.

- *Fax:* (703) 235–9707.

- *Mail:* Nancy Wong, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0612, Washington, DC 20598–0607.

*Instructions:* All written submissions received must include the words “Department of Homeland Security” and the docket number for this action. Written comments received will be posted without alteration at [www.regulations.gov](http://www.regulations.gov), including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received by the National Infrastructure Advisory Council, go to [www.regulations.gov](http://www.regulations.gov). Enter “NIAC” in the search line and the Web site will list all relevant documents for your review.

Members of the public will have an opportunity to provide oral comments on the topics on the meeting agenda below, and on any previous studies issued by the National Infrastructure Advisory Council. We request that comments be limited to the issues and studies listed in the meeting agenda and previous National Infrastructure Advisory Council studies. All previous National Infrastructure Advisory Council studies can be located at [www.dhs.gov/NIAC](http://www.dhs.gov/NIAC). Public comments may be submitted in writing or presented in person for the Council to consider. Comments received by Nancy Wong after 12:00 p.m. on September 9, 2015, will still be accepted and reviewed by the members, but not necessarily by the time of the meeting. In-person presentations will be limited to three minutes per speaker, with no more than 15 minutes for all speakers. Parties interested in making in-person comments should register on the Public Comment Registration list available at the meeting location no later than 15 minutes prior to the beginning of the meeting.

#### FOR FURTHER INFORMATION CONTACT:

Nancy Wong, National Infrastructure Advisory Council, Designated Federal Officer, Department of Homeland Security, (703) 235–2888.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The National Infrastructure Advisory Council shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation's critical infrastructure sectors. The NIAC will meet to discuss issues relevant to