

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.

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.

(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.

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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.

FOR FURTHER INFORMATION CONTACT: Dr. Perdita Taylor-Zapata via email at 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